**3rd meeting of the CIOMS Working Group on Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development**

**Geneva, 6-7 September 2022**

# Meeting Minutes

**Participants:**

Enrica Alteri (University of Geneva), Barbara Bierer (Harvard University), Malcolm Brown (Astellas), Domenico Criscuolo (Italian Society of Pharmaceutical Medicine), Andrzej Czarnecki (Eli Lilly), Luther Gwaza (WHO), Rieke van der Graaf (University of Utrecht), Tim Higenbottam (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine), Kenneth Kaitin (Tufts University), Sandor Kerpel-Fronius (Semmelweiss University), Ingrid Klingmann (President, PharmaTrain), Nilima Kshirsagar (ICMR, India), Raffael Kurek (Astra Zeneca), Michelle Limoli (FDA), Honorio Silva (IFAPP Academy), Stephen Sonstein (Committee on Accreditation of Academic Programs in Clinical Research), Ichiro Uchida (Osaka University), Roberto Verna (World Association of Societies of Pathology and Laboratory Medicine), Haruko Yamamoto (PMDA).

**Regrets**: Priya Bahri (EMA), Pravin Chopra (IFAPP Academy), David Gordon (WFME), Stuart Jones (King’s College, London), Katarina Kelin (Sanofi), Gustavo Kesselring (IFAPP Academy), Joel Krasnow (Bayer), Simon Maxwell (University of Edinburgh), Min Soo Park (Yonsei University College of Medicine, Seoul), Peter Stonier (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine), Pol Vandenbroucke (Pfizer), Adeline Verticelli (GSK)

**Secretariat:** Lembit Rago, Catherine Bates

**Day 1**

Lembit welcomed participants and reminded the group that the WG should aim to have a mature draft of the report ready by summer 2023, to allow time for editing. Therefore, if the WG could align around a vision of the report and set up writing teams by the end of this 3rd WG, this would be an achievement towards reaching the above-mentioned goal.

The WG could plan another in-person meeting when the draft is ready.

The group began the meeting by discussing the paper (Introduction/Chapter 1) provided by the subgroup[[1]](#footnote-1).

**Introduction**

Members discussed who the target audience should be and whether the title of the WG “Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development” was still appropriate.

Given the huge number of new participants in the field of drug development since the onset of COVID, the WG discussed whether the target audience shouldn’t be broadened beyond those who **participate** in drug development to those who **prescribe** medicinal products. Another perspective was that the scope shouldn’t be too broad either e.g. lay community. Perhaps there is a case for pharmacists and (non-industry) scientists, but not everyone. A solution could be to state that the WG is aware of the landscape, but that the report will focus on professionals participating in drug development.

Yet a third view, was that this exercise is not necessary. The title of the WG is fine. What is required, however, is to structure the overall environment such that standards for drug development are the same as those for medical affairs, toxicology, etc… How do we achieve this?

**Action items:**

* Andrzej to explain what drug development is (cradle to grave)
* Steve to provide an additional paragraph to define the health professionals who participate in drug development (e.g. patients, regulatory authorities).
* Steve to integrate changes to the Introduction
* Revise referencing: only statements of fact should be included, not entire publications.
* Consider changing title of the WG

**Chapter 1**

WG discussed the flow of this chapter. It should be given a more positive tone. Drug

development is a branch of science that brings value to patients. It is cross-functional and

complex.

The group then reviewed the title of Chapter 1 “Background and Problem Statement” and

Agreed that a more positive message was required here as well. The term “problem” should

be replaced (see Actions below). The chapter should state that there is a gap in training and

education which is the result of not having standards in these disciplines.

After lunch, Lembit announced the launch of the CIOMS report “Patient Involvement in the Development, Regulation and Safe Use of Medicine”.

After the discussion about the Introduction and Chapter 1, the WG looked at the Table

of Contents to review remaining chapter headings.

The WG also addressed the issue of certification and whether it is required for all stakeholder groups or only a few. Where does it belong in the report? Which institutions issue certification? Who is the training recommended for? The WG agreed to cover certification in Chapter 1, although not in detail.

Target audiences/course content

There was a suggestion to break the audiences up into those for whom training is essential, those for whom it is recommended and those for whom it is nice to have. The group agreed that trial participants don’t need training. A suggestion was that instead of looking at the different target audiences, one should look at the educational needs e.g. Basic (or other term e.g. Fundamental), Intermediate and Advanced. There will be a core training for all audiences and specific modules for those who require more in-depth content. The WG could use the EUPATI[[2]](#footnote-2) syllabus as a basis.

A question was raised about why the content and audience groups necessarily have to mesh. Could the WG not just describe each course level and let the relevant groups and content merge naturally?

Regarding sustainability, the WG agreed that it would be difficult to include this topic in the report, but it could be mentioned.

