16.1.2 Sample Case Report Form (Unique Pages Only)

This section contains the following document:

Sample case report form version 1.0, dated 04 March 2020

Birth Control (BC1)

Web Version 1 0 2 00; 0 Mar20

Segment A

s the subject a **fema e** of ch ldbearing po en ial or a ert le **male**? ☐ No ☐ Yes

If No, reason: Post-menopausal for >= 1 year / Tubal l gation / Bilateral oophorectomy / Hysterectomy / Essure / *Add tional Options L s ed Be ow

If Othe , specify:

If No, date of LMP, surgery, or diagnos s: (ddMMMyyyy) Exact date / Day only unknown / Day and month unknown / Day, month, and year unknown

	Method of Birth Control Code	f Other Spec fy	Start Date	Start Date Certa nty	End Date	End Date Certainty	Ongoing
Me hod 1 *(required)*	1 - Oral contraceptives 2 - Hormonal injec ions 3 - Hormonal implants - Contraceptive patches 5 - NuvaRing *Addi ional Opt ons Listed Below		(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Me hod 2	1 - Oral contraceptives 2 - Hormonal injec ions 3 - Hormonal implants - Contraceptive patches 5 - NuvaRing *Addi ional Opt ons Listed Below		(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
New Method *(f change n method)*	1 - Oral contraceptives 2 - Hormonal injec ions 3 - Hormonal implants - Contraceptive patches 5 - NuvaRing *Addi ional Opt ons Listed Below		(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
New Method *(f change n method)*	1 - Oral contraceptives 2 - Hormonal injec ions 3 - Hormonal implants - Contraceptive patches 5 - NuvaRing *Addi ional Opt ons Listed Below		(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
New Method *(f change n method)*	1 - Oral contraceptives 2 - Hormonal injec ions 3 - Hormonal implants - Contraceptive patches 5 - NuvaRing *Addi ional Opt ons Listed Below		(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
New Method *(f change n method)*	1 - Oral contraceptives 2 - Hormonal injec ions 3 - Hormonal implants - Contraceptive patches 5 - NuvaRing *Addi ional Opt ons Listed Below		(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐

Additional Selection Op ions for BC1

If No reason:
Vasectomy
Bilateral orchiectomy
Other

Method of birth control 1
6 - Intrauterine device, hormonal
7 - Intrauterine device, non-hormonal
8 - Barrier method plus spermicide
9 - Barrier method (alone)
10 - Spermicide (a one)
11 - Same-sex re a ionship
12 - Monogamous rela ionship wi h vasectomized partner
13 - Abstinence
99 - Other

Concomitant Medication (CMD)

Segment A
CM Number

Medica ion:

Start date:

(ddMMMyyyy)
Exact date
Day only unknown
Day and month unknown
Day, month, and year unknown

End date:

(ddMMMyyyy)
Exact date
Day only unknown
Day and month unknown
Day, month, and year unknown
Ongoing

Indicat on:

Was this medicat on taken for an Adverse Event?

No Yes, solici ed AE Yes, unsol c ted AE

f Yes, unsol c ted AE:

1
2
3
5
*Add tional Op ions L sted Below

(indicate pr mary AE only)

Was this medicat on taken for a condit on l s ed on the Medical History?

No Yes

f Yes, MH term:

1
2
3
5
*Add tional Op ions L sted Below

(indicate pr mary MH on y)

Additional Selection Op ions for CMD

CM Number (key field):

1
2
3

5
6
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13
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16
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31
32
33
3
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36
37
38
39
0
1
2
3

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6
7
8
9
50

Consent Agreement (CS1)

Web Version 1 0 2 02: 10Jul20

Segment A

Date informed consent s gned:	(ddMMMyyyy)
f reconsented, date of reconsent:	(ddMMMyyyy)
Comments:	

Demographics (DEM)

Web Version 1 0 1.00; 09Oct20

Sex: Ma e Female

Birth date: *(ddMMMyyyy)*

Ethnicity:

H spanic or La ino
Not H span c or La ino
Not reported
Unknown

Indicate No or Yes for each race listed below. Yes may be checked for more than one race. If a subject refuses to ident fy his or her race, check No to a l options.

American Indian or A askan Native: No Yes

As an: No Yes

Native Hawaiian or other Pac fic Islander: No Yes

Black or African Amer can: No Yes

Wh te: No Yes

Upon saving the screen, Race w ll be populated based on the subject s response to the ndividual race questions above.

Race:

UNKNOWN
MULTIPLE
AMERICAN INDIAN OR ALASKA NATIVE
ASIAN
NATIVE HAWA IAN OR OTHER PAC FIC ISLANDER
*Add tional Op ions L sted Below

Additional Selection Op ions for DEM

Race:
BLACK
WHITE

Study Status (DS1)

Web Version 1 0 .01; 27Apr20

Segment A

Study status:

Protocol comp eted
Early termination

Date of protocol comp et on termina ion: (ddMMMyyyy)

f early erminat on, ind cate reason:

Serious adverse event (other than death), specify AE #
Adverse event, other than serious adverse event, specify AE #
Lost to fol ow-up
Protocol deviation, specify DV #
Voluntary withdrawal by subject, specify
*Add tional Op ions L sted Below

f reason requires speci icat on:

AE number:

1
2
3
5
*Add tional Op ions L sted Below

DV number:

1
2
3
5
*Add tional Op ions L sted Below

Eligibil ty cr terion: Inclusion Exclusion

Cr terion number:

1
2
3
5
*Add tional Op ions L sted Below

Additional Selection Op ions for DS1

If early termination indicate reason:
Wi hdrawal by investigator, specify
COVID-19 pandem c, spec fy
Termina ion of site by sponsor
Termina ion of study by sponsor
Death, specify AE #
Enrol ed but treatment not adminis ered, spec fy
Pregnancy
Not el gib e at enrollment, spec fy and enter eligibi ity criter on #
Became ineligible after enrollment, spec fy and enter eligibil ty criterion #
Sol cited event, specify
Other, spec fy

AE number:
6
7
8
9
10
11
12
13
1
15
16
17
18
19
20
21
22
23
2
25
26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
2
3

5
6
7
8
9
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Criterion number:
6
7
8
9
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11
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13
1
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16
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Discontinuation of Treatment (DS2)

Web Version 1 0 1.01; 27Apr20

Segment A

Complete this form if subject discontinued study product.

Date treatment discontinued: *(ddMMMyyyy)*

Reason for d scontinuat on:

Serious adverse event (other than death), specify AE #
Adverse event, other than serious adverse event, specify AE #
Lost to fol ow-up
Protocol deviation, specify DV #
Voluntary withdrawal by subject, specify
*Add tional Op ions L sted Below

f reason requires speci icat on:

AE number:

1
2
3
5
*Add tional Op ions L sted Below

DV number:

1
2
3
5
*Add tional Op ions L sted Below

Eligibil ty cr terion: ☐ Inclusion ☐ Exclusion

Cr terion number:

1
2
3
5
*Add tional Op ions L sted Below

Wi l the subject remain in the study for fo low-up? ☐ No ☐ Yes

If No, subm t a Study Status form.

Additional Selection Op ions for DS2

Reason for discontinuation:
Wi hdrawal by investigator, specify
COVID-19 pandem c, spec fy
Termina ion of site by sponsor
Termina ion of study by sponsor
Death, specify AE #
Techn cal problems, spec fy
Pregnancy
Not el gib e at enrollment, spec fy and enter eligibi ity criter on #
Became ineligible after enrollment, spec fy and enter eligibil ty criterion #
Sol cited event, specify
Other, spec fy

AE number:
6
7
8
9
10
11
12
13
1
15
16
17
18
19
20
21
22
23
2
25
26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
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3

5
6
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8
9
50

Criterion number:
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NSS Protocol Deviation (DV2)

Deviation Number

Protocol deviation:
Out of window v s t
Incorrect vers on of ICF signed
Specimen result not obtained
Required procedure not conducted
Required procedure done incorrectly
*Add tional Op ions L sted Below

f Other, specify:

Specimen type:

Result type:

Descript on:

Affected visit number:

Start date: (ddMMMyyyy)

End date: (ddMMMyyyy)

Reason for p otocol deviation:
C in c error
Pharmacy er or
Laboratory error
Investigator/study decision
COV D-19 pandemic
*Add tional Op ions L sted Below

f Other, specify:

D d the dev at on resu t in subject termina ion of study fo low-up? ☐ No ☐ Yes

If Yes, subm t the Study Sta us form.

