**First (virtual) meeting of the CIOMS Working Group on Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development**

**26-27 April 2021**

# Meeting Minutes

## Members

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## Secretariat

## Lembit Rago, Kateriina Rannula, Catherine Bates

Regrets

David Gordon, Charlotte Kremer, Hervé le Louet

## Alternate for Jim Kremidas

## Introduction

Lembit began by thanking the group for joining this first meeting of the WG on recommended standards in education and training for health professionals participating in medicines development. He continued by saying that this meeting is timely because if one considers the situation today, with the COVID-19 crisis, it is more important than ever to prepare for the future and think about

1. What we could do to educate people so they are better prepared to become involved in medicines development
2. How to train health professionals to be part of development teams
3. How CIOMS could provide a global perspective to create more unified approaches
4. The implementation of the WG’s recommendations.

Lembit further explained that a lot of work has already been carried out in this area, which CIOMS intends to capitalize on. Also, this is why CIOMS has so many distinguished people in this WG who, in their respective disciplines, have helped to advance this agenda. We can also consider if new individuals need to be involved, but only if this is critical as the WG is already quite large. CIOMS has also tried to achieve a balance between the different backgrounds and areas of expertise for optimal composition.

As Hervé was not on the call, Lembit called on Peter to provide some [introductory remarks](http://cioms.ch/working_groups/educational-standards/).

CIOMS presentation on Working Groups

Lembit presented some slides about CIOMS to give members an overview of how the working groups operate. He mentioned that he would not present on CIOMS, but said he could share some materials with members so they can familiarize themselves with the organization. He then asked if there were any comments or questions about the WG presentation.

Domenico asked if CIOMS had previous experience on the topic of medical education or if it was the first time. Lembit responded that CIOMS had worked on a joint project with the International Union of Basic and Clinical Pharmacology (IUPHAR) and WHO in the area of clinical pharmacology. He added that CIOMS reports cover a wide range of topics that are relevant for this WG. While CIOMS does not have specific expertise in this regard, as a convening platform, it brings together experts from a wide range of disciplines to produce the reports. The secretariat is small so CIOMS must rely on its constituents.

Representation from Africa

Sandor asked if the Secretariat will send a participants’ list. Lembit answered that it will be sent out along with the minutes of this WG meeting. Dominique mentioned that members had received a list, but expressed concern that there were no participants from Africa, an important region in which to promote drug development as well as build manufacturing capacity. Is it due to difficulties in trying to identify the right participants or is there another reason?

Lembit responded that there had been some attempts to find experts there, but probably, the right people were not reached. If members know of any experts in Africa, CIOMS would be glad to contact them and inquire if they are interested in joining the WG.

Dominique followed up by stating he could suggest some names particularly in East Africa as there are a number of well-regarded regulatory agencies there that have built strong collaborations and are also developing standards. Lembit said, that most likely, CIOMS had focused on contacting academics, rather than officials from regulatory agencies.

Avoiding duplication

Ken observed that some WG members have extensive experience in developing educational programs for industry, including IFAPP and PharmaTrain. Other members have experience in training medical students or other individuals in the medical sciences. There are also courses that are available for professionals in clinical research who work in or around industry. He asked what the goal of the WG was that does not already exist? It seems one could take one of these programs and one would have a good outline of a drug development course. What is CIOMS looking for that does not already exist ?

As a response, Lembit stated that it would be useful to have an overarching framework and a harmonized approach, but maybe some other members of the WG might wish to voice an opinion on this question.

Representation from Africa

Regarding representation from Africa, Nilima suggested that CIOMS could reach out to the Drugs for Neglected Diseases Initiative (DNDi) as they work closely on clinical trials in Africa. CIOMS could inquire if someone there might be able to represent Africa. Nilima also recommended contacting Alexander Dodoo (Professor, Centre for Tropical Clinical Pharmacology, University of Ghana Medical School). Lembit agreed to try to identify experts from Africa, but they need to have experience in developing academic training programs.

Avoiding duplication

To Ken’s point about not duplicating existing work. Nilima stated that most programs are either national or regional in nature and therefore, a program by CIOMS would be useful as it would provide a global perspective. Also, while CIOMS could not cover all aspects of medicines development, but as the work progresses, the WG may be able to outline the scope of the program. Does the WG look at the discipline from end to end or will it only cover clinical development? These are questions the WG will be able to address in due course.

