Clinical trials : Fast-Track assessment process

Guidance to sponsors

13/03/2026

Summary

Introduction

Since January 31, 2022, European Regulation No. 536/2014 has governed the conduct of clinical trials on medicinal products for human use. All applications for authorization must be submitted via the European CTIS portal, which centralizes submissions for all European Union member states.

Authorization for a clinical trial is still based on a dual assessment. For clinical trials conducted solely in France, the ANSM evaluates the scientific, methodological, and regulatory aspects of the protocol (part I), and an ethics committee (Comité de protection des personnes, CPP) examines its ethical dimensions (part I and part II). If both assessments are positive, a unique administrative authorization to conduct the trial is granted.

As part of the new Fast-Track pilot procedure proposed in France, the process includes verification by the ANSM of the trial's eligibility for this accelerated procedure. This is under the request of the sponsor and prior to the submission of the authorization application via the CTIS (Clinical Trial Information System) portal, followed by an assessment within a significantly reduced timeframe.

A monitoring committee for the Fast-Track initiative has been established with the participation of the Direction Générale de l'Offre de Soins (DGOS), the ANSM, the Commission nationale des recherches impliquant la personne humaine (CNRIPH), the Conférence Nationale des Comités de Protection des Personnes (CNCP), and the Agence de l'innovation en santé (AIS). Its mission is to monitor the progress of this pilot project, ensure its smooth operation, and closely oversee the clinical trials included in this process throughout their development. An assessment of the procedure’s impact on the time required to set up trials resulting from such an accelerated process will be conducted. This is particularly relevant given that the process prioritizes the potentially most complex cases (first-in-class, rare diseases, pediatrics).

Scope of the fast-track

The Fast-Track will offer academic and industrial sponsors an accelerated pathway for certain categories of clinical trials on medical products, including advanced therapy medicinal products (ATMP):

In this initiative only Mononational Early-phase trials (Phase I or integrated Phase I/II) are eligibles; meeting at least one of the following criteria:

- relating to a serious, rare, or debilitating disease for which no appropriate treatment is available;
- and/or first-in-class, i.e., targeting a treatment with an entirely new mechanism;
- and/or including adolescents in adult trials, when appropriate.

Furthermore, certain conditions apply to the national fast track:

- The expedited assessment procedure is only applicable for applications which contain both Part I and Part II.
- For Integrated Phase I/II trials, Phase I has to be conducted in France.
- Master protocols or complex clinical trials may be eligible for expedited assessment, provided that no more than one investigational medicinal product does not have marketing authorisation at the time of submission.
- Clinical trials combined with a medical device and/or in vitro diagnostic device may be eligible
- A synopsis has to be provided.
- The sponsor shall provide a timetable with the provisional dates for the signing of the unique convention(s), the date of first participant inclusion, date of end of inclusion, and the publication of results. This timetable must only include accelerated deadlines.
- The sponsor commits to informing the ANSM of key milestones after the clinical trial has been authorized: signing of the “convention unique”, first site initiation visit, inclusion of the first participant, inclusion of the last participant, and publication of the results.

Sponsors are required to submit a complete, high-quality clinical trial application that meets the requirements of the REC, as well as those applicable to medical devices and in vitro diagnostics, and national requirements (particularly for Part II).

This initiative is being offered as part of a pilot phase. The ANSM and the Fast-Track Monitoring Committee reserve the right to modify the submission guidelines based on the experience gained.

Procedure Overview:

Fast-Track eligibility

The sponsor submits an application for Fast-Track eligibility via the online portal (https://demarche.numerique.gouv.fr/commencer/ansm-guichet-innovation-et-orientation-26). Eligibility will be determined by the ANSM based on the information provided by the sponsor.

In the online application process, the sponsor must select the “pre-submission” application type and the “eligibility Fast-Track procedure ANSM” pré-orientation option (see Figure 1). In addition, the sponsor must provide the CTIS number assigned to their application, if available. If the CTIS number is not available at the time of the request, the sponsor agrees to provide it as soon as possible to the address Ecphase.precoce@ansm.sante.fr
The eligibility form must be completed in Word format.

