Subject Enrollment ID	
Subject Identifier for the Study	
System Date	

First Visit/Screening Date	
First Run In Visit Date	
Visit Identifier	
Randomization Date/First IMP Allocation Date	
Randomization Time/First IMP Allocation Time	
Randomization Number	
Randomization Block Number	
Randomization Sequence Number	
Stratification Factor 1	
Stratification Factor 2	
Stratification Factor 3	
Stratification Factor 4	
Stratification Factor 5	
Treatment Number as Planned	
Treatment Arm as Planned	
Subgroup Information as Planned 1	
Subgroup Information as Planned 2	
Subgroup Information as Planned 3	
Treatment Side as Planned	Left ☐ Right ☐
Category for Treatment	
Date of Treatment Allocation	
Time of Treatment Allocation	
Date of Treatment Allocation (IVRS/IWRS)	
Time of Treatment Allocation (IVRS/IWRS)	
Is there a blind broken?	
Local Date of blind broken	
Function of the blind breaker	ESMS ☐ Investigator ☐ Pharmacist ☐ Study Nurse ☐
IVRS original export date and time	
IVRS Transaction ID	

Was the visit performed?	Yes ☐ No ☐
If yes, provide the date:	
Date of Visit	_____

Protocol Version	Original Protocol ■ Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐ Amendment 6 ☐ Amendment 7 ☐ Amendment 8 ☐ Amendment 9 ☐ Amendment 10 ☐ Version 1 ☐ Version 2 ☐ Version 3 ☐
Did the subject meet all eligibility criteria?	Yes ☐ No ☐

If no, specify Criterion Category(ies) and Number(s).

Criterion Category	Exclusion Criteria ☐ Inclusion Criteria ☐
Criterion Number and Description	
Criterion Number	
Technical field for Dynamic searchlist needs	Techdumval ■ Aged 18 to 30 years on the day of inclusion ☐ Informed consent form has been signed and dated ☐ Able to attend all scheduled visits and to comply with all study procedures ☐ Subject is pregnant, or lactating, or of childbearing potential and not using an effective method of contraception or abstinence from at least 4 weeks prior to vaccination until at least 12 weeks after... ☐

- [ ] Participation at the time of study enrollment (or in the 4 weeks preceding the study vaccination) or planned participation during the present study period in another clinical study investigating…
- [ ] Receipt of any vaccine in the 4 weeks preceding the study vaccination or planned receipt of any vaccine in the 4 weeks following study vaccination
- [ ] Previous vaccination against influenza in the previous influenza season (2018-2019) with any licensed or investigational influenza vaccine
- [ ] Previous vaccination against influenza in the 2019-2020 season with any licensed influenza vaccine
- [ ] Receipt of immune globulins, blood or blood-derived products in the past 3 months
- [ ] Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy, such as anti-cancer chemotherapy or radiation therapy, within the preceding 6 months; or...
- [ ] Have known active or recently active (12 months) neoplastic disease or a history of any hematologic malignancy
- [ ] History of influenza infection during the 2018-2019 or 2019-2020 influenza season, confirmed by laboratory tests (including rapid tests)

- [ ] Self-reported or documented seropositivity for human immunodeficiency virus, hepatitis B, or hepatitis C
- [ ] Known systemic hypersensitivity to any of the vaccine components, or history of a lifethreatening reaction to the vaccines used in the study or to a vaccine containing any of the same substances
- [ ] Thrombocytopenia or bleeding disorder, contraindicating IM vaccination based on Investigator's judgement
- [ ] Deprived of freedom by an administrative or court order, or in an emergency setting, or hospitalized involuntarily
- [ ] Alcohol abuse or substance abuse that, in the opinion of the investigator, might interfere with the study conduct or completion
- [ ] Chronic illness that, in the opinion of the investigator, is at a stage where it might interfere with study conduct or completion or predispose to complications associated with influenza infection
- [ ] Have any diagnosis, current or past, of chronic pulmonary diseases including asthma, cystic fibrosis and chronic pulmonary obstructive disease
- [ ] Have taken high-dose inhaled corticosteroids within 6 months prior to study vaccination
- [ ] Body Mass Index of 40 or higher

	History of cardiac disease such as congenital heart disease, heart failure, coronary artery disease (except isolated hypertension) ☐
	Health care personnel in inpatient and outpatient care settings, medical emergency-response workers, employees of nursing home and long-term care facilities who have contact with patients... ☐
	Moderate or severe acute illness/infection (according to investigator judgment) on the day of vaccination or febrile illness (temperature >= 100.4°F [>= 38.0°C]). A prospective subject should not be... ☐
	Identified as an Investigator or employee of the Investigator or study center with direct involvement in the proposed study, or identified as an immediate family member (i.e., parent, spouse, natural... ☐
	Personal or family history of GBS ☐

Informed Consent

INFORMED CONSENT OBTAINED	Informed Assent Obtained from Juvenile ☐ Informed Consent Obtained ☐ Archived Biopsy Informed Consent Obtained ☐ Archived Blood Samples Informed Consent Obtained ☐ Child Who Reached Age of Majority Informed Consent Obtained ☐ Drug Metabolism Enzyme Informed Consent Obtained ☐ Fresh Biopsy Informed Consent Obtained ☐ HIV Test Informed Consent Obtained ☐ Pharmacogenetic Analysis Informed Consent Obtained ☐ Pharmacogenetic Banking Informed Consent Obtained ☐ Pharmacogenomic Informed Consent Obtained ☐ Pharmacokinetics Informed Consent Obtained ☐ Study Informed Consent Obtained ■ Informed Consent Obtained for Use of Data and Samples for Future Research ☐ Informed Consent Obtained to Perform Autopsy ☐ Informed Consent Obtained to Perform HeFH Genotyping ☐ Informed Consent Obtained to Use Previous HeFH Genotyping ☐
INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED FOR STUDY
Date of Informed Consent	

INFORMED CONSENT OBTAINED	
	Informed Assent Obtained from Juvenile ☐
	Informed Consent Obtained ☐
	Archived Biopsy Informed Consent Obtained ☐
	Archived Blood Samples Informed Consent Obtained ☐
	Child Who Reached Age of Majority Informed Consent Obtained ☐
	Drug Metabolism Enzyme Informed Consent Obtained ☐
	Fresh Biopsy Informed Consent Obtained ☐
	HIV Test Informed Consent Obtained ☐
	Pharmacogenetic Analysis Informed Consent Obtained ☐
	Pharmacogenetic Banking Informed Consent Obtained ☐
	Pharmacogenomic Informed Consent Obtained ☐
	Pharmacokinetics Informed Consent Obtained ☐
	Study Informed Consent Obtained ☐
	Informed Consent Obtained for Use of Data and Samples for Future Research ■
	Informed Consent Obtained to Perform Autopsy ☐
	Informed Consent Obtained to Perform HeFH Genotyping ☐
	Informed Consent Obtained to Use Previous HeFH Genotyping ☐

INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED FOR USE OF DATA AND SAMPLES FOR FUTURE RESEARCH
Informed Consent Obtained for Use of Data and Samples for Future Research?	Yes ☐ No ☐

Year of Birth	
Date of Birth	
Age	
Age	
Unit	Hour ☐ Day ☐ Week ☐ Month ☐ Year ■
Sex	Male ☐ Female ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check all that apply):	
American Indian or Alaska Native	
Black or African American	
Native Hawaiian or Other Pacific Islander	
White	
Asian	
Not Reported	
Unknown	
If Asian, specify the origin reported by the subject. Check all that apply.	
Chinese	
Japanese	
Asian Indian	
Korean	
Other Asian Origin	
If Other, Specify.	
Not Reported	
Unknown	

Category for Clinical Event	Allergic Reaction ☐ Bone Fracture ☐ Hypersensitivity/Allergic Reaction ☐ Hypoglycemic Events ☐ Hypoglycemic Symptoms ☐ Injection Site Reaction ☐ Multiple Sclerosis ☐ Neurologic Disorder ☐ Suspected Dengue Event ☐ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Suspected Influenza Event ■
Did the subject experience any Influenza Like Illness since last visit?	Yes ☐ No ☐

If the subject experienced influenza like illness, provide all the action taken. If not, leave all the fields blank.

Episode ID	
Clinical Event Term	INFLUENZA LIKE ILLNESS
Pre-specified?	Yes ■ No ☐
Medication	
Health Care Visit	
Hospitalized	
No Action Taken	
Duration	Fixed Unit: Days
Duration Unit	Day ■
Laboratory confirmed?	Yes ☐ No ☐

List significant past or current diagnoses, for the following Body Systems: Blood and Lymphatic / Cardiovascular / Gastrointestinal / Hepatobiliary / Neurological / Psychiatric / Renal and urinary / Respiratory / Endocrine and metabolic / Neoplasms benign, malignant and unspecified / Musculoskeletal and connective tissue.

Has the subject experienced any significant past and/or current diseases?	Yes ☐ No ☐
If yes, complete the following questions.	
Unique ID	
Medical History Term	
Ongoing at Inclusion	

Category for Medication

- [ ] Anti-Cancer Therapy
- [ ] Anti-Hyperglycemic Therapy
- [ ] Antibiotic
- [ ] Asthma Controller
- [ ] Asthma Reliever
- [ ] Basal Insulin
- [ ] History of Anti-Hyperglycemic Therapy
- [ ] History of Lipid Modifying Therapy
- [x] History of Vaccination
- [ ] Hypoglycemic Treatment
- [ ] Lipid Lowering Therapy
- [ ] Lipid Modifying Therapy Excluding Statin Medication
- [ ] Non Medication Therapy
- [ ] Rescue Therapy
- [ ] SAE Complementary Information
- [ ] Statin Therapy
- [ ] Systemic Corticoid Therapy
- [ ] Other
- [ ] Category 1
- [ ] Category 2
- [ ] Category 3

Record information related only to \Influenza /Japanese Encephalitis/Yellow Fever/Diphtheria/Tetanus/Pneumococcal/Meningococcal/Licensed Dengue \vaccinations. Other vaccinations should be recorded in the Reportable Medications page.
Use exact spelling.