Simon commented on Ken’s point, saying it was extremely useful and that presumably, what the WG will do is to come together and create a document which will cover members’ different areas of expertise. It would set the basic expectations of what such a course should be. Then, the WG could determine if any areas are missing or if there are any aspects that are superfluous. The WG would not develop a new course, but rather, state what is best practice for the benefit for professionals in this area or anyone wishing to contribute to it at a later stage.

Lembit agreed that producing overall directions that could be harmonized is something the WG could do. Creating curricula, while they might be included as examples in certain areas, is not the objective of this WG.

Ingrid’s view was that the WG has a good basis in terms of the content for a curriculum in pharmaceutical medicine. Many in the WG worked on it and although it was a European initiative, it received broad acceptance from partners globally. It has also been updated since. What we do have consensus on is what the content should be and the competencies required of a physician in pharmaceutical medicine. PharmaTrain expanded the course to non-physicians to make sure there is an equivalent educational pathway for pharmaceutical development experts with the PharmaTrain specialist in Pharmaceutical Development. It has also been taken up by IFAPP. But what is missing is the global agreement on the need for systematic education. A document that described principles for education in the different disciplines of pharmaceutical development such as professionalism, reliability, patient protection and quality data would be an extremely important contribution to advancing the area.

Dominique concurred with the opinion that there are a lot of courses available, but only in the field of research, ethics and regulation. However, what is extremely puzzling to him, is that there is a drop in the number of clinical trials in Europe, a drop in the number of drug trials as a percentage of (total) clinical trials. A change is occurring and maybe it is a good time to reflect on what is required for good patient care, establish priorities and identify drug (pharmaceutical) clinical trials in the broader scope of public health. Connecting those principles would be an important achievement and one where Dominique sees added value (from CIOMS).

Representation from Africa

When Dominique mentioned Africa earlier, he was thinking about Margareth Ndomondo Sigonda in particular, who has been active in eastern Africa. The WG needs people who can take the lead in training and helping to spawn the next generation of not only physicians, but pharmacists, public health experts, administration officials/civil servants as well.

Defining the target audience

Honorio referred to the Ten Commandments. PharmaTrain provides the basic syllabus that can be adapted to all populations. If the WG sees this in the context of what is the basic knowledge for the different populations or sub-populations involving clinical research, while maintaining the principles of these « Ten Commandments », then the populations and the syllabus can be defined. Honorio added, building on Dominique’s comments, that the target audience for the training is not the experts, but rather individuals who can contribute to medicines development.

Rieke spoke next and began by saying that this was a good initiative, but wondered who the target audience really was and mentioned the Declaration of Helsinki that is focused on research. Whereas, it seems that the scope is broader in this case. Medicines development begins before research and if one wants to incorporate health economics as well, it is much broader. And if the audience is this broad, would we be able to implement the CIOMS principles? How would one ensure uptake by the various disciplines? Is the scope too broad ? Maybe the WG could align with an institution or company that could grant accreditation ?

Pravin put forward two observations in relation to emerging markets : one of the challenges is that so far, most of the programs focus on traditional audiences, but the center of gravity of clinical development is moving to emerging markets and the trust gap that exists has become an opportunity now as a result of the pandemic. CIOMS could bring the stamp of credibility and help to bridge the trust gap. In addition, from an operational perspective, a lot of focus has been on medicines development, from translation to bench to fairly close to approval.

A large emphasis has moved on with the increasing knowledge and acceptability of Artificial Intelligence (AI), real-world data and real-world evidence and that needs more focus to continue post-approval. Now it needs to move beyond that to continue the life- cycle and the opportunity to monitor, deliver and build competencies post-approval right up to the point at which real-world comes in. This is something the WG could build on as compared to what has been delivered in the past.

Curricula vs syllabi

In response to Ken’s and other comments, Peter’s perspective was that some of the contributions related to curricula, including references to target audiences or accreditation, which is fine. However, the WG should aim to develop core curricula. So, there is a global consensus about what a core curriculum should contain for any type of training program or audience. The other important topic is « syllabus » which is not the same as « curriculum ». A syllabus is a list of topics that define the boundaries of the knowledge of the discipline. A syllabus is not related to the target audience, but is related to the discipline. The importance of the WG is to gain a global consensus on a discipline through the definition of its syllabus.

