**5th meeting of the CIOMS Working Group on Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development**

**Geneva, 6-7 September 2023**

Meeting Minutes

**Participants:**

Enrica Alteri (University of Geneva), Priya Bahri (EMA), Barbara Bierer (Harvard University), Malcolm Brown (Astellas), Pravin Chopra (IFAPP Academy), Domenico Criscuolo (Italian Society of Pharmaceutical Medicine), Andrzej Czarnecki (Eli Lilly), Luther Gwaza (WHO), Rieke van der Graaf (University of Utrecht), Sandor Kerpel-Fronius (Semmelweiss University), Gustavo Kesselring (IFAPP Academy), Ingrid Klingmann (President, PharmaTrain), Nilima Kshirsagar (ICMR, India), Michelle Limoli (FDA), Honorio Silva (IFAPP Academy), Ena Singh (Pfizer), Stephen Sonstein (Committee on Accreditation of Academic Programs in Clinical Research), Ichiro Uchida (Osaka University),

**Regrets**: Matthew Farmer (Astra Zeneca), Sophia Goodison (GSK), Tim Higenbottam (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine), Kenneth Kaitin (Tufts University), Stuart Jones (King’s College, London), Peter Stonier (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine), Roberto Verna (World Association of Societies of Pathology and Laboratory Medicine), Haruko Yamamoto (PMDA).

**Secretariat:** Lembit Rago, Catherine Bates

**Actions/Decision Items**

General

* The report might not need a foreword
* An editorial committee should be formed
* The title of the report should remain as is for the time being. The WG to consider changing it to “recommendations” in lieu of “standards” at a later stage.

Audiences

a) Audiences will be reorganized to reflect the presence of HCPs in the following categories:

1) Biomedical professionals,

2) Regulators and HTA Experts (assessors),

3) HCPs not directly involved in developing meds,

4) Members of Ethics Committees

Therefore, what was initially Group 4 (General Public/Patients/Patient Advocacy Groups) is now

Group 5.

1. General public/patients/PAGs (i.e. Group 5)
* Should be stated in the main part of the report, not in the appendix.
* The EUPATI initiative should be featured as well.
* Group 5 recommendations will differ from those aimed at HCPs.
* A distinction should be made between patients who participate actively in clinical development and regulatory policy making and those who do not.

Introduction/Chapter 1

* Rewrite the Introduction and Chapter 1, taking on-board the comments received, as well as the discussions held at the 5th WG.
* Shorten the Introduction and Chapter 1 to streamline and avoid duplication.
* Mention target audiences in Chapter 1, but expand on them in Chapter 2

Chapter 2

Chapter 2 will be revisited based on amended Chapter 1.

Chapter 3

Competencies will be covered in Chapter 3, but the tables, moved to the Appendix per a) below.

Appendices

1. Appendices will include:
* Recommendations (previously, Chapter 4- see also point b) below)
* Model curricula (PharmaTrain, EMA, FDA)
* Glossary
* Tables that are currently in Chapter 3
1. The WG is tasked with putting forward suggestions for five recommendations, e.g. which audiences should benefit from following the recommendations of the CIOMS Education WG report.

Other

The WG will hold a call at the end of October to discuss progress (see Break-out session below). A doodle will be sent to the group.

Discussion highlights

Lembit welcomed participants and provided an overview of latest CIOMS publications. He presented his vision about how the WG should progress on the report’s preparation and described the target audience of the report:

The report aims to be useful for both health professionals with medical backgrounds as well as those from other disciplines associated with the development of medicines. The scope is not limited to training on clinical trials. The report will be about “medicines”, including combination products. Devices will not be included.

The group should be clear about who it wants to educate, namely Healthcare Professionals (HCPs) who generate relevant data during the exercise of their profession, but are not directly involved in medicines development. This is the audience for whom the WG needs a more precise idea of what it wants to recommend.

A career in medicines development is a continuum in which HCPs take on different roles. The two HCP audiences should not be seen in siloes. However, training, objectives and training providers for the two groups are very different. So, HCPs should be split into two groups, i.e. those involved in Meds. Dev. and those, not involved.

Maybe the WG should not start with “categories of things HCPs should do”. Instead, it should consider a knowledge base featuring different levels of proficiency and then see who fits into which levels, bearing in mind that the report would focus on the basic level only.

A competency-based learning framework could be used to achieve this (e.g. [JTF](https://mrctcenter.org/clinical-trial-competency/), [IFAPP](https://cioms.ch/wp-content/uploads/2023/09/Full-Core-Competencies-in-PM-MD-Version-1.2-PREPUBLICATION-FRONTIERS_Edited-by-PDS-HS-Sept-14.docx)). Honorio presented the IFAPP Core Competencies framework to the WG. Although the domains are similar in both the JTF and IFAPP, JTF focuses more on clinical research whereas IFAPP is broader in scope. The two could be combined to create the content for Chapter 3. One should start with the domains that are already there and add any that are missing. Same with the competencies. Neither framework addresses the scope of the report in an entirely satisfactory manner. So, competencies would have to be added for physicians and other healthcare providers who generate data and will do so in the future.

The challenge with the report at the moment is that it speaks to the audiences who will be trained as well as the organizations that will provide the training. This is confusing for the reader.

Break-out session: competency building exercise

The WG was divided into three subgroups and tasked with selecting the Domains and Competencies in the IFAPP Syllabus that are required for the following audiences:

1. HCPs directly involved in Meds Dev (Enrica, Honorio, Ichiro, Ingrid, Pravin, Steve)
2. HCPs not directly involved in Meds Dev (Andrzej, Gustavo, Lembit, Malcolm, Michelle, Nilima, Priya, Sandor)
3. HCPs more generally (Barbara, Ena, Rieke)

*Breakout group reports*

1. This team defined “HCPs directly involved in Meds Dev” as comprising two groups, namely

1a) Medicine developers working in the pharmaceutical industry who have a medical or related background

1b) HCPs (not in industry) who are involved in data generation … .

2) HCPs who assess data and make decisions about medicines development: regulators (including approval and post-authorisation surveillance responsibilities), HTA experts, payers, ethics committees. .

For Group 1a): the team agreed that the PharmaTrain syllabus would be suitable.

For Group 1b): the JTF and PharmaTrain syllabi would both need to be considered.

II) HCPs not directly involved in Meds Dev:

III) This team put forward a list of competencies that would be suitable for all HCPs regardless of their role. The WG agreed that it would produce the competencies for HCPs in groups I) and II) first and those for HCPs in group III, at a later stage.

**Action/Decision item**

The three subgroups agreed to finalize their respective competencies by year end. A WG call will be held at the end of October to update the group on progress. A doodle will be sent out to identify some dates.