



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

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October 29, 2009*



U.S. Department of Health and Human Services

Food and Drug Administration



# ■ ■ ■ Why Have We Joined Together

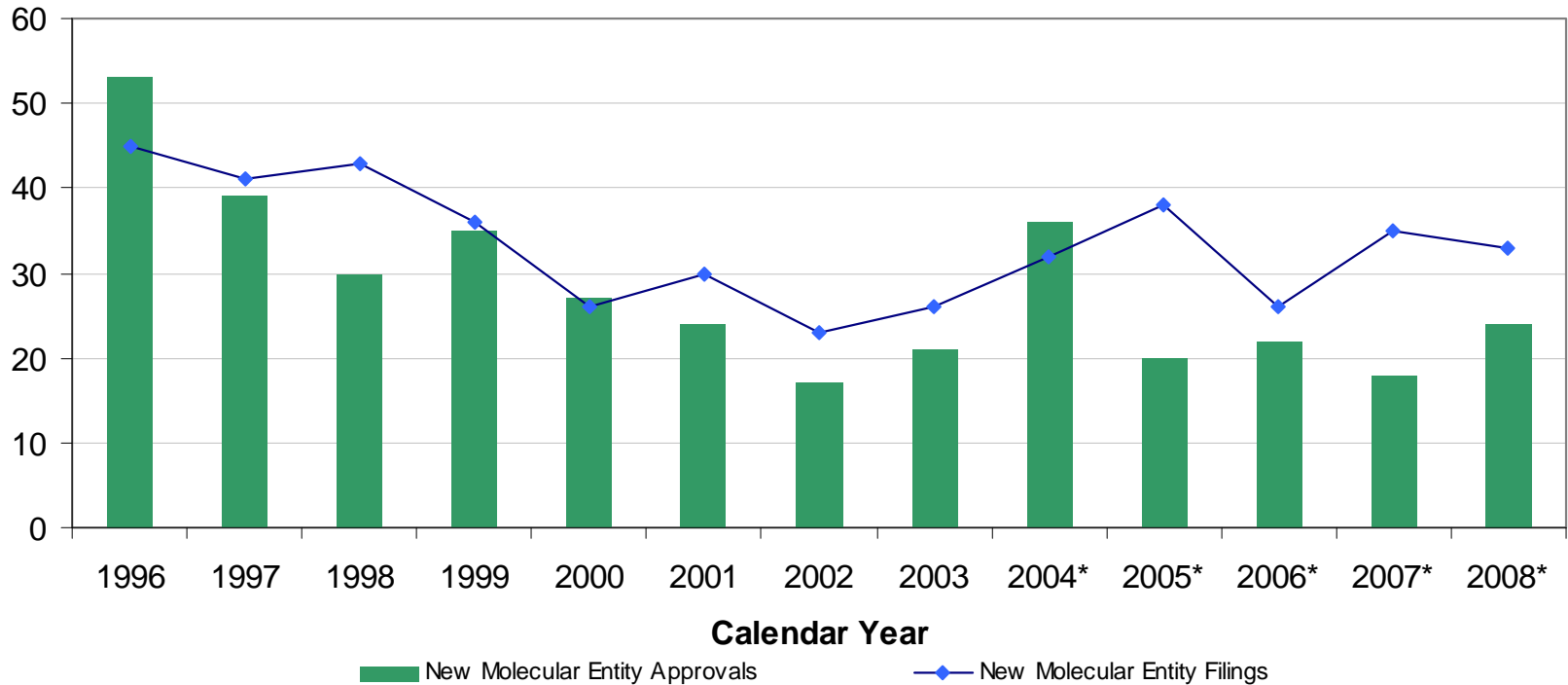
- Because we have to

## ■ ■ ■ 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)







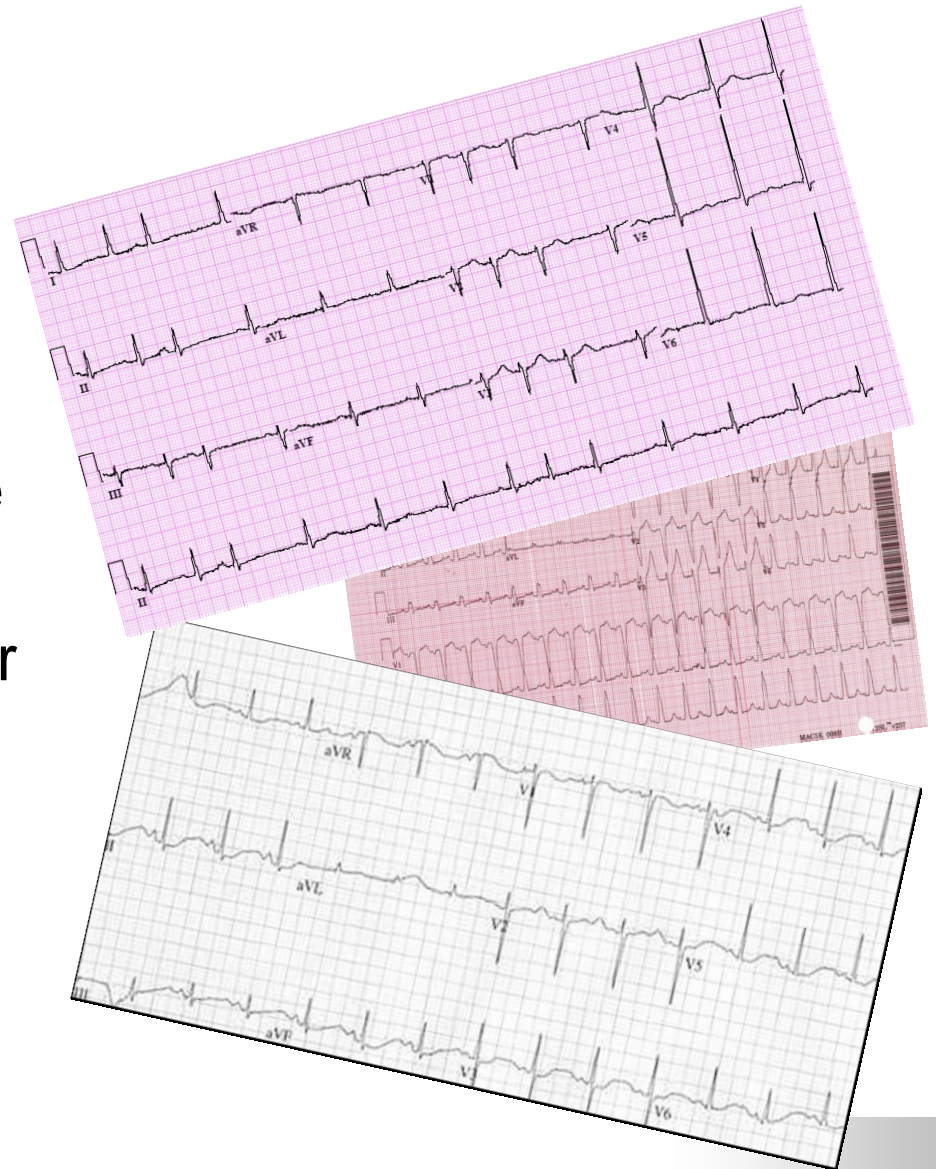