Does the deviation af ect, or cou d it poten ia ly a fect, product stab l ty? ☐ No ☐ Yes ☐ N/A

Dev a ion category:
E igib l ty enrollment
Treatment admin st at on schedule
Fol ow-up visit schedule
Protocol procedure/assessment
Treatment admin st at on

s th s deviation an Unant cipa ed Problem ? ☐ No ☐ Yes

Describe s eps taken to resolve or avoid recurrence of the deviation:

Does this devia ion meet RB reporting requirements? ☐ No ☐ Yes

f Yes, date IRB not fied: (ddMMMyyyy)

Comments:

Additional Selection Options for DV2

Deviation Number (key field):

1
2
3

5
6
7
8
9
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11
12
13
1
15
16
17
18
19
20
21
22
23
2
25
26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
2
3

5
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Protocol deviation:

Study product temperature excursion
Specimen temperature excursion
Other

Reason for protocol deviation:

Other

Protocol Deviation (DVD)

Segment A
Deviation Number

Protocol deviation:
Out of window v s t
Missed v s t/visit not conducted
D d not meet inclusion criterion
Met exclusion cri er on
Incorrect vers on of ICF signed
*Add tional Op ions L sted Below

f Other, specify:
Inclus on cr ter on:
Exclus on cr ter on:
Specimen type:
Number of al quots obtained:
(xx)
Result type:
Descript on:
Affected visit number:
Start date:
(ddMMMyyyy)
Reason for p otocol deviation:
Subject llness
Subject unable to comply
Subject refusal
C in c error
Pharmacy er or
*Add tional Op ions L sted Below

f Other, specify:

D d the dev at on resu t in an adverse event?
If Yes, complete an Adverse Event/Serious Adverse Event form as appropriate.
No Yes, solici ed AE Yes, unsol c ted AE
Specify solici ed AE:
Inj ec ion site pain
Erythema
Inj ec ion site swel ing
Indura ion
Headache
*Add tional Op ions L sted Below

AE number:
1
2
3
5
*Add tional Op ions L sted Below

D d the dev at on resu t in subject termina ion of study fo low-up?
If Yes, subm t the Study Sta us form.
No Yes

Does the deviation af ect, or cou d it poten ia ly a fect, product stab l ty?
No Yes N/A

Dev a ion category:
E igib l ty enrollment
Treatment admin st at on schedule
Fol ow-up visit schedule
Protocol procedure/assessment
Treatment admin st at on

s th s deviation an Unant cipa ed Problem ?
No Yes

Describe s eps taken to resolve or avoid recurrence of the deviation:

Does this devia ion meet RB reporting requirements?
No Yes

f Yes, date IRB not fied:
(ddMMMyyyy)

Comments:

Additional Selection Op ions for DVD

Deviation Number (key field):
1
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Protocol deviation:
ICF not signed prior to study procedures
M ssed treatment admin stration
Delayed treatment administra ion
Blood not collected
Urine not co lected
Too few al quots obtained
Specimen resu t not obtained
Required procedure not conducted
Required procedure done incorrectly
Study product temperature excursion
Specimen temperature excursion
Other

Reason for protocol deviation:
Laboratory error
Invest gator/study dec sion
Other
COVID-19 pandem c

Specify solicited AE:
Fat gue
Myalg a
Ar hralgia
Nausea
Fever
Chil s
WBC
Hemoglobin
Platelets
ALT
AST
ALP
Bilirubin (otal)
Creatinine
PT
PTT

Registration Confirmation (ERC)

Web Version 1 0 1.01; 22Nov15

Segment A

Assignment:	
Reg strat on date:	
Reg strat on time:	
Reg s ered by:	

20003A (ENR)

Subject D:

Enrollment da e:

(ddMMMyyyy)

Pro ocol vers on enro led under:

1 0
2 0
3 0
0

Does the subject meet all el gibi ity cri eria as specified in the current vers on of the p otocol?

☐ No ☐ Yes

If the subject does not meet a l eligibil ty cr teria, speci y which cr teria have not been met.

Criterion not met 1:

Provides writ en in ormed consent prior to init at on of any study procedures.
Be able to unders and and agrees o comply with study procedu es and be avai able for study visits.
Agrees to the col ection of venous blood per protocol.
Ma e or non-pregnant female, 18 years of age or greater, inclusive, at time of enro lment.
Ma e or non-pregnant female, 18 to 55 years of age, inclusive, at time of enrollment.
*Add tional Op ions L sted Below

Criterion not met 2:

Provides writ en in ormed consent prior to init at on of any study procedures.
Be able to unders and and agrees o comply with study procedu es and be avai able for study visits.
Agrees to the col ection of venous blood per protocol.
Ma e or non-pregnant female, 18 years of age or greater, inclusive, at time of enro lment.
Ma e or non-pregnant female, 18 to 55 years of age, inclusive, at time of enrollment.
*Add tional Op ions L sted Below

Criterion not met 3:

Provides writ en in ormed consent prior to init at on of any study procedures.
Be able to unders and and agrees o comply with study procedu es and be avai able for study visits.
Agrees to the col ection of venous blood per protocol.
Ma e or non-pregnant female, 18 years of age or greater, inclusive, at time of enro lment.
Ma e or non-pregnant female, 18 to 55 years of age, inclusive, at time of enrollment.
*Add tional Op ions L sted Below

Criterion not met :

Provides writ en in ormed consent prior to init at on of any study procedures.
Be able to unders and and agrees o comply with study procedu es and be avai able for study visits.
Agrees to the col ection of venous blood per protocol.
Ma e or non-pregnant female, 18 years of age or greater, inclusive, at time of enro lment.
Ma e or non-pregnant female, 18 to 55 years of age, inclusive, at time of enrollment.
*Add tional Op ions L sted Below

Additional Selection Op ions for ENR

Criterion not met 1:

Body Mass Index 18-35 kg/m2 inclusive, at screening.
BMI: 18-35 kg/m2 inclusive for < 56 years of age; 18-30 kg/m2 inclusive for >= 56 years of age
Women of childbearing poten ial must agree o use at least one form of contraception.
Women of childbearing poten ial must have a negative pregnancy test prior to vaccina ion.
Ma e subjects of chi dbearing po ential use an e fec ive form of contraception.
Ma e subjects agree to refrain from sperm donation until 3 months a ter last study vaccinat on.
Ma e subjects agree to refrain from sperm donation until 60 days a ter last study vaccinat on.
In good health
Oral temperature s ess than 100.0F (37.8C).
Pulse no greater han 100 beats per minute.
Systolic blood pressure s within the protocol e igib lity cri eria.
Systolic BP is 85 to 150 mm Hg, inclusive
Screening aboratory evalua ions are within acceptable normal ranges
Must agree to have samp es stored for secondary research
Agrees to adhere to Lifestyle Considerations throughout study durat on.
The subject must agree to refrain from dona ing blood or plasma during the study
Pos ive pregnancy test either at screening or just prior to each vaccine administration.
Female subject who is breastfeeding from the ime of first vac through 60 days of last vaccination.
Has any medical d sease or condit on hat precludes study par icipation.
Presence of se f-reported or med ca ly documented medical or psychiatric condi ion
Has an acute illness within 72 hours pr or to each vaccinat on.
Has a pos tive test for hep B, hep C or HIV antibodies at screening.
Has participated in ano her investigat onal study involving any inves iga ional product.
Currently enro led or in p ans o part cipate in another clinical trial
Has previously participa ed in an inves igat onal study involving LNPs.
Has a his ory of hypersens iv ty or severe al ergic react on to any previous vaccines.
Chronic use of any medica ions hat may be assoc ated wi h impaired immune responsiveness
Anticipa ing the need for immunosuppressive treatment within the next 6 mon hs
Received immunoglobulins and/or any blood or b ood produc s within the ast months.
Has any b ood dyscrasias or sign ficant disorder of coagulat on.
Has any chronic liver disease, including fatty liver.
Has a his ory of alcohol abuse or other recreat onal drug use within 6 months of study vaccination.
Has a pos tive test result for drugs of abuse at screening or be ore first vaccina ion.
Has any abnorma ity or body art that would interfere with he ability to observse ocal react ons.
Plans to receive a l censed, ive vaccine w hin weeks before or after each vaccinat on.
Plans to receive a l censed, inactiva ed vaccine within 2 weeks before or after each vaccination.
Receipt of any other 2019-nCoV or other experimental coronavirus vaccine at any ime
Receipt of any other SARS-CoV-2 or other experimental coronavirus vaccine at any time.
Known contact of anyone known to have 2019-nCoV infect on wi hin 2 weeks pr or to reg strat on.
Close contact of anyone known to have SARS-CoV-2 infec ion within 30 days prior to registration.
History of COVID-19 diagnosis
On current treatment with investigational agents for prophylax s of COV D 19
Has traveled to China w hin 30 days before the first vaccination.
Current use of any medications within 7 days pr or to vaccinat on.
The subject must agree to refrain from dona ing blood or plasma during the study.
Plan to travel ou side he US through 28 days after he 2nd vaccinat on.
Reside in a nursing home or other skil ed nursing faci ity or have a requirement for nursing care.
Non-ambulatory
For subjects >=56 years of age, history of chronic smoking w hin the pr or yea .
For subjects >=56 years of age, current smoking or vaping.
For subjects >=56 years of age, currently working w h h gh risk of exposure to SARS-CoV-2

