Subject Safety in First-in-Human (FIH) Studies: Perspectives, Pragmatism and Practice

ASCPT

March 18, 2017
Setting the Stage

• The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issues:
  – **Principles**: respect for persons, beneficence, and justice
  – **Informed consent**: information, comprehension, voluntariness
Setting the Stage

• Drug development requires FIH studies to inform on tolerability, PK and PD

• Protocols carefully reviewed by investigators, ethics review committees, and national regulatory agencies

• **TeGenero** – United Kingdom (2006)

• **Biotrial 10-2474** – (2016)
  – Fatty acid amide hydroxylase (FAAH) inhibitor (MAD)
    • Subject died January 17, 2016
    • A number of other subjects hospitalized
Setting the Stage

• Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products
  – Draft Guidance - 10 November 2016
  – End of public comment – 28 February 2017

• European Medicines Agency (EMA) – Workshop on ‘Guideline...medicinal products’
Speakers

• **First-in-Human Studies: Practical Aspects of Design and Control**
  – Jim Bush, MBChB, PhD, Covance Clinical Research Unit, Leads, United Kingdom

• **BIA 10-2474 Accident: Biotrial Crisis Management – Facts, Impact & Lessons**
  – Jean-Marc Gandon, PharmD, Biotrial, Rennes, France

• **Death (or SAE) in First-in-Human Studies: What Next? A Regulatory Perspective**
  – Jonathan P. Jarrow, MD, US Food and Drug Administration, Silver Spring, MD
Speakers

- **When First-in-Human Studies Result in Death: Legal and Regulatory Lessons**
  - Robin Fretwell Wilson, BA, JD, University of Illinois College of Law, Champaign, IL

- **An Industry View of First-in-Human Studies: Where can we Improve?**
  - Sarah Robertson, PharmD, Vertex Pharmaceuticals, Inc., Boston, MA

- **Panel Discussion – Questions from the Floor**