EMA
EUROPEAN MEDICINES AGENCY

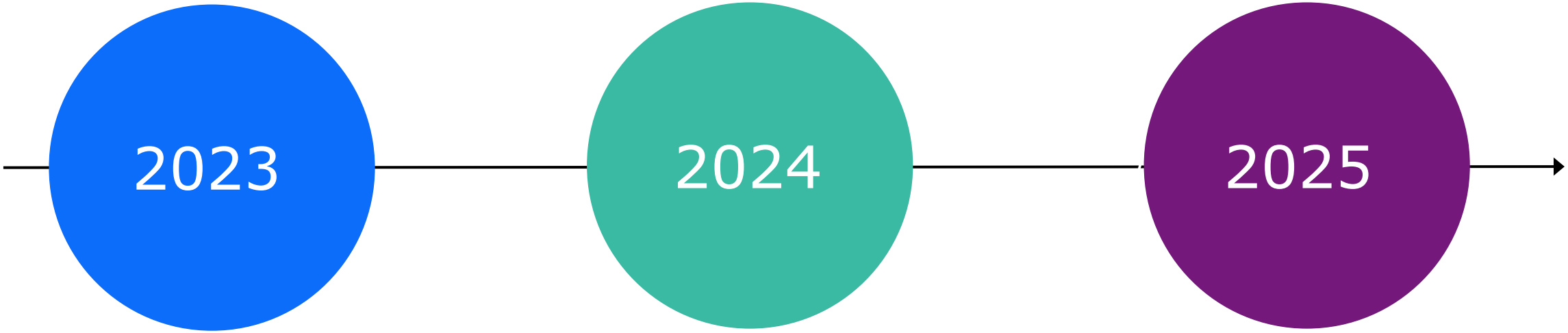
2023-2025 working party mandate highlights

PCWP and HCPWP joint meeting

Public and Stakeholders Engagement Department

Its been another successful mandate…

The final meeting of the 2023-2025 mandate…



The working parties

PCWP

HCPWP

And the co-chairs

Marko Korenjak, PCWP Co-Chair

Juan Garcia Burgos, EMA

Rosa Giuliani, HCPWP Co-Chair

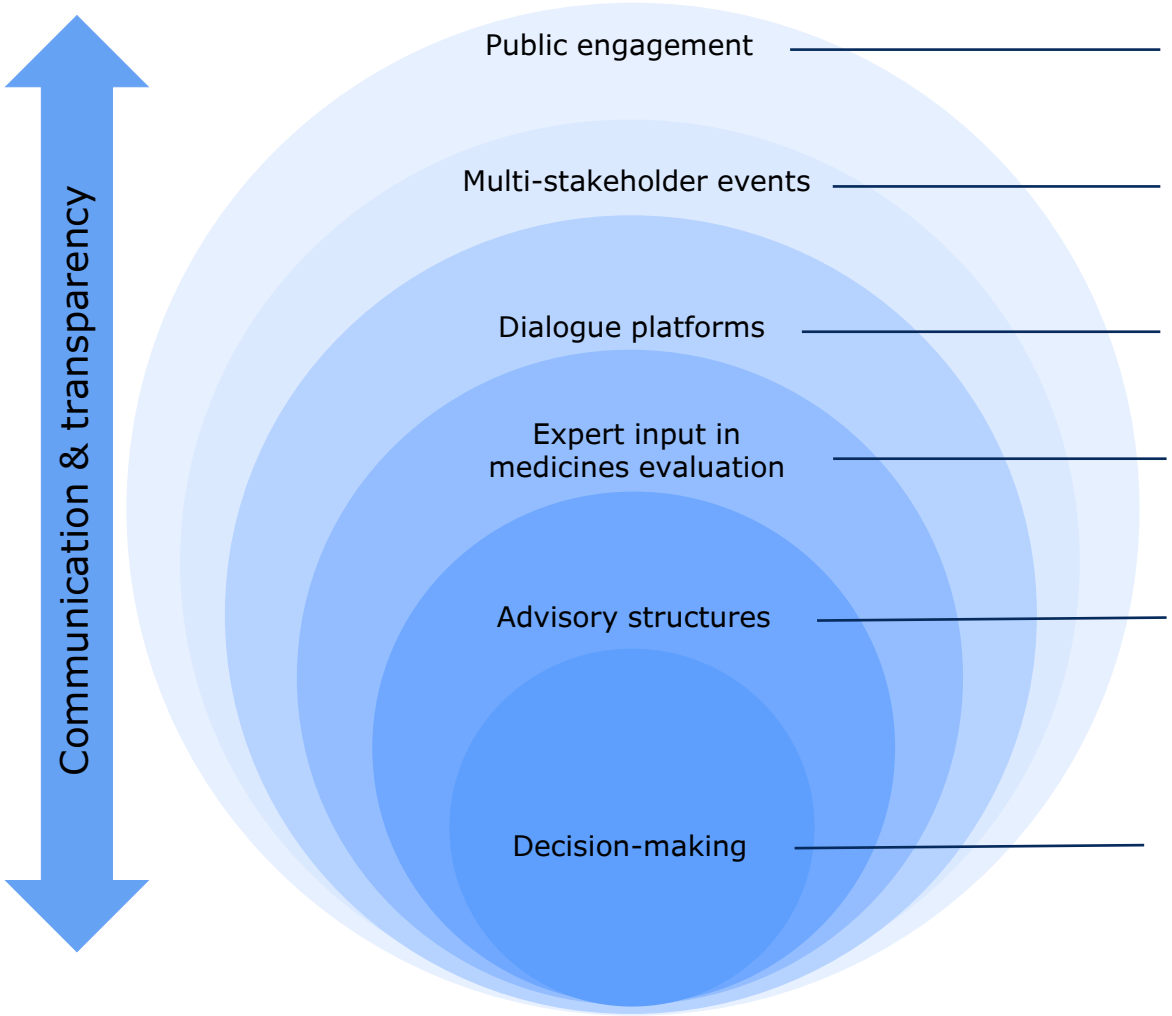
Network of eligible organisations maintained and expanded