Local Laboratory Results (LLR)

Segment A
Visit Number

Hematology

Were hematology tests performed? ☐ No ☐ Yes ☐ N/A

f No, reason not done:

f Other, specify:

Blood collec ion date for hematology: (ddMMMyyyy)

	Result	Units	C inical Significance	If Abnormal Relationship to Study Product	If Not Related Specify Alternate Etiology	What Action was aken with Study reatment?	Did he Result Cause the Subject to be Discontinued from the Study?
Hemoglobin	(xx.x)	g/dL mg/dL 10^3/uL /uL mL/min 1.73m2 *Add tional Options L s ed Be ow	C in cally sign ficant Not clinica ly signif cant	Not re ated Re ated		NC - Dose inc eased NC - Dose not changed RED - Dose reduced NT - Drug interup ed WD - D ug withdrawn *Addit onal Options Listed Be ow	No Yes
P atelets Count	(xxx)	g/dL mg/dL 10^3/uL /uL mL/min 1.73m2 *Add tional Options L s ed Be ow	C in cally sign ficant Not clinica ly signif cant	Not re ated Re ated		NC - Dose inc eased NC - Dose not changed RED - Dose reduced NT - Drug interup ed WD - D ug withdrawn *Addit onal Options Listed Be ow	No Yes
WBC	(xx.xx)	g/dL mg/dL 10^3/uL /uL mL/min 1.73m2 *Add tional Options L s ed Be ow	C in cally sign ficant Not clinica ly signif cant	Not re ated Re ated		NC - Dose inc eased NC - Dose not changed RED - Dose reduced NT - Drug interup ed WD - D ug withdrawn *Addit onal Options Listed Be ow	No Yes
PT	(xx.xx)	g/dL mg/dL 10^3/uL /uL mL/min 1.73m2 *Add tional Options L s ed Be ow	C in cally sign ficant Not clinica ly signif cant				
PTT	(xx.xx)	g/dL mg/dL 10^3/uL /uL mL/min 1.73m2 *Add tional Options L s ed Be ow	C in cally sign ficant Not clinica ly signif cant				

Chemistry

Were chem st y ests performed? ☐ No ☐ Yes ☐ N/A

f No, reason not done:

f Other, specify:

Blood collec ion date for chemistry: (ddMMMyyyy)

		Result	Units	Cl nical Sign ficance	f Abnormal Relationship to Study Product	If Not Re ated Specify Alternate Etiology	What Action was aken with Study reatment?	Did the Result Cause the Subject to be Discont nued from the Study?
Creatinine	< >	(x.xx)	g/dL mg dL 10^3/uL IU L mL/min/1.73m2 *Add tional Op ions Listed Below	Clin cally signi icant Not c inica ly s gnif cant	Not related Related		NC - Dose increased NC - Dose not changed RED - Dose reduced NT - Drug in errupted WD - Drug w thdrawn *Add tional Op ions L sted Be ow	No Yes
A anine Aminotransferase (ALT)	< >	(xxxx)	g/dL mg dL 10^3/uL IU L mL/min/1.73m2 *Add tional Op ions Listed Below	Clin cally signi icant Not c inica ly s gnif cant	Not related Related		NC - Dose increased NC - Dose not changed RED - Dose reduced NT - Drug in errupted WD - Drug w thdrawn *Add tional Op ions L sted Be ow	No Yes
Asparta e Aminotransferase (AST)	< >	(xxxx)	g/dL mg dL 10^3/uL IU L mL/min/1.73m2 *Add tional Op ions Listed Below	Clin cally signi icant Not c inica ly s gnif cant	Not related Related		NC - Dose increased NC - Dose not changed RED - Dose reduced NT - Drug in errupted WD - Drug w thdrawn *Add tional Op ions L sted Be ow	No Yes
ALP	< >	(xxxx)	g/dL mg dL 10^3/uL IU L mL/min/1.73m2 *Add tional Op ions Listed Below	Clin cally signi icant Not c inica ly s gnif cant	Not related Related		NC - Dose increased NC - Dose not changed RED - Dose reduced NT - Drug in errupted WD - Drug w thdrawn *Add tional Op ions L sted Be ow	No Yes
Total bi irubin	< >	(xx.x)	g/dL mg dL 10^3/uL IU L mL/min/1.73m2 *Add tional Op ions Listed Below	Clin cally signi icant Not c inica ly s gnif cant	Not related Related		NC - Dose increased NC - Dose not changed RED - Dose reduced NT - Drug in errupted WD - Drug w thdrawn *Add tional Op ions L sted Be ow	No Yes
Lipase	< >	(xxx.x)	g/dL mg dL 10^3/uL IU L mL/min/1.73m2 *Add tional Op ions Listed Below	Clin cally signi icant Not c inica ly s gnif cant	Not related Related		NC - Dose increased NC - Dose not changed RED - Dose reduced NT - Drug in errupted WD - Drug w thdrawn *Add tional Op ions L sted Be ow	No Yes

Female Subjects Only: Pregnancy Test

Was a pregnancy test perfo med? ☐ No ☐ Yes ☐ N/A

f No, reason not done:

f Other, specify:

f Yes, specimen type: ☐ Urine ☐ Serum

Specimen co lect on date: (ddMMMyyyy)

Result: ☐ Negative ☐ Positive

Serology

Were serology tests performed? ☐ No ☐ Yes ☐ N/A

f No, reason not done:

f Other, specify:

Blood collec ion date for sero ogy: (ddMMMyyyy)

HIV antibody: ☐ Non-Reactive ☐ Reactive

HCV antibody: ☐ Negative ☐ Positive

HBV surface antigen: ☐ Negative ☐ Positive

Urine Drug Screen

Was urine co lected or drug screening? ☐ No ☐ Yes ☐ N/A

f No, reason not done:

f Other, specify:

Specimen co lect on date: (ddMMMyyyy)

D d the subject test pos tive for amphetamines, barb turates, benzod azepines, cocaine, methadone, methaqualone, opiates, phencyc idine, and or propoxyphene? ☐ No ☐ Yes

Additional Selection Op ions for LLR

If No reason not done:
Other

Hemoglobin units
mmol/L
10^9/L
U/L
seconds

Hemoglobin action taken
NA - Not appl cab e

Medical History (MHD)

Web Version 1 0 2 00; 21Feb20

Segment A
Form number

Any med cal history?

No Yes

MH Number	Medical History erm	Start Date	Start Date Cer ainty	End Date	End Date Certainty	Ongo ng
1			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
2			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
3			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
5			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
6			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
7			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
8			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
9			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
10			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
11			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
12			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
13			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
1			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
15			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
16			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
17			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
18			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
19			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
20			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
21			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
22			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
23			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
2			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
25			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
26			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
27			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
28			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
29			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	
30			Exact date Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	

Additional Selection Op ions for MHD

Form number (key field):

1
2
3

5
6
7
8
9
10
11
12
13
1
15

Physical Exam (PE1)

Segment A
Visit Number

Was the physical exam performed, including assessment of any signs suggestive of P MMCs? No Yes

Was the physical exam performed, including an assessment for any signs suggestive of AESIs (including pro ocol specif ed AES s, MAAEs, NOCMCs, and P MMCs)? No Yes

Exam da e: (ddMMMyyyy)

Exam time *(24-hour clock)*: (hh mm)

f No, reason not done:

Subject unable to comply
Subject refusal
C inic error
Investigator decision
COV D 19 pandemic
*Add tional Op ions L sted Be ow

f Other, specify:

Any abnormal ties upon physical examinat on? No Yes

If abnorma ities are noted n any of the above systems, complete the table below. Record each abnorma ity on a separate row and indicate the abbreviation of the body system from above.

