EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Biotech Hub and Technology Transfer Offices (TTOs) Engagement Workshop — Draft agenda

16 Sep 2026, 09:30 – 16:30 (CEST)
Hybrid meeting/ EMA, Amsterdam

Background and objectives

This stakeholder workshop will bring together representatives of biotech hubs, Technology Transfer Offices (TTOs), innovation intermediaries, EMA, the European medicines regulatory network and the European Commission. It aims to raise awareness of existing EMA and network support available for early-stage medicine development and to help hubs and TTOs signpost developers towards the appropriate established route.

The workshop also provides an opportunity to discuss how EMA, the European medicines regulatory network, biotech hubs and TTOs can improve regulatory literacy and the clarity of signposting information, and how recurring, cross-cutting clarification needs may be captured and considered through existing channels.

The workshop supports the European Medicines Agency's Network Strategy to 2028 (EMANS 2028) and responds to needs identified through mapping and initial outreach with biotech hubs, TTOs and related innovation intermediaries.

Expected outcomes of the workshop

- Improve awareness of relevant EMA and European medicines regulatory network support available for early-stage medicine development.
- Improve understanding of when different established regulatory support routes may be relevant, including routes through which developers may seek product-specific interaction.
- Help biotech hubs and TTOs provide accurate first-line orientation and signposting without acting as regulatory advisers.
- Identify recurring, cross-cutting clarification needs and areas where existing information or signposting materials could be clearer.
- Inform proportionate factual follow-up through existing EMA and European medicines regulatory network structures.

Participation

Participation in this stakeholder workshop is by invitation only.

EMA Biotech Hub and Technology Transfer Offices (TTOs) Stakeholder Engagement Workshop — Draft agenda

16 Sep 2026, 09:30 – 16:30 (CEST)

Chaired by: Sebastian Asprella (EMA) | Strategic co-chair: Emmanuel Cormier (EMA)

09:20 Joining and technical checks – 10’

09:30 Welcome, strategic framing and EU context

Contributions

Welcome and strategic framing — 5’: Emmanuel Cormier (EMA)

High-level reflections on EMA engagement with biotech hubs and TTOs — 5’: Steffen Thirstrup (EMA)

EU biotech and health-policy context — 5’: Fabio D'Atri (European Commission, DG SANTE)

Research and innovation ecosystems: supporting the transition from research to medicine development — 5’: Anna-Pia Papageorgiou (European Commission, DG RTD)

Workshop objectives, scope and working method — 5’: Sebastian Asprella (EMA)

Transition — 5’

Session objective

Set the strategic and policy context, explain the distinction between the scope of the workshop and the established regulatory support routes being presented, and clarify the intended outputs and working method.

10:00 What we have heard from biotech hubs and TTOs

Contributions

Insights from mapping and stakeholder outreach — 15’: Sebastian Asprella (EMA)

Participant responses and validation of the findings — 10’

Priority questions for the workshop — 5’

Session objective

Present the main insights from stakeholder outreach, test the findings against participants’ ecosystem experience and identify priority questions for the day.

10:30 Navigating EMA support for innovation: existing support routes

Contributions

Innovation support and the Innovation Task Force — 8’: Enrico Tognana (EMA)

Practical support for micro, small and medium-sized enterprises — 8’: Leonor Enes (EMA)

When Scientific Advice becomes relevant — 7’: Iordanis Gravanis (EMA)

Questions and discussion — 22’

Session objective

Provide a practical, non-product-specific overview of relevant EMA support routes, including when each route may be appropriate, what type of interaction it supports and how early-stage developers can identify the right next step.

11:15 Coffee break

11:30 Navigating EMA support for innovation: network, National Innovation Offices and emergency perspectives

Contributions

Introduction and recurring themes — 4’: Sebastian Asprella (EMA)

European regulatory network perspective — 6’: Marjon Pasmooij (Dutch Medicines Evaluation Board)

National Innovation Office perspective — 6’: Bettina Ziegele (Paul-Ehrlich-Institut)

Emergency and crisis management perspective — 7’: Marco Cavaleri (EMA)

Discussion and prioritisation — 7’

Session objective

Identify recurring challenges when selecting early regulatory routes and clarify timing, preparedness, triage and handovers between national, EMA and European network mechanisms, including the distinct considerations that may apply in emergency and crisis contexts.

12:00 How TTOs and innovation intermediaries support early-stage developers

Contributions

Translational development, innovation acceleration and regulatory navigation — 8’: Savita Bernal (Inserm Transfert)

Technology transfer, spinouts and early regulatory navigation — 8’: Patrik Kehler (Max Planck Innovation, remote)

Moderated discussion — 24’

Summary of priority signposting needs — 5’

Session objective

Understand when regulatory questions arise in academic and translational projects, how teams are directed towards national, EMA or network support, and what practical signposting improvements would help TTOs and innovation intermediaries.

12:45 Lunch – 60’

13:45 Connecting national, European and cluster support networks

Contributions

No Wrong Door: Connecting National Innovation Support with EMA and European Regulatory Pathways — 10’: Isabella Schneider (BfArM)

Regulatory literacy, not regulatory advice: what existing cluster networks can carry — 8’: Hickmah Tagaully (Medicen Paris Region and Council of European BioRegions)

National Innovation Office response on coordination and handovers — 5’: Bettina Ziegele (Paul-Ehrlich-Institut)

Moderated discussion — 22’

Session objective

Explore how existing national, European regulatory and cluster networks can support consistent and sustainable signposting without creating parallel advice routes or new formal partnership structures.

14:30 From recurring questions to practical follow-up

Contributions

Proposed feedback-capture and routing approach — 8’: Sebastian Asprella (EMA)

European regulatory network response — 5’: Marjon Pasmooij (Dutch Medicines Evaluation Board)

TRS leadership perspective — 5’: Emmanuel Cormier (EMA)

Working discussion — 22’

Summary and next steps — 5’

Session objective

Test a light approach for capturing recurring, cross-cutting clarification and signposting needs and consider proportionate routing and follow-up through existing EMA and network structures.

15:15 Coffee break – 15’

15:30 Consolidating the workshop: priorities and practical takeaways

Contributions

What we heard today — 10’: Sebastian Asprella (EMA)

Reflections from participants in the room and online — 15’

Prioritising clarification and signposting needs — 10’

What happens next — 5’: Sebastian Asprella and Emmanuel Cormier (EMA)

Workshop evaluation and final reflections — 5’

Session objective

Validate the main findings from the workshop, identify the clarification and signposting needs that participants consider most important, and explain the proportionate follow-up that may take place through existing EMA and European medicines regulatory network structures. Proposed improvements should strengthen regulatory literacy and appropriate signposting without creating informal regulatory opinions, preferential access or routes that duplicate established regulatory mechanisms.

16:15 Next steps and closing remarks

Contributions

Summary of immediate follow-up — 8′: Sebastian Asprella (EMA)

Closing remarks — 7′: Emmanuel Cormier (EMA)

16:30 End of workshop