PANDRH Steering Committee February 12, 2004 Madrid, Spain

Report of the Bioequivalence Working Group

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4th Meeting of the Working Group

Mexico City

4-5 August 2003

PANDRH
Steering Committee Priorities

Urgent Issues:

- GMP (FDA)
- **BA/BE (FDA)**
- GCP (ANMAT)
- Counterfeit (ANVISA)

Work plan of Working Group

- Assessment of BE in countries
- Selection of team members
- Working group meeting
- Regulatory needs survey
- Selection of training materials
- Regional seminars

BE Working Group Members

- **Contact Person**: Justina Molzon (FDA)
- **Topic Lead**: Lizzie Sanchez (FDA)
- **ALIFAR:** Silvia Giarcovich
- **Argentina:** Ricardo Bolaños
- **Brazil:** Silvia Storpitis
- **Canada:** Conrad Pereira
- **Chile:** Ana Maria Concha
- **Costa Rica**: Lidiette Fonseca
- **FIFARMA**: Loreta Marquez
- **Jamaica:** Eugenie Brown
- **Venezuela:** Mara de Levy/Irene Goncalves
- **USP:** Roger Williams
- **University of Texas**: Salomon Stavchansky

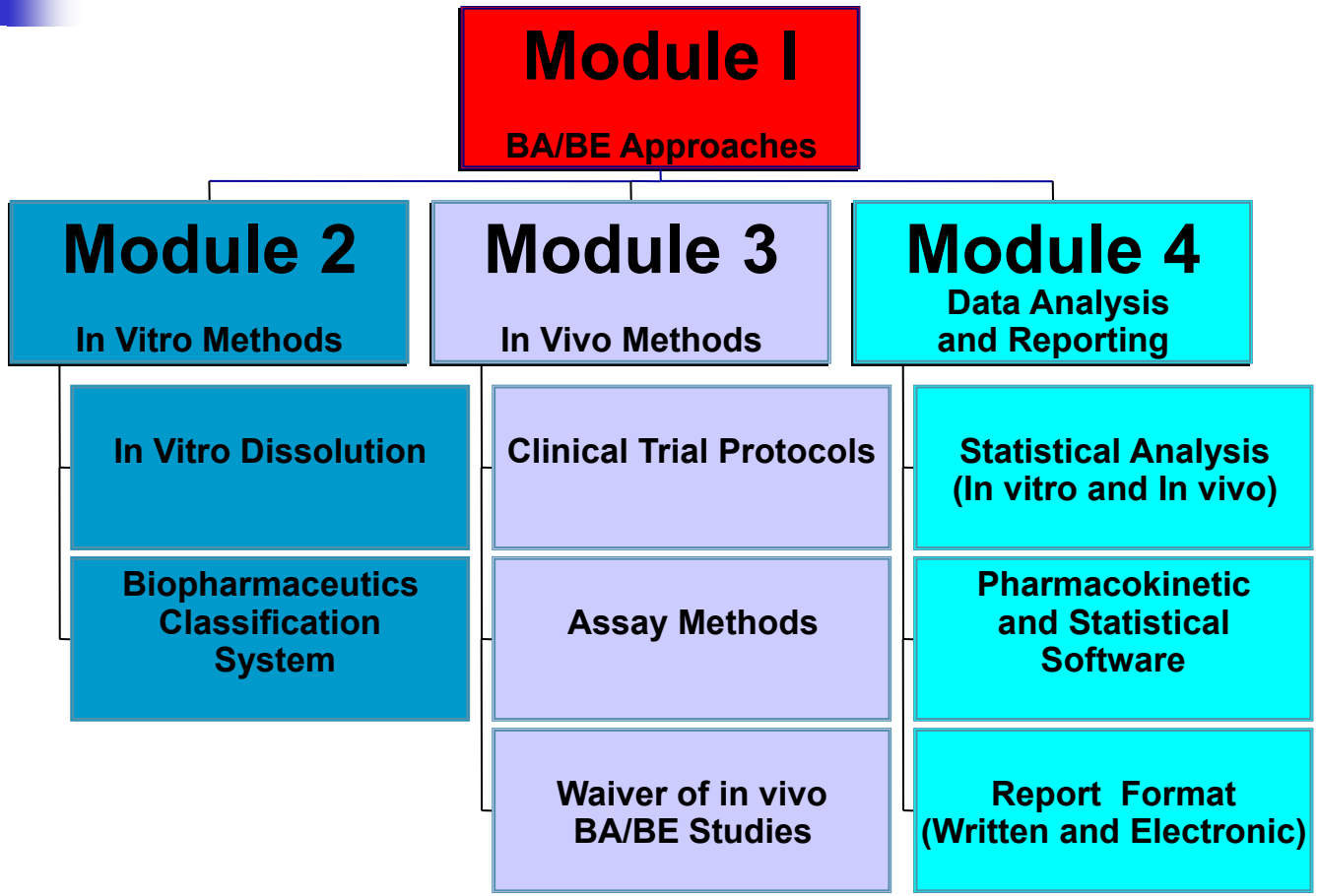
BE Working Group Meetings

- September 14, 2000—Washington, DC
- December 3-4, 2002—Caracas, Venezuela
- February 14-15, 2003—Brasilia, Brazil
- August 11-12, 2003—Mexico City, Mexico

1st Meeting of the Bioequivalence Working Group

- Focused on selection of training topics
- Developed a modular training program
- Determined resource materials to support the training modules
- Materials translated into Spanish

BA/BE Training Modules



2nd Meeting of the Bioequivalence Working Group

- Topics for Discussion:
- Criteria for prioritizing BE studies in countries where they are currently not being conducted
- Criteria for selecting BE drug comparator
- Indicators to be used by the WG/BE to follow up the implementation of BE in the Americas

3rd Meeting of the Bioequivalence Working Group

- Reviewed Recommendations from PANDRH III
- **Defined the group's MISSION**
  - The working group should contribute to harmonized bioequivalence criteria for the interchangeability of pharmaceutical products in the Americas
