

Guidance on the Belgian synchronized procedure within combined CTR – MDR/IVDR studies

This document aims at providing specific guidance for sponsors on the synchronized procedure of combined CTR – MDR/IVDR studies within Belgium.

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1. Definitions and abbreviations

CESP:	Common European Submission Portal
CTIS:	Clinical Trials Information System
CTR:	Regulation (EU) 536/2014 on clinical trials for medicinal products for human use
EC:	Ethics Committee
IVDR:	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices
MDR:	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
RFI:	Request For Information

2. Introduction

To facilitate the submission of combined studies at a national level, Belgium offers a synchronized submission procedure. This procedure aligns the timelines of both CTR¹ and MDR²/IVDR³ submission procedures, making it easier for sponsors to submit combined studies efficiently.

It is important to note is that this procedure involves synchronization of two separate processes running in parallel, it does not involve coordination and/or consolidation of CTR and MDR/IVDR assessments. Sponsors must submit the CTR and MDR/IVDR dossiers in parallel through their respective submission pathways. Synchronization allows validation questions and Request for Information (RFI) to be sent out at the same time, streamlines the process and enables alignment of documents across both applications.

The synchronized procedure includes the majority of combined clinical studies (both mono- and multinational) involving an investigational medicinal product AND an investigational MD/IVD of which the clinical trial needs to be submitted and approved through CTR and the clinical investigation/performance study needs to be submitted and approved through the “consolidated opinion” regulatory pathway of MDR/IVDR in Belgium.

Despite expedited timelines foreseen for Mononational Phase II/III, Phase III, Phase III/IV and Phase IV clinical trials, it remains possible to include these trials in the synchronised procedure. More details can be found in section 4.

Due to a significant mismatch in the timelines of the MDR/IVDR and CTR procedures, following clinical studies are explicitly out-of-scope of the synchronized procedure:

- Mononational Phase I, Phase I/II and Phase II trials;
- Dossiers with an ATMP IMP or FIH studies with Annex I IMP (cfr. Article 6 and Article 18 of the CTR);
- CTR dossiers submitted under the FAST-EU initiative/pilot;
- Substantial Modification dossiers;
 - Note that for substantial modifications limited to updated patient facing documents (such as the ICF) within combined studies, the simplified notification procedure can be followed in Belgium. The submission and approval of these common documents is sufficient through one of the

¹ [Clinical Trials Regulation \(EU\) No 536/2014](#)

² [Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex](#)

³ [In Vitro Diagnostic Regulation \(EU\) 2017/746](#)

two procedures (CTR or MDR/IVDR) before their implementation. More details can be found in the MDR and IVDR guidelines published on our website^{5,6}.

The synchronized procedure is voluntary and can only be initiated by the sponsor. To do this the sponsor needs to clearly mention his willingness to submit within the synchronized procedure in the cover letter. By doing so, the sponsor agrees to follow and accept the adapted timelines of the procedure. If for any reason the timelines of the procedure are not respected the synchronization stops and the respective procedures fall back to their “unsynchronized” legal deadlines.

All timelines mentioned in this guidance are expressed in calendar days. Due dates cannot fall on a Saturday, Sunday or Belgian public holiday. Should this be the case the due date will be moved to the next working day (cfr. regulation (EEC, EURATOM) NO 1182/71).

3. Synchronized timelines

3.1 Synchronized submission

The clinical investigation/performance study can be submitted up to 5 days before but no later than the CTR application in CTIS. **The cover letter of both submissions must clearly mention the willingness of the sponsor of processing both dossiers through the synchronized procedure.** Both cover letters must also contain clear references to the other related dossier submitted (Eudamed and/or EudraCT number) so we can make sure that the related CTR and MDR/IVDR dossiers are sent to the same independent Ethics Committee (EC). Note that it is possible to request the Eudamed (CIV-ID/PS-ID) number before submission, see our MDR and IVDR guidelines for more information.

