Agence nationale de sécurité du médicament et des produits de santé

Information Bulletin

Access to innovative treatments: ANSM maintains its “Fast Track” programme for medicinal products

After a successful test phase, ANSM has decided to maintain its two accelerated circuits for medicinal product clinical trial authorisation (Fast Track). These circuits were established on 15 October 2018 and then extended to Advanced Therapy Medicinal Products (ATMPs) and clinical trials having a complex design on 18 February 2019.

For innovative treatments and clinical trials having a complex design (**Fast Track 1**), the application processing time is 40 days, up to 110 days for clinical trials involving new ATMPs.
For clinical trials involving drugs already known to ANSM (**Fast Track 2**), the application processing time is 25 days for medicinal products and 60 days for ATMPs.

ANSM established the two short circuits (Fast Track) to reduce clinical trial application processing time and **accelerate access to innovation for patients waiting on therapeutic solutions.** This improvement in performance also makes it possible to prepare for the future European clinical trial regulation’s entry into force in France, scheduled for spring 2020. The guiding principle of these circuits is to promote better file preparation so that files meet quality and patient safety requirements.

The Fast Track programme has now been the subject of an evaluation. As of early September 2019, over 40 medicinal product clinical trial authorisations had been filed and processed through the "fast-track" procedure, respecting the Agency's commitment to respond within an accelerated timeframe. The procedure for ATMPs will be evaluated in the last quarter of 2019.

In light of this success and its commitment to promote access to innovation for patients while protecting their safety, ANSM has decided to maintain the Fast Track programme.

Documents pertaining to these accelerated circuits have been made available at:

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

For any questions about clinical trial application submission procedures or Fast Track pre-filing requests, please send an email to:**questions.clinicaltrials@ansm.sante.fr**

Clinical trial application files submitted through the Fast Track Procedure should still be sent to the standard email address: aec-essaiscliniques@ansm.sante.fr (refer to the practical guide for detailed procedures).