

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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/20/2020
----	--------------	--

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12031026]
2.	Birth Date:	UNK/UNK/1997
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:	

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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 _____
----	--	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Oct/20/2020
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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Form Comments](#)

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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
----	--	---

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/20/2020
2.	Weight:	[97.6]
3.	Unit:	kg
4.	Height:	[176.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/20/2020
2.	Randomization Number:	[110623]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
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	[BN8HKV]
5.b	Sample ID	[BN8HKW]
5.c	Sample ID	[BNLM00]
5.d	Sample ID	[BNLM01]

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
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	[BN8H8D]
-----	-----------	----------

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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/20/2020 12:10
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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/10/2020
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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/10/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
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	[BN1BCZ]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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/10/2020 09:36
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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **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	Dec/8/2020
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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1203**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject No:** 12031026**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/8/2020
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	[BN8HFF]
5.b	Sample ID	[BN8HFG]
5.c	Sample ID	[BNLM46]
5.d	Sample ID	[BNLM47]

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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_ILL - New
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 1203**Subject No:** 12031026**Generated By:**

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Not Started**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject Initials:** ---**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:	[]
----	------------------------	-----

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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:** 1203**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject No:** 12031026**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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?	
----	--	--

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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:** 1203**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject No:** 12031026**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: C4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1203**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject No:** 12031026**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	headache	Nov/7/2020 16:00	NO End Date Time: Nov/7/2020 17:00	Repeating Pages
2.	ADVERSE EVENT	2	inguinal hernia left	Nov/9/2020 16:00	NO End Date Time: Feb/19/2021 08:00	Repeating Pages

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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)	[headache]
4.	Start Date Time:	Nov/7/2020 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/7/2020 17:00
6.	Toxicity Grade:	2

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [stress induced]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[inguinal hernia left]
4.	Start Date Time:	Nov/9/2020 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 08:00
6.	Toxicity Grade:	2

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	<p>NO</p>

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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: [unknown]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	Comments
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	[2021143222]	

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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	[]

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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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.	Date:	//

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

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

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

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

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Unplanned Assessments

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

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

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/2/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[subject was called since he reported inguinal hernia with planned surgery on 09Feb2021 3rd vaccination was planned to 01MAR2021]

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Unplanned 2 - Unscheduled
Visit on Feb/10/2021

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned 2 - Unscheduled
Visit on Feb/10/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: C4591001

Visit: Unplanned 2 - Unscheduled
Visit on Feb/10/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/10/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Information was given that surgery for inguinal hernia was performed on 09FEB2021 including 1 overnight stay at surgery site, ConMed: Ibuprofen 400mg 3x/day starting 09FEB2021, AE onset corrected]

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Unplanned 3 - Unscheduled
Visit on Feb/11/2021

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

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[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: Unplanned 3 - Unscheduled
Visit on Feb/11/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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Unplanned Assessments

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Unplanned 3 - Unscheduled
Visit on Feb/11/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/11/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[further questions about start date of AE due to contradicting information]

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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?	

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Dec/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[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: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Disposition - Follow-Up

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/2/2021
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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

			Comments
1.	Withdrawal of Consent Date :	Not Applicable <hr/> //	

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	Comments
----	--	-------------------------------	--------------------------

Cause of Death

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ []

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

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

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Form Comments](#)

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	--	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN1BJP]
5.b	Sample ID	[BN1BJR]
5.c	Sample ID	[BNLM8R]
5.d	Sample ID	[BNLM8S]

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN1BM9]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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/1/2021 10:41
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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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?	

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1203) CRS Clinical Research Services Berlin

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Disposition - Treatment

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/8/2020

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Sybille Baumann	Approved	Mar-02-2021 18:00:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

Affidavit:

By my dated signature below, I, SybilleBaumann, 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: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-20-2020 10:14:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-20-2020 10:20:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
10	Feb-10-2021 15:28:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) [Redacted] [Redacted]	Drug for Vaccination 3 temporarily withdrawn or withheld

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-03-2021 12:43:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Disposition

Form: WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
1	Feb-03-2021 12:43:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-03-2021 12:43:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Disposition

Form: DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
1	Feb-03-2021 12:43:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 11:23:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[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
Sybille Baumann	Approved	Mar-02-2021 18:00:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

Affidavit:

