Public Conference on Clinical Drug Trials, Geneva, 30 September 2016

Globalisation of clinical drug trials & ethics: the Swissmedic perspective

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Outline

- Clinical trials: a changing landscape
- International requirements for clinical trials: Good Clinical Practices (GCP)
- How does Swissmedic ensure compliance with GCP
  - Inspections of clinical trials
  - Clinical trials submitted with marketing authorisation applications
- Summary

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Clinical trials: a changing landscape

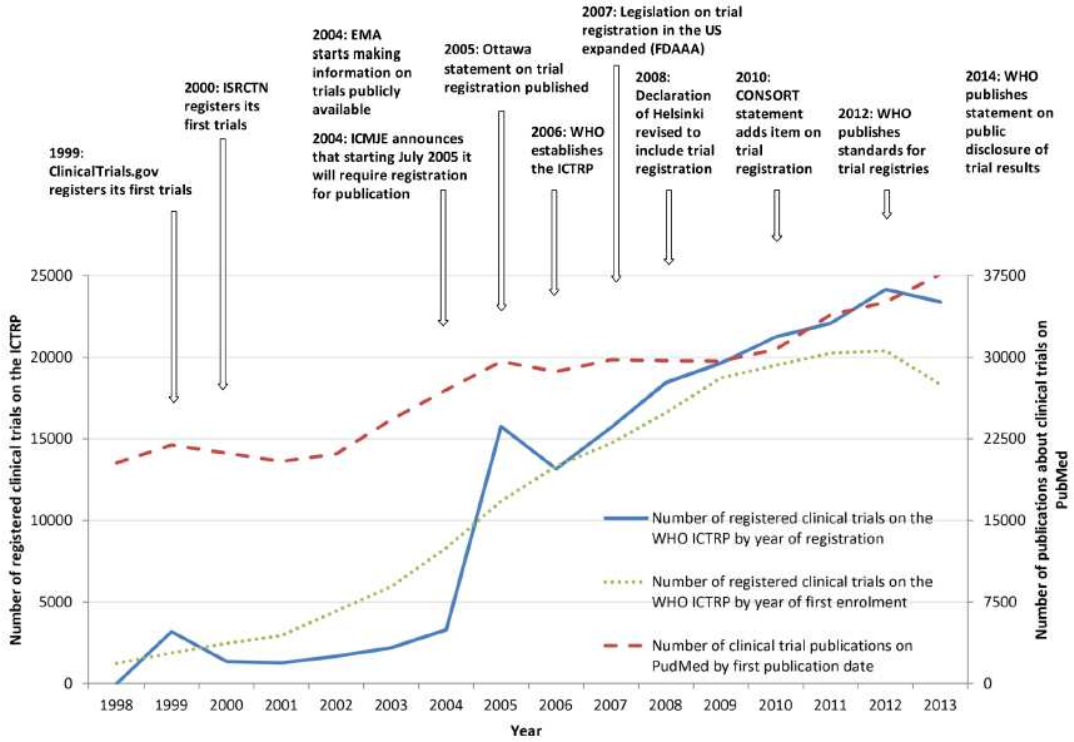

Figure 1 Annual numbers of registered clinical trials on the International Clinical Trials Registry Platform (ICTRP) and annual numbers of publications about clinical trials on PubMed from 1998 to 2013. The first trials in the ICTRP database were registered in 1994; 15 trials registered from 1994 to 1997 are not shown in the figure (all registered at the Australian New Zealand Clinical Trials Registry (ANZCTR)). CONSORT, Consolidated Standards of Reporting Trials; EMA, European Medicines Agency; FDA, Food and Drug Administration; FDAAA, Amendments Act; ICMJE, International Committee of Medical Journal Editors; ICTRP, International Clinical Trials Registry Platform; ISRCTN, International Standard Randomised Controlled Trial Number Register.

