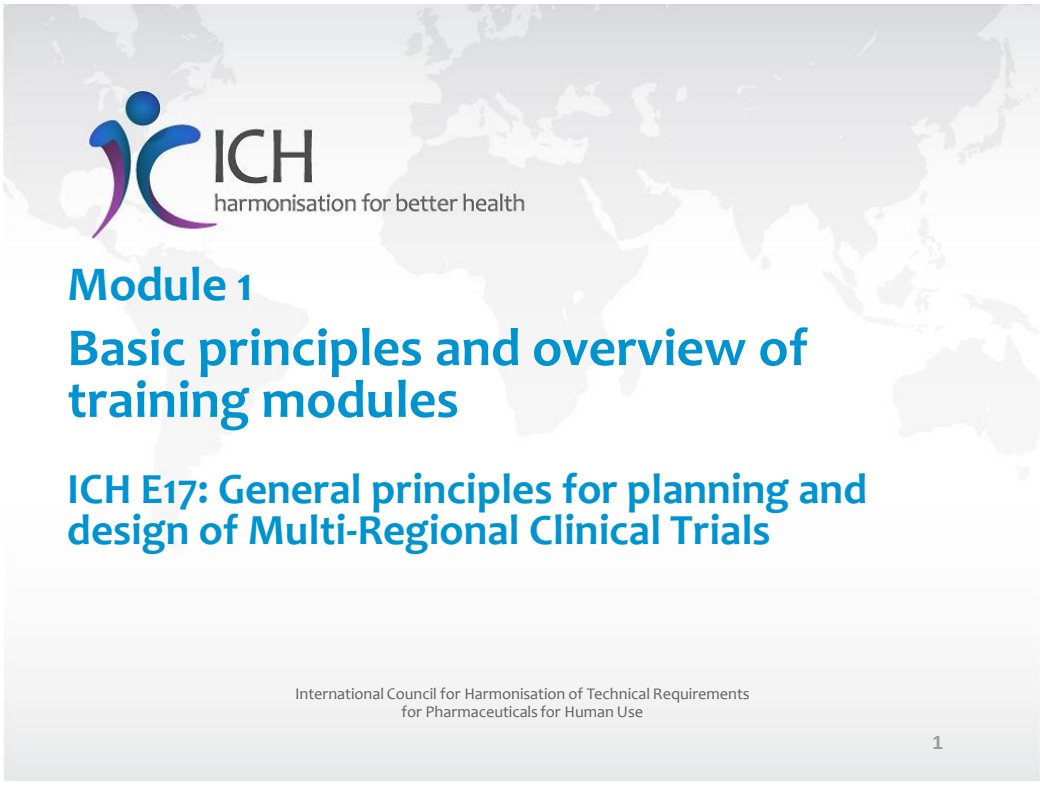

This presentation will give you an introduction to the basic principles of the ICH Guideline E17: General principles for planning and design of Multi-Regional Clinical Trials, as well as give you an overview of the training materials so that you can easily find information in this guidance.

