EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Early paediatric interaction meeting

Initial consultation on paediatric development

Early interaction meeting – What is it?

- It takes place in the early phase of drug development
- It focuses on overall development strategies
- To discuss potential paediatric needs and scope of development for paediatrics
- Not intended for evaluation of data to support PIP application

Early interaction meeting – Benefits

- It takes place at an early stage of product development
  - ✔ Early planning
  - ✔ Optimise resources
- Possibility to discuss global approach to paediatric development and timelines
  - ✔ Integrate with adult development
  - ✔ Avoid unnecessary studies in children
  - ✔ Early discussion on possible extrapolation
  - ✔ Early discussion on appropriateness of waiver
  - ✔ PIPs more likely to meet children's needs and PDCO requirements

Early interaction meeting – Applications from June 2015

- Received: 15
- Accepted: 4
- Different framework: 1
- Under discussion: 2
- Withdrawn: 2
- Declined: 6

Early interaction meeting – What's next

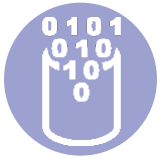
- Applications accepted until end of June 2016
- Review at the end of pilot phase considering feedback from all participating parties

Goal & Scope

To foster the development of ***medicines with high public health potential.***

Reinforce scientific and regulatory advice

- *Foster and facilitate early interaction*
- *Raise awareness of requirements earlier in development*



Optimise development for robust data generation

- *Focus efficient development*
- *Promote robust data generation*

Enable accelerated assessment

- *Promote generation of high quality data*
- *Facilitated by knowledge gained throughout development*

Building on existing framework;

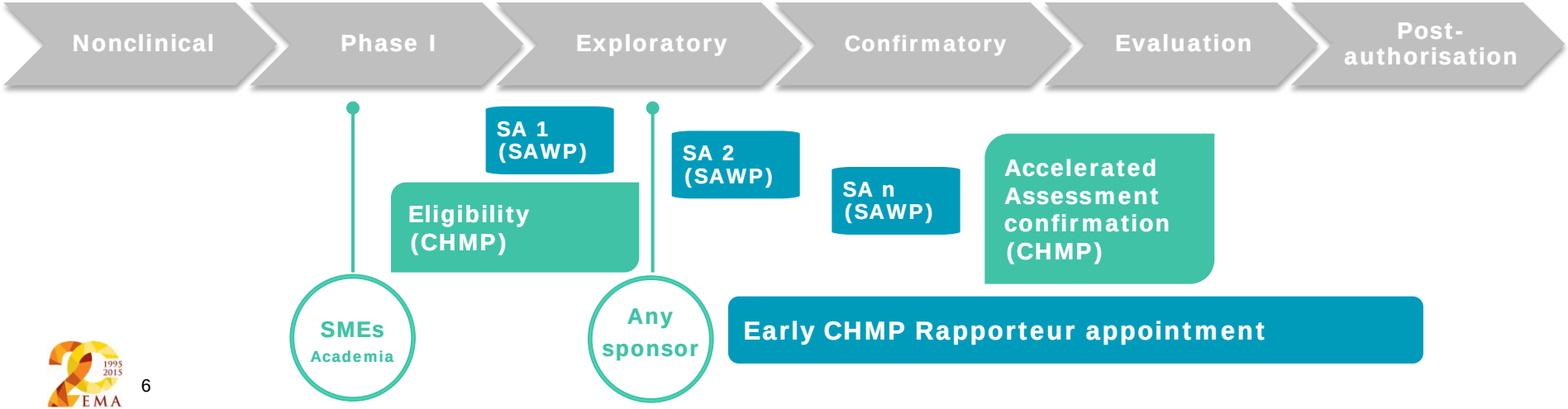
Eligibility according to existing ***Accelerated Assessment criteria****.*

