

Welcome

**American Conference
on
Pharmacometrics**

March 10, 2008

Why the Critical Path Institute? The “Critical Path Initiative”



“Improved methods for testing new medical products...

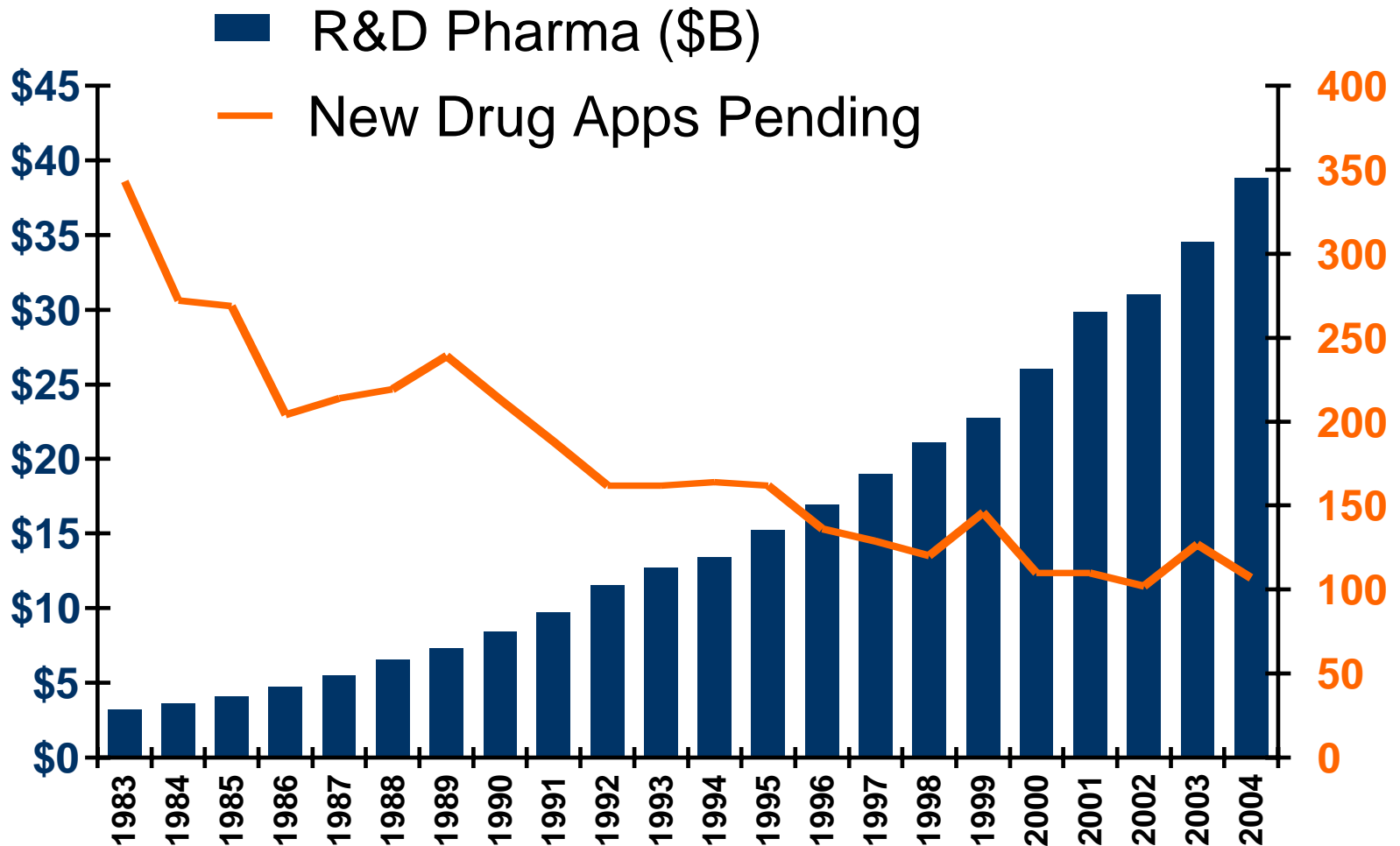
...effective collaboration among government, academia and the private sector”