Body System	Abnormal Findings	Reported as AE?	f Yes AE #	If Yes Spec fy Solicited AE
ABD - Abdomen CRD - Card ovascular/hea t EXT - Extrem ties GEN - General appearance HEP - Hepatob liary/spleen *Addi ional Opt ons Listed Below		No Yes, solici ed AE Yes, unso icited AE	1 2 3 5 *Addi ional Op ions Listed Below	Injec ion site pain Erythema Injec ion site swel ing Indura ion Headache *Add tional Op ions L sted Below

The above row is duplicated 29 more times.

Additional Selection Op ions for PE1

If No reason not done:
Other

Body system 1
HNT - HEENT
LYM - Lymph nodes
MSC - Muscu oskeletal
NEC - Neck
NRL - Neurolog cal
PLM - Pulmonary/chest
SKN - Skin

If yes AE number 1
6
7
8
9
10
11
12
13
1
15
16
17
18
19
20
21
22
23
2
25
26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
2
3

5
6
7
8
9
50

If yes solic ted AE 1
Fat gue
Myalg a
Ar hralgia
Nausea
Fever
Chil s
WBC
Hemoglobin
Platelets
ALT
AST
ALP
Bilirubin (otal)
Creatinine
PT
PTT

Segment A
Visit Number

Visit da e: (ddMMMyyyy)
D d the v s t occur? No Yes
D d the v s t occur? No Yes N/A
f Yes, specify v s t date: (ddMMMyyyy)
Visit type: C in c v s t Phone contact
f Yes, specify v s t type: C in c v s t Phone contact
Reason for supplemen al v s t:
Specimen co lec on
AE fo low-up
Postponed treatment administration
Re-screening
Other
f Other, specify:
f Re screening, jus if cation:
Trans ent i lness
Lab error
Equipment failure
Whi e Coat Syndrome
Improper samp e collec ion
f No, specify reason:
Subject illness or injury
Subject refusal
Scheduling d ficu ties
Unable to contact
Transportation problems
*Add tional Op ions L sted Below
f No, and reason s Site dec s on/error or Other, specify:

Visit Specific Information

Was a physical exam per ormed on the subject? No Yes N/A
Was the in ormed consent document signed and dated prior to any study p ocedures being performed? No Yes
Was the subject consented or eukapheresis? No Yes N/A
Were the inclus on/exclusion cri er a rev ewed? No Yes
Were the inclus on/exclusion cri er a rev ewed? No Yes N/A
f Yes, is the subject sti l eligible? No Yes
If No, subm t Discontinuation of Treatment form.
Was a physical exam per ormed on the subject? No Yes

Visit Specific Specimen Collection

Was 28 mL of blood drawn for screening labs? No Yes
f No, specify reason:
Subject unable to comply
Subject refusal
Technical prob em
C in c error
Laboratory error
*Add tional Op ions L sted Below
f Other, specify:
Was urine co lected or drug screen? No Yes
f No, specify reason
Subject unable to comply
Subject refusal
Technical prob em
C in c error
Laboratory error
*Add tional Op ions L sted Below
f Other, specify:
Was 8 mL blood drawn for hematology and chemistry labs? No Yes
f blood not col ected, reason not done:
Subject unable to comply
Subject refusal
Technical prob em
C in c error
Laboratory error
*Add tional Op ions L sted Below
f Other, specify:
Was 16 mL b ood drawn for sero ogical immunogenicity assays?
No - blood not col ected
No - part al b ood co lec on
Yes
f No, how much blood was co lected? (xx) mL
f blood not col ected, reason not done:
Subject unable to comply
Subject refusal
Technical prob em
C in c error
Laboratory error
*Add tional Op ions L sted Below
f Other, specify:
Was 80 mL b ood drawn for cellular immuno og cal assays (PBMC)?
No - blood not col ected
No - part al b ood co lec on
Yes
Was 0 mL b ood drawn for cellular immuno og cal assays (PBMC)?
No - blood not col ected
No - part al b ood co lec on
Yes
Was 16 mL b ood drawn for cellular immuno og cal assays (PBMC)?
No - blood not col ected
No - part al b ood co lec on
Yes
f No, how much blood was co lected? (xx) mL
f blood not col ected, reason not done:
Subject unable to comply
Subject refusal
Technical prob em
C in c error
Laboratory error
*Add tional Op ions L sted Below
f Other, specify:
Was 16 mL b ood drawn for secondary research (serum)?
No - blood not col ected
No - part al b ood co lec on
Yes
Was 8 mL blood drawn for secondary research (serum)?
No - blood not col ected
No - part al b ood co lec on
Yes
f No, how much blood was co lected? (xx) mL
f blood not col ected, reason not done:
Subject unable to comply
Subject refusal
Technical prob em
C in c error
Laboratory error
*Add tional Op ions L sted Below
f Other, specify:
Was 16 mL b ood drawn for product assay deve opment (serum)?
No - blood not col ected
No - part al b ood co lec on
Yes
Was 8 mL blood drawn for product assay development (se um)?
No - blood not col ected
No - part al b ood co lec on
Yes
f No, how much blood was co lected? (xx) mL
f blood not col ected, reason not done:
Subject unable to comply
Subject refusal
Technical prob em
C in c error
Laboratory error
*Add tional Op ions L sted Below
f Other, specify:
Was blood drawn at this visit? No Yes N/A
f Yes, reason b ood was drawn:

Female subjects only:
Was serum collected for pregnancy tes ing? *(N/A f female of nonch ldbearing potentia)* No Yes N/A
Was urine or serum collec ed for pregnancy testing? *(N/A f female of nonch ldbearing potential)*
No
Yes - blood
Yes - urine
N/A

If No to any of the above questions, subm t a Protocol Deviation form.

Adverse Events/Medications/Protocol Deviations

Medications/Protocol Deviations

D d the subject exper ence an adverse event *after treatment adm nistration?* No Yes
If Yes, subm t an Adverse Event form.
Have there been any changes in health status since the last v s t? No Yes
If Yes, answer each of the following questions.
New adverse event? No Yes
Includes AEs, SAEs, MAAEs, and NOCMCs. If Yes, subm t an Adverse Event form.
Has there been a new SAE, MAAE, or NOCMC since the ast visit? No Yes
s the subject curren ly taking any medica ions? No Yes
If Yes, subm t a Concom tant Medication form.
s the subject curren ly taking any new medica ions since screening? No Yes
If Yes, subm t a Concom tant Medication form.
Change in hea th history not othe wise reported as an adverse event (e g , the resolution of a p ob em noted at base ine)? No Yes
If Yes, update Medical History form.
New medicat on? No Yes
If Yes, subm t Concomitant Medication form.
Has there been a protocol deviat on? No Yes
If Yes, subm t a Protocol Deviation form.
Has there been a protocol deviat on since the last v s t? No Yes
If Yes, subm t a Protocol Deviation form.

Hematology

Were screening abs drawn speci ically to de ermine el gibi ity for the eukapheres s study? No Yes N/A
f No, reason not done:
Subject unable to comply
Subject refusal
C in c error
Investigator decision
COV D-19 pandemic
*Add tional Op ions L sted Below
f Other, specify
Blood collec ion date for hematology: (ddMMMyyyy)
Blood collec ion time for hematology: (hh:mm)
Hemog obin: (xx.x) g/dL
Hematocr t: (xx.x) %

Pregnancy Test

Was a serum or urine pregnancy est performed? No Yes N/A
f No, reason not done:

Subject unable to comply
Subject refusal
C in c error
Investigator decision
COV D-19 pandemic
*Add tional Op ions L sted Below

f Other, specify: ______

Serum or urine co lect on date: ______ (ddMMMyyyy)

Serum or urine co lect on time: ______ (hh:mm)

Vitals

Was weight assessed at th s v s t? ☐ No ☐ Yes

f No, reason not done:
Subject unable to comply
Subject refusal
C in c error
Investigator decision
COV D-19 pandemic
*Add tional Op ions L sted Below

f Other, specify: ______

Assessment da e: ______ (ddMMMyyyy)

We ght: ______ (xxx.xx) ☐ Pounds ☐ K lograms

Eligibility

D d the participant meet all el gib lity cri er a for the leukapheres s procedu e? ☐ No ☐ Yes

Cr terion not met 1:
Provides writ en in ormed consent or eukapheres s procedure
We ght >= 110 pounds
Screening laboratory evaluations are within acceptable ranges at the s te
Negative urine or serum pregnancy test within within 8 hours of the eukapheres s procedure
Adequate bi ateral antecubi al venous access
*Add tional Op ions L sted Below