Viergever RF, Li K. BMJ Open 2015;5:e008932 doi:10.1136/bmjopen-2015-008932

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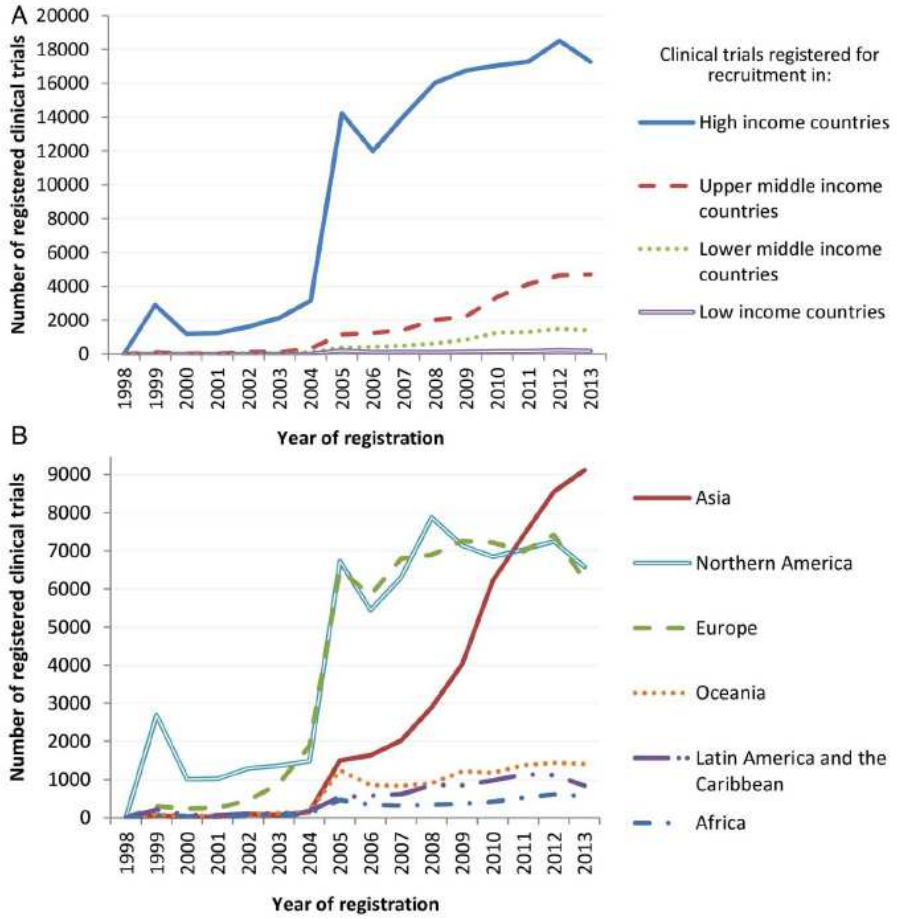
Clinical trials: a changing landscape

Figure 3 Annual numbers of clinical trials on the International Clinical Trials Registry Platform (ICTRP) registered for recruitment in country income groups (A) and geographical regions (B) from 1998 to 2013. Legend is ordered by numbers of registered trials in 2013. Numbers for further regional disaggregation for the year 2013 do not add up to regional totals because trials were regularly registered for recruitment in multiple regions. Information on countries or regions of recruitment was available for 179 724 interventional trials. A total of 113 trials only specified a region of recruitment (eg, Asia) and not a country of recruitment, and were not included for the income group analysis.