Eligible patients' and consumers' organisations

Eligible healthcare professionals' organisations

EMA

How do we engage our stakeholders in our work?



- Public engagement
  - Open consultations on policies and guidelines
  - Public hearings
  - Public meetings
- Multi-stakeholder events
  - Workshops
  - Webinars
  - Awareness days
- Dialogue platforms
  - Patients' and Consumers' Working Party (since 2006)
  - Healthcare Professionals' Working Party (since 2013)
  - Industry Standing Group (since 2022)
- Expert input in medicines evaluation
  - Ensure real life experience about diseases/ treatments in regulatory outcomes
  - Consultations and medicine-specific activities such as: scientific advice, scientific advisory groups, review of documents destined for the public.
- Advisory structures
  - Emergency task force (ETF)
  - Medicines (MSSG) and medical devices (MDSSG) shortages steering group
  - Big Data Steering Group
  - DARWIN EU Advisory Group
  - ACT EU multistakeholder platform Advisory Group
- Decision-making
  - Members of EMA Management Board
  - EC nominated members of scientific committees

Annual training

- Aimed at stakeholders involved in medicines-related activities
  - Patient
  - Consumer
  - Healthcare professionals
- Topics covered include:
  - Scientific advice
  - Review of documents
  - Competing interests
  - Health technology assessment

Other meetings and training activities

- Bilateral meetings with EMA and eligible organisations
- Annual meeting with civil society representatives and chairs of Management Board and scientific committee
- Webinars:

  2022:

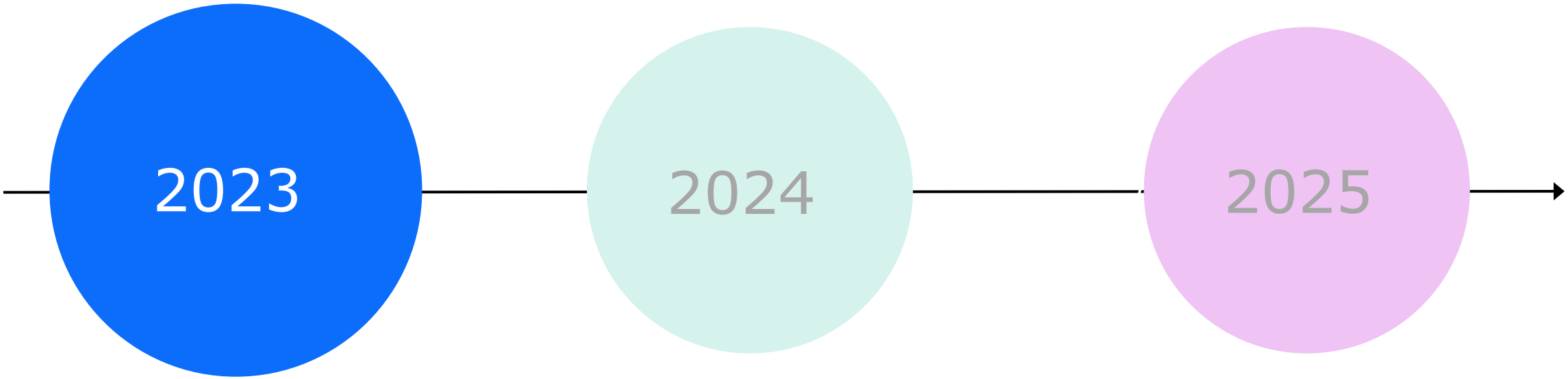
  - Information session on advanced therapy medicinal products (ATMPs) with PCWP and HCPWP on 28 June 2022

  2023

  - CHMP early contact of patient and HCP organisations - training webinar
  - Webinar on revision of the pharmaceutical legislation
  - Webinar on transparency rules for the EU Clinical Trials Information System CTIS

