ICH
harmonisation for better health

Module 1

Basic principles and overview of training modules

ICH E17: General principles for planning and design of Multi-Regional Clinical Trials

International Council for Harmonisation of Technical Requirements
for Pharmaceuticals for Human Use

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ICH HARMONISED GUIDELINE

General Principles
for Planning and Design of
Multi-Regional Clinical Trials
E17
(FINAL)

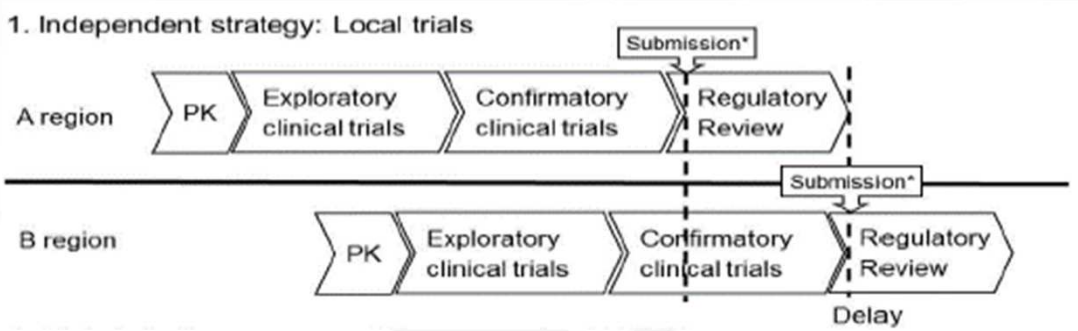
November 16th, 2017

ICH E17 guideline

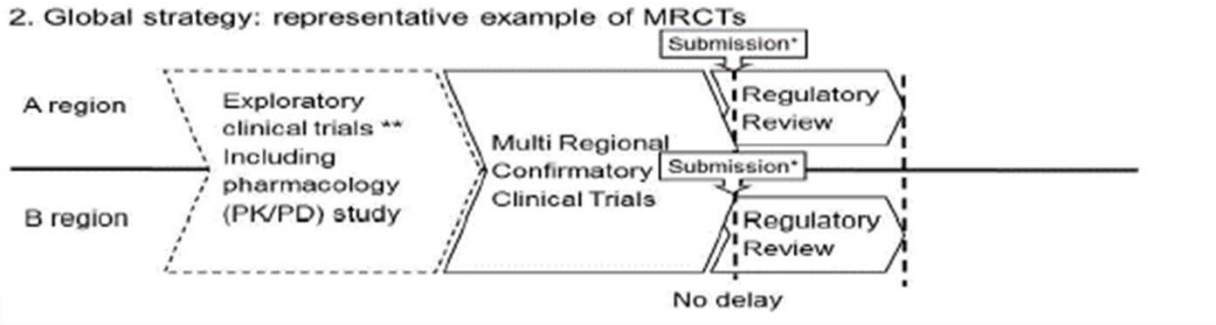
- Work started in June 2014
- Finalised in November 2017
  - **Multi-Regional Clinical Trial (MRCT) = a clinical trial conducted in more than one region under a single protocol.**
  - **Region = a geographical region, country or regulatory region.**

