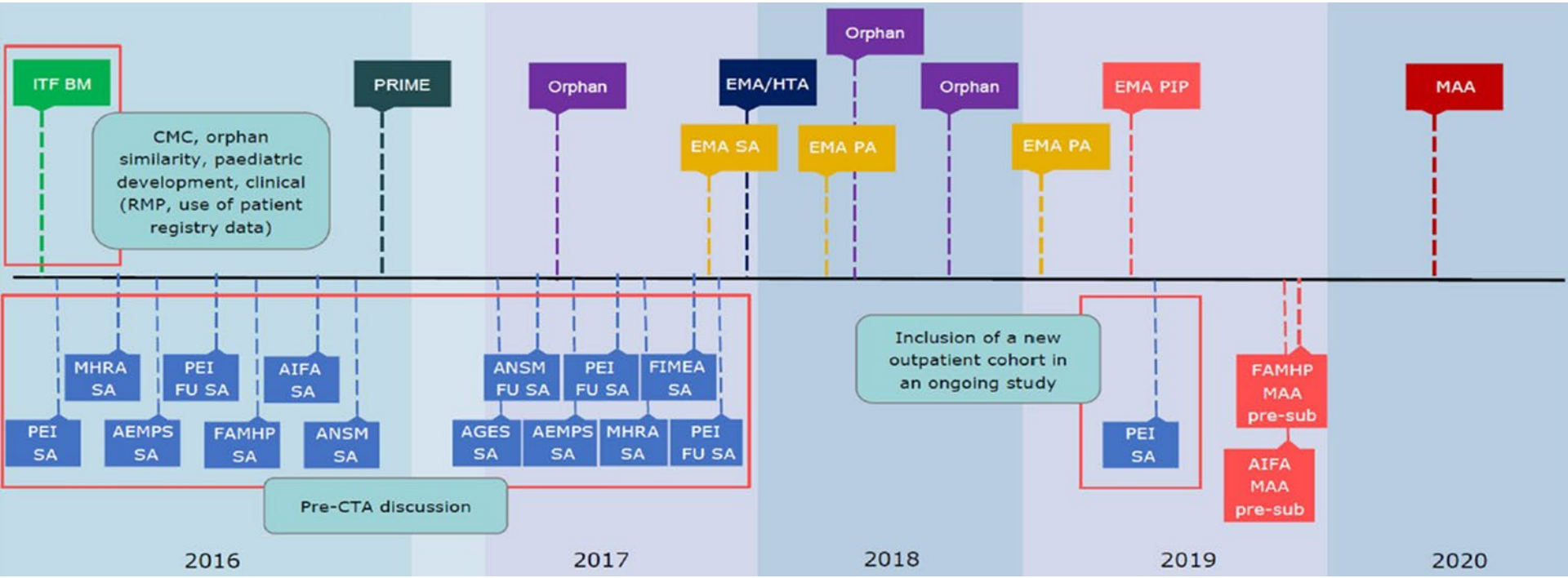
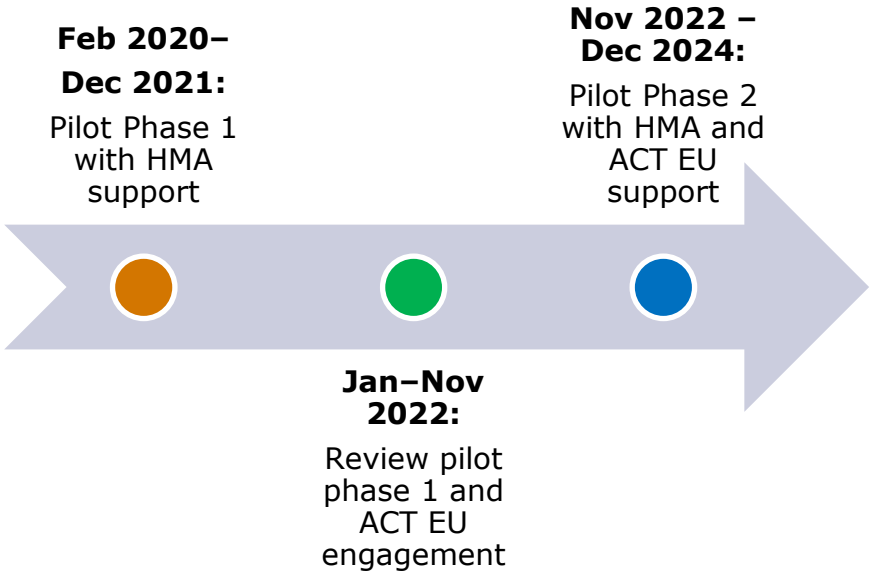
Simultaneous National Scientific Advice (SNSA)