  2024

  - Webinar on the Collaborare project
  - EUNTC introduction and navigation



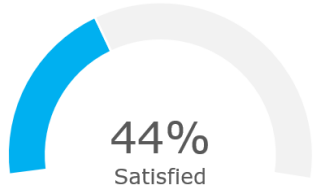
Key topics 2023

2023 Satisfaction survey to all eligible organisations

2023

- Run from 23 Feb to 24 Mar 2023
- Goals
  - ✓ Assess organisations' satisfaction
  - ✓ Gather feedback on interactions
  - ✓ Improve engagement activities
- Key findings
  - ✓ Generally high satisfaction and positive comments
  - ✓ Topics of interests and engagement methodologies reflective of Agency's priorities and ongoing work
  - ✓ Survey participation rates could be improved

Patient/consumer organisations

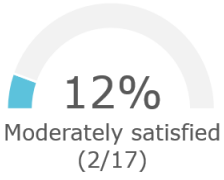


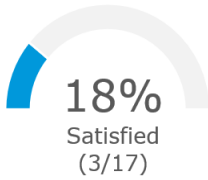
Answers: rating 1-5
1=not at all satisfied
2=slightly satisfied
3=moderately satisfied
4=satisfied
5=very satisfied

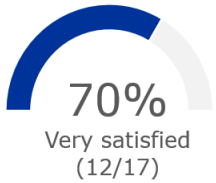
Recurring remarks:

- Community representation
- Variety of activities
- Good interactions with EMA

Healthcare professional organisations







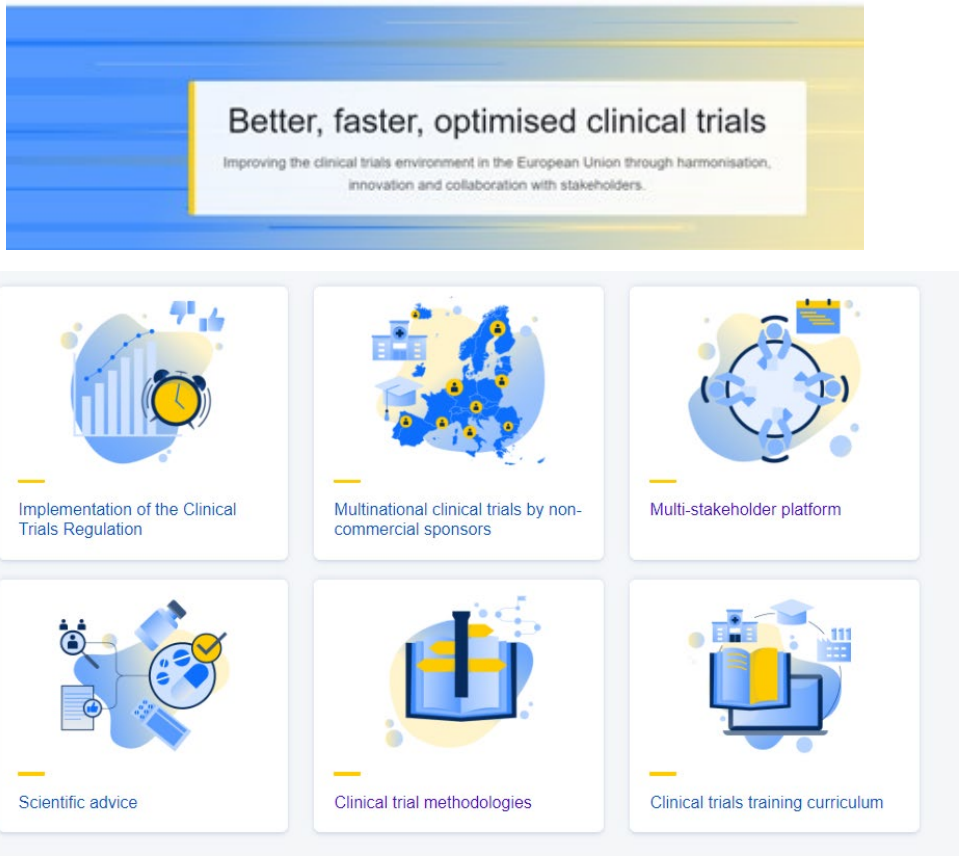
Recurring remarks:

- Quality/variety of activities
- Source of information/ communication
- Regular exchange (eg HCPWP/POG)

Accelerating clinical trials in the EU (ACT EU)

2023

- Public consultation (May)
- Multistakeholder workshop (Sep) on Clinical trials information system **(CTIS) transparency rules**
- Public consultation (Feb) on **Multistakeholder platform** and kick off workshop (June)
- Multistakeholder workshop on ICH E6(R3) Good Clinical Practice (Jul)
- Multistakeholder **methodology** workshop (Nov)



https://accelerating-clinical-trials.europa.eu/index_en

Activities around shortages

2023

- Patient and healthcare professional representation in the **executive steering groups** on shortages of medicines (MSSG) and medical devices (MDSSG)
- **Multistakeholder workshop** on shortages (Mar)
- Monitoring and managing **shortages of antibiotics** (Jan)
- Prevention campaign for autumn/winter season (Oct)
- **Set-up of a subgroup** to work on the implementation of the prevention guide for patient and HCP organisations

Use of real-world data for medicines approval

2023

- Patient and healthcare professional representation in the **Big Data Steering Group** (BDSG) and **DARWIN EU® Advisory Board**
- **Big Data Stakeholder forum** (Dec)

