11 April 2024
EMA/174688/2024

ACT EU Multi-stakeholder Platform Ad hoc representatives of the Advisory Group (MSP AG)

Informative session of ad hoc representatives of the MSP AG meeting, 11 April 2024, from 09:30 to 11:00 (CEST), Webex

Co-Chairs: Maria Jesús Lamas (MSP AG Regulatory co-chair), Juan Garcia Burgos (EMA)

1. Welcome and opening remarks by the Executive Director of the Spanish Agency of Medicines and Medicinal Products (AEMPS) and the Head of Public and Stakeholder Engagement Department at EMA

The Co-Chairs welcomed all ad hoc representatives of the multi-stakeholder platform advisory group (MSP AG) to this informative session which follows the inaugural meeting of the MSP AG with permanent members where the mandate and rules of procedures were adopted.

The importance of the group as a platform for collaboration in advancing clinical trials in Europe was emphasised. Ad hoc representatives of the MSP AG were encouraged to reflect on their respective contributions in alignment with the priorities outlined in the ACT EU workplan.

2. ACT EU workplan and key priorities - expected contribution from MSP AG

Ana Zanoletty (EMA) provided an overview of the ACT EU workplan and priorities, the benefits that the programme aims to deliver to stakeholders over the next four years and the link between the MSP AG and the programme (see presentation). Importantly the role of the MSP AG in providing both strategic and operational advice to the ACT EU Steering Group and programme representatives was discussed, highlighting key activities in the course of this year, including the expected contribution to the revision of the ACT EU multi-annual workplan.

Fatima Bennai-Sanfourche (Medtech & Pharma Platform, MPP) flagged MPP's involvement in the recent ACT EU multi-stakeholder workshops on methodology (23 November 2023) and clinical trials analytics (25-26 January 2024), noting the importance of exchanging perspectives across all key stakeholders and regulatory bodies. The importance of integrating discussions on medical devices into ACT EU and linking this with other initiatives, such as the COMBINE project, was flagged given the complexity of biologics and diagnostics development.

Pamela Kearns (European Society of Paediatric Oncology, SIOP-E) emphasized the importance of paediatric oncology clinical trials and highlighted related challenges in rapidly opening trials, in particular when innovative designs and rare diseases come into play. Additionally, the importance of

platform and adaptive trials, decentralisation, standardised approaches across Member States, education and training in modern clinical trial methodologies were stressed.

Laura Evangelista (European Association of Nuclear Medicine, EANM) highlighted the need for more clarity and agile practices in clinical trial design given the rapid developments in nuclear medicine, particularly advancements in addressing oncologic diseases. The challenges represented by the interlinks with other legislative requirements across Member States were also flagged.

Rebecca Stanbrook (European Industrial Pharmacist Group, EIPG) noted the value of having a group represented by diverse stakeholders. The need for harmonization and the importance of agility in adapting to the rapidly changing landscape of clinical trials were stressed.

Fergus Sweeney (Cancer Drug Development Forum, CDDF) highlighted CDDF's multi-stakeholder nature and articulated some of the group's priorities. The importance of ensuring active engagement in consultations and activities was stressed, with a request for early engagement with ad hoc representatives to ensure adequate time to prepare for MSP AG meetings.

Martine Dehlinger-Kremer (European CRO Federation, EUCROF) highlighted the challenges faced with the Clinical Trials Regulation in Europe and its implementation, highlighting in particular the perceptions of non-European companies in this respect. The importance of clinical research in Europe and providing patients access to innovative medicines was emphasised.

Sebastian Klammt (KKS Network, KKSN/ KKS-Netzwerk e. V.) emphasized the importance of harmonization and consistent approaches across Europe in designing and conducting clinical trials, especially when it comes to the academic sector. Decentralised clinical trials were flagged as a crucial area for focus in the coming years.

Jolanta Bilinska (World Patient Alliance) stressed the importance of the pharmacy in clinical trials, particularly concerning polypharmacy issues, the need for improved patient information platforms and the importance of the consent process.

Hilde Vanaken (European Forum Good Clinical Practise, EFGCP) flagged EFGCP's contribution in addressing discrepancies between legislation and terminology and stressed the importance of bringing together various stakeholders to identify priorities and enhance a comprehensive understanding of clinical trial processes.

