MEDECINS SANS FRONTIERES
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PREGNANCY REPORT FORM

Guidelines for completion

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List of abbreviations

CT	Clinical trial
INN	International Non-proprietary Name
PV	Pharmacovigilance
SAE	Serious adverse event
TB	Tuberculosis

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1. Introduction

Pregnancies occurring in clinical trials (CTs) or programs sponsored by MSF are collected and reported using a dedicated form. Unless described otherwise in the CT protocol or the program's PV guideline, pregnancies with or without serious outcomes are **reportable within 24 hours of awareness** to MSF Pharmacovigilance (PV) Unit using a Pregnancy Report Form:

Email: PVunit.GVA@geneva.msf.org

Additional information on already transmitted pregnancies, called follow-up information, should be reported similarly within 24 hours of awareness of the new information.

When applicable, Serious Adverse Event (SAE) Report Forms are additionally required to capture information on SAEs occurring in the course of the pregnancy in the mother and/or the foetus/child.

2 General instructions

The Pregnancy Report Form is designed to specifically follow mothers and foetuses/children exposed to drugs in the frame of CTs or programs. The available fields must be completed as much as possible with the relevant information available at the time of reporting.

The minimal information to be reported includes:

1. Name or any identifier of a **reporter** (e.g. a function such as 'nurse' is acceptable),
2. Any identifier of the **pregnant patient** (e.g. patient number, initials, date of birth),
3. **Exposure during/before pregnancy to at least one drug** (study drug in a CT/ delivered drug in a program).

The following general points aim at helping the completion of the Pregnancy Report Form:

- Dates should be provided in the "Day/Month/Year" format: dd/Mmm/yyyy (e.g. 06/Apr/2015). If the exact date is not known, a partial date can be provided and the full date completed later upon follow-up (e.g. UNK/Apr/2015).
- In case you need to add more information than a field allows you to enter, please reprint the page, add manually the mention 'Supplemental page', and capture the additional information.
- Upon receipt of follow-up information on a pregnancy already notified (e.g. pregnancy outcome is known), the initial information does not need to be fully repeated on the Pregnancy Report Form, only the new information with identifiers allowing to retrieve the initial information (site number, patient's identifiers, case number, etc.).
- In case corrections are needed, the correct vs. the incorrect information should be clearly identifiable and the correction should include the initials of the person who performed the modification and the date of such modification.
- All information about the patient must be anonymized in all documents before transmission to the MSF PV Unit.
- One Pregnancy Report Form should be populated for each separated pregnancy of a same patient. Multiple pregnancies should generally be captured within a same Pregnancy Report Form.

The MSF PV Unit is available for questions and further guidance on the Pregnancy Report Form completion.

3 Detailed instructions

3.1. Administrative information

		Case number:
PREGNANCY REPORT FORM		
Sponsor: Médecins Sans Frontières	**Protocol/Program n°:**	**Site n° (for studies) or country:**
Initial report: ☐	**Follow-up report:** ☐	**Date of report:** ____ / ____ / _____ (dd/Mmm/yyyy)

For CTs, protocol and site numbers should be informed. For other programs, the program number or name as well as the country of occurrence of the event should be entered.

When transmitting information on a pregnancy for the first time, the box 'initial report' should be ticked, when reporting supplementary information on a pregnancy previously transmitted, 'follow-up report' should be selected.

'Date of report' field's title is self-explanatory.

The field 'Case number' is available to capture the number of the case attributed by MSF PV unit; at time of initial reporting this field should be left blank.

3.2. Patient information (mother)

Patient information (mother)				
Patient n°: [Father ☐ Mother ☐]	**Mother initials:**	**Mother date of birth:** ___ / ___ / _____ (dd/Mmm/yyyy)	**Mother height:** ..... cm	**Mother weight:** ..... kg

In Pregnancy Report Forms, the patient is always the mother. For CTs and programs where patients are allocated an alpha-numeric identifier, the appropriate field ('Patient n°') should be populated with this information. In the cases, where the patient is the female partner of an enrolled male patient (drug exposure via father), the father's patient n° should be entered for reference. By using the tick boxes 'father' / 'mother', there is no ambiguity on who is referred to via the patient number.

All information about the parents must be anonymized. Other fields' titles are self-explanatory.

