Agence nationale de sécurité du médicament et des produits de santé

Point d'information

The ANSM expends the scope of the Fast Track clinical trials applications to clinical trials with a complex design and Advanced Therapy Medicinal Products (ATMP)

In order to improve access to innovative treatments for patients, the ANSM improves its Fast Tracks program which will offers reduced the timelines for authorization applications for clinical trials (CT) of medicinal products with respect for patient safety.
From 18 February 2019, medicinal drug trials with complex design and Advanced Therapy Medicinal Product (ATMP) will be eligible to the Fast Track program.

To meet France's public health priorities, the Fast Track program is open for early phase, paediatrics and rare disease clinical trials.

Thus, for innovative treatments and CT with complex design (Fast Track 1), the instruction timelines is 40 days, up to 110 days for CT with new ATMP. On the other hand, for the CT on drugs already known by the ANSM (Fast Track 2), the instruction period is 25 days for medicinal products and 60 days for ATMPs.

The instruction timelines will be a maximum of 40 or 25 days depending on the type of CT, compared to 60 days currently provided by the regulations for CT with medicinal products. Concerning the ATMP, the instruction time will be a maximum of 110 days or 60 days compared to 180 days (if case of questions) currently provided by the regulations.

Since October 15, 2018, the ANSM has set up two short circuits (Fast Track) in order to reduce the time taken to process clinical trial authorization applications in view of the entry into force of the future regulation. The guiding principle of these circuits is to allow a better preparation of the files so that they correspond to the requirements of quality and safety for the patients.

In the context of these accelerated circuits, documents are made available at :

https://www.ansm.sante.fr/Activites/Medicaments-et-produits-biologiques/Phase-test-dispositif-accelere-d-autorisation-d-essais-cliniques-Fast-Track/(offset)/10

For any questions about clinical trial submission procedures as well as for Fast Track pre-filing requests, a message can be sent to:**questions.clinicaltrials@ansm.sante.fr**

The Fast Track procedure clinical trial dossier is submitted to the usual email address*:* aec-essaiscliniques@ansm.sante.fr (refer to the practical guide for detailed procedures).