Vaccination History Type

- [ ] Antibiotic
- [ ] Antibiotics
- [ ] Diphtheria Vaccine
- [ ] Highlighted Dose
- [ ] Japanese Encephalitis Vaccine
- [ ] Licensed Dengue Vaccine
- [ ] Meningococcal Vaccine
- [ ] Non-Study Vaccines
- [ ] Pneumococcal Vaccine

	Post Study Treatment(s) ☐
	Prior Study Treatment ☐
	Seasonal Influenza Vaccine ■
	Tetanus Vaccine ☐
	Yellow Fever Vaccine ☐
Pre-Specified?	Yes ■
	No ☐
Year of Vaccination	SEASONAL INFLUENZA VACCINATION SINCE 01SEP2019
Vaccination received? *(If Yes, provide Details)*	Yes ☐
	No ☐
	Unknown ☐
Date of Last Administration	_____
Vaccination History Type	Antibiotic ☐
	Antibiotics ☐
	Diphtheria Vaccine ☐
	Highlighted Dose ☐
	Japanese Encephalitis Vaccine ☐
	Licensed Dengue Vaccine ☐
	Meningococcal Vaccine ☐
	Non-Study Vaccines ☐
	Pneumococcal Vaccine ☐
	Post Study Treatment(s) ☐
	Prior Study Treatment ☐
	Seasonal Influenza Vaccine ■
	Tetanus Vaccine ☐
	Yellow Fever Vaccine ☐
Pre-Specified?	Yes ■
	No ☐
Year of Vaccination	SEASONAL INFLUENZA VACCINATION BETWEEN 01SEP2018 AND 31AUG2019
Vaccination received? *(If Yes, provide Details)*	Yes ☐
	No ☐
	Unknown ☐
Date of Last Administration	_____

Vaccination History Type	Antibiotic ☐ Antibiotics ☐ Diphtheria Vaccine ☐ Highlighted Dose ☐ Japanese Encephalitis Vaccine ☐ Licensed Dengue Vaccine ☐ Meningococcal Vaccine ☐ Non-Study Vaccines ☐ Pneumococcal Vaccine ☐ Post Study Treatment(s) ☐ Prior Study Treatment ☐ Seasonal Influenza Vaccine ■ Tetanus Vaccine ☐ Yellow Fever Vaccine ☐
Pre-Specified?	Yes ■ No ☐
Year of Vaccination	SEASONAL INFLUENZA VACCINATION BETWEEN 01SEP2017 AND 31AUG2018
Vaccination received? *(If Yes, provide Details)*	Yes ☐ No ☐ Unknown ☐
Date of Last Administration	_____

Vaccination History Type	Antibiotic ☐ Antibiotics ☐ Diphtheria Vaccine ☐ Highlighted Dose ☐ Japanese Encephalitis Vaccine ☐ Licensed Dengue Vaccine ☐ Meningococcal Vaccine ☐ Non-Study Vaccines ☐ Pneumococcal Vaccine ☐ Post Study Treatment(s) ☐ Prior Study Treatment ☐ Seasonal Influenza Vaccine ■ Tetanus Vaccine ☐ Yellow Fever Vaccine ☐

Pre-Specified?	Yes ■ No ☐
Year of Vaccination	SEASONAL INFLUENZA VACCINATION BETWEEN 01SEP2016 AND 31AUG2017
Vaccination received? *(If Yes, provide Details)*	Yes ☐ No ☐ Unknown ☐
Date of Last Administration	_____

MH Category	Allergy ☐ Asthma ☐ Blood Disorder ☐ Cardiovascular Disorder ☐ Diabetes ☐ Disease History ■ Epistaxis ☐ Hepatobiliary Disorder ☐ Hyperlipoproteinemia ☐ Juvenile Idiopathic Arthritis ☐ Medical or Surgical ☐ Multiple Sclerosis ☐ Neurologic Disorder ☐ Polyposis ☐ Pompe Disease ☐ Renal Disorder ☐ Respiratory Disorder ☐ Rheumatologic Disorder ☐ Rhinosinusitis ☐ SAE Complementary Information ☐ Scleroderma ☐ Other ☐

Record information related only to Influenza disease history.

Pre-Specified?	Yes ■ No ☐
Type of Infection	LABORATORY-CONFIRMED INFLUENZA ILLNESS
Evaluation Interval	SINCE 01SEP2019
Was infection experienced during the evaluation interval? *(If Yes, Provide Details)*	Yes ☐ No ☐ Unknown ☐
Date	_____
Specify Symptoms	_____
Pre-Specified?	Yes ■ No ☐
Type of Infection	

	LABORATORY-CONFIRMED INFLUENZA ILLNESS
Evaluation Interval	BETWEEN 01SEP2018 AND 31AUG2019
Was infection experienced during the evaluation interval? *(If Yes, Provide Details)*	Yes ☐ No ☐ Unknown ☐
Date	
Specify Symptoms	
Pre-Specified?	Yes ■ No ☐
Type of Infection	LABORATORY-CONFIRMED INFLUENZA ILLNESS
Evaluation Interval	BETWEEN 01SEP2017 AND 31AUG2018
Was infection experienced during the evaluation interval? *(If Yes, Provide Details)*	Yes ☐ No ☐ Unknown ☐
Date	
Specify Symptoms	
Pre-Specified?	Yes ■ No ☐
Type of Infection	LABORATORY-CONFIRMED INFLUENZA ILLNESS
Evaluation Interval	BETWEEN 01SEP2016 AND 31AUG2017
Was infection experienced during the evaluation interval? *(If Yes, Provide Details)*	Yes ☐ No ☐ Unknown ☐
Date	
Specify Symptoms	

Central Data Category	☐ Ability to Perform Physical Activities of Daily Living Questionnaire (APPADL) ☐ Banking ☐ Biomarkers ☐ Cell-Mediated Immunity ☐ Central Imaging ☐ Clamp ☐ Diagnostic ☐ Drug Metabolism Enzyme ☐ ECG Telemetry ☐ Echocardiography ☐ Electronic Patient-Reported Outcome System (ePRO) ☐ Functional Test ☐ Genetic Variation ☐ HeFH Genotyping ☐ Holter ☐ Impact of Weight on Self Perceptions (IW-SP) ☐ Nasal Mucosa Brushing for RNA and Cytology ☐ Nasal Secretion Sampling ☐ Nasal Swabs for Microbiome ☐ Ophthalmological Test ☐ Patient Qualitative Assessment of Treatment (PQAT) ☐ Pharmacodynamics ☐ Pharmacogenetic Analysis ☐ Pharmacogenetic Banking ☐ Psychometric Test ☐ Pulmonary Function Tests ■ Serology ☐ Tumor Biopsy ☐ Virology ☐ Visual Analog Scale ☐ Weight-Related Symptom Measure (WRSM)
Specimen Type	☐ Adipose Tissue ☐ Amniotic Fluid

- [ ] Aqueous Humor
- [ ] Arterial Blood
- [ ] Arterial Cord Blood
- [ ] Atherosclerotic Plaque
- [ ] Bile
- [x] Blood
- [ ] Bone
- [ ] Bone Marrow
- [ ] Breast Milk
- [ ] Buffy Coat
- [ ] Stone
- [ ] Capillary Blood
- [ ] Myocardium
- [ ] Cerebrospinal Fluid
- [ ] Cerumen
- [ ] Circulating Tumor Cell
- [ ] Human Colostrum
- [ ] Cord Blood
- [ ] Cord Serum
- [ ] Dialysis Fluid
- [ ] Dried Blood Spot
- [ ] Vomitus
- [ ] Erythrocyte
- [ ] Expired Air
- [ ] Exudate
- [ ] Fibroblast
- [ ] Body Fluid or Substance
- [ ] Gastric Contents
- [ ] Hair
- [ ] Hair Follicle
- [ ] Plasma Infranatant
- [ ] Pleural Fluid Infranatant
- [ ] Serum Infranatant
- [ ] Interstitial Fluid
- [ ] Isolate
- [ ] Lavage Fluid
- [ ] Leucocytes
- [ ] Lochia

- [ ] Lung Surfactant
- [ ] Lymph
- [ ] Lysate
- [ ] Meconium
- [ ] Menstrual Blood
- [ ] Mucus
- [ ] Muscle Tissue
- [ ] Nail
- [ ] Nasal
- [ ] Nasopharyngeal
- [ ] Peripheral Blood
- [ ] Peripheral Blood Mononuclear Cell
- [ ] Sweat
- [ ] Pharyngeal
- [ ] Plasma
- [ ] Platelet
- [ ] Platelet-Poor Plasma
- [ ] Platelet-Rich Plasma
- [ ] Pleural Fluid
- [ ] Prostatic Fluid
- [ ] Pus
- [ ] Saliva
- [ ] Sebum
- [ ] Semen
- [ ] Seminal Fluid
- [ ] Serum
- [ ] Skeletal Muscle Tissue
- [ ] Smegma
- [ ] Smooth Muscle Tissue
- [ ] Soft Tissue
- [ ] Sputum
- [ ] Feces
- [ ] Striated Muscle Tissue
- [ ] Supernatant, Cells
- [ ] Plasma Supernatant
- [ ] Pleural Fluid Supernatant
- [ ] Serum Supernatant

	Synovial Fluid ☐
	Tissue ☐
	Transudate ☐
	Tumor Tissue ☐
	Urine ☐
	Venous Blood ☐
	Venous Cord Blood ☐
	Vitreous Humor ☐
	Whole Blood ☐
	Other ☐
Sample ID	
Was the sample collected?	Yes ☐
	No ☐
Reason sample not collected	
If yes, complete the following questions.	
Date of Collection	
Comment	

Treatment Name	RECOMBINANT QUADRIVALENT INFLUENZA VACCINE
Has vaccination been performed?	Yes ☐ No ☐
Reason Vaccination Not Performed	
If yes, complete the following questions.	
Date	
Dose Number	
Route	Intramuscular ☐ Intradermal ☐ Subcutaneous ☐
Site of Administration	Upper Arm ☐ Buttock ☐ Thigh ☐
Side	Left ☐ Right ☐
Comment	

Did any unsolicited systemic adverse events occur within 30 minutes after vaccination?	Yes ☐ No ☐

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ■

Systemic ☐

Solicited Reaction Name _____

Did the subject report Injection Site Pain at least once between Day 00 and Day 07 after vaccination?

