

Advisory Committee Meeting (ACM)

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PhilaSUG Meeting
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 - *FDA and the ACM*
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- Preparing for the ACM
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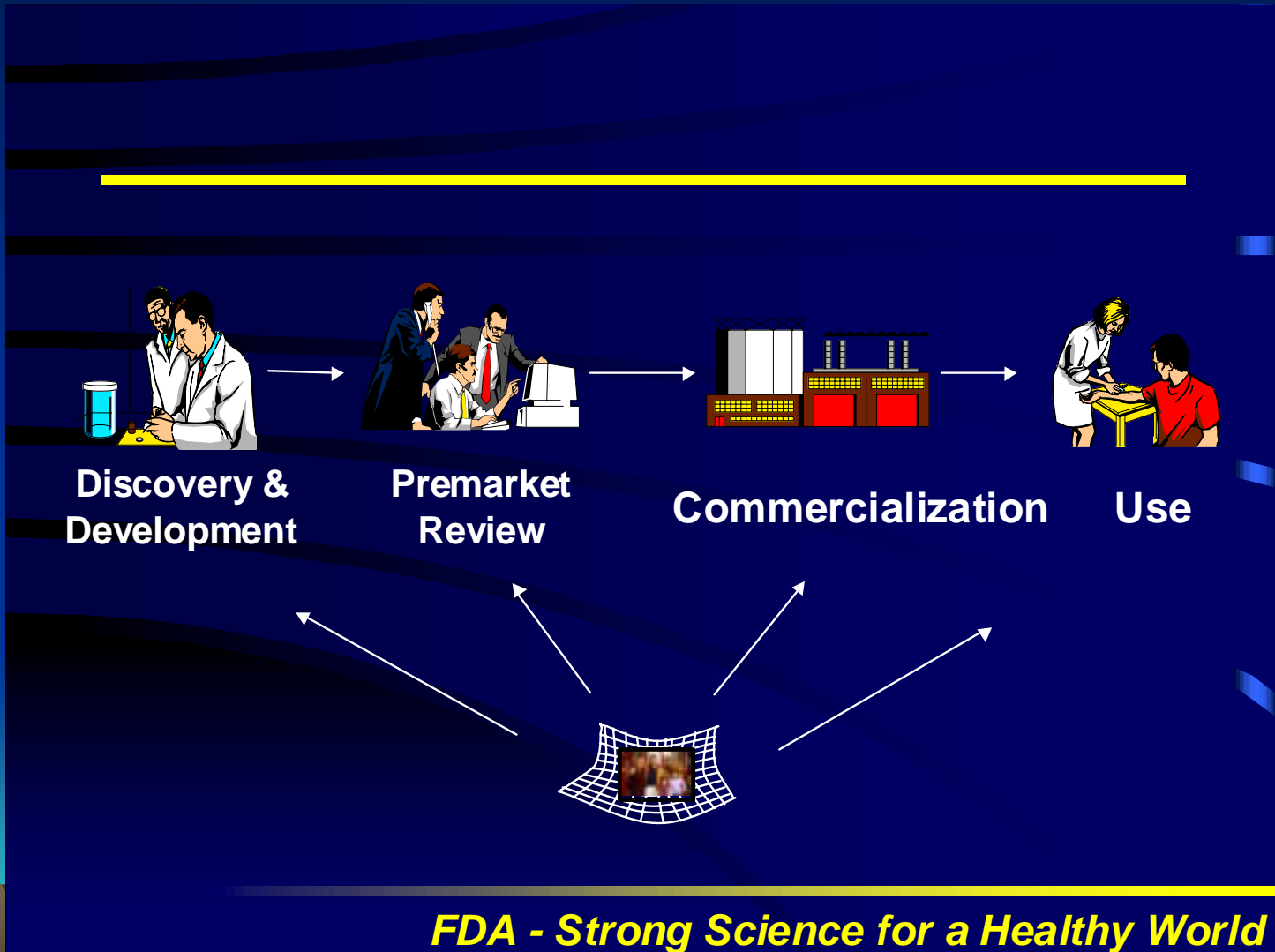


FDA Mission

- The mission of the Food and Drug Administration (FDA) is to promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner



FDA Life Cycle



FDA Organization

Center for Biologics Evaluation and Research (CBER)

Center for Devices and Radiological Health (CDRH)

Center for Drug Evaluation and Research (CDER)

Center for Food Safety and Applied Nutrition (CFSAN)

Center for Veterinary Medicine (CVM)

National Center for Toxicological Research (NCTR)



New Drug Application Process

- Sponsor Submits Application to FDA for review
- FDA conducts internal review of application
- Advisory Committee Meeting scheduled within six months of filing
- Advisory Committee recommendation
- FDA Approvable or Non-Approvable Letter



Advisory Committee

- Provides independent expert advice
- Lends credibility to the product review process
- Allows for a public discussion of controversial issues
- Keeps consumers abreast of trends in product development
- Advisory Committees are Product/Center related (31 in total)
- Assists in external review of FDA's intramural research programs



Committee Membership

- Experts engaged in cutting edge science, “clinical trial” research and independent consulting work.
- Academicians
- Clinicians
- Consumers
- Industry Representatives
- Patients and/or Patient Care Givers
- Diverse (age, race, sex, ethnicity, location)
- 4 years of service



Programmer Role

- Meeting Preparation
 - Preparing analysis for ACM presentation
- Mock ACM Rehearsal
- ACM Attendance



Preparing for the ACM

- *Anticipating FDA and Advisory Committee Questions.*
 - Programmer works closely with team on specifications and programming.

- *Preparing Core Slides (200+)*

Preparing Back-Up Slides (~1,400 – 2,000)



Preparing for the ACM

- Mock panel with external consultants
- Consultants posed questions as the FDA or AC members might ask and real-time results were provided
 - from backup slides
 - by SAS programmers
- Multiple rehearsals for presenters and support staff



The Actual ACM

- Setup of the room
- Tone of the meeting
- Role of the chairman
- Vote of the committee on pre-specified questions
- Role of Stat programmer during the meeting





FDA



Merck

Media



Public

Meeting Proceedings

- Tone of the Meeting – Serious and courtroom-like
- Role of the chairman - Facilitator
- Public Forum - 5 minute presentations
- Vote of the committee on pre-specified questions (Safety, Efficacy, Marketing)
 - The AC vote is not binding by the FDA, but taken into consideration

Role of SAS Programmer at ACM Meeting

- Location
 - Live
 - via Web-cast
- Data and Programs at the ready
- Program “on the fly” if needed
- Mock-ACM the day before



After the ACM

- Conversations between Regulatory and FDA
- Answering additional FDA questions
- The official FDA Approvable – Non Approval letter



Acknowledgements

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