18 May 2021
EMA/MB/243718/2021 Adopted
Management Board

# Minutes of the Extraordinary meeting of the Management Board on CTIS audit

Held virtually on 21 April 2021

The Chair of the Management Board opened the extraordinary meeting held to confirm, on the basis of the independent audit report, whether the EU clinical trials Portal and Database (EUPD) are fully functional and meet the functional specifications. The EUPD is one of the main deliverables of the Regulation (EU) No 536/2014 on Clinical Trials and the key component of the Clinical Trials Information System (CTIS). The extraordinary meeting was held fully in the form of a videoconference due to the extraordinary circumstances of the COVID-19 outbreak, as per the Management Board Rules of Procedure which were revised in March 2020 to allow virtual meetings and participation through a remote connection. The Chair asked for confirmation of the number of participants and of the quorum and received this assurance from the Management Board secretariat.

## 1. Draft agenda

[EMA/MB/221593/2021] The draft agenda circulated on 19 April was adopted without changes.

## 2. Declarations of competing interests related to the current agenda

The Management Board secretariat noted all declarations of interests of members had been assessed and members with restrictions had been informed before the meeting. Issues concerning possible conflicts of interest had been identified for topic *B.7 b) Confirmation of EUPD functionality in accordance with Art 82(2) of Clinical Trial Regulation* for two board members. Should the need for a vote on the above topic arise, the Chair would take up the matter again.

All members were reminded to declare any specific interests that could not be drawn from their current declaration of interests and that could be considered prejudicial to their independence with respect to the items on the agenda. No conflicts of interests were declared.

## 3. Welcome and order of proceedings

The Chair informed the board that the aim of the meeting is to confirm, on the basis of the independent audit report, whether the EUPD are fully functional and meet the functional specifications

and that, following introductions from EMA and the European Commission, the appointed auditors from KPMG would be invited to join part of the meeting in order to present the final audit report's methodology and findings. EMA would present the Agency's response to the audit findings with possibility for the board to ask questions to KPMG. Then the auditors would leave the meeting and the board would hear more details about the high-level Go-Live delivery plan, the Go-Live schedule (Project Release Plan) and training activities before discussing the endorsement of the full functionality.

# Points for discussion

# B.1 Introduction by the Executive Director

The EMA Executive Director thanked all involved parties, from Member States, EMA, DG SANTE, sponsor organisations and civil society representatives, for the great amount of work accomplished and stressed the need to bring CTIS into production and go-live so that European research can use the benefits that the Clinical Trial Regulation will bring. It is crucial that sponsors and Member States can use the system in practice, so that they can understand what is useful in the system functionality and help EMA fine tune its performance in the areas most important to users. Noting the significant work still needed before go-live and thereafter, EMA is committing the human and financial resources needed to support the development for go-live and in the following years. Budget plans are in place at the Agency to cover CTIS expenditure in the years 2021-2023 when a high level of support will be needed for the system. EMA has put in place a strong training programme and will be launching a dedicated helpdesk in order to support national teams and sponsors in using the system. It will be important that EMA, Commission and Member States reach out to sponsor organisations to work with them so that everyone can use the transition period granted by the Regulation to bring their teams and processes up to speed in a gradual way. EMA will work with Member States to provide the necessary helping hands and guidance through the training, helpdesk and public events, in order to make CTIS a success for European clinical research and for patients.

