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)

We Ve s 2 00 04Ma 20

e me A

s the subject a **ema e** o ch ldbea ing potential o a e t le **ma e**?

☐ No ☐ es

I No eason

os -menopausal o >= yea
ubal l gat on
Bi a e al oopho ectomy
Hys e ectomy
Essu e
*Add tional Options sted Below

I Othe speci y

I No da e o M su ge y o d agnosis

ddMMMyyyy)

Exact da e
Day on y unknown
Day and mon h unknown
Day month and yea unknown

	Me e	e e	a ae	a ae e a	a e	a e e a	
Me *equ ed)*	- O al cont acept ves 2 - Ho monal injections 3 - Ho monal implan s 4 - Cont aceptive pa ches 5 - NuvaRing *Add t onal Opt ons isted Below		ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day month and yea unknown	ddMMMyyyy)	Exact date Day on y unknown Day and month unknown Day month and yea unknown	☐
Me 2	- O al cont acept ves 2 - Ho monal injections 3 - Ho monal implan s 4 - Cont aceptive pa ches 5 - NuvaRing *Add t onal Opt ons isted Below		ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day month and yea unknown	ddMMMyyyy)	Exact date Day on y unknown Day and month unknown Day month and yea unknown	☐
e Me *change n me hod)*	- O al cont acept ves 2 - Ho monal injections 3 - Ho monal implan s 4 - Cont aceptive pa ches 5 - NuvaRing *Add t onal Opt ons isted Below		ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day month and yea unknown	ddMMMyyyy)	Exact date Day on y unknown Day and month unknown Day month and yea unknown	☐
e Me *change n me hod)*	- O al cont acept ves 2 - Ho monal injections 3 - Ho monal implan s 4 - Cont aceptive pa ches 5 - NuvaRing *Add t onal Opt ons isted Below		ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day month and yea unknown	ddMMMyyyy)	Exact date Day on y unknown Day and month unknown Day month and yea unknown	☐
e Me *change n me hod)*	- O al cont acept ves 2 - Ho monal injections 3 - Ho monal implan s 4 - Cont aceptive pa ches 5 - NuvaRing *Add t onal Opt ons isted Below		ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day month and yea unknown	ddMMMyyyy)	Exact date Day on y unknown Day and month unknown Day month and yea unknown	☐
e Me *change n me hod)*	- O al cont acept ves 2 - Ho monal injections 3 - Ho monal implan s 4 - Cont aceptive pa ches 5 - NuvaRing *Add t onal Opt ons isted Below		ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day month and yea unknown	ddMMMyyyy)	Exact date Day on y unknown Day and month unknown Day month and yea unknown	☐

Additional Selection Options for BC1

If No reason
Vasectomy
Bi ateral orchiectomy
Other
Method of b r h control 1
6 - Intrauterine device, hormonal
7 - Intrauterine device, non-hormonal
8 - Barrier method plus spermicide
9 - Barrier method (a one)
10 - Sperm c de (a one)
11 - Same-sex relationship
12 - Monogamous re ationship with vasectomized partner
13 - Abstinence
99 - Other

Concomitant Medication (CMD)

We Ve s 2 0 0 May20

e me A
M m e

Medica ion
Sta t date

Exact date
Day on y unknown
Day and month unknown
Day month and yea unknown

dd/MM/yyyy)

End date

Exact date
Day only unknown
Day and month unknown
Day mon h and yea unknown

dd/MM/yyyy) Ongo ng

ndicat on

Was this medica ion taken o an Adve se Event?

No es sol c ted AE es unsol c ted AE

I es unsolic ted AE

2
3
4
5
*Add t onal Opt ons isted Below

nd ca e p ma y AE on y)

Was this medica ion taken o a condi ion l s ed on the Medical Histo y?

No es

I es MH e m

2
3
4
5
*Add t onal Opt ons isted Below

nd ca e p ma y MH on y)

Additional Selection Options for CMD

CM 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

Consent Agreement (CS1)

e me A

Da e n o med consent signed
I econsented date o econsent
Commen s

dd/MM/yyyy)
dd/MM/yyyy)

Demographics (DEM)

We Ve s 00 09Oct20

Sex

Male ema e

Bi h date

ddMMMyyyy)

Ethn city

Hispan c o at no
Not H spanic o a ino
Not spo ed
Unknown

nd ca e No o es o each ace s ed be ow es may be checked o mo e han one ace a sub ec e uses o den y h s o he ace check No o a op ons

Ame can ndian o A askan Na ive

No es

Asian

No es

Na ive Hawa ian o othe aci c Islande

No es

Black o A ican Ame ican

No es

White

No es

Upon sav ng he sc een 'Race' w be popu a ed based on he sub ec 's esponse o he nd v dua ace ques ons above

Race

UNKNOWN
MU I E
AMERICAN INDIAN OR A ASKA NA IVE
AS AN
NA IVE HAWAI AN OR O HER ACI IC IS ANDER
*Add t onal Opt ons isted Below

Additional Selection Options for DEM

Race
BLACK
WHITE

Study Status (DS1)

We Ve s 4 0 27Ap 2

e me A

Study status

Da e o p otocol comp e ion te mina ion
I ea ly e m nat on ind ca e eason

otocol completed
Ea ly e mina ion

dd/MM/yyyy)

Se ious adve se event (o he han death) speci y AE #
Adve se event o he han se ous adve se event speci y AE #
ost o ol ow up
otocol dev at on speci y DV #
Volunta y wi hd awal by sub ect speci y
*Add t onal Opt ons isted Below

I eason equi es speci ication
AE numbe

2
3
4
5
*Add t onal Opt ons isted Below

DV numbe

2
3
4
5
*Add t onal Opt ons isted Below

E igibi i y c ite on
C te ion numbe

Inclusion Exc usion

2
3
4
5
*Add t onal Opt ons isted Below

Additional Selection Options for DS1

If early term nation ndicate reason
Withdrawal by invest ga or, specify
COV D-19 pandem c, spec fy
Termina ion of s te by sponsor
Termina ion of study by sponsor
Death, spec fy AE #
Enrolled but treatment not administe ed, specify
Pregnancy
Not el gible at enrollment, spec fy and enter el gibi ity criterion #
Became ineligib e after enrollment, specify and enter e igib ility criterion #
So ic ted event, spec fy
Othe , specify

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
50

Criterion 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

Discontinuation of Treatment (DS2)

e me A

We Ve s 0 27Ap 2(

Comp ete th s o m sub ect d scont nued study p oduct

Da e t ea rment discon inued

Reason o d scontinuat on

ddMMMyyyy)

Se ious adve se event (o he han death) speci y AE #
Adve se event o he han se ous adve se event speci y AE #
ost o ol ow up
otocol dev at on speci y DV #
Volunta y wi hd awal by sub ect speci y
*Add t onal Opt ons ista Below

I eason equi es speci ication

AE numbe

2
3
4
5
*Add t onal Opt ons ista Below

DV numbe

2
3
4
5
*Add t onal Opt ons ista Below

E igibi i y c ite on

Inclusion Exc usion

C te ion numbe

2
3
4
5
*Add t onal Opt ons ista Below

W ll the subject ema n in he study o ol ow-up?
No subm a S udy S a us o m

No es

Additional Selection Options for DS2

Reason for discontinuation

Withdrawal by invest ga or, specify
COV D-19 pandem c, spec fy
Termina ion of s te by sponsor
Termina ion of study by sponsor
Death, spec fy AE #
Technical prob ems, spec fy
Pregnancy
Not el gible at enrollment, spec fy and enter el gibi ity criterion #
Became ineligib e after enrollment, specify and enter e igib ility criterion #
So ic ted event, spec fy
Othe , specify