ACT EU multi-stakeholder platform kick-off workshop
23 June 2023
Presented by: Larry O'Dwyer (Co-chair EU Innovation Network)

Use of supports during product development / Target of SNSA



Evolution of SNSA

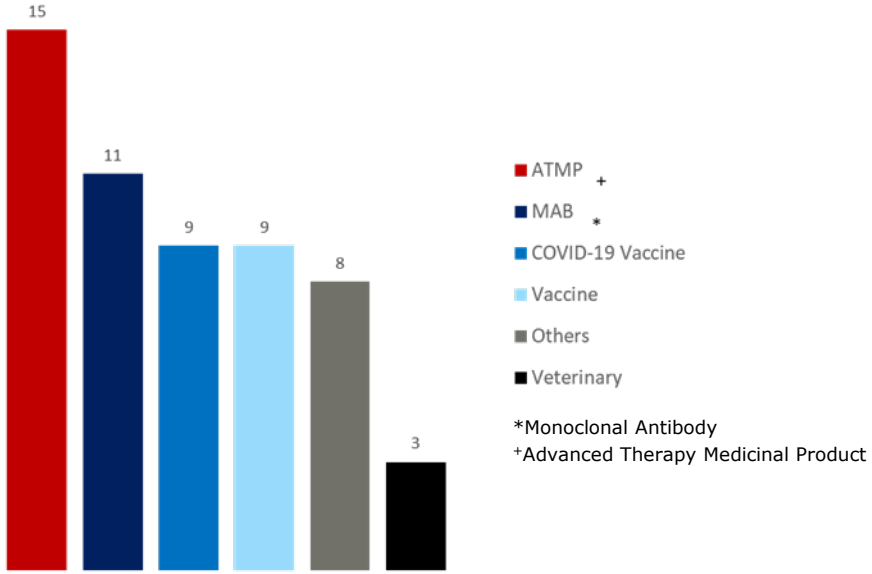


Scope

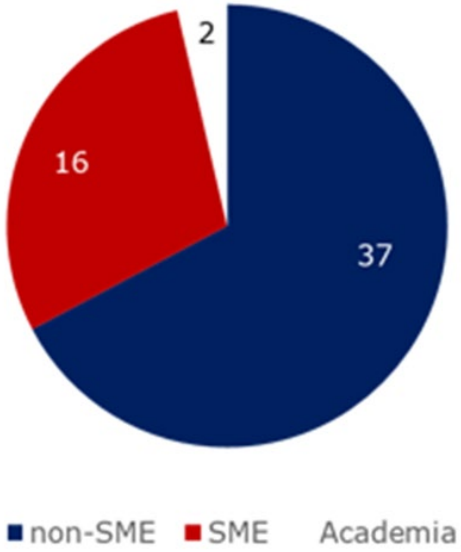
- Scope aligned with national SA
- Can be used to obtain advice from an early stage of development
- Specific emphasis in Phase 2 on SA related to CTs and encouraging additional use of SA by academia / SMEs
- Complements other available advice e.g. EMA SA

SNSA procedures (total 55 including 16 to date in phase 2)