Injection Site Pain
Yes ☐
No ☐

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

None _____
Medication _____
Health Care Provider Contact _____
Hospitalized _____

Enter the Maximum daily Intensity from Day 00 to Day 07. If the Intensity is missing, select Unknown.

Intensity at Day 00
Grade 1 ☐
Grade 2 ☐
Grade 3 ☐
Unknown ☐
None ☐

Intensity at Day 01
Grade 1 ☐
Grade 2 ☐
Grade 3 ☐
Unknown ☐
None ☐

Intensity at Day 02
Grade 1 ☐
Grade 2 ☐
Grade 3 ☐
Unknown ☐
None ☐

Intensity at Day 03
Grade 1 ☐
Grade 2 ☐
Grade 3 ☐
Unknown ☐
None ☐

Intensity at Day 04
Grade 1 ☐
Grade 2 ☐
Grade 3 ☐

	Unknown ☐
	None ☐
Intensity at Day 05	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
	None ☐
Intensity at Day 06	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
	None ☐
Intensity at Day 07	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
	None ☐

If a reaction is ongoing after Day 07, enter the Maximum Intensity available at the time of reporting.

Ongoing after Day 07?	

When the End Date is obtained, ensure that the Maximum Intensity is still correct while considering the interval from Day 8 until the End Date.

End date	

Enter the Maximum Intensity considering the interval from Day 08 until the End Date. If the Intensity is missing, select Unknown.

Maximum Intensity after Day 07	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
Caused Study Termination	Yes ☐
	No ☐
Intensity Method at Day 00	
Intensity Method at Day 01	
Intensity Method at Day 02	
Intensity Method at Day 03	
Intensity Method at Day 04	
Intensity Method at Day 05	

Intensity Method at Day 06	
Intensity Method at Day 07	
Maximum Intensity Method	

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ■

Systemic ☐

Solicited Reaction Name

Did the subject report Injection Site Erythema at least once between Day 00 and Day 07 after vaccination?

Injection Site Erythema — Yes ☐ No ☐

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

- None
- Medication
- Health Care Provider Contact
- Hospitalized

Enter the Maximum daily Measurement from Day 00 to Day 07. If the Measurement is missing, enter 'UNK' for Unknown.

Measurement at Day 00 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 01 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 02 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 03 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 04 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 05	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 06	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM

If a reaction is ongoing after Day 07, enter the Maximum Measurement available at the time of reporting.

Ongoing after Day 07?	

When the End Date is obtained, ensure that the Maximum Measurement is still correct while considering the interval from Day 8 until the End Date.

End date	

Enter the Maximum Measurement considering the interval from Day 08 until the End Date. If the Measurement is missing, enter 'UNK' for Unknown.

Maximum Measurement after Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement Unit	mm ■
Caused Study Termination	Yes ☐ No ☐
Measurement Method at Day 00	

Measurement Method at Day 01	
Measurement Method at Day 02	
Measurement Method at Day 03	
Measurement Method at Day 04	
Measurement Method at Day 05	
Measurement Method at Day 06	
Measurement Method at Day 07	
Maximum Measurement Method	

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ■

Systemic ☐

Solicited Reaction Name

Did the subject report Injection Site Ecchymosis at least once between Day 00 and Day 07 after vaccination?

Injection Site Ecchymosis — Yes ☐ No ☐

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

- None
- Medication
- Health Care Provider Contact
- Hospitalized

Enter the Maximum daily Measurement from Day 00 to Day 07. If the Measurement is missing, enter 'UNK' for Unknown.

Measurement at Day 00 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 01 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 02 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 03 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 04 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 05	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 06	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM

If a reaction is ongoing after Day 07, enter the Maximum Measurement available at the time of reporting.

Ongoing after Day 07?	

When the End Date is obtained, ensure that the Maximum Measurement is still correct while considering the interval from Day 8 until the End Date.

End date	

Enter the Maximum Measurement considering the interval from Day 08 until the End Date. If the Measurement is missing, enter 'UNK' for Unknown.

Maximum Measurement after Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement Unit	mm ■
Caused Study Termination	Yes ☐ No ☐

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ■

Systemic ☐

Solicited Reaction Name

Did the subject report Injection Site Swelling at least once between Day 00 and Day 07 after vaccination?

Injection Site Swelling — Yes ☐ No ☐

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

- None
- Medication
- Health Care Provider Contact
- Hospitalized

Enter the Maximum daily Measurement from Day 00 to Day 07. If the Measurement is missing, enter 'UNK' for Unknown.

Measurement at Day 00 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 01 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 02 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 03 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 04 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 05	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 06	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM

If a reaction is ongoing after Day 07, enter the Maximum Measurement available at the time of reporting.

Ongoing after Day 07?	

When the End Date is obtained, ensure that the Maximum Measurement is still correct while considering the interval from Day 8 until the End Date.

End date	

Enter the Maximum Measurement considering the interval from Day 08 until the End Date. If the Measurement is missing, enter 'UNK' for Unknown.

Maximum Measurement after Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement Unit	mm ■
Caused Study Termination	Yes ☐ No ☐
Measurement Method at Day 00	

Measurement Method at Day 01	
Measurement Method at Day 02	
Measurement Method at Day 03	
Measurement Method at Day 04	
Measurement Method at Day 05	
Measurement Method at Day 06	
Measurement Method at Day 07	
Maximum Measurement Method	

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ■

Systemic ☐

Solicited Reaction Name

Did the subject report Injection Site Induration at least once between Day 00 and Day 07 after vaccination?

Injection Site Induration — Yes ☐ No ☐

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

- None
- Medication
- Health Care Provider Contact
- Hospitalized

Enter the Maximum daily Measurement from Day 00 to Day 07. If the Measurement is missing, enter 'UNK' for Unknown.

Measurement at Day 00 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 01 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 02 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 03 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable — Fixed Unit: NM

Measurement at Day 04 — Fixed Unit: mm

If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 05	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 06	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement at Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM

If a reaction is ongoing after Day 07, enter the Maximum Measurement available at the time of reporting.

Ongoing after Day 07?

When the End Date is obtained, ensure that the Maximum Measurement is still correct while considering the interval from Day 8 until the End Date.

End date

Enter the Maximum Measurement considering the interval from Day 08 until the End Date. If the Measurement is missing, enter 'UNK' for Unknown.

Maximum Measurement after Day 07	Fixed Unit: mm
If the reaction is too large to measure, check 'NM' for Non Measurable	Fixed Unit: NM
Measurement Unit	mm ■
Caused Study Termination	Yes ☐ No ☐
Measurement Method at Day 00	

Measurement Method at Day 01	
Measurement Method at Day 02	
Measurement Method at Day 03	
Measurement Method at Day 04	
Measurement Method at Day 05	
Measurement Method at Day 06	
Measurement Method at Day 07	
Maximum Measurement Method	

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ☐

Systemic

Solicited Reaction Name

Enter the Maximum daily Temperature with one decimal value (e.g. 100.1 or 100.0) from Day 00 to Day 07. If the Temperature is missing, enter 'UNK' for Unknown and leave the Route blank.

Temperature at Day 00 Fixed Unit: °F

Temperature Route at Day 00 Oral / Axillary / Rectal

Temperature at Day 01 Fixed Unit: °F

Temperature Route at Day 01 Oral / Axillary / Rectal

Temperature at Day 02 Fixed Unit: °F

Temperature Route at Day 02 Oral / Axillary / Rectal

Temperature at Day 03 Fixed Unit: °F

Temperature Route at Day 03 Oral / Axillary / Rectal

Temperature at Day 04 Fixed Unit: °F

Temperature Route at Day 04 Oral / Axillary / Rectal

Temperature at Day 05 Fixed Unit: °F

Temperature Route at Day 05 Oral / Axillary / Rectal

Temperature at Day 06	Fixed Unit: °F
Temperature Route at Day 06	Oral ☐ Axillary ☐ Rectal ☐
Temperature at Day 07	Fixed Unit: °F
Temperature Route at Day 07	Oral ☐ Axillary ☐ Rectal ☐

If at least one daily Measurement is >=100.4°F, check Presence of Fever =YES.