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
50

Criterion 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

NSS Protocol Deviation (DV2)

ev a m e

We Ve s 3 03 27Ap 20

otocol deviat on

Out o window v s t
Inco ect ve sion o IC s gned
Spec men esu t not obta ned
Requi ed p ocedu e not conduc ed
Requi ed p ocedu e done nco ec ly
*Add t onal Opt ons ista Below

I Othe speci y
Spec men ype
Resu t ype
Desc iption
A ec ed v s t numbe
Sta t date
End date
Reason o p otocol dev a ion

ddMMMyyyy)
ddMMMyyyy)

Cl nic e o
ha macy e o
abo ato y e o
Invest gato study decision
COV D- 9 pandemic
*Add t onal Opt ons ista Below

I Othe speci y

Did the deviat on esult in subject e mina ion o study o low-up?
es subm he S udy S a us o m
Does the deviat on a ect o could t poten ial y a ect p oduct s abi ity?
No es N A
Deviat on catego y

E gibi ity en ollment
eatment adm n st ation schedule
ol ow-up v s t schedu e
otocol p ocedu e assessment
eatment adm n st ation

s this dev a ion an "Unan icipated ob em"?
No es
Desc ibe steps aken to eso ve o avo d ecu ence o the dev ation
Does this dev ation meet IRB epo t ng equi ements?
No es
I es date IRB noti ied
ddMMMyyyy)
Commen s

Additional Selection Options for DV2

Dev ation Number (key fie d)
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

Protocol deviation
Study product temperature excurs on
Specimen temperature excurs on
Other

Reason for protocol deviation
Other

Protocol Deviation (DVD)

We Ve s 3 02 27Ap 20

e me A
ev a m e

otocol deviat on

Out o window v s t
Missed vis t v s t not conduc ed
Did not meet nclusion c i e on
Met exc usion c i e ion
Inco ect ve sion o IC s gned
*Add t onal Opt ons isted Below

l Othe speci y

Inclusion c ite on

Exclusion c i e on

Spec men ype

Numbe o a iquo s obtained

Resu t ype

Desc iption

A ec ed v s t numbe

Sta t date

xx)

ddMMMyyyy)

Reason o p otocol dev a ion

Sub ect i lness
Sub ect unab e to comply
Sub ect e usal
Clinic e o
ha macy e o
*Add t onal Opt ons isted Below

l Othe speci y

Did the deviat on esult in an adve se event?
es comp e e an Adve se Even Se ous Adve se Even o m as app op a e

No es sol c ted AE es unsol c ted AE

Speci y sol c ted AE

Injection site pain
E ythema
Injection site swel ing
Indu at on
Headache
*Add t onal Opt ons isted Below

AE numbe

2
3
4
5
*Add t onal Opt ons isted Below

Did the deviat on esult in subject e mina ion o study o low-up?
es subm he S udy S a us o m

No es

Does the deviat on a ect o could t poten ial y a ect p oduct s abi ity?

No es N A

Deviat on catego y

E igibi ity en ollment
eatment adm n st ation schedule
ol ow-up v s t schedu e
otocol p ocedu e assessment
eatment adm n st ation

s this dev a ion an "Unan icipated ob em"?

No es

Desc ibe steps aken to eso ve o avo d ecu ence o the dev ation

Does this dev ation meet IRB epo t ng equi ements?

No es

I es date IRB noti ied

ddMMMyyyy)

Commen s

Additional Selection Options for DVD

Dev ation Number (key fie d)
1
2
3

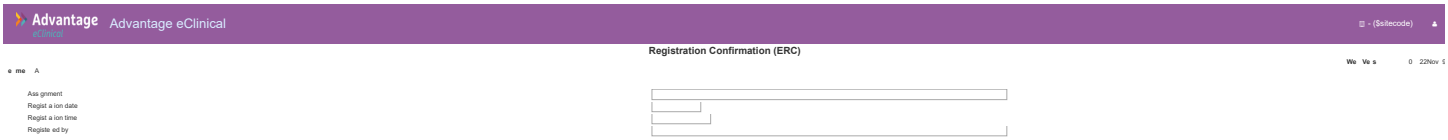
5
6
7
8
9
10
11
12
13
1
15
16
17
18
19
20
21
22
23
2
25
26
27
28
29
30
31
32
33
3
35
36
37
38
39
0
1
2
3

5
6
7
8
9
50

Protocol deviation
ICF not signed prior to study procedures
M ssed treatment administration
Delayed treatment administrat on
Blood not collec ed
Urine not co lected
Too few a iquo s obtained
Specimen result not obtained
Required procedure not conduc ed
Required procedure done incorrectly
Study product temperature excurs on
Specimen temperature excurs on
Other

Reason for protocol deviation
Laboratory error
Investigator/study decision
Other
COV D-19 pandem c

Specify so icited AE
Fa igue
Mya gia
Arthralgia
Nausea
Fever
Chi ls
WBC
Hemog obin
Plate ets
ALT
AST
ALP
Bi irubin (to al)
Crea inine
PT
PTT


Advantage eClinical
Registration Confirmation (ERC)
Assignment
Registration date
Registration time
Registered by

Advantage eClinical Advantage eClinical - ($sitecode)

20003A (ENR)

We Ve s 2 02 29May20

Sub ect ID

En o lment da e ddMMMyyyy)

otocol ve s on en o led unde

0
2 0
3 0
4 0

Does he sub ect meet a l el g bil ty c te ia as speci ed n the cu ent ve sion o the p o ocol?

No es

he sub ec does no mee a e g b y c e a spec y wh ch c e a have no been me

C te ion not met

ovides w i ten in o med consent p io o init a ion o any study p ocedu es
Be ab e to unde s and and ag ees to comp y wi h s udy p ocedu es and be avai able o s udy vis ts
Ag ees o the col ect on o venous blood pe p o ocol
Ma e o non-p egnant emale 8 yea s o age o g eate nclusive at ime o en o lment
Ma e o non-p egnant emale 8 o 55 yea s o age nclusive at time o en ollment
*Add t onal Opt ons isted Below

C te ion not met 2

ovides w i ten in o med consent p io o init a ion o any study p ocedu es
Be ab e to unde s and and ag ees to comp y wi h s udy p ocedu es and be avai able o s udy vis ts
Ag ees o the col ect on o venous blood pe p o ocol
Ma e o non-p egnant emale 8 yea s o age o g eate nclusive at ime o en o lment
Ma e o non-p egnant emale 8 o 55 yea s o age nclusive at time o en ollment
*Add t onal Opt ons isted Below

C te ion not met 3

ovides w i ten in o med consent p io o init a ion o any study p ocedu es
Be ab e to unde s and and ag ees to comp y wi h s udy p ocedu es and be avai able o s udy vis ts
Ag ees o the col ect on o venous blood pe p o ocol
Ma e o non-p egnant emale 8 yea s o age o g eate nclusive at ime o en o lment
Ma e o non-p egnant emale 8 o 55 yea s o age nclusive at time o en ollment
*Add t onal Opt ons isted Below

C te ion not met 4

ovides w i ten in o med consent p io o init a ion o any study p ocedu es
Be ab e to unde s and and ag ees to comp y wi h s udy p ocedu es and be avai able o s udy vis ts
Ag ees o the col ect on o venous blood pe p o ocol
Ma e o non-p egnant emale 8 yea s o age o g eate nclusive at ime o en o lment
Ma e o non-p egnant emale 8 o 55 yea s o age nclusive at time o en ollment
*Add t onal Opt ons isted Below

