Critical Path and Obligatory Drug-Device Safety Interactions: Drug Perspective

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Why Working Together is ‘Obligatory’

• Because we have to
  – Current paradigm is failing
  – Complex medical products development, like drug-device combinations, require ‘out-of-silo’ cooperation to get it right
Current Paradigm is Failing

- 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
Complex Therapeutics Require Coordinated Regulation

- Drug-Eluting Stents
“Working Together”

• Cooperation between Federals
  – CDER, CDRH
    • Efficient Process for assignment, review, safety tracking pre- and post-market
    • Essential in areas of complex medical therapeutics development (e.g., cardiac stents)
    • From Office of Combo Products
      – 2003: 81 Inter-Center Consults
      – 2009: 455 Inter-Center Consults
    • CV Device development and review as process model
“Working Together” (cont)

• Cooperation between Federal, Academic and Private Partners
  – Essential to reinvigorating medical products development
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)
Impact of FDA Efforts: Improved Use of Medicines

**Dual Anti-Platelet Trial**

- Issue related to the safe use of drug-coated coronary stents and anti-platelet drugs (e.g., clopidogrel, prausugrel, ASA)
- Response: consortium of academics, FDA, industry to conduct large simple trial to efficiently answer questions
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
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 example of a productive model

- Concern: collaboration requires sharing....