

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/19/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11971097]
2.	Birth Date:	UNK/UNK/1948
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:	

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/19/2020
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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetes mellitus type 2]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperuricemia]
	Start Date:	Jan/8/1998
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypercholesterolemia]
	Start Date:	Jan/8/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[renal insufficiency]
	Start Date:	Sep/26/2010
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anemia]
	Start Date:	Oct/9/2014
	Ongoing:	YES

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[arterial hypertension]
	Start Date:	Sep/10/2003
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coxarthrosis left hip]
	Start Date:	Mar/22/2017
	Ongoing:	YES

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/19/2020
2.	Weight:	[65.9]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[22.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/19/2020
2.	Randomization Number:	[270700]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BN8NZX]
5.b	Sample ID	[BN8NZY]
5.c	Sample ID	[BNM3YZ]
5.d	Sample ID	[BNM3Z0]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BN8NZD]
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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/19/2020 16:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
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

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/7/2020
2.	Erroneous Visit	

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[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
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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:	LEFT
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

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/7/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/7/2020
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	[BN8P3K]
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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/7/2020 15:27
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
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

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/5/2020
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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[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
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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:	LEFT
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

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BN8PB4]
5.b	Sample ID	[BN8PB5]
5.c	Sample ID	[BNLMK6]
5.d	Sample ID	[BNLMK7]

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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	[]
----	-----------	-----

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

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?	
----	--	--

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Acute Posterior Myocardial Infarction	Jan/3/2021 14:30	NO End Date Time: Jan/8/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Arm Swelling	Feb/13/2021 18:00	NO End Date Time: Feb/14/2021 16:00	Repeating Pages

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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)	[Acute Posterior Myocardial Infarction]
4.	Start Date Time:	Jan/3/2021 14:30
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/8/2021 UNK:UNK
6.	Toxicity Grade:	4
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [arterial hypertension, hypercholesterolemia, diabetes mellitus type 2]

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2021006704]

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Arm Swelling]
4.	Start Date Time:	Feb/13/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/14/2021 16:00
6.	Toxicity Grade:	1
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
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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	[]

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	fluzone 0.7 ml i. m	Dec/7/20 20	Repeating Pages

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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).	[fluzone 0.7 ml i.m]
5.	Date:	Dec/7/2020

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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?	

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Dec-2020 02:26

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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?	

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Dec/5/2020
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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[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 other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Disposition - Follow-Up

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/25/2021
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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/13/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/12/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[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: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

			Comments
1.	Date of Completion/Discontinuation /Death :	Feb/13/2021	
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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
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	[BN0PDX]
5.b	Sample ID	[BN0PDC]
5.c	Sample ID	[BNMXZ9]
5.d	Sample ID	[BNLMG2]

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
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	[BN0PDB]
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO	Comments
2.	Treatment Name	[BNT162b2]	
3.	Formulation:	INJECTION	
4.	Dose Date Time:	Feb/13/2021 11:03	
5.	Anatomical Location:	DELTOID MUSCLE	
6.	Body Side:	LEFT	
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	

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/5/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/5/2021
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	[BN0PGR]
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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:	Mar/5/2021 13:36
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
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

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Disposition - Treatment

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/5/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Matthias Luttermann	Approved	Mar-08-2021 22:18:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-19-2020 18:05:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-13-2021 11:54:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION -
Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
1	Feb-19-2021 15:47:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	Lars Pohlmeier (b) (4)	sate correct, vaccination delay due to temperature excursion and delayed decision for use of vaccination IP

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
1	Feb-19-2021 20:45:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	Lars Pohlmeier (b) (4)	no IP available for vaccination due to delayed arrival of IP

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Matthias Luttermann	Approved	Mar-08-2021 22:18:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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-08-2021 12:06:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Matthias Luttermann	Approved	Mar-05-2021 22:59:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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-05-2021 12:09:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Matthias Luttermann	Approved	Feb-22-2021 21:30:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**Affidavit:**

By my dated signature below, I, MatthiasLuttermann, 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.

Matthias Luttermann	N/A	Feb-22-2021 21:16:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Lars Pohlmeier	Approved	Feb-19-2021 20:46:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, LarsPohlmeier, 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.

