EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PRIME: Implementation of recommendations based on first 5 years' experience with the scheme: progress update

9th R&D Industry stakeholder platform meeting

Presented by Kevin Cunningham (Francesca Cerreta)

Identified areas for implementation – 8th R&D Industry Platform – July 2022

- Revised entry point(s) for PRIME
- Roadmap of regulatory interactions & development tracker
- Continuity and flexibility of SA
- Submission readiness meeting

Development tracker

Development tracker

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Pragmatic approach

- Focus on information linked to action
- Ease of access and update

- **Submitted by company**. Saved by EMA in IRIS. Content ownership: company.
- When: **updates critical to development & evidence generation.** Less critical information also cumulated at the same time.
- First column= highlights new information, the rest records the status of earlier submissions. Earlier versions retrievable in SharePoint (Rapporteur+EMA).
- Tracks critical development areas (**not all areas will be applicable to all products**, specific areas can be added)
- **Blueprint for development roadmap**: KOM-> regulatory interactions SA PIP OD ITF-> Submission readiness meeting
- **Gantt chart** of planned global regulatory interactions. Format chosen by the company

New in this update: For information or normal SA planned Feedback needed Rapid advice sought	**Area**	**Summary of the topic (brief description)**	**Milestones**	**Impact on B/R** Low Med High	**Company Observations**	**SA planned/advised** (target date if known)	IRIS case number of previous **SA/PIP/ OD/ ITF** on the topic
	I. QUALITY						
	Stability						
	Specifications	*<clarify which specifications, additional lines if necessary>*					
	Manufacturing issues and process controls						
	Comparability (changes to manufacturing process / site)						
	GMP Issues						
	Other (specify)						
	NONCLINICAL						
	Carcinogenicity						
	Reprotox/Germ line integration						
	Animal model						
	Chronic toxicity						
	Immunotoxicity						

Development tracker

Pilot (1 year):

- Planned to commence Q1 2023
- basis for KOM, SA interactions; submission readiness
- Revise/enhance post-pilot

Proposed **metrics** (draft):

- How many times accessed/updated, by whom
- Questionnaires Cy/Rap- usefulness, user friendliness, suggested changes