Presence of Fever?	Yes ☐ No ☐

If Presence of Fever is checked NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

None	
Medication	
Health Care Provider Contact	
Hospitalized	

If ongoing after Day 07 is checked YES, enter the Maximum Temperature available at the time of reporting, Route and End Date. If NO, leave these questions blank.

Ongoing after Day 07?	
Maximum Temperature after Day 07	Fixed Unit: °F
Maximum Temperature Route	Oral ☐ Axillary ☐ Rectal ☐

When the End Date is obtained, ensure that the Maximum Temperature is still correct while considering the interval from Day 8 until the End Date.

End date	
Caused Study Termination	Yes ☐ No ☐
Measurement Unit	F ■

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ☐

Systemic

Solicited Reaction Name

Did the subject report Headache at least once between Day 00 and Day 07 after vaccination?

Headache — Yes / No

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

- None
- Medication
- Health Care Provider Contact
- Hospitalized

Enter the Maximum daily Intensity from Day 00 to Day 07. If the Intensity is missing, select Unknown.

Intensity at Day 00 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 01 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 02 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 03 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 04 — Grade 1 / Grade 2 / Grade 3

	Unknown ☐
	None ☐
Intensity at Day 05	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
	None ☐
Intensity at Day 06	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
	None ☐
Intensity at Day 07	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
	None ☐

If a reaction is ongoing after Day 07, enter the Maximum Intensity available at the time of reporting.

Ongoing after Day 07?	

When the End Date is obtained, ensure that the Maximum Intensity is still correct while considering the interval from Day 8 until the End Date.

End date	

Enter the Maximum Intensity considering the interval from Day 08 until the End Date. If the Intensity is missing, select Unknown.

Maximum Intensity after Day 07	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Unknown ☐
Caused Study Termination	Yes ☐
	No ☐
Intensity Method at Day 00	
Intensity Method at Day 01	
Intensity Method at Day 02	
Intensity Method at Day 03	
Intensity Method at Day 04	
Intensity Method at Day 05	

Intensity Method at Day 06	
Intensity Method at Day 07	
Maximum Intensity Method	

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ☐

Systemic

Solicited Reaction Name

Did the subject report Malaise at least once between Day 00 and Day 07 after vaccination?

Malaise — Yes / No

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

- None
- Medication
- Health Care Provider Contact
- Hospitalized

Enter the Maximum daily Intensity from Day 00 to Day 07. If the Intensity is missing, select Unknown.

Intensity at Day 00 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 01 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 02 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 03 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 04 — Grade 1 / Grade 2 / Grade 3 / Unknown

	None ☐
Intensity at Day 05	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐ None ☐
Intensity at Day 06	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐ None ☐
Intensity at Day 07	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐ None ☐

If a reaction is ongoing after Day 07, enter the Maximum Intensity available at the time of reporting.

Ongoing after Day 07?	

When the End Date is obtained, ensure that the Maximum Intensity is still correct while considering the interval from Day 8 until the End Date.

End date	

Enter the Maximum Intensity considering the interval from Day 08 until the End Date. If the Intensity is missing, select Unknown.

Maximum Intensity after Day 07	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐
Caused Study Termination	Yes ☐ No ☐
Intensity Method at Day 00	
Intensity Method at Day 01	
Intensity Method at Day 02	
Intensity Method at Day 03	
Intensity Method at Day 04	
Intensity Method at Day 05	
Intensity Method at Day 06	

Intensity Method at Day 07	
Maximum Intensity Method	

Category of Reaction	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ■ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Subcategory of Reaction	Administration Site ☐

Systemic

Solicited Reaction Name

Did the subject report Myalgia at least once between Day 00 and Day 07 after vaccination?

Myalgia — Yes / No

If the answer is NO, then leave all the fields below blank.

Action Taken *(Check all that apply)*

- None
- Medication
- Health Care Provider Contact
- Hospitalized

Enter the Maximum daily Intensity from Day 00 to Day 07. If the Intensity is missing, select Unknown.

Intensity at Day 00 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 01 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 02 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 03 — Grade 1 / Grade 2 / Grade 3 / Unknown / None

Intensity at Day 04 — Grade 1 / Grade 2 / Grade 3 / Unknown

	None ☐
Intensity at Day 05	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐ None ☐
Intensity at Day 06	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐ None ☐
Intensity at Day 07	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐ None ☐

If a reaction is ongoing after Day 07, enter the Maximum Intensity available at the time of reporting.

Ongoing after Day 07?	

When the End Date is obtained, ensure that the Maximum Intensity is still correct while considering the interval from Day 8 until the End Date.

End date	

Enter the Maximum Intensity considering the interval from Day 08 until the End Date. If the Intensity is missing, select Unknown.

Maximum Intensity after Day 07	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐
Caused Study Termination	Yes ☐ No ☐
Intensity Method at Day 00	
Intensity Method at Day 01	
Intensity Method at Day 02	
Intensity Method at Day 03	
Intensity Method at Day 04	
Intensity Method at Day 05	
Intensity Method at Day 06	

Intensity Method at Day 07	
Maximum Intensity Method	

Record reportable medications taken during the 28 days safety follow up period/between D00 and the next visit. Reportable means: Category 1, 2 and 3 medications including ongoing medications on the day of the first vaccination.
Category 1*: Medications impacting or that may have an impact on the evaluation of the safety (e.g., antipyretics, analgesics, and non-steroidal anti-inflammatory drugs [NSAIDs], steroids/corticosteroids and any other class of medications that could affect the safety as per project needs)*

Category 2*: Medications impacting or that may have an impact on the immune response (e.g. other vaccines, blood products, antibiotic classes that may interfere with bioassays used by the Global Clinical Immunology [GCI], steroids/corticosteroids, immunesuppressors, immune-modulators with immunosuppressive properties, anti-proliferative drugs such as DNA synthesis inhibitors, and any other class of medications that may affect the immune response as per project needs)*

Category 3*: Medications impacting or that may have an impact on both the safety and the immune response (e.g., steroids/corticosteroids)*

Did the subject report any reportable medications?	Yes ☐ No ☐
If yes, complete the following questions.	
Unique ID	_____
Medication	_____
Category	Category 1 ☐ Category 2 ☐ Category 3 ☐
Prophylactic Medication	Yes ☐ No ☐
Start Date	_____
Ongoing at End of Study	_____
End Date	_____
Prohibited Medications	Yes ☐ No ■

Completion of Primary Series

- [ ] Blinded Treatment
- [ ] Booster Phase
- [ ] Completion
- [ ] Dose-Finding Follow-Up
- [ ] Double Blind
- [ ] Extension
- [ ] Extension Follow-Up
- [ ] First Follow-Up
- [ ] First Run-In
- [ ] First Screening
- [ ] First Treatment
- [ ] First Wash-Out
- [ ] Follow-Up
- [ ] Immunogenicity Follow-Up
- [ ] Long-Term Follow-Up
- [ ] Open Label Treatment
- [x] Primary Series
- [ ] Run-In
- [ ] Safety Follow-Up
- [ ] Screening
- [ ] Second Follow-Up
- [ ] Second Run-In
- [ ] Second Screening
- [ ] Second Treatment
- [ ] Second Wash-Out
- [ ] Single Blind
- [ ] Treatment
- [ ] Washout

Disposition Event

- [x] Protocol Disposition Event
- [ ] Protocol Milestone
- [ ] Protocol Event

Check Completed if the subject completed the study else check the main reason for discontinuation.

What was the subject's status?

- [ ] Completed
- [ ] Adverse Event
- [ ] Protocol Deviation
- [ ] Withdrawal by Subject
- [ ] Lost to Follow-Up

Status Date	
If the subject did not complete the study, provide details.	
Provide Details	

Trial Period	
	Blinded Treatment ☐
	Booster Phase ☐
	Completion ☐
	Dose-Finding Follow-Up ☐
	Double Blind ☐
	Extension ☐
	Extension Follow-Up ☐
	First Follow-Up ☐
	First Run-In ☐
	First Screening ☐
	First Treatment ☐
	First Wash-Out ☐
	Follow-Up ☐
	Immunogenicity Follow-Up ☐
	Long-Term Follow-Up ☐
	Open Label Treatment ☐
	Primary Series ■
	Run-In ☐
	Safety Follow-Up ☐
	Screening ☐
	Second Follow-Up ☐
	Second Run-In ☐
	Second Screening ☐
	Second Treatment ☐
	Second Wash-Out ☐
	Single Blind ☐
	Treatment ☐
	Washout ☐
Visit	
Comment	

Category of Adverse Event

- [ ] Adverse Event
- [ ] Adverse Event of Special Interest
- [ ] Allergic Reaction
- [ ] ALT Increase
- [ ] Asthma Exacerbation Event
- [ ] Bleeding Event
- [ ] Bone Fracture
- [ ] Drug Allergy Event
- [ ] Epistaxis Event
- [ ] Foreign Body Reaction Event
- [ ] Hypercalcemia
- [ ] Hypoglycemia
- [ ] Increased Calcitonin
- [ ] Increased Lipase/Amylase
- [ ] Infection Event
- [ ] Injection Site Reaction
- [ ] Metabolic Acidosis Event
- [ ] Neurologic Disorder
- [ ] Overdose
- [ ] Pancreatic Event
- [ ] Peripheral Neuropathy Event
- [x] Pregnancy
- [ ] Renal Failure
- [ ] Serious Hypoglycemia
- [ ] Solicited
- [ ] Suspected or Confirmed Cerebrovascular Event
- [ ] Suspected or Confirmed Diabetic Ketoacidosis
- [ ] Suspected or Confirmed Heart Failure
- [ ] Suspected or Confirmed Myocardial Infarction / Unstable Angina
- [ ] Unsolicited
- [ ] Vasculitis Event
- [ ] Other

Did any pregnancy occur?

