Reinforcing coordination between scientific advice (SA) and CT approval

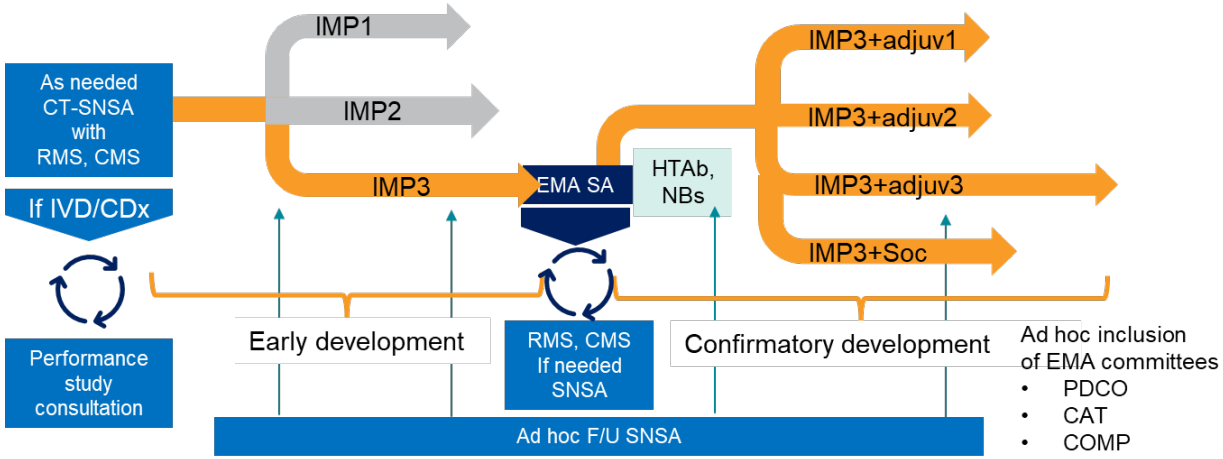
Which changes would enhance the scientific advice activities currently offered and facilitate clinical trial activity in the EU?

Ideal SNSA composition: RMS, CMSs, ECs, patients (as applicable) ad hoc members e.g., NBs, Committees members

Building on coordinated and consolidated SNSA, a **modulated CT-specific SNSA**	Continuum of pre-CTA SA with CTA assessment	Aligment of SNSA countries with RMS, CMS and EMA committees	SA Reliance mechanism for any CMS not partaking in the initial advice
Short timeline (15-30 days) for written only feedback on 2-3 Qs in one area (e.g. CMC, tox) – building on national health authority scientific advice flexibilities	Bridging mechanism of reporting MS (RMS) & concerned MS (CMS) with SNSA participating countries	Especially important for PDCO, CAT, COMP	Might even include the eventual RMS and in the case of additional concerned member states
Normal timelines (60-90 days) when questions in several areas (e.g. CMC & tox & clinical) – from request to meeting or written feedback	Knowlege management system Can include a mechanism to include common questions in CTR Q&A	Legal framework adaptation might be required	SA recognition of prior SA to any CMS/RMS, newly added CMSs

confidential platform for flagging SA needs in advance of CTA filing → Hosted by CTCG?

How can the coordination of advices be improved to ensure that CT design is adequate for CT approval as well as to generate data for future marketing authorisation applications?



- Coordination between SAWP & RMS, CMS is especially needed during confirmatory development phase
- Increased coordination needed for ATMPs, paediatric and orphan developments
- For CTAs with IVDs/CDx, coordination with notified bodies

RMS: reporting member state
CMS: concerned member state
IVD: in vitro diagnostics
CDx: companion diagnostics

Knowledge exchange

SNSA: simultaneous scientific advice
HTAb: heath technology assessment bodies
NBs: notified bodies

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