Clinical Research
“Challenges in Developing Countries”

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Developing Countries Vaccine Manufacturers Network

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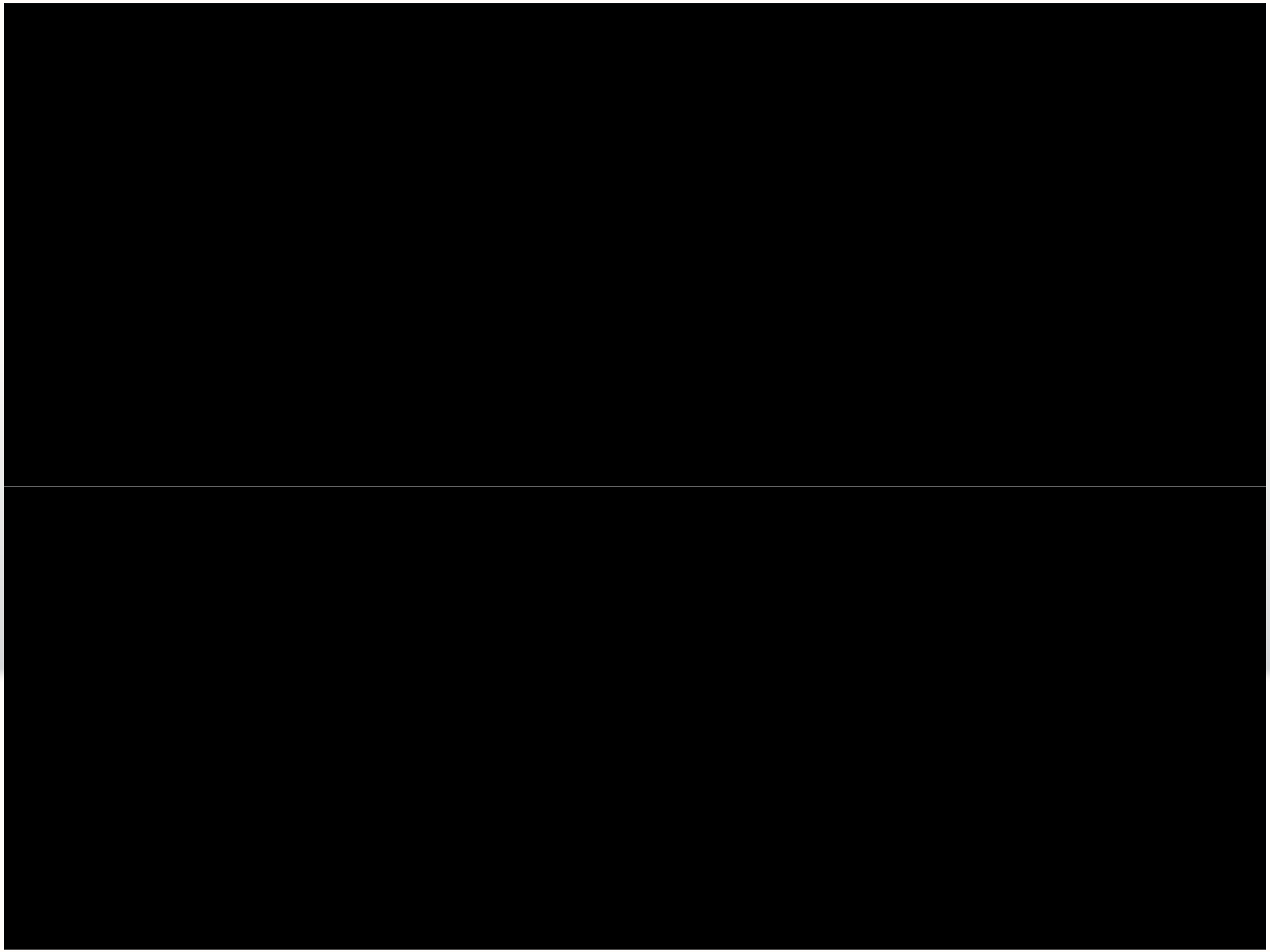
Rio de Janeiro - Brazil



Challenges to Perform Clinical Trials in Developing Countries

- **Human Resources**: Limited number of experienced PI's and staff; limited experience in GCP.
- **General Conditions:** Limitations in Infrastructure for Clinical Trials.
- **Sociocultural:** Local culture, traditions, social organizations and media, religion and politics *1 - **6
- **Logistic:** Local import / export policies, cold chain shipment / storage.
- **Institutions limitations:** NRA inexperienced in CTA assessment; IRB's.
- **Illiteracy, Indigeneous language barrier**: Informed Consent.
- **Perception of coercion & exploitation** *1

