

# 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:
  - **The Belmont Report:** Ethical Principles and Guidelines for the Protection of Human Subjects of Research – September 30, 1978
  - **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)
  - Major changes in design, Duff Comm. Report (2006) and revised EU Guidelines (2007)
- **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  - Draft Guidance - 10 November 2016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’**
  - London, UK – 28 March, 2017

# Speakers

- ***First-in-Human Studies: Practical Aspects of Design and Control***
  - Jim Bush, MBChB, PhD, Covance Clinical Research Unit, Leeds, United Kingdom
- ***BIA 10-2474 Accident: Biotech Crisis Management – Facts, Impact & Lessons***
  - Jean-Marc Gandon, PharmD, Biotech, 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***