We hear of new topics which should be included e.g. AI, patient engagement and have the right to be represented in a syllabus. Similarly, there might be topics which the WG believes are no longer necessary and should be removed. So to summarize, a syllabus has to do with the discipline of medicines development. The other has to do with the derivation of a syllabus toward courses and curricula that have different purposes and audiences. They are not the same as having the syllabus for a given discipline which defines the knowledge for that subject.

Haruko told the group that some years ago, a team from Japan tried to import a PharmaTrain program to Japan. She commended the program and said it was very good, but it takes a long time. So the participants must dedicate most weekends for two years. So, Haruko suggested that different curricula need different audiences where each curriculum is suited to a specific audience. The curricula must be « layered » to suit different target groups.

Lembit agreed with Haruko’s views and added that the WG could produce a framework with some high level principles. Earlier approaches were probably more focused on some parts whereas today, pharmaceutical development is seen more as a life cycle and the post-marketing part has not really been addressed because the focus has been on getting the product to the market. If the WG targets healthcare professionals, this is again a different case because, they all have different backgrounds. Professionals in early stage research are not medical doctors. Then one moves on from pre-clinical to clinical which is where the medical professionals are involved. Then, with the post-approval and marketing activities, the discipline requires different specializations still.

In addition, these have evolved because drug development is evolving quite quickly as well. If you look at COVID, some of the products are approved through different pathways with limited data. The same is happening with rare diseases. So, one must assume that product development continues after marketing authorization, i.e. product development is not finished. This is something we need to look at. Most of the WG members have backgrounds from the medical sciences, but there are a lot of other expertise needed across the life cycle of medicines development so how will the WG address this issue ?

Is the WG focusing more on clinical development ? Are we opting for a comprehensive approach that covers the whole life cycle ? Are there some sections that the WG should focus on as priorities ?

Tim stated that he supports Peter’s view, but it could be put in the context of what’s happening in medicine as a whole. One is seeing an enormous range of different skill sets in the field of medicine because of a change in technology. This is true in industry as it is in clinical practice. Peter is referring to people being competent in different areas of the process of developing medicines and devices as well because therapeutic and diagnostic devices amount to about 1/3 of sales of total medicinal products in the world today. The WG have to break the issue down and the way to move forward is to have areas in which people develop their capabilities in.

It may be the powerful need of people to do the follow up and maintenance of the product as is required by the authorization it receives. Devices are a much more complex area, but there is a comparable pathway for devices. But the WG might want to look at it right from the beginning of the development of the idea of the medicine. This could be the stepping-stone to the first in human and first in patient work through the subsequent parts with the regulatory and the whole process of clinical development and the interaction with patients.

Modular process

So, Tim sees this as a modular process where people could spend time on a specific module. It would all be part of what Tim described as Peter’s grand curriculum, but it would include modules that people both from a medical or clinical background or scientific background would be able to gain sufficient knowledge and capabilities to practice in these areas.

The difference between medicine and a scientist has to do largely, although not exclusively, with the understanding and communication with patients.

That is something that is built into the core general parts of the curriculum for training medical people, surgical people who have that core skill sets for treating patients. That has a separate element from the modularization of the training. So, rather than looking at it as a single curriculum, the WG should view it as a collective of modules that people could undertake to gain the skills and knowledge they need in their job. Throughout their career, they might need a path to move from one module to another. This would be a simple route forward that mimics what is happening in clinical practice and it will be familiar to most health care professionals, be they medical or scientific.

Ingrid concurred with Tim’s contribution. In 2021, the situation is different from that in 2010, 2012, 2015. Today, we have an understanding that people who enter the field of pharmaceutical development come with different backgrounds and experience that are all relevant because one is dealing with a complex and broad subject. The other aspect is that in the last 10 years, there has been a massive increase in the number of courses that cover different topics in the medicines development process with curricula that are extremely well designed and relevant. Ingrid does not feel it is right to decide what aspects are good and which ones are less good. That is not what she believes the WG should focus on. What the WG could do is to figure out how best to utilize the talent based on our backgrounds and respective experience in course delivery to change the delivery of the courses from face-to-face to all types of virtual and that would not have been expected only three years ago. The WG has become much more experienced and better in these areas.

What COVID has taught us is that we need people with a solid background who know what to do when a situation like COVID arises and solutions are required in an efficient way. So, if the WG can define the process globally for how to best utilize talent and experience in course-delivery and find strategic and concrete way to build competencies for key areas in medicines development.