- set-up of a **drafting group** to draft a **reflection paper** on **Patient Experience Data** - kick-off meeting (Dec)

10th anniversary of the HCPWP

2023

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Draft Agenda - Healthcare Professionals' Working Party (HCPWP) meeting

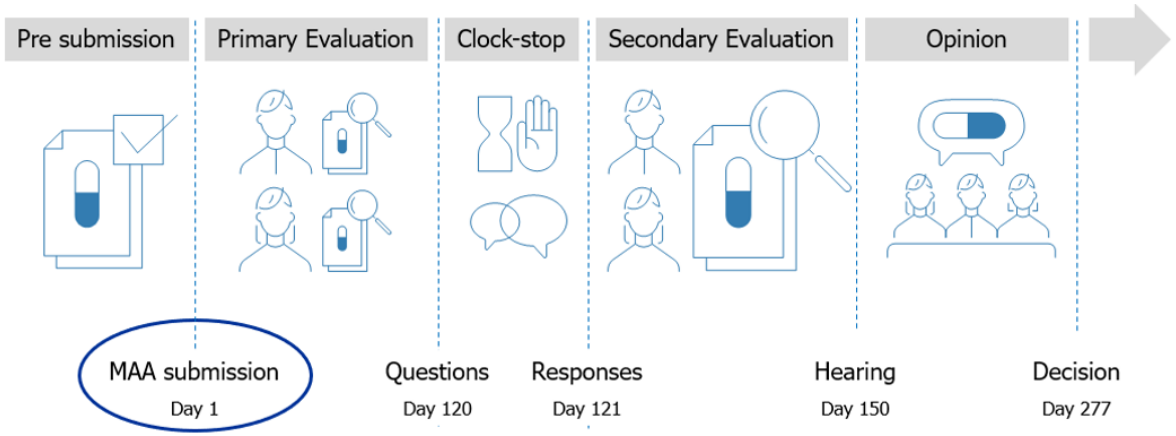
27 June 2023, 13:30hr to 17:45hrs – meeting room: 2A / Webex
Co-Chairs: Juan Garcia Burgos (EMA) and Rosa Giuliani (HCPWP)

Time	Topic	Speaker
13:15	Registration and reimbursement arrangements	
13:30	Welcome and introduction / Health and safety information Disclosure of interests / Adoption of the agenda	Juan Garcia Burgos (EMA)
13:35	Opening remarks by the Executive Director	Emer Cooke (EMA)
Marking 10 years of the HCPWP		
1. The beginning of our journey		
13:45 13:55	1.1. Setting the foundations towards healthcare professionals' engagement at EMA 1.2. Perspectives from the former HCPWP co-chairs	Isabelle Moulon (EMA, retired) Gonzalo Calvo (EACPT) Ulrich Jaeger (EHA)
14:15	Overall discussion - Perspectives from organisations *Open floor to organisations for overall discussion*	All
2. Where we are today		
14:25	2.1. Remarks from the current HCPWP co-chairs	Rosa Giuliani (ESMO) Juan Garcia Burgos (EMA)

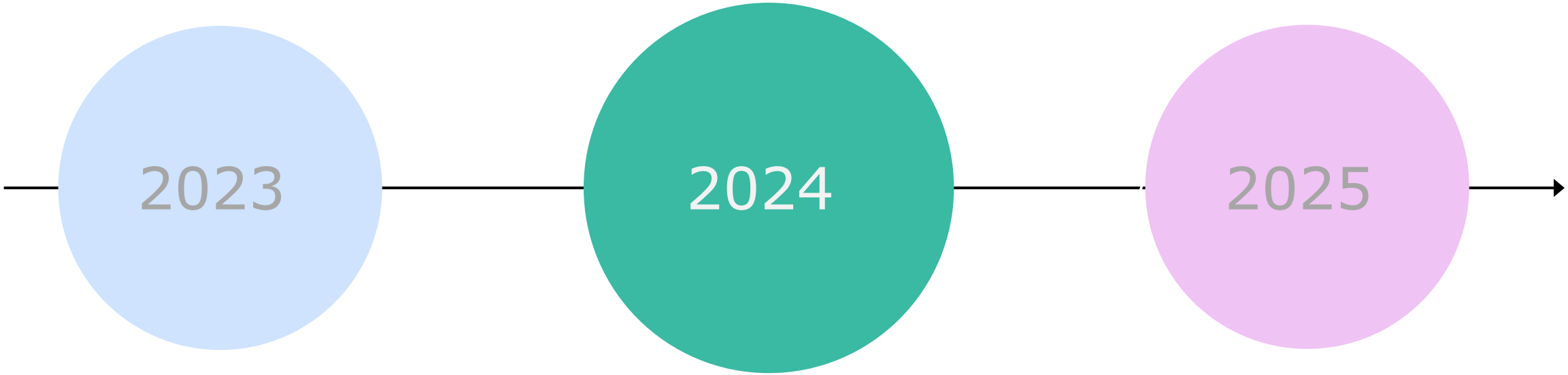
EMA

CHMP early contact expanded to HCP organisations

2023



HEALTHCARE PROFESSIONAL EXPERIENCE OF: **indication**
Please include below any aspects that are of particular importance to healthcare professionals, such as information on: • the standard of care or available treatments and to what extent they cover the intended indication; • the treatment duration; and, if in your view, the duration needs to be optimised; • any possible therapeutic/unmet medical needs; • what benefits you would hope for in new medicines; as well as what level of side-effects you would consider manageable for patients; • considerations for pregnant people/people of child-bearing potential, where applicable. Please also mention any aspects about the condition or its treatment that you feel are not well-understood or not sufficiently considered. Please include anything else you feel is important for EMA to know. Please try to keep your main points to 1-2 pages; if necessary, include more details in an appendix.

