EMA
EUROPEAN MEDICINES AGENCY

Pre-**S**ubmission **I**nteractions **G**roup – PreSIG

Pilot phase update

Revised pre-submission interaction model

Industry stakeholder platform meeting - 20 November 2026

Thomas Castelnovo – Head of therapies for Immune and Inflammatory diseases



Agenda

1. Status against what we announced in June
2. JCA scope declaration moves earlier in the pilot
3. Pilot participation – Applicants enrolled
4. Why applicants declined and who enrolled
5. Flexibility built into the pilot
6. Next steps

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Status against what we announced on 15th June

Pilot phase – timing, documents and outreach as of 6th November

Item	Announced in June	Status
Pilot launch	Target September; minimum duration of 18 months	*Launched in September; web announcement:* Pre-submission interactions model pilot
Revised EMA PSI form	Enhanced applicant guidance and questions	*Published in September*
Joint PSM list - EUSTART	Quality, nonclinical and clinical topics for the briefing package	*Published in September*
Guidance on the new model	Support for pilot participants	*Published in September*
Outreach	Direct outreach to applicants, inviting them to join the pilot	*Proactive contacts from Sept - ongoing*
KPIs	Defined to measure success and need for refinement	*Finalisation of KPIs ongoing*

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JCA declaration moves earlier in the pilot

Declaring products in JCA scope to the HTA Secretariat (Oncology & ATMP from Jan 2025; orphan medicines from Jan 2028)

Current process

Declaration at LoI stage (-7months)

Pilot

Request for Rapporteur appointment (–9 months)

–9 months
Rapporteur appointment: declare JCA scope

–2 months
LoI: confirm agreed submission date to HTA Secretariat

MAA
submission

- Pilot annex “Status of product development ” updated to remind applicants to inform the HTA Secretariat when the application falls within the JCA scope
- Applicants will confirm the agreed submission date to the HTA Secretariat at LoI stage

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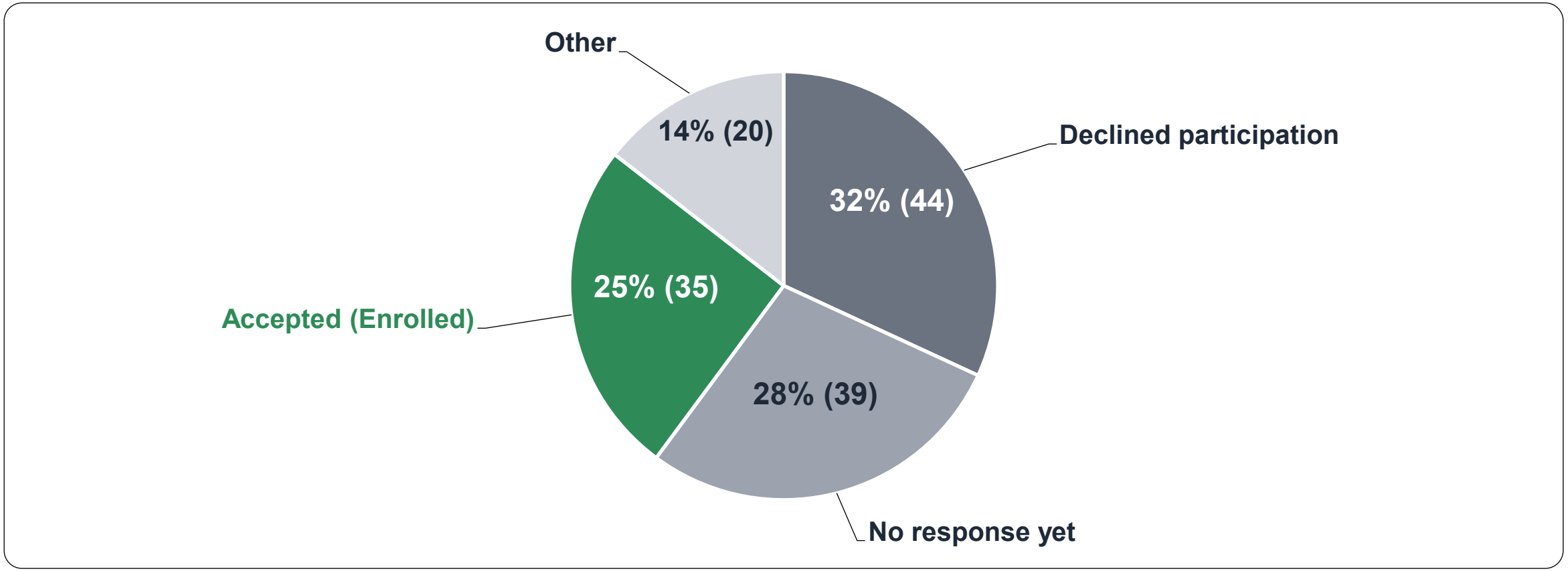
Pilot participation: 25% of contacted applicants enrolled (n=138)

