French Fast-Track for Clinical Trials

Launch date: 16 March 2026

Objective

The French national fast-track procedure aims to significantly shorten evaluation timelines for eligible clinical trial applications, while maintaining robust ethical and scientific standards.

Eligibility Criteria

Applies to single-country (France) Phase I or integrated Phase I/II trials meeting at least one of the following conditions:

- **Serious, rare, or debilitating diseases** with no appropriate treatment available.
- **First-in-class** investigational product with an entirely new mechanism of action.
- **Inclusion of adolescents** (12–18 years) in an adult trial.

Additional requirements:

- Trial must fall under EU Regulation 536/2014 or be a combined trial involving an IMP and an in-vitro diagnostic medical device.
- For integrated Phase I/II designs, Phase I must take place in France.
- Master protocols or complex designs may be eligible if no more than one IMP lacks a marketing authorisation at submission.

Benefits of the Fast-Track

Authorisation Timelines by ANSM	Current Procedure (EU Regulation)	French Fast-Track Procedure
Authorisation timeline without questions	31 days	**14 days**
Authorisation timeline with question(s)	106 days	Max. 49 days
Advanced Therapy Medicinal Products	Up to 50 additional days	No additional timeline

How to submit an application?

1. Submit your request using the dedicated eligibility form via the "*Démarches numériques*" portal. Sponsor must provide a detailed synopsis and a forecast timeline (contract signature, first-in-participant, end of recruitment, results publication). ANSM commits to responding within **48 hours**.
2. If your request is deemed eligible, submit your application via the CTIS portal, respecting the one-week submission slot assigned to you, which ensures that the fast-track process will apply to your submission.
3. Send an email to: DGOS-plateforme-riph@sante.gouv.fr on the day you submit in CTIS, indicating the CTIS number of your dossier so that it can be assigned to a CPP participating in this fast-track scheme.

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