We highly appreciate prior notification by e-mail when there is an intent to submit a combined study via the synchronized procedure, please include the estimated submission timeframe in your e-mail. However this notification is not mandatory.

The dossier content must fulfil the EU and national requirements as specified in our respective national guidelines for clinical trials⁴, clinical investigations⁵ and performance studies⁶. These requirements are the same as for dossiers submitted outside the synchronized procedure.

The clinical investigation/performance study is submitted via the CESP portal and the related clinical trial via CTIS. In case of multiple MDR/IVDR applications related to the same CTR application, a synchronized assessment is only possible if these MDR/IVDR applications are submitted up to 5 days before but no later than the CTR application in CTIS.

⁴ [Clinical trials for human medicines | FAMHP](#)

⁵ [Medical devices and active implantable medical devices | FAMHP](#)

⁶ [In vitro diagnostic medical devices \(IVD\) | FAMHP](#)

3.2 Synchronized validation

From the date of CTR dossier reception, the CTR and MDR/IVDR dossier will be validated within 10 days. Individual validation questions will be formulated for the CTR and MDR/IVDR dossier and shared with the sponsor via CTIS for the clinical trial and via e-mail for the clinical investigation/performance study on the same day.

When the sponsor receives the validation questions, he has 10 days to provide a complete response. The response must be provided **on the same day** for the CTR and MDR/IVDR dossier, but separately via CTIS for the clinical trial and via e-mail or CESP for the clinical investigation/performance study. Note that no deadline extension is possible for the MDR/IVDR dossier within the synchronized procedure in order to retain alignment with the timeline in CTIS.

In case no validation questions are formulated for the CTR or MDR/IVDR dossier, but there are validation questions for the MDR/IVDR or CTR dossier, a 'dummy' validation question will be posted in CTIS/via mail resp. to make sure the timelines stay synchronized. The sponsor can reply to this dummy question with a generic statement e.g. *"Response to the dummy validation question on the same day as the MDR/IVDR/CTR validation questions in scope of synchronized procedure."*

Once the response is received from the sponsor, the validation of the related CTR and MDR/IVDR dossier will be completed within 5 days. If both dossiers are considered to be complete, the T0 (validation conclusion) will be set in CTIS for the CTR dossier and the Acknowledgment of Receipt (AoR) letter, including the same T0, will be shared on the same day with the sponsor by e-mail for the MDR/IVDR dossier.

If the validation questions are insufficiently answered for the CTR and/or MDR/IVDR dossier, the application(s) will be rejected and the synchronized procedure will end at this stage. The related dossier that was considered to be complete can still be processed individually, outside the synchronized procedure.

If the sponsor cannot provide the response to the validation questions within the timeframe of 10 days, the synchronized procedure will end at this stage. Note that for clinical investigation/performance studies the sponsor may request a 20-day extension to provide a response to the validation questions. As this legal extension is only possible for clinical investigation/performance studies, this extension can only be granted outside of the synchronized procedure. If necessary, the sponsor may request this extension for the clinical investigation/performance study but in this case the synchronization ends and the applications will be processed individually.

The sponsor of the validated dossier always has the option to withdraw the dossier and resubmit it together with the rejected dossier. In this way the synchronized procedure may be restarted for the related CTR and MDR/IVDR dossiers.

3.3 Synchronized assessment

The T0 is considered Day 0 from which the synchronized assessment will start. Both dossiers will now be assessed in parallel.

Within 45 days a separate list of RFI will be formulated for the CTR and MDR/IVDR dossier and shared with the sponsor on the same day, through CTIS for the clinical trial and by e-mail for the clinical investigation/performance study.

As RFI for Part I and Part II in CTIS are almost never issued on the same day, we aim to synchronize the RFI of the MDR/IVDR procedure with the **RFI of the Part II procedure** in CTIS. This ensures a synchronized assessment of the ethical aspects, as the assessing EC is the same.

