

Speaker Abstracts

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Risks and challenges in engagement in LMIC

INTRODUCTION

Compelling ethical and scientific considerations now require that CHIMs are also undertaken in LMICs, but there are challenges posed by this relatively new research methodology in places where policy, culture, and practice is yet to accommodate CHIMs. To engage stakeholders in LMICs, the CHIMs agenda has entirely been driven by investigators who often have to wear multiple hats for any progress to be achieved.

CHALLENGES

Awareness: Investigators not only need to educate themselves and their research teams, they actually have to introduce the basics of the concept to local stakeholders at all levels.

Resources: Nearly always, engagement with stakeholders take the form of workshops and meetings which require specific funding that the investigator must source. Moreover, the actual CHIMs work requires sufficient infrastructure, equipment, staff and logistics that must be in place.

Regulatory environment: In the absence of specific regulations and laws, investigators often have to engage local authorities to help them find “legal loopholes” to facilitate acceptance and review of CHIMs work. Given the lack of awareness and exposure, some level of competence needs to be imparted in order to obtain a meaningful review and guidance.

Technical gaps: Concepts which are “globally unresolved” i.e. the requirement for the challenge agent to be a GMP or GMP-like product, pose exceptionally huge challenges when engaging local regulators in LMICs- they quickly associate this to increased risk.

Researched community: Communicating the lofty idea of CHIMs in societies that are generally research naïve can be difficult. Funders, sponsors and the international community are on the one hand concerned about potential exploitation and the need for individual informed voluntarism against risks; locally, there mere language, how to communicate, community perceptions, and getting the levels of compensation right are critical issues.

APPROACH BEING TAKEN

Our experience has included sustained engagement at every possible contact with gatekeepers including local authorities- ethics committees, ministry of health, regulatory and biosafety authorities, community gate keepers, civic leadership and public media. In parallel, creating a team of motivated scientists kept abreast through key literature and international exposure.

To introduce CHIMs, we had to start with use of Rotarix- a live attenuated vaccine as a challenge agent. Beyond this, we can now look to other possibilities such as shigella.

CONCLUSION

There are real challenges to introducing CHIMs in LMICs but they can be overcome by careful well thought strategies and sustained momentum. It took long to get the international/funding community to accept, and it is taking even longer for the local stakeholders to follow through. Strong indigenous leadership is needed to achieve this in LMIC settings.