Additional Selection Options for ENR

Criterion not met 1

Body Mass Index 18-35 kg/m2 inclusive, at screening.
BMI: 18-35 kg/m2 inclusive or < 56 years of age; 18-30 kg/m2 inclusive for >= 56 years of age
Women of chi dbearing po en ial must agree to use at least one form of contraception.
Women of chi dbearing po en ial must have a negative pregnancy est pr or o vaccina ion.
Male subjec s of chi dbearing potential use an effec ive form of contraception.
Male subjec s agree to refrain from sperm donat on until 3 months a ter ast study vaccination.
Male subjec s agree to refrain from sperm donat on until 60 days af er ast study vaccination.
In good health
O al empe ature s ess than 100 0F (37.8C).
Pu se no greater than 100 beats per minute.
Systolic b ood pressure s w thin the protocol eligibil ty cr ter a.
Systolic BP s 85 o 150 mm Hg, inclusive
Screening laboratory evaluations are within acceptab e normal ranges
Must ag ee to have samp es s ored for secondary resea ch
Agrees to adhere to Li esty e Considerat ons throughout study durat on.
The subject must agree to refrain from donating blood or p asma during the study
Positive pregnancy test either at screening or just pr or o each vaccine administra ion.
Fema e subject who s breast eeding from the time of irst vac through 60 days of last vaccinat on.
Has any medical disease or cond tion that precludes study par icipation.
Presence of self-repor ed or medically documented med cal or psych atr c condi ion
Has an acute i lness within 72 hours pr or o each vaccina ion.
Has a positive test or hep B, hep C or HIV an ibod es at screening.
Has participated in another investigat onal study involving any investigat onal product.
Currently enro led or in p ans to participate in another clinical trial
Has prev ously participated in an investigat onal study involving LNPs.
Has a history of hypersensitivity or severe al ergic react on to any prev ous vaccines.
Chronic use of any med cations that may be assoc ated w th impaired immune responsiveness
Ant cipa ing the need for immunosuppressive treatment w thin the next 6 months
Received immunoglobulins and/or any blood or b ood products within the ast months.
Has any blood dyscrasias or s gn ficant disorder of coagulation.
Has any chron c iver disease, including fatty iver.
Has a history of a cohol abuse or other recrea ional drug use within 6 months of study vaccina ion.
Has a positive test result for drugs of abuse at screening or be ore first vaccination.
Has any abnormal ty or body art that wou d interfere with the abi ity to obse vse ocal reactions.
Plans to receive a l censed, live vaccine within weeks be ore or after each vaccinat on.
Plans to receive a l censed, inactivated vaccine within 2 weeks before or af er each vaccination.
Receipt of any other 2019-nCoV or other experimental coronavirus vaccine at any time
Receipt of any other SARS-CoV-2 or other experimen al co onavirus vaccine at any time.
Known con act of anyone known o have 2019-nCoV infection w thin 2 weeks pr or to registra ion.
Close contact of anyone known to have SARS-CoV-2 infect on w thin 30 days prior to registrat on.
History of COVID-19 diagnosis
On current treatment w th investigat onal agents for prophylax s of COVID 19
Has trave ed to China w thin 30 days before the irst vaccinat on.
Current use of any medicat ons within 7 days prior to vaccinat on.
The subject must agree to refrain from donating blood or p asma during the study.
Plan to travel outside the US through 28 days a ter the 2nd vaccinat on.
Reside in a nursing home or other skil ed nursing facil ty or have a requi rement for nursing care.
Non-ambu atory
For subjects >=56 years of age, history of chronic smoking w thin the prior year.
For subjects >=56 years of age, current smoking or vaping.
For subjects >=56 years of age, currently working with h gh risk of exposure to SARS-CoV-2

e me A
V s m e

We Ve s 4 02 09 u20

Hematology

We e hematology ests pe o med?
I No eason not done

No es N A
Subject unable o comply
Subject e usual
Cl n c e o
nvestigato decis on
COVID- 9 pandem c
*Add tional Options sted Be ow

I O he speci y

Blood col ect on da e o hematology

ddMMMyyyy

	es	s	a a e	A ma ea s	e a e e A e ae	W a A as Take T ea me ?	e es a se e e e s e m e ?
Hemoglob n	xx x)	g d mg d 0^3 u IU m m n 73m2 *Add tional Opt ons sted Below	Cl n ca ly signi cant Not cl n ca ly signi cant	Not e a ed Related		INC - Dose inc eased NC - Dose not changed RED - Dose educed IN - D ug inte up ed WD - D ug wi hd awn *Addit onal Opt ons sted Below	No es
ate ets Count	xxx)	g d mg d 0^3 u IU m m n 73m2 *Add tional Opt ons sted Below	Cl n ca ly signi cant Not cl n ca ly signi cant	Not e a ed Related		INC - Dose inc eased NC - Dose not changed RED - Dose educed IN - D ug inte up ed WD - D ug wi hd awn *Addit onal Opt ons sted Below	No es
WBC	xx xx)	g d mg d 0^3 u IU m m n 73m2 *Add tional Opt ons sted Below	Cl n ca ly signi cant Not cl n ca ly signi cant	Not e a ed Related		INC - Dose inc eased NC - Dose not changed RED - Dose educed IN - D ug inte up ed WD - D ug wi hd awn *Addit onal Opt ons sted Below	No es
	xx xx)	g d mg d 0^3 u IU m m n 73m2 *Add tional Opt ons sted Below	Cl n ca ly signi cant Not cl n ca ly signi cant				
	xx xx)	g d mg d 0^3 u IU m m n 73m2 *Add tional Opt ons sted Below	Cl n ca ly signi cant Not cl n ca ly signi cant				

Chemistry

We e chemist y tes s pe o med?
I No eason not done

No es N A
Subject unable o comply
Subject e usual
Cl n c e o
nvestigato decis on
COVID- 9 pandem c
*Add tional Options sted Be ow

I O he speci y

Blood col ect on da e o chem st y

ddMMMyyyy

		es	s	a a e	A ma ea s	e a e e A e ae	W a A as Take T ea me ?	e es a se e e e s e m e ?
C ea inine	< >	x xx)	g d mg d 0^3 u IU m min 73m2 *Add t onal Opt ons sted Below	C n ca ly s gni cant Not c n ca ly s gni cant	Not e ated Re ated		INC - Dose nc eased NC - Dose not changed RED - Dose educed IN - D ug inte upted WD - D ug wi hd awn *Addi ional Op ions s ed Be ow	No es
A anine Am not ans e ase (A)	< >	xxxx)	g d mg d 0^3 u IU m min 73m2 *Add t onal Opt ons sted Below	C n ca ly s gni cant Not c n ca ly s gni cant	Not e ated Re ated		INC - Dose nc eased NC - Dose not changed RED - Dose educed IN - D ug inte upted WD - D ug wi hd awn *Addi ional Op ions s ed Be ow	No es
Aspa a e Aminot ans e ase AS)	< >	xxxx)	g d mg d 0^3 u IU m min 73m2 *Add t onal Opt ons sted Below	C n ca ly s gni cant Not c n ca ly s gni cant	Not e ated Re ated		INC - Dose nc eased NC - Dose not changed RED - Dose educed IN - D ug inte upted WD - D ug wi hd awn *Addi ional Op ions s ed Be ow	No es
A	< >	xxxx)	g d mg d 0^3 u IU m min 73m2 *Add t onal Opt ons sted Below	C n ca ly s gni cant Not c n ca ly s gni cant	Not e ated Re ated		INC - Dose nc eased NC - Dose not changed RED - Dose educed IN - D ug inte upted WD - D ug wi hd awn *Addi ional Op ions s ed Be ow	No es
otal b li ub n	< >	xx x)	g d mg d 0^3 u IU m min 73m2 *Add t onal Opt ons sted Below	C n ca ly s gni cant Not c n ca ly s gni cant	Not e ated Re ated		INC - Dose nc eased NC - Dose not changed RED - Dose educed IN - D ug inte upted WD - D ug wi hd awn *Addi ional Op ions s ed Be ow	No es
pase	< >	xxx x)	g d mg d 0^3 u IU m min 73m2 *Add t onal Opt ons sted Below	C n ca ly s gni cant Not c n ca ly s gni cant	Not e ated Re ated		INC - Dose nc eased NC - Dose not changed RED - Dose educed IN - D ug inte upted WD - D ug wi hd awn *Addi ional Op ions s ed Be ow	No es