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*1_Clinical trials in developing countries: Discussions at the '9th International Symposium on Long Term Clinical Trials', London,UK,19-20.Jun2000
** 6_ The World Medicines Situation 2011 _3rd Edition_Guitelle Baghdadi-Sabeti, Department of Essential Medicines and Pharmaceutical Policies, WHO, Geneva Department of Essentia2011_Jillian Clare Kohler, University Of Toronto, Canada, , www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch20_wGoodGov.pdf *** 7 http://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-12-145

Challenges to Perform Clinical Trials in Developing Countries

- **Compensation:** Ethical compensation/ reimbursement for the poor must be adequate (expenses and work loss), documented in ICF, and IRB approved.
- **Supplies:** Supply of quality clinical trial material (not vaccine), quality refrigerators, electricity shortage and back up for critical storages.
- **Lab limitation:** No certified lab for specific pathogen detection.
- **Translation of Documents:** - Need for fast translation avoiding delay in the submissions.
  - Lack of experienced translators in the medical field.
- **Globalization of Clinical Trials:** Importance of follow the same high GCP standard in global trials; competitive enrolment impacts countries with slow approval processes.

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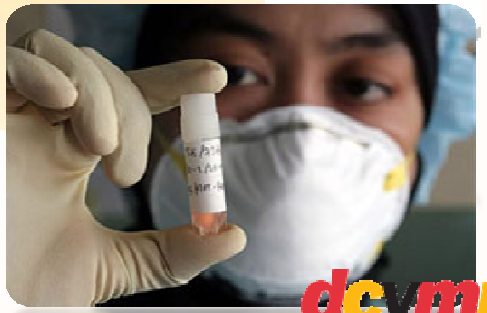
Challenges to Perform Clinical Trials in Developing Countries (cont.)

- **Contracts and institution bureaucracy –** On average how long do site level contracts take to execute?
- **Catchment area for recruitment and potential population eligible and willing to participate.**
- **Identification of key opinion leaders in each country who could serve as PI.**
- **Costs:** Regulatory, investigators, CRO, couriers, laboratories.
- **Presence of industry and/or Clinical Research Organizations in the country.**
- **Low awareness of enrolment opportunities into clinical trials.**



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Challenges to Perform Clinical Trials in Developing Countries (cont.)

- **Study overcrowding:** With the emergence of more CROs across many countries and higher clinical trial density per site in major agglomerations, recruitment and retention of research participants is often difficult .

- **Unpreparedness of some regulatory agencies and ethic committees to evaluate protocols (ie. Rare diseases).**

- **Regulatory Frameworks for CTA assessment:** Can be a challenge in some developing countries (or regions due to lack of harmonized regulatory bodies and varying rules and requirements across region.

Ref. www.interfarma.org.br, folha de São Paulo, Feb22.2011

Challenges to Perform Clinical Trials in Developing Countries (cont.)

- **New Drug Registration Regulations:** Some countries (i.e. China and Korea) require a local or regional population to be included in a clinical study if a sponsor ultimately wants to gain permission for local marketing.

- **ICF:** Different ages for legal consent redefining the concept of 'children' and modifying the criteria of inclusion of protocols. (i.e. Cameroon, legal age is 21 years old).

- **Lack of site operational procedures (SOP).**

http://harvardpublichealthreview.org/global-clinical-trials-ethics-harmonization-and-commitments-to-transparency/

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“International Regulatory Engagement Deserves Particular Mention”

Clinical Trial Regulations differ from country to country, making more difficult to establish common approaches to current pressing Ethical issues.

i.e. Regulatory authority requires participant access to trial medications after trial, while another country does not.

Is it then fair or ethical for one participant to have access to the drug while another participant in the same trial does not, simply based on his or her place of residence?