Ernest Spitzer (European Cardiovascular Research Institute, ECRI) recognized the importance of initiatives aimed at understanding, implementing, and standardizing procedures within clinical trials. He highlighted the creation of a multistakeholder group within ECRI that can help identify priorities, and the importance of utilizing modern technology, such as web-based tools and social media, for widespread sharing of information.

Christoph Gerlinger (European Federation of Statisticians in the Pharmaceutical Industry, EFSPI) reported the need to find new methods for decision-making in those cases where full-scale phase 3 trials are not feasible due to a lack of patients, expressing willingness to contribute to the ongoing work on methodological guidelines in this field.

Amelia Hursey (Parkinson's Europe) emphasized the importance of initiatives like the MSP AG to clarify how clinical research connects across Europe and highlighted the importance of continuing community engagement post-research to enrich the patient involvement beyond trial participation.

Justyna Paprocka (Polish Society of Child Neurologist/ Medical University of Silesia in Katowice) emphasized the importance of safe acceleration of trials and their results, especially concerning metabolic diseases.

Teresa Catarina Páscoa Madeira (CoLAB TRIALS) highlighted the CoLAB TRIALS support for researchers and medical professionals in navigating regulatory frameworks and developing digital tools. Teresa highlighted the challenges experienced at national level during clinical trial planning and implementation, and the need to identify adequate support strategies while maintaining regulatory compliance, participant safety, and data quality, ultimately stimulating innovation in Europe.

Mira Zuidgeest (University Medical Centre Utrecht, UMC Utrecht) highlighted the need to focus on trial innovations, including decentralisation and embedding of trials in clinical practice, the use of real world data sources, and the need for appropriate funding schemes to lower operational barriers for multi-country clinical trials. Improving diversity in clinical trials and the importance of training was stressed.

Actions arising:

- There is a need to facilitate ad-hoc representative's participation, and EMA will reflect on extended timelines to enable adequate involvement of ad hoc representatives in the lead up to the meetings.
- EMA to follow up with a formal call for priorities.

2. Membership of the MSP AG - tour de table

Representatives from twenty (20) stakeholder organisations attended the meeting. During the tour de table the representatives who had not already introduced themselves presented their activities and those of their respective organisations.

3. Mandate and rules of procedure of the MSP AG

Ornela Ademi (EMA) presented the mandate and rules of procedure of the MSP AG (see presentation). The aim of the presentation was to present the key points of the document, and explain the role and expected contribution of the ad hoc representatives.

Fergus Sweeney (CDDF) welcomed the mandate, however, expressed concerns in regard to the risk of not sufficiently involving ad hoc representatives in the activities of the group, and questioned how this would be addressed.

Juan Garcia Burgos (EMA) highlighted the desire to make the MSP AG as inclusive as possible, while ensuring manageable discussions. It was emphasized that decisions on ad hoc representative attendance to meetings would be subject to agenda topics. To ensure the group remains fully

informed, agendas and meeting minutes will be shared in advance of meetings; in addition, all representatives will be invited to the MSP annual meeting. It was further clarified that all MSP AG representatives (permanent and ad hoc) will be able to propose agenda topics to the MSP AG secretariat. The involvement of ad hoc representatives in all written consultations or exchanges was also confirmed.

It was also confirmed that meetings would be hybrid in nature, offering both virtual and face-to-face options, and that in order to enable sufficient forward planning, a two-year meeting calendar would be published.

Ana Zanoletty (EMA) emphasized the importance of the ACT EU teams having a good understanding of the organisations participating in the group, to ensure the right level of outreach to the ad hoc representatives.

Fatima Bennai-Sanfourche (MPP) further flagged the need to have adequate representativeness and expertise on medical devices trials within the group, highlighting that the COMBINE project may not be able to address all the issues faced in this space.

Ana Zanoletty (EMA) acknowledged the comments, confirming the links between ACT EU and the COMBINE project at multiple levels, and the need for the ACT EU programme to remain open to changing priorities.

4. Conclusions and next steps – forward planning of the meetings

Ornela Ademi (EMA) informed of the upcoming publication of all relevant MSP AG documents meeting materials on the multi-stakeholder platform webpage, and the planned publication of a 2024-2025 MSP AG meeting schedule, which is currently under preparation.