Female Subjects Only: Pregnancy Test

Was a p egnancy test pe o med?
I No eason not done

No es N A
Subject unable o comply
Subject e usual
Cl n c e o
nvestigato decis on
COVID- 9 pandem c
*Add tional Options sted Be ow

I O he speci y
I es specimen ype
Specimen col ec ion date
Resu t

U ne Se um
ddMMMyyyy
Negat ve osit ve

Serology

We e se o ogy tests pe o med?
I No eason not done

No es N A
Subject unable o comply
Subject e usual
Cl n c e o
nvestigato decis on
COVID- 9 pandem c
*Add tional Options sted Be ow

I O he speci y
Blood col ect on da e o se o ogy

ddMMMyyyy

H V antibody
HCV antibody
HBV su ace ant gen

Non-Reactive Reac t ve
Negat ve osit ve
Negat ve osit ve

Urine Drug Screen

Was u ine co lec ed o d ug sc eening?
I No eason not done

No es N A
Subject unable o comply
Subject e usual
Cl n c e o
nvestigato decis on
COVID- 9 pandem c
*Add tional Options sted Be ow

I O he speci y
Specimen col ec ion date

ddMMMyyyy

Did the subject est posi ive o amphetam nes ba bitu ates benzodiazep nes cocaine methadone me haqualone opiates phencyc idine and o p opoxyphene?

No es

Additional Selection Options 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

Any medical histo y?

No es

M m e	Me a s To m	a ae	a ae e a	a e	a e e a	
			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
2			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
3			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
4			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
5			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
6			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
7			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
8			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
9			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
0			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
2			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
3			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
4			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
5			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
6			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
7			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
8			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
9			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
20			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
2			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
22			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
23			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
24			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
25			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
26			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
27			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
28			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
29			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	
30			Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day on y unknown Day and month unknown Day month and yea unknown	

Additional Selection Options for MHD

Form number (key fie d)
1
2
3
5
6
7
8
9
10
11
12
13
1
15

Physical Exam (PE1)

e me A
V s m e

We Ve s 2 0 0 May20

Was the physical exam pe o med includ ng assessment o any signs suggestive o IMMCs?
Was the physical exam pe o med includ ng an assessment o any signs sugges ive o AE S s (includ ng p otocol speci ed AESIs MAAEs NOCMCs and MMCs ?
Exam date
Exam time 24-hou c ock)
I No eason not done

No es
No es
dd/MM/yyyy)
hh mm)
Sub ect unab e to comply
Sub ect e usal
O nic e o
Invest gato dec sion
COV D- 9 pandemic
*Add t onal Opt ons isted Below

I O he speci y

Any abno mal ties upon physical exam nat on?

abno ma es a e no ed n any o he above sys ems comp e e he ab e be ow Reco d each abno ma y on a sepa a e ow and nd ca e he abb ev a on o he body sys em om above

s em	A ma s	e e as A ?	es A #	es e e A
ABD - Abdomen CRD - Ca d ovascu a hea t EX - Ext emit es GEN - Gene al appea ance HE - Hepa obi la y sp een *Addi ional Options sted Be ow		No es solic ted AE es unsol c ted AE	2 3 4 5 *Add tional Options sted Be ow	Injec ion site pain E ythema Injec ion site swel ing Indu ation Headache *Add t onal Opt ons isted Below

Additional Selection Options for PE1

If No reason not done
Other
Body system 1
HNT - HEENT
LYM - Lymph nodes
MSC - Muscu oskele al
NEC - Neck
NRL - Neurological
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 so icited AE 1
Fa igue
Mya gia
Arthralgia
Nausea
Fever
Chi ls
WBC
Hemog obin
Plate ets
ALT
AST
ALP
Bi irubin (to al)
Crea inine
PT
PTT

e me A
V s m e

Visit da e
Did the visit occu ?
Did the visit occu ?
I es speci y vis t date
V sit type
I es speci y vis t ype
Reason o supplemen al visit

I Othe speci y
I Re sc een ng jus i ica ion

I No speci y eason

I No and eason s S te decis on e o o Othe speci y

Visit Specific Information

Was a physical exam pe o med on the subject?
Was the in o med consent document s gned and dated p io o any study p ocedu es being pe o med?
Was the subject consen ed o leukaphe es is?
We e the inclus on exclus on c te ia eviewed?
We e the inclus on exclus on c te ia eviewed?
I es is the subject s ill el g b e?
No subm D scon nua on o T ea men o m
Was a physical exam pe o med on the subject?

Visit Specific Specimen Collection

Was 28 m o b ood d awn o sc een ng abs?
I No speci y eason

I Othe speci y
Was u ine co lec ed o d ug sc een?
I No speci y eason

I Othe speci y
Was 8 m b ood d awn o hematology and chemist y labs?
I blood not collected eason not done

I Othe speci y
Was 6 m blood d awn o se ological mmunogen c ty assays?

I No how much b ood was co lec ed?
I blood not collected eason not done

I Othe speci y
Was 80 m blood d awn o cel ula mmuno og cal assays (BMC ?

Was 40 m blood d awn o cel ula mmuno og cal assays (BMC ?

Was 6 m blood d awn o cel ula mmuno og cal assays (BMC ?

I No how much b ood was co lec ed?
I blood not collected eason not done

I Othe speci y
Was 6 m blood d awn o seconda y esea ch (se um)?

Was 8 m b ood d awn o seconda y esea ch (se um)?

I No how much b ood was co lec ed?
I blood not collected eason not done

I Othe speci y
Was 6 m blood d awn o p oduct assay deve opment (se um)?

Was 8 m b ood d awn o p oduct assay development (se um ?

I No how much b ood was co lec ed?
I blood not collected eason not done

I Othe speci y
Was b ood d awn at this v s t?
I es eason blood was d awn

ema e sub ec s on y
Was se um col ected o p egnancy test ng? *N A ema e o nonch dbea ng po en a)*
Was u ine o se um col ected o p egnancy test ng?
N A ema e o nonch dbea ng po en a)

No o any o he above ques ons subm a o oco Dev a on o m

Adverse Events/Medications/Protocol Deviations

Medications/Protocol Deviations

Did the subject expe ence an adve se event *a e ea men adm n s a on?*
es subm an Adve se Even o m
Have the e been any changes in hea th sta us s nce the last v s t?
es answe each o he o ow ng ques ons
New adve se event?
nc udes AEs SAEs MAAEs and NOCMCs es subm an Adve se Even o m
Has the e been a new SAE MAAE o NOCMC s nce he ast v sit?
s the subject cu ent y taking any med cat ons?
es subm a Concom an Med ca on o m
s the subject cu ent y taking any new med cat ons since sc een ng?
es subm a Concom an Med ca on o m
Change in heal h h sto y not o he w se epo ted as an adve se event (e g he eso u ion o a p oblem noted at base ine)?
es upda e Med ca H s o y o m
New medica ion?
es subm Concom an Med ca on o m
Has he e been a p o ocol dev a ion?
es subm a o oco Dev a on o m
Has he e been a p o ocol dev a ion since he ast v sit?
es subm a o oco Dev a on o m

Hematology

We e sc een ng abs d awn speci ca ly o dete mine e igib li y o he eukaphe esis study?
I No eason not done