Lars Pohlmeier	N/A	Feb-19-2021 20:44:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Lars Pohlmeier	Approved	Feb-19-2021 16:24:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, LarsPohlmeier, 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:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

Lars Pohlmeier	N/A	Feb-19-2021 15:47:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Feb-18-2021 22:24:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
Affidavit: By my dated signature below, I, MatthiasLuttermann, 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-18-2021 13:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Feb-15-2021 17:02:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
Affidavit: By my dated signature below, I, MatthiasLuttermann, 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-12-2021 14:12:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Feb-09-2021 01:02:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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.

Matthias Luttermann	N/A	Feb-09-2021 00:55:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Matthias Luttermann	Approved	Jan-25-2021 22:43:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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.

Matthias Luttermann	N/A	Jan-25-2021 18:00:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Matthias Luttermann	Approved	Jan-17-2021 21:29:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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.

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

Matthias Luttermann	N/A	Jan-17-2021 21:27:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Jan-12-2021 22:33:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
Affidavit: By my dated signature below, I, MatthiasLuttermann, 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.				
Matthias Luttermann	N/A	Jan-12-2021 22:28:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Jan-08-2021 22:49:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
Affidavit: By my dated signature below, I, MatthiasLuttermann, 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 12:52:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Jan-05-2021 23:25:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Matthias Luttermann	Approved	Dec-07-2020 19:47:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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-07-2020 11:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Matthias Luttermann	Approved	Dec-05-2020 15:14:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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.

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

(b) (6)	N/A	Dec-05-2020 11:30:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Nov-08-2020 22:44:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
Affidavit: By my dated signature below, I, MatthiasLuttermann, 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-07-2020 14:49:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Nov-03-2020 16:54:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
Affidavit: By my dated signature below, I, MatthiasLuttermann, 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	Oct-31-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Matthias Luttermann	Approved	Oct-30-2020 10:43:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Affidavit:

By my dated signature below, I, MatthiasLuttermann, 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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-19-2020 18:04:16 (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-19-2020 18:04:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Oct-19-2020 18:04:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/19/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-19-2020 18:04:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11971097	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:04:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: UNK/UNK/1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-19-2020 18:04:44 (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-19-2020 18:04:44 (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-19-2020 18:04:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 18:05:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-19-2020 18:05:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 18:05:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 18:05:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Oct-19-2020 18:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: diabetes mellitus type 2 Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 18:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetes mellitus type 2	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Oct-19-2020 18:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: hyperuricemia Start Date: Jan/8/1998 Ongoing: YES	Initial Entry
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:39:09 (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-19-2020 18:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hyperuricemia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/1998	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-19-2020 18:39:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 Medical History Term: hypercholesterolemia Start Date: Jan/8/2020	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

			Ongoing:	YES
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:39:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 18:39:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypercholesterolemia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:39:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2020	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:39:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-19-2020 18:40:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: renal insufficiency Start Date: Sep/26/2010 Ongoing: YES	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:40:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 15:42:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-20-2020 19:43:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	stable disease under control
Oct-20-2020 19:33:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	medical history reports a number of serious ongoing conditions (renal insufficiency, hypertension,diabetes): please confirm that they are all controlled and stable and that the patient fulfils inclusion criterion 3.
Oct-19-2020 18:40:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: renal insufficiency	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:40:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/26/2010	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:40:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

I.e

Date	Location	User	Value	Reason
Oct-19-2020 18:41:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: anemia Start Date: Oct/9/2014 Ongoing: YES	Initial Entry

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:41:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 18:41:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: anemia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:41:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2014	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:41:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-19-2020 18:41:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6 :	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

			Medical History Term: arterial hypertension Start Date: Sep/10/2003 Ongoing: YES	
--	--	--	---	--

I.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:41:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 18:41:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: arterial hypertension	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:41:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2003	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:41:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Oct-31-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: Medical History Term: Coxarthrosis left hip Start Date: Mar/22/2017 Ongoing: YES	Changed Information

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Oct-29-2020 22:01:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: Line/MH Nu 7 mber: Medical Hist insertion of endop ory Term: rothesis left hip Start Date: Mar/22/2017 Ongoing: YES	Changed Information
Oct-20-2020 00:03:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: Line/MH Numb 7 er: Medical Histor endoprothesis l y Term: eft hip Start Date: Mar/22/2017 Ongoing: YES	Changed Information
Oct-19-2020 18:43:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 7 er: Medical History endoprothetic l Term: eft hip Start Date: Mar/22/2017 Ongoing: YES	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:43:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-31-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Coxarthrosis left hip	Changed Information
Oct-30-2020 05:49:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.
Oct-29-2020 22:01:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-29-2020 22:01:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: insertion of endoprosthesis left hip	Changed Information
Oct-29-2020 18:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued :Opened	Please update the term to reflect the query response of "Insertion of Prosthesis."