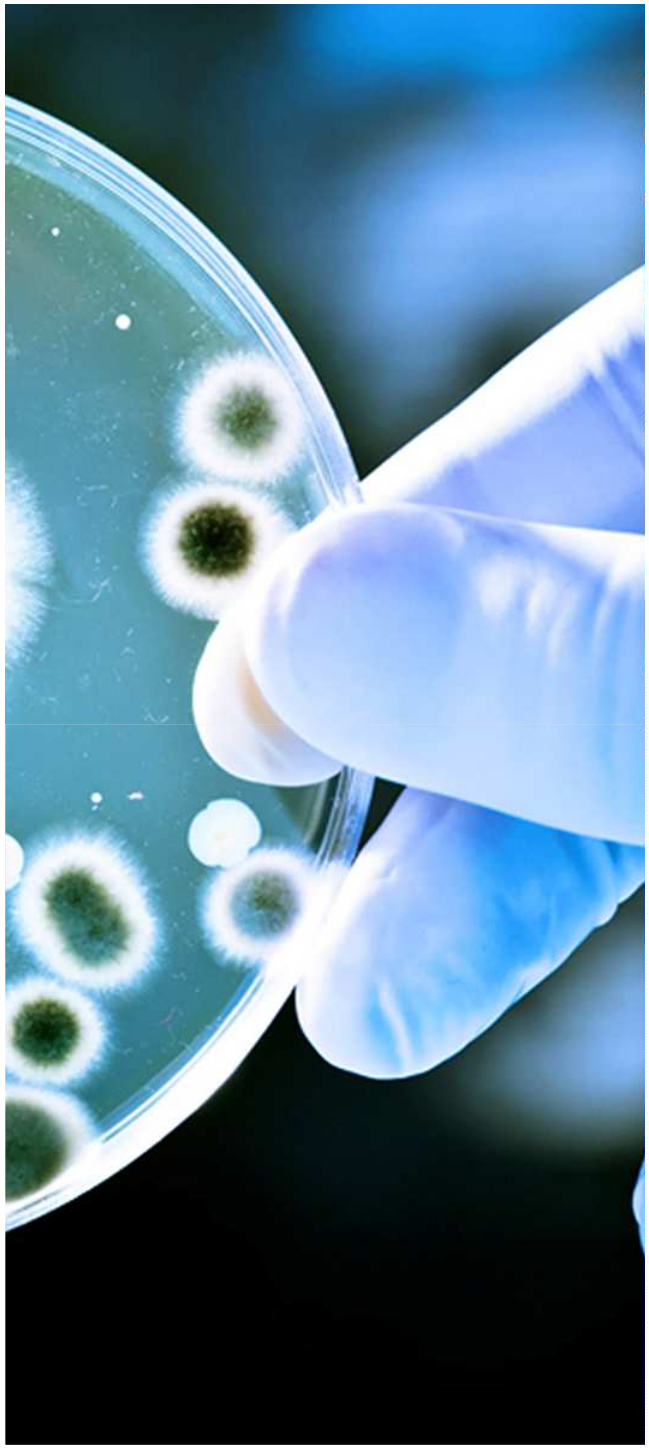
i.e. If one regulatory authority requires compensation for serious adverse events or death related to participation in a clinical trial while another does not.

Is it then fair or ethical to “value” one life differently than another?

Harmonization of the regulations, requirements, and directions will help to ensure that ethical solutions to these issues, even if challenging, are at least feasible.

“Globalization of Clinical Trials”

Globalization will continue only if trial design, conduct and implementation are maintained at a high ethical standard and the integration of ethical principles will help to improve the ethical conduct of such trials, enhance public trust, and preserve the integrity of the science conducted.



“Challenges Can Result in Delays”

Study delays can keep

your product out of the

hands of the patients

who needs them and

can also put millions

in potential revenue at risk.

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Non Experient Sites and Physicians
How to proceed?

- **Feasibility & Site Assessment Visit: Identify the deficiencies and weaknesses of each site and site staff.**

- **Training: Train and prepare site staff (GCP/ICH, local and international regulations, study specific procedures, IATA Dangerous Goods Certification (International Air Transport) regulations if necessary etc) to perform a clinical study** SHIPPER'S DECLARATION FOR DANGEROUS GOODS.mp4

- **SOP: Request to site to write the Standard Operational Procedures .**

  http://www.paho.org/english/ad/ths/ev/GCP-Eng-doct.pdf

- **Equipments: Donate study specific equipments (if allowed by each country regulation).**

Conditions: Geography, Infrastructure Limitations, Traditions, Social Organizations and Politics
How to proceed?

- **Geography: Evaluate the conditions to travel to each site due the distance, to shipment of materials and samples to plan the study.**

- **Infraestructure Limitation: Verify other possibilities as Satellite sites, hire laboratories (i.e. diagnostic imaging lab).**

- **Previous Knowledge: Traditions, social organizations and politics (religious holidays, community leaders).**

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The internet initiatives...

- **Objective:**
  Develop research culture training the resources, promoting study sites of excellence from which other local researchers can copy good practices.

- **Creation of Platforms where researchers can share experiences and resources with professionals of developing countries.**

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Challenges for Clinical Trial

The challenges of clinical research are not restricted to a single country, thus transnational communication on clinical trials requires initiation and co-ordination by a transnational organisation, with the objective to facilitate better clinical research, relevant to the needs of patients everywhere.

Each year, the "**International Clinical Trials Day"** is celebrated around the world on or near the **20th of May** in order to celebrate the day that **James Lind** started his famous trial on the **20th of May 1747** (*www.jameslindlibrary.org).

I need to remember that the Clinical Trials will not improve in my country without my participation !

Let’s start it now ?

QUESTIONS?


obrigado
Dank U
Merci
mahalo
Köszi
спасибо
Grazie
Thank you
mauruuru
Takk
Gracias
Dziękuję
Děkuju
danke
Kiitos