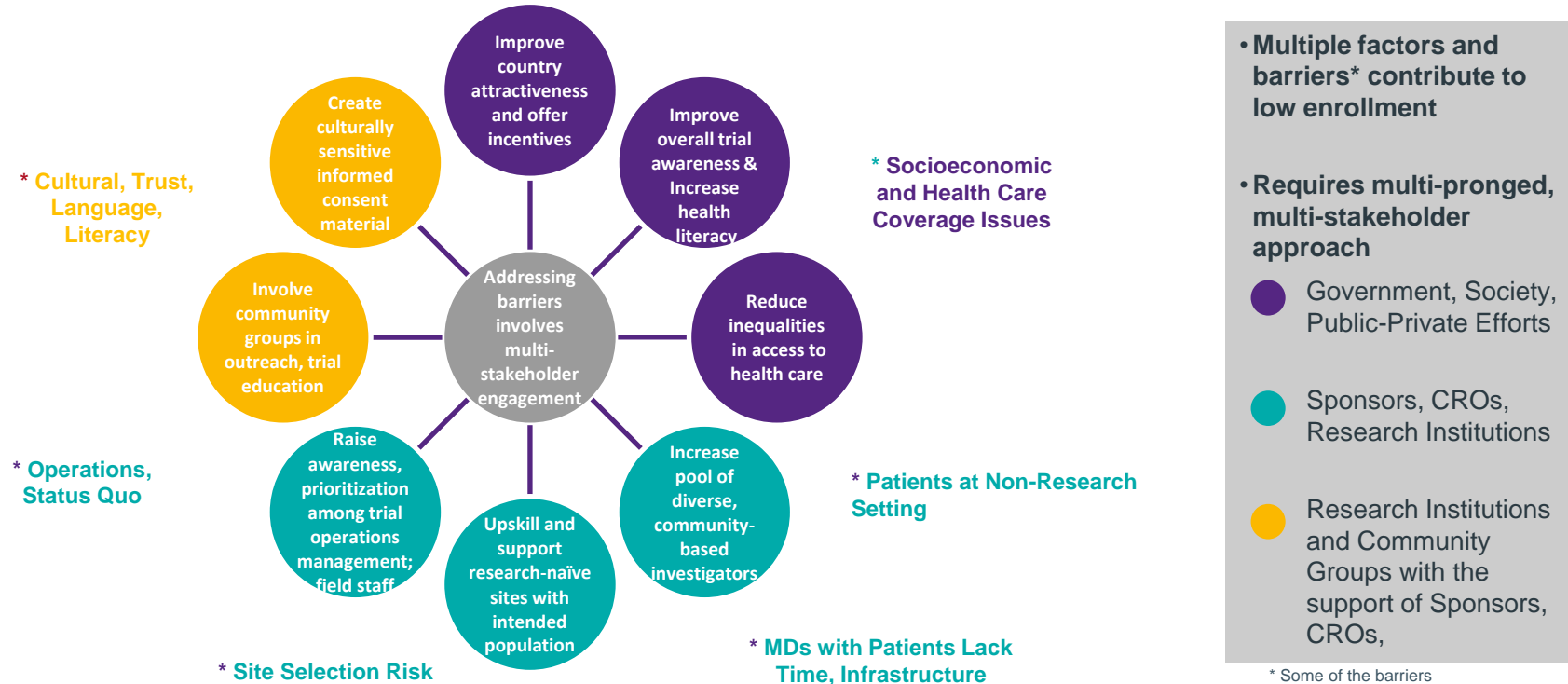


CRT Plenary Meeting
5-6 July 2023
Steigenberger Herrenhof Hotel Vienna
“The Future of Clinical Trials: towards Diversity and Inclusion”

15:10-16:00	Breakout session 1 – 2 groups – 45 mins	
Group 1: Trial conduct and execution: How to assure geographical representativeness and include LMICs	<i>Lead: Dr Kristine Buchholtz (NovoNordisk), Rapporteur: Prof. Habib Gamra</i>	

Known Barriers of low enrollment in clinical trials

Many of these barriers explain the poor inclusion of LMIC in CT



Thoughts and suggestions to increase LMICs inclusion in CTs ESC

- 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