- [ ] Yes

No ☐

Category of Adverse Event	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ■ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ☐ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ☐ Vasculitis Event ☐ Other ☐
Unique ID	_____

Event	PREGNANCY
Date of Last Menses	
Did the mother experience any adverse event linked to the pregnancy?	Yes ☐ No ☐
Outcome	Ongoing ☐ Normal Delivery ☐ Abnormal Termination/Delivery with Complication ☐ Fatal ☐
Termination/Delivery Date	

Related AE ID	
Parent	FATHER
Age	
Rh Factor	
Height (cm)	
Weight (kg)	
Smoking History (Cigarettes per Day)	
Alcohol (Drinks per Day)	
Substance Abuse, specify	
Hypertension	☐ Yes ☐ No ☐ Unknown
Diabetes	☐ Yes ☐ No ☐ Unknown
Epilepsy	☐ Yes ☐ No ☐ Unknown
Psychiatric Illness	☐ Yes ☐ No ☐ Unknown
HIV Serology	☐ Yes ☐ No ☐ Unknown
Hepatitis Serology	☐ Yes ☐ No ☐ Unknown
Other Relevant Medical History (notably thyroid disorders, asthma, allergic disease, heart disease, depression, sexually transmitted disease)	
Parent	MOTHER
Age	
Rh Factor	
Height (cm)	
Weight (kg)	
Smoking History (Cigarettes per Day)	

Alcohol (Drinks per Day)	_____
Substance Abuse, specify	_____
Hypertension	Yes ☐ No ☐ Unknown ☐
Diabetes	Yes ☐ No ☐ Unknown ☐
Epilepsy	Yes ☐ No ☐ Unknown ☐
Psychiatric Illness	Yes ☐ No ☐ Unknown ☐
HIV Serology	Yes ☐ No ☐ Unknown ☐
Hepatitis Serology	Yes ☐ No ☐ Unknown ☐
Other Relevant Medical History (notably thyroid disorders, asthma, allergic disease, heart disease, depression, sexually transmitted disease)	_____

Related AE ID	
Immunization Status	
Rubella	Yes ☐ No ☐ Unknown ☐
Toxoplasmosis	Yes ☐ No ☐ Unknown ☐
CMV	Yes ☐ No ☐ Unknown ☐
Gynecological Details	
Contraception	Yes ☐ No ☐ Unknown ☐
Specify Contraception	Oral ☐ Intrauterine ☐ Topical ☐ Other ☐
If Other, specify	
Normal Menstrual Cycles	Yes ☐ No ☐ Unknown ☐
Infertility	Yes ☐ No ☐ Unknown ☐
Specify Infertility Treatment	

Related AE ID	
Date of Last Menses	
Estimated Date of Delivery	
Medical Assistance or Hospitalization during Pregnancy	Yes ☐ No ☐
If yes, specify	
Multiple Fetuses	Yes ☐ No ☐
Relevant Comments about Pregnancy	
Obstetrical History	Previous Pregnancies (If Ectopic or Molar Pregnancy or Other Complication, Please Specify in Comments Field) ■ Live Births, without Congenital Anomalies/Malformations ☐ Live Births, with Congenital Anomalies/Malformations (Specify Congenital Anomalies in Comments Field) ☐ Spontaneous Abortions Prior to 20 Weeks Gestation (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (Fetal Defects) (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (No Fetal Defects or Unknown) (Please Specify Gestational Age in Comments Field) ☐ Fetal Deaths (>20 Weeks Gestation) (Please Specify Gestational Age in Comments Field) ☐
Number	
Comments	
Obstetrical History	Previous Pregnancies (If Ectopic or Molar Pregnancy or Other Complication, Please Specify in Comments Field) ☐

	■ Live Births, without Congenital Anomalies/Malformations ☐ Live Births, with Congenital Anomalies/Malformations (Specify Congenital Anomalies in Comments Field) ☐ Spontaneous Abortions Prior to 20 Weeks Gestation (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (Fetal Defects) (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (No Fetal Defects or Unknown) (Please Specify Gestational Age in Comments Field) ☐ Fetal Deaths (>20 Weeks Gestation) (Please Specify Gestational Age in Comments Field)
Number	
Comments	
Obstetrical History	☐ Previous Pregnancies (If Ectopic or Molar Pregnancy or Other Complication, Please Specify in Comments Field) ☐ Live Births, without Congenital Anomalies/Malformations ■ Live Births, with Congenital Anomalies/Malformations (Specify Congenital Anomalies in Comments Field) ☐ Spontaneous Abortions Prior to 20 Weeks Gestation (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (Fetal Defects) (Please Specify Gestational Age in Comments Field)

	Elective Termination (No Fetal Defects or Unknown) (Please Specify Gestational Age in Comments Field) ☐ Fetal Deaths (>20 Weeks Gestation) (Please Specify Gestational Age in Comments Field) ☐
Number	
Comments	
Obstetrical History	Previous Pregnancies (If Ectopic or Molar Pregnancy or Other Complication, Please Specify in Comments Field) ☐ Live Births, without Congenital Anomalies/Malformations ☐ Live Births, with Congenital Anomalies/Malformations (Specify Congenital Anomalies in Comments Field) ☐ Spontaneous Abortions Prior to 20 Weeks Gestation (Please Specify Gestational Age in Comments Field) ■ Elective Termination (Fetal Defects) (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (No Fetal Defects or Unknown) (Please Specify Gestational Age in Comments Field) ☐ Fetal Deaths (>20 Weeks Gestation) (Please Specify Gestational Age in Comments Field) ☐
Number	
Comments	
Obstetrical History	Previous Pregnancies (If Ectopic or Molar Pregnancy or Other Complication, Please Specify in Comments Field) ☐

	Live Births, without Congenital Anomalies/Malformations ☐ Live Births, with Congenital Anomalies/Malformations (Specify Congenital Anomalies in Comments Field) ☐ Spontaneous Abortions Prior to 20 Weeks Gestation (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (Fetal Defects) (Please Specify Gestational Age in Comments Field) ■ Elective Termination (No Fetal Defects or Unknown) (Please Specify Gestational Age in Comments Field) ☐ Fetal Deaths (>20 Weeks Gestation) (Please Specify Gestational Age in Comments Field) ☐
Number	
Comments	
Obstetrical History	Previous Pregnancies (If Ectopic or Molar Pregnancy or Other Complication, Please Specify in Comments Field) ☐ Live Births, without Congenital Anomalies/Malformations ☐ Live Births, with Congenital Anomalies/Malformations (Specify Congenital Anomalies in Comments Field) ☐ Spontaneous Abortions Prior to 20 Weeks Gestation (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (Fetal Defects) (Please Specify Gestational Age in Comments Field) ☐

	Elective Termination (No Fetal Defects or Unknown) (Please Specify Gestational Age in Comments Field) ☑ Fetal Deaths (>20 Weeks Gestation) (Please Specify Gestational Age in Comments Field) ☐
Number	
Comments	
Obstetrical History	Previous Pregnancies (If Ectopic or Molar Pregnancy or Other Complication, Please Specify in Comments Field) ☐ Live Births, without Congenital Anomalies/Malformations ☐ Live Births, with Congenital Anomalies/Malformations (Specify Congenital Anomalies in Comments Field) ☐ Spontaneous Abortions Prior to 20 Weeks Gestation (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (Fetal Defects) (Please Specify Gestational Age in Comments Field) ☐ Elective Termination (No Fetal Defects or Unknown) (Please Specify Gestational Age in Comments Field) ☐ Fetal Deaths (>20 Weeks Gestation) (Please Specify Gestational Age in Comments Field) ☑
Number	
Comments	

Related AE ID	
Maternal/ Paternal/ Relative Obstetrical History	CONGENITAL MALFORMATION
Occurred	Yes ☐ No ☐
Specify (Relatives and Details)	
Maternal/ Paternal/ Relative Obstetrical History	CHILDREN DYING YOUNG
Occurred	Yes ☐ No ☐
Specify (Relatives and Details)	
Maternal/ Paternal/ Relative Obstetrical History	CHROMOSOMAL ABNORMALITY
Occurred	Yes ☐ No ☐
Specify (Relatives and Details)	
Maternal/ Paternal/ Relative Obstetrical History	DEVELOPMENTAL DELAY
Occurred	Yes ☐ No ☐
Specify (Relatives and Details)	
Maternal/ Paternal/ Relative Obstetrical History	HEREDITARY DISEASE
Occurred	Yes ☐ No ☐
Specify (Relatives and Details)	
Maternal/ Paternal/ Relative Obstetrical History	PERTINENT GYNECOLOGIC INFORMATION
Occurred	Yes ☐ No ☐
Specify (Relatives and Details)	
Maternal/ Paternal/ Relative Obstetrical History	CONSANGUINITY BETWEEN PARENTS
Occurred	Yes ☐ No ☐
Specify (Relatives and Details)	
Maternal/ Paternal/ Relative Obstetrical History	OTHER
Occurred	Yes ☐

No ☐

Specify (Relatives and Details) _____

Related AE ID	
Examination	AMNIOCENTESIS
Examination Details for Genetics Screening and Other Examination	
Examination Date	
Result	Normal ☐ Abnormal ☐
Abnormalities	
Examination	ALPHA FETAL PROTEIN (AND OTHER SERUM MARKERS)
Examination Details for Genetics Screening and Other Examination	
Examination Date	
Result	Normal ☐ Abnormal ☐
Abnormalities	
Examination	CHORIONIC VILLI SAMPLING
Examination Details for Genetics Screening and Other Examination	
Examination Date	
Result	Normal ☐ Abnormal ☐
Abnormalities	
Examination	FETAL STRESS TEST
Examination Details for Genetics Screening and Other Examination	
Examination Date	
Result	Normal ☐ Abnormal ☐
Abnormalities	
Examination	UTERINE ULTRASOUND
Examination Details for Genetics Screening and Other Examination	
Examination Date	
Result	Normal ☐ Abnormal ☐

