

Cardiac Safety Research Consortium

Paul Pomerantz

Executive Director, DIA

December 9, 2010



- Established 1963, outside Phila., Pa.
- 18,000 Members
- Multi-disciplinary; multi-stakeholder representing:
 - Industry
 - Regulatory
 - Patient Groups
 - Academia
- Global
 - North America
 - Europe
 - Asia: India, China, Japan, Korea
 - Other developing regions including Latin America

- DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.

- DIA fosters innovation to improve health and well-being worldwide by:
 - Providing **invaluable forums** to exchange vital information and discuss current issues related to medical products, technologies and services;
 - Delivering **customized learning** experiences;
 - Building, **maintaining and facilitating trusted relationships** with and among individuals and organizations that drive and share DIA values and mandates; and
 - Offering a **multi-disciplinary neutral environment**, respected globally for integrity and relevancy.

- Conferences/Webinars
- Training
- Publications
- Community
 - SIACS
 - Workgroups and Task Forces
- Global regulators together worldwide
- Build global research/regulatory capacity

Challenges in Cardiac Safety (from a non-scientist)

- Impact/challenge of new science (genetics, genomics)
 - Unrealized potential of personalized medicine
- Growing consumer awareness and concern (trust is an issue)
 - Poor track record of transparency
- Mechanisms for reporting and learning about real world experience; link with health informatics
- Multi-stakeholder dimension of the challenge
- Human resources; trained people in the disciplines needed to monitor safety and interpret real world outcomes.

Relevant DIA Strategies

- Commitment to regulatory science
- DIA Forums/Conferences/Training
- Safety and Pharmacovigilance
 - Conferences and training
 - Global SIAC
- Comparative Effectiveness Research
 - RWOTF
 - Content at Annual Meeting/EuroMeeting
- “Voice of the Patient” Initiatives
- Globalization
- Health Informatics

Cardiovascular Safety in Drug Development: QT, Arrhythmias, Thrombosis, and Bleeding

April 12-13, 2010 Arlington, VA

Cardiovascular Safety, QT, and Arrhythmia in Drug Development

April 30-May 1, 2009 Washington DC

Cardiovascular Safety, QT, and Arrhythmia in Drug Development

April 7-8, 2008 Bethesda, MD

Cardiovascular Safety, QT, and Arrhythmia in Drug Development

April 12-13, 2007: Washington Marriott Hotel, Washington, DC

Conferences (Continued)

Challenges and Practical Aspects of Assessing Clinical QT Prolongation/ Proarrhythmia Risk and Implications for the Critical Pathway

May 8-9, 2006: Washington, DC

The Use of ECGs in Clinical Trials: A Public Discussion of the Proposed ICH E14 Regulatory Guidance

April 11-12, 2005 Bethesda, MD

ECGs in Clinical Trials: The New Regulatory Realities

October 3, 2003: Bethesda, MD

ECGs In Clinical Trials: The New Regulatory Realities

October 7, 2002: Arlington, VA

ECGs In Clinical R&D: Proving the Compound is Safe

May 7, 2001: Arlington, VA

4th DIA European Cardiac Safety Conference

October 25-26, 2010 Nice, France

3RD Annual Cardiac Safety Conference

December 4-5, 2008 Barcelona, Spain

2nd Cardiac Safety Conference

December 3-4, 2007 Prague, Czech Republic

Cardiac Safety Conference

December 4-5, 2006 Berlin, Germany

Conferences (Other)

Cardiac Safety, Japan:

1st DIA Cardiac Safety Workshop in Japan

May 25-26, 2010: Tokyo, Japan

Diabetes US:

Development of Type 2 Diabetes Mellitus Drugs: State of the Art Cardiovascular Safety Assessments

October 5-6, 2010 Washington, DC

Cardiovascular Safety & Development of Type 2 Diabetes Mellitus Medications: Current State of the Art & Opportunities to Advance the Science

September 23-24, 2009 Washington, DC

**Cardiovascular Safety in Drug Development:
State-of-the-art Assessments**

April 14-15, 2011 Washington, DC

**Development of Type 2 Diabetes Mellitus Drugs:
State of the Art Cardiovascular Safety
Assessments**

October 2011: Dates/hotel to be determined

- Educational conferences/publications
- RWOTF
 - Workforce and training
 - Inventory related projects.
- Forum at EuroMeeting (March)
 - Bring together HTA agencies, regulators, industry and patient groups.
- NA Annual Meeting (June): Explore how agencies globally are addressing their work in terms of priority setting, collecting and using evidence. Several sessions on science and methodology.

- Collaboration with Clinical Data Interchange Standards Consortium
- Collaboration with HIMSS
 - Integrating the Health Care Enterprise
 - Interoperability Showcase
- Bio-Informatics Working Group

- Patient Fellowship Program
 - Europe
 - North America
- Educational Programs
- Publications
- Strategic Alliances
 - NHC/IAPO
 - NORD/EURODIS

- Build public trust through transparency and patient group engagement
- Promote collaboration between government, academia, professional organizations, industry and patient groups
 - Identify need for systems
 - Identify need for capacity building