Outcomes for applicants contacted up to 6 Nov 2026 to participate in the pilot for applications planned until Q4-27



Other (14%): Will confirm later 9 · Application withdrawn 6 · Wrong contact details 5

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Why applicants declined and who enrolled

Reasons for declining (n = 44)

Primary reason	n	%
Submission delayed or timeline not defined	9	20%
No reason given	9	20%
Data or information not available in time	8	18%
Existing or already planned interaction	8	18%
No specific topics or perceived need	5	11%
Resource constraints, competing priorities	4	9%
Declined by the Rapporteur	1	2%

Timing-related reasons (data availability or delayed submission) account for 17 of 44 declines (39%).

One primary reason per applicant. Percentages rounded.

Enrolled applicants (n = 35)

Category	n	%
Eligibility basis (Art. 3, Reg. (EC) 726/2004)		
3(1) Ind. 4 – Orphan medicinal product	10	29%
3(2)a – New active substance	5	14%
3(1) Ind. 1 – Biotech medicinal product	5	14%
3(1) Ind. 3 – NAS, mandatory CP indication	4	11%
Art. 31 Reg. 1901/2006 – PUMA	4	11%
3(3) – Generic / hybrid	3	9%
3(2)b – Innovation or patient interest	3	9%
3(1) Ind. 1a – ATMP	1	3%
Company type		
SME (7)	1	3%
Non-SME	34	97%

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Flexibility built into the pilot

What EMA offers applicants joining the revised PSI model

Open to all products and company sizes

New and known active substances, biosimilars, generics, hybrids and ATMPs, for all types of MA (full MA, CMA, etc.)

Rolling participation

Expressions of interest accepted on a rolling basis, with no pre-set number of applications

Flexible PSI milestones -7 to -3M

Indicative timing, not strict dates: the window we expect to work best to optimize planning visibility & submission readiness

Data-driven exchange

Late data availability: target a later joint PSM; follow-up possible if no agreement on submission date at the PSM

LoI submission date

Expected around 2M before submission. A later LoI can be considered, to be agreed with the Rapporteurs. Earlier LoI possible

Testing the limits

- A later PSM (or LoI) date can be accommodated as a documented case, as long as it stays within a reasonable margin of the indicative timing, to learn together how the model can flex
- Trade-off: a PSM close to submission leaves little time to act on the advice, and serious issues raised late can affect the submission date & predictability

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Next steps

Continuing the pilot

- ❑ Keep expressions of interest open on a rolling basis
- ❑ Continue outreach to applicants planning MAA submission until at least Sept 2028
- ❑ Finalise & monitor KPIs and collect feedback from applicants, Rapporteurs and EMA
- ❑ Learn from the analysis & refine the model, update guidance and documents as needed

Get involved

Planning an MAA submission between February 2027 and September 2028? Please contact us if you would like to join the pilot. Your experience and feedback will help us improve the model.

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Thank you

Questions & Answers

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