By my dated signature below, I, SybilleBaumann, 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-01-2021 11:22:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Sybille Baumann	Approved	Feb-17-2021 16:30:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

By my dated signature below, I, SybilleBaumann, 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-15-2021 14:59:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Sybille Baumann	Approved	Feb-12-2021 11:03:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

By my dated signature below, I, SybilleBaumann, 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-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Sybille Baumann	Approved	Feb-04-2021 16:56:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

By my dated signature below, I, SybilleBaumann, 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-03-2021 07:53:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Sybille Baumann	Approved	Dec-11-2020 18:15:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

By my dated signature below, I, SybilleBaumann, 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-08-2020 13:08:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-17-2020 17:14:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

Affidavit:

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

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

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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Nov-02-2020 13:52:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Transcription Error
Oct-20-2020 09:52:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 09:52:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Oct-20-2020 09:52:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/20/2020	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-20-2020 09:52:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12031026	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-20-2020 11:43:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: UNK/UNK/1997	Transcription Error
Oct-20-2020 09:52:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1997	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-20-2020 09:53:24 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: MALE	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Sarajevo, Skopje,
Warsaw, Zagreb

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-20-2020 09:53:11 (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-20-2020 09:53:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-20-2020 10:14:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/20/2020	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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-20-2020 10:14:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-20-2020 10:14:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-20-2020 10:14:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-20-2020 10:15:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: The subject is NOT k nown to be HIV POSI TIVE	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 176.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Record Ide 1	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Sarajevo, Skopje, Warsaw, Zagreb			ntifier:: Temperatu 37.0 re: Temperatu C re Unit: Temperatu ORAL re Location CAVIT :: Y
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7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: C	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-20-2020 10:15:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-20-2020 10:16:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-20-2020 10:16:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 110623	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-20-2020 13:23:18 (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-20-2020 13:23:18 (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-20-2020 13:23:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 13:23:18	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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:** 1203**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject No:** 12031026**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 13:23:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 13:23:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Sample ID BN8HK : V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 13:23:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: BN8HKV	Initial Entry

5.b

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-20-2020 13:23:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample I BN8HK D: W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 13:23:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BN8HKW	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 13:24:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample ID BNLM0 : 0	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 13:24:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BNLM00	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 13:24:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample ID BNLM0 : 1	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 13:24:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BNLM01	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-20-2020 13:24:41 (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-20-2020 13:24:41 (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-20-2020 13:24:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 13:24:41	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 13:24:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 13:24:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID BN8H8 : D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 13:24:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BN8H8D	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-20-2020 13:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-20-2020 13:25:36 (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-20-2020 13:25:36 (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
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-20-2020 13:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020 12:10	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-20-2020 13:25:36 (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-20-2020 13:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-20-2020 13:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-20-2020 13:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-20-2020 13:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: YES	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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-20-2020 13:25:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGEN ICITY E-DIARY CO LLECTED FOR THI S SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-13-2020 11:34:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 15:18:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	in e-Diary as of 12NOV2020 15:18 no severe reaction is present for this subject
Nov-12-2020 15:06:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	the patient reported a severe reaction on Nov.11th: is an unplanned assessment or telehealth visit going to be performed?
Nov-10-2020 14:04:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/10/2020	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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(b) (4)

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

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptom O s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

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Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

2.b Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

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Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO

2.c Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

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

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Subject Initials: ---

Generated By:

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(b) (4)

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(b) (4), (b) (6)	HI L LS	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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2.d Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (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-10-2020 14:05:02 (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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Header Text: C4591001

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Subject Initials: ---

Generated By:

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(b) (4)

Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed? :	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (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-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

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Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

2.f

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><u>Data Entry:</u></p> <p>Symptom:: DI AR RH EA</p> <p>Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?:</p>	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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Subject No: 12031026

Subject Initials: ---

Generated By:

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(b) (4)

2.f Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN	Initial Entry

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Subject No: 12031026

Subject Initials: ---

Generated By:

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(b) (4)

Were fever or NO
r systemic sy
mptoms pres
ent on the la
st day the Su
bject Diary
was complet
ed?:

2.g Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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Header Text: C4591001

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Site Name: (1203) CRS Clinical Research Services Berlin

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Subject Initials: ---

Generated By:

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(b) (4)

<p>Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever o NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary w as completed ?:</p>	<p>Initial Entry</p>
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Header Text: C4591001