Cr terion not met 2:
Provides writ en in ormed consent or eukapheres s procedure
We ght >= 110 pounds
Screening laboratory evaluations are within acceptable ranges at the s te
Negative urine or serum pregnancy test within within 8 hours of the eukapheres s procedure
Adequate bi ateral antecubi al venous access
*Add tional Op ions L sted Below

Cr terion not met 3:
Provides writ en in ormed consent or eukapheres s procedure
We ght >= 110 pounds
Screening laboratory evaluations are within acceptable ranges at the s te
Negative urine or serum pregnancy test within within 8 hours of the eukapheres s procedure
Adequate bi ateral antecubi al venous access
*Add tional Op ions L sted Below

Cr terion not met :
Provides writ en in ormed consent or eukapheres s procedure
We ght >= 110 pounds
Screening laboratory evaluations are within acceptable ranges at the s te
Negative urine or serum pregnancy test within within 8 hours of the eukapheres s procedure
Adequate bi ateral antecubi al venous access
*Add tional Op ions L sted Below

If all c iteria were met, but the procedure was not performed, ndicate the reason(s) the procedure was not performed:

Time commitment: ☐ No ☐ Yes

Concern of potent al risks: ☐ No ☐ Yes

Unable to contact subject: ☐ No ☐ Yes

Other: ☐ No ☐ Yes

f Other, specify: ______

Leukapheresis Procedure

Was eukapheresis performed? ☐ No ☐ Yes

Start time: ______ (hh:mm)

Stop time: ______ (hh:mm)

Volume co lected: ______ (xxx) mL

Were there any compl cations during co lec ion? ☐ No ☐ Yes

Additional Selection Op ions for VD1

If No specify reason:
Temporar ly out of area
Subject forgot
Site dec sion/error
COVID-19 pandem c
Other

If No specify reason:
Invest gator decision
Other

If No reason not done:
Other

Criterion not met 1:
No use of b ood thinners, aspirin, NSAIDs, at least 5 days before the leukapherer s procedure
Enrollment in cohorts 2, 3, 5 or 6 and complated the 2-dose vaccina ion series

Vital Signs (VS1)

Segment A
Visit Number

Date: _____ *(ddMMMyyyy)*

Were vital signs assessed at this visit? ☐ No ☐ Yes

If No, reason not done:

Subject unable to comply
Subject refusal
Clin c error
Inves igator dec s on
COVID-19 pandem c
*Addi ional Opt ons Listed Below

If Other, spec fy: _____

Subjects must not eat or dr nk anyth ng hot or cold, or smoke within 10 minutes prior to tak ng oral temperature.

Assessment ime *(24-hour clock)*	emperature Units	emperature (°F)	emperature (°C)	Pulse *(beats minute)*	Systolic Blood Pressure *(mmHg)*	Diastolic Blood Pressure *(mmHg)*
_____ *(hh:mm)*	☐ Fahrenhe t ☐ Ce sius	_____ *(xxx.x)*	_____ *(xx x)*	_____ *(xxx)*	_____ *(xxx)*	_____ *(xxx)*

Were height and weight assessed at th s v s t? ☐ No ☐ Yes

If No, reason not done:

Subject unable to comply
Subject refusal
Clin c error
Inves igator dec s on
COVID-19 pandem c
*Addi ional Opt ons Listed Below

If Other, specify: _____

Assessment ime *(24-hr clock)*	Weight Un ts	Weight (pounds)	Weight (kilograms)	Height Units	Height (inches)	Height (centimeters)
_____ *(hh:mm)*	☐ Pounds ☐ K lograms	_____ *(xxx x)* lb	_____ *(xxx x)* kg	☐ Inches ☐ Cen imeters	_____ *(xx.x)* in	_____ *(xxx.x)* cm

BMI: _____ *(xx.x)* kg/m²

Additional Selection Op ions for VS1

If No reason not done:

Other

Segment A
Date of initial report

Birth order number:

1
2
3

Pregnancy outcome (for this fetus):
If spontaneous abortion/miscarriage, still b rth, or therapeutic abortion, complete an AE/SAE form.

Live birth
Spontaneous abor ion/miscarriage (<20 wks)
S ill birth (>= 20 weeks)
E ective abort on
The apeu ic abort on

Indicate the source of information: (may check Yes to more than one)

Mother:
Family member:
Phys c an/med cal chart:
Other:
f Yes, specify:

☐ No ☐ Yes
☐ No ☐ Yes
☐ No ☐ Yes
☐ No ☐ Yes

Maternal Outcome

End of pregnancy weight:	Da e of end of pregnancy we ght:	Da e cer ainty:	Weight units:	Weight (lb):	Weight (kg):
	(ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐ Pounds ☐ Ki og ams	(xxx.x) lb	(xxx.x) kg

Labor, Delivery, and Post Partum Information

D d the subject exper ence any of the maternal comp icat ons isted during labo , delivery, or post-partum?
If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

☐ No ☐ Yes ☐ Unknown ☐ N/A

Abrupt o placentae	Eclamps a	GBS-positive
Abnormal b eeding/hemorrhage	Emergency Cesarean section due to fetal d stress	Ol gohydramnios
Anaphylaxis	Endometrit s	P acen a previa
Bacteremia	Fetal d stress	Polyhydramnios
Cho ioamnion tis	Fever > 100. °F or 38 0°C	Pre-eclamps a
Coagu at on d sorders	Gesta ional diabetes	Pregnancy induced hyper ension
Cord prolapse		Preterm abor

D d the subject exper ence any other maternal compl cations during th s pregnancy?
If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

☐ No ☐ Yes ☐ Unknown

Was there any fe al d stress during labor and de ivery?
If Yes, complete an Adverse Event form.

☐ No ☐ Yes ☐ Unknown ☐ N/A

Neonatal Outcome Live Birth and Still Birth Only

Date of live birth or sti l birth:

(ddMMMyyyy)

Delivery:

☐ Vaginal ☐ Cesarean sect on

Sex:

☐ Ma e ☐ Female

Infant fe al gestational age at live birth or st ll bi th:

(xx) weeks and (x) days

Size for gesta ional age:

☐ SGA ☐ AGA ☐ LGA

Infant Measurements

Birth we ght	☐ Pounds ☐ K lograms	(xx.x) lb	(xx.x) kg
Length	☐ Inches ☐ Cen imeters	(xx.x) in	(xx.x) cm
Frontal occip tal circumfe ence (FOC)	☐ Inches ☐ Cen imeters	(xx.x) in	(xx.x) cm

Apgar score, 1 minu e (eave b ank for Sti l Birth):

(xx)

Apgar score, 5 minu es (leave blank for S ill Birth):

(xx)

Cord pH:

(x.x)

Congenital anomal es:
(If Yes, complete an SAE form)

☐ No ☐ Yes

One Month Follow Up Live Birth Only

Has the infant been diagnosed with any congenital anomal es since birth? *(Not previous y reported above)*
If Yes, complete a Serious Adverse Event form.

☐ No ☐ Yes ☐ Unknown

Has the infant been ll or hospitalized? *(Does not include we l-ch ld vis ts)*

☐ No ☐ Yes ☐ Unknown

f Yes, specify:

One or Two Month Follow Up Still Birth Only

Was there an autopsy?

☐ No ☐ Yes ☐ Unknown

f Yes, was an etiology for the st ll birth dent fied?

☐ No ☐ Yes ☐ Unknown

f Yes, specify:

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Date of termina ion:

(ddMMMyyyy)

Fetal gestational age at termina ion:

(xx) weeks and (x) days

Any abnormal ty in product of conception?

☐ No ☐ Yes ☐ Unknown ☐ N/A

f Yes, specify:

Reason for therapeut c abortion:

☐ Ma ernal cond tion disease ☐ Fetal condi ion/disease

Comments:

Pregnancy Outcome 2 (X2D)

Web Version 1 0 1 01; 21Feb20

Segment A
Date of nitial report

Birth order number:

1
2
3

Pregnancy outcome (for this fetus):

Live birth
Spontaneous abor ion/miscarriage (<20 wks)
S ill birth (>= 20 weeks)
E ective abort on
The apeu ic abort on

If spontaneous abortion/misca riage, still b rth, or therapeutic abo tion, complete an AE/SAE form.

Indicate the source of nformation: (may check Yes to more than one)

Mother: ☐ No ☐ Yes
Family member: ☐ No ☐ Yes
Phys c an/med cal chart: ☐ No ☐ Yes
Other: ☐ No ☐ Yes

f Yes, specify:

Labor, Delivery, and Post Partum Information

Was there any fe al d stress during labor and de ivery? ☐ No ☐ Yes ☐ Unknown ☐ N/A

If Yes, complete an Adverse Event form.

