

ACPS Nonclinical Studies Subcommittee

September 24, 1999

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Nonclinical Studies Subcommittee

Functions:

- To provide advice on improved scientific approaches to nonclinical drug development and regulation
- A means to foster collaboration among FDA, industry, academia, and the public

Objectives

1. To recommend approaches and mechanisms to improve:
 - ♦ NC information for effective drug development
 - ♦ predictivity of NC tests for human outcomes
 - ♦ linkage between NC and clinical studiesand
2. To facilitate collaborative approaches to advancing the science and regulation of drug development

Potential collaborators

- FDA
 - ♦ CDER
 - ♦ CBER
- Industry
 - ♦ PhRMA
 - ♦ BIO
- Academia
- Public Institutions

Potential Nonclinical Studies Focus Areas

- Optimization of regulatory approaches
- Biomarkers and surrogate markers
- Noninvasive technologies
- Models for metabolic profiling & interactions
- Knowledge management/communication

History and Next Steps

- CDDI
- **NCSS Subcommittee meeting 8/31/99**
 - Define objectives and operating principles
 - Define focus areas
 - Discuss initial projects and mechanisms for implementation
 - Define operating structure
- **Select initial projects and form EWGs**
- **EWGs identify collaborators and identify resources**

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Subcommittee Members

- Jim MacGregor, CDER
- Dave Essayan, CBER
- Jack Reynolds, PhRMA
- Joy Cavagnaro, BIO
- Jay Goodman, Michigan State University
- Jack Dean, ACPS (Sanofi)
- Gloria Anderson, ACPS (Morris Brown Univ.)

Working Structure

- FDA Principal Coordinator (Jim MacGregor)
- Chair (Jack Reynolds, PhRMA)
- Operating principals to be defined
- NCSS-Steering committee role
- Expert Working Groups (Manage and execute projects)
- Funding vehicles (Future, as necessary)