CRT Plenary Meeting

5-6 July 2023
Steigenberger Herrenhof Hotel Vienna

“The Future of Clinical Trials: towards Diversity and Inclusion”

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<th>Time</th>
<th>Breakout session 1 – 2 groups – 45 mins</th>
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<td>15:10-16:00</td>
<td><strong>Group 1:</strong> Trial conduct and execution: How to assure geographical representativeness and include LMICs</td>
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**Lead:** Dr Kristine Buchholtz (NovoNordisk),
**Rapporteur:** Prof. Habib Gamra
Many of these barriers explain the poor inclusion of LMIC in CT

Known Barriers of low enrollment in clinical trials

- Improve country attractiveness and offer incentives
- Improve overall trial awareness & increase health literacy
- Reduce inequalities in access to health care
- Increase pool of diverse, community-based investigators
- Upskill and support research-naive sites with intended population
- Increase overall trial awareness & increase health literacy
- Create culturally sensitive informed consent material
- Involves multi-stakeholder engagement
- Improve country attractiveness and offer incentives

Multiple factors and barriers* contribute to low enrollment

Requires multi-pronged, multi-stakeholder approach
- Government, Society, Public-Private Efforts
- Sponsors, CROs, Research Institutions
- Research Institutions and Community Groups with the support of Sponsors, CROs,

* Some of the barriers
Thoughts and suggestions to increase LMICs inclusion in CTs

- Challenges for sponsors to include LMICs in practice:
  - In naïve countries/centers to clinical research, the quality of research will be questionable.
  - For some kind of clinical trials such as device based CTs, the standard of care in LMICs in terms of expertise and equipment is not as good as in western countries, and thus there might be an issue of safety and reliability of the data.
Thoughts and suggestions to increase LMICs inclusion in CTs

• CROs have a major role to play:
  • Raise awareness among the medical community but also the population
  • Contribute in the training of the future researchers
  • Create culturally sensitive informed consent with the local language

• Digital technology/ Cell phones might help in:
  • screening
  • collecting data
  • follow up

Digital tools will be provided in limited resources countries
Cost saving approach
Thoughts and suggestions to increase LMICs inclusion in CTs

• Large research institutions such as PHRI has successfully involved LMICs in CTs but in the same time contributed in the training of the research teams combining two missions:
  - Inclusion
  - Capacity building

  *This should be a model to follow*

• Potential role of:
  - Political institutions such the African Union Africa health Africa Health
  - CVCT MEMA

In capacity building
Harmonizing the regulatory procedures
Improving the trust of sponsors in conducting trials in those regions
Thoughts and suggestions to increase LMICs inclusion in CTs

- Conditions for trial registration should include diversity and geographic representation
- Including researchers from LMIC in the steering committee of trials might contribute in building expertise and increase motivation of those researchers in boosting research in their own countries