Neonatal Outcome Live Birth and Still Birth Only

Date of live birth or sti l birth: (ddMMMyyyy)

Delivery: ☐ Vaginal ☐ Cesarean sect on

Sex: ☐ Ma e ☐ Female

Infant fe al gestational age at live birth or st ll bi th: (xx) weeks and (x) days

Size for gesta ional age: ☐ SGA ☐ AGA ☐ LGA

Infant Measurements

Birth we ght	☐ Pounds ☐ K lograms	(xx.x) lb	(xx.x) kg
Length	☐ Inches ☐ Cen imeters	(xx.x) in	(xx.x) cm
Frontal occip tal circumference (FOC)	☐ Inches ☐ Cen imeters	(xx.x) in	(xx.x) cm

Apgar score, 1 minu e (eave b ank for Sti l Birth): (xx)

Apgar score, 5 minu es (leave blank for S ill Birth): (xx)

Cord pH: (x.x)

Congenital anomal es: ☐ No ☐ Yes *(If Yes, complete an SAE form)*

One Month Follow Up Live Birth Only

Has the infant been diagnosed with any congenital anomal es since birth? *(Not previous y reported above)* ☐ No ☐ Yes ☐ Unknown

If Yes, complete a Serious Adverse Event form.

Has the infant been ll or hospitalized? *(Does not include we l-ch ld vis ts)* ☐ No ☐ Yes ☐ Unknown

f Yes, specify:

One or Two Month Follow Up Still Birth Only

Was there an autopsy? ☐ No ☐ Yes ☐ Unknown

f Yes, was an etiology for the st ll birth dent fied? ☐ No ☐ Yes ☐ Unknown

f Yes, specify:

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Date of termina ion: (ddMMMyyyy)

Fetal gestational age at termina ion: (xx) weeks and (x) days

Any abnormal ty in product of conception? ☐ No ☐ Yes ☐ Unknown ☐ N/A

f Yes, specify:

Reason for therapeut c abortion: ☐ Ma ernal cond tion disease ☐ Fetal condi ion/disease

Comments:

Pregnancy Outcome 3 (X3D)

Segment A
Date of nitial report

Birth order number:

1
2
3

Pregnancy outcome (for this fetus):

Live birth
Spontaneous abor ion/miscarriage (<20 wks)
S ill birth (>= 20 weeks)
E ective abort on
The apeu ic abort on

If spontaneous abortion/misca riage, still b rth, or therapeutic abo tion, complete an AE/SAE form.

Indicate the source of nformation: (may check Yes to more than one)

Mother: ☐ No ☐ Yes
Family member: ☐ No ☐ Yes
Phys c an/med cal chart: ☐ No ☐ Yes
Other: ☐ No ☐ Yes

f Yes, specify:

Labor, Delivery, and Post Partum Information

Was there any fe al d stress during labor and de ivery? ☐ No ☐ Yes ☐ Unknown ☐ N/A

If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

Neonatal Outcome Live Birth and Still Birth Only

Date of live birth or sti l birth: *(ddMMMyyyy)*

Delivery: ☐ Vaginal ☐ Cesarean sect on

Sex: ☐ Ma e ☐ Female

Infant fe al gestational age at live birth or st ll bi th: *(xx)* weeks and *(x)* days

Size for gesta ional age: ☐ SGA ☐ AGA ☐ LGA

Infant Measurements

Birth we ght	☐ Pounds ☐ K lograms	*(xx.x)* lb	*(xx.x)* kg
Length	☐ Inches ☐ Cen imeters	*(xx.x)* in	*(xx.x)* cm
Frontal occip tal circumference (FOC)	☐ Inches ☐ Cen imeters	*(xx.x)* in	*(xx.x)* cm

Apgar score, 1 minu e: *(xx)*

Apgar score, 5 minu es: *(xx)*

Cord pH: *(x.x)*

Congenital anomal es: ☐ No ☐ Yes

One Month Follow Up Live Birth Only

Has the infant been diagnosed with any congenital anomal es since birth? *(Not previous y reported above)* ☐ No ☐ Yes ☐ Unknown

If Yes, complete a Serious Adverse Event form.

Has the infant been ll or hospitalized? *(Does not include we l-ch ld vis ts)* ☐ No ☐ Yes ☐ Unknown

f Yes, specify:

One or Two Month Follow Up Still Birth Only

Was there an autopsy? ☐ No ☐ Yes ☐ Unknown

f Yes, was an etiology for the st ll birth dent fied? ☐ No ☐ Yes ☐ Unknown

f Yes, specify:

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Date of termina ion: *(ddMMMyyyy)*

Fetal gestational age at termina ion: *(xx)* weeks and *(x)* days

Any abnormal ty in product of conception? ☐ No ☐ Yes ☐ Unknown ☐ N/A

f Yes, specify:

Reason for therapeut c abortion: ☐ Ma ernal cond tion disease ☐ Fetal condi ion/disease

Comments:

Pregnancy Outcome 4 (X4D)

Web Version 1 0 1 01; 21Feb20

Segment A
Date of nitial report

Birth order number:

1
2
3

Pregnancy outcome (for this fetus):

Live birth
Spontaneous abor ion/miscarriage (<20 wks)
S ill birth (>= 20 weeks)
E ective abort on
The apeu ic abort on

If spontaneous abortion/misca riage, still b rth, or therapeutic abo tion, complete an AE/SAE form.

Indicate the source of nformation:(may check Yes to more than one)

Mother: ☐ No ☐ Yes
Family member: ☐ No ☐ Yes
Phys c an/med cal chart: ☐ No ☐ Yes
Other: ☐ No ☐ Yes

f Yes, specify:

Labor, Delivery, and Post Partum Information

Was there any fe al d stress during labor and de ivery? ☐ No ☐ Yes ☐ Unknown ☐ N/A

If Yes, complete an Adverse event form.

Neonatal Outcome Live Birth and Still Birth Only

Date of live birth or sti l birth: (ddMMMyyyy)
Delivery: ☐ Vaginal ☐ Cesarean sect on
Sex: ☐ Ma e ☐ Female
Infant fe al gestational age at live birth or st ll bi th: (xx) weeks and (x) days
Size for gesta ional age: ☐ SGA ☐ AGA ☐ LGA

Infant Measurements

Birth we ght	☐ Pounds ☐ K lograms	(xx.x) lb	(xx.x) kg
Length	☐ Inches ☐ Cen imeters	(xx.x) in	(xx.x) cm
Frontal occip tal circumference (FOC)	☐ Inches ☐ Cen imeters	(xx.x) in	(xx.x) cm

Apgar score, 1 minu e: (xx)
Apgar score, 5 minu es: (xx)
Cord pH: (x.x)
Congenital anomal es: ☐ No ☐ Yes *(If Yes, complete an SAE form)*

One Month Follow Up Live Birth Only

Has the infant been diagnosed with any congenital anomal es since birth? *(Not previous y reported above)* ☐ No ☐ Yes ☐ Unknown

If Yes, complete a Serious Adverse Event form.

Has the infant been ll or hospitalized? *(Does not include we l-ch ld vis ts)* ☐ No ☐ Yes ☐ Unknown

f Yes, specify:

One or Two Month Follow Up Still Birth Only

Was there an autopsy? ☐ No ☐ Yes ☐ Unknown

f Yes, was an etiology for the st ll birth dent fied? ☐ No ☐ Yes ☐ Unknown

f Yes, specify:

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Date of termina ion: (ddMMMyyyy)
Fetal gestational age at termina ion: (xx) weeks and (x) days
Any abnormal ty in product of conception? ☐ No ☐ Yes ☐ Unknown ☐ N/A

f Yes, specify:

Reason for therapeut c abortion: ☐ Ma ernal cond tion disease ☐ Fetal condi ion/disease

Comments:

Pregnancy Report and Follow Up (XPD)

Web Version 1 0 2 01; 21Feb20

Segment A
Date of nitial report

Pregnancy Follow Up *Update as Applicable During Follow-Up*

Was fol ow-up contact made with the subject during the pregnancy? ☐ No ☐ Yes
If Yes, ist dates that contact was made, and update the other sections of this form, as necessary.

