

Buildup

Breakthrough

Pharmacometrics 2020

Joga Gobburu

FDA



Pharmacometrics 2020

- Academia, industry and regulatory agencies are in the *Business of Pharmacometrics* together
- These are really my opinions and not FDA policy. Please provide feedback on this presentation & vision
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Pharmacometrics 2020

- Current State of Affairs
 - Vision – '*Business of Pharmacometrics*'
 - Questions that need discussion
 - Strategic goals
 - Commitment

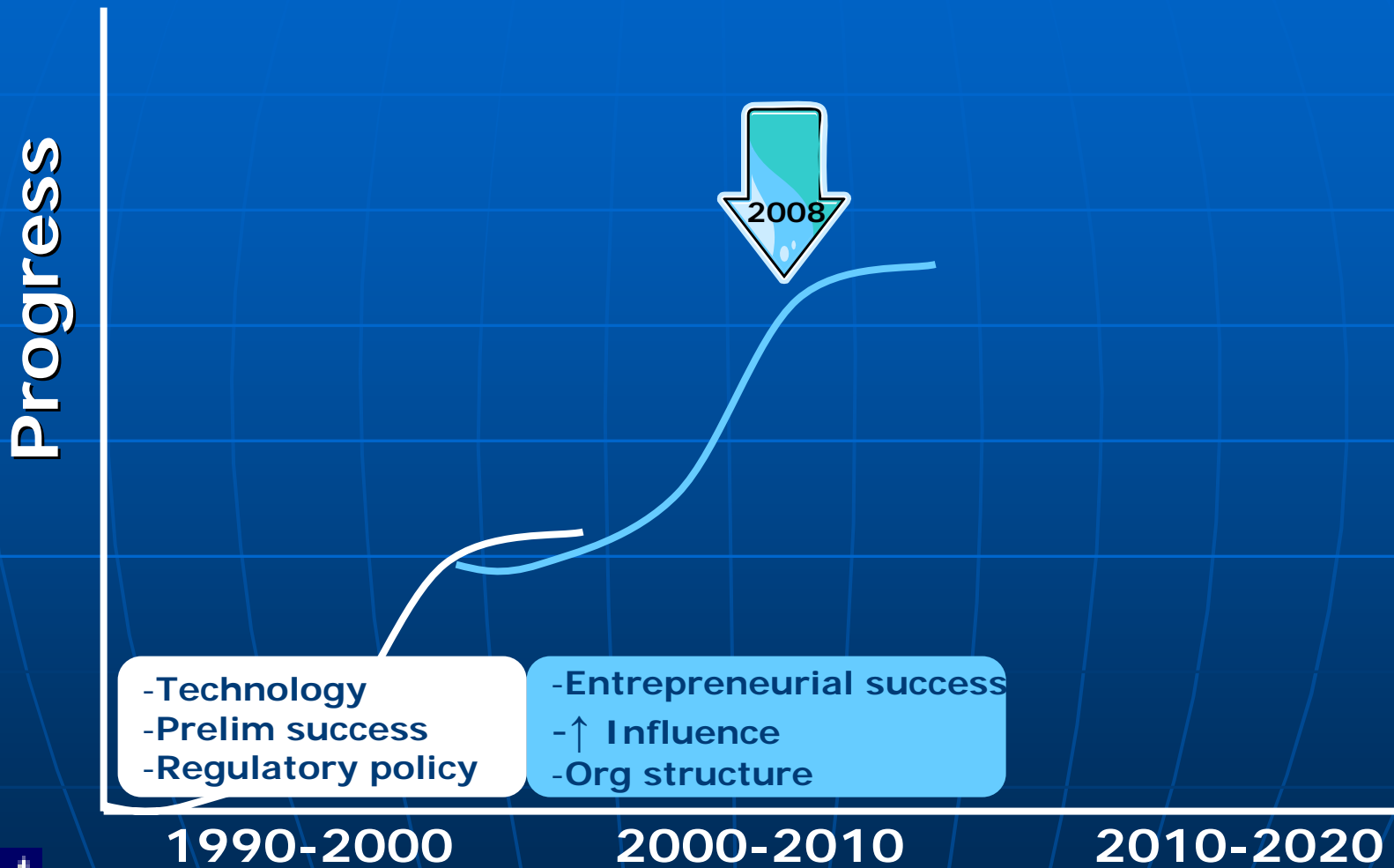


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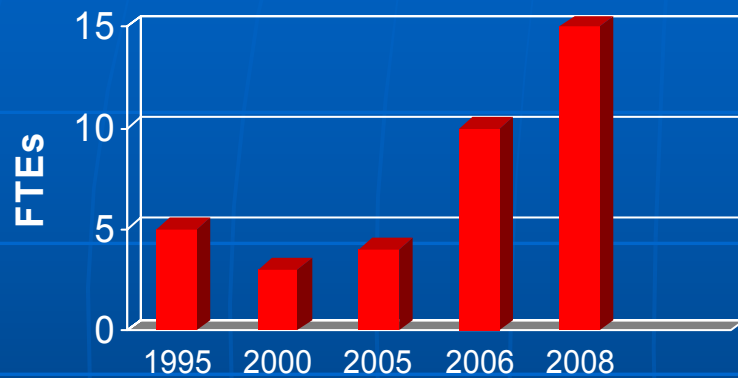


Pharmacometrics is transforming the quality of drug development and regulatory decision making!!!

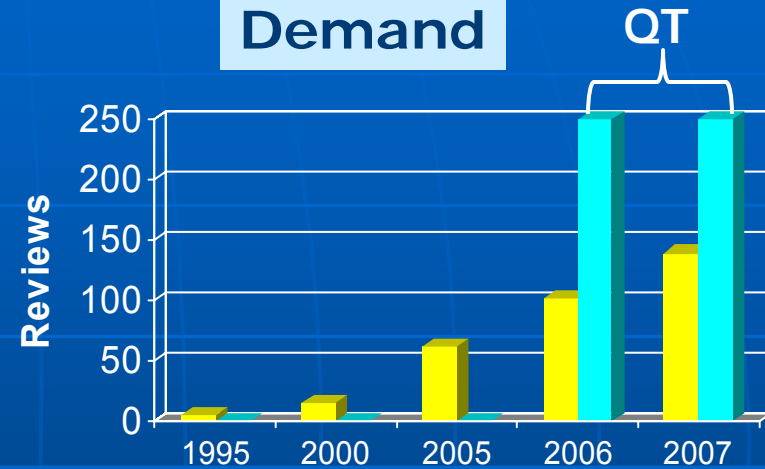


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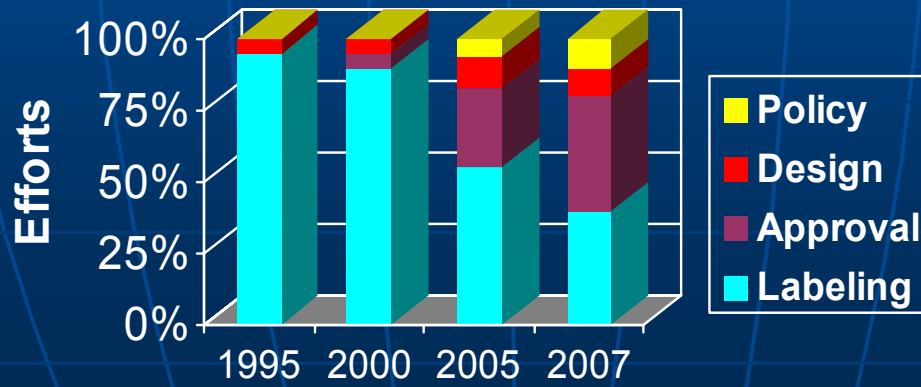
Resources