Flexibility of SA

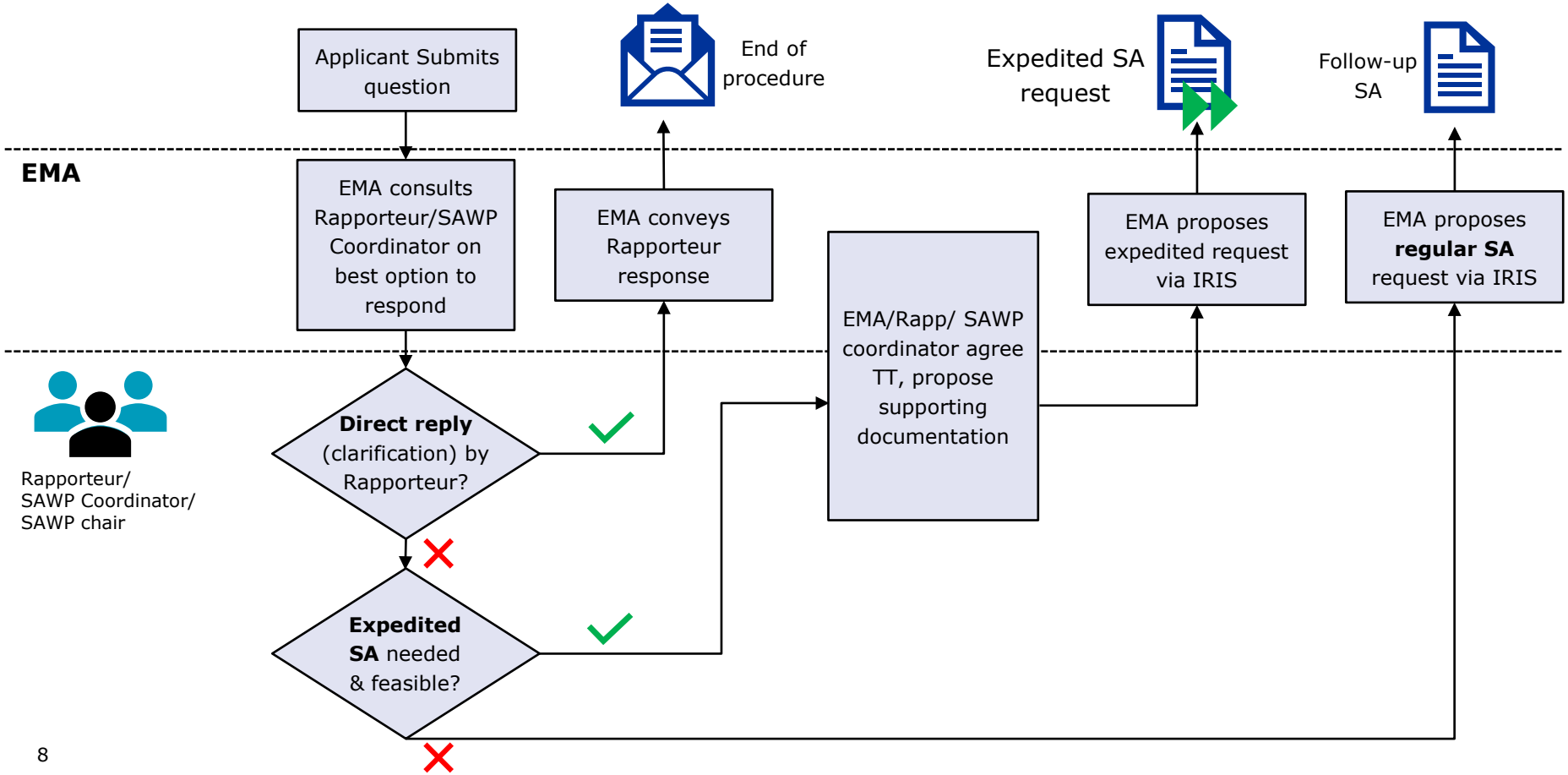
Agreement on continuity and flexibility of scientific advice

1. Strengthen the involvement of the **SAWP Coordinator from the Rapporteur delegation** in SA requests (by means of increase predictability of SA requests through **roadmap of regulatory interactions**)

