Clinical Trials Coordination Group and MedEthics EU

FAST-EU

Facilitating and Accelerating Strategic Clinical Trials in the EU

External Guidance for Sponsors,
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1. Abbreviations

AxMP	Auxiliary Medicinal Product
CCI	Commercially Confidential Information
CT	Clinical Trial
CTA	Clinical Trial application
CTCG	Clinical Trials Coordination Group
CTIS	Clinical Trials Information System
CTR	Regulation (EU) No. 536/2014
DAR	Draft assessment report
EC	Ethics Committee
EoI	Expression of Interest
EU	European Union
FAR	Final assessment report
FAST-EU	Facilitating and Accelerating Clinical Trials in the EU
HMA	EU Heads of Medicines Agencies
IB	Investigator's Brochure
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
LoI	Letter of Intent
MSC	Member State Concerned
NCA	National Competent Authority
RMS	Reporting Member State
SM	Substantial Modification

2. Introduction and pilot context

FAST-EU (Facilitating and Accelerating Strategic Clinical Trials) is a **pilot initiative** by HMA, CTCG and MedEthics EU implemented within the framework of the Clinical Trials Regulation (CTR). FAST-EU is a voluntary pilot with a limited number of applications per month.

The objective of FAST-EU is to accelerate the coordinated assessment and authorisation of **multinational clinical trial applications** by applying ambitious internal coordination timelines and reinforced cooperation between Member States, while fully maintaining scientific, safety and ethical standards.

FAST-EU aims for an

- **overall duration of 70 calendar days (10 weeks)** for initial applications from submission to Part I conclusion, including sponsor response times.
- **overall duration of maximum 42 calendar days (6 weeks)** for substantial modifications related to a conditional approval, blocking the initiation of a FAST-EU trial, from submission to Part I/Part II conclusion, including sponsor response times.

FAST-EU operates **entirely within CTIS** and **does not modify legal rights or obligations**.

3. Background and rationale

Multinational clinical trials are essential to enable sufficient patient recruitment, generate robust evidence and **ensure that European patients are represented** in the development of innovative medicinal products.

FAST-EU aims to:

- **improve predictability and efficiency** of assessment timelines,
- **strengthen coordination** between Member States,
- demonstrate the EU's capacity for **rapid and coherent regulatory action**,
- and facilitate **timely patient access** to innovative therapies.

FAST-EU **fully integrates Ethics Committee opinions of all participating Member States Concerned** within the accelerated process.

The list of participating Member States can be found in Annex II.

4. Scope

FAST-EU applies to:

- **initial applications for multinational clinical trials** involving more than one Member State, and
- **all categories of investigational medicinal products (IMPs)**,
- **substantial modifications** to Part I and/or Part II submitted **to address a conditional approval that is currently blocking** the initiation of a trial approved under FAST-EU

FAST-EU does **not** apply to:

- mono-national clinical trials
- partial submissions under Article 11 of the CTR
- resubmissions of previously lapsed, withdrawn, invalid or rejected trials
- substantial modifications **not related to conditions**
- subsequent additions of Member States
- combination trials where the authorisation/notification process cannot be completed within the FAST-EU timeframe*

**Under Regulation (EU) No. 2017/745 (MDR) and 2017/746 (IVDR) there are different authorisation and notification processes depending on the investigational device and the study type. Furthermore, processes as heterogenous among Member States. The intention of the last bullet point is to maintain the benefit of FAST-EU despite different authorisation or notification timelines under MDR/IVDR. In case of uncertainty, the sponsor should inquire with the Coordination Office.*

5. Selection for the FAST-EU pilot

5.1 Pilot capacity and selection

As FAST-EU is a **pilot initiative with limited capacity**, not all eligible applications can be accommodated. It is foreseen to include a minimum of two trials per month with weekly submission slots (e.g. Week 1 and Week 3). The purpose is a balanced distribution of workload among RMS and MSCs.

Prerequisites:

- multinational clinical trial with several participating MSCs in the EU/EEA
- readiness of the dossier for submission (i.e. the dossier is finalised and ready for submission in CTIS)

Selection of applications into the FAST-EU pilot is performed by the FAST-EU Selection Committee, which is composed of members of CTCG and MedEthics EU, acting in conjunction with the proposed RMS.

5.2 Selection considerations

To manage workload and ensure predictability, FAST-EU applications are allocated to **defined time slots** per month. Where multiple Expressions of Interest are received within a similar timeframe, eligible applications may be prioritised and allocated to different FAST-EU pilot slots based on the following considerations:

- number of MSCs (aiming for a high number of MSCs),
- suitability and availability of the proposed RMS (and flexibility to change RMS, if needed),
- relevance and complexity of the clinical trial,
- prior engagement in EU-level pre-assessment activities (e.g. EMA Scientific Advice, PRIME),
- overall workload and capacity across participating authorities.