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Oct-26-2020 09:02:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Insertion of Prosthesis is correct
Oct-25-2020 16:11:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Saumitra Dubey TMS Query (b) (4)	Query 2: Reissued :Opened	Coding Query: Thanks for the response. Coding of the verbatim can not happen with existing term. Kindly update the term and add insertion of prosthesis OR update the term as suggested previously.
Oct-20-2020 14:54:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Endoprosthesis Left Hip was necessary due to Coxarthrosis left Hip
Oct-20-2020 11:45:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Clarify ENDOPROTHESIS LEFT HIP as follows...Device only term. Are you reporting INSERTION? REMOVAL? INFECTION OF? COMPLICATION WITH? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Oct-20-2020 07:37:07 (UTC+01:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Sarajevo, Skopje, Warsaw, Zagreb				
Oct-20-2020 00:03:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-20-2020 00:03:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: endoprosthesis left hip	Changed Information

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Oct-19-2020 23:51:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify ENDOPROTHETIC LEFT HIP as follows...Device only reported. Are you reporting INSERTION? REMOVAL? INFECTION OF? Or other? Please update the verbatim term to further specify. Thank you.
Oct-19-2020 18:43:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: endoprothetic left hip	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:43:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/22/2017	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Nov-02-2020 12:18:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-31-2020 12:32:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Query was updated
Oct-30-2020 16:29:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	no term coding reported for this condition

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Oct-19-2020 18:43:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Oct-19-2020 18:08:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 65.9	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 170.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 22.8	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

7.a

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.2 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (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-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-19-2020 18:08:39 (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-19-2020 18:08:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-19-2020 18:44:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:44:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 270700	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 18:09:21 (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-19-2020 18:09:21 (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-19-2020 18:45:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 18:09:21 (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-19-2020 18:09:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 18:45:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8NZX	Initial Entry

5.a Sample ID

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Oct-19-2020 18:45:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8NZX	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 18:45:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN8NZY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:45:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8NZY	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 18:46:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNM3YZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:46:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNM3YZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-19-2020 18:46:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNM3Z0	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:46:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNM3Z0	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 18:09:36 (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-19-2020 18:09:36 (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-19-2020 18:46:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 18:09:36 (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-19-2020 18:09:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 18:46:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8NZD	Initial Entry

5.a Sample ID

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Oct-19-2020 18:46:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8NZD	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-19-2020 18:10:30 (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
Oct-19-2020 18:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-19-2020 18:10:30 (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
Oct-19-2020 18:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020 16:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-19-2020 18:10:30 (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
Oct-19-2020 18:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

7. Route:

Date	Location	User	Value	Reason
Oct-19-2020 18:10:30 (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-19-2020 18:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-19-2020 18:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 06-Jul-2020 21:53
Site No: 1197
Subject No: 11971097
Generated By: (b) (4)
Form: REACTOGENICITY DIARY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-19-2020 18:10:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS SU BJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-07-2020 15:50:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FA TIG UE	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.c Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> CH IL LS <u>Were fever or systemic sym</u> <u>ptoms present on the last da</u> <u>y the Subject Diary was co</u> <u>mpleted?:</u> NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry VO MIT ING NO
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (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-07-2020 15:51:19 (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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry DIA RR HE A NO

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.f Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> NEW OR WORSE ED MUS CLE PAI N <u>Were fever or system</u> NO <u>ic symptoms present</u> <u>on the last day the Su</u> <u>bject Diary was com</u> <u>pleted?:</u>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSE NED 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
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.h

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (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-07-2020 15:51:19 (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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio NO ns present on the last day t he Subject Diary was com pleted?:	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN A : T INJE CTION SITE Were injection site reac NO tions present on the last day the Subject Diary was completed?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-07-2020 15:51:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date:

Date	Location	User	Value	Reason
Nov-07-2020 15:52:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-07-2020 15:52:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Loca ORAL CAVI tion:: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-07-2020 15:52:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-07-2020 15:52:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-07-2020 15:52:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Nov-07-2020 15:52:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: C4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-07-2020 14:49:04 (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-07-2020 14:49:04 (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-07-2020 14:49:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-07-2020 14:49:04 (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-07-2020 14:49:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-07-2020 14:49:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8P3K	Initial Entry

