ansm
National Agency of Medicine and Health Product Safety

Different management procedures for Category 1 clinical trials of medications

Category 1[1] — ANSM decision + EC opinion

Categories 2 et 3[1] — Submitted for EC opinion + ANSM information

Medecines

ATMP | DM / DMDIV | HPS | Other trials

With the comment "PREC" if the trial is from the "Early phases of clinical trials" unit.
Trials of phase 1 or phase 1-2 (as soon as phase 1 takes place on French territory) performed on healthy volunteers or patients.

Procédures

	Standard	Pilot phase	Fast track[2]		VHP
OBJECTIVES		Strengthened coordination between EC/ANSM	Fast access to innovation		Evaluation coordinated among member states
ACTION PRIOR TO SUBMISSION			**FT1R** (access to innovation with pre-submission meeting) → Preliminary meeting with ANSM 2 to 6 weeks prior	**FT1D** (access to innovation with additional document)	**FT2** (support for development)
TIME PERIOD	< 60 calendar days	36 days without questions or 60 days	21 days without questions or 40 days	21 days without questions or 40 days	14 days without questions or 25 days / 78 days + 10 days (national phase)

EC: ethics committee
ATMP: advanced therapy
DM: medical devices

DMDIV: In vitro diagnostic medical devices
HPS: excluding health products
VHP: voluntary harmonisation procedure

(1) **Category 1** research involving the human person **(RIPH)** according to the Jardé law (art. L. 1121-1 of the CSP): interventional research involving an intervention not justified within the person's usual care. **Category 2 RIPH:** interventional research involving only minimal risks and constraints. **Category 3 RIPH:** non-interventional research involving neither risks nor constraints, in which all actions are performed and all products are used in the usual way.

(2) Eligibility based on defined criteria.

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