3.3. Relevant drug(s) exposure before/during pregnancy

	Relevant drug(s) exposure before/during pregnancy							
1	**Drug name (INN)**	.....	.....	.....	.....	.....	.....	.....
	Daily dose & route							
	Batch number							
	Treatment start date (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
	Treatment stop date (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
	Drug taken by	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐
2	**Action taken in response to the pregnancy**							
	Dosage maintained	☐	☐	☐	☐	☐	☐	☐
	Dose reduced	☐	☐	☐	☐	☐	☐	☐
	New daily dose							
	On (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
	Drug permanently withdrawn	☐	☐	☐	☐	☐	☐	☐
	On (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
	Drug interrupted	☐	☐	☐	☐	☐	☐	☐
	From (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
	To (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
	Not applicable	☐	☐	☐	☐	☐	☐	☐

1. Up to 7 drugs can be entered, if more drugs have to be reported, the page can be re-printed with the mention 'Supplemental page' added manually. Information on each drug including the International Non-proprietary Name (INN - preferred) (or trade name/active substance), daily

dose, route of administration, batch number and administration dates should be mentioned. Tick boxes allow identification of whether the mother or the father was taking the drug(s).

- As a convention, in a CT, all study drugs (including Standard of Care drugs) are to be considered relevant drug exposures. In the post-marketing setting, medical judgment should apply when selecting relevant drug exposure. As a general rule, in a tuberculosis (TB) program, at least all ongoing TB treatments administered at time of event should be considered relevant drug exposures. Other drugs can be recorded as relevant drug exposure as per best medical judgment (e.g. highly active antiretroviral therapy).
    - In the cases, where the patient is the female partner of an enrolled male patient (drug exposure via father), the father's relevant drugs should be entered. Any relevant pregnancy exposure to a drug taken by the mother should be additionally entered (see also section 4.2). Tick boxes allow identification of whether the mother or the father was taking the drug(s).
- In the special situation where the pregnancy itself is considered a drug adverse reaction, e.g. if one of the drug is considered to have interacted in any way with the contraception method used, this information should be specifically highlighted and all drugs including contraceptives should be listed.

2. Action taken following pregnancy knowledge should be documented for each drug using the possibilities presented in the table. Action taken is considered not applicable, if the drug was already stopped before pregnancy or taken by the father (drug exposure via father).

3.4. Pregnancy information

Pregnancy information			
Date of 1st day of last menstrual period *(dd/Mmm/yyyy)*	____ / _____ / _____	**Estimated date of delivery** *(dd/Mmm/yyyy)*	____ / _____ / _____
Pregnancy test	☐ **Positive urine test** Date: ____ / _____ / _____	☐ **Positive blood test** Date: ____ / _____ / _____	☐ **Positive ultrasound** Date: ____ / _____ / _____
Pregnancy outcome			
1. Did the patient experience any complication during pregnancy?	☐ **Yes. Specify**:		
	☐ **No**		
2. Did the patient give birth to (a) live infant(s)?	☐ **Yes. Date of delivery** *(dd/Mmm/yyyy)*: ____ / _____ / _____		
	☐ **No. Specify reason:**		
3. Was the infant normal at birth?	☐ **Yes**		
	☐ **No. Specify abnormality and reason:**		
Additional comment on pregnancy/delivery			

General information on the pregnancy should be collected including the last menstrual period date and the estimated date of delivery (for ongoing pregnancies). The positive pregnancy tests undertaken to confirm pregnancy as well as the corresponding dates should be entered.

Pregnancy outcome information should be captured as follows:

1. Pregnancy complications should be described as free text,
2. Pregnancy outcome should be detailed:
    - Live birth should be captured as well as date of delivery.
    - In case of detrimental pregnancy outcomes, details on the type of outcome (e.g. miscarriage, foetal death in utero) and underlying causes (when known) should be provided as free text. Elective abortion should also be captured in this field, highlighting the reason for such procedure (e.g. patient's choice, foetal defects).

- In case of foetal defects/congenital anomalies, the reporter is expected to create an SAE Report Form to capture detailed information on the foetal abnormality (see also section 4.1).

- For ongoing pregnancies, when last menstrual period and/or estimated delivery date is unknown, it is advised to mention the pregnancy is ongoing in the field Additional comment on the course of pregnancy.

3. Any abnormality in the infant should be briefly described; in parallel the reporter is expected to create an SAE Report Form to capture detailed information on the infant's abnormality (see also section 4.1).

Additional comments on the course of the pregnancy and/or delivery can be entered as free text.

3.5. Infant(s) information

Infant(s) information						
Infant number	Sex	Length *(cm)*	Weight *(g)*	APGAR score	Exposure during breastfeeding	Comment
1	F ☐ M ☐				Yes ☐ No ☐	
2	F ☐ M ☐				Yes ☐ No ☐	
3	F ☐ M ☐				Yes ☐ No ☐	

This section aims at capturing detailed information on the live infant(s). For multiple pregnancies, the order of the babies at birth should be followed when filling in the table. Fields' titles are self-explanatory; a free text field is available for any additional comment on the infant's health.