# B.2 European Commission

The DG SANTE representative noted the preparatory work for the EUPD continues and recognised that there are still areas for development and improvement ahead of go-live. At the time of go-live, the Commission expects the Minimum Viable Product to be delivered and the identified blocking issues to be resolved. CTIS depends on people, processes and systems. Training is now critical, and all stakeholders need to use the remaining time to get prepared. The European Commission continues to monitor the KPIs until go-live date on 31 January 2022. The board needs to take an important decision today. At the same time the European Commission is aware that many issues regarding how Regulation (EU) No 536/2014 will be integrated in national frameworks remain. The Commission is ready to provide any legal support for national implementation and will continue to do so within the Commission Clinical Trials Expert Group. The Commission would also like to launch in 2021 a Joint Action on clinical trials from the EU4Health programme. It is important that Member States MSs decide leadership for that Joint Action soon. Publication of the European Commission notice confirming full functionality of the EUPD will start as soon as the Management Board letter of endorsement is received. The Commission will draft an act that is intended to be published on 31 July 2021 so that the Clinical Trials Regulation can start to apply six months later. The Commission thanked all colleagues in the Coordination Group, the EMA's IT teams and EMA staff for the good collaboration. The Chair noted that according to Article 82 of the Regulation (EU) No 536/2014, the Board is asked to endorse the audit report conclusions but the final decision on the full functionality of the EUPD is for the European

Commission. To that end, DG SANTE has to launch an internal consultation of its services before the publication of the official Commission Notice. The DG SANTE representative clarified that the Notice has to be published exactly on 31 July 2021 and not earlier, in order to enable the go-live to take place on 31 January 2022, in line with the project planning.

## B.3 Introduction – EU Portal and Database (EUPD)

EMA described the main milestones for sharing the audit results with the CTIS governance. The first draft of the final audit report was circulated on 8 April and then a reformatted version was shared on 14 April. On 16 April an ad-hoc informal meeting of the Management Board was organised to prepare for the endorsement at the 21 April meeting, while on 19 April a meeting of the Coordination Group (CG) was organised on the same topic. The CTIS and the Clinical Trials Regulation provide significant advantages to many users. For sponsors there will be a single application and maintenance process, regardless of the number of Member States concerned, including one single dossier and timeline. CTIS will cover clinical trial application to NCAs, ethics committees and registration of the clinical trial in a public register. In addition, harmonised and simplified end-to-end electronic application procedures over the life cycle of clinical trials across the EU will be put in place. With approximately 3-4000 clinical trials of medicines authorised annually, 1.8 million practising physicians and 2.6 million hospital beds available, the EU is a leader in health research and the Clinical Trials Regulation will facilitate and further invigorate this leadership position. CTIS will provide a secure database for clinical trials and dedicated workspaces for sponsors to interact with Member States and for Member States to prepare their assessments and send them to sponsors, while a website giving access to detailed information on clinical trials will be available for the public.

EMA reminded the board that on 31 January 2022 a first year of transition will start during which a sponsor can choose to submit their new trial applications either via the new (i.e. CTIS) or the old system (i.e. according to the national laws implementing Directive 2001/20/EC). After January 2023 and during the following two years, all new trial applications will have to be submitted via CTIS only, but the old system will remain available for ongoing trials. From three years after the date of application of the regulation, i.e. after 31 January 2025, all clinical trials not yet completed will have to be moved to the new system and Directive 2001/20/EC will definitively cease to apply. When considering 2020 figures in EudraCT, academic sponsors mostly do mono-national trials (1251 mono national vs 95 multi-member state trials), while about half of the trials sponsored by pharmaceutical industry are multi-member state (1071 mono national vs 918 multi-member state trials). Typically, multi-member state trials are conducted on average in 3-4 EU Member States. Multi Member State trials under the Voluntary Harmonisation Procedure should be transitioned gradually to CTIS in order to allow time for Member States and large sponsors to gain experience with the new system. EMA will look at the EudraCT to identify which MSs are typically involved together in multistate trials and this can support partnering in developing processes, especially for smaller countries. Furthermore, the Agency will reinforce the training programme during the transition period and set up a dedicated service desk with 5-7 staff members for frontline support, who can answer immediately or redirect to technical or business teams for further assistance. EMA has a framework contract in place for CTIS development and maintenance and the IT team that has worked so far will continue. The budget has been planned already. A hyper care period is planned immediately post go-live as it is expected more support will be needed at the beginning of the transition period.