Selection considerations **may be adapted** during the pilot phase based on experience.

Participation in FAST-EU **is not guaranteed**, even when the formal eligibility criterion of "multinational clinical trial" is met.

6. Application for a FAST-EU Pilot Slot

6.1 Expression of interest

Sponsors wishing to participate in the FAST-EU pilot must submit an **Expression of Interest (Letter of Intent)** by e-mail to the FAST-EU Coordination Office prior to submission of the clinical trial application in CTIS. If the sponsor needs to protect CCI, they can submit the Expression of Interest via **EudraLink**.

At this point the application dossier should be **finalised and ready for submission** earliest within two working days after confirmation of inclusion in FAST-EU.

The Expression of Interest serves solely to request allocation of a **FAST-EU pilot slot** and does **not** constitute a clinical trial application, pre-submission assessment, or regulatory evaluation.

6.2 Content and submission of the Letter of Intent

A **template for the Letter of Intent** is available in Annex I of this document and should be used.

The Letter of Intent shall be concise and include, as a minimum, the following information:

- EU-CT number, sponsor protocol code and trial title
- a description of the trial (including design, phase, population and key objectives) or, alternatively, a synopsis of the protocol
- a description of the investigational medicinal product(s),
- the **Member States concerned**,
- the **proposed Reporting Member State (RMS)** and potential alternative RMS candidates,
- prior engagement in EMA Scientific Advice or PRIME
- concerned National Ethics Committee for some MSCs (in line with current practice for the CTR/CTIS Cover Letter)

The completed Letter of Intent shall be submitted **by e-mail** to the FAST-EU Coordination Office at **FAST-EU@hma.eu**.

6.3 Response and next steps

The sponsor can expect a response via e-mail regarding participation in the FAST-EU pilot **within 5 working days** of submission of the Letter of Intent.

The response e-mail will indicate:

- whether a FAST-EU pilot slot can be allocated, and
- when exactly the sponsor may proceed with submission of the clinical trial application in CTIS under FAST-EU
- the final RMS (proposed or alternative).

As under the CTR the proposal for an RMS is non-binding and another RMS might take responsibility for the trial.

If participation in FAST-EU cannot be accommodated or submission on the communicated date is not feasible, the sponsor may proceed with submission of the clinical trial application under the standard CTR procedure and timelines.

Not being included in in FAST-EU has no impact or reflection on the subsequent clinical trial application.

7. Governance and roles

7.1 Reporting Member State (RMS)

The RMS coordinates the FAST-EU process and:

- acts as a contact point for the sponsor during the procedure
- monitors and enforces FAST-EU timelines,
- consolidates Part I/Part II validation and Part I assessment considerations,
- discusses and streamlines Part I RFI with MSCs,
- issues Requests for Information (RFIs) for validation and Part I,
- coordinates validation decision and Part I conclusion,
- may trigger fallback to standard CTR timelines where necessary (see section 12)

7.2 Member States Concerned

Participating Member States:

- perform validation and assessment activities (Part I and Part II) according to CTR within FAST-EU timelines,
- contribute to RFIs and response assessments,
- retain full responsibility for Part II assessment and their national CTR decisions.

7.3 FAST-EU Coordination Office

The EMA hosts a FAST-EU Coordination Office with an **administrative and supportive role**.

The Coordination Office:

- communicates application to RMS and MSCs,
- supports timeline tracking and documentation,
- plans discussion meetings for RMS and MSCs, if applicable
- acts as a contact point for general queries on FAST-EU (not for a specific trial)

The EMA Coordination Office does **not** enforce timelines. This is the role of the RMS.

The Coordination Office can be reached at **FAST-EU@hma.eu**.

7.4 FAST-EU selection committee

The Selection Committee consists of the Chairs of the CTCG and MedEthics EU.

The Selection Committee ensures that CTAs enter FAST-EU that are

- relevant regarding trial indication and population
- balanced considering RMS-ships among participating Member States
- informative for the purpose of the pilot to inform future decision making by the European Commission for the Biotech Act

The final decision on acceptance and slot allocation is taken by the RMS.

7.5 Sponsor

Participation in FAST-EU is **voluntary** for sponsors.

The sponsor:

- expresses interest in participation in FAST-EU to the Coordination Office
- submits the initial application via CTIS in the allocated submission slot **after** receipt of confirmation,
- responds to RFIs within the defined timelines of FAST-EU
- accepts the need for flexibility with regard to responding to RFIs

Legal rights and obligations of the sponsor are **not affected**.