I Othe speci y
B ood co lec on da e o hematology
B ood co lec on t me o hematology
Hemog obin

Hema oc t

Pregnancy Test

Was a se um o u ne p egnancy test pe o med?
I No eason not done

Sub ect unab e to comply
Sub ect e usal
Cl nic e o
Invest gato dec sion
COV D- 9 pandemic
*Add t onal Opt ons isted Below

I Othe speci y

Se um o u ine co lection da e — ddMMMyyyy)

Se um o u ine co lection t me — hh mm)

Vitals

Was weight assessed at h s v sit? — No / es

I No eason not done

Sub ect unab e to comply
Sub ect e usal
Cl nic e o
Invest gato dec sion
COV D- 9 pandemic
*Add t onal Opt ons isted Below

I Othe speci y

Assessment date — ddMMMyyyy)

We ght — xxx xx) / ounds / Ki og ams

Eligibility

Did the pa icipant meet a l e igibi ity c te ia o the leukaphe es s p ocedu e? — No / es

C te ion not met

ovides w i ten in o med consent o eukaphe esis p ocedu e
We ght >= 0 pounds
Sc eening labo ato y eva uat ons a e w th n accep able anges at he si e
Negat ve u ne o se um p egnancy test w th n w th n 48 hou s o the leukaphe es s p ocedu e
Adequa e b late al an ecub tal venous access
*Add t onal Opt ons isted Below

C te ion not met 2

ovides w i ten in o med consent o eukaphe esis p ocedu e
We ght >= 0 pounds
Sc eening labo ato y eva uat ons a e w th n accep able anges at he si e
Negat ve u ne o se um p egnancy test w th n w th n 48 hou s o the leukaphe es s p ocedu e
Adequa e b late al an ecub tal venous access
*Add t onal Opt ons isted Below

C te ion not met 3

ovides w i ten in o med consent o eukaphe esis p ocedu e
We ght >= 0 pounds
Sc eening labo ato y eva uat ons a e w th n accep able anges at he si e
Negat ve u ne o se um p egnancy test w th n w th n 48 hou s o the leukaphe es s p ocedu e
Adequa e b late al an ecub tal venous access
*Add t onal Opt ons isted Below

C te ion not met 4

ovides w i ten in o med consent o eukaphe esis p ocedu e
We ght >= 0 pounds
Sc eening labo ato y eva uat ons a e w th n accep able anges at he si e
Negat ve u ne o se um p egnancy test w th n w th n 48 hou s o the leukaphe es s p ocedu e
Adequa e b late al an ecub tal venous access
*Add t onal Opt ons isted Below

a c e a we e me bu he p ocedu e was no pe o med nd ca e he eason s) he p ocedu e was no pe o med

ime comm tment — No / es

Conce n o potent al sks — No / es

Unab e to contact sub ect — No / es

Othe — No / es

I Othe speci y

Leukapheresis Procedure

Was leukaphe es s pe o med? — No / es

S a t t me — hh mm)

S op ime — hh mm)

Vo ume collected — xxx) m

We e the e any comp icat ons du ng col ect on? — No / es

Additional Selection Options for VD1

If No specify reason
Temporarily out of area
Subject orgot
Site dec s on error
COV D-19 pandem c
Other

If No specify reason
Investigator dec s on
Other

If No reason not done
Other

Criterion not met 1
No use of blood thinners, aspirin, NSAIDs, at least 5 days be ore the leukaphereris procedure
Enrollment in cohorts 2, 3, 5 or 6 and compla ed the 2-dose vaccina ion series

Vital Signs (VS1)

We Ve s 02 27Ap 2

e me A
V s m e

Da e *ddMMMyyyy)*

We e vital signs assessed at h s visi ?

No es

I No eason not done

Sub ect unab e to comply
Sub ect e usal
Cl n c e o
Investigato dec s on
COV D- 9 pandemic
*Add tional Opt ons sted Below

I O he spec y

Sub ec s mus no ea o d nk any h ng ho o co d o smoke w h n 10 m nu es p o o ak ng o e empe a u e

Assessme T me 24-hou c ock)	Tem e a e s	Tem e a e)	Tem e a e)	se bea s m nute)	s sss e mmHg)	as sss e mmHg)
hh mm)	ah enheit Ce s us	xxx x)	xx x)	xxx)	xxx)	xxx)

We e he ght and we ght assessed at this v s t?

No es

I No eason not done

Sub ect unab e to comply
Sub ect e usal
Cl n c e o
Investigato dec s on
COV D- 9 pandemic
*Add tional Opt ons sted Below

I O he spec y

Assessme T me 24 h c ock)	We s	We s)	We k ams)	e s	e es)	e e me e s)
hh mm)	ounds Kilog ams	xxx x) lb	xxx x) kg	Inches Cent mete s	xx x) n	xxx x) cm

BMI xx x) kg m²

Additional Selection Options for VS1

If No reason not done

Other

e me A
a e a e

Bi h o de numbe

egnancy outcome (o h s etus)
spon aneous abo on m sca age s b h o he apeu c abo on comp e e an AE SAE o m

nd ca e he sou ce o n o ma on may check es o mo e han one)
Mothe
am ly membe
hysic an med cal cha t
O he
I es speci y

Maternal Outcome

End o p egnancy weight	Date o end o p egnancy we ght *ddMMMyyyy)*	Da e ce a n y Exact date Day only unknown Day and month unknown Day month and yea unknown	Weight un ts ounds K log ams	Weight (b) *xxx x)* lb	We ght (kg) *xxx x)* kg

Labor, Delivery, and Post Partum Information

Did the subject expe ence any o he mate nal compl cat ons isted du ng abo del ve y o post-pa tum?
es comp e e an Adve se Even Se ous Adve se Even o m as app op a e

Ab uptio placentae	Ec ampsia	GBS-posi ive
Abno mal bleeding hemo hage	Eme gency Cesa ean sect on due o etal dist ess	Gl gohyd amn os
Anaphylaxis	Endomet it s	acen a p evia
Bacte emia	e al dist ess	olyhyd amn os
Cho ioamn oni is	eve > 00 4 o 38 0 C	e-ec ampsia
Coagulat on diso de s	Gestational diabetes	egnancy nduced hype tens on
Co d p olapse		ete m abo

Did the subject expe ence any othe ma e nal comp ications du ng th s p egnancy?
es comp e e an Adve se Even Se ous Adve se Even o m as app op a e
Was the e any etal d st ess du ing labo and de ive y?
es comp e e an Adve se Even o m

Neonatal Outcome Live Birth and Still Birth Only

Da e o l ve bi th o st ll bi th
De ive y
Sex
n ant e al ges at onal age at l ve bi th o st ll bi h
Size o ges a lonal age

a Meas ems s

Bi th weight	ounds Ki og ams	*xx x)* b	*xx x)* kg
eng h	Inches Cent me e s	*xx x)* n	*xx x)* cm
ontal occipi al ci cum e ence (OC)	Inches Cent me e s	*xx x)* n	*xx x)* cm

Apga sco e minu e (leave blank o S i l Bi h)
Apga sco e 5 minu es leave blank o St ll Bi th)
Co d pH
Congeni al anoma ies
es comp e e an SAE o m)

One Month Follow Up Live Birth Only

Has he n ant been diagnosed w th any congen tal anomal es s nce bi h? *No p ev ous y epo ed above)*
es comp e e a Se ous Adve se Even o m
Has he n ant been ll o hospi a ized? *Does no nc ude we -ch d v s s)*
I es speci y

One or Two Month Follow Up Still Birth Only

Was the e an au opsy?
I es was an etio ogy o he st ll bi h dentified?
I es speci y

