

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/15/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11941002]
2.	Birth Date:	UNK/UNK/1963
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Oct/15/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Arterial Hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/15/2020
2.	Weight:	[96.1]
3.	Unit:	kg
4.	Height:	[190.0]
5.	Unit:	cm
6.	Body Mass Index:	[26.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	EAR

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/15/2020
2.	Randomization Number:	[269471]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8HZH]
5.b	Sample ID	[BN8HZJ]
5.c	Sample ID	[BNMD1W]
5.d	Sample ID	[BNMD1X]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8HZB]
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/15/2020 13:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/21/2020
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/5/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	EAR

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8HLT]
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/5/2020 14:51
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/3/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8HSC]
5.b	Sample ID	[BN8HSD]
5.c	Sample ID	[BNMD9W]
5.d	Sample ID	[BNMD9X]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Feb/04/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/04/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Feb/4/2021
2.	Date of First Symptom Started:	Feb/2/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Feb/13/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/04/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[]
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:54

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)
[Form Comments](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Feb/04/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[collected on site]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Feb/04/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/4/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN15JH]
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Feb/04/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55**eCRF Audit Trail History****Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Category of Clinical Event :	Subcategory of Clinical Event t	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Feb/04/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:58

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/04/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/04/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/04/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/04/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Date:	Vital Signs Details			Form Instance
1.	Feb/4/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	128	67	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Feb/04/2021

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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[Form Audit Trail](#)

Vital Signs

1.	Date:	Feb/4/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[128]
	Diastolic:	[67]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[83]

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Feb/04/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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[Form Comments](#)
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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:55

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Feb/04/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Imaging			
1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Mar/11/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/11/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN15LW]
5.b	Sample ID	[BN15LX]
5.c	Sample ID	[BNMPNS]
5.d	Sample ID	[BNMPNT]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Pain at injection site	Jan/11/2021 20:00	NO End Date Time: Jan/13/2021 08:00	Repeating Pages
2.	ADVERSE EVENT	2	enlarged lymph nodes (right axillar)	Feb/2/2021 UNK:UNK	NO End Date Time: Feb/13/2021 08:00	Repeating Pages

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at injection site]
4.	Start Date Time:	Jan/11/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/13/2021 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[enlarged lymph nodes (right axillar)]
4.	Start Date Time:	Feb/2/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/13/2021 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Vaxigrip	Sep/25/2020	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Vaxigrip]
5.	Date:	Sep/25/2020

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/02/2021

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/2/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/02/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/02/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/2/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Patient reported moderate Fatigue/tiredness since this morning. Vacc reaction.]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[]
	Unit:	
	Temperature Location:	

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Dec/3/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/11/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/11/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN15CB]
5.b	Sample ID	[BN15CC]
5.c	Sample ID	[BNMPK5]
5.d	Sample ID	[BNMPK6]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN15C4]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 14:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/1/2021
2.	Erroneous Visit	

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/1/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN15HZ]
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Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/1/2021 14:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/1/2021
3.	Comments:	[]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/1/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/3/2020

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Andreas Eich	Approved	Mar-12-2021 13:47:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Oct-19-2020 11:21:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
4	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
6	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
7	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
8	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
9	Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
3	Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Item	Date	User	Comment
4	Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Item	Date	User	Comment
5	Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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6	Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

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Form	Feb-05-2021 10:46:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Status: Data Complete

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Item	Date	User	Comment
1	Feb-05-2021 10:46:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete

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Item	Date	User	Comment
5.b	Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Item	Date	User	Comment
5.b	Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5.c	Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

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Item	Date	User	Comment
5.c	Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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5.d	Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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5 f	Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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5.g	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.g	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5 h	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Item	Date	User	Comment
5 h	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5 h	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5 h	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.i	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.i	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

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Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.i	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

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Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.i	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.j	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.j	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.j	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.j	Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Feb/04/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Feb-05-2021 10:55:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Feb/04/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Feb-05-2021 10:55:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable
1	Feb-05-2021 10:55:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Feb/04/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2.a	Feb-05-2021 10:55:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Feb-05-2021 10:55:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Feb-05-2021 10:55:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Feb-05-2021 10:55:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Feb-05-2021 10:55:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

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Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
4	Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5	Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
6	Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
1	Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
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Subject No: 11941002

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Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
4	Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Jan-11-2021 15:09:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Andreas Eich	Approved	Mar-12-2021 13:47:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-11-2021 15:12:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Mar-08-2021 08:47:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-02-2021 10:24:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Andreas Eich	Approved	Mar-02-2021 09:03:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Feb-17-2021 08:44:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-16-2021 11:58:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Feb-15-2021 08:42:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-07-2021 09:49:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-06-2021 09:48:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-01-2021 14:49:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Jan-18-2021 10:36:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Jan-16-2021 13:30:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Jan-12-2021 17:48:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Jan-08-2021 17:54:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Dec-04-2020 11:00:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Dec-03-2020 15:49:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Nov-09-2020 15:04:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-05-2020 15:43:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Andreas Eich	Approved	Oct-29-2020 16:33:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Affidavit:

