What is CSRC, How Does it Work, and Why Have We Joined Together?

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Why Have We Joined Together

• Because we have to
Some Challenges

- Patients and Caregivers want:
  - Rapid access to safe and effective new medical products
  - Better information about how to use these products after approval
  - Assurance that benefits outweigh risks

- Inefficient medical product development:
  - Is failing to keep pace with the new scientific discoveries
  - Is delaying access to new innovations and limit information on appropriate use of approved products
CDER CY New Molecular Filings and Approvals
(1996 - 2008)

*beginning in 2004 these figures include BLAs for therapeutic biologics
Reinvigorating Efficient Product Development

• The old approach is not working
• Change requires collaboration to capitalize on the expertise and resources of multiple groups (PhRMA, FDA, Academia....)
• FDA sees the challenges, and is willing enter into appropriate partnerships to foster innovation
Consortia Can Successfully Address Scientific Challenges & Reinvigorate Product Development
Consortia in other Medical Areas

CAMD

- Coalition Against Major Diseases
- Focus on Parkinson’s and Alzheimer’s
- Collaboration: C-Path and Brookings Institutes, Academic and Industry
- Aims to clarify natural history using shared data from placebo use (aim: natural history of the disease)
- Support disease modeling and improved trial efficiency
Public-Private Partnerships (cont)

Sentinel

- Collaboration to evaluate the safety of marketed medical products (provisions in section 905 of FDA Amendments Act mandate this activity)
- Develop linked databases on data from millions of lives from electronic healthcare records
  - HMOs
  - Claims databases
  - Federal healthcare institutions
- Develop tools to query data in multiple electronic repositories
- Allows data mining and signal detection analysis (e.g., in large populations, sub-populations)
Challenge: Sharing Is Hard
The Challenge of Sharing

ECG Data Warehouse

- Collaboration to build a repository of more than 2 million ECGs in a single electronic data warehouse
- Enabling academic and industry research on better markers of cardiac toxicity
- Result: more efficient trial conduct and improved patient safety
The Challenge of Sharing (cont)

ECG Data Warehouse

- Need: data available to academics and investigators to analyze
  - Moxifloxacin/Placebo
Summary

• Why share? Why CSRC?
  – We all have a shared goal of reinvigorating efficient medical product development to deliver on the promise of the new science
  – One sector cannot do this alone
  – Success requires appropriate collaboration and data-sharing

• CSRC is a productive model
• Concern: collaboration requires sharing....