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**

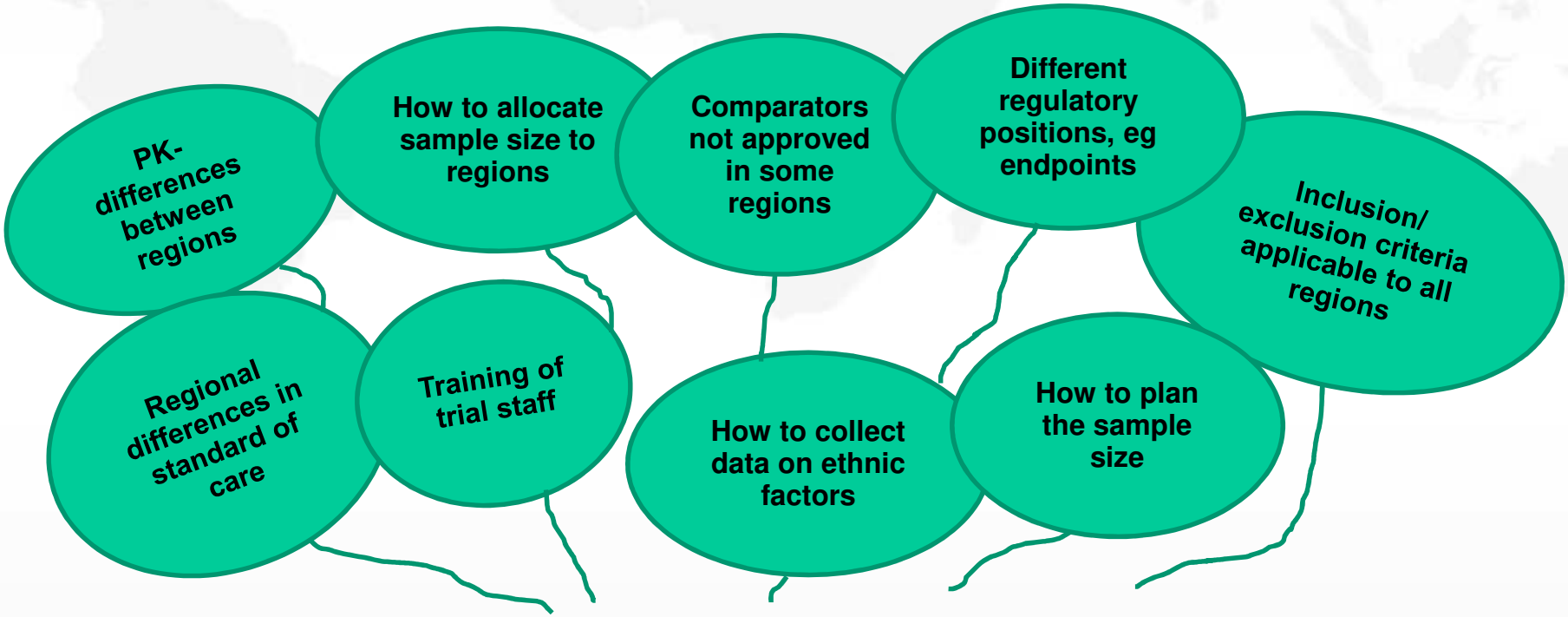


The purpose of E17 is to describe general principles and strategic programme issues for the planning and design of multi-regional clinical trials to ensure that data from such trials can be accepted by regulatory authorities across regions and countries as the primary source of evidence, to support marketing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

Which are the advantages associated with MRCTs according to E17?

- **Facilitates a more efficient development of new medicines and increase the possibility of having the new medicine approved in several different regions at the same time**
- **Efficient way to be able to recruit a sufficient number of trial subjects within a reasonable timeframe**
- **Provides an opportunity to learn more about how treatment effects can vary between different regions and populations and may explain reasons for differences**

Which challenges need to be considered when planning an MRCT?



Conducting an MRCT may be possible in spite of these concerns!
Challenges at the planning stage may translate into new knowledge!

How can E17 help to handle the challenges?

Overview of training materials

- **Training material intended to provide clarity on key aspects of the guideline in order to facilitate a harmonized interpretation and implementation by industry and regulators in the ICH and non-ICH regions**
- **Training material does not provide additional guidance beyond E17**

Overview of Training material

General modules

- Animated video; Main message of MRCTs
- Module 1; Overview of training material/Basic principles

Technical modules

- Module 2; Preconsideration of regional variability when recruiting diverse populations in global development
- Module 3; Selection of doses
- Module 4; Sample size allocation
- Module 5; Pooling strategies
- Module 6; Evaluation of consistency
- Module 7; Selection of comparators

Table of Contents and related training modules

Module 1/video

Module 2

Module 3

Module 4/5

Module 6

Module 7

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**