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

Who is this form being completed?

- Participant
- Participant’s partner

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:

Sex

- M
- F

Principal investigator:

Name:
Please answer this question

Phone Number:

Name of reporting host institution:

Site name:

Site number:

Please answer this question

Please answer this question

Please answer this question

Please answer this question
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

Methods used for delivery, specify:

List number:

Record details of children born with defects:

Foetal/Neonatal status
If birth defect, complete Adverse Event Form

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

- Yes
- No

Infant Information

Date of birth/miscarriage/termination

Gestational weeks at birth/miscarriage/termination (Weeks)

Infant's Sex

- Male
- Female
- Unknown

Length (cm)
Weight (kg)

Initial APGAR Score (1-10)

Second APGAR Score (1-10)

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):
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 24 hour deadline. The PI can then sign the form on their return.

On receipt the JRMO will:

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