VI Pan-American Conference for the Harmonization of Pharmaceutical Regulation (CPARF)

Work Group

Good Clinical Practices

Results and Perspectives

_Strengthening of National Regulatory Authorities within the Context of Health Systems_

Brasilia, Brazil

July 06-08, 2011
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Members of the Work Group:

- José Peña, OPS Focal Point, Network Coordinator
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- Pamela Payne-Wilson, (Alternate Member), Barbados
- Dr. João Carlos Fernandes, (Full Member), Brazil
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Background:

- Restructuring of the group and selection of coordinator (June – July 2010)
- Approval and commissioning of the Work plan of the group (August 2010)
- Selection of the subjects for the preparation or correction of documents:
  - Clinical Studies in Pediatrics
  - Researcher Manual
  - Considerations on the use of placebos
  - Inspections
- Assignment of those responsible for the subjects to be discussed (August September 2010)
- Holding virtual meeting and ongoing contact through electronic mail (2010 – 2011)
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Background:

- Completion of the first three documents (First quarter 2011)
- Review and modification of the documents by the BPC Work Group (first quarter 2011)
- Presentation for public consulting of the documents on the OPS page (March to May 2011)
- Receipt of comments from different institutions and ARN among them: ALIFAR, AFIDRO, CIOMS, Health Canada, FDA, Panama, Colombia (May 2011)
- Modification of the documents to incorporate the comments made (May – June 2011)
- Presentation of the final versions of the three documents (June 2011)
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Guidelines for the Researcher Manual:

Document prepared and adapted based on the review of

ICH E6 (R1) Guidelines, Guidelines for Good Clinical Practices

Objective:

To provide the guidelines for writing and updating the Researcher Manual
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Guidelines for the Researcher Manual:

Scope:

⇒ **General Considerations:** Identification, Statement of Confidentiality, Responsibilities of clinical researchers, General instructions for completing and reviewing the Data Collection Notebooks, Evaluation by the Ethics Committee.

⇒ **Contents:** Table of Contents, Summary, Introduction, Physical, Chemical, Pharmaceutical Properties and Formulation, Nonclinical Studies, Effects on Human Beings, Summary of Data and Guidelines for Researchers.
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Guidelines for Performing Clinical Studies in Pediatrics:

Document prepared and adapted based on the review of ICH E11 Guidelines: Clinical Research on Medications in a Pediatric Population

Objective:

To establish the guidelines for clinical research on pharmaceutical products and medical devices in children, and to allow the performance of these studies in the Americas Region in a rigorous, scientific, and safe manner.
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Guidelines for Performing Clinical Studies in Pediatrics:

Scope:

→ Start time for pediatric studies in the product development program
→ Types of studies: Pharmacokinetics / Pharmacodynamics, efficacy and safety
→ Classification by age of the pediatric patients
→ Ethical aspects in pediatric studies
→ Complete information of the studies performed on children in the country of origin, by the country where the registration for sale is being requested
→ Need and requirements to perform clinical studies in children in the country where it is going to be registered because of insufficient data from the country of origin
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Considerations on the Use of Placebos

Document prepared and adapted based on the review of

ICH E10Guidelines: Selection of Control Group and Aspects Related to Clinical Studies

Objective:

To present general guidelines for clinical research on pharmaceutical products that seek to demonstrate safety and efficacy in a treatment, using the placebo as a control group
Considerations on the Use of Placebos

Considerations on the use of placebos:

Aspects discussed:

- Description of the placebo control group
- Ethical Principles and International Guidelines
- Types of designs for clinical studies
- Advantages and disadvantages of clinical studies controlled with placebos
- Ethical aspects of clinical studies controlled with placebos
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Action Plan

1. Provide training within the framework of the “Good Clinical Practices, Document for the Americas” Guidelines.

2. Promote and extend the use of a public registry of clinical studies based on the experiences of countries that have a primary registry, for greater transparency in the activity.

3. Prepare documents on: Inspections, Adverse Events and Non-Inferiority Studies
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Thank you very much!