Visit: V2_VAX2_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

2.h Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (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-10-2020 14:05:02 (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
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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Subject Initials: ---

Generated By:

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(b) (4)

Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE RE D NE SS Were injection site reactions presented on the last day the Subject Diary was completed?: N O	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (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-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

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Subject Initials: ---

Generated By:

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(b) (4)

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTI ON S ITE	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

			Were injections present on the last day the Subject Diary was completed?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-10-2020 14:05:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-10-2020 14:05:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location: Oral Cavity: 1 36.6 C CAVITY Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:16 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Sarajevo, Skopje, Warsaw, Zagreb				
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2.a Temperature:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-10-2020 14:05:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Nov-10-2020 14:05:27 (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-10-2020 14:05:27 (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-10-2020 14:05:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 14:05:27	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb				Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 14:05:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 14:05:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BN1BC : Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-10-2020 14:05:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN1BCZ	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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-10-2020 14:06:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-10-2020 14:06:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-10-2020 14:06:11 (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
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-10-2020 14:06:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/10/2020 09:36	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-10-2020 14:06:11 (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
Nov-10-2020 14:06:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-10-2020 14:06:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-10-2020 14:06:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-10-2020 14:06:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-08-2020 13:08:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Dec/8/2020	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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptom O s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:11

Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 Subject Initials: ---

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

(b) (4)

2.b Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **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.c Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:11

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	HI L LS	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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2.d Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (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
Dec-08-2020 13:10:40 (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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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:11

Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed? :	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (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-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

2.f

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

2.f Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:11

			Were fever or NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever o NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary w as completed ?:	Initial Entry
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

2.h Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (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-08-2020 13:10:40 (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
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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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE RE D NE SS Were injection site reactions presented on the last day the Subject Diary was completed?: N O	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (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-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **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-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTI ON S ITE	Initial Entry

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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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-08-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: 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: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **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
Dec-08-2020 13:09:15 (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-08-2020 13:09:15 (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-08-2020 13:09:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 13:09:15	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

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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: 1203 Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 Subject Initials: ---

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

(b) (4)

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-08-2020 13:09:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-08-2020 13:09:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BN8HF : F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 13:09:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HFF	Initial Entry

5.b

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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Site No: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

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

(b) (4)

Date	Location	User	Value	Reason
Dec-08-2020 13:09:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BN8HF : G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 13:09:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8HFG	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-08-2020 13:09:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNLM4 : 6	Initial Entry

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

5.c Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 13:09:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BNLM46	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-08-2020 13:10:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID BNLM4 : 7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 13:10:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BNLM47	Initial Entry

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Generated By:

(b) (4)

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Form Status:

Site Name: (1203) CRS Clinical Research Services Berlin

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Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

Header Text: C4591001

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Generated By:

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(b) (4)

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Date	Location	User	Value	Reason
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

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(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (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
Nov-10-2020 14:08:21 (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
Nov-12-2020 11:06:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answe	headache was

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Header Text: C4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified
Site No: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin
Subject No: 12031026 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

15:59:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(b) (4), (b) (6) [REDACTED]	red	induced to stress at university, thus a COVID 19 illness visit was not indicated in the opinion of the investigator
Nov-11-2020 15:53:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINQUERY-Nausea/fatigue/headache/nasal congestion/runny nose may represent a potential COVID-19 symptom, please consider whether a COVID-19 illness visit may be indicated. Thank you
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020 16:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/7/2020 17:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

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Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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(b) (4)

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> stress induced	Initial Entry

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Subject No: 12031026

Subject Initials: ---

Generated By:

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(b) (4)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Generated By:

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(b) (4)

Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESO LVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-10-2020 14:08:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Generated By:

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(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-24-2021 20:53:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you for the confirmation.
Feb-17-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answer	after further

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Subject Initials: ---

Generated By:

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

(b) (4)

<p>09:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb</p>		<p>(b) (4), (b) (6)</p>	<p>ed</p>	<p>clarification subject stated that symptom onset was on 9thNovember, Follow-UP SAE report has already been sent to safety board, physician consultation was on 16NOV2020 and in Jan2021, hospitalization was on 09FEB2021</p>
<p>Feb-16-2021 21:02:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb</p>	<p>ACV0PFEINFP6000</p>	<p>Giselle Castillo (b) (4)</p>	<p>Query 1: Opened</p>	<p>CLINICAL_ Per report, "adverse event symptom onset was on 22Dec2020". Pls clarify symptom of onset and if the subject went to ED/was hospitalized on that date. Thanks.</p>