Sandor joined the discussion by saying that in the last year, GCP and the whole monitoring has become virtual which has revolutionized how we conduct clinical trials. Therefore, what the WG could do is to educate in a hands-on manner on how to perform clinical trials with all the modern possibilities which have been developed in the last few years. It is a completely new way of approaching quality assurance of good clinical trials. So, Sandor recommends creating a course that combines both a theoretical component while also encompassing the new possibilities that exist today in running clinical trials.

Lack of required skills

Joel offered to expand on some of the earlier comments about newer technologies, in particular, engineered technologies, including cell therapies, primarily in oncology and gene therapy, etc… A lack of skills in these areas has been observed in his organization and that attempts have been made to retrain individuals some of whom have extensive industry experience. However, retraining is not always successful as it requires fundamental skills in basic science for many of these individuals and being able to translate them into the human experience with the caveat that some of the clinical models do not translate well. As mentioned previously, as one moves forward with all these new technologies, a different skill set will be required for certain technologies and they are not necessarily the same as so-called « traditional » technologies. His organization is in the process of examining these requirements to gain a better understanding.

Nilima congratulated the WG on the excellent comments to date, including how to find new ways of conducting Good Clinical Practice (GCP). What COVID has taught us is that a rapid response to new situations is essential. One has to be able to launch clinical trials quickly and some times, Clinical Research Organizations (CRO) have to hire individuals who do not have sufficient training. While we work on the syllabus and then the curriculum, the WG would need to see how to train professionals so they can perform basic duties and be operational in a short time. In regions such as Africa and India as well, where research has not been a priority thus far, research is now absolutely critical in trying to overcome COVID. Nilima recommended taking this into account when developing the CIOMS curriculum.

Stephen told the WG that he was in the process of analyzing data that what collected over the last six months, a self-assessment of competencies from research professionals. The data confirms a lot of what Peter described in his introduction and that Ingrid has mentioned as well, namely that there is a significant lack of self-assessed competencies from individuals such as principal investigators where over 25% have a low understanding of investigational product development, protocol development and scientific concepts in general. In terms of other individuals, who partake in the clinical research enterprise, e.g. clinical coordinators, clinical monitors, the same lack of understanding exists. In addition, there is no entry level education requirement. How many clinical investigators do you know who have hired their secretary and turned them into a clinical coordinator?

Stephen added that the WG, with a global scope and extensive experience, could make it more recognizable that medical schools should include content on the conduct of research, especially clinical research and that for other professionals who work in the field, there should be entry level education, at least a post high school level of scientific education. Lembit agreed this was an important point.

Target audience/topics/online or in-person?

Roberto (Verna) asked if the WG should focus on one big project or many smaller ones? Should the WG only deal with pharmaceutical medicine or medical devices, AI, digital health? Is this effort aimed at medical doctors? Biologists? Biotechnology experts? Pharmacists? Or all of them? Can there be an entry level program for all of them or should there be some differentiation? What is important is to define exactly what the WG wants to do. Should it run a big online program for all medical doctors, biologists, etc… ? If so, how many programs? In person or online, in real time or pre-recorded?

Lembit suggested that the main challenge is to know what to deliver. How to deliver it can be addressed at a subsequent stage. Given that most of the WG have medical backgrounds, so does the WG focus on medical doctors entering the field of pharmaceutical development or do we take the wider approach. If it is the latter, the difficulty is that CIOMS could raise topics that it has the relevant constituencies for, but CIOMS does not have other constituencies. So, does the WG intend to cover the whole life cycle of product development? One would need to start with the bigger picture and then become more focused.

Responding to Lembit’s remarks, Roberto highlighted that he was doing this in Italy and covering the whole range of topics, namely pharmaceutical medicine, regulatory aspects, medical affairs, AI, devices. So, in accordance with relevant standards, one could transpose this into an international program.

Not part of medical school curricula

Ken said that what was important is to know who the audience is. Whether it is a curriculum for industry professionals, for clinical investigators who are not in industry or for students in medical school, each one will be significantly different from the other. The needs are different and in terms of educating future physicians, it will be extremely difficult to cover more than a few hours of material because students have to prepare for their Board exams and there is not a lot of time for other subjects. So, the idea of inserting a curriculum into a medical school curriculum would be difficult. What would be useful, however, is to have a flexible program that can be used for the various groups, thereby ensuring a level of education that is appropriate for their status, whether it is for industry, non-industry clinical investigators or students.

