**Side Meeting on the Current Global Regulatory and Ethical Landscape for CHIM studies including Regional/Global Collaborative Guidance- Organized as a part of the 2019 World Conference on Access to Medical Products**

November 20,21st, 2019

Taj Palace Hotel, New Delhi, India

**Conclusion of the meeting**

Conducting controlled human infection model (CHIM) studies in an endemic setting like India can be very valuable and contribute to addressing public health needs by helping to guide the development of products most suited to the populations in need. However, India needs to approach CHIM studies carefully as stakeholders in India are new to this type of engagement in clinical trials . Sustained and transparent public and community engagement are essential for robust outcomes and ethical considerations. Guidance which is India specific should take into consideration global best practice and include the Indian regulatory processes. Important areas that need to be covered in guidance are clear and unambiguous informed consent, participant recruitment and payment and compensation in the Indian context. CHIM studies in India require regulatory and clinical capacity building, training and collaborations (both at regional and global levels). Regulators in India recognize the value of such studies and are contributors to and supportive of the draft guidance being developed. Ethical and regulatory guidance for CHIM studies are presently under development by WHO and AVAREF respectively.

**Recommendations:**

* Regulatory guidance on requirements with regards to challenge agents/strains (stability, reproducibility of data, clarity of GMP and GMP like considerations) need to be clearly defined. Regulators may collaborate for increased clarity on the inclusion of such studies for generating efficacy data and the use of this data for licensure. Dissemination of the process and methodology taken up by US FDA for market authorization of Vaxchora, the cholera vaccine will promote greater understanding of the processes at NRAs.
* Develop collaboration and engagement between clinician researchers, scientists, ethicists and communications staff. Research sites with experience in CHIM studies can be engaged for capacity building .
* Training of ethics committees, regulatory review committees and researchers
* More cross-regional (AVAREF and SEAR) and global collaborations will promote engagement in CHIM studies
* A defined communication strategy and embedding social science research into the conduct of these studies is recommended.
* Public and community engagement is crucial for all clinical research, including CHIM studies, to build public confidence in clinical research.

**Summary and Next Steps**

CHIM studies are important and valuable in endemic settings but it is important that these are done at a limited number of sites that which can ensure high quality clinical care and the most informative science and product development. As next steps at the national level; the Department of Biotechnology (DBT) and the European Union had issued a joint call for Influenza vaccines where CHIM studies were required to be a part of the application. While the application did not mandate that the Influenza CHIM study should be conducted in India, it is intended to promote the capacity of Indian researchers to conduct CHIM studies. DBT will hold a consultation on the Influenza project with the Indian regulator by February 2020 where building capacity for CHIM studies in sites in India with oversight from the regulatory authority will be discussed. Following this meeting, a roadmap for CHIM studies in India will be prepared with a list of future activities which will include a detailed strategy for communication and outreach. The draft guidance will be refined based on all the inputs received from all relevant stakeholders.

Internationally, WHO is working on ethical guidance for CHIM studies and the second consultative meeting to discuss the guidance has been planned in February 2020. At the regional level AVAREF is also looking to develop guidance for CHIM studies and the AVAREF plans for the guidance will be discussed further at the SEAR meeting later in the year to ensure regional alignment.