**Memorandum of Understanding
Between the United States Food and
Drug Administration and the C-Path
Institute**

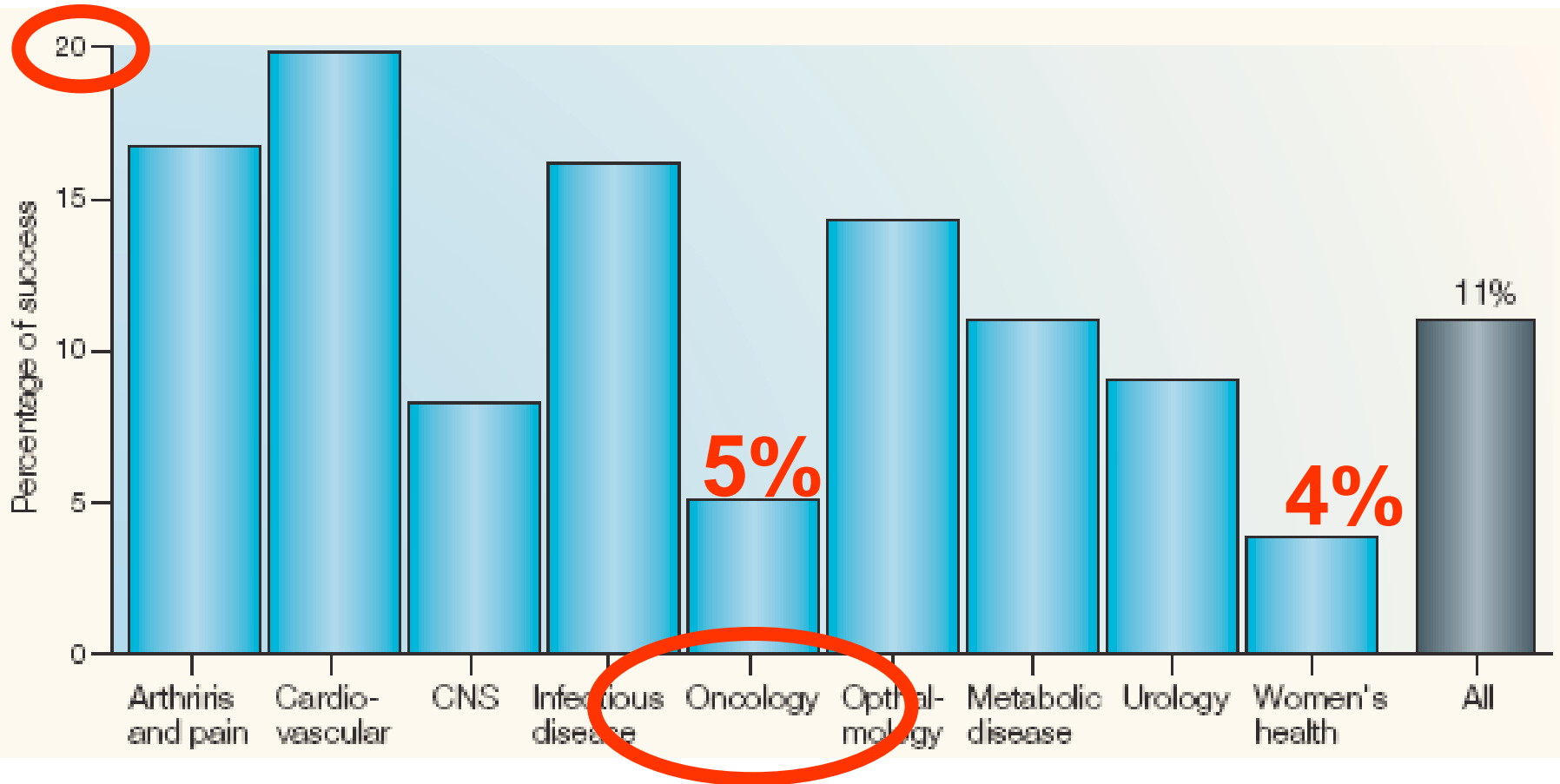
AGENCY: Food and Drug Administration,
HHS.