By my dated signature below, I, AndreasEich, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-15-2020 16:51:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Oct-15-2020 16:51:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Oct-15-2020 16:51:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/15/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-15-2020 16:50:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11941002	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-16-2020 23:37:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DM001_03
Oct-16-2020 13:09:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-16-2020 13:09:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1963	Changed Information
Oct-16-2020 11:54:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4989006;Site is in Germany or South Africa, however Date of Birth is complete.

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Oct-15-2020 17:42:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: (b) (6)/1 963	Transcription Error
Oct-15-2020 16:50:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1 973	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-15-2020 16:53:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-15-2020 16:53:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Oct-15-2020 16:53:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 16:55:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-16-2020 09:39:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 09:39:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 09:39:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Oct-16-2020 09:46:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Arterial Hypertension Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 09:46:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-16-2020 09:46:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Arterial Hypertension	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 09:46:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 09:46:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.b

Date	Location	User	Value	Reason
Oct-16-2020 09:47:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History T Hyperlipidem erm: ia Start Date: UNK/UNK/2 019 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 09:47:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-16-2020 09:47:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperlipidemia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 09:47:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 09:47:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-16-2020 09:47:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 190.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26.6	Initial Entry
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7.a

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location:: EAR	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-16-2020 09:48:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EAR	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-16-2020 09:49:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-16-2020 09:49:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 269471	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 09:49:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 09:49:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 19:20:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 12:59:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 09:49:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 09:49:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a

Date	Location	User	Value	Reason
Oct-16-2020 19:20:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8HZH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 19:20:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HZH	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 19:21:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8HZJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 19:21:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HZJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 19:40:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMD1W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 19:40:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMD1W	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.d

Date	Location	User	Value	Reason
Oct-16-2020 19:40:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMD1X	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 19:40:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMD1X	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 09:49:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 09:49:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 19:27:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 12:59:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 09:49:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 09:49:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.a

Date	Location	User	Value	Reason
Oct-16-2020 19:27:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8HZB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 19:27:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HZB	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/15/2020 13:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-16-2020 09:51:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-16-2020 09:51:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 15:43:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last d O ay the Subject Diary was c ompleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb			TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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2.b Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-06-2020 12:17:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing ? NO Stop Date: Oct /21/ 2020	Transcription Error

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.c Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-09-2020 07:59:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site
Nov-06-2020 12:17:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-06-2020 12:17:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Oct/21/2020	Transcription Error
Nov-06-2020 09:57:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, HEADACHE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb

2.d

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.e Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.g

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste mic symptoms prese nt on the last day the Subject Diary was co mpleted?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCL E PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
--	--	--	---	--

2.h Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-05-2020 15:44:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 16:01**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-05-2020 15:44:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-05-2020 15:44:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.3 Temperature Unit: C Temperature Location:: EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-05-2020 15:44:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Nov-05-2020 15:44:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EAR	Initial Entry

Header Text: C4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 15:45:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 15:45:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-05-2020 16:40:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 15:45:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 15:45:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 16:40:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8HLT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 16:40:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HLT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020 14:51	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Nov-05-2020 15:45:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-03-2020 15:49:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/3/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb			TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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2.b Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.c Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.f Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms prese nt on the last day the Subject Diary was co mpleted?:	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.g Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS Were injection site reactio NO ns present on the last day t he Subject Diary was com pleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-04-2020 09:45:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-03-2020 15:49:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-03-2020 15:49:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-03-2020 15:49:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 15:49:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-03-2020 15:49:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-03-2020 15:49:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8HSC	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:49:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HSC	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-03-2020 15:50:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8HSD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:50:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HSD	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 15:50:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMD9W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:50:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMD9W	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-03-2020 15:50:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMD9X	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.d Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:50:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMD9X	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Feb/04/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-05-2021 19:55:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-05-2021 10:45:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	done
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-05-2021 07:29:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Date of Visit is completed but Self Swab CRF is not initiated. Please review and update the data as appropriate. Thanks
Feb-04-2021 20:07:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-04-2021 15:17:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 15:17:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Feb/04/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

				review and update as appropriate.
Feb-04-2021 15:17:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-04-2021 15:17:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-04-2021 15:17:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)***1. Date of Assessment:***

Date	Location	User	Value	Reason
Feb-26-2021 11:25:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-26-2021 11:23:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Feb-05-2021 10:34:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