## B.4 Results of the EUPD independent audit

The KPMG Audit Manager and Lead Auditor presented the KPMG team as well as the audit approach, timelines and final results. The final audit report was split into two sections. In the assurance part

(Section II, Reasonable Assurance), KPMG concluded that the EUPD meets the functional specifications agreed by the Management Board. Factual findings on the EMA's release plan for go-live and post-go live are included in Section III on Quality Assurance. The audit report provides an evidence-based opinion to enable the Management Board to confirm whether or not the legal objectives of Article 80 and 82 of the EU Clinical Trials Regulation have been complied with. For the audit, KPMG used a core team, a specific team on performance and scalability and a cyber security team.

The approach was to split engagement into two reports. The first part, in section II, aims to conclude on full functionality and was carried out according to internationally agreed audit standards. For the Quality Assurance on the release plan and non-functional specifications, in section III, both international quality assurance techniques and KPMG own methodologies were used. To provide a Reasonable Assurance, KPMG started with transforming the agreed functional specifications for general aspects, EU Portal, Workspace and EU Database into a set of 101 controls. KPMG then inspected all the available documentation and participated in demonstration sessions organised with Product Owners and EMA who operated the functionalities in presence of the auditors. For the Quality Assurance (QA), six themes were identified as follows: compliance in general with the non-functional specifications, user friendliness, security, performance and scalability, data confidentiality and data protection, preparation for go-live of the new system. Together with EMA, KPMG selected 10 areas of the QA control framework (listed in Annex A of the Audit Report), such as trainings, which were tested using the proprietary KMPG Global Enterprise Transformation Tool (GETT) methodology.

As regards to the timelines, in September 2020 KPMG performed a risk assessment to transform the functional specifications in controls, in October and November they organised deep-dive sessions with EMA to better understand the functioning of the EUPD and finalised an audit plan in November. In November-December, the first fieldwork took place and included inspection of documentation, inquiries with responsible officers at EMA, and testing of all the processes. Findings, impact classification and recommendations for improvement were then formulated. In December, the preliminary findings were shared with EMA and on that basis the Agency prepared an Improvement Action Plan in January-February 2021. Re-testing of the controls which had findings at the first visit has been the focus of the second field work in March and on 8 April a final audit report was presented to EMA.

With reference to the final audit results, 98 out of 101 controls had no exception and 3 exceptions (one important and two minor) were noted for the Reasonable Assurance. The first one, classified as important, relates to user management and authentication: the user authorisation matrix had obsolete permissions that refer to technical debt. This has no impact on user functionality and therefore these permissions can be removed from the CTIS. The second exception, classified as minor, determined that it is unclear what the removal time is in the go-live version of the CTIS. In the test version an update job from the workspace to the EU database is performed every 15 minutes. In the live version this will be a daily job. It is unclear whether removal of documents will be part of this daily job or will take place on a more regular basis (or will have immediate effect). The third exception, classified as minor, relates to publication of clinical trials data and information: any user can upload sensitive information, such as personal data, and EUPD is not scanning documents for personal data, as this was considered a responsibility of sponsors. As a compensating factor, EMA will add a banner informing users that responsibility for what is published lies with them. In relation to the Quality Assurance, 138 controls were performed and for some areas, e.g. on performance and scalability and security, some room for improvement was identified.

The board heard a presentation of how EMA will address the audit recommendations. EMA confirmed that the three exceptions noted as part of the Reasonable Assurance are planned to be addressed with the approach and timelines for their resolution described in the project release plan. The removal of the technical debt as part of the user authorisation matrix, which has no impact on user functionality, will be addressed by EMA post go-live. The second exception will be addressed by setting the standard

document publication process to run every 24 hours with further fine tuning planned for go-live. The ad-hoc removal of data from the public view will be defined as part of a Standard Operating Procedure (SOP) with the necessary configurations in the system implemented prior to go-live. As regards the third exception, EMA will also update the banner informing users that responsibility for what is published lies with them.

