Federal Agency for Medicines and Health Products
Eurostation II – Place Victor Hortaplein 40/40
1060 BRUSSELS
www.fagg.be - www.afmps.be

DG Pre/Division Research & Development

Guidance for submission of DSURs
to the R&D division.

To sponsors of clinical trials

Division Research & Development
Tel. : 02/528 40 00
Fax : 02/528 40 01
e-mail : ct.rd@fagg-afmps.be

Your letter from	Your reference	Our reference	Annex	Date
		FAMHP/R&D/DSUR		10/02/2021

Guidance for submission of DSURs to the R&D division.

Dear Sir/Madam,

This document is intended to update the information relating to the submission of a Development Safety Update Report (DSUR).

Submitting the DSUR:

The DSUR must comply with the format mentioned in the ICH E2F guideline. The ASR format is no longer acceptable.

The DSUR is submitted once a year to the FAMHP and to the Ethics Committee which is empowered to issue the single opinion after the FAMHP's first authorization of an IMP in a clinical trial and for the entire duration that a clinical trial with that IMP is still ongoing **in Belgium**, i.e. until the last patient last visit (LPLV) **in Belgium**, or until the "end of trial" criteria as defined in the protocol are met. We consider a trial to be "ongoing" as from the day of the first authorisation, not as from its actual start.

For clinical trials lasting less than one year, the DSUR does not have to be submitted. In such cases, the clinical study report as part of the end of trial notification acts as a DSUR.
Publishing the clinical study report on the EudraCT-EU Clinical Trials Register is sufficient.
For clinical trials ending before the end of the DSUR period (data lock point = DLP), the DSUR does not have to be submitted. For clinical trials ending within 60 days after the DLP (i.e. the DSUR submission deadline), the DSUR has to be submitted.

Should there be no patients participating in the trial in Belgium, a document mentioning that no patients are enrolled in Belgium can be provided instead of the DSUR. This document must be sent every year until the end of the trial conducted in Belgium.

Additional documents:

The DSUR must be accompanied by:
- All relevant documents concerning the DSUR; SmPC, IB, RSI, etc.
- A signed cover letter.
- The template "DSUR – submission for Belgium".

Sending the DSUR:

The Development Safety Update Report is submitted in non-protected pdf format.
All documents can be copied and pasted (except signature pages).
Documents must be sent via the Common European Submission Portal (CESP).

Fee:

Fee amounts are indexed and published annually in the Belgian Official Gazette. They can also be found on our website.
The Agency issues an invoice to the sponsor after receipt of the DSUR.
The amount due is calculated in function of the number of ongoing trials in Belgium per IMP at the time of submission of the safety report, with a maximum of 5 times the amount.
These fees and the rules for payment could be reviewed in the light of experience with these DSUR reports at national and European level.

Annual safety report to the FAMHP is no longer required:

The Agency must be notified by mail when submitting the annual safety report to the FAMHP is no longer required, for example:
- because the clinical trial has been completed in all countries = submission of the "Declaration of the End of Trial Form" (sections D1 + D2 completed).
- because the clinical trial with the medicinal product concerned has been completed in Belgium but is still ongoing elsewhere = submission of the "Declaration of the End of Trial Form" (section D1 completed).
- for clinical trials lasting less than one year.
- for clinical trials ending before the end of the DSUR period (DLP).
- ...

The end of the local and global trial must be notified to the FAMHP by means of Annex 3 (Declaration of the End of Trial Form).

As a reminder:

The "Development International Birth Date" (DIBD) is used to determine the start of the annual period for the DSUR. The safety report must follow the international DSUR structure, as described in the ICH E2F guideline.
The DIBD is the date of the first (worldwide) authorisation of an IMP trial. The data lock point of the DSUR should be the last day of the one-year reporting period.
For an IMP trial, the DSUR should be submitted no later than 60 days after the DSUR data lock point.

Concretely, this means that:

1. The annual safety report is sent in digital format (unprotected pdf format) via CESP.
2. The DSUR only has to be submitted for ongoing trials in Belgium.
3. The template "DSUR - submission for Belgium" and a signed cover letter are to be included in the report.
4. The fee, depending on the number of ongoing trials per IMP, is paid after receipt of the invoice.