The dossier requirements according to Annex I of CTR also apply in FAST-EU. The differentiation in global and national Part I aspects of the Biotech Act will not be piloted in FAST-EU (see section 8.2 and section 10).

8. FAST-EU procedure and timelines for initial applications

8.1 Overall concept

FAST-EU operates **entirely within CTIS** and **does not modify rights or obligations** according to CTR. The main difference are the shortened timelines.

FAST-EU aims for an **overall duration of 70 calendar days (10 weeks)** from submission to conclusion of Part I and Part II, including sponsor response times.

FAST-EU applies **parallel workflows**, starting on the date of CTIS submission (Day 0):

- Validation
- Part I assessment
- Part II assessment

FAST-EU timelines are **internal coordination targets**, counted in **calendar days**, and operate **within the current legal CTR timelines**.

The parallel workflows are currently not supported by CTIS.

8.2 Validation phase under FAST-EU

The pilot is built on the assumption that core documents (e.g. protocol, IB or IMPD) are present at the time of submission. Therefore, **missing core documents** will be requested early in the validation phase with a minimal timeline of **two working days** and the risk of lapse of application. Such requests do not replace the regular consolidated validation RFI.

8.3 Detailed timelines

Part I and Part II validation

- Initial validation assessment: Day 7 after submission
- Sponsor response: until Day 14
- Assessment of responses/ Validation decision: Day 21

Part I assessment

- Initial assessment (DAR): Day 28 after submission
- Member State considerations: Day 35
- Consolidation by RMS: Day 42
- Sponsor response to RFI: until Day 54*
- Assessment of responses/ Part I conclusion: Day 70

Part II assessment

- Initial assessment: Day 42
- Sponsor response to RFI: until Day 54*
- Assessment of responses/ Part II conclusion: Day 70

National decision

The national decision will be taken by each MSC according to CTR and CTIS timelines. MSC are encouraged to take the national decision without undue delay.

All timelines are counted in calendar days. Where a deadline falls on a public holiday, the deadline is extended to the next working day in accordance with Regulation (EEC, Euratom) No 1182/71.

* *The maximum timeline according to CTIS business rules will be given.*

9. FAST-EU procedure and timelines for substantial modifications

9.1 Notification

One week before the planned* **submission date** of a SM restricted to fulfilling a conditional approval of a FAST-EU initial application in CTIS **the sponsor** should inform the FAST-EU coordination office and the RMS of the submission. **This is essential because otherwise it cannot be detected that this is a FAST-EU SM in time for the accelerated approval timelines.**

In addition, in the cover letter for the SM the sponsor should state that this is a substantial modification related to a conditional approval of a FAST-EU initial application, and that the changes are restricted to those requested by the RMS and/or MSC to lift the condition. **An SM outside the defined scope of FAST-EU can be rejected as invalid during the validation phase.**

9.2 Critical validation issues

The provision of both **clean and track-changes versions** of the documents to be modified, **together with a comprehensive summary of the changes**, is essential. The summary may be provided either as a separate document or as part of the relevant document to be modified. If any of the required documents are missing, it will become a **critical validation issue** to be resolved within two working days.

9.3 Detailed timelines

SM validation part I and part II

- Initial validation assessment: Day 7 after submission
- Sponsor response: until Day 14
- Assessment of responses/ Validation decision: Day 21

Part I assessment

- Initial assessment (DAR): Day 21 after submission
- Member State considerations: Day 25
- Consolidation by RMS: Day 28
- Sponsor response to RFI: until Day 35

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* *"Planned submission date" means that it is not a breach of procedure if the submission is one day early or one day late. But sponsors should aim to keep the planned submission date to relieve the coordination office and Member States from additional administrative burden.*

- Assessment of responses/ Part I conclusion: Day 42

Part II assessment

- Initial assessment: Day 28
- Sponsor response to RFI: until Day 35
- Assessment of responses/ Part II conclusion: Day 42

National decision

The national decision will be taken by each MSC according to CTR and CTIS timelines (5 calendar days). MSC are encouraged to take the national decision without undue delay.

All timelines are counted in calendar days. Where a deadline falls on a public holiday, the deadline is extended to the next working day in accordance with Regulation (EEC, Euratom) No 1182/71.

10. Requests for Information (RFIs)

10.1 Validation RFIs

If required, a **single consolidated validation RFI** is issued, clearly identifying:

- Part I validation considerations,
- Part II validation considerations,

10.2 Assessment RFIs

During assessment normally:

- a **single round of Part I RFI** and
- a **single round of Part II RFI** per MSC is issued.

Sponsors are expected to provide **complete and consolidated responses** within the defined timelines. Due to the short timelines of FAST-EU a second round of RFI for further clarification might not be possible. This can lead to conditions or rejection if the sponsor's response is not sufficient.

