

## **Recommended standards of education and training for health professionals participating in medicines development**

### **I. Introduction**

The development of new medicines is a critical part of health innovation.

Following the exponential advancement in the basic biomedical sciences and clinical medicine observed in the last 50 years, drug (medicines) development has become a complex set of disciplines with distinct scientific methodology and established needs for education.

The key disciplines in medicines development include clinical research, bioethics, drug safety, regulatory sciences, health economics and medical affairs. However, there is currently not a holistic approach and thus the education programmes available provide only partial knowledge of the entire process.

As an example:

- the Declaration of Helsinki only states that clinical research must be “*conducted by individuals with appropriate ethics and scientific education, training, and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.*”
- The need for education on ethical principles to conduct biomedical research or Health-related Research Involving Humans has been extensively described in CIOMS Ethical Research Guidelines 2016 and the Belmont Report.
- The need to update Good Clinical Practice (GCP) guidelines has recently been recognized by ICH.

In general, medical schools worldwide do not include medicines development and its disciplines as part of their undergraduate syllabus, and few include them in their postgraduate programmes.

The needs within education and training in clinical research and medicines development among members of the clinical research team have already been studied and documented. Studies have shown that members of clinical research team often lack education in the principles of medicines development. Even ICH E6 refers to investigators’ qualifications but with no specific requirements for the type of training other than GCPs.

Insufficient education and training have also been identified by the European Union Innovative Medicines Initiative (EU-IMI) as a significant barrier to the effective development of new medicines. All biomedical professionals involved in medicines development should have a full understanding of the overall process for an effective integration of their activities.

Furthermore, there is currently no postgraduate education requirement for individuals performing and managing clinical trials and other medicines development related activities such

as members of clinical research teams, ethics committees, hospital review boards, hospital administrators etc., regardless of their professional background.

## **II. THE ISSUES**

Because of the lack of or insufficient education and training, medical practitioners and other professionals (pharmacists, nurses) tend not to get involved in clinical trials or other medicines development related activities.

This has become a significant hinderance in attracting and retaining participants in any particular study with the respective consequences (delayed recruitment and data collection, insufficient quality of the study leading to the possible qualification of the study site as ineligible for further participation in clinical trials).

More recently the COVID-19 pandemic has brought the role of medicines development centre stage for society.

Thus, there is a need for more comprehensive education and training of the medicines development process based on an international harmonized competency-based syllabus endorsed by scientific and professional global organizations.

## **III. NEED FOR A CIOMS WORKING GROUP**

### III.1 Background

Taking into consideration that:

- CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety. <https://cioms.ch/about/>
- CIOMS reports are in-depth guidance documents which serve as worldwide references and guidance for specific subject matters.
- CIOMS has worked in the past in drug development related activities as described at [https://cioms.ch/drug\\_development\\_research/](https://cioms.ch/drug_development_research/)

CIOMS is well positioned as a unique global and scientific organization to develop a multi-stakeholder consensus report related to harmonization guidelines for education and training in medicines development.

The CIOMS guideline would serve as a worldwide reference for postgraduate programmes as well as for the competency-based knowledge needed for professionals working in pharmaceutical and biotechnology companies involved in product development and marketing.

### III.2 Aim of the Working Group (WG)

The main objective of this working group would be to discuss and develop a consensus report giving recommendations on the principles of competency-based knowledge needed for healthcare professionals working in medicines development.

In order to support this, the CIOMS WG would propose standard guidelines promoting harmonization across all stakeholders working in and providing education in medicines development.

### III.3 Composition of the group

Senior scientists with relevant scientific and research backgrounds will be invited from regional and national drug regulatory authorities, leading innovative biopharmaceutical companies, clinicians, academicians, World Medical Association, World Federation for Medical Education (WFME), International Union of Basic and Clinical Pharmacology (IUPHAR) and non-commercial research organizations related to medicines development.

A balanced approach will be used for selection of experts such that no constituency would have a preponderance of influence within the WG.

### III.4 Work process and milestones.

To be defined

### III.6 Deliverables

The below list gives some of the possible deliverables:

- harmonized guidelines for education and training in medicines development
- syllabus for academic courses leading to certification.
- syllabus and an online course of fundamentals in medicines development

It will be the first task of the working group to agree a final list.

## **IV. CONCLUSION**

There is a strong need to launch this Working Group to develop consensus-based recommendations to address the issues listed above. Furthermore, the collaborative efforts brought together to accomplish this task could create the environment for the adoption of these guidelines by the participating stakeholders and the development of future well trained healthcare professionals to develop better medicines.