In case no RFIs are formulated for the CTR or MDR/IVDR dossier, but there are RFIs for the MDR/IVDR or CTR dossier, a 'dummy' RFI will be posted in CTIS/via mail resp. to make sure the timelines stay synchronized. The sponsor can reply to this dummy RFI with a generic statement e.g. *"Response to the dummy RFI on the same day as the MDR/IVDR/CTR RFI(s) in scope of synchronized procedure."*

The sponsor has **maximum 12 days** to provide a complete response to both lists of RFI. The response must be provided **on the same day** for the CTR and MDR/IVDR dossier, but separately through CTIS for the clinical trial and by e-mail or CESP for the clinical investigation/performance study.

If the sponsor is unable to provide a response to both lists of RFI within 12 days, the synchronized assessment of both dossiers will end and they will be handled separately according to the respective CTR and MDR/IVDR timelines.

3.4 Final MDR/IVDR and CTR decision

After assessment of the responses to the RFI, the final decision will be individually issued for the related CTR and MDR/IVDR dossier within their respective procedure. For the MDR/IVDR dossier, the final decision letter will be shared with the sponsor by e-mail no later than Day 74. For the CTR dossier, the final decision will be shared via CTIS no later than Day 81.

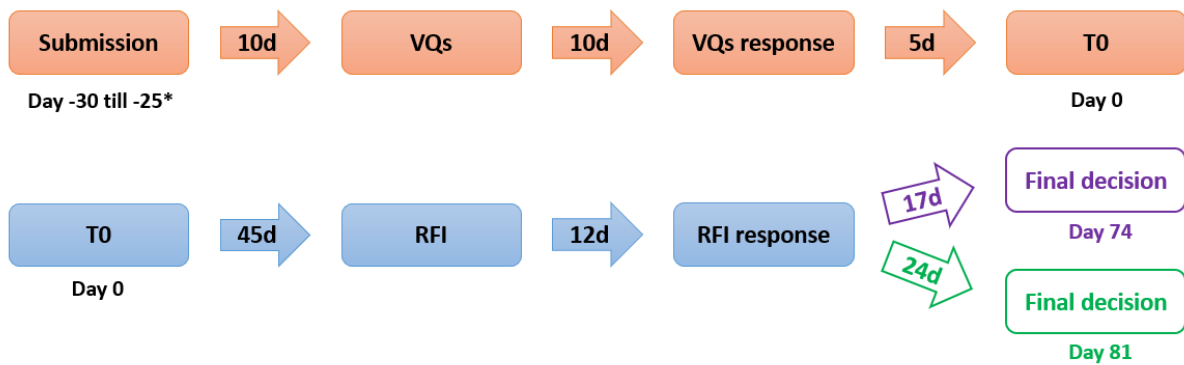
4. Synchronized expedited timelines for mononational Fast Track trials

Mononational Phase II/III, Phase III, Phase III/IV and Phase IV clinical trials follow an expedited timeline for review and assessment in Belgium. When a combined submission includes a clinical trial that falls within one of these categories, the related clinical investigation/performance study will be synchronized to the expedited timelines as follows:

- validation will be performed within 7 days;
- assessment of the validation question responses will be performed within 5 days;
- synchronized assessment will take 28 days;
- assessment of the RFI responses will take 12 days;
- the final decision will be shared no later than Day 57 of the synchronized assessment procedure

For these mononational trials, deadline extensions available under the MDR/IVDR procedure cannot be applied, as such extensions do not exist under CTR. Synchronization requires both procedures to follow the CTR timelines.

Annex I - Flowchart for the synchronized procedure



Legend:

 Synchronized validation	 MDR/IVDR final decision	VQs: Validation Questions
 Synchronized assessment	 CTR final decision	RFI: Request for Information
		d: days

* MDR/IVDR application can be made up to 5 days before CTR (Day -30), but no later than the CTR application (Day -25)

Expedited timelines for mononational Fast Track trials

