Different management procedures for Category 1 clinical trials of medications

**Medicines**

With the comment “PREC” if the trial is from the “Early phases of clinical trials” unit.

Trails 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**
  - Strengthened coordination between EC/ANSM
  - FT1R: [access to innovation with pre-submission meeting]
  - Preliminary meeting with ANSM 2 to 6 weeks prior
  - 2 to 6 weeks prior (access to innovation with pre-submission meeting) (support for development)
  - 21 days without questions or 40 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)

- **Pilot phase**
  - Fast access to innovation
  - FT2: [access to innovation with additional document]
  - Evaluation coordinated among member states

- **Fast track (2)**
  - Evaluation coordinated among member states

- **VHP**
  - [support for development]
  - 21 days without questions or 40 days

**OBJECTIVES**

- Strengthened coordination between EC/ANSM
- Fast access to innovation
- Evaluation coordinated among member states

**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)

**ACTION PRIOR TO SUBMISSION**

- ANSM decision + EC opinion
- Submitted for EC opinion + ANSM information

**Categories 2 et 3 (1)**

**Categories (1)**

- ANSM decision + EC opinion
- Submitted for EC opinion + ANSM information

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**EC: ethics committee**

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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.