ansm
Agence nationale de sécurité du médicament et des produits de santé

Different management procedures for Category 1 clinical trials of Advanced Therapy Medicinal Product (ATMP)

Category 1(1) — ANSM decision + EC opinion

Categories 2 and 3(1) — Submitted for EC opinion + ANSM information

- Medecines
- **ATMP**
- DM / DMDIV
- HPS
- Other trials

Procedures

	Standard	Fast track(2)	VHP
OBJECTIVES		Fast access to innovation and support for development	Evaluation coordinated among member states
ACTION PRIOR TO SUBMISSION		**FT1R** (access to innovation) / **FT2R** (support for development)	
		Preliminary meeting with ANSM 4 to 8 weeks prior CTA submission	
TIME PERIOD	90 calendar days without questions or 180 days	83 calendar days without questions or 110 days	33 calendar days without questions or 60 jours
			108 calendar days + 10 days (national phase)

EC: ethics committee
ATMP: advanced therapy medicinal product
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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