First meeting (virtual) of the CIOMS Working Group XIII Defining Intent, and Guiding Harmonization and Ethics Standards for Real-World Data and Real-World Evidence in Regulatory Decision-Making

1-1.50 pm CET, 30 March 2020, on Zoom

Minutes

Participants

Yoshiko **Atsuta** (Japan Data Center for Hematopetic Cell Transplantation), Elodie **Aubrun** (Novartis), Laurent **Azoulay** (McGill University), Elodie **Baumfeld Andre** (Pfizer), Stella **Blackburn** (IQVIA), Monika **da Luz Carvalho Soares** (Anvisa), Elisa **Gomez-Reino** (Alexion), Sean **Hennessy** (University of Pennsylvania), Steffen **Heß** (Bundesinstitut für Arzneimittel und Medizinprodukte), Alar **Irs** (State Agency of Medicines, Estonia), Akihiro **Ishiguro** (Pharmaceuticals and Medical Devices Agency, Japan), Solomon **Iyasu** (Merck, Merck Sharp & Dohme Corp), Michele **Jonsson-Funk** (University of North Carolina), Juhaeri **Juhaeri** (Sanofi), Andrea **Machlitt** (Bayer), Robertino **Mera** (Gilead), Daisaku **Sato** (Pharmaceuticals and Medical Devices Agency, Japan), David **Wormser** (Novartis), Kristina **Zint** (Boehringer Ingelheim), and Sanna **Hill**, Hervé **le Louët**, Sue **le Roux**, and Lembit **Rägo** (CIOMS).

Regrets

Thomas **Brookland** (Roche), **Lu** Hong (National Medical Products Administration, China), Britta Haenisch (Bundesinstitut für Arzneimittel und Medizinprodukte), Miguel **Mayer** (Universitat Pompeu Fabra Barcelona), Andreas **Rudkjoebing** (World Medical Association), and Azuma **Yuichiro** (Pharmaceuticals and Medical Devices Agency, Japan).

Introduction

- Hervé le Louët, President, CIOMS, welcomed the new working group (WG) members, with special thanks to everyone for sparing their time during the Covid-19 pandemic. Hervé wished to be able to meet face-to-face soon once the circumstances permit. He then excused himself due to a very urgent meeting.
- Lembit Rägo, Secretary General, CIOMS, chaired the meeting from this time onwards, commenting on the unusual circumstances and how we are all having to learn a new way of working remotely.
- Lembit also highlighted how the Covid-19 emergency renders all the more topical the subject of the CIOMS WG XIII: Defining Intent, and Guiding Harmonization and Ethics Standards for Real-World Data (RWD) and Real-World Evidence (RWE) in Regulatory Decision-Making.
- There then followed a “Tour de table” for all to introduce themselves.

Discussion

- Lembit explained a few practical matters about the CIOMS WGs in general:
  - Each WG has its own section on the CIOMS website where the WG documents are available. Some content is open to the public e.g. the Concept Note and minutes, and other content is available only to the WG members behind password-protection e.g. working documents and publications of outstanding importance shared among the WG members. The WG XIII web pages will become live soon.
  - The draft minutes from WG teleconferences and meetings will always be provided to the members for review and approval. The members will have an opportunity to specify if content is considered confidential and should not be made available to the public. In such cases, only redacted minutes will be placed on the web pages available to the public.
  - Where WG members consent to meetings being recorded for the purposes for taking minutes, these recordings will not be used for any other purpose and will be deleted as soon as possible.
  - The CIOMS Secretariat will provide a support staff member to the WG to act as a primary contact, in this case Sanna, who will help with setting up Zoom meetings, teleconferences, etc, writing minutes, and who will assist with general communications throughout the guidance production process.
  - CIOMS will make available sample CIOMS reports to show what the CIOMS work products look like, including their overall structure, and how real-life examples are integrated into the body copy and/or the appendices.
- The WG XIII subject, RWD/RWE, includes an ethical dimension and the WG does not as yet include an ethicist. Lembit proposes that once the guidance content is more clear from a technical perspective, that we do one of three things:
  a) Invite an ethicist to join the WG;
  b) Form a separate ethics group to give input;
  c) Create a separate document referring to the technical document.

  This can be decided at a later date.
- Lembit suggested that at this stage it would be helpful to divide the WG into three subgroups, where each subgroup would be composed of representatives from academia, industry and regulatory agencies, also from different geographical areas. The subgroups could be composed randomly by CIOMS, with suggestions for Chairs, for the WG's review. Each subgroup would be tasked with defining the WG's high-level guidance content (major topics to be covered, potential chapters and respective subsections in the chapters, appendixes etc.), and we could then merge the proposals to arrive at a single vision on what the content would look like for the whole WG.
- There was some discussion over the subgroups' objectives and sizes, but in the end, the above was agreed. Size-wise, we will inevitably end up with 5-6 people present at a subgroup meeting at any one time due to some unavoidable absences. This was considered to be a work-able size meeting.
- Michele recommended using Google Docs in order to work in a synchronised manner and avoid version control problems.
- Once this stage of the WG's task has been completed, and we have mapped out the topics we want to address, we can discuss how to make use of the WG resources and it may become necessary to divide into different groups or smaller groups for the subsequent stages.
- Solomon questioned whether the WG's objectives would be limited to regulatory applications or requirements alone. Lembit clarified that we can extend beyond if it makes sense within the scope of the Concept Note, and this is largely within the hands of the WG.
- If the WG feels the need to cover subjects for which the WG currently does not have the specialists on board, we can look to strategically inviting new WG members.

- CIOMS is hoping to secure commitment from some other organisations such as the U. S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) in the near future, as currently the Covid-19 challenge has made their time availability challenging.
- The WG will aim to share the three different high-level guidance contents by the latest in three months, i.e. end of June. This will allow for existing workloads, and Covid-19 responsibilities and disturbances.
- Sanna will set up virtual subgroup meetings, either on Zoom or as conference calls, or other formats as the subgroups wish.

Closing remarks

- Lembit appreciates everyone giving up their time and offering their kind support at this difficult time.
- It is great to get this work under way, even if a face-to-face meeting would have been ideal.
- In three months' time, we will have put in place the WG vision.
- It would be helpful to start thinking early about defining a way forward that would result in a logical flow of different topics, avoiding redundancies and repetitions, and how to make the best use of the appendixes.
- CIOMS hopes to be able to hold a face-to-face meeting in late August or early September.
- Lembit finished by wishing all good health during the Covid-19 crisis.

Actions

Who?	**What?**
Sanna	Send to WG members examples of older CIOMS guidelines. [Done}
Sanna	Share proposed subgroup lists and Chairs, and if these are accepted, then set up telecommunications or Zoom meetings for the next steps.
Sanna	Prepare the WG web pages.