Abnormalities	
Examination	GENETIC SCREENING (PROVIDE DETAILS)
Examination Details for Genetics Screening and Other Examination	
Examination Date	
Result	Normal ☐ Abnormal ☐
Abnormalities	
Examination	OTHER (PROVIDE DETAILS)
Examination Details for Genetics Screening and Other Examination	
Examination Date	
Result	Normal ☐ Abnormal ☐
Abnormalities	

Related AE ID	
Delivery, Spontaneous Abortion, Termination or Fetal Death Date	
Enter Details for each Child/Fetus	
Sex	Male ☐ Female ☐
APGAR Score (1 min)	
APGAR Score (5 min)	
Delivery Mode	Vaginal ☐ Caesarean Section ☐
Week of Gestation	
Weight (g)	
Height (cm)	
Head Circum (cm)	
Outcome	Normal Live Birth ☐ Abnormal Live Birth ☐ Stillbirth ☐ Late Fetal Death (At Least 28 Weeks of Gestation) ☐ Early Fetal Death (20-27 Weeks of Gestation) ☐ Spontaneous Abortion (Less Than 20 Weeks of Gestation) ☐ Ectopic Pregnancy ☐ Elective Termination ☐ Maternal Death Resulting in Fetal Death ☐
Congenital Anomaly	Yes ☐ No ☐
If Yes, specify Anomaly	
If Neonate Death: Cause	
In case of abortion, fetal death or maternal death, was an autopsy performed?	Yes ☐ No ☐ Unknown ☐
If Autopsy: Results	
Labor/Delivery	
Complication during Labor or Delivery	Yes ☐ No ☐

If any complication, specify	
Medication during Labor (If Yes, report in Medication linked to Pregnancy CRF)	Yes ☐ No ☐
Clear Amniotic Fluid	Yes ☐ No ☐
Normal Placenta	Yes ☐ No ☐

Related AE ID	
Newborn Condition	BREAST FEEDING (NO NEED TO SPECIFY)
Occurred	Yes ☐ No ☐
If yes, specify	
Newborn Condition	NEONATAL ILLNESS
Occurred	Yes ☐ No ☐
If yes, specify	
Newborn Condition	DEVELOPMENTAL DELAY OR IMMATURITY
Occurred	Yes ☐ No ☐
If yes, specify	
Newborn Condition	CORRECTIVE TREATMENT RECEIVED BY NEWBORN
Occurred	Yes ☐ No ☐
If yes, specify	
Newborn Condition	INTENSIVE CARE RECEIVED
Occurred	Yes ☐ No ☐
If yes, specify	
Newborn Condition	TRANSFERRED TO INTENSIVE CARE UNIT OR PEDIATRIC DEPARTMENT (SPECIFY ALSO THE DURATION)
Occurred	Yes ☐ No ☐
If yes, specify	

Related AE ID	
Product	
Prior to or at Time of Conception	
During Pregnancy	
Labor and Delivery	
Breast Feeding	
Indication	
Dose and Unit	
Route	Auricular ☐ Buccal ☐ Conjunctival ☐ Cutaneous ☐ Dental ☐ Dietary ☐ Electro-Osmosis ☐ Endocervical ☐ Endosinusial ☐ Endotracheal ☐ Enteral ☐ Epidural ☐ Extraamniotic ☐ Extracorporeal Circulation Administration Via ☐ Hemodialysis Infiltration ☐ Interstitial ☐ Intraabdominal ☐ Intraamniotic ☐ Intraarterial ☐ Intraarticular ☐ Intrabiliary ☐ Intrabronchial ☐ Intrabursal ☐ Intracameral ☐ Intracardiac ☐ Intracartilaginous ☐ Intracaudal ☐ Intracavernous ☐

- [ ] Intracavitary
- [ ] Intracerebral
- [ ] Intracisternal
- [ ] Intracorneal
- [ ] Intracoronal Dental
- [ ] Intracoronary
- [ ] Intracorporus Cavernosum
- [ ] Intradermal
- [ ] Intradiscal
- [ ] Intraductal
- [ ] Intraduodenal
- [ ] Intradural
- [ ] Intraepidermal
- [ ] Intraesophageal
- [ ] Intragastric
- [ ] Intragingival
- [ ] Intrahepatic
- [ ] Intraileal
- [ ] Intrajejunal
- [ ] Intralesional
- [ ] Intraluminal
- [ ] Intralymphatic
- [ ] Intramedullary
- [ ] Intrameningeal
- [ ] Intramuscular
- [ ] Intramuscular or Subcutaneous
- [ ] Intranodal
- [ ] Intraocular
- [ ] Intraovarian
- [ ] Intrapalatal
- [ ] Intraparenchymal
- [ ] Intrapericardial
- [ ] Intraperitoneal
- [ ] Intrapleural
- [ ] Intraprostatic
- [ ] Intrapulmonary
- [ ] Intrasinal
- [ ] Intraspinal

- [ ] Intrastomal
- [ ] Intrasynovial
- [ ] Intratendinous
- [ ] Intratesticular
- [ ] Intrathecal
- [ ] Endothoracic
- [ ] Intratubular
- [ ] Intratumoral
- [ ] Intratympanic
- [ ] Intrauterine
- [ ] Intravascular
- [ ] Intravenous
- [ ] Intravenous Bolus
- [ ] Intravenous Drip
- [ ] Intraventricular
- [ ] Intravesical
- [ ] Intravitreal
- [ ] Iontophoresis
- [ ] Irrigation
- [ ] Laryngeal
- [ ] Nasal
- [ ] Nasogastric
- [ ] Occlusive Dressing Technique
- [ ] Ophthalmic
- [ ] Oral
- [ ] Oral Gavage
- [ ] Oromucosal
- [ ] Oropharyngeal
- [ ] Parenteral
- [ ] Percutaneous
- [ ] Periarticular
- [ ] Peridural
- [ ] Perineural
- [ ] Periodontal
- [ ] Perivenous
- [ ] Rectal
- [ ] Inhalation
- [ ] Retrobulbar

	Soft Tissue ☐
	Subarachnoid ☐
	Subconjunctival ☐
	Subcutaneous ☐
	Sublingual ☐
	Submucosal ☐
	Subtenon ☐
	Topical ☐
	Transdermal ☐
	Transmammary ☐
	Mucosal ☐
	Transplacental ☐
	Transtracheal ☐
	Transtympanic ☐
	Unassigned ☐
	Ureteral ☐
	Intraurethral ☐
	Vaginal ☐
	Other ☐
	Unknown ☐
	Not Applicable ☐
Start Date	
End Date	
Duration (Days) (If start or end dates are not known)	

Related AE ID	
Did the mother experience any relevant non-serious adverse events during the pregnancy?	Yes ☐ No ☐
If Yes, describe (Diagnosis, start date, stop date and corrective medication)	

To be completed only if it is required by local regulation.

Provide information on the neonate outcome at 6 months after birth (i.e. neonate's health status).

Related AE ID	
6 Months Follow-up	

Category of Adverse Event	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ☐ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ■ Vasculitis Event ☐ Other ☐
Subcategory of Adverse Event	Administration Site ■

	Systemic ☐
Were there any Adverse Event to report?	Yes ☐ No ☐
Category of Adverse Event	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ☐ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ■

	Vasculitis Event ☐ Other ☐
Subcategory of Adverse Event	Administration Site ☐ Systemic ■
Were there any Adverse Event to report?	Yes ☐ No ☐

Category of Adverse Event	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ☐ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ■ Vasculitis Event ☐ Other ☐
Subcategory of Adverse Event	Administration Site ■

Systemic ☐

Unique ID _____

Enter any Unsolicited Injection Site Reactions occurring within the 28-day collection period as well as SAEs during the entire study period including during the 90-day fup period.

Adverse Event _____

Start Date _____

Appeared after Visit _____

If the reaction is ongoing, enter the Maximum Intensity/Measurement available at the time of reporting.

Ongoing? _____

When the End Date is obtained, ensure that the Maximum Intensity/Measurement is still correct while considering the entire duration.

End Date _____

Enter the Maximum Measurement OR Maximum Intensity considering the entire Adverse Event duration.

Maximum Measurement *(If the Maximum Measurement is missing, enter 'UNK' for Unknown.)* Fixed Unit: mm

_____

Maximum Measurement Unit mm ■

If the reaction is too large to measure, check 'NM' for Non Measurable. Fixed Unit: NM

_____

Maximum Intensity *(If the Maximum Intensity is missing, select Unknown.)*

Grade 1 ☐
Grade 2 ☐
Grade 3 ☐
Unknown ☐

Maximum Measurement or Intensity Method _____

Relationship to Investigational Product

Not Related ☐
Related ■

Action Taken (Check all that apply.)