Science advances....

drug development declines



Success Rates



AIDS Drug Development



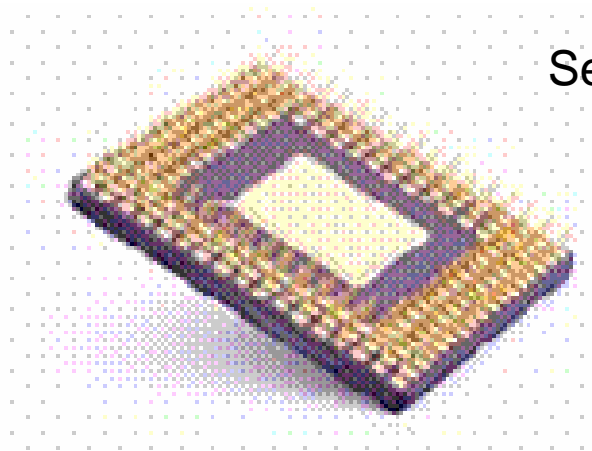
	IND to NDA (yrs)	NDA to Approval (mos)
Zidovudine (AZT)	1.4	3.5
Didanosine (DDI)	2.8	6.3
Zalcitabine (DDC)	5.1	7.6
Stavudine (D4T)	5.0	5.9
3TC	4.0	4.4
Saquinavir	2.8	3.2
Ritonavir	2.2	2.3
Indinavir	3.1	1.4
Mean	3.3 years	4.3 months

Knowledge is Power...

Knowledge shared is Power Multiplied

Robert Noyce

Sematech's First President and CEO



Pharmaceutical companies have innovative, but different, tests to predict drug toxicity

But...

- . Methods are not independently validated
- . FDA can't be certain of evidence of drug safety

Needed:

- . Standardized approach
- . Best of class strategies

PSTC Members



FDA

- ✧ Federico Goodsaid
- ✧ James L. Weaver
- ✧ Joseph Hanig
- ✧ Karol Thompson
- ✧ David Jacobson-Kram
- ✧ Michael Orr
- ✧ Weida Tong
- ✧ Felix Frueh
- ✧ Wendy Sanhai

EMA

- ✧ Spiros Vamvakas
- ✧ Jean-Marc Vidal
- ✧ Klaus Olejniczak
- ✧ Marisa Papaluca-Amati
- ✧ Nirosha Amerasinghe
- ✧ Peter Kasper
- ✧ Romaldas Maciulaitis
- ✧ Sonja Beken
- ✧ Markku Pasanen
- ✧ Beatriz Silva Lima
- ✧ Bernd Liedert

An International Endeavor



An International Endeavor

PSTC Convenes 190 Scientists Every 2 Weeks



PSTC Biomarker Submission to FDA, EMEA, PMDA



FDA, White Oak
July 12, 2007

Nephrotoxicity

- 7 biomarkers
- Detect injury 3x faster at 1/10 dose

FDA Voluntary Data Submission (VXDS)

