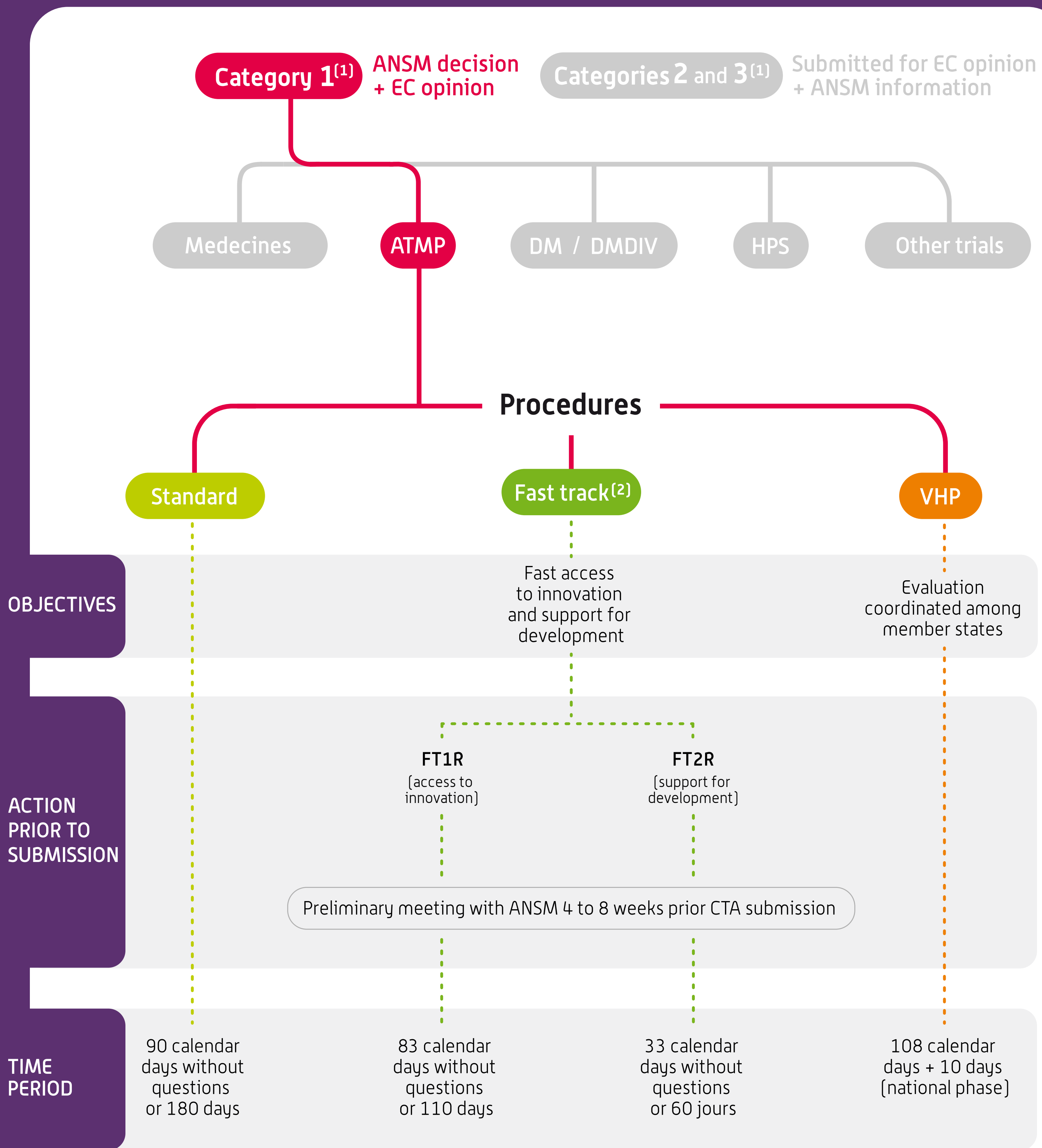


Different management procedures for Category 1 clinical trials of Advanced Therapy Medicinal Product (ATMP)



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.