CLINICAL TRIALS REGISTRATION FACTS

1. Clinical trials are research studies that prospectively assign human participants or groups of humans to one or more health related interventions in order to evaluate the effects on health outcomes [1]. Clinical trials are important because they can provide evidence to inform health decisions. Many of the treatments available for patients today were once tested in clinical trials.

2. Clinical trials that are well-designed and well-executed can allow participants to play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research [2].

3. Clinical trial registration is the publication about the design, conduct and administration of clinical trials [1]. Clinical Trial Registration is deemed a good research practice and an ethical and moral responsibility. Trial registration has been repeatedly identified in different forums as instrumental in allowing proper health research governance and monitoring, and is considered an important tool to build public confidence and trust in health research.

4. In 2004, following the recommendations of the Mexico Ministerial Summit, the WHO set up the International Clinical Trials Registry Platform (ICTRP) "to ensure that a complete view of research is accessible to all those involved in health care decision-making" [3]. The ICTRP aims to make information about all clinical trials involving humans publicly available in multiple languages.

5. In August 2006, adherence to ICTRP was discussed during the 11th World Congress on Public Health in Rio de Janeiro. In 2007, BIREME/PAHO published a recommendation on the Registry of Clinical Trials for the editors of Latin American journals.

6. By December 2010, the number of clinical trial records identifiable in ICTRP's Search Portal was around 123,000 and one-third of the trials were actively recruiting participants.

7. Since 2005, there has been a significant increase in the number of clinical trials registered in the Americas. However, the rate of registered trials is still low. According to a recent study, only 17% of a sample of randomized controlled trials published in 2010 were registered. Between 2008 and 2009, PAHO and BIREME worked with DECIT (Departamento de Ciência e Tecnologia), ANVISA (Agência Nacional de Vigilância Sanitária) and FIOCRUZ (Fundação Oswaldo Cruz) to develop an open-source software ("Open Trials") that allows users to create their own registry that meets requirements and comply with ICTRP standards and best practices. "Open Trials" was funded by the MoH of Brazil, Fiocruz and PAHO and was launched in November 2010.

8. WHO Primary Registries fulfill specific standards and meet requirements about content, quality and validity, accessibility, unique identification, technical capacity and administration. In 2010, two Primary Registries were accredited by the International Clinical Trial Registry Platform (ICTRP) of the World Health Organization.
    - The Cuban Public Registry of Clinical Trials (RPCEC) is the first Spanish registry in the Americas. It is an online database developed by the National Center for Clinical Trials Coordination (CENCEC). The registry is intended for public service in Cuba, although it is available for registrants of other countries. A video of the event is available.
    - The Brazilian Clinical Trials Registry (REBEC), the first in Portuguese, focuses on trials recruiting in Brazil. REBEC is the first registry to use the "Open Trials" software, which is available free of charge from PAHO.

9. Key elements that justify having clinical trial registries in the LAC Region:
    - Countries will benefit from a harmonized framework, as well as guidance on clinical trial registration. Trial registration can facilitate research governance within countries.

- Countries will benefit from regional collaboration in clinical trial registration. Awareness about ongoing clinical trials may reduce unnecessary research, improve research visibility, and streamline the integration of new research into research synthesis.
- Awareness of existing and ongoing research allows better identification of knowledge gaps and areas that need to be further researched, as well as recruitment of participants.

References:

[1] http://www.who.int/ictrp/en/

[2] http://clinicaltrials.gov/ct2/info/understand

[3] Ministerial Summit on Health Research: the Mexico Statement on Health Research. Knowledge for better health: strengthening health systems. Mexico, DF, 16 to 20 November, 2004. [On line]. Available at http://www.who.int/rpc/summit/agenda/Mexico_Statement-English.pdf