As regards to the Quality Assurance findings, the Agency recognises all remaining actions on performance and scalability. In relation to IT security, EMA will arrange for further tests six months post go-live and update or finalise security documentation where applicable. Prior to go-live, EMA's service provider will ingest Application and Database logs into the Security Information and Event Management solution to aggregate and analyse data to catch abnormal behaviour or potential cyberattacks.

As regards performance and scalability, overall the main criteria have been met, but some transactions did not meet individual performance criteria. Continuous testing and development of system performance (as part of the development process) will address the current performance concerns such as response times and failure rates. Observations on the Application Programming Interface (API) in support of Member States are marked for improvement after go-live. In addition to the EMA's Management Response, the project release plan includes detailed timelines and references to the KPMG control numbers so that each improvement action can be traced to the audit report.

In conclusion, EMA noted that, as regards achieving full functionality and the review of the Agency's Project Plan for the delivery of the go-live and post- go-live release(s), the auditor's report establishes that EUPD as part of the CTIS is meeting all the six criteria for the audit defined by the board in March 2020. The EUPD is: i) providing the defined functionality set out in the functional specifications to achieve the goals and objectives of the Clinical Trials Regulation; ii) supporting the day to day business processes throughout the life cycle of a clinical trial including oversight and management of Member States, ensuring a workflow with monitoring and supervision by the relevant parties; iii) providing access to clinical trials information by the general public; iv) functioning in a manner that is user-friendly to avoid unnecessary work in accordance with Article 80 of the Clinical Trials Regulation, a specific "non-functional" requirement; v) meeting the agreed non-functional requirements as regards performance, scalability and security, taking into account the need to support multiple users and an increase in volume of data over time based on the criteria for performance and scalability; vi) complying with the disclosure rules to the functional specifications as regards data confidentiality and protection of personal data. EMA agrees with the audit results and audit report and, as described in its Management Response, will take care of any remaining issues that have been identified.

After the EMA's presentation, members thanked the auditor and the Agency for the extensive work made to develop and test the system and then KPMG left the meeting.

# B.5 Project Release Plan for go-live and post-go-live

[EMA/MB/224749/2021; EMA/216931/2021; EMA/216922/2021] The Board noted a presentation by EMA on the updated EUPD delivery plan for the go-live and post go-live, detailing its scope, phases, and success factors as well as for the monitoring together with the EU Clinical Trials Coordination Group (CG).

Scope of work for CTIS Go-Live includes the Minimum Viable Product items (business, legal and technical) defined by the prioritisation group as well as the projected findings from Readiness Confirmation (RC) and user testing activities. The outcomes of the independent audit have been included into the delivery plan, either before or after go-live. Changes to the delivery model are required to enable multiple streams to happen in parallel. The scope of work must be strictly managed

during the whole process and focus must be on issues blocking day to day operations. Freeze period will have to be used to implement part of the technical scope and issues blocking user testing. Overall, available capacity is enough to implement the MVP scope, but there is limited contingency for unexpected events.

The delivery plan includes three phases before go-live: audit leftovers, until May 2021; pre-freeze period, until September, focussing on implementation of business and legal MVP requirements and fixes from RC 15; freeze period, until January 2022, focussing on finalisation of the rest of the scope, i.e. technical MVP by October and intense user testing and fixing until December, while preparation for go-live will take place in January 2022. After go-live, a six-month hyper care period will be dedicated to user support and further technical stabilisation. After July 2022, a period of system enhancement will start and its exact plan shall be further detailed at a later stage.

To enable the successful delivery of CTIS Go-Live version, the following key factors need to be met: focus and improvement of the quality of delivery; strict management of the MVP scope; design focusing on MVP definition; go-live Blocker definition criteria to be strictly followed and additional tasks to be kept to minimum. Readiness for go-live will be closely monitored in terms of progress and quality of delivery using KPIs defined by the Monitoring Subgroup of the CG. KPIs for progress will focus on comparing planned vs actual situations in terms of technical analysis and design, development stage and fixing from user testing. Quality KPIs relate to the number of bugs raised after each testing, percentage of acceptance criteria met after each sprint and Blocker, Critical and Major (BCM) bugs raised during business validation.