When Chapters 2-4 are completed, the WG could draw up 10-15 principles. The WG should schedule a meeting to discuss them.

**Actions:**

* Amend chapter title and replace “Problem Statement” with “Future Needs”
* Malcolm will send a new version of the chapter to the team[[3]](#footnote-3)
* Create a statement that explains the rationale for the WG and insert it as a text box.
* Insert a second text box for lessons learned from COVID.
* Move issues related to clinical trials to the latter part of the chapter
* Move “Ethics Committees” out of the group with lay audiences and parts about target audiences from Chapter 1 to the Introduction.
* Include examples from global locations: one example from LMICs and one from UMICs/HICs[[4]](#footnote-4)
* Part of the section on Competency-based education could be moved as well.
* Ingrid + WG to review TOCs of both subgroups to ensure all points are captured
* Barbara to rewrite Section 1.1 and change the focus to cover devices. Amend infographic to reflect new scope.
* Ken to provide a section about how the landscape has evolved and current challenges. Training is required to understand these developments e.g. expanded access and other changes in regulatory policy.
* Move some of Section 1.2.1 to other chapters, later in the report.
* Ingrid to review Section 1.3 to determine which parts could be moved e.g. Appendix.
* Barbara to rewrite Section 1.4: leave high level concepts as is, but move detail to Chapter 3
* Remove references to “Group 1”, “Group 2”, “Group 3”.
* Agree definitions of who biomedical professionals are.
* Barbara, Steve and Ingrid to provide suggestions for the core training/specific modules.
* Ingrid and Nilima to review EUPATI materials and determine how to integrate them into Chapter 4 (LMICs)
* WG to meet to discuss the 10-15 principles of education when these become available.

**Day 2**

Lembit announced that the objective for Day 2 was to finish reviewing the TOC for the remaining chapters, namely Chapters 2,3 4 and 5.

Promoting better understanding of medical product development

A graphic representation could be included to help audiences and training providers as well

as political decision makers to gain a better understanding of what the development of

medical products is about. There was a suggestion to leave out references to the general

public. Although a proposal was made to add a paragraph about how the general public

needs some help in understanding medical product development. Where this fits in the

report is undecided as yet. The WG to assess.

Pharmacists and other healthcare professionals should be mentioned in the report, but their

specificities should not be described in detail.

Ultimately, training should be included in undergraduate medical education, but at the

moment, specialist training could be the objective.

The group discussed how the report should be publicized. A subgroup shall be formed to plan an advocacy campaign.

**Actions:**

* Honorio to work on Chapter 3
* Insert graphic representation of audiences/training providers to raise awareness (see above comment)
* Consider changing the title of Chapter 5
* Enrica and Lembit to draft the report Foreword

Lembit called for volunteers to form writing teams for the different chapters as follows:

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| --- | --- | --- | --- |
| Chapter number | Title | Team lead | Members |
| 1. | Background and Future Needs | Honorio | Barbara, Domenico, Enrica, Ingrid, Nilima, Peter, Sandor, Steve |
| 2. | Needs and Benefits of Education | Malcolm | Andrzej, Barbara, Domenico, Honorio, Ken, Malcolm, Raffael, Tim, |
| 3. | Educational Objectives/Options (working title) | Enrica | Haruko, Honorio, Ingrid, Ken, Michelle, Rieke, Roberto, Sandor, Steve |
| 4. | Syllabus Proposals/ Content | Ingrid | Domenico, Ichiro, Ken, Luther, Nilima, Sandor |
| 5. | Good Education Practice Principles | Honorio | Barbara, Ingrid, Nilima, Tim |

Members who were not present in Geneva were contacted subsequent to the meeting and invited to join the above teams.

The WG agreed to the following timeline:

* **Friday, Sept 30th** 🡺 Comments/new draft of Chapter 1 to be shared with the WG
* **Friday, Sept 30th** 🡺 All chapter outlines to be shared with the WG
* **Mid-Oct** 🡺 Form editorial committee with chapter leads. Chapter leads to

hold virtual meeting to discuss the outlines

* **Thursday, Dec 15th**  🡺 1st drafts to be shared with WG
* **End January/beg Feb 2023** 🡺 4th WG (virtual)
* **End June 2023** 🡺 Publish report

1. Honorio, Peter, Nilima, Domenico, Sandor, Steve [↑](#footnote-ref-1)
2. European Patients Alliance for Therapeutic Innovation [↑](#footnote-ref-2)
3. Chapter 1: Lead: Honorio, Team: Peter, Ingrid, Barbara, Sandor, Nilima, Enrica, Steve, Domenico [↑](#footnote-ref-3)
4. Upper Middle Income Countries/High Income Countries [↑](#footnote-ref-4)