



Fifth virtual meeting 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

15 and 17 December 2020, Virtual Meeting

Meeting Minutes

Participants

Enrica Alteri (former EMA), Yoshiko Atsuta (Japan Data Center for Hematopoietic Cell Transplantation), Elodie Aubrun (Novartis), Laurent Azoulay (McGill University), Stella Blackburn (IQVIA), Mariette Boerstoele* (Alexion), Sean Hennessy (University of Pennsylvania), Steffen Heß (Bundesinstitut für Arzneimittel und Medizinprodukte), Sanna Hill (CIOMS), Alar Irs (State Agency of Medicines, Estonia), Solomon Iyasu (Merck, Merck Sharp & Dohme Corp), Michele Jonsson Funk (University of North Carolina), Laurie Lambert* (CADTH), Jie Li* (US FDA), Andrea Machlitt (Bayer), Robertino Mera (Gilead), Kateriina Rannula (CIOMS), Lembit Rägo (CIOMS), David Wormser (Novartis), and Kristina Zint (Boehringer Ingelheim).

First day only

Thomas Brookland (Roche), Juhaeri Juhaeri (Sanofi) and Monica da Luz Carvalho Soares (Agência Nacional de Vigilância Sanitária, Brazil).

Second day only

Elodie Baumfeld Andre (Roche), Wim Goettsch (Utrecht Centre for Pharmaceutical Policy), Anja Schiel (Norwegian Medicines Agency), and David Townsend* (Maastricht University).

Regrets

John Concato* (US FDA), Britta Haenisch (Bundesinstitut für Arzneimittel und Medizinprodukte), Lu Hong (National Medical Products Administration, China), Akihiro Ishiguro (Pharmaceuticals and Medical Devices Agency, Japan), Miguel-Angel Mayer (Universitat Pompeu Fabra Barcelona), and Andreas Rudkjoebing (World Medical Association).

Alternates did not attend

Gracy Crane (Roche), Kinue Nishioka and Daisaku Sato (Pharmaceuticals and Medical Devices Agency, Japan).

* New to the working group since the previous Working Group XIII meeting.



DAY 1: 15 December 2020

Introduction

- Lembit welcomed the Working Group XIII members and opened the meeting as Chairman for the two days.
- The meeting agenda was adopted.
- Kateriina was rapporteur at the meeting.

Chapter teams' presentations

Chapter 1. Introduction

- Sean presented the Chapter 1 draft and the notes below reflect only the WG's discussion points.
- A novel definition for Real World Data (RWD) was proposed by the Chapter 1 team and the WG agreed.
- Michele commented on the report's intended audience described in Chapter 1, including patients, caregivers and healthcare professionals instead of only professionals developing the research and involved in making regulatory and HTA decisions. She enquired about its possible implications on writing the report as the audience would be broader.
- Enrica suggested using the term "patient organisation" instead of "patient". Patient organisations are relevant collaboration partners to regulators and industry representatives interacting throughout the product lifecycle.
- She continued by bringing the example of EMA data workshops, where patient organisations are represented in discussing their data management viewpoints.
- Stella responded that as patients are increasingly involved and interested in research and its outcomes, they constitute a relevant audience.
- Monica suggested including academics in the intended audience.
- Lembit commented that when writing the document intended as a guideline for several stakeholders, it is common practice to involve the stakeholders' representatives in the writing process. Not all parties mentioned in the introduction as the target audience are represented in the WG.
- Laurie suggested involving other relevant groups by asking them to review the final draft.
- Stella added that even if regulators approve a drug, but payers disagree with the evidence provided, the medicine will not be available.
- Lembit concluded that one possibility would be to involve additional stakeholders in the WG and another to state in the document that in addition to the primary audience, there are stakeholders to whom the topic would also be of value or interest. The WG agreed.
- Juhaeri commented on the RWD definition proposed by the Chapter 1 team: "RWD can be obtained from many sources including patient registries, electronic health records, administrative billing (claims) data /.../" and he enquired whether the list of data sources is exhaustive or is it presented as a list of examples.
- Sean responded that it is not exhaustive and additional examples are welcome.