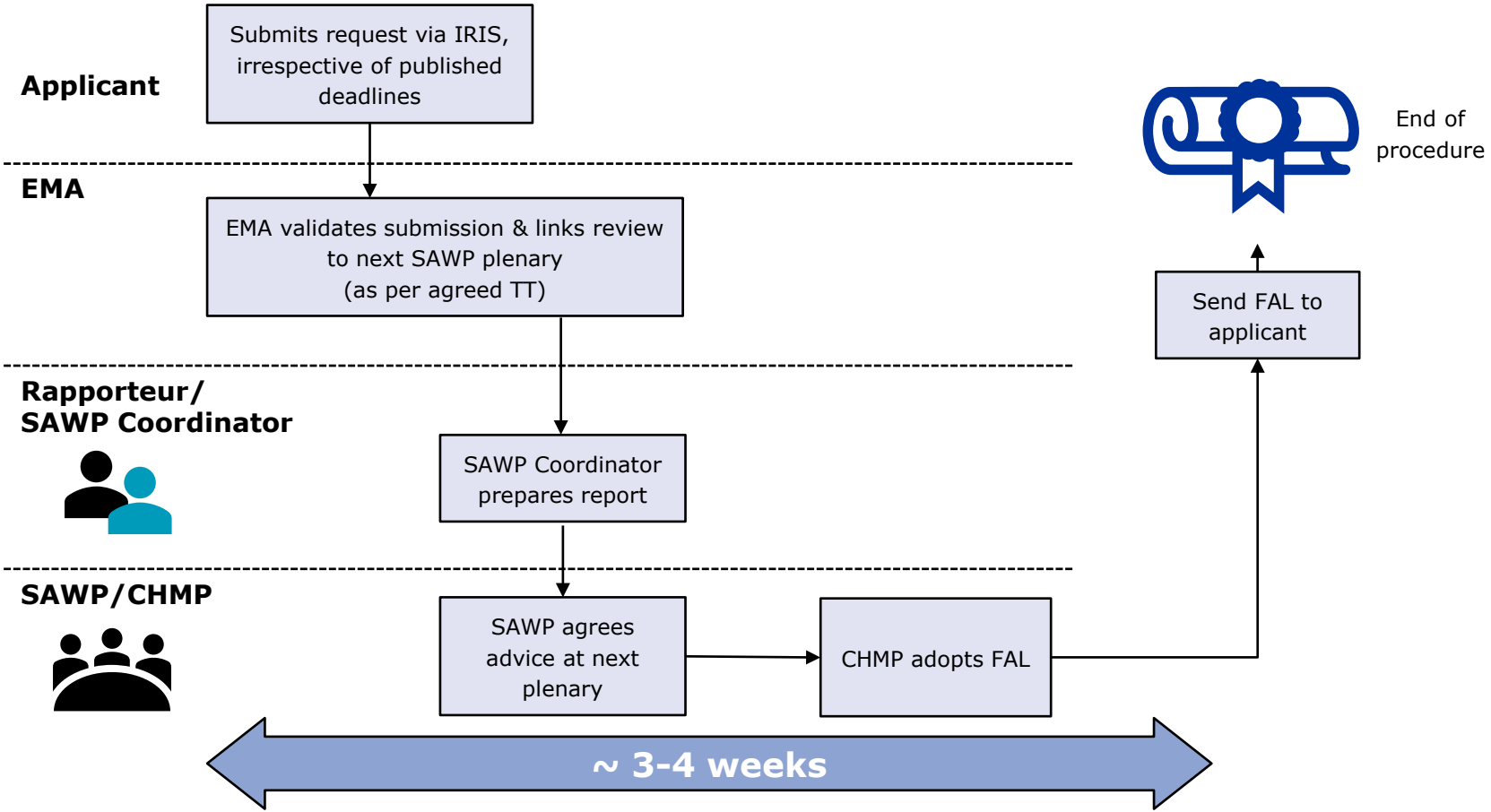
2. Explore **flexible approaches to address queries** from PRIME applicants depending on nature & urgency of the query

   - Primary contact for company requests remains EMA
   - EMA to discuss Rapporteur/SAWP Coordinator to explore
     - if issue can be addressed directly by the Rapporteur **(*clarification*)**
     - if too complex for clarification by Rapporteur or requiring network input → **scientific advice**
     - **expedited advice procedure** for issues related to a **previously discussed development program**, with a **clearly-defined scope**, that is **urgent/critical**
   - Updated public guidance, initiate 1 year pilot Q1 2023

