Update on CSRC Activities

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Co-Chair Executive Committee

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Mission & Milestones

To advance scientific knowledge on cardiac safety for new and existing medical products by building a collaborative environment based upon the principles of the FDA’s Critical Path Initiative as well as other public health priorities.

- 2006 — Launch FDA Critical Path Initiative with Duke University
- Key Initiatives
  - Research Programs
  - Think Tanks
  - White Papers
CSRC

Collaborative, non-competitive environment to focus on cardiac safety issues during drug development

A neutral ground that creates opportunities to share existing knowledge and data to facilitate

- Improvements in CV safety monitoring and risk management in drugs/devices development
- Allow for more efficient/effective drug/device development to ensure that these products get to the patients that need them
- Ensure that efforts are practical and can be implemented in a reasonable timeframe

Learn ↔ Influence
Drug induced QT prolongation

Regulatory Guidance

Drug d/c due to QT

CHMP Points to Consider

Canadian Concept Paper

ICH E-14 ICH S7B

ICH E-14 Q&A

ICH E-14 Q&A


Dedicated ECG studies

Terfenadine Sertindole

Astemizole Grepaflox.

Sparflox.

Levacetylmethadol

Thioridazine

Cisapride

Arrhythmias in HV Biologics

Diabetes

Oncology

PR-QRS

ECG reading methodologies

QT vs HR

CiPA

CSRC has been critical in the implementation and evolution of cardiovascular risk assessment in drug development
11 years of Cardiac Safety Research

Addressing critical areas of cardiac safety:

- The need for more efficient means of detecting pro-arrhythmia
- Blood pressure
- Cardiovascular safety biomarker monitoring
- Cell therapies for CV indications
- Cardiac imaging
- Cardiac safety in special populations, such as
  - Diabetics
  - Women
  - Pediatrics
  - Oncology
- Anticoagulant-induced bleeding and reversal agents
- Social Listening for cardiovascular safety detection
Sharing Knowledge

11 years of excellence in cardiac safety research

- Completed 14 projects
- ECG Warehouse
- Non-CV CRFs
- 46 publications
- 6 collaborative committees
- 48 scientific meetings
Key Initiatives in the last year

**Think Tanks**
- Cardiac Safety Signals in Oncology Studies
- Sudden Cardiac Death in the Young
- Regenerative medicine

**White Papers**
- Long term ECG monitoring
- Drug-induced cardiac safety in infants and neonates
- Prevention of sudden cardiac death in the young
- CV adjudication for medical devices
- Social Listening for cardiovascular safety

**Research Projects**
- National Cardiac Screening Warehouse Pilot Study
- Restricted Mean Survival Time (RMST) statistical analysis approach for analyzing diabetes
- Arrhythmias in HVs
Some of what’s coming…

- Real time safety surveillance
- Cardio-oncology
- Social media for safety surveillance
- Cardiovascular safety in pediatric population and development of reference standards
- Regenerative medicine
- Education in cardiovascular safety
  - Fellowship in cardiovascular safety in drug development
  - DIA Collaboration on real world evidence
- New collaborations (e.g. ACCP)
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