- Juhaeri agreed and reminded all to decide at a later stage whether to add a spontaneous reporting system or surveys to the list.
- The WG agreed to use “benefits and risks” instead of “benefits and harms” throughout the document.
- Laurie suggested including a definition of “harm” and “risk” to the definition section and Michele agreed.
- Laurie also suggested mentioning CIOMS earlier in the introduction and stating why the document is being written.
- Stella responded that it had not been the aim to include the definition of harm in the introduction as the goal was to define the content of chapters. She agreed that they should add the term to the Glossary.
- Lembit agreed that a Glossary would be compiled to include the definitions of all relevant terms. He added that Cumulative Glossary with all the terms collected from CIOMS WG’s reports is being compiled by another group and will soon be shared with WG XIII.
- Sean suggested mentioning the Glossary in the introduction to inform readers where to find the terms and definitions and enquired whether the current report will have its Glossary or refer to the pre-existing one.
- Lembit responded that each report would have its Glossary but would benefit from the Cumulative Glossary.
- Sanna added that the Cumulative Glossary can be shared as a work-in-progress document for the WG members to obtain an overview of how the terms are presented and what is included.
- Laurie cautioned WG members not to duplicate each other’s sections and suggested that section 1.1. should be finalized after the rest of the chapters are drafted.
- Monica suggested all the Chat comments be included in the minutes.
- Sanna urged all state which part of the discussion their comment addresses.

Chapter 2. Uses of RWE in the regulatory process during the product life cycle

- Alar presented the Chapter 2 draft and the notes below reflect only the WG’s discussion points.
- Enrica commented that identification of patient populations for studies both in the pre-authorization phase and potentially in the post-authorization phase should be used.
- She suggested adding to the post-approval phase:
 1. The use of RWD to evaluate the safety of a medicine in a vulnerable population that is not extensively studied;
 2. The assessment of the intervention’s effectiveness – considering that the efficacy of vaccines is very topical, it would be worth including.
- Alar responded that the Chapter 2 team aimed to include a short theoretical explanation of the potential uses of the data followed by a list of actual cases. All additional examples by WG members would be welcome.
- Solomon commented that in terms of the long-term studies, assessment of effectiveness in the post-approval setting is essential. He continued bringing the example of vaccine settings, where durability and protection need to be followed up for several years, e.g. HPV vaccine and Zostavax, where additions to the labels have been added based on long-term follow-up studies.
- He added that in the pre-approval setting, several examples of RWD are used to either identify drug development tools like biomarkers, the biomarker epidemiology, and the predictive value



for progression, which especially in the oncologist settings is a critical component of the RWD use. He commended using examples and referred to a document including FDA decisions based on RWD for different indications, from which examples for the chapter could be included.

- Alar responded that there are a few publications containing comparisons of data usage policies at the EMA and the FDA. Any concrete, further examples Solomon would have of any setting would be welcome.
- Stella and Juhaeri agreed that the chapter is well structured and clear. Juhaeri suggested adding more concrete examples on safety, both during the pre-approval and the post-approval phase.
- Kristina added that a figure is planned to be included in the chapter displaying the entire life cycle of a compound and presenting how all aspects of RWE support the life cycle. The aim is not to necessarily include cases for each element, but it would be appreciated if WG members would share specific examples that they consider essential to be included.
- Stella suggested using an example regarding Rheumatoid Arthritis (RA), saying that the rates of adverse events for a particular drug in the RA population can be significantly higher than compared to e.g. the cardiovascular diseases population. It is essential to be able to predict the expected effects in the population treated so that we can be clear which effects result from the drug used.
- Jenni commended employing use cases and continued that the FDA can only provide examples of submissions in the public domain. She suggested finding more use cases at the Duke-Margolis Center for Health Policy, where there are publications on RWE.
- Mariette suggested investigating the publications circulated by CIOMS by Baumfeld et al., and by Robert Reynolds, and to identify the most relevant information from those.
- Kirstina agreed and added that it had been the intent of the Chapter 2 team.
- Lembit added that if some examples are not in the public domain, they could be included if the owners of the data agree to it.
- Jenni suggested an alternative approach of not using specific drug names but including a high-level summary of the experience to avoid confidentiality issues.
- Stella added that a lot of information in the public domain could be found in the EPAR (European Public Assessment Reports) and Alar agreed.
- Laurie commented that examples from different manufacturers should be employed to avoid a perception of bias.
- Monica suggested using examples of OTC drugs and RWD & RWE would be most welcome.
- Lembit suggested investigating the OTC industries umbrella organization and requesting examples of RWE and RWD from there.
- Michele recommended using the examples and suggested shortening the title of the chapter to “Uses of RWE during the product life cycle” so as not to limit the content to concerning only regulatory decisions, and Alar agreed.
- Yoshiko enquired whether there were any WG members from PMDA participating in this chapter, as they would provide a valuable addition.
- Sanna confirmed that Akihiro Ishiguro and Kinue Nishioka are from PMDA but were unable to join the meeting. She suggested requesting for their contribution to Chapter 2.