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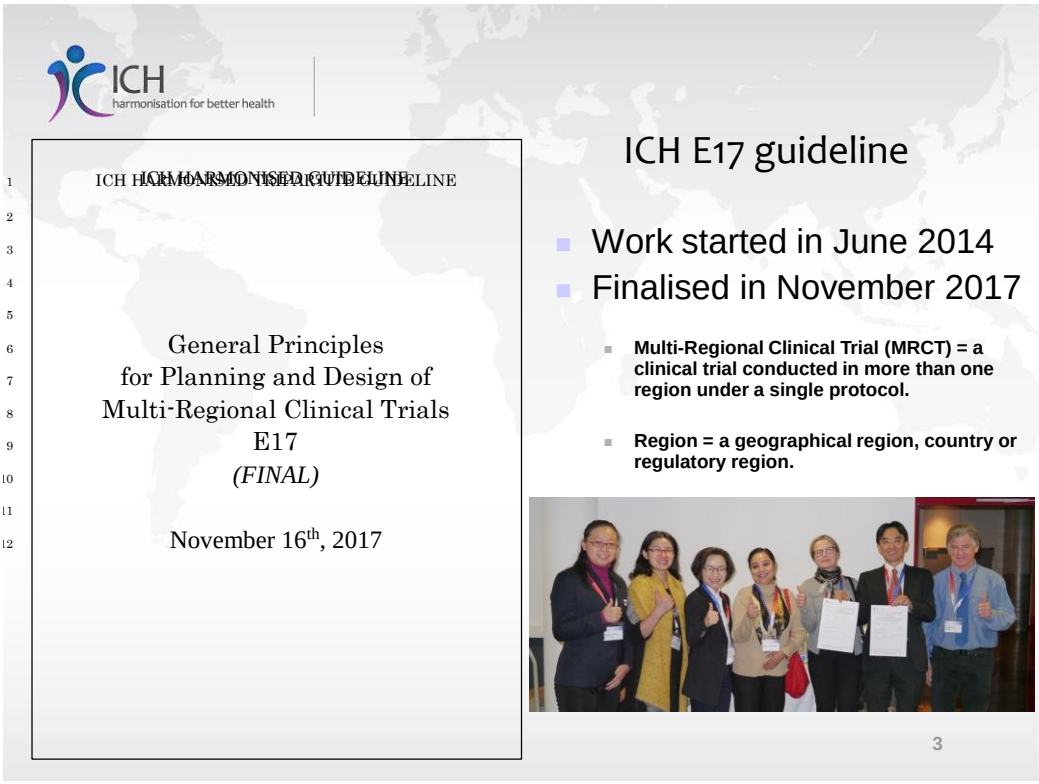
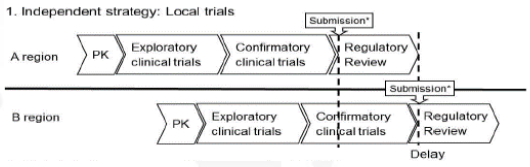


The drafting of the E17 guideline started in 2014 and the guideline was finalized in November 2017. It has since then been adopted by regulators and pharmaceutical industry in all ICH regions.

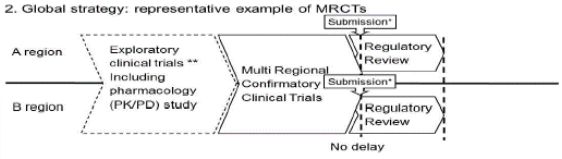
During the time the guideline was drafted, a large number of comments were received, requesting additional clarification of some of the principles in the guideline. Therefore, it was considered important to develop training and presentation materials to ensure that the E17 guideline is well understood and is implemented consistently amongst different stakeholders in both ICH and non-ICH regions.

Why was the E17 Guideline drafted?

- **Historically, clinical trials of a new medicine were often performed separately in different regulatory regions to fulfil the requirements of each region**.



- **More recently, global regulatory strategies are also used to plan and conduct studies**



The purpose of E17 is to describe general principles and strategic programme issues for the planning and design of multi-regional clinical trials to ensure that data from such trials can be accepted by regulatory authorities across regions and countries as the primary source of evidence, to support marketing approval of medicinal products

