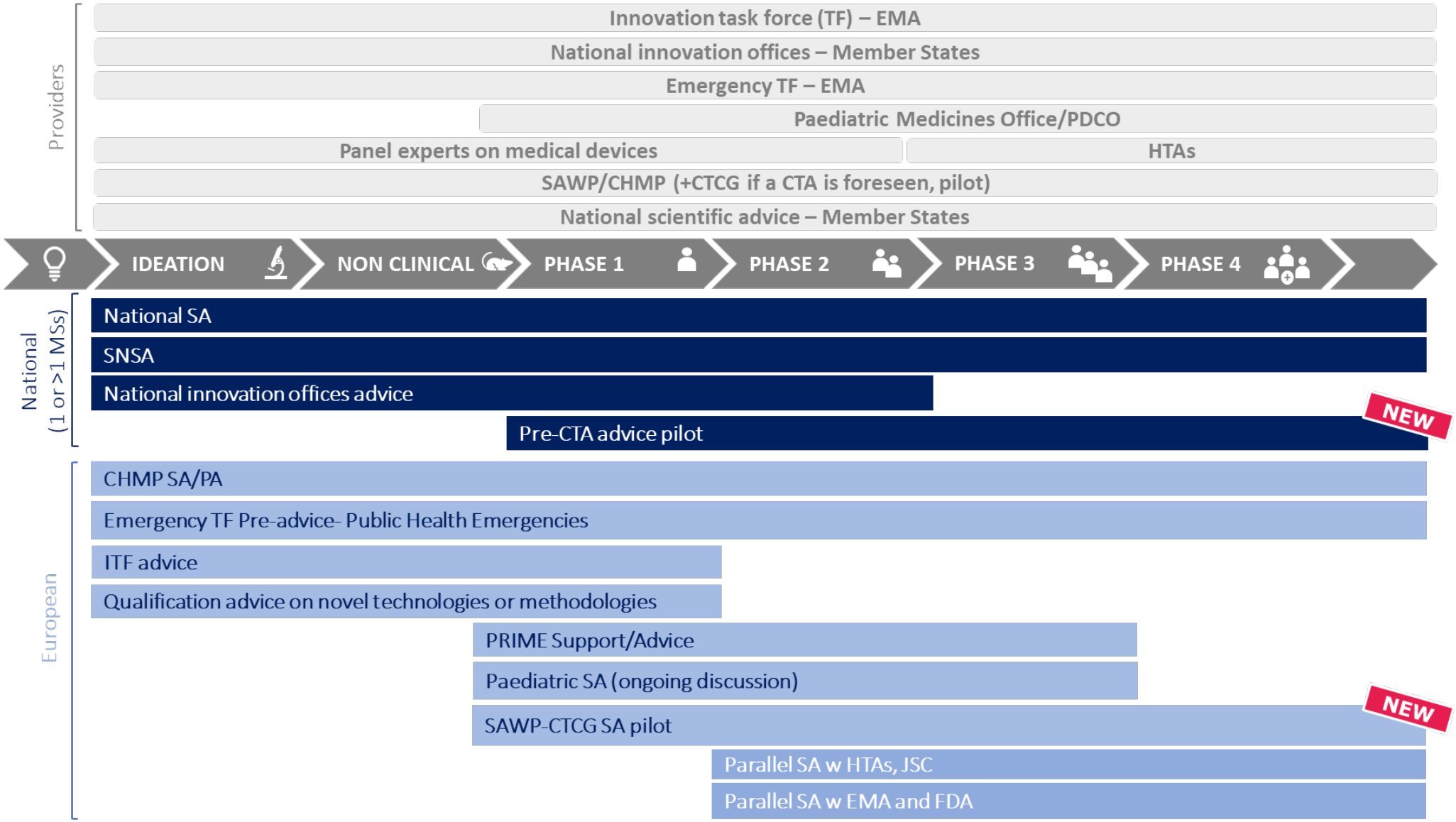
Consolidated advice on clinical trials Industry perspective

ACT EU multi-stakeholder platform annual meeting

22 October 2024

Scientific Dialogue options in the EU



Pre-CTA advice

Improvement implemented	Area	Opportunity for improvement
Regulatory and technical aspects related to clinical trial applications (CTAs)	Scope	Need to wait until we have more experience
Clearly defined criteria for eligibility	Procedure	Explore the possibility of increasing the number of questions allowed (> 5) and establishing discussion meetings in case of complex questions
Predictable and clear procedure timelines (~40d)	Timing	Opportunity to streamline the pre-validation (eligibility check) and validation phase
Participation of several NCAs in the procedure	Participation of stakeholders	Systematic involvement of RMS and all the CMS Ethics committees (ECs) involvement in case of questions related to the Part 2 of the CTA
Consolidated view of Member States as output	Outcome	Ensure distribution of the final position to all MSs for consideration when reviewing the CTA

SAWP-CTCG scientific advice

Improvement implemented	Area	Opportunity for improvement
Scientific advice on clinical trials and on requirements for marketing authorisation applications	 Scope	Need to gain more experience from the pilot Combined studies?
Same process as CHMP/SAWP advice (i.e. a longer procedure is not foreseen)	 Procedure	Need to gain more experience from the pilot Explore the possibility of reducing the validation phase
Involvement of CTCG/CTA assessors from all MSs (?)	 Participation of stakeholders	Systematic involvement of RMS and all the CMS Allow involvement of Ethic committees and Notified Bodies when necessary Involvement of PDCO representatives for paediatric CTs
Consolidates the views of SAWP (responsible for advice on MAAs) and the MSs represented at CTCG (that oversee CTAs) to minimise avoidable divergences	 Outcome	Recognition of advice by all entities involved in CTs

Key Takeaways

What is improved if pilots are implemented permanently?

- ✓ **Scientific consistency in the decision-making process**: More coordination in scientific decisions taken by different actors (EMA Committees, NCAs, ECs, etc.)
- ✓ **Optimization of procedures**: the anticipation and resolution of possible problems can streamline the procedures for CTs application, evaluation and authorization
- ✓ **Increase in scientific dialogue** between regulators and sponsors in EU

What are we still missing?

- Further progression of discussions aimed at solving problems with CTR implementation
- Securing adequate resources from the network
- Multi-stakeholder SA for combined studies/combination products
- A detailed reflection on the scope of SA for paediatric developments