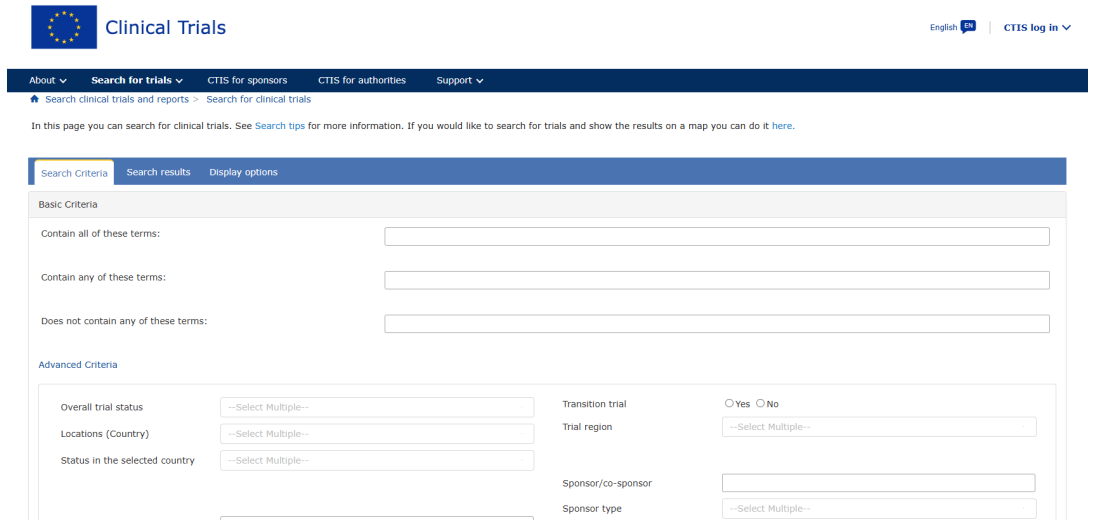


Key topics 2024

Ongoing ACT EU activities

2024

- **Multistakeholder platform (MSP) Advisory Group** established, and co-chair elected
  - MSP Advisory Group meetings (Mar/Apr/Jul/Sep)
  - **EU Multistakeholder platform** annual meeting (Oct)
- **Clinical Trials Analytics** workshop (Jan)
- Presentation of the Clinical trials information system **(CTIS) revised transparency rules** and **new version of the public portal** to PCWP/HCPWP (Jul)



Shortages: a focus on of GLP-1 receptor agonists

2024

- Patient and healthcare professional **representation in** the **executive steering groups** on shortages of medicines (MSSG) and medical devices (MDSSG)
- **Multistakeholder workshop** on shortages of GLP-1 receptor agonists (Jul)
- **Communication activities** (press briefing, Instagram LIVE, social media campaign)

Multistakeholder workshop on psychedelics

2024

16-17 April

Workshop objectives:

- Hear the views of stakeholders and experts on the therapeutic potential of psychedelics;
- Provide further clarity on defining the safe and effective use of psychedelics;
- Inform on regulatory challenges associated with the development and evaluation of psychedelic medicines;
- Define areas for which further regulatory guidance is required.

https://www.ema.europa.eu/en/events/ema-multi-stakeholder-workshop-psychedelics-towards-eu-regulatory-framework

Vaccine update

2024

Vaccines Outreach Strategy (VOS) updated, and Vaccines outreach group restarted

- Update of messaging on COVID-19 vaccines with focus on reassuring on the safety, following MEP's questions
- Working on new ways of communicating on vaccines for the public
- Proposal for information ecosystem management to identify misinformation and knowledge gaps on vaccines
- Scientific publications on vaccines

EVIP

- European Vaccination Information Portal (EVIP) communication plan and content review progressed
- EVIP Steering Committee - Communication Plan and content review to be further progressed

Consultations (surveys)

2024

- Review of the **package leaflet template** (QRD template): package leaflet improvement. Survey to patients, consumers and healthcare professionals on **'key information section'** and benefits/risks balance in March. Responses received from 96 patients/HCPs.

- **Biosimilars:** Surveys to HMA, patients, consumers, HCPs and industry on biosimilars completed in May and being analysed. Responses received from 64 patients and 168 HCPs.