- first submission of its kind

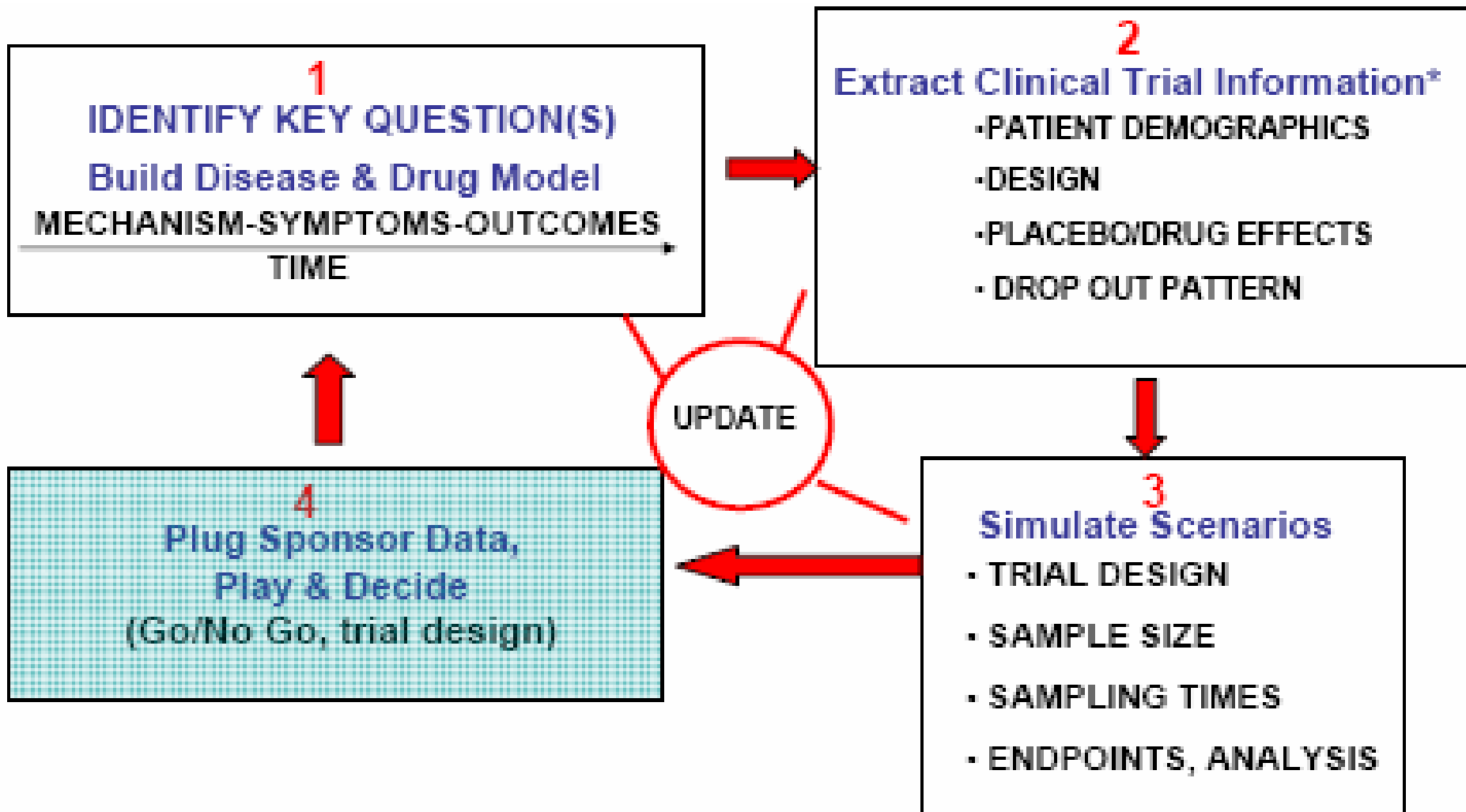
Translation Team

- Abbott, Amgen, AstraZeneca, GSK, Pfizer, Roche, J&J

"If these work in the clinic there is no doubt they would be first line"

Janet Woodcock, FDA

Model-based Development



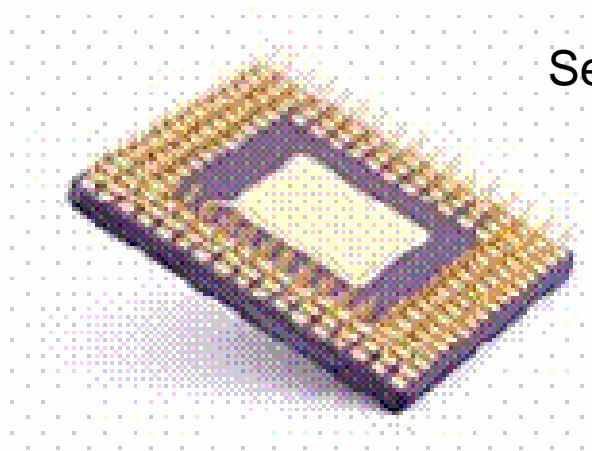
* Variety of model validation approaches were employed

Knowledge is Power...

Knowledge shared is Power Multiplied

Robert Noyce

Sematech's First President and CEO



Welcome to Arizona !!!

