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

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Members of the Work Group:

- José Peña,OPS Focal Point,Network Coordinator
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- Junia FordeWalcott(Main) Trinidad &Tobago
- Pamela Payne-Wilson(Alternate Member), Barbados
- Dr.Joao 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 E11Guidelines: 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:

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!