5.a Sample ID

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-07-2020 14:49:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8P3K	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-07-2020 15:53:11 (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
Nov-07-2020 15:53:11 (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
Nov-07-2020 15:53:11 (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
Nov-07-2020 15:53:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/7/2020 15:27	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-07-2020 15:53:11 (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
Nov-07-2020 15:53:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

7. Route:

Date	Location	User	Value	Reason
Nov-07-2020 15:53:11 (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-07-2020 15:53:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-07-2020 15:59:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-05-2020 11:30:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020	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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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-05-2020 11:31:09 (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?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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-05-2020 11:31:09 (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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IG UE	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**2.c Symptom:**

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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-05-2020 11:31:09 (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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
			VO MIT ING NO	

2.e Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
			DIA RR HE A NO	

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

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2.f Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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-05-2020 11:31:09 (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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED 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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE ED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAI N	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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

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Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S subject Diary was completed ?:	Initial Entry
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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-05-2020 11:31:09 (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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:09 (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-05-2020 11:31:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

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:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-05-2020 12:55:48 (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-05-2020 12:55:48 (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-05-2020 12:55:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-05-2020 12:55:48 (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-05-2020 12:55:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-05-2020 12:55:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8PB4	Initial Entry

5.a Sample ID

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Dec-05-2020 12:55:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8PB4	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-05-2020 12:56:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8PB5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-05-2020 12:56:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8PB5	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-05-2020 12:56:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLMK6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-05-2020 12:56:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLMK6	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-05-2020 12:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLMK7	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sample ID

Date	Location	User	Value	Reason
Dec-05-2020 12:56:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNLMK7	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Jan-05-2021 11:23:47 (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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (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: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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1. Category:

Date	Location	User	Value	Reason
Jan-05-2021 11:23:47 (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
Jan-05-2021 11:23:47 (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-19-2021 16:35:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	OK
Feb-15-2021 12:53:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Update was done
Feb-10-2021 21:03:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	An update has not been noted. Escalated to CRA
Feb-04-2021 12:27:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Follow up reports were sent to Pfizer Drug Safety Unit
Feb-01-2021 17:32:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	thanks for your response. No FU form has been submitted and information has nt been updated. Kindly clarify.
Jan-26-2021 07:15:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	done
Jan-26-2021 01:31:39 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	Thanks for clarifying. Please provide this

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Skopje, Warsaw, Zagreb				information in a FU form so it is added to the safety report
Jan-25-2021 09:32:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Pharynxsmear for Coronar PCR
Jan-24-2021 16:44:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	Answer is not clear. Pls clarify information on safety report ("culture was negative"). Was this result from a urine, blood or other type of culture? Thank you.
Jan-20-2021 16:20:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	throat swab was taken in the hospital
Jan-20-2021 00:39:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	Per report AER#2021006704, the subject had a "culture was negative". Pls clarify if this was a urine, blood or other type of culture. Thanks.
Jan-15-2021 00:40:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Thank you for the prompt response.
Jan-12-2021 14:52:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	done
Jan-10-2021 17:44:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per report, "The subject underwent lab tests and procedures... and therapeutic measures were taken". However, this information is missing on safety report, kindly provide details on relevant lab tests (including covid testing) and tx in a FU

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Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

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Subject Initials: ---

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				form. Thanks
Jan-08-2021 14:13:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-07-2021 23:54:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Query 1: Answered	No prior Cardiac disease
Jan-06-2021 15:36:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise if subject has any known prior cardiac disease. Thanks
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute Posterior Myocardial Infa rction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/3/2021 14:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-17-2021 21:28:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: NO End Date Time: Jan/8/2021 UNK:UNK	Changed Information
Jan-05-2021 11:23:47 (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
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

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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
Jan-08-2021 12:53:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-07-2021 23:54:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Query 2: Answered	Already done and confirmed
Jan-06-2021 13:21:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:Acute Posterior Myocardial Infarction(Onset date:03Jan2021) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-06-2021 04:28:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute Posterior Myocardial Infarction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

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			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
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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
Jan-05-2021 11:23:47 (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
Jan-13-2021 18:05:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-12-2021 22:28:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-12-2021 22:28:20 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	Matthias Luttermann	Data Entry: NOT RELATED	Changed Information