Demand



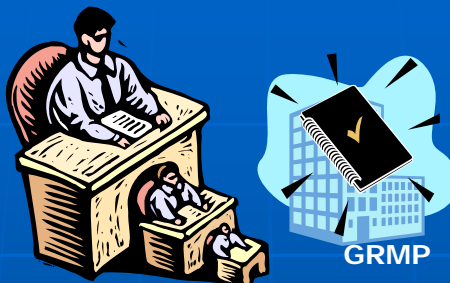
Focus



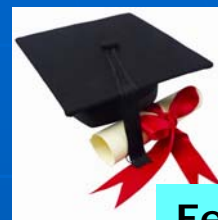
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Presentation at Advisory Committee Meetings



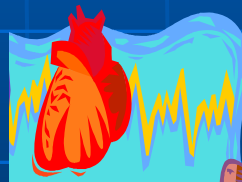
Recognized by Senior Mgmt



Fellowships/Sabbaticals
-Brundage, Don Berry
-Fellows, AAPS CRADA
-Critical Path



Influenced key decisions

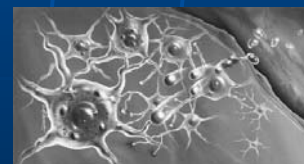


QT Policy & Leadership



Non-small lung Cancer model

**AC Meeting
March 18, 2008**



**Parkinson Disease:
Modification Claims**

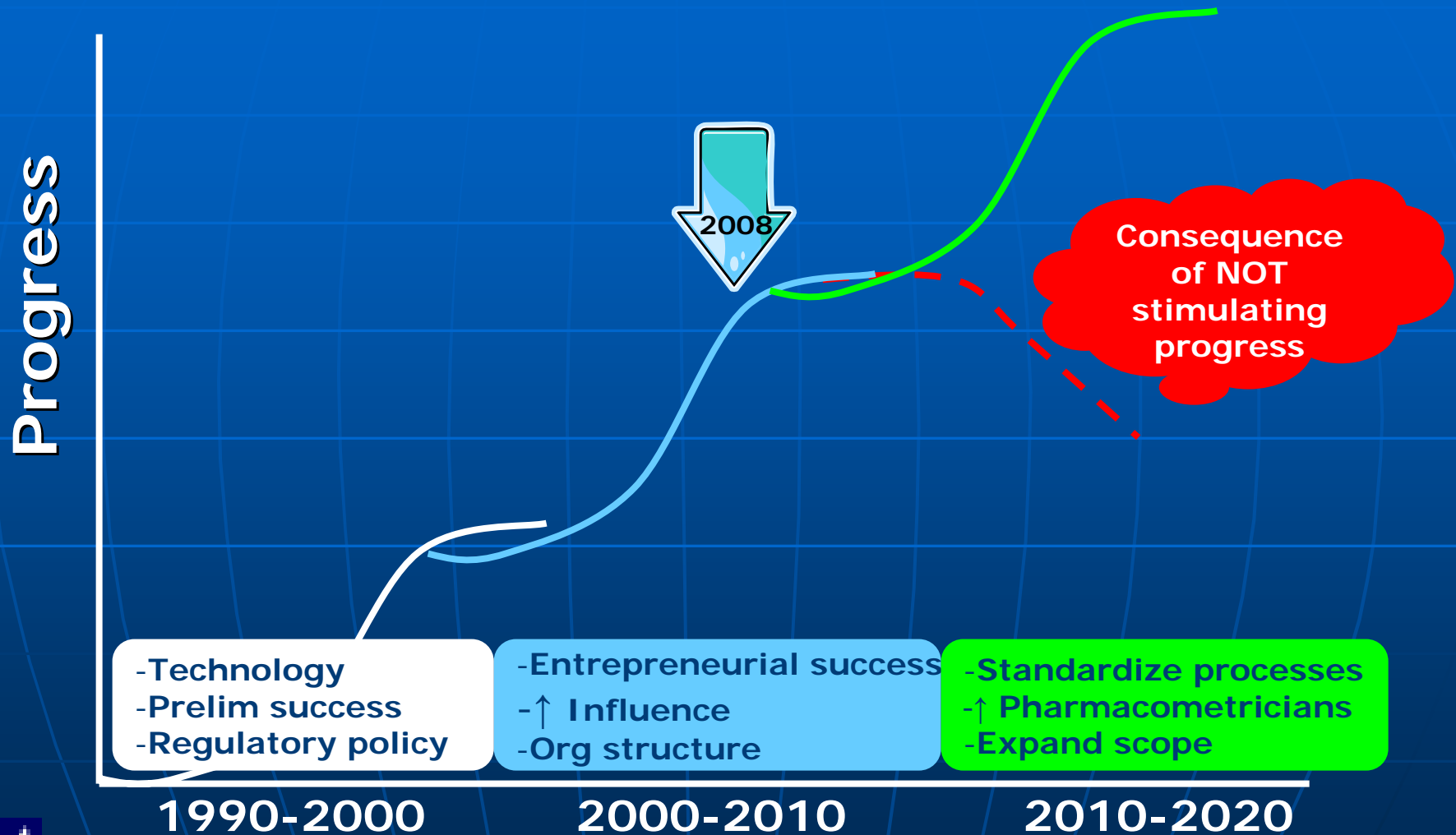
**Conference, DC
April 28-29, 2008**



GRMP=Good Review Mgmt Processes

Gobburu, ACoP 2008

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External Advances Affecting Pharmacometrics

PGx

"Assay"
technology

Pharm
Eco/
Health
Policy

R&D Productivity

Innovative
trial
designs

Computnl
advances

Predictive
Biology



2020 Vision

'Business of Pharmacometrics'

Pharmacometrics will lead/influence -

Reducing late phase attrition from 50% to 25% in 2015, 10% in 2020

Requiring of dose individualization

Pharmacometrics is the science that deals with quantifying pharmacology and disease *to influence drug development and regulatory decisions*



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How do we increase our influence on drug development/regulatory decisions?

Who are our customers in 2020?

What are our core products in 2020?



Pharmacometrics 2020

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- **Strategic goals**
- **Commitment**



Pharmacometrics 2020

Strategic Goals