- Alar agreed and added that currently the “Evidential requirements” and “Engagement with regulators” sections are primarily based on the FDA's view on RWD and RWE. A short section on the European regulators’ view has been drafted but other regions need to be added.
- Yoshiko commented on the CAR-T registry that was approved by the EMA as there is a similar registry in the United States and in Japan, which are also collaborating. She offered to provide information about that data collection program.
- Alar suggested requesting that the Japanese regulatory participants provide PMDA’s view or possibly that of a specific RWE program, because there are no representatives of Japanese authorities in Chapter 2 team and Lembit agreed.
- Laurie commented on having read several examples from NICE, which would be of value.
- Michelle commented that including and comparing multiple perspectives from different regulators would be valuable instead of writing large sections of text that relate to each of the regulators.
- Lembit commented that regulators are in different stages of using RWD and RWE and that the policy and guidance documents might not be readily accessible.
- Laurie suggested adding information about the regulators’ different views to the document.
- Jenni suggested the chapter would benefit from adding more information on the drug development process, extending beyond the post-marketing period, and including both safety and efficacy information at different stages.
- Alar commented that the general acceptance of RWD and RWE by EMA and FDA are currently different, so it would be useful to describe the differences as well. He added that it is difficult to find a publication describing the conservative side of European regulations and that concrete examples would be most welcome.
- Stella agreed to search for and send references to the public letters by German authors.
- Alar added that perhaps the discussions are a bit ahead of the actual situation and it would be helpful to have the reality of RWD and RWE use be reflected in the document.
- Jenni suggested providing a link to a guidance by MHRA providing its overall view on RWE and Alar agreed.
- Solomon agreed to provide a link to documents from the Chinese regulatory bodies.

Chapter 3: Real world data and data sources

- Juhaeri and Robertino presented the Chapter 3 draft and the notes below reflect only the WG’s discussion points.
- Stella commented that prospective studies were not mentioned in the chapter regarding primary data collection, and Juhaeri and Robertino agreed that it should be added.
- Solomon commented that there are specific questions which healthcare databases are inadequate to answer and long-term extensions of trials may be used to collect RWD.
- Juhaeri agreed that extended clinical trials constitute an increasingly used, valuable data source.
- Stella offered to provide an example referring to the PROTECT study where data was collected prospectively on OTC and prescription drug usage in pregnant women, as there was no other possibility of collecting the information.
- Juhaeri concluded to include a section on ad hoc data collection, including extensions of trials.



- Solomon commented that there are several data sources, including public health databases that are leveraged to inform clinical development or provide context for regulated decisions. Bringing the example of HIV programs surveillance data, he added that recency assay or CDC (Centres for Disease Control and Prevention) surveillance system might be necessary instead of providing context for prevention trials in HIV.
- Juhaeri responded by commenting that the section entitled “Other traditional data sources” mentions NHANES (National Health and Nutrition Examination Survey) with its vast database, and added that the HIV example could be included there.
- Solomon suggested that when dealing with RWD, the data sources’ importance for endpoint strategy in clinical trials often fails because of the incorrect endpoint.
- Juhaeri agreed that the endpoint strategy is one of the factors that may have been neglected and should be described in more detail in Chapter 2 but could also be mentioned in Chapter 3.
- Stella suggested including EudraVigilance (European Union Drug Regulating Authorities Pharmacovigilance) on the list of databases. She commented that a spontaneous reporting system might have its limitations, but in some cases, e.g. historically when PML (Progressive multifocal leukoencephalopathy) was first appearing or in cases of phocomelia reappearing, which would be reported, the spontaneous system was and could be used.
- Juhaeri agreed that in some instances one event reported would be sufficient.
- Solomon added that spontaneous reports are perhaps the first source of data for such signals in the context of the controversies around using healthcare databases for the nervous signal detection.
- Robertino continued presenting the section entitled “Emerging data sources”.
- Stella commented on the “emerged curated data” and suggested that when talking about new sources of data that have not been considered before, the curation of existing data would be better suited under section “new ways of using healthcare results data”.
- She suggested adding the example of wearables and implantables, e.g. link recorders.
- Robertino responded that he intended to describe, that from the sponsor’s point of view, a completely different electronic medical record is being managed than before. Ancillary data (PDFs, images, texts, etc.) are used which had been previously unavailable.
- He continued that instead of another medical record, there is another layer of computation on a directory medical record, and it allows replication of outcomes and exposures.
- Michele suggested discussing the challenges of data sources and then highlighting the advance in each data context, indicating that the challenges are now being addressed. The approach could be highlighted as an emerging way.
- Juhaeri suggested focusing the section on the emerging, i.e. the ancillary part of using the data, connecting the ancillary data into the traditional data to have a new approach.
- Michele responded that she had suggested a structural change. In describing the different RWD sources, one of the common challenges is the regulator’s difficulty in accepting data that is not generated in a highly standardized manner, which could be highlighted as an example of providing an additional layer of standardization.
- Robertino and Juhaeri agreed to consider modifying the structure of the section.
- Jenni offered to provide articles with examples of using technology in data collection, including for COVID-19 patients.