#	Date (dd/MMM/yyyy)	#	Date (dd/MMM/yyyy)
1		5	
2		6	
3		7	
		8	

Maternal Information *Complete at Time of Initial Report*

Indicate the source of nformation (may check Yes to more than one):

Mother: ☐ No ☐ Yes
Family member: ☐ No ☐ Yes
Phys c an/med cal chart: ☐ No ☐ Yes
Other: ☐ No ☐ Yes
f Yes, specify:

Pregnancy Status *Update as Applicable During Follow-Up*

Pregnancy status: ☐ Pregnancy ongoing ☐ Ou come known ☐ Ou come unknown
For known pregnancy outcomes, record pregnancy outcome data for each fetus

Current Pregnancy Information *Complete at Time of Initial Report*

Number of fetuses: 1 / 2 / 3

Date of last menstrual pe iod: *(ddMMMyyyy)*
Estimated de ivery date: *(ddMMMyyyy)*
How was es imated de ivery date dete mined? ☐ Last menstrual period ☐ U trasound
f Ultrasound, estimated date of exam: *(ddMMMyyyy)*

P e-pregnancy weight	Date of pre-pregnancy we ght: *(ddMMMyyyy)*	Date certainty:	We ght uni s:	We ght (lb):	Weight (kg):
		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐ Pounds ☐ K lograms	*(xxx x)* lb	*(xxx.x)* kg

Previous Pregnancy Information *Complete at Time of Initial Report*

Grav da (total number of pregnancies including the current pregnancy): *(xx)* ☐ Unknown

Ex lud ng the current pregnancy, provide numbers for the following (record "0" if none):
Para events

Live births: *(xx)* ☐ Unknown
Extremely preterm (EPT) births (< 25 weeks): *(xx)* ☐ Unknown
Very preterm (VPT) bi ths (25 0/7 - 31 6 7 weeks): *(xx)* ☐ Unknown
Early preterm births (32 0/7 - 33 6/7 weeks): *(xx)* ☐ Unknown
La e preterm births (3 0/7 - 36 6/7 weeks): *(xx)* ☐ Unknown
Early erm births (37 0/7 - 38 6/7 weeks): *(xx)* ☐ Unknown
Fu l term births (39 0/7 - 0 6/7 weeks): *(xx)* ☐ Unknown
La e term births (1 0/7 - 1 6/7 weeks): *(xx)* ☐ Unknown
Post term births (≥ 2 0 7 weeks): *(xx)* ☐ Unknown
Sti lbirths (≥20 weeks): *(xx)* ☐ Unknown
Spontaneous abortion/miscarr age (20 weeks): *(xx)* ☐ Unknown
Elective abor ions: *(xx)* ☐ Unknown
Therapeutic abor ions: *(xx)* ☐ Unknown
Therapeutic abortions are def ned as abortions due to medical reasons for the mother or fetus.
Any major congeni al anomal es w th a previous pregnancy? ☐ No ☐ Yes ☐ Unknown
f Yes, specify:

Current Pregnancy Information *Update as Applicable During Follow-Up*

D d the subject exper ence any of the maternal comp icat ons isted during th s pregnancy? ☐ No ☐ Yes ☐ Unknown
If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

Abrupt o placentae	Eclamps a	Oligohydramn os
Abnormal b eeding/hemorrhage	Endometrit s	Placen a previa
Anaphylaxis	Fetal d stress	Polyhydramnios
Bacteremia	Fever > 100. °F or 38 0°C	Pre eclamps a
Cho ioamnion tis	Gesta ional diabetes	Pregnancy induced hypertension
Coagu at on d sorders	GBS-positive	Pre erm abor

D d the subject exper ence any other maternal compl cations during th s pregnancy? ☐ No ☐ Yes ☐ Unknown
If Yes, complete an Adverse Event/Serious Adverse Event form, as appropriate.

Pregnancy Risk Factors *Update as Applicable During Follow-Up*

D d the subject use tobacco products, drink alcohol, or use other ll c t drugs during this pregnancy? ☐ No ☐ Yes ☐ Unknown

Pregnancy Substance Use Log

ype of Substance	Route	Amount *(xxx.x)*	Un t	Frequency	Start Date (ddMMMyyyy)	Start Date Certainty	End Date (ddMMMyyyy)	End Date Certainty	Ongoing
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
lco ol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	I t a sc la Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	O ce Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		E act da e Day only unknown Day and month unknown Day, month, and year unknown		E act date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐
Alcohol Amphetamine Anabol c stero ds Barbiturates Bath sa ts (synthetic cathinones) *Addit onal Opt ons Listed Below	Intramuscular Intravenous Nasal O al Smoking *Addit onal Options Listed Below		Bag Cigar Cigarette eC ga ette Fluid ounce (US) *Addit onal Opt ons Listed Below	Once Once per day Once per month Twice per day Twice per month *Addit onal Options Lis ed Be ow		Exact da e Day only unknown Day and month unknown Day, month, and year unknown		Exact date Day only unknown Day and month unknown Day, month, and year unknown	☐

A standard drink is defined as 1 12oz bottle of beer, 1 glass 4oz non-fortified wine, or 1 mixed dr nk with 1oz liquor.

Has the subject aken any med cations during the pregnancy (over-the-counter and prescrip ion)? ☐ No ☐ Yes ☐ Unknown
If Yes, complete the Concomitant Medications form.
Comments:

Additional Selection Op ions for XPD

ype of substance 1
Benzodiazepines
Cocaine
Codeine
Dextromethorphan (DXM)
Fentanyl and analogs
Flunitrazepam
GHB
Hash sh
Heroin
Hydrocodone Bitartrate Hydromorphone
Inhalants
K2/Spice (synthet c marijuana)
Ketamine
LSD
Mar juana
MDMA
Meperidine
Mesca ine
Methadone
Methamphetamine
Methylphenidate
Morphine
Opium
Oxycodone HCL
Oxymorphone
PCP and analogs
Propoxyphene
Psi ocybin
Salvia divinorum
Sleep med cat ons
Tobacco

Substance route 1
Subcutaneous

Substance unit 1
Gram
Joint
Li er
M lligram
Ounce
Pack
Standard drink

Substance frequency 1
Every 2 mon hs
1 time per week
2 times per week
3 times per week
times per week
5 times per week
6 times per week

Adverse Event (ZAE)

Segment A
AE Number

Adverse event:
Start date: (ddMMMyyyy)
End date: (ddMMMyyyy) Ongoing
Associated w th dose number:
1
2
Sever ty: Mi d Moderate Severe
f Severe, Duration: < 8 hours ≥ 8 hours
Relationship o study treatment: Not rela ed Related
f Not Re ated, the event is re ated o:
1 - Study procedure
2 - Other medical condi ion or i ness
3 - Other drug
- Other
f Not Re ated, specify alternative et o ogy:
What act on was taken with the study treatment?
INC - Dose increased
NC - Dose not changed
RED - Dose reduced
INT - Drug in errupted
WD - Drug w thdrawn
*Add tional Op ions L sted Below
D d the adverse event cause the subject to be discontinued from the study? No Yes
Outcome:
R - Recovered/ esolved
RS - Recove ed/resolved w th sequelae
O - Recovering/resolving
NR - Not recovered/Not resolved
F - Fatal
s the event an Adverse Event of Special Interest (AESI)? No Yes
If Yes, ndicate category of AESI below
s the event a Med cally Attended Adverse Event (MAAE)? No Yes
s the event a New Onset Chronic Med cal Condit on (NOCMC)? No Yes
s th s event an Unant cipated Prob em ? No Yes

Serious Adverse Events

s the adverse event serious? No Yes
f Yes, date event became an SAE: (ddMMMyyyy)
s the adverse event assoc ated w th a congen tal anomaly or birth defect? No Yes
D d the adverse event esult in persistent or s gnif cant disabi ity or incapac ty? No Yes
D d the adverse event esult in death? No Yes
D d the adverse event esult in init al or prolonged hosp ta izat on for the subject? No Yes
s the adverse event li e threatening? No Yes
s the adverse event a medica ly important event not covered by other serious cr teria? No Yes Specify

Halting Criteria

Check th s box if, in the opin on of the site inves igator, this event shou d be evalua ed for possible cont ibution toward the halting cr te ia for the group, cohort, or study.

Comments:

Additional Selection Op ions for ZAE

AE Number (key field):

1
2
3

5
6
7
8
9
10
11
12
13
1
15
16
17
18
19
20
21
22
23
2
25
26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
2
3

5
6
7
8
9
50

What action was taken with the study treatment?

