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
  - jogarao.gobburu@fda.hhs.gov
Pharmacometrics 2020

- Current State of Affairs
- Vision – ‘Business of Pharmacometrics’
- Questions that need discussion
- Strategic goals
- Commitment
Pharmacometrics 2020

- Current State of Affairs
  - Vision – ‘Business of Pharmacometrics’
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  - Commitment
Pharmacometrics is transforming the quality of drug development and regulatory decision making!!!

- Technology
- Prelim success
- Regulatory policy

- Entrepreneurial success
- ↑ Influence
- Org structure

Gobburu, ACoP 2008
FDA Pharmacometrics

Resources

FTEs

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Demand

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Focus

Efforts

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Gobburu, ACoP 2008
Presentation at Advisory Committee Meetings

Recognized by Senior Mgmt

Influenced key decisions

QT Policy & Leadership

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

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
**Pharmacometrics** is transforming the quality of drug development and regulatory decision making!!!
Pharmacometrics 2020

Current State of Affairs

Vision – ‘Business of Pharmacometrics’

Questions that need discussion

Strategic goals

Commitment
External Advances Affecting Pharmacometrics

- PGx
- Pharm Eco/Health Policy
- Computational advances
- Predictive Biology
- Innovative trial designs
- "Assay" technology

R&D Productivity
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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Current State of Affairs

Vision – ‘Business of Pharmacometrics’

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Strategic goals

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

Who are our customers in 2020?

What are our core products in 2020?
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Current State of Affairs

Vision – ‘Business of Pharmacometrics’

Questions that need discussion

Strategic goals

Commitment
Pharmacometrics 2020
Strategic Goals

**Train 500 Pharmacometricians**
- Technical track
- Disease track
- Drug development track

**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

Industry, Foundations should fund academia
Academia should adapt to industry/regulatory needs
**FDA Pharmacometrics 2020**

**Strategic Goals**

<table>
<thead>
<tr>
<th>Train 20 Pharmacometricians</th>
<th>International Harmonization</th>
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<tr>
<td>-Technical track</td>
<td>-Share expertise between global regulatory bodies</td>
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<tr>
<td>-Disease track</td>
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<td>-Drug development track</td>
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<tr>
<th>Implement 15 Standard Templates</th>
<th>Integrated Quantitative CP Summary</th>
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<tr>
<td>-Develop disease specific data, analysis standards</td>
<td>-All NDAs should have exposure-response analyses</td>
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<td>-Expect industry to follow</td>
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<th>Develop 5 Disease Models</th>
<th>Design by Simulation: 100% Pediatric WRs</th>
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<tr>
<td>-Create public disease model library</td>
<td>-Leverage prior knowledge to design Pediatrics Written Request trials</td>
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Current State of Affairs

Vision – ‘Business of Pharmacometrics’

Specific Challenges

Potential Solutions

Commitment
Pharmacometrics 2020
Strategic Goals

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Gobburu, ACoP 2008
“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