- She continued to ask whether the Chapter 3 team would consider describing artificial intelligence (AI) technology, machine learning (ML), and deep learning just at a high level because it is specific to the new data sources. These techniques determine the level of credibility of the results.
- Stella suggested that ML in radiology could be used to obtain objective outcomes when using RWD, e.g. have ML to identify and perhaps measure changes from previous images.
- Robertino continued by presenting the section on emerging data sources and concluded that there is minimal opportunity for social media to provide adverse events or patient-recorded outcomes.
- Lembit and Sean agreed, and Sean added that perhaps social media is not suited for safety signals but could be used for identifying the reasons why people stop taking medicines.
- Andrea commented that there are a few exceptions where social media has value, e.g. abuse or misuse of drugs, but agreed with Robertino's assessment.
- Stella referred to a project which concluded that social media was not a useful resource. She added that it would be good to include that information.
- Juhaeri offered to send the project mentioned, IMI WEB-RADR, to Robertino.
- Robertino recommended including tokenisation in this chapter but Lembit suggested the topic of privacy and patients' rights should be discussed in Chapter 5.
- Jenni added that synthetic data, which is not a real data set but based on a real patient records, can be used to conduct preliminary research.
- Michelle commented on using ML and biases and enquired whether the topic should be addressed in Chapters 3 or 4.
- Stella added that there had been instances of using AI to identify patients with rare diseases. It has been found that the number of diagnoses can be increased up to ten times compared to the ones in clinical practice just by searching for patterns in the databases.
- Stella agreed to try to provide a publication on the topic.

Chapter 4: Key scientific considerations in regulatory RWE generation

- Michele introduced the Chapter 4 draft and the notes below reflect only the WG's discussion points.
- Yoshiko presented the draft she had provided for "Data source and data quality, integrity, transparency for data transformations, fitness for purpose".
- Laurie suggested considering Chapters 2 and 4 together to ensure good harmonization and avoid duplication of efforts. Elodie and Michele agreed.
- Lembit added that the final coordination will be performed in the editorial phase, but it would be beneficial to agree on different aspects of the document before to the greatest extent possible.
- Stella enquired what is meant with the last sentence in patient population section: "when mandatory reporting is obliged by regulation for patient registers".
- Yoshiko responded that the focus is more on the secondary use of that registry data, so if that registry has mandatory reporting required by regulation when thinking about population, it is clearer that generalization or external validity is protected by that mandatory reporting system.



- She continued, that one example of mandatory reporting is the cancer registry in Japan, where all incidences are reported.
- Sean commented on a paper on “wrong question bias” and enquired whether the topic should be discussed in Chapter 4.
- Michele responded that it might have been conceptually what had been addressed at the beginning of the chapter with the potential need to refine the research questions explicitly. She asked whether the beginning of the chapter would be a suitable place to discuss the “wrong question bias” and Sean agreed.
- Laurie suggested using more examples throughout the document, and Michele agreed.
- Stella said she is not sure whether traditionally we get the comparison arms from old RCTs, as regulators are increasingly expressing their opinion of not wanting to use historical data. She added that external controls are quite often from RWD.
- Stella continued that the section includes rather a lot of information on RCT as opposed to study designs using RWE.
- Michele responded that in terms of balance, Solomon, who drafted the section, was reflecting on the degree to which RWD is being used in the context of a randomized study as a way to potentially minimize the patient burden for follow-up outcome ascertainment.
- Laurie commented that the section might include too much detail, and Michele responded that it is easier to edit the text at the final stage so in that sense it is better to have more.
- Andrea presented the transparency reporting protocol registration.