Train 500 Pharmacometricians

- Technical track
- Disease track
- Drug development track

Industry,
Foundations
should fund
academia

Academia
should adapt
to industry/
regulatory
needs



Design by Simulations: 100% Protocols

- Late/early phase clinical trials
- Dynamic 'Learn-Apply' cycles

Efficient data visualization/analysis tools

- Soft/hardware should not be bottlenecks
- Ready access to prior information

Increase Pharmacometric Awareness

- ↑ Presence at Clinical conferences
- Publish success stories
- Hire diverse expertise



FDA Pharmacometrics 2020 Strategic Goals

Train 20 Pharmacometricians

- Technical track
- Disease track
- Drug development track

International Harmonization

- Share expertise between global regulatory bodies

Implement 15 Standard Templates

- Develop disease specific data, analysis standards
- Expect industry to follow

Integrated Quantitative CP Summary

- All NDAs should have exposure-response analyses

Develop 5 Disease Models

- Create public disease model library

Design by Simulation: 100% Pediatric WRs

- Leverage prior knowledge to design Pediatrics Written Request trials



Pharmacometrics 2020

- Current State of Affairs
- Vision – *'Business of Pharmacometrics'*
- Specific Challenges
- Potential Solutions
- **Commitment**



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FDA Pharmacometrics





“This is not the end. It is not even the beginning of the end. But it is, perhaps the end of the beginning.”

Winston Churchill



Acknowledgement

- FDA Pharmacometrics group, Larry Lesko and all other colleagues for their encouragement and guidance