Referring to Lembit’s statements earlier about the wide range of backgrounds and areas of expertise that exist across the product development life cycle, Min Soo Park explained that it is difficult to focus on one population and administer specific training. His students come from a variety of different backgrounds who would like to know about the overall drug development process so they know what to do should they be required to work at certain stages and understand what is going on and are able to perform what is expected of them. So, it is difficult to focus on one population only. As a pharmaceutical physician, one cannot be expected to do everything as Peter Stonier described in his textbook.

What is important, however, is to ensure one has the right mix of backgrounds who work together to deliver a successful drug development program. Most physicians are not interested in knowing about the whole process anyway, but want to know who the other professionals are that they can hand over the project and take it to the next stage.

One cannot satisfy everybody and therefore, the WG should find a common ground by describing what are the expectations at the different stages and who should take the lead at each stage. This is the scope we should aim for.

Building on Min Soo’s input, Nilima said when one talks about education, one talks about knowledge, skills and attitude. If one breaks down the drug development process into smaller parts, it is a team effort where groups of people carry out different tasks. The WG should try to break the process down and see what is expected of each group. In this way, one can see where the gaps are in an individual’s training. So, if it is a medical professional for example, he/she may not have had a lot of training in statistics. If it is pharmacist, he/she may not have had training in understanding the pathological tests. What is it that the WG would want these professionals to know about as well as the skills and attitudes for a job that he/she is doing. That is what should be broken down and listed. There are people with all sorts of backgrounds entering the field of medicines development so they need to know what is required of them. In this way, CIOMS could help people to know what additional knowledge/skills they need to take on a job in medicines development.

Lembit suggested that the modular approach is a reasonable one because people do not all have the same needs.

Competency vs competence

Peter raised a point about generic professional competencies and a generic professional framework. If one talks about competencies and competence, the questions of behavioral competency framework, interpersonal management and leadership skills must also be mentioned. Should the WG include such skills in its initiative? They are an important part of developing competencies and competence, but they are not traditionally, covered in technical syllabi, whereas they shoud be. Will the WG embrace them in this project ?

Referring to Michelle Limoli’s written comment, Dominique agreed that the WG’s mission is not to develop curricula, but rather, it should focus on developing the principles that curricula should be based on. There is an interesting [paper which was published in 2020 in the Journal of the American Medical Association (JAMA)](https://jamanetwork.com/journals/jama/fullarticle/2763595) by an ethics committee in China and which Dominique also experienced in Switzerland, namely that COVID gave rise to a large number of self-appointed clinical trial « experts » who were submitting applications that were often time unsound and not fit for purpose. One should begin at undergraduate level and build up on that to the next level, to know what a Masters student needs to know. There are a lot of quality programs around, but what the WG can do is to provide some structure to these programs.

Scope: adult education

Stuart came back on earlier comments about disciplines. He said the scope of the WG is adult education, post-graduate education which is vocational in nature. So, it should not matter that there is no medicinal chemist in the WG or a molecular biologist. The conversation should be about developing medicines and whether someone has been trained as a physician or a biochemist or a geneticist should not really matter. The WG is not trying to design curricula for undergraduate medical school, but is trying to shape these professionals into something that is useful for developing medicines. So, if we take the above idea, the scope is not that wide because the document CIOMS will produce will be focused on the job in question. Although, depending on the job under discussion, it may have specificities based on the country of origin. For example, the way medicines are developed in Switzerland may be different from the way they are developed in Japan even if the medicines that are produced are consumed all around the world.

Referring to PharmaTrain, Stuart said it was designed for medics and pharmaceutical physicians and could form a good basis although it would need to be widened in scope to include a global representation. Also, the audience would have to encompass professionals beyond pharmaceutical physicians. An example could be healthcare professionals as opposed to pharmaceutical physicians. So, it might be worthwhile to think about a core set of principles or syllabus as Peter mentioned earlier and look at it again in light of using it as a basis for training. With this in mind, the actual picture is not too broad. The focus is the job of developing medicines, which everyone in this group knows about.

Focus on undergraduates

Dominique disagreed with Stuart and posited that the WG does need to focus on undergraduate students. About 75% of physicians are reluctant to get involved in research and the reason is that the importance and value of performing research was not communicated to them at the time they were undergraduates. He has experience in teaching about patients’ rights and bioethics for more than 20 years. There was a significant change when they stopped teaching last year students and began teaching first years. My most successful classes were the ones I taught the first week of medical school. That is when it becomes important to study law and bioethics because the faculty included these subjects in the curriculum.