Product Type



Type of applicant



Focus of advice: mainly (early) clinical stage

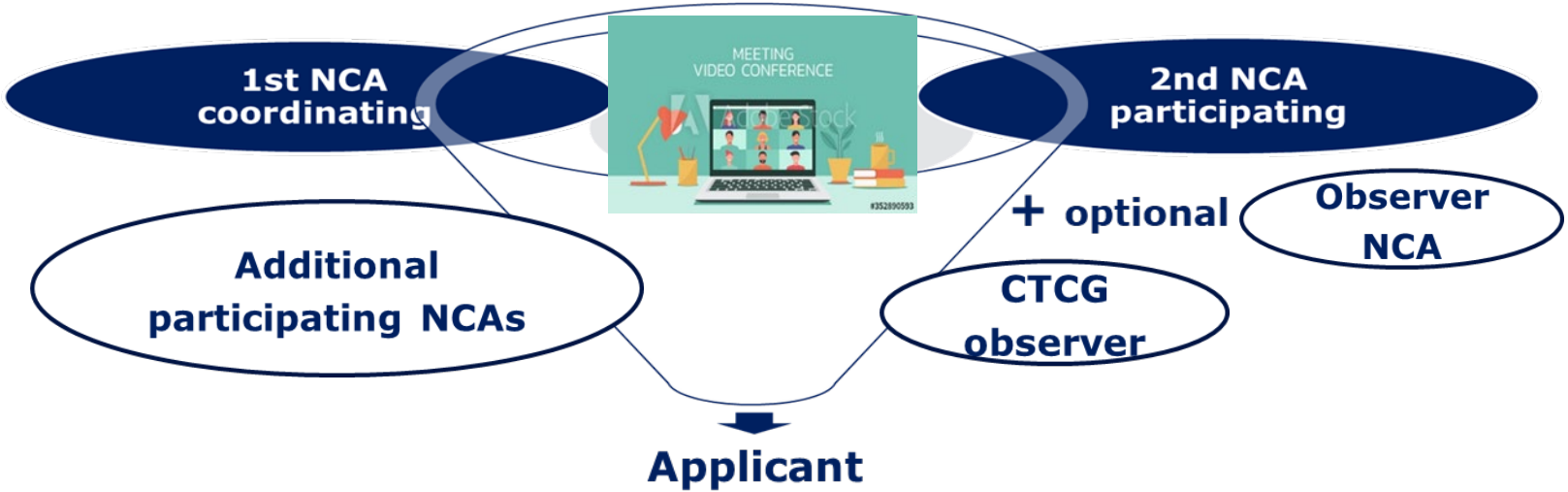
SNSA – Participating NCAs

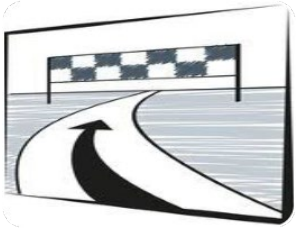
No.	Member State*	National Competent Authority	Leading/ participating NCA	Observer Role
1	Austria	AGES	X	
2	Belgium	FAMHP	X	
3	Czech Republic	SUKL – Czech Republic	X	
4	Denmark	DKMA	X	
5	Finland	FIMEA	X	
6	France	ANSM	X	
7	Germany	PEI	X	
8	Hungary	OGYEI	X	
9	Ireland	HPRA	X	
10	Italy	AIFA		X
11	Netherlands	MEB+	X	
12	Netherlands	CCMO+		X
13	Norway	NOMA	X	
14	Poland	URPL	X	
15	Portugal	INFARMED	X	
16	Sweden	MPA	X	
17	Spain	AEMPS	X	

*Basis=EEA;
+The Medicines Evaluation Board (MEB) is the Dutch competent authority responsible for assessing medicinal products (eg. scientific advice, marketing authorisation applications) and for monitoring the risk of medicines for human use, and for promoting the proper use of medicines. The MEB is however not responsible for the evaluation of clinical trials applications.
The Central Committee on Research Involving Human Subjects (CCMO) is the Dutch competent authority responsible for the evaluation of clinical trial applications.

NCA participation on opt-in basis per procedure

SNSA Procedure - outline





- Single entry point (SNSA@pei.de), common application form & briefing book. Existing national fees apply.
- Agreed process and predictable timetable set at the start of the procedure with flexibility under special circumstances
- Clearly documented outcome of position of each NCA in meeting report

Opportunities with SNSA

- Consolidated advice from > 1 NCA which facilitates convergence
- Clarification of NCA requirements for novel / complex issues – potential for consideration by CTCG
- Flexible format that can be adapted where appropriate
- Facilitate subsequent multi-national CT applications
- Early identification of challenges / critical issues that require further consideration (e.g. via EMA SA)

Further Information

- Further information available at:

  https://www.hma.eu/about-hma/working-groups/eu-innovation-network-eu-in/eu-innovation-network-eu-in.html
- Updated procedural guidance will be published in coming weeks
- For any queries please email: snsa@pei.de