NA - Not appl cab e

Laboratory Reference Ranges (ZLR)

Web Version 1 0 1 03: 01Jul20

Parameter

Effective Date	Sex	Un ts	Reference Range Lower Limit	No Lower Limit	Reference Range Upper L mit	No Upper Lim t	Min Age inclusive (years)	Max Age inclusive (years)
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		
	Ma e Female Both	g/dL mg/dL 10^3/uL IU/L mL/min/1 73m2 *Addit onal Opt ons Listed Below		☐		☐		

Additional Selection Op ions for ZLR

Parameter (key field):	Units 01
Hemoglobin	mmol/L
Alanine Aminotransferase	10^9/L
Aspar ate Aminotransferase	U/L
Creatinine	seconds
eGFR	%
Blood Urea N trogen	
Potassium	
Magnesium	
Total Bi irubin	
White Blood Ce ls	
Platelets	
Alkaline Phosphatase	
Lipase	
Prothrombin Time	
Partial Thromboplastin Time	
Hematocrit	

Solicited Local Events (ZRL)

Web Version 1 0 1.01; 27Apr20

Segment A
Dose Number
Period Number

Symptom ype	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Ongo ng after Day 8?	Maximum Sever ty/Measurement after Day 8	Stop Date
Date:	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)			
C ick th s bu ton only if the subject had **no symptoms**	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms			
What side was assessed?	Left Right										
Pain	None Mild Modera e Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Moderate Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Moderate Severe Not Done	None Mild Modera e Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Modera e Severe Not Done	No Yes	1-M ld 2-Modera e 3-Severe	(ddMMMyyyy)
E ythema (Redness)	None Mild Modera e Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Moderate Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Moderate Severe Not Done	None Mild Modera e Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Modera e Severe Not Done	No Yes	1-M ld 2-Modera e 3-Severe	(ddMMMyyyy)
Indura ion (Hardness) / Edema (Swel ing)	None Mild Modera e Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Moderate Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Moderate Severe Not Done	None Mild Modera e Severe Not Done	None Mi d Moderate Severe Not Done	None M ld Modera e Severe Not Done	No Yes	1-M ld 2-Modera e 3-Severe	(ddMMMyyyy)
E ythema Redness measu ement - S ze *(mm)*	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	No Yes	(xxx)	(ddMMMyyyy)
Indura ion (Hardness) / Edema (Swel ing) measurement - Size *(mm)*	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	(xxx)	No Yes	(xxx)	(ddMMMyyyy)

Comments:

Additional Selection Op ions for ZRL

Dose Number (key f eld):

1
2
3

5
6
7
8
9
10

Period Number (key field):

1
2
3

5
6
7
8
9
10

Solicited Systemic Events (ZRS)

Web Version 1 0 1.01; 27Apr20

Segment A
Dose Number
Period Number

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Ongoing after Day 8?	Maximum Severity/Measurement a ter Day 8	Stop Date
Date:	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)	(ddMMMyyyy)			
Un t: Fahrenheit / Ce sius											
Temperature	(xxx.x) F	(xxx.x) F	(xxx.x) F	(xxx.x) F	(xxx.x) F	(xxx.x) F	(xxx.x) F	(xxx.x) F	No Yes	(xxx.x) F	(ddMMMyyyy)
	(xx.x) C	(xx.x) C	(xx.x) C	(xx.x) C	(xx.x) C	(xx.x) C	(xx.x) C	(xx.x) C	No Yes	(xx.x) C	(ddMMMyyyy)
Cl ck this but on if the subject had **no symptoms**	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms	No Symptoms			
Chil s	None / M ld / Modera e / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	None / Mild / Moderate / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Modera e / Seve e / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	No Yes	1-M ld / 2-Moderate / 3-Severe	(ddMMMyyyy)
Fatigue	None / M ld / Modera e / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	None / Mild / Moderate / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Modera e / Seve e / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	No Yes	1-M ld / 2-Moderate / 3-Severe	(ddMMMyyyy)
Myalgia	None / M ld / Modera e / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	None / Mild / Moderate / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Modera e / Seve e / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	No Yes	1-M ld / 2-Moderate / 3-Severe	(ddMMMyyyy)
Arthra g a	None / M ld / Modera e / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	None / Mild / Moderate / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Modera e / Seve e / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	No Yes	1-M ld / 2-Moderate / 3-Severe	(ddMMMyyyy)
Headache	None / M ld / Modera e / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	None / Mild / Moderate / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Modera e / Seve e / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	No Yes	1-M ld / 2-Moderate / 3-Severe	(ddMMMyyyy)
Nausea	None / M ld / Modera e / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	None / Mild / Moderate / Severe / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Modera e / Seve e / Not Done	None / Mi d / Moderate / Severe / Not Done	None / M ld / Moderate / Severe / Not Done	No Yes	1-M ld / 2 Mode ate / 3-Severe	(ddMMMyyyy)

Commen s:

Additional Selection Op ions for ZRS

Dose Number (key f eld):

1
2
3

5
6
7
8
9
10

Period Number (key field):

1
2
3

5
6
7
8
9
10

Systemic Events Attribution (ZSA)

Web Version 1 0 1 00; 28Feb20

Segment A
Dose Number
Period Number

Grade 3 Systemic Reactions Within 7 Days After Administration

Systemic Reaction	Reaction Date	Post Administration Day	Severity	Attributed to Alternate Etiology	If Yes Specify Alternate Etiology	Medical History or Other
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	
				No Yes	1 2 3 5 *Addit onal Options Listed Below	

Comments:

Additional Selection Op ions for ZSA

Dose Number (key f eld):

1
2
3

5
6
7
8
9
10

Period Number (key field):

1
2
3

5
6
7
8
9
10

AE or medical history 1

6
7
8
9
10
11
12
13
1
15
16
17
18
19
20
21
22
23
2
25
26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
2
3

5
6
7
8
9
50

Medical History

Other

Treatment Administration Record (ZVR)

Web Version 1 0 3.00; 27Apr20

Segment A
Visit Number

Visit da e: (ddMMMyyyy)

Baseline Assessment (prior to treatment administration)

Assessment of Systemic Symptoms

Arth algia/joint pain: None / M ld / Modera e / Severe / Not Done

Chi ls: None / M ld / Modera e / Severe / Not Done

Fa igue: None / M ld / Modera e / Severe / Not Done

Headache: None / M ld / Modera e / Severe / Not Done

Mya gia: None / M ld / Modera e / Severe / Not Done

Nausea: None / M ld / Modera e / Severe / Not Done

Treatment Administration Information

Record the treatment number as recorded on the study product. Do not record from the Enrollment Conf rmation page.

Treatment administrat on site: Left arm Right arm

Time administered (2 -hour c ock): (hh:mm)

In tials of individual who administe ed the treatment:

Post Administration Assessment

Time of assessment (2 -hour c ock): (hh:mm)

Assessment to take place no sooner than 60 minutes after administration

Assessment of Systemic Reactions

Systemic Reaction	Severity	Attributed to Alternate Etiology	Specify Alternate Etiology	Medical History or Other
Arth algia/joint pain	None / Mild / Modera e / Severe / Not Done	No Yes	1 / 2 / 3 / 5 *Addit onal Opt ons Listed Below	
Chi ls	None / Mild / Modera e / Severe / Not Done	No Yes	1 / 2 / 3 / 5 *Addit onal Opt ons Listed Below	
Fa igue (Tiredness)	None / Mild / Modera e / Severe / Not Done	No Yes	1 / 2 / 3 / 5 *Addit onal Opt ons Listed Below	
Headache	None / Mild / Modera e / Severe / Not Done	No Yes	1 / 2 / 3 / 5 *Addit onal Opt ons Listed Below	
Mya gia (Body aches/ Muscular pain)	None / Mild / Modera e / Severe / Not Done	No Yes	1 / 2 / 3 / 5 *Addit onal Opt ons Listed Below	
Nausea	None / Mild / Modera e / Severe / Not Done	No Yes	1 / 2 / 3 / 5 *Addit onal Opt ons Listed Below	

Assessment of Local Reactions

Pain: None / Mi d / Mode ate / Severe / Not Done

Indura ion (Hardness)/ Edema (Swelling): None / Mi d / Mode ate / Severe / Not Done

Erythema (Redness): None / Mi d / Mode ate / Severe / Not Done

Indura ion at inject on site measu ement *(mm)*: (xxx) mm Not Done

Erythema at injection si e measurement *(mm)*: (xxx) mm Not Done

Additional Selection Op ions for ZVR

Arthralgia AE or MH

6
7
8
9
10
11
12
13
1
15
16
17
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19
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21
22
23
2
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26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
2
3

5
6
7
8
9
50

Medical History

Other