- **Prioritized objectives**

Prioritized Objectives

1. Develop science based criteria for products requiring in vitro and/or in vivo BE studies and those not requiring BE studies
2. Develop prioritized lists (core nucleus/recommended) of those pharmaceutical products where in vivo BE studies are necessary
3. Develop a list of pharmaceutical products where in vivo BE studies are not necessary
4. Develop a list of comparator drug products for use in the Americas region

4th Meeting of the Bioequivalence Working Group

- Listed science based criteria for products requiring in vitro and/or in vivo BE studies and those not requiring BE
- Developed prioritized list of pharmaceutical products where in vivo BE studies are necessary
- Documents will be posted on PANDRH web for comment (under construction)

Update of WG Activities

- BE Study
  - Questionnaire was distributed
  - Responses:
    - 9 (50%) from Spanish speaking countries
    - 2 from English speaking countries
  - Remaining countries encouraged to provide requested information

Update of WG Activities

- Consolidated document on criteria for BE studies
- List of priority products
- Members in process of reviewing the documents for next meeting
- Comments to be incorporated into the document

Update of WG Activities

- Regional Comparator
- Subgroup met January 12, 2004 and advanced the discussion of the subject
- Three documents developed
  - ALIFAR opinion on the topic
  - Statement of Reference Product (USP)
  - Product of reference: situational analysis (FIFARMA)
- WG members sent documents for review

Update of WG Activities

- BE Seminars
  - In process of organizing BE seminar in Argentina
- Next meeting of the WG to be held at same time as seminar

Update of WG Activities

- Main topic for SC consideration—Regional Comparator
- Presentation to the SC for information, discussion and comments
- Issue will be discussed with WG
- Then seek the SC approval