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

**Category 1**  
ANSM decision + EC opinion

** Categories 2 and 3**  
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**

- Preliminary meeting with ANSM 4 to 8 weeks prior to 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

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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.