# Challenge: Sharing Is Hard



# ■■■ The Challenge of Sharing

## ECG Data Warehouse

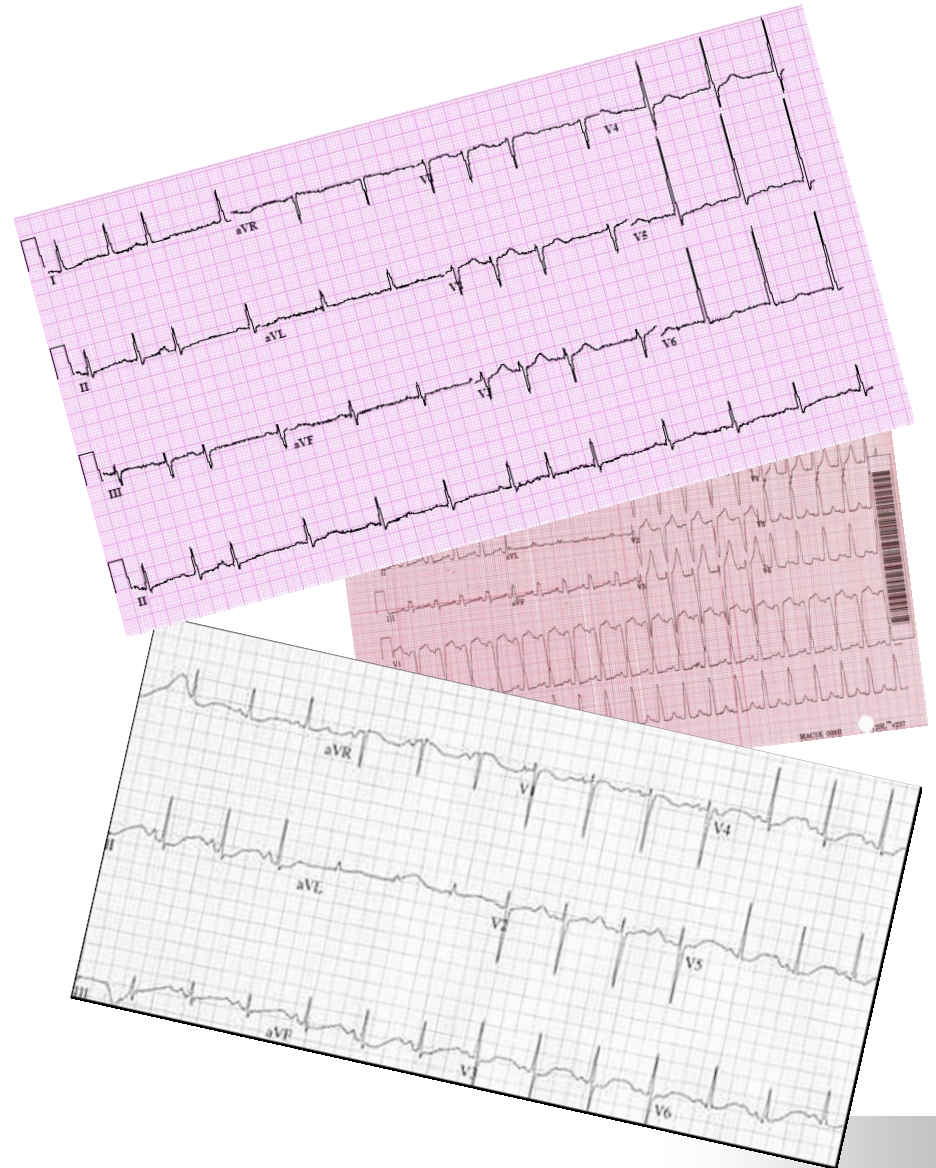
- Collaboration to build a repository of more than 2 million ECGs in a single electronic data warehouse
- Enabling academic and industry research on better markers of cardiac toxicity
- Result: more efficient trial conduct and improved patient safety



# ■■■ 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....**