Closing remarks

- Lembit thanked the WG members for the beneficial discussions and for their efforts in finding time for drafting the chapters.
- Sanna confirmed that she would send the WG members the combined chapters document with a few new comments from reviewers. She urged all to use the most recent version of the document in order to avoid version control problems.
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DAY 2: 17 December 2020

Introduction

- Lembit welcomed the Working Group XIII members and introduced a new member joining the WG: David Townend, Professor of Health and Life Sciences Jurisprudence, Department of Health, Ethics and Society, Maastricht University.
- WG members agreed to a virtual group photograph that would be uploaded to the CIOMS website on the WG’s dedicated page open to the public.

Preliminary thoughts on ethics and personal data regarding the content of Chapter 5

- David presented his thoughts on ethics and personal data, and the notes below reflect only the WG’s discussion points.
- Laurie commended the presentation as involving ideas that are essential for all to understand, adding that there will never be one uniform manner of managing ethics and privacy issues.



Discussions on who decides whether it is safe enough to use treatments that can be lifesaving are ongoing, especially during the COVID-19 pandemics.

- Lembit commented that the amount of data collected from various sources at an enormous speed is continuously increasing, but the benefits from that are not as evident as they could be.
- He added that regarding individual data privacy, increasingly better treatments are expected whereas the readiness to contribute and share one's own personal data are objected to, raising issues of personal data sharing to be explored and balanced for all to benefit from.
- Lembit suggested Chapter 5 to include the current situation concerning ethics and privacy and propose new routes of action.
- Laurie reflected on placebo groups and said that patients there take risks to receive the benefits, so the amount of certainty needed before giving access to treatments needs to be discussed.
- Laurie enquired whether the idea of patient engagement in the design and conduct of a RWE project needs to be discussed in chapter 5.
- Lembit responded that the plan is to connect to CIOMS WG XI Patient Involvement in Development and Safe Use of Medicines. They have patient organisations represented and would provide valuable insight on the matter.
- Solomon commented that most of the discussion regarding healthcare databases tends to tackle the issues of data privacy, data confidentiality, identity and linkage to the identified data, and issues concerning ownership.
- He enquired whether David supported the idea of privacy not existing anymore and enquired on his opinion about the vast amount of RWD and people's right to define themselves versus the set of data defining people.
- David responded that he would need to consider the predetermination question more thoroughly, as it addresses inclusion and diversity issues. He admitted not agreeing with the idea of privacy being normative and added that it is difficult for a state or individual to argue another individual's privacy. Privacy is transactional and changes over time.
- David continued that the state needs to have access to individual data, and public interest must be employed when negotiating the need to access something an individual considers private.
- He added that confidentiality is a negotiated space, and elaborated that since 1890, privacy has been defined as an exclusionary right and confidentiality is more enabling in a more contractual way.
- Enrica commented that the value of healthcare data does not derive from individual data. It is essential to determine the intermediary who analyses the data that is collected from a multitude of individuals. She added that there is no direct gratification in health care and the benefits of sharing one's data might be visible in ten years or later.
- David agreed and added that how to build trust with the intermediaries is the essential question.
- Michele commented that the data's value derives from the counterfactuals that can be assembled by combining the data from large groups of individuals together. It is the collective data that can be scientifically benefitted from.
- Stella elaborated that individual people removing their data can render the data set less beneficial because the main idea of using RWE over clinical trials is the generalizability based on a larger population. If various groups of people decide to deny their data to be used, it could theoretically alter the results and negatively affect society.