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Da e o te mination
etal ges at onal age at te m nat on
Any abno mal ty in p oduct o concept on?
I es speci y
Reason o the apeut c abo t on
Commen s

2
3
4

ve bi th
Spontaneous abo tion misca iage <20 wks)
Still bi h (>= 20 weeks)
E ect ve abo tion
he apeu ic abo t on

No es
No es
No es
No es

No es Unknown N A

No es Unknown
No es Unknown N A

ddMMMyyyy)
Vaginal Cesa ean section
Male ema e
xx) weeks and *x)* days
SGA AGA GA

xx)
xx)
x x)
No es

No es Unknown
No es Unknown

No es Unknown
No es Unknown

ddMMMyyyy)
xx) weeks and *x)* days
No es Unknown N A

Mate nal cond t on disease etal condi ion d sease

Pregnancy Outcome 2 (X2D)

We We s 0 2 eb2(

e me A
a e a e

Bi h o de numbe

egnancy outcome (o h s etus)

spon aneous abo on m sca age s b h o he apeu c abo on compe e an AE SAE o m
nd ca e he sou ce o n o ma on may check es o mo e han one)
Mothe
am ly membe
hysic an med cal cha t
O he
I es speci y

2
3
4

ve bi th
Spontaneous abo tion misca iage <20 wks)
Still bi h (>= 20 weeks)
E ect ve abo tion
he apeu ic abo t on

No es
No es
No es
No es

Labor, Delivery, and Post Partum Information

Was the e any etal d st ess du ing labo and de ive y?
es compe e an Adve se Even o m

No es Unknown N A

Neonatal Outcome Live Birth and Still Birth Only

Da e o I ve bi th o st ll bi th
De ive y
Sex
n ant e al ges at onal age at l ve bi th o st ll bi h
Size o ges a ional age

a Meas eme s

Bi th weight	ounds Klog ams	xx x) lb	xx x) kg
engh	Inches Cent mete s	xx x) in	xx x) cm
ental occ p tal ci cum e ence (OC)	Inches Cent mete s	xx x) in	xx x) cm

ddMMMyyyy)
Vaginal Cesa ean section
Male ema e
xx) weeks and xx) days
SGA AGA GA

Apga sco e minu e (leave blank o S I l Bi h)
Apga sco e 5 minu es leave blank o St ll Bi th)
Co d pH
Congeni al anoma ies

xx)
xx)
x x)
No es es compe e an SAE o m)

One Month Follow Up Live Birth Only

Has he n ant been diagnosed w th any congen tal anomal es s nce bi h? No p ev ous y epo ed above)
es compe e a Se ous Adve se Even o m
Has he n ant been ll o hospi a ized? Does no nc ude we -ch d v s s)
I es spec y

No es Unknown

No es Unknown

One or Two Month Follow Up Still Birth Only

Was the e an au opsy?
I es was an etio ogy o he st ll bi h dent ied?
I es speci y

No es Unknown
No es Unknown

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Da e o te mination
etal ges at onal age at te m nat on
Any abno mal ty in p oduct o concept on?
I es speci y
Reason o the apeut c abo t on
Commen s

ddMMMyyyy)
xx) weeks and x) days
No es Unknown N A

Mate nal cond t on disease etal condi ion d sease

Pregnancy Outcome 3 (X3D)

We Ve s 0 2 eb20

e me A
a e a e

Bi h o de numbe

egnancy outcome (o h s etus)

spon aneous abo on m sca age s b h o he apeu c abo on compe e an AE SAE o m
nd ca e he sou ce o n o ma on may check es o mo e han one)
Mothe
am ly membe
hysic an med cal cha t
O he
I es speci y

Labor, Delivery, and Post Partum Information

Was the e any etal d st ess du ing labo and de ive y?
es compe e an Adve se Even Se ous Adve se Even o m as app op a e

Neonatal Outcome Live Birth and Still Birth Only

Da e o I ve bi th o st ll bi th
De ive y
Sex
n ant e al ges at onal age at l ve bi th o st ll bi h
Size o ges a ional age

a Meas eme s

Bi th weight	ounds Kilog ams	xx x) lb	xx x) kg
ength	Inches Cent mete s	xx x) in	xx x) cm
ontal occ p tal ci cum e ence (OC)	Inches Cent mete s	xx x) in	xx x) cm

Apga sco e minu e
Apga sco e 5 minu es
Co d pH
Congeni al anoma ies

One Month Follow Up Live Birth Only

Has he n ant been diagnosed w th any congen tal anomal es s nce bi h? *No p ev ous y epo ed above)*
es compe e a Se ous Adve se Even o m
Has he n ant been ll o hospi a ized? *Does no nc ude we -ch d v s s)*
I es spec y

One or Two Month Follow Up Still Birth Only

Was the e an au opsy?
I es was an etio ogy o he st ll bi h dent ied?
I es speci y

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Da e o te mination
etal ges at onal age at te m nat on
Any abno mal ty in p oduct o concept on?
I es speci y
Reason o the apeut c abo t on
Commen s

2
3
4

ve bi th
Spontaneous abo tion misca iage <20 wks)
Still bi h (>= 20 weeks)
E ect ve abo tion
he apeu ic abo t on

No es
No es
No es
No es

No es Unknown N A

ddMMMyyyy)
Vaginal Cesa ean section
Male ema e
xx) weeks and xx) days
SGA AGA GA

xx)
xx)
x x)
No es

No es Unknown

No es Unknown

No es Unknown
No es Unknown

ddMMMyyyy)
xx) weeks and xx) days
No es Unknown N A

Mate nal cond t on disease etal condi ion d sease

e me A
a e a e

Bi h o de numbe

egnancy outcome (o h s etus)

spon aneous abo on m sca age s b h o he apeu c abo on comp e e an AE SAE o m
nd ca e he sou ce o n o ma on may check es o mo e han one)
Mothe
am ly membe
hysic an med cal cha t
O he
I es speci y

Labor, Delivery, and Post Partum Information

Was the e any etal d st ess du ing labo and de ive y?
es comp e e an Adve se even o m

Neonatal Outcome Live Birth and Still Birth Only

Da e o I ve bi th o st ll bi th
De ive y
Sex
n ant e al ges at onal age at I ve bi th o st ll bi h
Size o ges a ional age

a Meas eme s

Bi th weight	ounds Kilog ams	xx x) lb	xx x) kg
ength	Inches Cent mete s	xx x) in	xx x) cm
ontal occ p tal ci cum e ence (OC)	Inches Cent mete s	xx x) in	xx x) cm

Apga sco e minu e
Apga sco e 5 minu es
Co d pH
Congeni al anoma ies

One Month Follow Up Live Birth Only

Has he n ant been diagnosed w th any congen tal anomal es s nce bi h? No p ev ous y epo ed above)
es comp e e a Se ous Adve se Even o m
Has he n ant been ll o hospi a ized? Does no nc ude we -ch d v s s)
I es spec y

One or Two Month Follow Up Still Birth Only

Was the e an au opsy?
I es was an etio ogy o he st ll bi h dent ied?
I es speci y

Pregnancy Outcome Spontaneous, Elective or Therapeutic Abortion Only

Da e o te mination
etal ges at onal age at te m nat on
Any abno mal ty in p oduct o concept on?
I es speci y
Reason o the apeut c abo t on
Commen s

Pregnancy Outcome 4 (X4D)

We Ve s 0 2 eb2(

2
3
4

ve bi th
Spontaneous abo tion misca iage <20 wks)
Still bi h (>= 20 weeks)
E ect ve abo tion
he apeu ic abo t on

No es
No es
No es
No es

No es Unknown N A

ddMMMyyyy)
Vaginal Cesa ean section
Male ema e
xx) weeks and xx) days
SGA AGA GA

xx)
xx)
x x)
No es es comp e e an SAE o m)