If these topics are not taught in the early years of medical school, the discipline will lose the individuals that it wants to train and who could become pharmaceutical development professionals in the future. In particular, in the area of real-world data and other new approaches, one needs practitioners and if one does not reach them when they are undergraduates, it will be more challenging to convince them when they have begun their careers. Naturally, the objective is to develop medicines according to the state of the art, as efficiently as possible, but if the practitioners or the civil society involved, the process will be slower.

Lembit supported Dominique’s view that the undergraduate population should not be overlooked. And given that health care is changing so rapidly, it is important that students are taught about pharmaceutical development and regulatory affairs at an early stage.

Tim voiced a comment that he liked the idea of reaching out to undergraduates. Programs were established at medical schools in Brighton and Sussex, designed by them, and which bring in specialists from pharmaceutical medicine as support. These curricula describe how « things are done » and include regulatory, clinical aspects. So, Tim is a strong supporter of this approach. He added that the principles of medicines development are shared by all in the WG and are underpinned by the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Common Technical Document (CTD). It contains all the different components of the medicines development process. It is slightly different from devices. The abbreviated 510(k) form for the US Federal Drug Administration (FDA) is similar and provides an idea of the overall development process (for devices).

ICH-Common Technical Document and SmPCs

Regarding a curriculum, the aim is to give people an understanding of all the elements that are contained in the CTD and its subsequent summary which, in Europe, is the Summary of Product Characteristics (SmPC). It is surprising how close the curriculum of the above-mentioned medical schools follows the SmPC. It is likely that it would be the same across all specialties that are included in medicines development. They must all follow the (ICH) guidance, which were signed off by FDA, EMA and PMDA. They are followed all around the world. It is our common language and the WG could focus on how to deliver elements of that for individuals entering the field of pharmaceutical development. Tim concurred that fitting such a program into an existing medical school curriculum, is not possible. However, if the WG could explain the language and the terminology so these individuals are prepared when they are in practice. Tim summarized by saying that the WG are talking about the same process, the same common document and the same SmPCs, all of which describe the same aspects of work and that is what needs to be grasped in order to train people, regardless of whether they are scientists or medics.

Lembit thanked Tim for these insightful comments and gave Michelle an opportunity to speak. As one of the few regulators in the WG, she asked if some of the members from academia or industry could summarize what exactly the issues are that should be addressed in the WG. What is missing? There are many programs available, many training programs, although most are on a national level. Most medical schools have curricula for clinical research and drug development. So, Michelle asked what are some of the specifics that this WG needs to focus on.

Honorio put forward that the WG’s mandate is to produce a syllabus which can then be turned into a curriculum. The objective is to deliver a core syllabus that can be adapted to various subpopulations. The adaptation to these subpopulations is a curriculum. Ultimately, the ambition is to have a syllabus that can be adapted to general practitioners, nurses, ethics committees. The WG should agree a basic syllabus. The PharmaTrain syllabus could be used as a benchmark and elements could be added as developments occur in the future.

Concluding remarks and Day 2

Lembit thanked everyone for their input and shared with the WG some information about how Day 2 would play out. The WG will be divided into two subgroups that could each further discuss the deliverable and then come together to reach a consensus on what the final product should look like. The CIOMS Secretariat will create the two subgroups and let members know which one they have been assigned to. In order to deliver an end product, the group needs a clear vision of the problem it wants to solve, who the audience is and what the basic building blocks are of what the group wants to achieve, the chapters to be included, whether or not appendices are needed. While there are a considerable number of curricula available, what is needed is a set of general principles. There is no point in saying that it is fantastic to have such a large number of curricula in place today because it is clear that the situation is not fantastic and that is the problem. Also, due to COVID as expressed by Dominique, many people began to conduct research without having the basic skills. Scientific journals also published articles that were not scientifically sound. Some peer review panels were ill-equipped to review articles and many poor quality papers were published as a result.

If one looks at the work force from the perspective of regulators and drug development, it might look like everything is proceeding as it should. However, it is clear that certain experts are missing and are not there when they are needed.

**Action items:**

* WG members to share different curricula/training programs with the Secretariat.
* Subgroups 1 and 2 to convene (virtually) to begin drafting high level content of the WG report
* Catherine to support subgroups and help to organize meetings.