Q&A on pregnancy follow-up

History table		
Prepared by: BAREC & College Board Approved by : College Board Date of endorsement : 10/07/2026		
Previous version	Adopted version	Summary of changes
Version 1 (04/07/2025)	Version 2 (05/08/2026)	Clarification on the inclusion of information for pregnant participants and parental consent for follow-up of the child after birth

Q&A

Question

What should be considered in the follow-up of a pregnant participant and pregnant partner in an interventional clinical trial?

Answer

In a clinical trial, a new medicinal product is being investigated. In order to optimise the knowledge about any potential teratogenic or embryotoxic/foetotoxic effects of a medicinal product and the doses and concentrations at which such effects will develop, it is desirable to gather information and to monitor both pregnant participants/partners and their offspring.

Pregnant participant

The majority of medicinal products or chemical substances administered to a pregnant woman could have effects on the foetus either before the placenta is fully developed or subsequently, if they can cross the placenta to at least some extent. Medicinal products may have a different impact at different stages of pregnancy.

The follow-up of a pregnant participant is subject to pharmacovigilance requirements. This means that the study sponsor is obligated to monitor and report all adverse events, including those occurring during pregnancy, to the competent authorities. Efforts should be made to collect data on the drug effects as well as the outcome for both mother and fetus.

Consent for the follow-up of the pregnant participant's health condition and the processing of personal data is not required to the extent there is a legal obligation to report the adverse event. In such cases, the legal basis under the GDPR would be Article 6(1) (c) of the GDPR (legal obligation) and the justification for the processing of special category data would be Article 9(2)(i) of the GDPR (reasons of public interest related to public health to ensure high standards of quality and safety of health care and of medicinal products or medical devices). This has been confirmed by both the EU Commission (in Q3, 1) and the European Data Protection Board (in section 2.1) for clinical trials under the CTR.

Even though there might not be an obligation to collect consent for the processing of personal data, data subjects always need to be informed about the processing of their personal data (Article 13 and 14 GDPR). It is preferable to add this information in the Main ICF (cfr. Section 6.4 of Belgian ICF template). This pregnancy follow-up of the pregnant participant can also be included in a separate information letter or informed consent form (ICF).

On the other hand, an informed consent form (ICF) for the **follow-up of the health status of the (born) child** for drug safety purposes is necessary ("infant authorization"). It is thus not sufficient to solely inform the participant and other parent about this follow-up. It is preferable to obtain two signatures on a specific ICF for further follow-up of the child (see also: https://barec.be/paediatricclinical-trials-single-parent-or-both-parents-signature-needed/). This follow-up can also be included as an option in the Main ICF signed by the participant upon joining the clinical trial, including the addition of an option and signature for the potential other parent.

Pregnant partner

The follow-up of a pregnant partner involves collecting data on the health and development of the pregnant partner (and optionally the child) without interventions. This follow-up should be detailed in the clinical trial protocol of the CTR-study, including the duration of the follow-up (including that of the child). The follow-up should be specified in time, e.g. until x months after birth.

Written consent from the pregnant partner is required (unless it concerns purely the registration of a product's safety and there is a legal obligation to report the adverse event).

This follow-up falls under the Law of May 7, 2004, on experiments on the human person. We refer to Article 62 of the Advisory Committee on Bioethics, which notes that the clinical trial (interventional drug study (e.g. CTR-study)) in which a male participant is involved is distinct from the observational study set up in case of his partner's pregnancy (monitoring effects on pregnancy). These are two separate studies, but they can and should be described within a single study protocol of the CTR-study.

While elements of earlier guidance—such as Article 62 of the Advisory Committee on Bioethics—date from before the implementation of the CTR and may not fully reflect the current regulatory context, they still provide useful considerations. BAREC emphasizes that, under the CTR, the follow-up of a pregnant partner should be regarded as part of the original clinical trial and reviewed by the same EC responsible for the main CTR-study.

Because the law of May 7, 2004, on experiments on the human person, is applicable to the follow-up of the pregnant partner, this also implies that Article 29 of this law (liability and insurance) applies. Therefore, a compliant insurance clause should be included in the ICF for the pregnant partner. Participation of the pregnant partner in this observational study is voluntary. A thorough and adequate Pregnant partner ICF is required. It is acceptable if this ICF is submitted via an amendment when this exceptional situation arises.

A separate ICF for the child ("infant authorization") can be prepared if data on the child's health status concerning the drug's safety will be collected once the child is born but it is also possible and preferable to include this follow-up in the Pregnant partner ICF. It is recommended to secure two signatures on the ICF for continued follow-up of the child.

There may also be additional requirements for the pregnant partner beyond simply collecting their data, such as completing questionnaires or participating in phone contacts. In that case, it qualifies as an interventional study. This means that a separate ICF is definitely needed to properly inform the partner and obtain consent for their participation in the interventional aspects of the study.

Justification follow-up

The necessity of conducting follow-up, particularly of the pregnant participant, pregnant partner, or child, should take into account e.g. the available preclinical and clinical data regarding drug exposure during pregnancy, known effects of similar substances on pregnancy or fetal development and the pharmacokinetics of the investigational drug, especially its half-life. The drug's half-life will determine how long the substance remains active within the body and its potential to cause long-term effects. However, in case (pre)clinical data show the investigational drug or its metabolites binding covalently to the target, the pharmacokinetic half-life is likely to underestimate the duration of action and the pharmacokinetics cannot be used as surrogate for the duration of the pharmacodynamic effects.

If the drug or any metabolites have a short half-life, meaning it is rapidly cleared from the system, the need for prolonged follow-up may be reduced. In such cases, a more limited or shorter follow-up period could be justified, especially if there is no evidence suggesting long-term residual effects of the drug on pregnancy or fetal development.

When determining the follow-up strategy, the study protocol should outline a clear rationale, supported by pharmacokinetics.