No es Unknown

No es Unknown

No es Unknown
No es Unknown

ddMMMyyyy)
xx) weeks and xx) days
No es Unknown N A

Mate nal cond t on disease etal condi ion d sease

Advantage eClinical — Advantage eClinical — - ($sitecode)

Pregnancy Report and Follow Up (XPD)

e me A
a e a e

We Ve s 2 0 2 eb20

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

Was ol ow-up con act made wi h the subject du ing the p egnancy? — No / es

es s da es ha con ac was made and upda e he o he sec ons o h s o m as necessa y

#	Date dd MMM yyyy)	#	Da e (dd MMM yyyy)
		5	
2		6	
3		7	
4		8	

Maternal Information *Complete at Time of Initial Report*

nd ca e he sou ce o n o ma on may check es o mo e han one)

Mothe — No / es

am ly membe — No / es

hysic an med cal cha t — No / es

O he — No / es

I es speci y

Pregnancy Status *Update as Applicable During Follow-Up*

egnancy status — egnancy ongo ng / Ou come known / Ou come unknown

o known p egnancy ou comes eco d p egnancy ou come da a o each e us

Current Pregnancy Information *Complete at Time of Initial Report*

Numbe o etuses — 2 / 3 / 4

Da e o last menst ual pe od — ddMMMyyyy)

Estimated del ve y date — ddMMMyyyy)

How was est ma ed delive y da e dete mined? — ast menst ual pe iod / U t asound

I U t asound est ma ed date o exam — ddMMMyyyy)

e-p egnancy weight	Date o p e-p egnancy we ght	Date ce tainty	Weight un ts	We ght (lb)	Weight (kg)
	ddMMMyyyy)	Exact date Day only unknown Day and month unknown Day mon h and yea unknown	ounds / K log ams	xxx x) b	xxx x) kg

Previous Pregnancy Information *Complete at Time of Initial Report*

G avida (o al numbe o p egnancies including the cu ent p egnancy) — xx) Unknown

he cu en p egnancy p ov de numbe s o he o ow ng eco d 0 none)

ive bi hs — xx) Unknown

Ext emely p ete m (E) bi hs < 25 weeks) — xx) Unknown

Ve y p ete m (V) bi hs 25 0 7 - 3 6 7 weeks) — xx) Unknown

Ea y p ete m bi ths (32 0 7 - 33 6 7 weeks) — xx) Unknown

a e p ete m bi ths (34 0 7 - 36 6 7 weeks) — xx) Unknown

Ea y te m bi hs 37 0 7 - 38 6 7 weeks) — xx) Unknown

u l e m bi ths (39 0 7 - 40 6 7 weeks) — xx) Unknown

a e te m bi hs (4 0 7 - 4 6 7 weeks) — xx) Unknown

ost e m bi ths – 42 0 7 weeks) — xx) Unknown

St llbi ths (–20 weeks) — xx) Unknown

Spontaneous abo ion misca age (<20 weeks) — xx) Unknown

Elective abo t ons — xx) Unknown

he apeut c abo t ons — xx) Unknown

The apeu c abo ons a e de ned as abo ons due o med ca easons o he mo he o e us

Any majo congenital anoma ies wi h a p evious p egnancy? — No / es / Unknown

I es speci y

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

Did the subject expe ence any o he mate nal compl cat ons isted du ng th s p egnancy? — No / es / Unknown

es comp e e an Adve se Even Se ous Adve se Even o m as app op a e

Ab uptio placentae	Ec ampsia	O igohyd amnios
Abno mal bleeding hemo hage	Endomet it s	lacenta p ev a
Anaphylaxis	e al dist ess	o yhyd amnios
Bacte emia	eve > 00 4 o 38 0 C	e eclamps a
Cho ioamn oni is	Gestational diabetes	egnancy induced hype ension
Coagulat on diso de s	GBS-pos t ve	e e m labo

Did the subject expe ence any othe ma e nal comp ications du ng th s p egnancy? — No / es / Unknown

es comp e e an Adve se Even Se ous Adve se Even o m as app op a e

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

Did the subject use tobacco p oducts d nk a cohol o use o he l icit d ugs du ing this p egnancy? — No / es / Unknown

e a sa e se

T e sa e	e	Am xxx x)		e e	a a e MMM)	a a e e a	a e MMM)	a e e a	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	
Alcohol Amphe am ne Anabol c ste oids Ba bi u ates Bath sal s (synthetic cathinones) *Addi ional Op ions s ed Be ow	nt amuscula nt avenous Nasal O al Smoking *Addi ional Op ions s ed Be ow		Bag Ciga Ciga e te eCiga et e u d ounce (US) *Add t onal Opt ons isted Below	Once Once pe day Once pe month wice pe day wice pe month *Add t onal Opt ons isted Below		Exact date Day only unknown Day and month unknown Day mon h and yea unknown		Exact date Day only unknown Day and month unknown Day month and yea unknown	

A s anda d d nk s de ned as 1 12oz bo e o bee 1 g ass 4oz non- o ed w ne o 1 m xed d nk w h 1oz quo

Has he sub ect taken any medica ions du ing the p egnancy (ove -the-counte and p esc p ion ? — No / es / Unknown

es comp e e he Concom an Med ca ons o m

Commen s

Additional Selection Options for XPD

ype of substance 1
Benzodiazepines
Cocaine
Codeine
Dextromethorphan (DXM)
Fentanyl and ana ogs
Flunitrazepam
GHB
Hashish
Heroin
Hydrocodone Bitartrate Hydromorphone
Inhalants
K2/Spice (synthet c mar juana)
Ketamine
LSD
Marijuana
MDMA
Meperidine
Mesca ine
Methadone
Methamphetamine
Methylphenidate
Morphine
Opium
Oxycodone HCL
Oxymorphone
PCP and analogs
Propoxyphene
Ps locybin
Salvia divinorum
Sleep medicat ons
Tobacco

Substance route 1
Subcutaneous

Substance unit 1
G am
Joint
Li er
M li gram
Ounce
Pack
Standard drink

Substance frequency 1
Every 2 months
1 ime per week
2 imes per week
3 imes per week
imes per week
5 imes per week
6 imes per week

Adverse Event (ZAE)

We Ve s 2 00 27Ap 20

e me A
A m e

Adve se event

Sta t date — ddMMMyyyy)

End date — ddMMMyyyy) Ongo ng

Associated wi h dose numbe — 2

Seve i y — Mi d Mode ate Seve e

I Seve e Du at on — < 48 hou s ≥ 48 hou s

Re a ionship to study t eatment — Not e a ed Related

I Not Re a ed the event is e ated to — - Study p ocedu e / 2 - O he medical condi ion o i lness / 3 - O he d ug / 4 - O he

I Not Re a ed speci y al e native et o ogy

What ac ion was taken w th the s udy t eatmen ? — INC - Dose inc eased / NC - Dose not changed / RED - Dose educed / IN - D ug inte up ed / WD - D ug withd awn / *Add t onal Opt ons isted Below

Did the adve se event cause he sub ect to be d scon nued om he study? — No es

Outcome — R - Recove ed eso ved / RS - Recove ed esolved with sequelae / O - Recove ng esolving / NR - Not ecove ed Not eso ved / - ata

s the event an Adve se Event o Spec al n e est AESI)?
es nd ca e ca ego y o AES be ow — No es

Is he event a Medically At ended Adve se Event (MAAE ? — No es

Is he event a New Onset Ch onic Medical Cond t on (NOCMC)? — No es

s this event an "Unan icipated ob em"? — No es

Serious Adverse Events

s the adve se event se ous? — No es

I es date event became an SAE — ddMMMyyyy)

Is he adve se event associated wi h a congen tal anomaly o bi th de ect? — No es

D d the adve se event esult in pe s s ent o signi icant disab l ty o ncapacity? — No es

D d the adve se event esult in death? — No es

D d the adve se event esult in in tial o p o onged hospi a ization o he sub ect? — No es

Is he adve se event i e h eaten ng? — No es

Is he adve se event a med ca ly mpo tant event not cove ed by othe "se ious" c i e a? — No es Speci y

Halting Criteria

Check h s box i in the op n on o he s te invest gato this event shou d be eva uated o poss b e cont but on towa d the ha ting c i e ia o he g oup coho t o s udy

Commen s

Additional Selection Options for ZAE

AE Number (key fie d)

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 he study treatment?

