152nd SESSION of the WHO EXECUTIVE BOARD

(Geneva, 30 January- 7th February 2023)

9:30 AM (CET))

सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

Agenda 12.1: Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination

(Word count: 348)

Thank you Chair!

India acknowledges the need for strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination. This will play a key role in ensuring safety, efficacy and quality of medicines.

We agree that self-assessment tools with indicators for the maturity of the clinical trial ecosystem at national and international levels will help understand the gaps and improve the system.

India believes that:

a. The mapping of clinical trial networks should be an ongoing exercise and the results available in the public domain.
b. The secretariat should play a pivotal role in building capacities wherever required by providing expertise and help harmonize the regulatory and ethics related differences in multi-country collaborations.

India recognizes that there is a need for strengthening the global clinical trial ecosystem such that large, multi-country trials with adequate representation of population who will benefit from the concerned intervention can be conducted in a well-designed and well-regulated manner.

Active participation and not mere token representation of the LMIC partners at all stages of the life cycle of a clinical trial starting from conceptualization, protocol development to actual implementation of the protocol is critical.

Channelizing the international funding resources towards unmet and neglected needs of underserved and developing populations has to be prioritized besides an unambiguous credit sharing.

Chair,

In cases of new investigational products, the product should also be made available in developing countries including requisite applications for marketing approvals in all countries where the drug has been tested.

Negotiations regarding a compatible pricing structure should be done and concessions should be built in, for the spending ability on healthcare in resource limited settings.

Chair,

Responsible clinical trial data sharing can lead to more transparent regulations, generate new research hypotheses, and increase scientific knowledge.

In instances of multi-country trials, adequate measures and safeguards are to be put in place to ensure that unnecessary transfer of samples is not mandated, and the collected samples are utilized only for the purpose stated in the mutually agreed upon study proposal.

India supports efforts by WHO in this direction.

Thank you!