Feb-16-2021 11:59:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Feb/13/2021	New Information
Feb-16-2021 11:58:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Feb/15/2021	New Information
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry
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4.b Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORT NESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-26-2021 11:25:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Transcription Error
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-26-2021 11:25:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

4.f

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TA : STE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREAS s: ED SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Symptom Present: NO
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4.i Symptoms:

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-05-2021 10:27:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 11:23:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	New Information
Feb-08-2021 11:30:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms enlarged lumph nod - Other: es (right axillar)	Transcription Error
Feb-07-2021 09:49:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms enlarged lumph kno - Other: ts (right axillar)	Transcription Error
Feb-05-2021 10:34:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms enlarged lumph kno - Other: ts, right axillar. Fatigue, slackness.	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-26-2021 11:23:55	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb				
Feb-08-2021 13:05:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.
Feb-08-2021 11:30:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-08-2021 11:30:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: enlarged lump h nodes (right axillar)	Transcription Error
Feb-07-2021 15:42:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Clarify ENLARGED LUMPH KNOTS (RIGHT AXILLAR) as follows...The term is unclear. If reporting ENLARGED LYMPH NODES (RIGHT AXILLAR), update the verbatim term as such. Otherwise clarify and update the term as appropriate. Thank you.

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-07-2021 13:57:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Feb-07-2021 09:49:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-07-2021 09:49:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: enlarged lump h knots (right axillar)	Transcription Error
Feb-05-2021 12:08:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Feb-05-2021 10:34:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: enlarged lump h knots, right axillar. Fatigue, slackness.	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Feb-05-2021 10:38:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-09-2021 11:26:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 12:06:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-08-2021 12:06:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-05-2021 19:54:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please update the Trade Name as per CCG 8.31.4 from drop down list. If Trade Name is Unknown; Choose 'Other' and specify 'NALT Unknown' per CCG.
Feb-05-2021 10:38:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 12:06:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-05-2021 10:38:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry
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3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 12:06:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-05-2021 10:38:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Feb-08-2021 12:06:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-05-2021 10:38:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Feb-08-2021 12:06:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-05-2021 10:38:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry
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6. Trade Name:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-08-2021 12:06:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 10:38:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-05-2021 10:38:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-05-2021 10:44:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-05-2021 10:38:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-05-2021 10:38:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-05-2021 10:44:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: collected on site	Initial Entry
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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-04-2021 15:17:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-04-2021 15:17:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 15:18:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 15:17:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 15:17:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 15:18:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN15JH	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 15:18:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN15JH	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1.a

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-05-2021 10:38:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-05-2021 10:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-05-2021 10:53:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-05-2021 10:53:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-05-2021 10:53:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Feb/04/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-05-2021 10:46:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Feb-05-2021 10:46:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Feb-05-2021 10:46:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-05-2021 10:46:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form Version: 10-Oct-2020 15:58

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form Version: 10-Oct-2020 15:58

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form Version: 10-Oct-2020 15:58

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

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Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

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Generated Time (GMT): 29-Mar-2021 12:55

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			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

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5.g Sponsor ID:

Date	Location	User	Value	Reason
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5.g Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021**Form Version:** 10-Oct-2020 16:02**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applc	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

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Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

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Subject Initials: ---

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

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Site No: 1194

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Generated Time (GMT): 29-Mar-2021 12:55

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			Test::	Not Applicable	
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Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

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5.g Sponsor ID:

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5.g Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.h Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form Version: 10-Oct-2020 16:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
--	---------------------	---

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.j Sponsor ID:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Feb-05-2021 10:47:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Feb/04/2021

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/04/2021

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date:

Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 12 8 Diastolic:: 67 Respiratory Rate in respira 16 tions/minute: Heart Rate in beats/minute: 83	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 128	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 67	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/04/2021

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Feb-05-2021 10:54:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 83	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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I. Date:

Date	Location	User	Value	Reason
Feb-05-2021 10:55:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-05-2021 10:55:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Oxygen Saturation: Not Applicable	Initial Entry
Feb-05-2021 10:55:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation:	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-05-2021 10:55:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Feb-05-2021 10:55:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Feb-05-2021 10:55:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Feb-05-2021 10:55:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Feb-05-2021 10:55:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/04/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

6. Ongoing?

Date	Location	User	Value	Reason
Feb-05-2021 10:56:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-05-2021 10:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/11/2021

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:12:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/11/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-12-2021 08:47:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/11/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Data Origin

Date	Location	User	Value	Reason
Mar-11-2021 15:12:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 15:12:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-12-2021 16:02:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	data updated
Mar-12-2021 08:48:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	done
Mar-12-2021 04:56:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7679352;DM: Kindly confirm if visit is not erroneous if correct, enter response to COVID-19 Illness Visit on DOV CONV CRF. If visit

