EMA
EUROPEAN MEDICINES AGENCY

Pre-Submission **I**nteractions **G**roup – PreSIG

Proposal to pilot a revised pre-submission interaction model

Industry stakeholder platform meeting - 15 June 2026

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Agenda

- What is PreSIG?
- PreSIG’s objectives
- PreSIG’s proposal for a revised pre-submission interaction (PSI) model
- PreSIG ongoing work and next steps
- Pilot phase

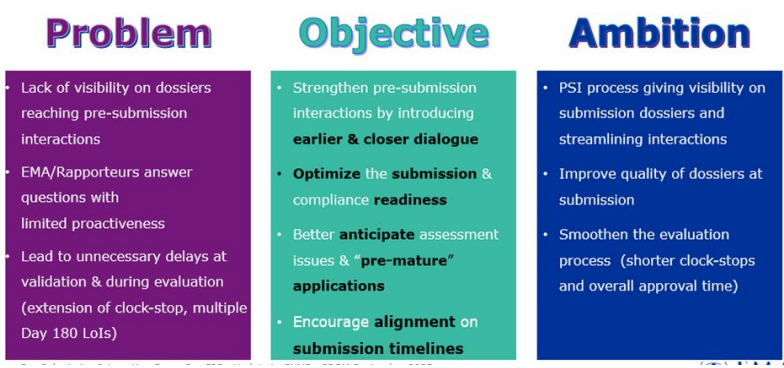
What is PreSIG?

- Joint Committee-EMA–Industry working group
  - 7 CHMP & CAT members (incl. Chairs)
  - 9 industry representatives (EFPIA, EUCOPE, Europa Bio, SME and larger companies)
  - 5 EMA staff

- Created in January 2025 to re-think Pre-Submission Interactions (PSI) for initial MAA
  - Lack of visibility on upcoming applications
  - Pre-mature applications
  - Submission timelines and multiple delays

- Work in 2025–26: several meetings, brainstorming & presentations including CHMP/CAT/NCAs

PreSIG objectives

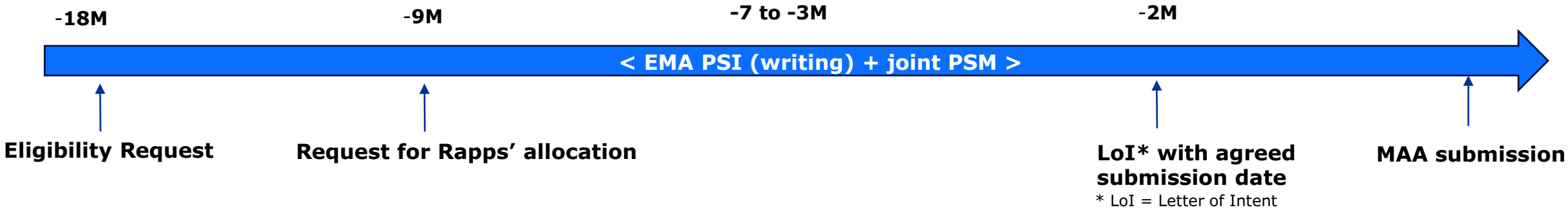


- ❑ Introduce an earlier and more comprehensive dialogue to strengthen PSI
- ❑ Expected outcomes
  - ➢ Optimize the submission readiness
  - ➢ Identify "pre-mature" applications & assessment issues
  - ➢ Encourage alignment on submission timelines

Why investing more in PSI?

- ❑ Improve dossiers quality at submission
- ❑ Give a better predictability on submission timelines
- ❑ Smoothen the evaluation process (shorter clock-stops and overall assessment time)
- ❑ Regulatory driver : upcoming New Pharmaceutical Legislation
  - ➢ Art 5 :".. applicant shall agree with the Agency the submission date *of a MAA."*

PreSIG proposal for a revised PSI model



- ❑ Request for appointment of the Rapporteurs @-9M (2M earlier than in current process)
- ❑ Followed by PSIs
- ❑ LoI* submission @-2M (latest) with agreed submission date
  - ➢ **Shared ownership between the applicant, Rapps. and EMA on submission timing -> Enhanced planning visibility**
  - ➢ **Schedule incorporates flexibility to absorb timelines shift**
    - ○ Companies with late data availability shall be encouraged to target late joint PSM (data-driven PSM)

✓ Model agreed with CHMP and EMA upper management: Full support for running a pilot phase on the revised model

Revised PSI model vs. current one

Revised PSI model	**Current PSI model**
Rapps. allocation and PSI before LoI -> allow informed discussion on submission date	LoI triggers rapps. allocation followed by PSI -> no/limited information to discuss on submission date
Single joint PSM (Rapps./EMA/applicant)	Multiple PSM formats
Targeted submission-readiness questions and guidance in EMA written PSI and joint PSM	No or limited submission-readiness questions in both EMA written PSI and PSM
Agreement on submission date during PSI	No agreement on submission date during PSI

LoI: letter of intent; PSM: pre-submission meeting ; PSI: Pre-submission Interaction

PreSIG - Ongoing work & Next steps

- Revision of the existing EMA PSI form to support written interaction with EMA, including enhanced applicant guidance and questions on procedural, compliance, and regulatory affairs aspects

- Creation of a list to support all participants in the preparation for the joint PSM and facilitate identification of topics for discussion -> covers relevant quality, nonclinical and clinical aspects to be addressed in the briefing package
  - Identify “premature submissions” requiring substantial new data submission during the review
  - Support agreement with the applicant on the submission date
  - Facilitate a smooth evaluation process and minimize the need for clock-stop extensions

- Creation of a Guidance on the new model to support participants in the pilot
- Pilot phase preparation, including KPIs definition to measure success & need for refinement

  - PreSIG members involved in the review of all forms & guidance
  - Documents available before pilot launch to all stakeholders on EMA website

Revised PSI model – High level process flow

1. Applicant requests appointment of the Rapporteurs @-9M
   - *by* submitting an annex named: " *Status of development for product <XX> at the time of the request for the appointment of Rapporteurs - i.e. the existing annex of current Letter of Intent*

2. Applicant initiates PSI in writing with EMA @ ~6M
   - By submitting the revised EMA PSI form -> submission as usual no change

3. Applicant schedules a joint PSM & submits a briefing package addressing relevant points from the joint PSM list
   - During the joint PSM, the Rapporteurs give a feedback on the dossier completeness and the proposed submission date
   - Either agreement reached during PSM or follow-up exchange to be considered thereafter

4. Applicant submits their LoI @ -2M with the agreed date
   - If the date differs from the initially intended date declared at eligibility, no penalty applies - Penalties apply only for changes to the date specified in the LoI

Pilot phase – Timing, Duration, Eligibility and Participation Criteria

Work in progress

- Timing: After the summer (Sept target) - Duration: minimum of 18 months
- Eligibility: All products and type of applications are welcomed
  - NAS, KAS, Biosimilars, Generics, Hybrids, ATMP for all types of MA applied for (full MA, CMA, etc.)
- Participation criteria: time
  - Applicants planning for MAA submission **from Jan/Feb 2027** are eligible to participate in the pilot
    - In practice: applications with intended EMA PSI in writing in Sept/Oct followed by joint PSM in Nov/Dec
    - These 1st products in pilot will have completed Rapporteurship allocation in the current PSI model
  - The pilot will accept expressions of interest on a rolling basis – no pre-set numbers of applications defined
- Communication to raise awareness: EMA website, outreach to industry associations and contact applicants whose applications are scheduled from Jan 2027, suggestions are welcome
  - A numbers of Rapporteurs/NCAs have already expressed interest in participating

Thank you