Overview of PRIME scheme

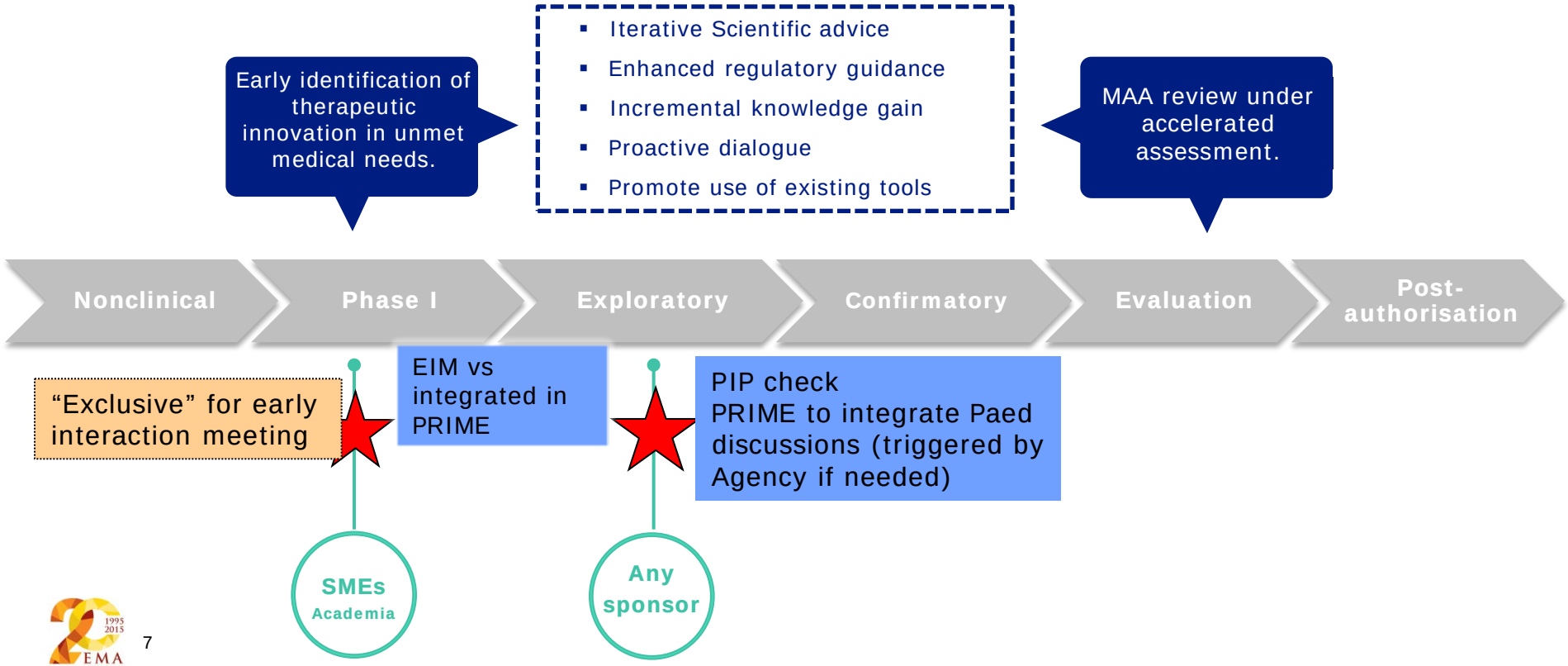
Early identification of therapeutic innovation in unmet medical needs.

- Iterative Scientific advice
- Enhanced regulatory guidance
- Incremental knowledge gain
- Proactive dialogue
- Promote use of existing tools

MAA review under accelerated assessment.



Overview of PRIME scheme



Thank you for your attention

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Difference between early interaction and pre-submission meetings

Pre-submission

- It takes place shortly before submission of PIP application
- Intended to ensure a smooth validation
- Pre-assessment of the scientific documents is not the aim of this meeting

Early interaction

- It takes place at an early stage of product development
- To discuss global approach to paediatric development and timelines
- To discuss scientific issues related to paediatric development