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Skopje, Warsaw, Zagreb		(b) (4)	If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> arterial hypertension, hypercholesterolemia, diabetes mellitus type 2	
Jan-12-2021 22:05:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	I suggest to mention the known risk factors under OTHER causes
Jan-12-2021 16:36:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	I suggest to mention the known risk factors under OTHER causes
Jan-12-2021 14:27:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Positive Family History for Coronary Heart Disease and Diabetes Mellitus Typ II as positive Risk Factor
Jan-11-2021 15:38:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please report the most probable cause of this MI: of note patient's medical history was positive for important risk factors , as hypertension, hypercholesterolemia, diabetes.
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Acute Disease	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

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Subject Initials: ---

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Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-18-2021 06:44:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-17-2021 21:27:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Jan-17-2021 21:27:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: RECOVERED/RESOLVED	Changed Information
Jan-17-2021 11:52:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	SAE RECON 2: Outcome was recorded as RECOVERING/RESOLVING in AE CRF. Please confirm if this should be updated to recovered/resolved per previous query response (The Patient recovered 08 Jan 2021).

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Jan-15-2021 10:10:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Lars Pohlmeier (b) (4)	Query 2: Answered	The Patient recovered 08 Jan 2021
Jan-13-2021 11:24:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Op ened	SAE RECON 1: Outcome was updated to RECOVERED/RESOLVED in Safety database however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-12-2021 17:43:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	done
Jan-11-2021 10:53:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021006704,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-06-2021 04:30:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Closed	Auto closed by Validation Check: VC_AE001_35
Jan-05-2021 23:22:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Changed Information
Jan-05-2021 23:22:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: RECOVERING/RESOLVING	Changed Information
Jan-05-2021 16:17:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW6700250;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Jan-05-2021 11:23:47 (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?

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Date	Location	User	Value	Reason
Jan-05-2021 11:23:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-08-2021 12:52:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021006704	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (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
Mar-05-2021 12:22:28 (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
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Arm Swelling	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/13/2021 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/14/2021 16:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	1
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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
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (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-05-2021 12:31:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-05-2021 12:31:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Arm Swelling: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-05-2021 12:22:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Dec-07-2020 11:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-07-2020 11:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-07-2020 11:37:14 (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
Dec-07-2020 11:37:14 (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
Dec-07-2020 11:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fluzone 0.7 ml i m	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Dec-07-2020 11:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-05-2020 11:31:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-05-2020 11:31:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 18:00:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: Jan/25/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-09-2021 00:55:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allo wance(s) and confirmed to ha ve received only placebo at V accination 1/2	Transcription Error
Jan-25-2021 18:01:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 18:00:58 (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-25-2021 18:00:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-25-2021 18:01:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-25-2021 18:01:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-13-2021 11:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/13/2021	Changed Information
Feb-12-2021 14:12:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/12/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-15-2021 05:31:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-13-2021 11:57:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Due to TemperatureExcursion of IP Product Vaccination Day was 13/Feb/2021
Feb-13-2021 11:54:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Feb-13-2021 11:54:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/12/2021	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-08-2021 15:49:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Mar-08-2021 12:06:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Changed Information
Mar-08-2021 12:06:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Feb/1 3/202 1	Changed Information
Mar-08-2021 06:54:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued: Opene d	DM : Form unfrozen. Please review and update. Else, clarify.
Mar-05-2021 22:56:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Query 2: Ans wered	Correct date should be 13-FEB-2021, but cannot be changed; frozen?
Mar-05-2021 11:13:00 (UTC+01:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW7607873;Date of Completion/Discontinuation /Death on Disposition

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Sarajevo, Skopje, Warsaw, Zagreb				Screening for Further Vaccination is not equal to Date of Visit in the same visit. Please review and update as appropriate.
Feb-22-2021 07:33:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 20:46:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Lars Pohlmeier (b) (4)	Query 1: Answered	See comment
Feb-19-2021 20:37:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Was there a temporary delay of vaccination? is recorded as "No" on vaccination form. Please review and update if there was a delay in vaccination.
Feb-19-2021 15:47:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Lars Pohlmeier (b) (4)	Query 1: Answered	Changed data per query
Feb-19-2021 11:26:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thank you for response. Since there was a vaccination delay, Kindly consider to update the response for temporary delay of vaccination on the vaccination form. Else clarify.
Feb-18-2021 22:16:44	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Query 1: Answered	date correct, vaccination delay because of

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb			wered	temperature excursion and time costing process to release vaccination from quarantine
Feb-18-2021 09:05:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Op ened	Date is reported as 12Feb2021, but subject received vaccination on 13Feb2021. Please confirm the date is correct as entered or update if necessary. Otherwise clarify. Thank you.
Feb-12-2021 14:13:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Feb/1 2/202 1	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-12-2021 14:13:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-18-2021 22:17:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 13:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is COMPLETED but "Specify Status" is Provided.
Feb-12-2021 14:13:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