None _____

Medication _____

Health Care Provider Contact _____

Hospitalized _____

Caused Study Discontinuation

Yes ☐
No ☐

Is the event an AESI?	Yes ☐ No ■
Serious	Yes ☐ No ☐
If Serious=Yes only, check all seriousness criteria that apply, Outcome, Elapsed time and Relationship to Study Procedures below.	
Congenital Anomaly or Birth Defect	_____
Significant Disability	_____
Death	_____
If Yes, complete the Date of Death.	
Date of Death	_____
Hospitalization	_____
Life Threatening	_____
Other Medically Important Event	_____
Outcome	Recovered or Resolved ☐ Recovered or Resolved with Sequelae ☐ Recovering or Resolving ☐ Not Recovered or Not Resolved ☐ Fatal ☐ Unknown ☐
If lower than 24 hours, Elapsed Time from last Administration *(Provide the duration in hours and minutes).*	_____
Relationship to Study Procedures	Not Related ☐ Related ☐

Category of Adverse Event	Adverse Event ☐ Adverse Event of Special Interest ☐ Allergic Reaction ☐ ALT Increase ☐ Asthma Exacerbation Event ☐ Bleeding Event ☐ Bone Fracture ☐ Drug Allergy Event ☐ Epistaxis Event ☐ Foreign Body Reaction Event ☐ Hypercalcemia ☐ Hypoglycemia ☐ Increased Calcitonin ☐ Increased Lipase/Amylase ☐ Infection Event ☐ Injection Site Reaction ☐ Metabolic Acidosis Event ☐ Neurologic Disorder ☐ Overdose ☐ Pancreatic Event ☐ Peripheral Neuropathy Event ☐ Pregnancy ☐ Renal Failure ☐ Serious Hypoglycemia ☐ Solicited ☐ Suspected or Confirmed Cerebrovascular Event ☐ Suspected or Confirmed Diabetic Ketoacidosis ☐ Suspected or Confirmed Heart Failure ☐ Suspected or Confirmed Myocardial Infarction / Unstable Angina ☐ Unsolicited ■ Vasculitis Event ☐ Other ☐
Subcategory of Adverse Event	Administration Site ☐

Systemic ■

Unique ID

Enter any Unsolicited Systemic Events occurring within the 28-day collection period. Enter SAE and AESI occurring during the entire study period including during the 90-day fup period.

Adverse Event

Immediate — Yes ☐ No ☐

Start Date

Appeared after Visit

If the event is ongoing, enter the Maximum Intensity/Temperature available at the time of reporting.

Ongoing?

When the End Date is obtained, ensure that the Maximum Intensity/Temperature is still correct while considering the entire duration.

End Date

For Fever episodes, enter the Maximum Temperature with one decimal value (e.g. 38.1). Otherwise, enter the Maximum Intensity of the event considering the entire Adverse Event duration.

Maximum Temperature *(If the Maximum Temperature is missing, enter 'UNK' for Unknown.)* — Fixed Unit: °F

Maximum Measurement Unit — F ■

Temperature Route — Oral ☐ Axillary ☐ Rectal ☐

Maximum Intensity *(If the Maximum Intensity is missing, select Unknown.)* — Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Unknown ☐

Maximum Intensity Method

Relationship to Investigational Product — Not Related ☐ Related ☐

Action Taken (Check all that apply.)

None

Medication

Health Care Provider Contact

Hospitalized	
Caused Study Discontinuation	Yes ☐ No ☐
Is the event an AESI?	Yes ☐ No ☐
Serious	Yes ☐ No ☐
If Serious=Yes only, check all seriousness criteria that apply, Outcome, Elapsed time and Relationship to Study Procedures below.	
Congenital Anomaly or Birth Defect	
Significant Disability	
Death	
If Yes, complete the Date of Death.	
Date of Death	
Hospitalization	
Life Threatening	
Other Medically Important Event	
Outcome	Recovered or Resolved ☐ Recovered or Resolved with Sequelae ☐ Recovering or Resolving ☐ Not Recovered or Not Resolved ☐ Fatal ☐ Unknown ☐
If lower than 24 hours, Elapsed Time from last Administration *(Provide the duration in hours and minutes).*	
Relationship to Study Procedures	Not Related ☐ Related ☐

Related AE ID	
Subject's Weight (Kg)	
Subject's Height (cm)	
Initial or Prolonged Hospitalization	Initial ☐ Prolonged ☐ Not Applicable ☐
If Not Applicable is checked, Hospitalization and Discharge Dates should be empty.	
Hospitalization Date	
Discharge Date	
Safety Narrative	
Rationale for Final Investigator Causality	
Additional Relevant Medical History	Yes ☐ No ☐
Additional Relevant Previous or Concomitant Medication	Yes ☐ No ☐
Additional Relevant Laboratory Results	Yes ☐ No ☐

MH Category	Allergy ☐ Asthma ☐ Blood Disorder ☐ Cardiovascular Disorder ☐ Diabetes ☐ Disease History ☐ Epistaxis ☐ Hepatobiliary Disorder ☐ Hyperlipoproteinemia ☐ Juvenile Idiopathic Arthritis ☐ Medical or Surgical ☐ Multiple Sclerosis ☐ Neurologic Disorder ☐ Polyposis ☐ Pompe Disease ☐ Renal Disorder ☐ Respiratory Disorder ☐ Rheumatologic Disorder ☐ Rhinosinusitis ☐ SAE Complementary Information ■ Scleroderma ☐ Other ☐
Related AE ID	
Medical History Term	
Start Date	
Ongoing at SAE onset	
End Date	

MH Category	Allergy ☐ Asthma ☐ Blood Disorder ☐ Cardiovascular Disorder ☐ Diabetes ☐ Disease History ☐ Epistaxis ☐ Hepatobiliary Disorder ☐ Hyperlipoproteinemia ☐ Juvenile Idiopathic Arthritis ☐ Medical or Surgical ☐ Multiple Sclerosis ☐ Neurologic Disorder ☐ Polyposis ☐ Pompe Disease ☐ Renal Disorder ☐ Respiratory Disorder ☐ Rheumatologic Disorder ☐ Rhinosinusitis ☐ SAE Complementary Information ■ Scleroderma ☐ Other ☐
Related AE ID	
Check If No Medical History to report	
Medical History List	
Medical History Term	
Start Date	
Ongoing at SAE onset	
End Date	

Category for Medication	Anti-Cancer Therapy ☐ Anti-Hyperglycemic Therapy ☐ Antibiotic ☐ Asthma Controller ☐ Asthma Reliever ☐ Basal Insulin ☐ History of Anti-Hyperglycemic Therapy ☐ History of Lipid Modifying Therapy ☐ History of Vaccination ☐ Hypoglycemic Treatment ☐ Lipid Lowering Therapy ☐ Lipid Modifying Therapy Excluding Statin ☐ Medication ☐ Non Medication Therapy ☐ Rescue Therapy ☐ SAE Complementary Information ■ Statin Therapy ☐ Systemic Corticoid Therapy ☐ Other ☐ Category 1 ☐ Category 2 ☐ Category 3 ☐
Related AE ID	
Medication	
Start Date	
End Date	
Ongoing at SAE onset	
Route	Auricular ☐ Buccal ☐ Conjunctival ☐ Cutaneous ☐ Dental ☐ Dietary ☐ Electro-Osmosis ☐ Endocervical ☐

Endosinusial ☐
Endotracheal ☐
Enteral ☐
Epidural ☐
Extraamniotic ☐
Extracorporeal Circulation ☐
Administration Via Hemodialysis ☐
Infiltration ☐
Interstitial ☐
Intraabdominal ☐
Intraamniotic ☐
Intraarterial ☐
Intraarticular ☐
Intrabiliary ☐
Intrabronchial ☐
Intrabursal ☐
Intracameral ☐
Intracardiac ☐
Intracartilaginous ☐
Intracaudal ☐
Intracavernous ☐
Intracavitary ☐
Intracerebral ☐
Intracisternal ☐
Intracorneal ☐
Intracoronal Dental ☐
Intracoronary ☐
Intracorporus Cavernosum ☐
Intradermal ☐
Intradiscal ☐
Intraductal ☐
Intraduodenal ☐
Intradural ☐
Intraepidermal ☐
Intraesophageal ☐
Intragastric ☐
Intragingival ☐

Intrahepatic ☐
Intraileal ☐
Intrajejunal ☐
Intralesional ☐
Intraluminal ☐
Intralymphatic ☐
Intramedullary ☐
Intrameningeal ☐
Intramuscular ☐
Intramuscular or Subcutaneous ☐
Intranodal ☐
Intraocular ☐
Intraovarian ☐
Intrapalatal ☐
Intraparenchymal ☐
Intrapericardial ☐
Intraperitoneal ☐
Intrapleural ☐
Intraprostatic ☐
Intrapulmonary ☐
Intrasinal ☐
Intraspinal ☐
Intrastomal ☐
Intrasynovial ☐
Intratendinous ☐
Intratesticular ☐
Intrathecal ☐
Endothoracic ☐
Intratubular ☐
Intratumoral ☐
Intratympanic ☐
Intrauterine ☐
Intravascular ☐
Intravenous ☐
Intravenous Bolus ☐
Intravenous Drip ☐
Intraventricular ☐
Intravesical ☐

- [ ] Intravitreal
- [ ] Iontophoresis
- [ ] Irrigation
- [ ] Laryngeal
- [ ] Nasal
- [ ] Nasogastric
- [ ] Occlusive Dressing Technique
- [ ] Ophthalmic
- [ ] Oral
- [ ] Oral Gavage
- [ ] Oromucosal
- [ ] Oropharyngeal
- [ ] Parenteral
- [ ] Percutaneous
- [ ] Periarticular
- [ ] Peridural
- [ ] Perineural
- [ ] Periodontal
- [ ] Perivenous
- [ ] Rectal
- [ ] Inhalation
- [ ] Retrobulbar
- [ ] Soft Tissue
- [ ] Subarachnoid
- [ ] Subconjunctival
- [ ] Subcutaneous
- [ ] Sublingual
- [ ] Submucosal
- [ ] Subtenon
- [ ] Topical
- [ ] Transdermal
- [ ] Transmammary
- [ ] Mucosal
- [ ] Transplacental
- [ ] Transtracheal
- [ ] Transtympanic
- [ ] Unassigned
- [ ] Ureteral