Following the EMA's presentation, questions were raised by members as regards the functionality to download from the system. It was noted that this functionality, which could be very useful for ethics committees that may not be very familiar with CTIS, is not foreseen until end 2022 or early 2023 and it was requested if this could be introduced sooner. EMA replied that the download functionality is being considered as it will also be needed by sponsors, but the Agency and Product Owners have looked at what features are essential for all users at go-live and it was agreed that while some forms will be available for download to Member States, some other parts will only be done after the hyper care period following go-live, as part of the planned enhancements. Requests were made by members for the Commission guidance documents in EudraLex volume 10 related to the implementation of the Clinical Trial Regulation to be adapted to explain how Member States can still comply with the Regulation despite the limitations of the system due to the MVP. EMA explained that at the Coordination Group it was agreed with the Product Owners that the Commission would adapt its guidance documents to clarify what can be done with MVP. A suggestion was made for the Commission Notice to also state what is not being implemented, e.g. possibility to submit partial submission, so that all stakeholders would know from the Official Journal what will be available to users. Finally, some members asked if the EMA has a plan B in case the CTIS does not go live. EMA replied that a recovery plan will be put in place to describe how the system can be rebooted if it goes down after a major incident.

# B.6 Training and Communication

EMA presented a high-level planning for the CTIS training and communication programmes, which will continue after go-live. Production of training materials started in early 2020 and these have been gradually published on EMA website since February 2021. Because of the large number of expected users and their high turnover, especially in the sponsor area, robust and clear training materials should be made available online and a revision process is foreseen. For Member States, the Agency is pursuing a train-the-trainer approach and started in 2020 asking Member States and EEA countries to nominate master trainers for NCA and ethics committees who can then train the CTIS users within

their own organisations. A virtual training environment ("sandbox") is being planned to be put in place initially for master trainers and then for other users in their organisations. Some users will also need dedicated trainings because of their specific roles. For sponsors, the training programmes is structured around three strands: a) train-the-trainers component for sponsor master trainers; b) component for SMEs and academia, for which a high turnover, e.g. once-in-a-lifetime use, is expected so training approach is different; c) sponsor end user knowledge transfer programme, which will start later in 2021. At present 61% of the training materials catalogue is complete and online. By end of Q3 2021, EMA plans to complete the full circle of materials and already implement the first revisions. More revisions are planned throughout the freeze period and beyond. Online training materials include FAQs, quick guides, interactive eLearning modules, videoclips, instructor guides, infographics and additional ad hoc support materials. Dissemination tools currently being used are mainly webinars, but a well-simulated training environment ("sandbox") will become available in Q4 of this year based on initial planning. Train-the-trainer courses are being prepared for NCAs and for large sponsors, such as CROs and big pharmaceutical companies. All MS NCAs and ethics committees and EEA countries have appointed master trainers and their trainings are ongoing; their feedback to date is positive and some Member States have already gradually started to cascade the training to their colleagues at national level. For sponsors, around 100 master trainers will be trained in 2021 and first courses will start in June. EMA is using internal staff and in addition experts available from Member States and sponsors (Product Owners) and the European Commission in order to develop the training materials and to train in particular the sponsor master trainers. For SMEs and Academia, a first training session was organised in two parts on 22 February and 4 March with more than 2000 users interested and 950 invited, representing almost all Member States as well as from third countries. Presentations, recordings and a report from this training session will be available on the EMA website soon. To train end users, Member States will be able to use the online tools, the direct support and training provided by master trainers, as well as a limited number of events to be based on CTIS user personas (profiles). A dedicated service desk, including technical and business support for users, will be set up by EMA in time for go-live. The users of the simulated training environment will also be supported by a dedicated helpdesk. Communication is currently ensured via direct email distributions, the CTIS trainings webpage on the EMA website, a restricted webpage for authorities and newsletters issued at least on a quarterly basis. Forthcoming dissemination events will include the ECRIN International Clinical Trials Day for researchers on 20 May and an EMA CTIS Info Day event in Q3 2021. A more elaborate communication campaign is currently being developed. An important element in the training programme is the concept of 'user persona' which are archetypes/visual models linking a set of CTIS functions to certain uses. User Persona are being developed in liaison with Member States and Sponsor representatives and are expected to help user groups to better understand their roles in CTIS and ultimately simplify the choices on how to assign people to certain CTIS's uses. Some workshops on these organisational roles will be planned soon.