4. Specify Status:

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Feb-18-2021 22:17:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry:	Changed Information
Feb-18-2021 13:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Data is correct	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Feb-12-2021 14:48:46 (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-12-2021 14:48:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-19-2021 23:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: C losed	Response satisfies query
Feb-19-2021 09:36:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: A nswered	Date of collection is correct
Feb-19-2021 04:47:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: O pened	DMW7314605;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Feb-16-2021 07:42:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: C losed	As per site confirmation - updated PD tracker

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Feb-15-2021 13:00:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: A nswered	date confirmed
Feb-15-2021 09:51:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: O pened	PDQ: Date of collection 12-Feb-2021 is not equal to Date of visit. Please review and update the data or else clarify. Thanks.
Feb-12-2021 15:11:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: D eleted	Close Auto Query
Feb-12-2021 14:48:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C andidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 14:48:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: YES Date of C ollection: Feb/12/ 2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 15:11:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN0PDX	Initial Entry

5.a Sample ID

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Feb-12-2021 15:11:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN0PDX	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-12-2021 15:11:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN0PDC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 15:11:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN0PDC	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-12-2021 15:11:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMxz9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 15:11:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMxz9	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-12-2021 15:11:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLMG2	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 15:11:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLMG2	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:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-12-2021 14:13:56 (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-12-2021 14:13:56 (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-12-2021 14:14:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 14:13:56 (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-12-2021 14:13:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 14:14:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN0PDB	Initial Entry

5.a Sample ID

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten
Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Feb-12-2021 14:14:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN0PDB	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-23-2021 14:04:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 21:16:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Feb-22-2021 21:16:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: NO	changed data per query
Feb-22-2021 13:46:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	As per CCG: If the reason for delaying vaccination is not in the pre- defined list, "NO" should be selected to "Was there a temporary delay of vaccination" as the reason is documented via form/item level comment.
Feb-19-2021 20:45:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Lars Pohlmeier (b) (4)	Query 1: Answered	See comment
Feb-19-2021 20:44:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Reason(s) for Temporary Delay of Vaccination' is not entered. Please review and update as appropriate.
Feb-19-2021 20:44:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Lars Pohlmeier (b) (4)	Data Entry: YES Date of First Delay:	Changed Information

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			Feb/12/2021	
Feb-13-2021 11:53:40 (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-13-2021 11:53:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-13-2021 11:53:40 (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-13-2021 11:53:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/13/2021 11:03	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-13-2021 11:53:40 (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
Feb-13-2021 11:53:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Feb-13-2021 11:53:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Feb-13-2021 11:53:40 (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-13-2021 11:53:40 (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-13-2021 11:53:40 (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-13-2021 11:53:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 12:09:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/5/2021	Initial Entry

Header Text: C4591001**Visit:** V102_VAX4**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:** 1197**Site Name:** (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher**Subject No:** 11971097**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-05-2021 12:09:52 (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-05-2021 12:09:52 (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
Mar-05-2021 12:10:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 12:09:52 (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-05-2021 12:09:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 12:10:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN0PGR	Initial Entry

5.a Sample ID

Header Text: C4591001

Visit: V102_VAX4

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: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Mar-05-2021 12:10:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN0PGR	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-05-2021 13:36:32 (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
Mar-05-2021 13:36:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-05-2021 13:36:32 (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
Mar-05-2021 13:36:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/5/2021 13:36	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-05-2021 13:36:32 (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
Mar-05-2021 13:36:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1197

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject No: 11971097

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

7. Route:

Date	Location	User	Value	Reason
Mar-05-2021 13:36:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-05-2021 13:36:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-05-2021 13:36:32 (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
Mar-05-2021 13:36:32 (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
Mar-05-2021 13:36:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Subject Status

Date	Location	User	Value	Reason
Dec-05-2020 11:31:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-19-2020 18:44:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-19-2020 18:05:32 (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-05-2020 11:31:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/5/2020	Initial Entry
Oct-19-2020 18:44:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Oct-19-2020 18:05:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry

090177e196ae3f1b\Final\Final On: 01-Apr-2021 05:10 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1197

Subject No: 11971097

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1197) Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 10:43:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Matthias Luttermann (b) (4)	Data Entry: Click Here to Enable	Initial Entry