Revamp of Human Medicines Highlights

2024

- EMA's monthly newsletter intended primarily for patients, consumers and healthcare professionals
- 2023 Survey and interviews with representatives of eligible organisations to guide improvement process
- Launch of the revamped newsletter in May
  - More attractive look
  - Mobile-friendly interface
  - Multi-language online version
  - Possibility to develop editorial content, e.g. theme issues
  - Reduces quantity of emails to stakeholders


February 2025

Human Medicines Highlights

The newsletter for patients, consumers and healthcare professionals

EMA
EUROPEAN MEDICINES AGENCY

Follow us

- In this issue
- Information on medicines
- Upcoming events
- Scientific committee and working party activities
- How EMA involves stakeholders
- EMA news
- Recent events
- Open consultations
- EMA publications

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Fourth joint meeting of the PCWP and Patient Engagement Collaborative (FDA-CTTI)

2024

U.S. FOOD & DRUG ADMINISTRATION | CLINICAL TRIALS TRANSFORMATION INITIATIVE | EUROPEAN MEDICINES AGENCY

AGENDA

Joint Meeting of CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients' and Consumers' Working Party (PCWP)

June 18, 2024
9:00 am – 11:30 am (EDT) / 15.00 – 17.30 (CEST)

8:45/14.45 ***Meeting open early for optional icebreaker and audio check***

9:00 / 15.00 Welcome & Overview of Agenda

Facilitator: Morgan Hanger, Executive Director, CTTI

- Welcome and Setting the Scene

9:10 / 15.10 Presentations

Facilitator: Maria Mavris, European Medicines Agency

- Speaker 1: Caroline Voltz, EMA
  Team Lead, Oncology, Advanced Therapies and Haematological Diseases Office

  Presentation: EORTC Workshop: How can patient-reported outcomes (PRO) and health-related quality of life (HRQoL) data could inform regulatory decisions.

- Speaker 2: Fraser Bocell, CDRH, FDA
  Psychometrician, Division of Patient-Centered Development

  Presentation: FDA-CDRH-NIH Workshop on Patient-Reported Outcomes and Vision Related Quality of Life Questionnaires

- Question & Answer

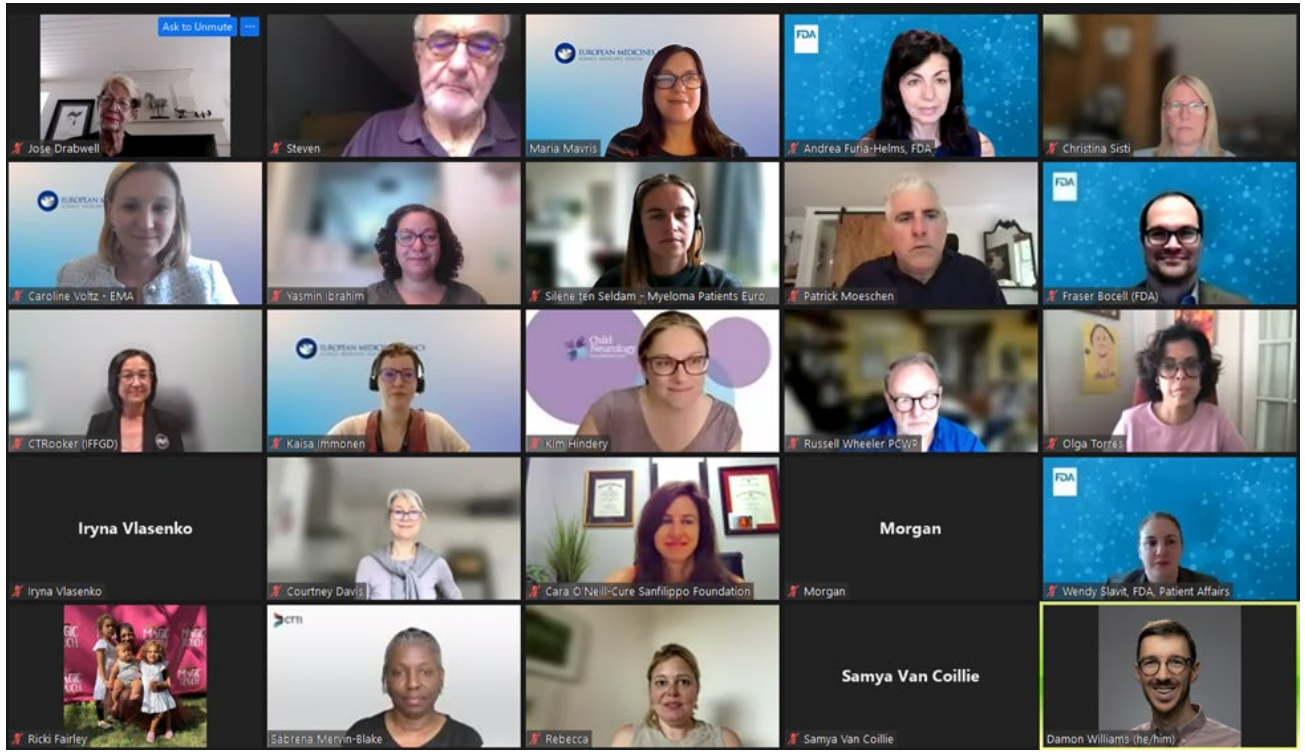
9:40 / 15.40 Break

9:55 / 15.55 PEC and PCWP Member Reactions

Facilitator: Wendy Slavit, U.S. Food and Drug Administration

- PCWP Member: Silene ten Seldam
  Myeloma Platform Europe
- PEC Member: Ceciel Rooker
  International Foundation for Gastrointestinal Disorders (IFFGD)