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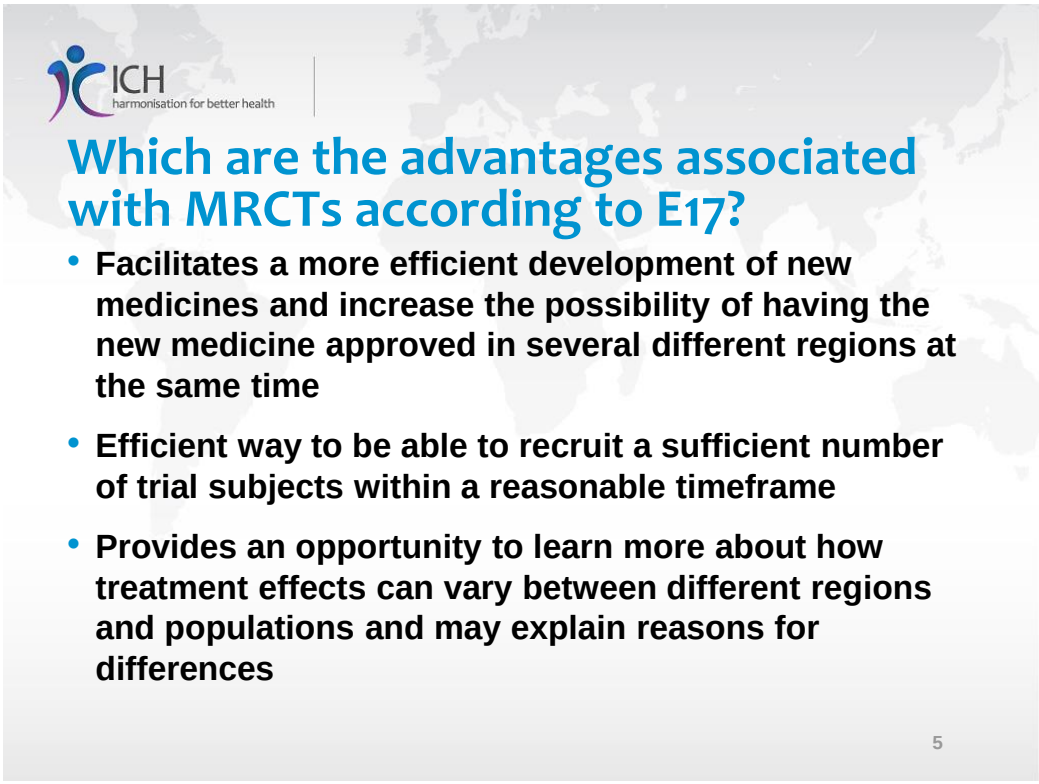
Before presenting the training material itself, we will present a summary of the main messages of the E17 guideline.

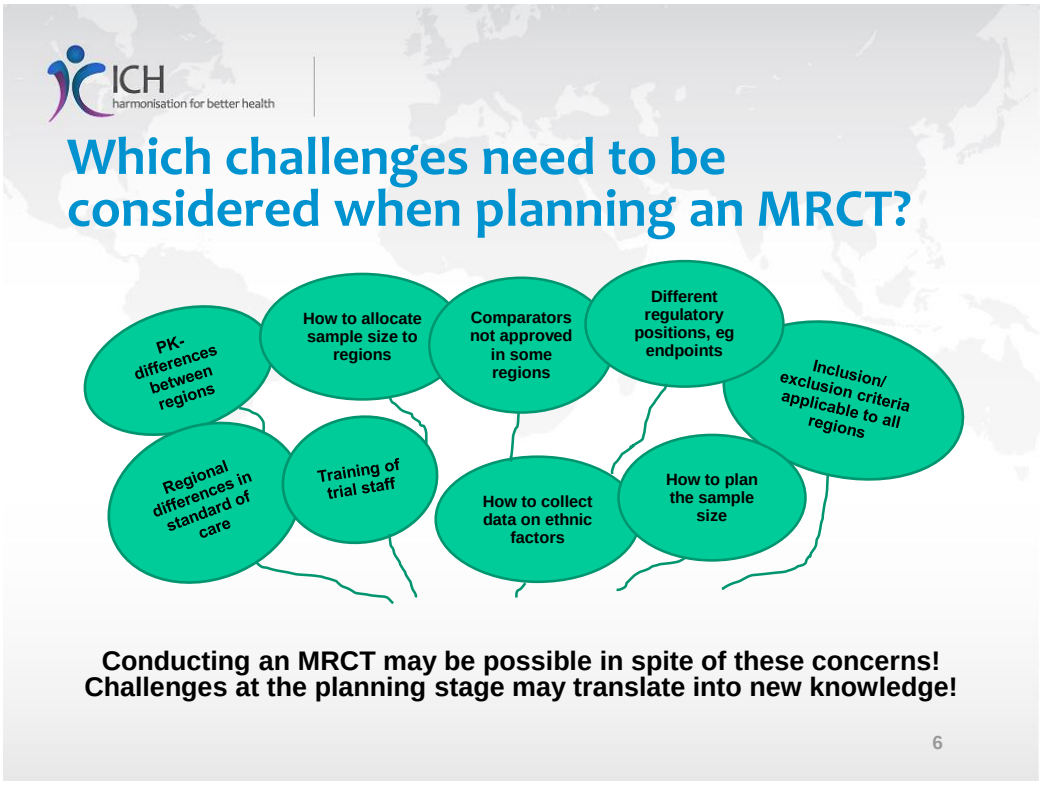
Historically, clinical trials of new medicines were often performed separately in different regions to fulfil the local requirements for approval of the medicine. However, in more recent times, it is common that new drug development trials occur in several geographical regions at the same time under a single protocol. This is what is meant by the expression "multiregional clinical trial". As a result of this development, it was considered important to have a guideline with the main objective to provide guidance on optimal planning and design of multiregional clinical trials and thereby ensure that data from such trials can be accepted for approval in different parts of the world at the same time.