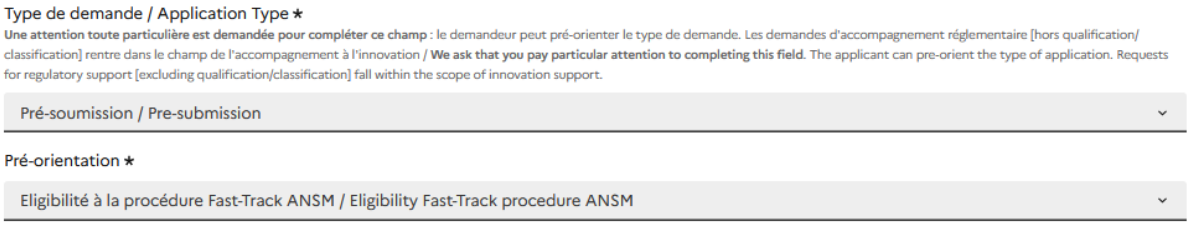

Figure 1 : Démarche numérique

The ANSM is committed to responding to the sponsor within 48 hours.

If a trial is eligible for the Fast-Track process, the ANSM will designate a one-week slot starting from the submission date proposed by the sponsor during which the sponsor may submit its application. This slot will be determined based on the proposed submission date and the number of applications submitted during that period. If the clinical trial is submitted outside of this slot, Fast-Track status will not be guaranteed.

Otherwise, the ANSM will inform the sponsor of the reasons for denying the Fast-Track designation.

Validation and assessment

The Sponsr indicates in the cover letter the project's eligibility for the Fast-Track as well as the reference number for the démarche numérique, and notifies via email of the submission of the application, including the CTIS reference number:

- The ANSM via the email Ecphase.precoce@ansm.sante.fr for clinical trials, and by adding EC.DM-COS@ansm.sante.fr in the case of a combined trial (clinical investigation for a medical device or performance study for an in vitro diagnostic medical device)
- The DGOS (DGOS-plateforme-riph@sante.gouv.fr) to ensure that the case is assigned to an ethic committee participating in this program.

The admissibility and evaluation of the clinical trial will be conducted in accordance with the procedures established by the CTR, with the clinical trial submitted to the CTIS, and in accordance with the regulations applicable to medical devices (MD) and in vitro diagnostic medical devices (IVD).

With regard to the validation of clinical trials, the ANSM is committed to prioritizing and accelerating applications. A complete and compliant application will, as a result, undergo a faster validation process.

The ANSM will provide the applicant with the applicable timeline for the start of its evaluation.

For chemical and biological drugs, a specific timeline is established (Figure 2).

For advanced therapy medicinal products (ATMPs), the mononational timeline applies without utilizing the additional 50 days provided for under the CTR (Figure 3).

For combination trials, the timeline for the performance study or clinical investigation will follow that of chimical/biological drugs or MTIs, depending on the product.

Please note that if the calculation of a due date falls on a holiday or a weekend, the due date will automatically be postponed to the next business day. No eligibility requests will be processed during the winter clock-stop or between July 15 and August 15, and no slots will be allocated during these periods.