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/11/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

				is erroneous, mark erroneous visit button on DOV CONV CRF and clear data and add Form level comment of 'Not Applicable' on this CRF
Mar-11-2021 15:12:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 15:12:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 15:12:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar /11/ 2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 15:12:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN15LW	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/11/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:12:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN15LW	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-11-2021 15:13:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN15LX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:13:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN15LX	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-11-2021 15:13:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMPNS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:13:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMPNS	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-11-2021 15:13:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMPNT	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.d Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:13:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMPNT	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Category:

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pain at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 11:00:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021 20:00	Transcription Error
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-26-2021 11:00:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/13/2021 08:00	Transcription Error

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/13/2021 08:00	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-26-2021 10:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Category:

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: enlarged lymph nodes (right axilla r)	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 11:33:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-03-2021 14:29:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

Mar-03-2021 14:29:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/13/2021 08:00	New Information
Mar-03-2021 14:19:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY-: Please confirm if the event "enlarged lymph node, right axillar" remains ongoing (start date Feb 02, 2021). Else, review if update can be applied to end date and outcome status. Thank you
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?**If Yes, record the type of medication error on the Medication Error Log.**

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Feb-26-2021 11:20:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-03-2021 14:30:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-03-2021 14:30:20 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Transcription Error

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb				
Mar-03-2021 14:29:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE enlarged lymph nodes (right axillar): Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-26-2021 11:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Jan-16-2021 13:30:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-16-2021 13:30:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-16-2021 13:30:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-16-2021 13:30:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-16-2021 13:30:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vaxigrip	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-16-2021 13:30:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/02/2021

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-02-2021 10:53:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/02/2021

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Assessments

Date	Location	User	Value	Reason
Feb-02-2021 10:54:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 10:53:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-02-2021 10:53:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/02/2021

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-02-2021 10:54:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-02-2021 10:54:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/2/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Feb-02-2021 10:54:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Patient reported moderate Fatigue /tiredness since this morning. Vacc reaction.	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-04-2020 09:34:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-04-2020 09:34:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-04-2020 09:34:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4) [REDACTED]

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 17:54:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/8/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-08-2021 17:55:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 17:54:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-08-2021 17:54:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national r ecommendations and confir med to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-11-2021 15:08:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-11-2021 15:08:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/11/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-11-2021 15:09:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-11-2021 15:09:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-11-2021 15:09:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 15:10:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 15:10:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 15:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 15:10:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-11-2021 15:10:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 15:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN15CB	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN15CB	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-11-2021 15:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN15CC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN15CC	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-11-2021 15:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMPK5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMPK5	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 15:10:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMPK6	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.d Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMPK6	Initial Entry

Header Text: C4591001**Visit:** V101_VAX3**Form Version:** 22-Apr-2020 21:03**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 15:11:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 15:11:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 15:11:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 15:11:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-11-2021 15:11:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 15:11:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN15C4	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:11:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN15C4	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/11/2021 14:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-11-2021 15:46:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-08-2021 17:55:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-08-2021 17:55:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 14:49:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** V102_VAX4**Form Version:** 22-Apr-2020 21:03**Site No:** 1194**Subject No:** 11941002**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-01-2021 14:49:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-01-2021 14:49:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 14:50:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 14:49:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-01-2021 14:49:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 14:50:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN15HZ	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 14:50:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN15HZ	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021 14:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-01-2021 14:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 08:50:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021	Initial Entry

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-02-2021 08:51:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-02-2021 08:51:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/1/2021	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1194**Site Name:** (1194) IKF Pneumologie GmbH Co KG, Institut fuer
klinische Forschung**Subject No:** 11941002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-03-2021 15:46:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-03-2021 10:00:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Date is correct. Please see V103 for EOT2.
Mar-02-2021 17:47:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7569849;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-02-2021 10:24:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Mar/1 /2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-02-2021 10:24:11 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1194

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject No: 11941002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb

3. Status:

Date	Location	User	Value	Reason
Mar-02-2021 10:24:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Subject Status

Date	Location	User	Value	Reason
Dec-04-2020 09:34:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-16-2020 09:49:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-16-2020 09:39:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-04-2020 09:34:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/3/2020	Initial Entry
Oct-16-2020 09:49:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Initial Entry
Oct-16-2020 09:39:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Initial Entry

090177e196ae3f18\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1194

Subject No: 11941002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1194) IKF Pneumologie GmbH Co KG, Institut fuer klinische Forschung

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-29-2020 16:25:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Andreas Eich (b) (4)	Data Entry: Click Here to Enable	Initial Entry