29 June 2022
EMA/775191/2021
Stakeholders and Communication Division

PCWP/HCPWP joint meeting

1 – 2 June 2022

Chair: J. Garcia Burgos (EMA), via WebEx

1. Welcome and introduction

1. Opening remarks

Melanie Carr (EMA) opened the meeting, welcoming all participants at the start of this new mandate of the working parties.

Juan Garcia-Burgos (EMA) highlighted the topics and focus of the meeting.

2. Tour de Table

2.1 Members introduction

All members introduced themselves and their organisations.

3. Clinical Trials

3.1 Update on objectives, progress and timelines of ICH GCP E6 revision
This session was organised as a follow up to previous discussions held at the level of the PCWP and HCPWP related with the ongoing revision of the ICH E6 GCP (please also refer to initial workshop back in June 2020) and in response to specific concerns raised by some PCWP members.

The ongoing revision foresees a ccomplete rewriting of the ICH E6(R2) Guideline and comprises three documents (See presentation):

- 12 Key principles of GCP
- Annex 1: traditional interventional trials, reflecting the content of E6(R2) with updates where needed
- Annex 2: designs such as pragmatic clinical trials, decentralized clinical trials and trials that incorporate real world data sources (e.g., electronic health records, hospital discharge summaries, claims data, patient/disease registries)

The guideline is expected to enter the public consultation phase in November/December 2022 for the key principles and annex 1. In March 2023, work should start in relation to annex 2.

3.2 Discussion of specific issues
After a structured discussion where several points were identified, it was agreed to focus the discussion on the draft guideline of the E6 GCP principles to develop a position statement outlining patients' and healthcare professionals' views, to be shared with ICH, and thus contribute to the guidance's development process. The key priority was to translate identified considerations into actionable points or

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recommendations.

3.3 Approach to consolidate feedback and next steps

A detailed summary of points raised will be prepared, in support of drafting process to be led by Francos Houÿez (PCWP) and Piotr Szymański (HCPWP) with a progress report to PCWP/HCPWP expected in September. A call for volunteers to support the drafting process will be launched in due course.

4. COVID-19 update

4.1 Update on vaccines and therapeutics

Marco Cavaleri (EMA) gave an update on EMA's activities related to COVID-19 vaccines and therapeutics since the last working party meeting. He highlighted the overall status of COVID-19 vaccines in the EU, including boosters for the elderly, mRNA vaccines composition and other vaccines in the pipeline vaccine. He also touched on the Monkeypox outbreak. (See presentation).

4.2 Safety surveillance on vaccines and therapeutics

Priya Bahri (EMA) provided an overall update on COVID-19 vaccines/therapeutics surveillance. She also highlighted some new strategies to tailor existing pharmacovigilance approaches, close international collaboration, engagement with the public and new risk minimisation advice for early detection of adverse reactions describing the continuous pharmacovigilance improvement cycle. (See presentation).

The Working parties will be kept up to date on COVID-19 activities.

For latest updates visit this link.

4.3 Opening our Procedures at EMA to Non-EU authorities (OPEN) pilot

Martin Harvey (EMA) presented the OPEN pilot (Opening our Procedures at EMA to Non-EU authorities). OPEN has facilitated the assessment of data by multiple authorities, deepened collaboration and moved exchange of information to active engagement. It has also allowed regulators to accelerate and align on decisions, leading to fewer labelling differences, while maintaining independence in the decision making. Overall OPEN has demonstrated the value of international collaboration to avoid duplication of efforts, improve efficiency, and bring vaccines and medicines to patients earlier. (See presentation).

EMA will now engage with all stakeholders to consolidate OPEN in a stepwise approach.

5. Big Data

5.1 General update

Peter Arlett (EMA) gave an update on progress of the joint HMA-EMA BDSG workplan 2021-2023; there has been steady progress on data transformation delivery as part of the EU Network strategy 2025 with continued involvement of patients and healthcare professionals. Peter also highlighted the 3rd BDSG workplan which will cover 2023-2025. (See presentation).

Stay up to date on Big Data here: Big Data webpage

5.2 Pilot on raw data analysis

Angela Bradshaw (Alzheimer Europe) and Eftychia-Eirini Psarelli (EMA) presented an update of the pilot on raw data analysis. Raw data / Individual Patient Data (IPD) / Patient Level Data (PLD) / is data at an individual patient level which is assessable for reanalysis or additional analyses, and this can be structured in various electronic formats. The overall aim of the pilot is to determine the regulatory benefit to access and analyze this data. During 2022 there will be proof-of-concept pilots to learn about the practicalities and benefits of such an approach. Next steps will be feedback from pilots, interim lessons learned to be

available in 2023 and final lessons learned published in 2024. (See presentation)

5.3 DARWIN EU®

Andrej Segec (EMA), Aldo Maggioni (ESC), and Elizabeth Vroom (UPPMD) presented an update on progress with DARWIN EU®, showing the updated timeline, ongoing and finalised studies and the CHMP pilot on real world evidence which will be initiated in June/July 2022 for 12-18 months. Within Darwin EU there will initially be 10 partners onboarded with the first pilot studies in 2022 for a number of use cases across the medicines lifecycle, aiming for > 100 studies per year conducted by 2025. The Data Protection Impact Assessment & Data Use Agreement is being developed. (See presentation)

6. EMA communications and information on medicines for patients and healthcare professionals

6.1 Use of EMA communications

Elisabeth Fleck presented results from EMA's targeted communications survey 2022. The survey was sent to all eligible patient/consumer and HCP organisations and aimed to determine the relevance and satisfaction of three types of EMA targeted communications; Human Medicines Highlights Newsletter, committee communications (CHMP, PRAC) and safety communications. Responses were received from 61 organisations (78%) and the key findings show that EMA targeted communication materials are relevant for PCOs / HCPOs, are communicated in a timely and clear manner and they are regularly disseminated by one third of PCOs / HCPOs. The survey responses also provided constructive suggestions which will be shared with the medical writers, communications team, design team and other relevant colleagues across EMA to discuss further how improvements can be made. (See presentation).

7. Looking ahead into 2022

7.1 Feedback from streamlining eligibility self-certification

Nathalie Bere (EMA) presented feedback from the survey related to the streamlining of the annual re-assessment of eligibility. The aim of the survey was to understand if eligible organisations find the new system was more efficient that the previous system. Nathalie highlighted the overall eligibility process and the changes made to achieve a more streamlined electronic self-certification system.

The feedback received from 28 organisations showed that overall, the new system is considered better with an overall satisfaction score of 4,2 / 5. Proposals for improvement that were received will be also considered and implemented where possible. (See presentation)

7.2 Adoption of PCWP/HCPWP work plan 2022-2025

Maria Mavris (EMA) presented the 2022-2025 Joint Work Plan for adoption. Maria highlighted again the workplan structure, the meeting dates and the steps taken so far for the development and adoption of the workplan. Following the presentation, the Workplan was considered adopted and will be published in July

7.3 Call for Co-chairs

Ivana Silva (EMA) presented the process for the upcoming call and election of the new PCWP/HCPWP co-chairs. The call for co-chair candidates was launched in June and the election of co-chairs will take place in the margin of the WPs plenary meeting on 22 September. (See presentation)

Wrap up / end of meeting