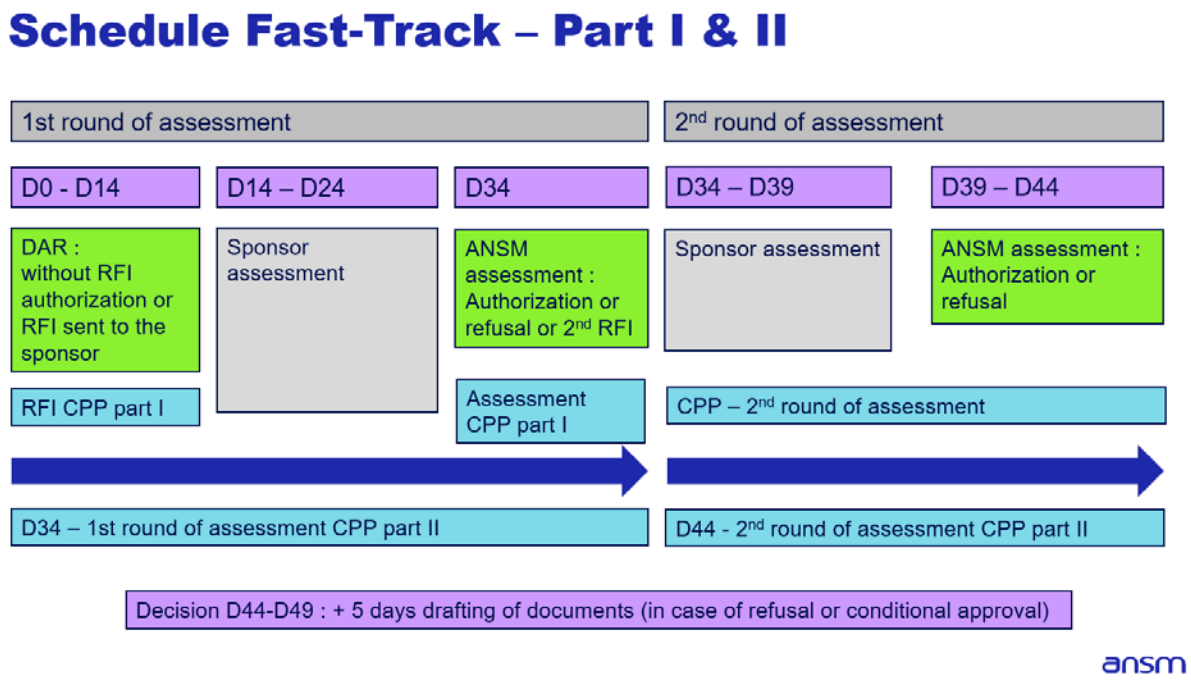

Figure 2 Timeline for the Fast-Track procedure for clinical trials of chemical and biological drugs

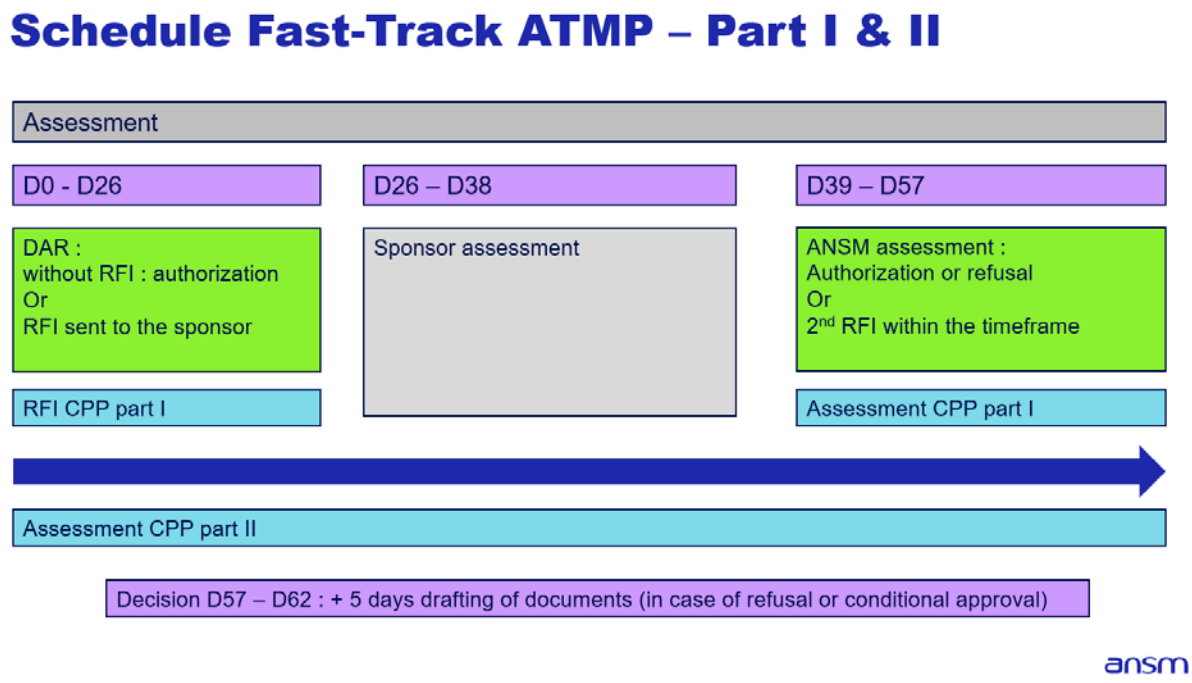

Figure 3 : Fast-Track procedure timeline for MTI trials

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