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Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: inguinal hernia le ft	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 15:04:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Nov/9/2020 16:00	Changed Information
Feb-12-2021 16:39:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	as discussed with SI today site will wait for hospital record to be sure about the start date of the SAE
Feb-12-2021 13:39:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	discrepancy: per info documented on 11Feb21 in source symptoms started on 9Nov2021

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Subject No: 12031026

Subject Initials: ---

Generated By:

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(b) (4)

Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Dec/22/2020 16:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 20:16:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Mar-01-2021 12:45:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-01-2021 12:45:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO End Date Time: Feb/19/2021 08: 00	New Information
Feb-26-2021 21:40:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	CLINQUERY: Please confirm if "inguinal hernia left" remains ongoing (start

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1203**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject No:** 12031026**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

				Nov 09, 2020). Else, review if update can be applied to end date and outcome status. Thank you
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 2	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Logs - Unscheduled

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Feb-17-2021 02:15:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 22:03:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Closed	Response satisfies query
Feb-11-2021 08:08:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answer ed	Answer Auto Query
Feb-11-2021 08:08:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: YES Is this serious e vent associated with congenital anomaly or birt h defect? NO Did this serious event result in d eath? NO	Transcription Error

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			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? NO Other medically important serious event NO	
Feb-11-2021 06:44:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Kindly consider to tick all the seriousness criteria's reported in CRF field.

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Generated By:

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(b) (4)

				Thank you.
Feb-10-2021 15:25:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Answered	Event is serious due to required surgery with hospitalization for 1 night
Feb-10-2021 15:23:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Feb-10-2021 15:23:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE inguinal hernia left: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-10-2021 15:23:58	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Changed Information

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(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(b) (4), (b) (6)	Did this serious event require or prolong hospitalization? YES	
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-10-2021 12:48:01 (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:	Initial Entry

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(b) (4)

			OTHER	
			<i>If Other, specify:</i>	
			unknown	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 21:19:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Feb-11-2021 15:38:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-11-2021 15:38:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Feb-11-2021 13:53:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Blinded treatment phase is complete and open label phase has not yet started (vax

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Generated By:

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				3 not yet given). As such, please review this entry. Temporary delays are not classified as 'drug withdrawn'
Feb-10-2021 15:28:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: DRUG WITHDR AWN	Changed Information
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NOT APPLICAB LE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-10-2021 15:29:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Changed Information
Feb-10-2021 12:48:01	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

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(UTC+01:00)
Sarajevo, Skopje,
Warsaw, Zagreb

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-10-2021 15:26:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Changed Information
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:46:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Cl osed	Close Auto Query
Mar-01-2021 12:46:13 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry : RECOVER	New Information

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Subject No: 12031026

Subject Initials: ---

Generated By:

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Sarajevo, Skopje, Warsaw, Zagreb			ED/RESOLVED	
Mar-01-2021 12:45:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE inguinal hernia left: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-10-2021 15:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : RECOVERING/RESOLVING	Changed Information
Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
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Feb-10-2021 12:48:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-17-2021 02:15:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021143222	Initial Entry

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Generated By:

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 07:53:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Feb/2/2021	Initial Entry

Header Text: C4591001

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Subject No: 12031026

Generated By:

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Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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1. Assessments

Date	Location	User	Value	Reason
Feb-03-2021 07:56:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 07:53:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-03-2021 07:53:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCO ME	Initial Entry

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Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled
Visit on Feb/02/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1203**Subject No:** 12031026**Generated By:**

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Form: CONTACT OUTCOME - UNPLANNED - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1203) CRS Clinical Research Services Berlin**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Feb-03-2021 07:56:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-03-2021 07:56:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/2/2021 Contact Outcome: VISIT NOT REQ UIRED, INVESTI GATOR DECISIO N	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
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Feb-03-2021 07:56:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject was called since he reported inguinal hernia with planned surgery on 09Feb2021 3rd vaccination was planned to 01MAR2021	Initial Entry
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Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 15:30:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Feb/10/2021	Initial Entry

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1. Assessments

Date	Location	User	Value	Reason
Feb-10-2021 15:32:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 15:30:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-10-2021 15:30:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: CONTACT OUTCOME	Initial Entry