So, what are the advantages with multiregional clinical trials compared to trials performed in a single region? Multiregional clinical trials can facilitate more efficient development of new medicines and increase the possibility of having the new medicine approved in several different regions at the same time. Thereby, patients may have earlier access to new medicines worldwide.

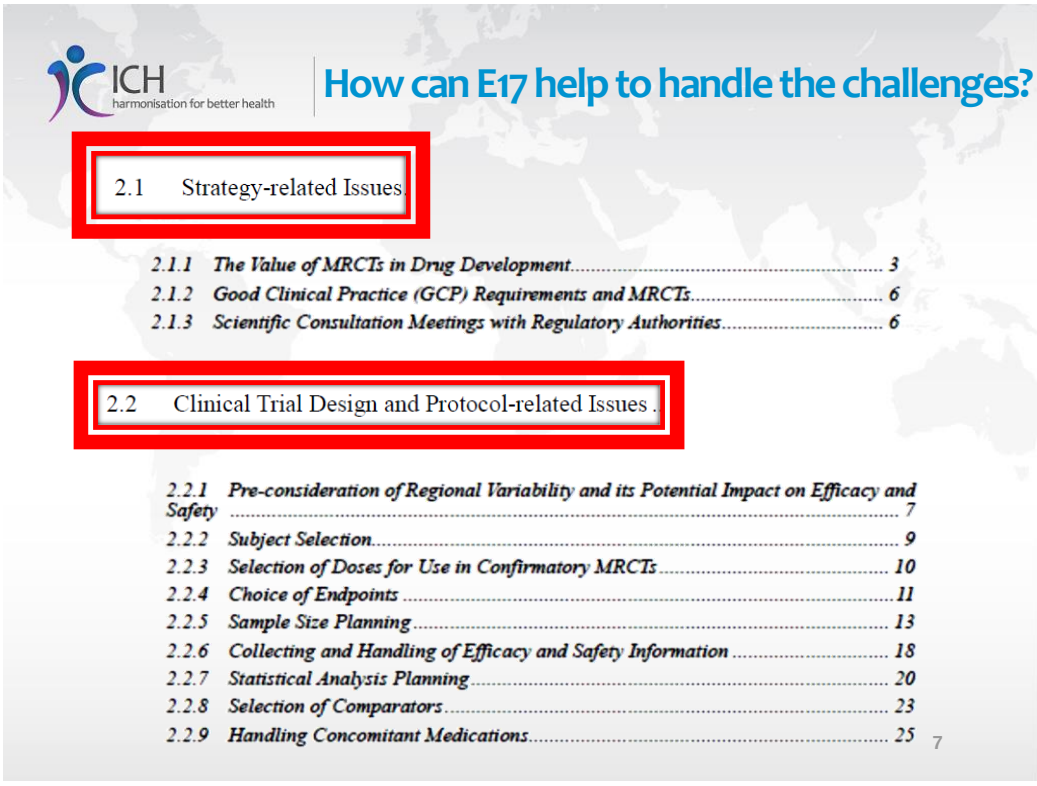
To perform a multiregional clinical trial is also an efficient way to be able to recruit a sufficient number of trial subjects within a reasonable timeframe. This may be particularly important when either the disease being treated is rare or when large numbers of subjects are required.

Multiregional clinical trials may also provide an opportunity to learn more about how treatment effects can vary between different regions and populations and may also help us to understand the reason why these differences exist.



There may be challenges associated with conducting multiregional clinical trials and therefore, the E17 guideline emphazises that regional differences that may have impact on the results of treatment with the new medicine should be considered at the planning stage. Such differences may include medical practice, diet, socio-economic factors as well as differences in the response to the treatment due to variations in the subject's metabolism of the medicine.

