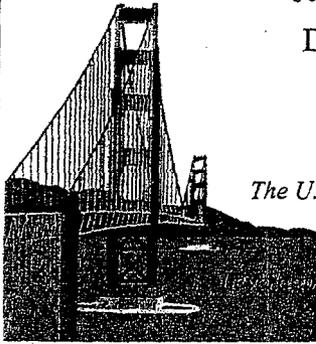


## Safety Review for New Products: *Safety Assurance in Clinical Trials*

James Nickas, PharmD  
Director, Drug Safety  
Genentech, Inc.



*The U.S. Food and Drug Administration*

*Comes to Stanford*

*Working - Collaborating with Stakeholders*

*March 23, 2000*

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- Stephen Dilly, MD, PhD
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- Robert Garnick, PhD
  - ◆ Vice President, Regulatory Affairs

## The Bottom Line

Safety Assurance  
in Clinical Trials • Good Safety-related  
Decision Making

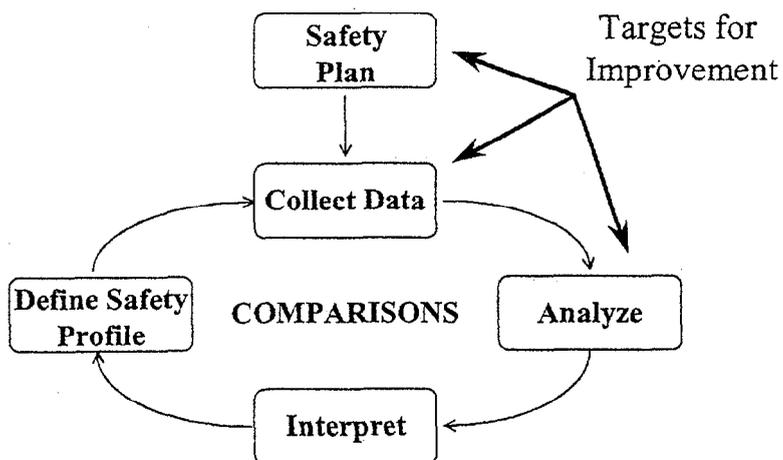
&

Good Safety-related  
Decision Making • High Quality  
“Safety Data”

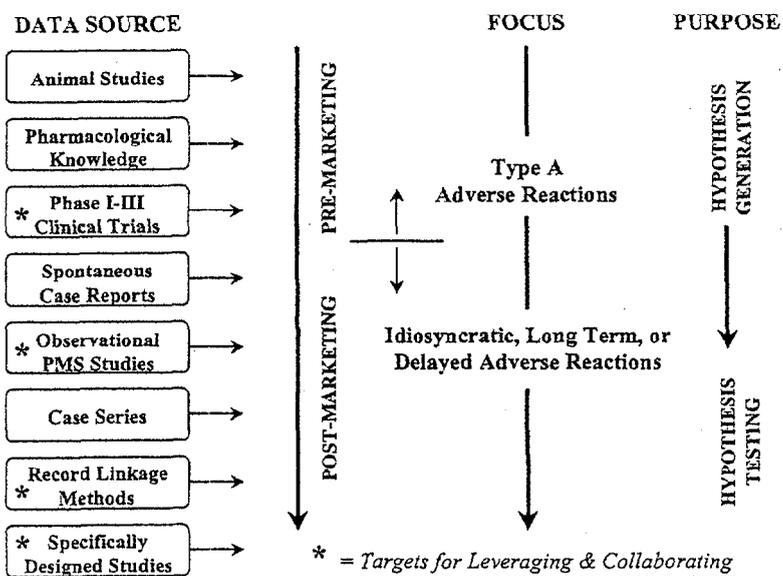
## What Might Result in Significant Improvements?

- Hypothesis-driven, knowledge based safety monitoring plans
- Breakthroughs in the way we collect and review safety data during clinical trials
- Improving the signal to noise ratio in clinical trials

## The Process of Elucidating a Product Safety Profile



## \*Adopt Product Life Cycle Safety Monitoring Approach\*



## Leveraging Ideas

- Work more closely and consistently w/sponsors & investigators to maximize the potential of studies to identify safety signals
- Consider forming an FDA advisory committee that specializes in developing safety monitoring plans and data collection/analyses methodologies

## Leveraging Ideas

- Work w/applicable thought leaders to refine and standardize processes for safety data identification, collection and analyses
- Work w/applicable thought leaders to develop guidelines for recognition and accurate recording of “treatment emergent adverse events” during clinical trials

## Leveraging Ideas

- Work w/therapeutic area thought leaders to develop standardized lists of important clinical outcomes and disease-symptom endpoints to be monitored during clinical trials

## Leveraging Ideas

- Finalize, publicize and promote Draft Guidance issued in November 1996:  
“Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review”
  - ◆ Incorporate desired safety data displays and analyses strategies so that industry can provide the Agency what it wants