18 June



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One year report of HCP organisations in early dialogue

2024

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2024
EMA/225343/2024
Stakeholders & Communication Division

Early dialogue with healthcare professional organisations for marketing authorisation applications: 1-year report

1. Background/rationale

A pilot for early dialogue with patient organisations for orphan Marketing Authorisation Applications ran from January 2021 to May 2022. This pilot was supported by EMA's Committee for Medicinal Products for Human Use (CHMP) and aimed to capture patients' perspectives at the start of the evaluation of marketing authorisation applications, in order to provide insights to assessors to be considered early during the assessment process (as appropriate), to complement other engagement methodologies later in the process (e.g. scientific advisory groups and oral explanations), and to facilitate any further interactions as the procedures progress.

Patient perspectives requested include patients' experience, concerns and needs related to their condition, in particular: standard treatments and how acceptable they are; therapeutic/unmet medical needs; quality of life; what benefits would be hoped for in new medicines; and what level of side effects would be considered acceptable.

An outcome report on the pilot was published in July 2022. It concluded positively, with CHMP (Co) Rapporteurs recognising the usefulness and benefit of reaching out to patient organisations at the start of the assessment of (orphan) marketing authorisation applications. The added value was the assessment teams receiving direct insights from stakeholders which was a useful complement during the assessment of the marketing authorisation application dossier.

Based on this positive outcome, it was proposed to confirm the pilot methodology as a routine practice, and to extend it to non-orphan medicinal products as well as healthcare professional (HCP) organisations.

Early dialogue with HCP organisations started in May 2023. This report presents the outcome after twelve months of engagement, from May 2023 to April 2024, included.

- **Responses received**

In total, 54 inputs were received from HCP organisations. The ratio of responses received *vs* requests sent to HCP organisations is presented in **Figure 1**:

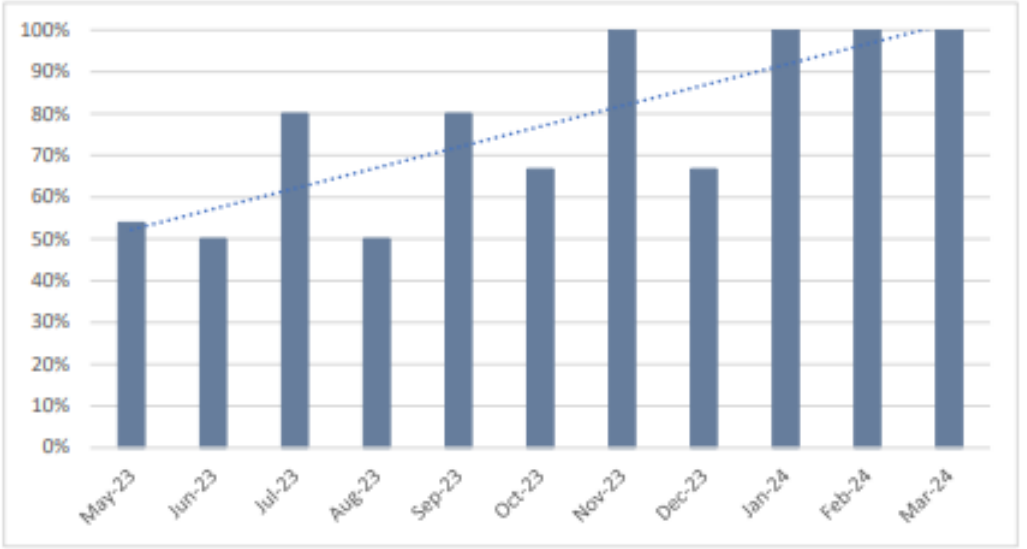

Figure 1: percentage of inputs received *vs* inputs requested from HCP organisations