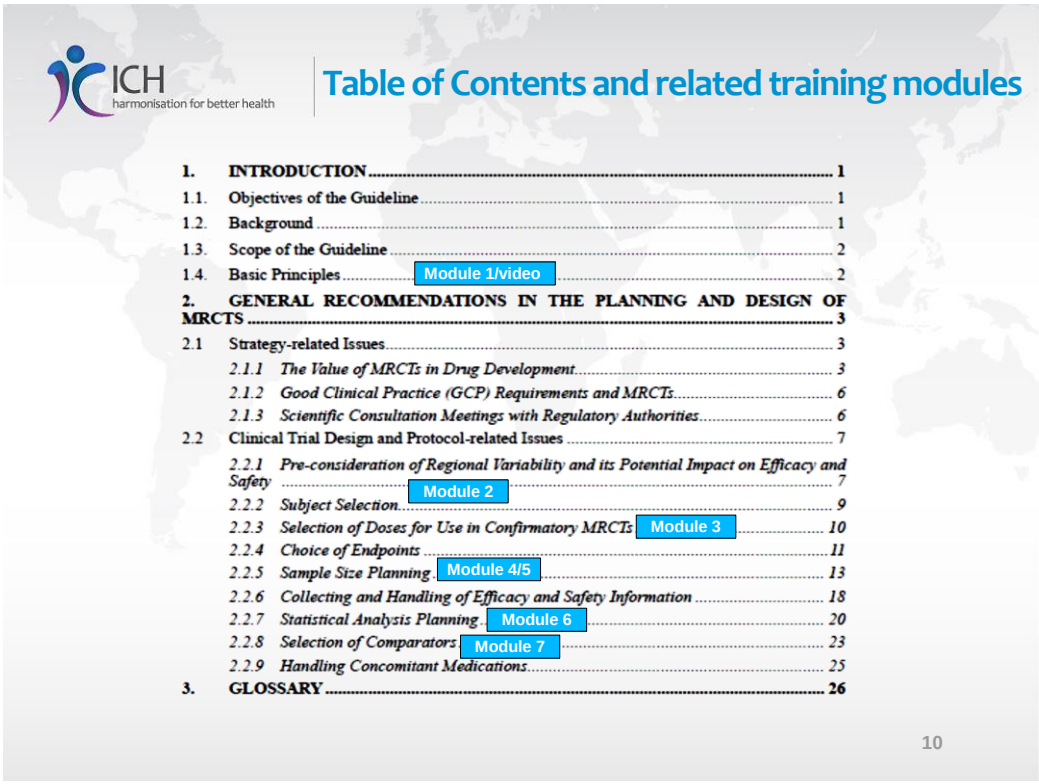
We hope that you will find the E17 guideline helpful in providing suggestions on how to plan and design a study despite these potential differences, as well as how to interpret the results. In fact, a thorough planning that includes accounting for the possibility of regional differences, may ultimately increase our knowledge about the importance of such differences.



So, how can the E17 guideline help to handle challenges that may arise when you plan a multiregional clinical trial? As you can see from the table of contents, the guideline includes sections handling both strategy-related issues, as well as design and protocol related concerns. These sections provide guidance on many aspects such as selection of subjects, doses, comparators and endpoints as well as how to plan and allocate the sample size.

We hope you found this introduction of the basic principles helpful. You may now wish to review the other training modules! This material is intended to provide clarity on some of the key aspects of the guideline, but it will not introduce any new concepts or additional guidance to what is currently in the E17 guideline.

The training material is divided into modules. The first two modules aim at providing a general overview of the main messages and basic principles of the E17 guideline while module 2 – 7 are focused on specific sections of the E17 guideline and provides a more in-depth explanation. In the technical modules you will also find written notes that will further explain and expand on important issues.



This slide shows the table of contents of the E17 guideline and in which module of the training material you can find specific topics addressed.

Finally…

- **We hope this training material will be useful and help you to understand and use the E17 guideline in your planning and/or assessment of multiregional clinical trials**

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Finally, we hope that the training material will be useful and help you to understand and use the E17 guideline in your planning or assessment of multiregional clinical trials.