Several board members complimented EMA for having successfully developed a comprehensive training programme in cooperation with Member States and for covering NCAs, ethics committees and sponsors. The representative of DG SANTE asked if an overview of the training plans by Member States was available and if EMA had any plans to translate its trainings in national languages. EMA replied that training needs vary across Member States depending on the organisational model at national level. Master trainers prepare national training plans and have been invited to share them with the Agency to help create an overview at EU level, but this might only be available in a few months. The Agency prepares the extensive training materials in English and any translations would have to be done at national level as needed. Due to the high demand, there is a need for EMA and Member States to continue to work together to provide trainings to as many users as possible. The Agency is considering making available communication packs on CTIS, which might facilitate awareness at national level, but it counts on Member States to make the necessary translations.

## B.7 Confirmation of EUPD functionality in accordance with Article 82(2) of the Clinical Trial Regulation

## a) Functional Specifications

EMA described in detail the content of Article 82 of the Clinical Trial Regulation: paragraph 1 refers to the functional specifications, which were agreed in April 2015 and subject to a minor update on 8 March 2021; paragraph 2 states the Management Board has to inform the Commission that it has verified the EUPD has achieved full functionality and the systems meet the requirements of the functional specifications. EMA also noted this has been independently confirmed by the independent audit report.

A representative of the EU Clinical Trials Regulation Coordination Group (CG) provided the CG's feedback on the audit results. Seven years were needed to reach this milestone, but it was recognised that implementation is the most demanding effort in order to make the EU a very advanced and attractive region for clinical research. The Management Board was regularly informed on progress via a joint effort by EMA, Member States and the European Commission. Based on all explanations, there are still issues to be solved before go-live, however the CG is confident that by the end of 2021 a functional tool to manage clinical trials in the EU will be available. The CG is pleased with an impressive training programme and insists on ensuring a large participation by both Member States and sponsors. The CG recommended that the board endorses the audit findings to pave the way for entry into force of the Clinical Trials Regulation.

## b) In accordance with Article 82(2) of Regulation (EU) No 536/2014 the Board is invited to confirm it has verified on the basis of the independent audit report that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications drawn up pursuant to paragraph 1 of the same Article of Regulation (EU) No 536/2014

[EMA/MB/224771/2021; EXT/MB/44907/2021] The board endorsed the independent audit report and the decision to confirm to the European Commission that it has verified on the basis of the independent audit report that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications drawn up pursuant to Article 82(1) of Regulation (EU) No 536/2014.

The Chair decided to put the decision to a vote. The vote took place electronically and openly, in full view of all present. The results were as follows:

| Members | In favour | Against | Abstained | Not present | Competing interests identified |
|---|---|---|---|---|---|
| 35 | 30 | 1 | 0 | 2 | 2 |

The full details of votes by delegation and proxies can be found in Annex 1.

## c) Letter to EC DG SANTE - Confirmation of functionality of the EU portal and the EU database in accordance with Article 82(2) of Regulation (EU) No 536/2014

[EMA/MB/223838/2021; EMA/MB/210238/2021] The board noted a draft letter to inform the European Commission about the outcome of the verification of full functionality in accordance with Article 82(2) of Regulation (EU) No 536/2014.

The Chair informed the board that the letter would be sent to DG SANTE on 21 April 2021. As next steps, according to Article 82(3) of Regulation (EU) No. 536/2014, the "Commission shall, when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the Official Journal of the European Union" and this is currently planned on 31 July 2021.

