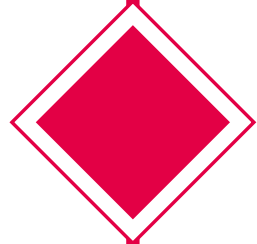
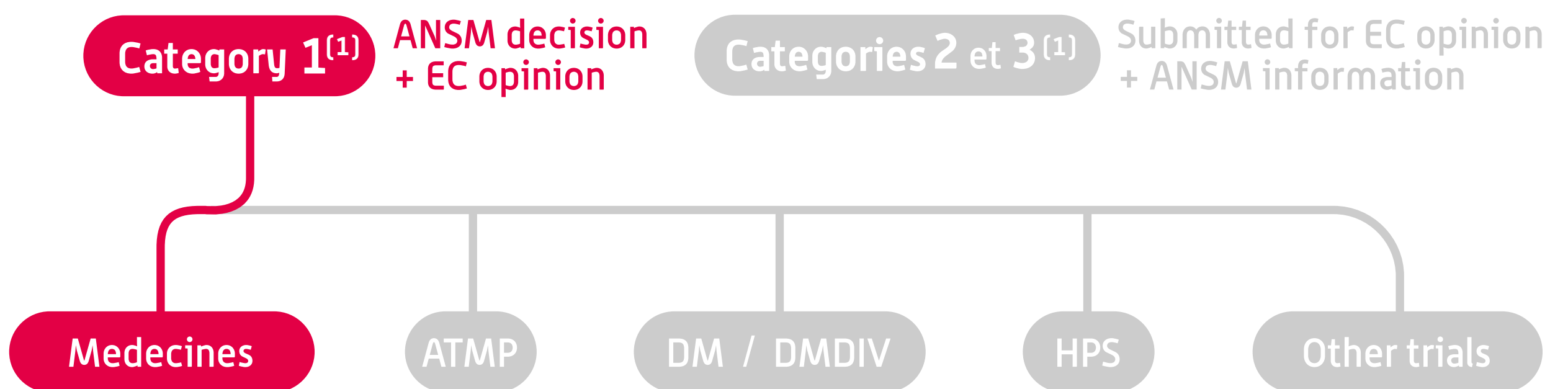


Different management procedures for Category 1 clinical trials of medications



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



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.