- Lembit added that data sharing issues need to be extensively explained to the public due to the lack of understanding of the consequences of some actions. He suggested adding the information to the guidance which would be valuable to several stakeholders.
- Michele added that possibly the public awareness has risen regarding the COVID-19 vaccine trials and suggested an opportunity for the WG to use that knowledge and describe other uses of data to build the general understanding of the risks and benefits participating in trials.
- Laurie commended the idea and added that other COVID-19 therapies would also constitute valuable examples, and Michele agreed.
- Laurie commented that citizens are aware that donating their blood benefits many in need, the same is with data.
- David added that data becomes one of the areas where people can exert control over their lives; they can refuse when offered the possibility of sharing information.
- Lembit added that in some legislations, under exceptional legal cases, data can be accessed regardless of what has been individually stated. People would be more confident in trusting the system when they believe that efficient data governance principles are implemented.
- David agreed and elaborated on a distinction between not-yet patients and patients, suggesting that as an individual becomes a patient, an enthusiasm to participate will increase due to personal experience.
- Solomon commented on the ethical analysis of healthcare data and the danger of incorporating unconscious biases when using ML algorithms. He continued by enquiring about including the discussion on the predictions and inferences made regarding the public to benefit from the collective usage of their data and the predictions made about certain groups and phenotypes defined by setting characteristics to be included in Chapter 5.
- Stella commented that regulation tends to emerge in response to something negative or something that is perceived as having a negative effect. Regarding medical confidentiality, the public would not agree to have health data presented in newspapers but would expect to know if their neighbour would have medical conditions making them possibly dangerous to the society. Regulations cannot be overly general and should consider individual situations.
- David enquired whether all WG members would be involved in drafting Chapter 5.
- Lembit responded that the final document is a consensus report, but usually every chapter has agreed on chapter leads who are more active in drafting and then other members comment to finalize the draft.
- David suggested the WG members inform Sanna if they would prefer to be in the lead group or discussion group in drafting Chapter 5.
- Lembit agreed and also suggested including additional people with experience in dealing with the before-mentioned issues to work with Chapter 5.
- David added that he would prefer to strengthen the team from non-usual contributors to ethics debates to benefit from diversity and inclusion. [Post-meeting comment: Yoshiko would like to join this team.]
- Enrica suggested Lembit contact former colleagues at WHO and Lembit responded that it would be extremely difficult given the current worldwide situation.
- Lembit concluded the discussion expressing hope to return to the topics during the future WG meetings and thanked David for the initial insightful discussion.



Coordination and cross-referencing

- Lembit addressed the agenda topic of coordination and cross-referencing by saying that the chapter teams would continue working independently, but that before the next meeting, the combined chapter document would be assembled and distributed again.
- Sanna added that several chapters will include references to the same of subjects and it would read better if the chapters referred to each other's mentions of the subject.
- Stella suggested that it would be valuable to invite Dinesh to talk to the chapter leads at the early stage to consult about layout and drafting principles.
- Lembit agreed to enquire whether Dinesh would be able to find time in January and suggested sharing an Editorial Guidance being prepared by WG XI that would provide valuable information.
- Sanna confirmed having sent the Editorial Guidance to the WG members and added that the guidance document offers suggestions on how to have uniformity across chapters, present references, give instructions, etc. She offered to resend the guidance. The author of the guidance, Dinesh, is fine-tuning the document and the new version of it would be available next year.
- Lembit concluded that he would approach Dinesh and discuss organising a short meeting with the chapter leads.

Case studies

- Lembit continued by describing the case example template created by WG XII also beneficial to the current WG.
- Sanna added that the document has not been distributed yet but will be shared as soon as possible. She continued that the Chair of WG XII has investigated how case examples have been presented in various CIOMS reports and combined a suggested template to facilitate writing case examples regarding what kind and to which extent include information.
- Sanna suggested the template could be adapted and proposed some WG members to review the case examples and identify the elements to be adjusted for the template to be used.
- Lembit added that the case study template document should not be adapted in full but would be valuable to consider when deciding how to present the examples.
- An editorial group would be formed at the final stage of drafting to fine-tune the manuscript which then would be sent to the entire WG to be accepted.
- Sanna added that regarding case studies, she has noted down various members from the working group who have offered to provide case studies on a certain subject. She shared the list with the WG to revise the ideas provided by WG members so far and urged all to send her the ideas to be added to the list.

Timelines for the future meetings and conclusions

- Lembit enquired whether there are suggestions regarding the timelines of future WG meetings and proposed early February.



- Stella suggested organizing more frequent but shorter meetings, maybe two or three hours per month.
- Sean proposed discussing two chapters in 60 minutes, Michele responded that 30 minutes per chapter might not be enough.
- The WG agreed to discussing one chapter at a time and have shorter meetings.
- Lembit concluded that Sanna would e-mail the Doodle polls to fix the date.
- Sanna enquired about the report implementation and dissemination point in the agenda and whether it should be discussed.
- Lembit responded that it might be too early to discuss that point and reflected on some good experience of conducting webinars, bringing the example of a recent successful webinar with the clinical research centre in Shanghai with more than 2000 people listening in. Several other ways to introduce the public to the created resource are available as well and will be discussed in the future.
- Lembit concluded the meeting by thanking all for their commitment and excellent work.