# List of participants

**Chair:** Christa Wirthumer-Hoche

| | Participants |
|---|---|
| Belgium | Xavier de Cuyper *(member)* |
| Bulgaria | Bogdan Kirilov *(member)* |
| Czechia | *Apology received (member)* |
| Croatia | Siniša Tomić *(alternate)* |
| Denmark | Mette Hansen *(alternate)*<br>Nikolas Jørgensen *(observer)* |
| Germany | Karl Broich *(member)* |
| Estonia | Kristin Raudsepp *(member)* |
| Ireland | Rita Purcell *(alternate)* |
| Greece | Eleftherios Pallis *(member)* |
| Spain | César Hernández *(alternate)*<br>Maria Alcaraz *(observer)* |
| France | Christelle Ratignier-Carbonneil *(member)* |
| Italy | Nicola Magrini *(member)* |
| Cyprus | Helena Panayiotopoulou *(member)* |
| Latvia | *Apology received (member* |
| Lithuania | Gytis Andrulionis *(member)* |
| Luxembourg | *Apology received (member)* |
| Hungary | Mátyás Szentiványi *(member)* [1]<br>Beatrix Horvath *(alternate)* |
| Malta | Anthony Serracino-Inglott *(member)* |
| Netherlands | Hugo Hurts *(member)*<br>Michiel Hendrix *(observer)* |
| Austria | Thomas Reichhart *(alternate)* |
| Poland | Grzegorz Cessak *(member)* |
| Portugal | Rui Santos Ivo *(member)* |
| Romania | Roxana Stroe *(member)* |
| Slovakia | Zuzana Baťová *(member)* |
| Slovenia | Momir Radulović *(member)* [1] |
| Finland | Eija Pelkonen *(member)* |
| Sweden | Björn Eriksson *(member)*<br>Åsa Kumlin Howell *(alternate)* |

[1] *Competing interest declared resulting in no participation in decision with respect to agenda points 4, B.4, B.5, B.7, B.10, B.12.b*

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|---|---|
| European Parliament | Tonio Borg<br>*Apology received* |
| European Commission | Andrzej Rys *(alternate)* (DG SANTE)<br>*Apology received* (DG GROW)<br>Agnès Mathieu (DG SANTE) (*observer*)<br>Kristof Bonnarens (DG SANTE) (*observer*) |
| Representatives of patients' organisations | Ioannis Natsis<br>*Apology received* |
| Representative of doctors' organisations | Wolf Dieter Ludwig |
| Representative of veterinarians' organisations | Nancy de Briyne |
| Observers | *Apology received* (Iceland)<br>*Apology received* (Liechtenstein)<br>Audun Hågå (Norway) |

| | |
|---|---|
| European Medicines Agency | Emer Cooke<br>Fergus Sweeney<br>Nerimantas Steikūnas<br>Hilmar Hamann<br>Stefano Marino<br>Peter Arlett<br>Sabine Brosch<br>Ruben Pita<br>Petri Paakkonen<br>Aleksandra Dacic-Pilcevic<br>Fia Westerholm<br>Pieter Vankeerberghen<br>Hilde Boone<br>Riccardo Mezzasalma<br>Sophia Albuquerque<br>Rebecca Harding<br>Apolline Lambert<br>Marianne Wood |

# ANNEX 1 - Vote on the endorsement of full functionality of the EUPD as per agenda item B.7b

**Votes by proxy have been allocated as follows:**

- Kerstin Jorna, DG GROW to Andrzej Rys, DG SANTE
- Mattias Groote (EP representative) to Tonio Borg (EP representative)
- Svens Henkuzens (Latvia) to Kristin Raudsepp (Estonia)
- Marco Greco (Patient representative) to Yannis Natsis (Patient representative)
- Irena Storová, Czechia, to Zuzana Baťová, Slovakia

| In favour | Against | Abstain | Not present | Competing interest identified |
|---|---|---|---|---|
| 30 | Czechia | 0 | France<br>Luxembourg | Hungary<br>Slovenia |