3.6. Relevant medical history

Relevant medical history *(with focus on relevant prior gynaecological/obstetric history)*	

Relevant medical history of the mother should be included, especially gravidity, parity and abortus, as well as relevant gynaecological diseases.

3.7. Reporter information

Reporter				
Name of reporter:	Role in trial/program:	Date of awareness: ____/_____/_____	Address: Email: Phone:	Date and signature: ____/_____/_____

Titles in this section are self-explanatory. For CTs, the Investigator or co-Investigator is responsible to approve and sign the Pregnancy Report Form. In post-marketing programs, the relevant function (physician, nurse, etc.) should sign the form as per program's PV guideline.

4 Focuses

4.1 When to create foetus/child cases?

In the situations where a female patient exposed in the frame of CT or a program is found to be pregnant, a Pregnancy Report Form should be populated and transmitted to MSF PV Unit. This is also the process for a pregnancy in the female partner of a male patient exposed in the frame of a CT/program.

In addition, any SAE occurring in the mother or the foetus/child has to be recorded and transmitted to MSF PV Unit using an SAE Report Form.

- In the event of an SAE in the mother (e.g. late miscarriage), an SAE Report Form should record the serious mother's event with the patient being the mother. In addition, the Pregnancy Report Form should capture all pregnancy information.

- In the event of an SAE in the foetus/child (e.g. spina bifida), an SAE Report Form should record the serious child's event with the patient being the child. In addition, the Pregnancy Report Form captures all pregnancy information.
- If both the mother and the foetus/child experienced SAEs (e.g. vaginal haemorrhage and foetal distress), 2 SAE Report Forms should be completed (1 for vaginal haemorrhage in the mother and 1 for foetal distress in the baby), as well as 1 Pregnancy Report Form that captures all pregnancy information.

4.2 What should be done for drug exposure via father?

In the cases, where a pregnancy occurs in the female partner of an enrolled male patient (i.e. the father is treated in the frame of the MSF-sponsored CT or MSF program and not the mother):

- All patient information (age, date of birth, height and weight) should be entered for the mother. Only the father's patient n° should be entered for reference (ticking the box "father").
    - *Example, the wife of the male patient n°002 enrolled in the TEST program is found pregnant. Her name is MM, she is born in 1976 and her height is 165 cm / weight 50 kg.*
- Relevant drugs taken by the father should be entered and identified using the tick box "father". Any relevant exposure to a drug taken by the mother should be entered and identified using the tick box "mother".
    - *Example, the male patient n°002 was treated with interferon in the frame of the TEST Program, this drug is entered as relevant pregnancy exposure. In addition, his wife (MM) was receiving efavirenz during pregnancy.*

All other fields should be completed as guided in sections 3.4 to 3.7. The mother's information must be treated in a confidential way with the same precautions as the father's information. Signature of an Informed Consent should be considered for the mother, as applicable.

						Case number:	
PREGNANCY REPORT FORM							
Sponsor: Médecins Sans Frontières			**Protocol/Program n°:** TEST program			**Site n° (for studies) or country:** Chile	
Initial report: ☒			**Follow-up report:** ☒			**Date of report:** 15 / DEC / 2015 (dd/Mmm/yyyy)	
Patient information (mother)							
Patient n°: 002 [Father ☑ Mother ☐]	**Mother initials:** MM		**Mother date of birth:** 05 / OCT / 1976 (dd/Mmm/yyyy)		**Mother height:** 165 cm	**Mother weight:** 50 kg	
Relevant drug(s) exposure before/during pregnancy							
Drug name (INN)	Interferon alpha	Efavirenz					
Daily dose & route	3miU 3 times a week SC	600 mg/day PO					
Batch number	K 002	Unknown					
Treatment start date (dd/Mmm/yyyy)	04 / JAN / 2015	___/___/2010	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
Treatment stop date (dd/Mmm/yyyy)	___/___/_____	___/APR/2015	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
Drug taken by	Father ☑ / Mother ☐	Father ☐ / Mother ☑	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐	Father ☐ / Mother ☐
Action taken in response to the pregnancy							
Dosage maintained	☐	☐	☐	☐	☐	☐	☐
Dose reduced	☐	☐	☐	☐	☐	☐	☐
New daily dose							
On (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
Drug permanently withdrawn	☐	☐	☐	☐	☐	☐	☐
On (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
Drug interrupted	☐	☑	☐	☐	☐	☐	☐
From (dd/Mmm/yyyy)	___/___/_____	___/APR/2015	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
To (dd/Mmm/yyyy)	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____	___/___/_____
Not applicable	☑	☐	☐	☐	☐	☐	☐

5 References

ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. 27 October 1994.

ICH E2B(R2) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports. 5 February 2001.