



**First Meeting of the Joint Clinical Assessments subgroup
of the Member State Coordination Group on HTA
24 April 2023**

Summary minutes

The first meeting of the Joint Clinical Assessments (JCA) subgroup of the Member State Coordination Group on Health Technology Assessment (HTACG) was held on 24 April 2023 in Brussels. Representatives from 25 Member States, as well as Iceland and Norway in observer capacity, attended the meeting (either in person or remotely). Poland and Slovenia were not present as they have not designated their representatives to the JCA subgroup yet.

The meeting was chaired ad interim by Roisin Adams (Ireland), Chair of the HTACG

The agenda of the meeting was approved with no changes.

Introduction of subgroup members

A tour de table was held to give to every Member State and observer the opportunity to present themselves.

Information point: The IT platform for subgroups

The Commission presented the developments of the HTA IT platform, which will in the future be used by the subgroups in their collaborative work. The technical functionalities are being set up by the Commission, and users' needs are integrated into the development through an IT users working group consisting of 13 Member States and Norway. It was explained that Release-2 of the HTA IT platform is scheduled for end of 2023. The needs of the IT platform will be developed in line with the needs of the subgroups and CG and will specifically be developed with the workflows and processes of these structures at the force. The subgroups' identification of the specific needs in terms of IT support for the performance of their tasks is a key element in the development of the IT platform.

Member States confirmed that it was not anticipated that commercially confidential information will be shared before 2025. A stepwise approach is being adopted to the release of the IT platform: to enable an optimal workspace, one subgroup could be used as a pilot to test workflows and capacity of the system.

Member States articulated the need for a data sharing platform in this interim period. Following the SG needs for data storage and working together different solutions should be explored.

Point 1: Terms of reference for the subgroup and work programme 2023-2024

Subgroups received the Terms of Reference adopted by the HTACG in advance of the meeting and they used it as a basis for a discussion on the first work priorities and a preliminary work programme for 2023-2024.

Member States agreed to undertake the mapping of current available experience, especially from EUnetHTA 21, in order to avoid duplication of work. The work developed by the Heads of Agency Group (HAG), the roles and responsibilities matrix, was also identified as an important contribution. This mapping exercise should also identify any gaps to be covered.

Task assignment and distribution were also discussed by the subgroup. The possibility to convene ad-hoc groups to address specific deliverables was addressed and recommended by the subgroup.

The JCA subgroup addressed the need to define the remits of the different subgroups in order to avoid duplication of work, especially regarding the Methodology subgroup. Priority setting for the subgroups production was anticipated as an important topic to address jointly. Further it was suggested to develop hands-on groups or authoring groups with representatives from multiple sub-groups.

The frequency of meetings was discussed. The next meetings are planned for **23 May** and **7 July** in virtual format, **5 October** in hybrid format, and **12 December** in virtual format. The subgroup decided to meet monthly but keep a flexible approach to the duration of meetings, pending the coming Joint Chairs Meeting and the evolving needs.

Interactions with the European Medicines Agency (EMA) and the Medical Devices Coordination Group (MDCG) were also mentioned as a topic for future discussions. The importance of information sharing was highlighted, specifically timelines and warning on changing indications, as well as the legal basis for information exchange of confidential nature. The Commission can facilitate the contacts with EMA for the subgroup.

The Commission informed the subgroup on the Stakeholders Network. The first meeting will take place on 14 June in Brussels. The Call for Expressions of Interest ended in February with 70 applications, resulting on 44 entities being accepted to the Stakeholder Network. The JCA subgroup proposed the participation of Chairs and Co-chairs of the subgroups at this first meeting to actively enquire about the Network expectations from the subgroups. It is foreseen, that the JCA subgroup, along with the other subgroups, will interact with the Stakeholders Network; therefore, the types of interaction and timing should be appropriately defined. The Commission supported this interaction as the Stakeholder Network forms an integral part of HTA Regulation framework.

Member States (France, The Netherlands, Italy and Portugal) shared their experience on information exchanges with EMA, before the regulatory process was finished, and specifically on the joint clinical assessment process.

Member States expressed the need to build national capacity, highlighting the need to align with the expected number of total assessments. A plan needs to be developed to reflect the number of assessments per year and the capacity available.

Member States proposed to have presentations on national procedures, including PICO exercises, as a learning exercise. Furthermore, a procedure should be created on how to develop work between

meetings. It was highlighted that methodology and other relevant documents produced by EUnetHTA 21 should be made available for the members of the JCA subgroup, as this will serve as a basis for the work

Point 2: Election of the Chair and Co-Chair of the subgroup

The interim chair introduced the point and requested the eligible nominees to present themselves and the elections of the Chair and Co-chair of the Joint Clinical Assessment subgroup were held by secret ballot.

Paul de Boissieu (Haute Autorité de Santé, France) was elected as Chair of the JCA subgroup and **Anne Willemsen** (Zorginstituut Nederland, The Netherlands) was elected as Co-chair of the JCA subgroup.

The interim Chair (for the election of the Chair) and the elected Chair (for the election of the Co-Chair) counted and verified all votes, with the support of the HTACG Secretariat.

The newly elected Chair and Co-Chair were congratulated and chaired the rest of the meeting.

Conclusions

The Chairs thanked participants and summarised the main points of the discussion.

The next JCA subgroup meeting will take place on **23 May 2023 virtually**. Among the topics to be considered for the agenda: coordinate working with other subgroups to avoid overlaps, selection and review of the deliverables and results from EUnetHTA 21, assessment of the proposal to undertake a PICO to understand the process before 2025, and external communication and public awareness (for example with the Stakeholders Network).

END