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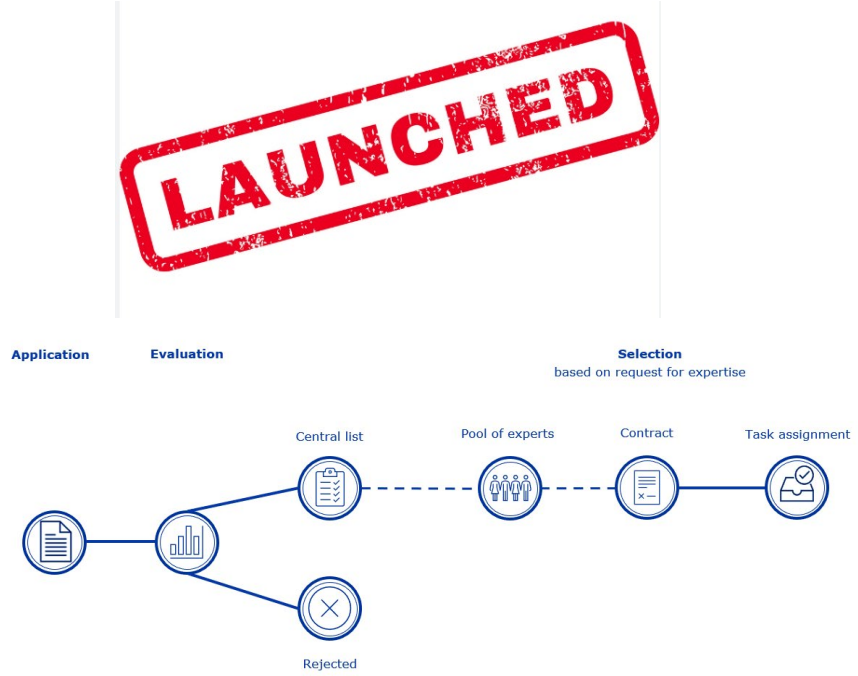
HCPWP drafting group for HCP engagement framework

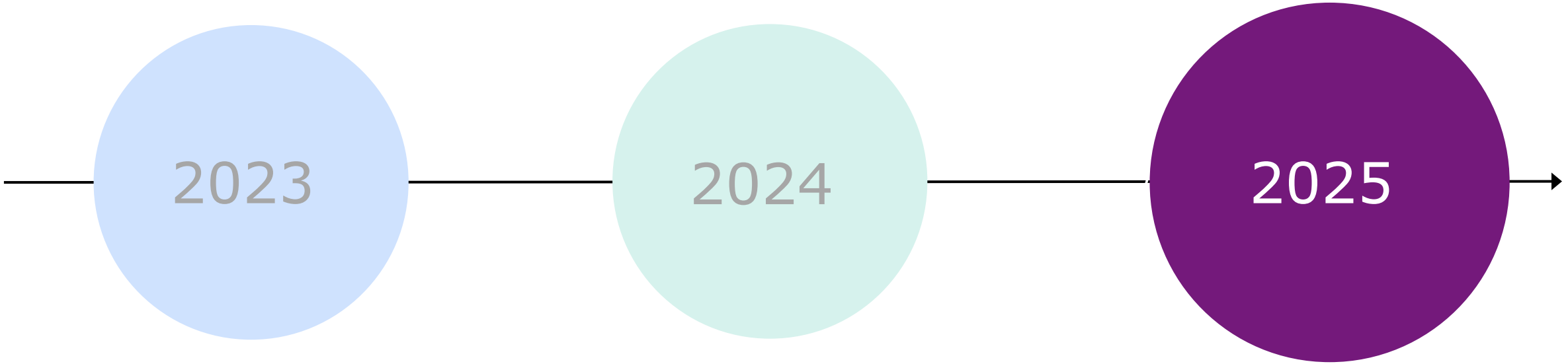
2024

- Establishment of drafting group
- Collection of input
- Discussion at HCPWP

Remuneration of experts for involvement in EMA activities

2024





Key topics 2025

European medicines agencies network strategy

2025

The European medicines agencies network **strategy (EMANS) to 2028** is available below.

It focuses on six areas:

- **Accessibility**
- Leveraging **data, digitalisation and artificial intelligence**
- **Regulatory science**, innovation and competitiveness
- **Antimicrobial resistance** and other health threats
- **Availability** and supply
- **Sustainability** of the European medicines' agencies network
- **Webinar** held on 13 February

ACT EU workshop on ICH E6 (R3)

2025

19-20 February

The objectives of this workshop are to:

- provide an overview of major changes in ICH E6(R3) guideline
- highlight key concepts for adaptation of Good Clinical Practice to recent developments in trial design, organisation and technology, and how these will help to future-proof the guideline;
- enable discussion with stakeholders on the implementation of ICH E6(R3);
- provide a brief update on the draft ICH E6(R3) Annex II.

Patient experience data (PED)

2025

Reflection paper on PED

- Drafting of the reflection paper of the EU approach to patient experience data
- Contributions from patients and healthcare professional representatives

Increasing PED transparency in the CHMP assessment report

- CHMP assessment report (AR) template updated reflect PED and its use by regulators

Participation in CollaboRARE project

- EMA contributed to research proposal for the CollaboRARE project
- Small pilot launched to explore use

THANK YOU from the Public and Stakeholder Engagement Department

Juan Garcia Burgos

Nathalie Macle

Patients

Maria Mavris

Kaisa Immonen

Marina Dobreva

Healthcare professionals

Ivana Silva

Maria Bonafonte

Corina Popescu

Industry

Marie-Helene Pinheiro

Maria Filancia

Linda Malaguti

Scientific publications and research

Rosa Gonzalez-Quevedo

Jarno Janssen

Florence Borrelly-Konyakhin

S-DIVISION MISSION STATEMENT

Through **communication, engagement and transparency**, we provide citizens and other stakeholders with information they need about medicines to help them make informed decisions.

We engage with stakeholders, so their views are considered in the work of EMA.

EMA

Stakeholders and Communication Division

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

public-engagement@ema.europa.eu

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