	Intraurethral ☐
	Vaginal ☐
	Other ☐
	Unknown ☐
	Not Applicable ☐
Indication	
Causal Relationship to the SAE	Yes ☐
	No ☐

Category for Medication	Anti-Cancer Therapy ☐ Anti-Hyperglycemic Therapy ☐ Antibiotic ☐ Asthma Controller ☐ Asthma Reliever ☐ Basal Insulin ☐ History of Anti-Hyperglycemic Therapy ☐ History of Lipid Modifying Therapy ☐ History of Vaccination ☐ Hypoglycemic Treatment ☐ Lipid Lowering Therapy ☐ Lipid Modifying Therapy Excluding Statin ☐ Medication ☐ Non Medication Therapy ☐ Rescue Therapy ☐ SAE Complementary Information ■ Statin Therapy ☐ Systemic Corticoid Therapy ☐ Other ☐ Category 1 ☐ Category 2 ☐ Category 3 ☐
Related AE ID	
Check If No Medication to report	
Medication List	
Medication	
Start Date	
End Date	
Ongoing at SAE onset	
Route	Auricular ☐ Buccal ☐ Conjunctival ☐ Cutaneous ☐ Dental ☐ Dietary ☐

Electro-Osmosis ☐
Endocervical ☐
Endosinusial ☐
Endotracheal ☐
Enteral ☐
Epidural ☐
Extraamniotic ☐
Extracorporeal Circulation ☐
Administration Via Hemodialysis ☐
Infiltration ☐
Interstitial ☐
Intraabdominal ☐
Intraamniotic ☐
Intraarterial ☐
Intraarticular ☐
Intrabiliary ☐
Intrabronchial ☐
Intrabursal ☐
Intracameral ☐
Intracardiac ☐
Intracartilaginous ☐
Intracaudal ☐
Intracavernous ☐
Intracavitary ☐
Intracerebral ☐
Intracisternal ☐
Intracorneal ☐
Intracoronal Dental ☐
Intracoronary ☐
Intracorporus Cavernosum ☐
Intradermal ☐
Intradiscal ☐
Intraductal ☐
Intraduodenal ☐
Intradural ☐
Intraepidermal ☐
Intraesophageal ☐

- [ ] Intragastric
- [ ] Intragingival
- [ ] Intrahepatic
- [ ] Intraileal
- [ ] Intrajejunal
- [ ] Intralesional
- [ ] Intraluminal
- [ ] Intralymphatic
- [ ] Intramedullary
- [ ] Intrameningeal
- [ ] Intramuscular
- [ ] Intramuscular or Subcutaneous
- [ ] Intranodal
- [ ] Intraocular
- [ ] Intraovarian
- [ ] Intrapalatal
- [ ] Intraparenchymal
- [ ] Intrapericardial
- [ ] Intraperitoneal
- [ ] Intrapleural
- [ ] Intraprostatic
- [ ] Intrapulmonary
- [ ] Intrasinal
- [ ] Intraspinal
- [ ] Intrastomal
- [ ] Intrasynovial
- [ ] Intratendinous
- [ ] Intratesticular
- [ ] Intrathecal
- [ ] Endothoracic
- [ ] Intratubular
- [ ] Intratumoral
- [ ] Intratympanic
- [ ] Intrauterine
- [ ] Intravascular
- [ ] Intravenous
- [ ] Intravenous Bolus
- [ ] Intravenous Drip

Intraventricular ☐
Intravesical ☐
Intravitreal ☐
Iontophoresis ☐
Irrigation ☐
Laryngeal ☐
Nasal ☐
Nasogastric ☐
Occlusive Dressing Technique ☐
Ophthalmic ☐
Oral ☐
Oral Gavage ☐
Oromucosal ☐
Oropharyngeal ☐
Parenteral ☐
Percutaneous ☐
Periarticular ☐
Peridural ☐
Perineural ☐
Periodontal ☐
Perivenous ☐
Rectal ☐
Inhalation ☐
Retrobulbar ☐
Soft Tissue ☐
Subarachnoid ☐
Subconjunctival ☐
Subcutaneous ☐
Sublingual ☐
Submucosal ☐
Subtenon ☐
Topical ☐
Transdermal ☐
Transmammary ☐
Mucosal ☐
Transplacental ☐
Transtracheal ☐
Transtympanic ☐

	Unassigned ☐
	Ureteral ☐
	Intraurethral ☐
	Vaginal ☐
	Other ☐
	Unknown ☐
	Not Applicable ☐
Indication	
Causal Relationship to the SAE	Yes ☐
	No ☐

Laboratory Category	Bacteriology ☐ Banking ☐ Biomarkers ☐ Chemistry ☐ Clamp Glucose ☐ Coagulation ☐ Cytology ☐ Drug Screen ☐ Genetic Variation ☐ Hematology ☐ Hormonology ☐ Meal Test ☐ Microbiology ☐ Parasitology ☐ Pharmacodynamic ☐ Pharmacogenomic ☐ Pregnancy ☐ SAE Complementary Information ■ Serology ☐ Urinalysis ☐ Virology ☐
Normal Range Type	Local Reference Ranges ■ Sponsor Reference Ranges ☐
Related AE ID	
Specimen Type	Adipose Tissue ☐ Amniotic Fluid ☐ Aqueous Humor ☐ Arterial Blood ☐ Arterial Cord Blood ☐ Atherosclerotic Plaque ☐ Bile ☐ Blood ☐ Bone ☐ Bone Marrow ☐ Breast Milk ☐ Buffy Coat ☐ Stone ☐

- [ ] Capillary Blood
- [ ] Myocardium
- [ ] Cerebrospinal Fluid
- [ ] Cerumen
- [ ] Circulating Tumor Cell
- [ ] Human Colostrum
- [ ] Cord Blood
- [ ] Cord Serum
- [ ] Dialysis Fluid
- [ ] Dried Blood Spot
- [ ] Vomitus
- [ ] Erythrocyte
- [ ] Expired Air
- [ ] Exudate
- [ ] Fibroblast
- [ ] Body Fluid or Substance
- [ ] Gastric Contents
- [ ] Hair
- [ ] Hair Follicle
- [ ] Plasma Infranatant
- [ ] Pleural Fluid Infranatant
- [ ] Serum Infranatant
- [ ] Interstitial Fluid
- [ ] Isolate
- [ ] Lavage Fluid
- [ ] Leucocytes
- [ ] Lochia
- [ ] Lung Surfactant
- [ ] Lymph
- [ ] Lysate
- [ ] Meconium
- [ ] Menstrual Blood
- [ ] Mucus
- [ ] Muscle Tissue
- [ ] Nail
- [ ] Nasal
- [ ] Nasopharyngeal
- [ ] Peripheral Blood

- [ ] Peripheral Blood Mononuclear Cell
- [ ] Sweat
- [ ] Pharyngeal
- [ ] Plasma
- [ ] Platelet
- [ ] Platelet-Poor Plasma
- [ ] Platelet-Rich Plasma
- [ ] Pleural Fluid
- [ ] Prostatic Fluid
- [ ] Pus
- [ ] Saliva
- [ ] Sebum
- [ ] Semen
- [ ] Seminal Fluid
- [ ] Serum
- [ ] Skeletal Muscle Tissue
- [ ] Smegma
- [ ] Smooth Muscle Tissue
- [ ] Soft Tissue
- [ ] Sputum
- [ ] Feces
- [ ] Striated Muscle Tissue
- [ ] Supernatant, Cells
- [ ] Plasma Supernatant
- [ ] Pleural Fluid Supernatant
- [ ] Serum Supernatant
- [ ] Synovial Fluid
- [ ] Tissue
- [ ] Transudate
- [ ] Tumor Tissue
- [ ] Urine
- [ ] Venous Blood
- [ ] Venous Cord Blood
- [ ] Vitreous Humor
- [ ] Whole Blood
- [ ] Other

Collection Date _____

Test Name	
Result	
Units	
Other Test Unit, Specify	
What was the lower limit of the reference range for this test?	
What was the upper limit of the reference range for this test?	

Laboratory Category	Bacteriology ☐ Banking ☐ Biomarkers ☐ Chemistry ☐ Clamp Glucose ☐ Coagulation ☐ Cytology ☐ Drug Screen ☐ Genetic Variation ☐ Hematology ☐ Hormonology ☐ Meal Test ☐ Microbiology ☐ Parasitology ☐ Pharmacodynamic ☐ Pharmacogenomic ☐ Pregnancy ☐ SAE Complementary Information ■ Serology ☐ Urinalysis ☐ Virology ☐
Related AE ID	
Complementary Investigations	

Related AE ID	
Nullification Reason	

Related AE ID	
I, as Investigator, reviewed the current set of information and I confirm a SAE/Safety Event case is declared for this subject.	
Investigator Validation	

Subject Death Date	
Primary Cause of Death	
Secondary Causes of Death	
Autopsy Performed	Yes ☐ No ☐ Unknown ☐
If No or Unknown, was a verbal autopsy performed?	Yes ☐ No ☐

If autopsy was performed, please update the causes of death according to death certificate.

Subject Status Code	
Subject Status Start Date	
Subject Status End Date	
Subject Status Comment	