Subject: _____
Data event: _____
Form: Pregnancy Follow Up Reporting Form
Last saved on form version: _____
Current Form version: 1.0 (2022-07-07)
Study version: 5

Study: ILANA
Filled out by: _____
Filled out date: _____
Printed Time: 2023-01-16 10:20

Form: **Pregnancy Follow Up Reporting Form**

Pregnancy Follow Up Reporting Form

Once you have become aware of an SAE, please email this signed form to research.safety@qmul.ac.uk and the trial manager on Blizard-ILANA@qmul.ac.uk WITHIN 24 hours of learning of the event.

Report type

- ◯ Initial
- ◯ Follow-up

Please answer this question

Who is this form being completed?

- ◯ Participant
- ◯ Participant's partner

Please answer this question

If the project is multi-site, the section below should be completed by the main site trial coordinator prior to sending the template to the sites

Full title of trial: ILANA- Implementing Long-Acting Novel Antiretrovirals

Sponsor: QMUL

IRAS number: 313217

Chief investigator:

Name: Prof. Chloe Orkin

Email: c.m.orkin@qmul.ac.uk

Phone Number: 020 7377 7457

This section should be completed by the SITE:

Patient's age at time of event:

.....

Please answer this question

Sex

- ◯ M
- ◯ F

Please answer this question

Principal investigator:

Name:

Please answer this question

Email:

Please answer this question

Phone Number:

Please answer this question

Trial coordinator local site:

Name:

Please answer this question

Email:

Subject: _____
Data event: _____
Form: Pregnancy Follow Up Reporting Form
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Please answer this question

Phone Number:

Please answer this question

Name of reporting host institution:

Site name:

Please answer this question

Site number:

Please answer this question

Subject: _____
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Pregnancy status

While pregnancy itself is not an AE or SAE, any pregnancy complication or elective termination of a pregnancy for medical reasons will be recorded as an AE or SAE as described in the protocol. A spontaneous abortion is always considered to be an SAE and will be reported as described in the protocol. Furthermore, any SAE occurring as a result of a post-study pregnancy and considered reasonably related to the investigational product by the Investigator will be reported to GSK per the protocol. Whilst the Investigator is not obligated to actively seek this information in former study participants, he/she may learn of an SAR through spontaneous reporting.

If applicable, record the outcome:

- ○ Normal birth
- ○ Stillbirth
- ○ Foetal death
- ○ Spontaneous abortion
- ○ Elective abortion
- ○ Other
- ○ Not applicable

Please answer this question

Methods used for delivery, specify:

Please answer this question

List number:

Please answer this question

Record details of children born with defects:

Foetal/Neonatal status

- ◯ Normal
- ◯ Birth Defect (i.e., structural/chromosomal disorder)
- ◯ Other disorder (e.g., non-structural, premature birth, intrauterine death/stillbirth)

Please answer this question

If birth defect, complete Adverse Event Form

Select adverse event

Please answer this question

If birth defects are diagnosed, is the origin of the defect known?

- ◯ Yes
- ◯ No

Please answer this question

If yes, please specify

Please answer this question

Infant Information

Date of birth/miscarriage/termination

Please answer this question

Gestational weeks at birth/miscarriage/termination (Weeks)

Please answer this question

Infant's Sex

- ◯ Male
- ◯ Female
- ◯ Unknown

Please answer this question

Length (cm)

Please answer this question

Weight (kg)

Please answer this question

Initial APGAR Score (1-10)

Please answer this question

Second APGAR Score (1-10)

Please answer this question

Additional Information

Drug Exposures during Pregnancy

Please list all medications (including study medications) the subject received during the study period (e.g. prescription, OTC, vaccines, recreational, alcohol, etc.).

Select medication

Person completing the form if not the PI

Name:

Medical profession (i.e. doctor or dentist):

Email:

Phone Number:

Date:

Please answer this question

Investigator's Name

Subject: _____
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Please answer this question

Please note in cases where the PI is not readily available to sign the pregnancy form a sub investigator may sign in their absence to meet the 24hour deadline. The PI can then sign the form on their return.

On receipt the JRMO will:

- Acknowledge receipt
- Enter information in to the sponsors database
- Request clarification/additional information
- Save this document