Agence nationale de sécurité du médicament et des produits de santé

Announcement

ANSM implements Fast Track clinical trial authorization program

To more quickly offer patients access to innovative treatments, the ANSM has set up two Fast Track options that will expedite processing of applications for the authorization of clinical trials of medicinal products—without compromising patient safety. The new system will come into force starting 15 October 2018 and concerns clinical trials of innovative treatments as well as new trials of known substances. Fast Track processing times will not exceed 25 or 40 days, depending on the type of trial, whereas current regulations call for 60 days.

Making healthcare innovation more quickly available to patients is a priority heralded by the French government at the eighth meeting of the Strategic Council for the Healthcare Industries (CSIS) and written into the 2018 work plan of the ANSM, the guarantor of the safety and quality of authorized medicines.

This new system aims to shorten clinical trial authorization application processing times, prepare the ANSM for greater responsiveness in view of upcoming European regulations on clinical trials—coming into effect no later than 2020—and improve the quality and safety of the clinical trials proposed in submitted applications.

In setting up Fast Track procedures, the paramount objective has been to ensure faster turnaround for
– making innovative treatments available to patients ('Access to innovation' → Fast Track 1)
– launching new clinical trials on known substances ('Support for development' → Fast Track 2)

Beginning 15 October 2018, sponsors are invited to participate in an initial test run of the procedure, on a voluntary basis. Eligibility conditions for the new Fast Track procedures are described in the associated *Practical Information Guide for Applicants*. Eligible applicants must either submit a special Application Form (Fast Track 1 or 2) or schedule a presubmission meeting (Fast Track 1 only), details of which are given in the guide. Through this new system, the ambition of the ANSM has been to ensure applications are better prepared so that they meet safety and quality requirements in the best interest of patients.

Following is a list of documents related to the Fast Track procedures:

- Guide pratique d'information aux promoteurs (French)
- Practical Information Guide for Applicants (English)
- FT1 Application Form (English)
- FT2 Application Form (English)
- Guidance to Complete the Additional Fast Track Document [i.e. FT1 or FT2 Application Form] (English)

If you have a question about clinical trial application submission procedures or would like to schedule a Fast Track 1 presubmission meeting e-mail questions.clinicaltrials@ansm.sante.fr

Submit Fast Track clinical trial applications to the usual e-mail address :
aec-essaiscliniques@ansm.sante.fr
(for more details, see *Practical Information Guide for Applicants*).