**6th meeting of the CIOMS Working Group on Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development**

**26 October 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), Matthew Farmer (Astra Zeneca), Sophia Goodison (GSK), Rieke van der Graaf (University of Utrecht), Tim Higenbottam (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine)Sandor Kerpel-Fronius (Semmelweiss University), Gustavo Kesselring (IFAPP Academy), Simon Maxwell (University of Edinburgh), Liming Shao (Fudan University), Honorio Silva (IFAPP Academy), Ena Singh (Pfizer), Stephen Sonstein (Committee on Accreditation of Academic Programs in Clinical Research), Peter Stonier (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine), Roberto Verna (World Association of Societies of Pathology and Laboratory Medicine), Haruko Yamamoto (PMDA).

**Regrets**: David Gordon (WFME), Luther Gwaza (WHO), Stuart Jones (King’s College, London), Kenneth Kaitin (Tufts University), Ingrid Klingmann (President, PharmaTrain), Nilima Kshirsagar (ICMR, India), Michelle Limoli (FDA), Ichiro Uchida (Osaka University)

**Secretariat:** Lembit Rago, Catherine Bates

**Minutes of the 5th WG/ greater clarity on definition of HCP audience**

The group reviewed the comments in the minutes and discussed the composition of the “HCPs directly involved in medicine development” audience, 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: regulators would fit into this group as well

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

The WG agreed on the need to fine-tune the definition of the “healthcare professionals” audience and make a clearer distinction between who they are vs who they are not. In particular, their role as data generators requires further discussion, e.g. primary vs secondary data. As an example, Lembit mentioned that increasingly, regulators also generate data. Hence, the need for greater clarity in this regard.

**Update on Introduction and Chapter 1**

Enrica presented these [slides](https://cioms.ch/wp-content/uploads/2023/10/CIOMS-Education-26_10_2023_Intro-Chapter-1_Alteri.pptx)

Does the last paragraph of the Introduction (see below) belong in the Introduction or should it be

moved to a different chapter? Also, is the statement that the CIOMS guidance “provides a model syllabus” (see yellow highlight) consistent with the intent of the WG?

*“This report describes the development, life cycle and regulatory environment of medicinal*

*products as well as current trends and the challenges faced by medicines developers today. It*

*contains an overview of the competencies required to work in medicines development in an*

*effective and ethical manner. Importantly, it provides a model syllabus that can be tailored to*

*suitable levels for the main groups of participants in medicines development (for example:*

*Basic, Skilled, and Advanced), as well as updated as needed. In addition, it could be used to*

*implement educational programmes for health professionals at all stages of medicines*

*development/regulation. Shorter educational programmes could be developed for health*

*professionals who treat patients, but are not directly involved in medicinal product development.*

*Finally, additional knowledge of medicines development and regulation will also be valuable for*

*policy makers, science writers, and others in their efforts to inform patients, advocacy groups,*

*and society at large.”*

(Please see the slides for further changes)

**Other discussion highlights:**

* Malcolm thanked Enrica for her presentation and suggested that he wait for a final version of the Introduction/Chapter 1 before completing Chapter 2.
* Lembit reminded the WG that some parts of Chapter 1 could be moved to the Appendix if needed.

**Competencies**

**Discussion highlights**

Setting expectations for HCPs not directly involved

The group was reminded to exercise caution when developing the recommendations/advice for HCPs who are not directly involved in meds dev which is a large proportion of HCPs today. This audience has little or no interaction with clinical trials, the pharmaceutical industry or medicines development. So, the report should not “overstep the mark” and expect more from these HCPs or the people who will train them, than what can be reasonably expected in an increasingly crowded and complex educational world.

In connection with the above comment, maybe the WG could be more prescriptive about competencies for HCPs who are directly involved and less so, for HCPs who are not directly involved. The latter HCPs should be aware [of the competencies], but the key is “trust”. Rather than be too detailed about the requirements, the report should aim to build trust in the healthcare system as this is what leads to better outcomes. (Please see [Special Report by Edelman on Trust and Health](https://www.edelman.com/trust/2023/trust-barometer/special-report-health))

Different domains?

IFAPP and JTF cover most of the competencies for HCPS so the CIOMS report can keep the domains on a general level and not go into too much detail. References from existing curricula can be added as examples. Do the different HCP audiences really require different domains? Couldn’t the domains be the same for both groups, but have different levels of competency (e.g. three levels) in each to suit the various audiences?

How to distinguish between HCPs dir. involved and not dir. involved into two groups?

A point was made that maybe separating the HCPs into two groups might be too

simplistic, i.e. there are some HCPs whose role is exclusively to develop medicines and

keep them on the market, be it in industry, a research organization [academia] or

regulatory body. At the other end of the spectrum, there are patients, the end users of the

medicines, who are not involved in developing medicines, except in cases when they

provide data and feedback [to regulatory authorities].

This too, however, requires a basic understanding of why the data is important. In between these two extremes, there are professionals working in hospitals who treat patients, but are also involved in clinical trials, but on a part- time basis. So, they can be considered medicines developers, but not to the same degree as HCPs who work in medicines development full- time.

Preamble

The WG discussed the Preamble (for HCPS not directly involved in meds dev) which was prepared by Nilima and includes comments from Lembit and Priya. Does each HCP audience need its own preamble or can one be drafted that is appropriate for all?

Subgroup III- Ethics

Regarding Subgroup III (Ethics), the WG needs to decide where to insert these competencies. Should they be a stand-alone section or integrated into the domains of Subgroups I and II? The WG will discuss this and finalize the domains for Subgroups I and II first and then, address the Ethics competencies at a later stage. A call will be held for members of Subgroups I and II for this purpose.

**Recommendation suggestions**

**Discussion highlights**

- Recommendations received from members were grouped around a set of topics and placed in a table for enhanced readability and review by the WG.

- Catherine will share the table with the WG for comment

**Editorial Committee (EC)**

Several members have kindly put their name forward to join the EC. The composition will be announced shortly.