NA - Not appl cab e

e ve a e	ex	s	e e e e a e e m	e m	e e e e a e e m	e m	M A e s ve ea s)	Max A e s ve ea s)
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						
	Ma e emale Both	g d mg d 0^3 u U m mn 73m2 *Addi ional Options s ed Be ow						

Additional Selection Options for ZLR

Parameter (key f eld)	Units 01
Hemog obin	
Alanine Aminotransferase	
Aspartate Aminotransferase	
Crea inine	
eGFR	
Blood U ea N trogen	
Potassium	
Magnesium	
Total Bi irubin	
Wh te Blood Cells	
Plate ets	
Alkaline Phospha ase	
Lipase	
Prothrombin Time	
Part al Thromboplastin Time	
Hematocr t	
	mmol/L
	10^9/L
	U/L
	seconds
	%

Solicited Local Events (ZRL)

We Ve s 0 27Ap 20

e me A
se m e
e m e

m m T e	a	a 2	a	a 4	a	a	a 7	a	a e a ?	Max m m eve Meas eme a e a	a e
Da e	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy			
Cl ck this bu ton only i he sub ect had s m ms	m ms	m ms	m ms	m ms	m ms	m ms	m ms	m ms			
What side was assessed?	e t R ght										
ain	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	No es	-Mi ld 2-Mode ate 3-Seve e	ddMMMyyyy
E ythema Redness)	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	No es	-Mi ld 2-Mode ate 3-Seve e	ddMMMyyyy
Indu ation (Ha dness) Edema (Swell ng)	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	None Mi d Mode ate Seve e Not Done	No es	-Mi ld 2-Mode ate 3-Seve e	ddMMMyyyy
E ythema Redness measu ement - Size *mm)*	xxx)	xxx)	xxx)	xxx)	xxx)	xxx)	xxx)	xxx)	No es	xxx)	ddMMMyyyy
Indu ation (Ha dness) Edema (Swell ng) measu ement - Size *mm)*	xxx)	xxx)	xxx)	xxx)	xxx)	xxx)	xxx)	xxx)	No es	xxx)	ddMMMyyyy

Comments

Additional Selection Options for ZRL

Dose Number (key field)

1
2
3

5
6
7
8
9
10

Period Number (key fie d)

1
2
3

5
6
7
8
9
10

Solicited Systemic Events (ZRS)

e me A
so m e
e m e

	a	a 2	a	a 4	a	a	a 7	a	a e a ? Max m m eve a e a	Meas eme a e
Date	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy		
Unit	ah enheit / Ce sius									
empe atu e	xxx x)	xxx x)	xxx x)	xxx x)	xxx x)	xxx x)	xxx x)	xxx x)	No es	xxx x) 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 es	xx x) C ddMMMyyyy)
Cl ck this bu ton i the subject had s m ms										
Chil s	None / Mild / Mode a e / Seve e / Not Done								No es	-M ld / 2-Mode ate / 3-Seve e ddMMMyyyy)
at gue	None / Mild / Mode a e / Seve e / Not Done								No es	-M ld / 2-Mode ate / 3-Seve e ddMMMyyyy)
Myal g a	None / Mild / Mode a e / Seve e / Not Done								No es	-M ld / 2-Mode ate / 3-Seve e ddMMMyyyy)
A h alg a	None / Mild / Mode a e / Seve e / Not Done								No es	-M ld / 2-Mode ate / 3-Seve e ddMMMyyyy)
Headache	None / Mild / Mode a e / Seve e / Not Done								No es	-M ld / 2-Mode ate / 3-Seve e ddMMMyyyy)
Nausea	None / Mild / Mode a e / Seve e / Not Done								No es	-M ld / 2-Mode ate / 3-Seve e ddMMMyyyy)
Commen s										

Additional Selection Options for ZRS

Dose Number (key field)

1
2
3

5
6
7
8
9
10

Period Number (key fie d)

1
2
3

5
6
7
8
9
10

Grade 3 Systemic Reactions Within 7 Days After Administration

s em ea ea a e s-A m s a a eve A e A e a e es e A e a e Me a s e

No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below
No es		2 3 4 5 *Add t onal Opt ons ist ed Below

Commen s

Additional Selection Options for ZSA

Dose Number (key field)
1
2
3

5
6
7
8
9
10

Period Number (key fie d)
1
2
3

5
6
7
8
9
10

AE or med cal 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

e me A
V s m e

Visit da e *dd/MM/yyyy)*

Baseline Assessment (prior to treatment administration)

Assessment o System c Symptoms

A th a g a joint pain: None / M ld / Mode ate / Seve e / Not Done

Chi ls: None / M ld / Mode ate / Seve e / Not Done

a igue: None / M ld / Mode ate / Seve e / Not Done

Headache: None / M ld / Mode ate / Seve e / Not Done

Mya gia: None / M ld / Mode ate / Seve e / Not Done

Nausea: None / M ld / Mode ate / Seve e / Not Done

Treatment Administration Information

Reco d he ea men numbe as eco ded on he s udy p oduc Do no eco d om he En o men Con ma on page

ea ment administ a ion s te e t a m Right a m
ime administe ed (24-hou c ock) *hh mm)*
n t a s o individual who admin s e ed the t eatment

Post Administration Assessment

ime o assessment (24-hou clock) *hh mm)*

Assessmen o ake p ace no soone han 60 m nu es a e adm n s a on

Assessment o System c React ons

s em ea	eve A e A e a e	e A e a e	Me a s e
A th a g a joint pain	None / Mi d / Mode a e / Seve e / Not Done — No es	2 / 3 / 4 / 5 / *Add t onal Opt ons isted Below	
Chi ls	None / Mi d / Mode a e / Seve e / Not Done — No es	2 / 3 / 4 / 5 / *Add t onal Opt ons isted Below	
a igue (i edness)	None / Mi d / Mode a e / Seve e / Not Done — No es	2 / 3 / 4 / 5 / *Add t onal Opt ons isted Below	
Headache	None / Mi d / Mode a e / Seve e / Not Done — No es	2 / 3 / 4 / 5 / *Add t onal Opt ons isted Below	
Mya gia (Body aches Muscula pa n)	None / Mi d / Mode a e / Seve e / Not Done — No es	2 / 3 / 4 / 5 / *Add t onal Opt ons isted Below	
Nausea	None / Mi d / Mode a e / Seve e / Not Done — No es	2 / 3 / 4 / 5 / *Add t onal Opt ons isted Below	

Assessment o Loca React ons

a n: None / Mi d / Mode ate / Seve e / Not Done

Indu at on Ha dness) Edema Swel ing): None / Mi d / Mode ate / Seve e / Not Done

E y hema (Redness): None / Mi d / Mode ate / Seve e / Not Done

Indu at on at injection site measu ement *mm)* *xxx) mm*
Not Done

E y hema at n ect on s te measu ement *mm)* *xxx) mm*
Not Done

Additional Selection Options for ZVR

Arthralgia AE or MH

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