



# Critical Path: Looking Forward

*Cardiac Safety Research Consortium*  
*October 29, 2009*



**FDA**

U.S. Department of Health and Human Services

Food and Drug Administration





*Insanity: doing the same thing over and over again and expecting different results.*

– Albert Einstein, *(attributed)*

## ■ ■ ■ FDA's Mission Statement

**... responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.**

**... for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.**





# The Critical Path Initiative

## Definitions

- There is a “critical path” of medical product development stretching from candidate identification to commercial production and use
- Involves serial evaluation of product performance through preclinical testing, clinical evaluation, and manufacturing
- FDA’s Critical Path Initiative focuses on ***the science*** used to do these evaluations

## Principles

- Facilitate infrastructure and “toolkit” development – **Not** focus on development of specific products
- Encourage collaborative efforts among government, academia, industry, and patient groups





# CTTI

## Clinical Trials Transformation Initiative

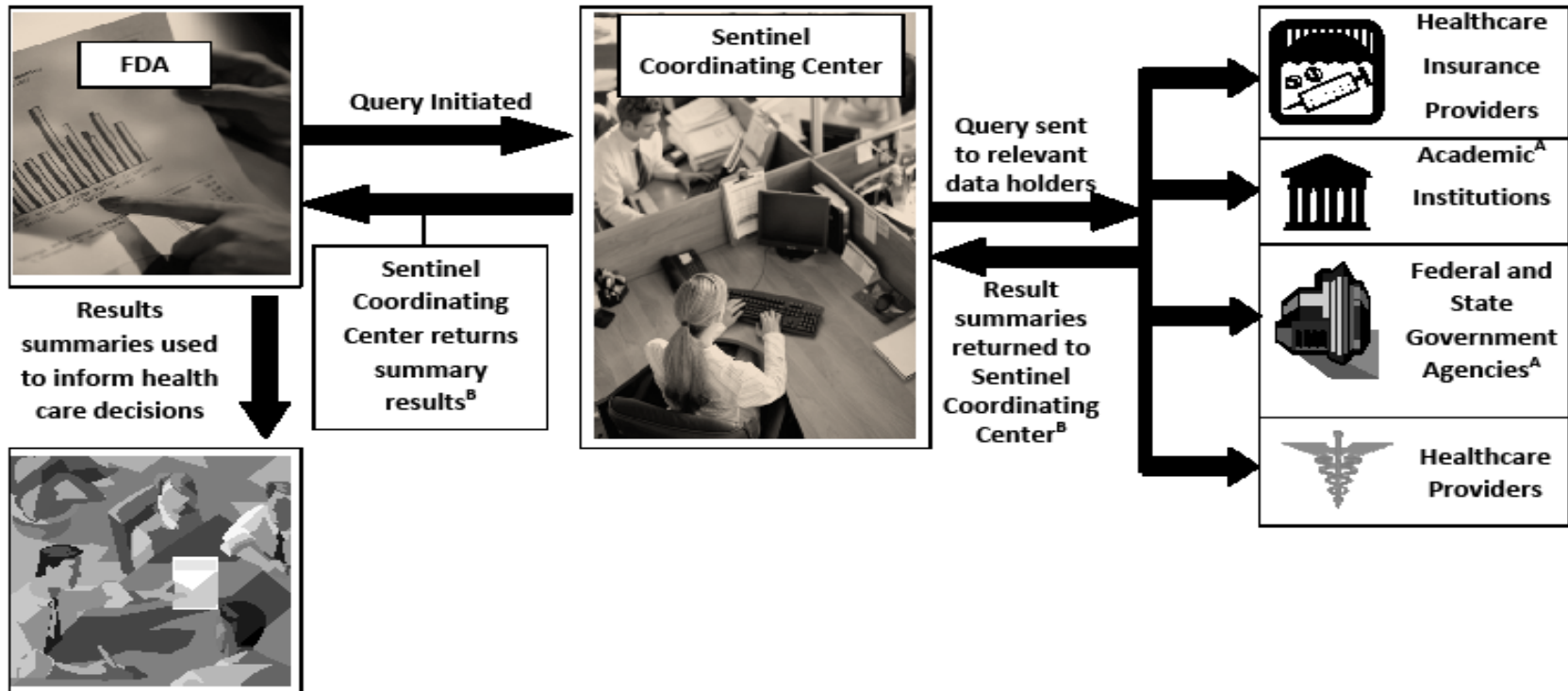
- Perception that current clinical trials enterprise is outdated, inefficient
- CTTI = unique global forum that brings together all those responsible for aspects of clinical trials (more than 50 members)

## Mission and Scope

- Conduct projects supporting mission to identify practices that will increase quality/efficiency of clinical trials
- Generate evidence about ***how to improve the design and execution of clinical trials***



## Overview of the Sentinel Query Process



- A. Only those academic institutions and federal and state government agencies with automated data will be recipients of queries.
- B. No entities will have access to protected health information that they do not already hold. Instead, those whose queries are accepted by the Sentinel Coordinating Center for processing will receive results summaries from analyses conducted by each data holder that receives and agrees to respond to those queries. Results summaries will not include protected health information.





# DAPT Trial

## **Effort unprecedented in level of cooperation (acad. industry, gov)**

- 4 device firms
- 4 drug companies
- 1 CRO
- FDA (possibly other Federal agencies)

## ***Will set standard for future collaborations of this nature***

- One trial vs many separate trials, reducing overall costs
- FDA is developing least burdensome approach for trial re number/type of regulatory applications
- Faster overall enrollment
- Expedited trial completion to provide answers to clinical community
- Greater transparency

***First patient enrolled September 28, 2009***





## Looking Forward

### **Trend toward consensus on problems**

- Lack of information
- Lack of data standardization
- Lack of clear “priority list”

**Solutions are not simple**

**What is the role of this community?**