Expedited SA procedure: Decision path



Expedited SA procedure: Outline II



Submission readiness meeting

Submission Readiness meeting: Objectives and Scope

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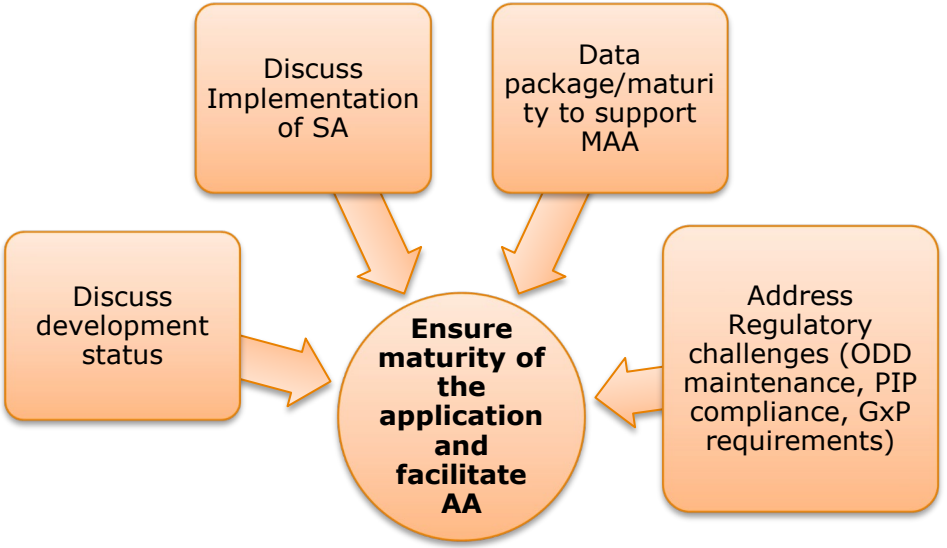
More than 50% PRIME MAAs start as AA but revert to standard TT

SA non-adherence rarely fully justified → MOs/OCs, delays at MAA [average of 4.2 MOs per MAA LoQ (range: 1-10)]

Industry and regulator surveys: strengthen engagement in the period between KOM and MAA



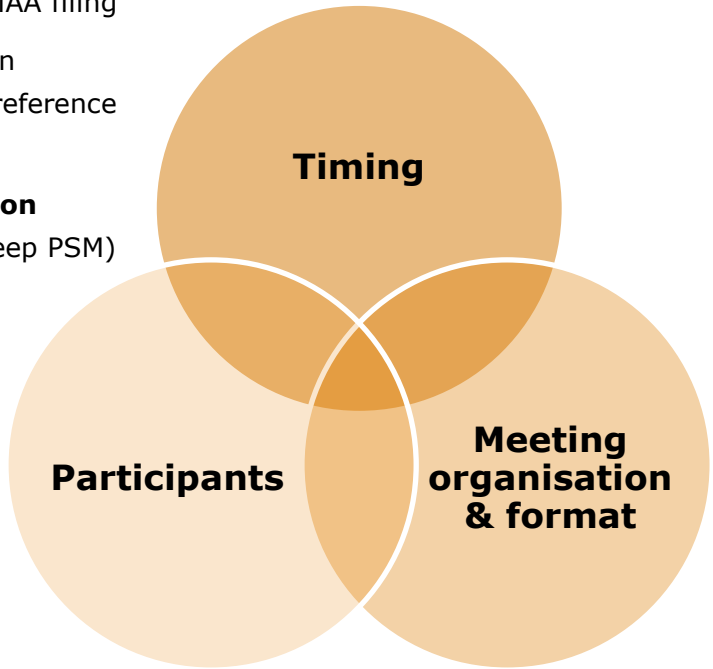
Readiness meeting - Other aspects

- **1 year to 9 months** prior to MAA filing
- Allow some **flexibility** based on applicant's and Rapporteur's preference and type of development

- Could **replace need for pre-submission meeting** (unless Rapp preference to keep PSM)

- **Participants as per KOM**[*)], i.e. Rapporteur team, CHMP vice chair/CAT chair, SAWP chair, additional experts (COMP, PDCO), EMA product team

[*)] to be potentially expanded in the future once network capacity allows



- Organisation of meeting: **virtual/remote**
- **Chair/Lead**: Co-chairing with support from EMA

- **Duration: 2h**
- **'Internal' preparatory meeting**: Separate in advance of meeting; duration (1h)
- Agenda management as per KOM based on **agenda template**
- **Supportive documentation** – briefing book, draft RMP if available, draft AA request if data available, other documentation (e.g. IMPD) if/as needed

Any questions?

Further information

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