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-10-2021 15:32:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: YES Date of Contact: Feb/10/2021 Contact Outcome: VISIT NOT RE QUIRED, INVE STIGATOR DE CISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
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Feb-10-2021 15:32:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Information was given that surgery for inguinal hernia was performed on 09 FEB 2021 including 1 overnight stay at surgery site, ConMed: Ibuprofen 400mg 3 x/day starting 09 FEB 2021, AE onset corrected	Initial Entry
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1. Date of Visit

Date	Location	User	Value	Reason
Feb-15-2021 14:59:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

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1. Assessments

Date	Location	User	Value	Reason
Feb-15-2021 15:01:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 14:59:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-15-2021 14:59:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCO ME	Initial Entry

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-15-2021 15:01:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-15-2021 15:01:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/11/2021 Contact Outcome: VISIT NOT REQ UIRED, INVESTI GATOR DECISIO N	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
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090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Unplanned 3 - Unscheduled
Visit on Feb/11/2021

Form Version: 22-Apr-2020 21:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

Feb-15-2021 15:01:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: further questions abao ut start date of AE du e to contradicting info rmation	Initial Entry
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Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-08-2020 13:10:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-08-2020 13:10:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 12:43:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Feb/2/2021	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1203 **Site Name:** (1203) CRS Clinical Research Services Berlin

Subject No: 12031026 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Feb-03-2021 12:43:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 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	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-03-2021 12:42:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Feb/2/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-03-2021 12:42:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: ASSESS ELIGIBIL ITY FOR ADDITI ONAL VACCINAT ION	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-03-2021 12:43:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Not Applicable	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Feb-03-2021 12:43:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Not Applicable	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-01-2021 11:22:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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1. Consent Was:

Date	Location	User	Value	Reason
Mar-01-2021 11:23:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Mar/1/2021	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-01-2021 11:24:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-01-2021 11:24:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENIN G 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-01-2021 11:24:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-01-2021 11:25:03 (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-01-2021 11:25:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 11:25:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021	ACV0PFEINFP6000	auto query	Query 1: Can	'Sample

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

11:25:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(autoquery)	didate	Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 11:25:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-01-2021 11:25:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN1 BJP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:25:29 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN1BJP	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Sarajevo,
Skopje, Warsaw,
Zagreb

5.b

Date	Location	User	Value	Reason
Mar-01-2021 11:25:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BN1 ID: BJR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:25:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN1BJR	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-01-2021 11:26:05 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sampl BNL e ID: M8R	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Skopje, Warsaw,
Zagreb

5.c Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:26:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLM8R	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-01-2021 11:26:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BNL ID: M8S	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

5.d Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:26:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLM8S	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Mar-01-2021 11:26:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 11:26:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 11:27:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021	ACV0PFEINFP6000	auto query	Query 1: Can	'Sample

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

11:26:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(autoquery)	didate	Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 11:26:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-01-2021 11:27:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BN1B ID: M9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:27:26 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN1BM9	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Sarajevo, Skopje, Warsaw, Zagreb				
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

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-01-2021 11:31:18 (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-01-2021 11:31:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-01-2021 11:31:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Mar-01-2021 11:31:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021 10: 41	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-01-2021 11:31:18 (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-01-2021 11:31:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-01-2021 11:31:18	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC+01:00)
Sarajevo, Skopje,
Warsaw, Zagreb

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-01-2021 11:31:18 (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-01-2021 11:31:18 (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-01-2021 11:31:18 (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

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (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: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

investigational product administration?

Date	Location	User	Value	Reason
Mar-01-2021 11:31:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Dec-08-2020 13:10:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-20-2020 10:16:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-20-2020 10:14:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-08-2020 13:10:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/8/2020	Initial Entry
Oct-20-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1203

Site Name: (1203) CRS Clinical Research Services Berlin

Subject No: 12031026

Subject Initials: ---

Generated By:

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

(b) (4)

10:16:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(autocalc)	Oct/20/2020	
Oct-20-2020 10:14:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Initial Entry

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1203

Subject No: 12031026

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1203) CRS Clinical Research Services Berlin

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-15-2020 19:35:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Sybille Baumann (b) (4)	Data Entry: Click Here to Enabl e	Initial Entry

090177e196ae3f12\Final\Final On: 01-Apr-2021 05:08 (GMT)