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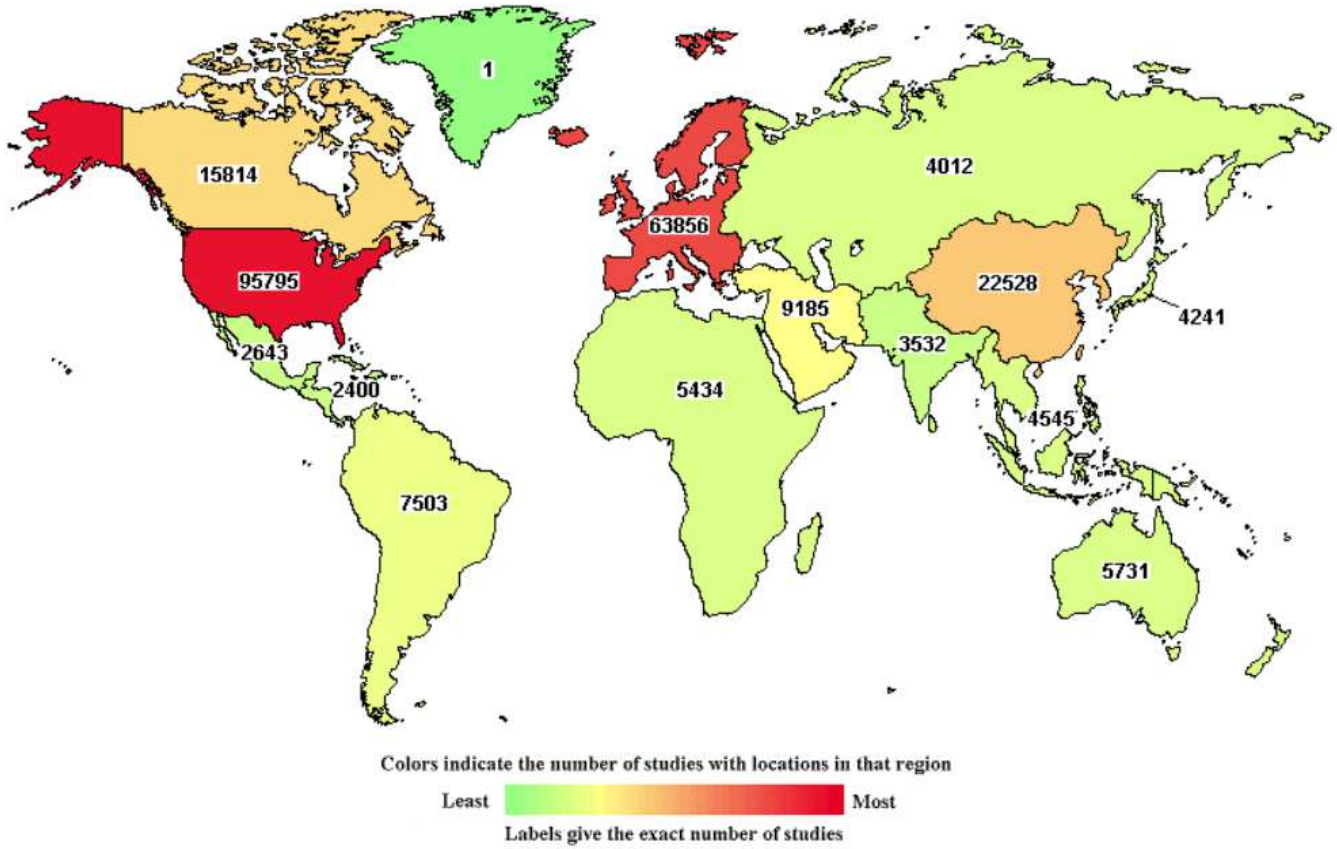
Clinical trials: a changing landscape



Source:https://ClinicalTrials.gov

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• International requirements for clinical trials: Good Clinical Practice (GCP)

- Good Clinical Practice (GCP) Guidelines are recognised as the “golden” standard in clinical research on an international level
- Basic principles: Compliance with GCP provides assurance that the **rights, safety, well-being of trial subjects are protected**, and that the clinical trial data are credible and reliable (quality and integrity)
- All clinical trials must comply with GCP guidelines
- Each Final Study Reports contains a statement that the clinical trial was performed according to GCP guidelines

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How does Swissmedic ensure compliance with GCP?

Inspections of clinical trials

The aims of the GCP inspections are to

- make sure trial conduct is/was **in accordance with applicable regulatory requirements** which include local regulations and ethical standards (Therapeutic Product Act, Human Research Act, Ordinances [ClinO], ICH E6])
- make sure that the **protection of the rights, safety and well-being of trial participants is guaranteed**
- verify that the data reported from the trial are **credible and accurate** (protection of future patients)

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How does Swissmedic ensure compliance with GCP?

Clinical trials submitted with marketing authorisation applications

What our clinical reviewers check based on the documentation submitted by the applicant:

- Has the study been performed according to the detailed study protocol?
- Is the study report based on what the protocol and the statistical analysis plan (SAP) outlines?
- Are the investigators qualified to perform the study? ☞ CV!
- Are the study protocol and patient information documents reviewed and approved by an independent ethics committee?

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Summary

- Clinical trials **must comply with GCP** guidelines in order to be **performed** in Switzerland and to **be accepted in a marketing authorisation dossier** in Switzerland.
- By taking the necessary steps to ensure compliance with GCP guidelines, Swissmedic ensures that the **basic principles** of the GCP guidelines are complied with and thus that of the **rights, safety and well-being of trial participants are protected**.

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Thank you for your attention!

Questions?

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