11. Interaction with CTIS and legal CTR timelines

FAST-EU operates entirely within CTIS and follows CTR workflows as closely as possible.

FAST-EU:

- does not alter CTIS submission requirements

- does not modify legal decision-making responsibilities,
- does not affect appeal rights or post-authorisation obligations.

Where FAST-EU internal timelines cannot be met and continuation within FAST-EU is no longer feasible, the procedure may continue under applicable CTR timelines (see section 12).

12. Fallback to standard CTR timelines

Minor deviations from FAST-EU timelines during the coordinated assessment are documented for pilot evaluation purposes but do not automatically result in fallback, if the procedure can be continued under FAST-EU timelines.

If at some point the coordination effort outweighs the timeline benefit, the RMS may trigger fallback to CTR timelines and regular task management by CTIS.

Fallback:

- does not invalidate assessment work already performed,
- does not require re-submission,
- allows the procedure to continue seamlessly under the CTR.

13. Outcome of FAST-EU

At the conclusion of FAST-EU, the sponsor receives **full legal CTR decisions** by each Member State Concerned, issued through CTIS. The national decision will follow CTIS timelines, but MSC are encouraged to take the national decision without undue delay.

FAST-EU does not change the legal nature of CTR decisions.

Annex I – Expression of Interest Template:





FAST-EU Expression of Interest

The Expression of Interest should include the required information. It is not necessary to extract the page from the guide.

Sponsor: Sponsor Name

EU Clinical Trial number: Trial Number

Protocol Number: Protocol Number/Acronym

Protocol Title: Protocol Title

Proposed RMS: RMS Country

Please indicate RMS alternatives, if applicable.

Proposed MSC: MSC Countries

Description of the Trial:

Phase, Design, Indication, Population, Key Objectives …

Alternatively, a synopsis of the protocol can be provided.

Description of the IMP(s):

Chemical, Biological or ATMP, Combination Product, Mode of Action …

☐ **SAWP/CTCG Advice**

☐ **PRIME**

Other Information:

For Spain or Italy please provide the responsible Ethics Committee. The list of Italian Ethics Committees participating in the FAST-EU project is available on the AIFA website and at the following link. For the Spanish Ethics Committees please see the AEMPS website at the following link (see the section "CEIm adheridos a procedimientos de evaluación acelerada").

Annex II – Participating Member States:

- **Austria (AT)**
- **Belgium (BE)**
- **Bulgaria (BG)**
- **Croatia (HR)**
- **Cyprus (CY)**
- **Czech Republic (CZ)**
- **Germany (DE)**
- **Denmark (DK)**
- **Estonia (EE)**
- **Finland (FI)**
- **France (FR)**
- **Greece (GR)**
- **Hungary (HU)**
- **Ireland (IE)**
- **Italy (IT)**
- **Latvia (LV)**
- **Lithuania (LT)**
- **Netherlands (NL)**
- **Norway (NO)**
- **Poland (PL)**
- **Portugal (PT)**
- **Romania (RO)**
- **Spain (ES)**
- **Slovenia (SI)**
- **Slovakia (SK)**
- **Sweden (SE)**

Annex III – History of Changes

Version 1.1, 28.01.2026:

- Greece added to the list of participating MSCs.
- Clarification that the Letter of Intent is only to be found in Annex I. “Mandatory” was changed to a strong recommendation. The content of the LoI is relevant, but there is no need to extract the page from the guidance.
- Added that the LoI can be submitted via Eudralink if the sponsor wants to protect confidential information.
- Clarification that weekly slots per month are meant to distribute the workload e.g. Week 1 and Week 3.
- Clarification that the proposed RMS is non-binding and another RMS might take responsibility for the trial
- Footnote for sponsor response to RFI corrected since extension of the 12 days due to weekend will happen rarely in FAST-EU.
- Correction of typos and format.

Version 1.2, 26.03.2026:

- Lithuania joined FAST-EU and was added to Annex II.
- Combination trials were generally excluded because the benefit of faster assessment is lost due to the regular duration of the MDR/IVDR procedure.
- It was clarified that the two trials per month are a minimum goal. Up to four trials were included in the submission rounds so far.

Version 1.3, 02.11.2026:

- The scope of FAST-EU was extended to include substantial modifications for FAST-EU trials where there was a conditional approval, and a condition is currently blocking the initiation of the trial. The process is described in the new Chapter 9.
- Since the exclusion of combination trials caused some confusion, and sponsors were coming up with special cases, it is now clarified that a combination trial is acceptable as long as the benefit of the faster FAST-EU approval is not lost due to longer MDR/IVDR timelines.
- The labelling of validation considerations was removed since the evaluation of “Part I national validation issues” is no longer an objective of FAST-EU.