Pretest: 21st Century Acronymes

- FDA
- CDER
- CPA
- PDUFA
- PRO
- ICH
- E9
- NDA
- IND
- CDISC
- BLA
- HL7
- CDASH
- CAMD
- FDAAA
- FR
- ADaM
- CPI
- ARSI
- IMI
- CRO
“21st Century Review” at the Center for Drug Evaluation and Research (CDER): So Many Data, So Little Time*

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Friday, April 16, 2010

*Or … How I *Learned* to Stop Worrying and *Love the Critical Path, the FDAAA and the PDUFAs*
Disclaimer

Views expressed in this presentation are those of the speaker and not, necessarily, of the Food and Drug Administration.
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Science & Statistics

- **Science** is concerned with understanding variability in nature
- **Statistics** is concerned with making decisions about nature in the presence of variability

At CDER
We Are “In the Business” of Making
DECISIONS based on DATA
Alternate Title

Too Many Decisions, Too Little Time
Truth-in-Advertising

- A CDER-Centric View of My FDA World
Outline

• Some Background
  – Organization
  – The Regulatory World
    • Laws, Regulations and Guidance
    • 21st Century Statistical Review

• Too Many Data, Too Little Time
  – The Critical Path
  – The Food and Drug Administration Amendments Act (FDAAA) and the Prescription Drug Users Fee Act IV (PDUFA IV)

• Visioning and Planning: How Do “We” Do This Right?
FDA – White Oak, MD
The Regulatory World

- FDA Mission
- Laws, Regulations and Guidance
- 21st Century Statistical Review
So, ... Why Do We Need an FDA?
Mission of the FDA

- ...protecting the public health ... safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.

- ... responsible for advancing the public health by helping to speed innovations...
The “Traditional” Regulatory “Mantra”

- Laws
- Regulations
- Guidance
• Laws
• Regulations
• Guidance
Acts/Laws

• Passed by U.S. Congress

• Acts/Laws Important to FDA
  – 1906 -- Food Drug and Cosmetics (FD&C) Act
  – 1938 -- Food Drug and Cosmetics (FD&C) Act
  – 1962 – Kefauver-Harris Amendment to the FD&C Act
  – 1997 -- FDA Modernization Act (FDAMA)
    • …recognized the Agency would be operating in a 21st century characterized by increasing technological, trade and public health complexities.
  – 2007 -- FDA Amendments Act (FDAAA)*
    • FDA is committed to achieve the long-term goal of an automated standards base information technology (IT) environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product life cycle.

* Including PDUFA IV
Regulations

• Written by FDA to enforce the law
• Code of Federal Regulations (CFR)
• Examples:
  – 21 CFR 314.50 -- The NDA
    • provide general requirements for submitting marketing applications to CDER
    • Subpart B--Applications Sec. 314.50 Content and format of an application.
  – 21 CFR 11 –Good practice for all computerized processes
    • Sponsors and Government
    • Paved way for submission
      – Systems
      – Guidance
      – Procedures
    • “…intended to permit the widest possible use of electronic technology…”
    • [http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm)
Guidance

- The means used to communicate the Science
- Represents the Agency’s current thinking
- Not binding on FDA or the public
- An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations or both.
Laws & Regulation

Guidance & Initiatives

Arnold

Mr. Rogers
Statistical Review of Clinical Trials Data at CDER

• Efficacy and safety
• Confirmatory/Exploratory – focus on evaluating sponsor’s results (we are “reviewers”)
• Check appropriateness of statistical models and conclusions – programs & analysis datasets
• Assess quality/completeness of data
• Evaluate the impact of sponsor’s analytical decisions – derived variables, missing/messy data (“quirks” – R. Helms) – sensitivity analyses
• Answer new, review-related statistical questions
• Communication with sponsors
• Archive results
Tradition:
Throw It Over the Wall

FDA

NDA/BLA/SUPPLEMENT

SPONSOR
Tradition:
Reviewer Catches/Runs With It

NDA/BLA/SUPPLEMENT

STATISTICAL REVIEWER
The 21st Century Review Initiative is a set of performance standards the Center for Drug Evaluation and Research (CDER) follows when doing drug reviews that involve multiple offices. The standards address meetings and timelines to identify problems early in the review process. The goal is to make the drug review process more organized and integrated, and ensure all decision makers are heard. Review team members are mutually accountable for raising and addressing differing points in a timely manner over the course of the drug review.
The New “Mantra” – The 21st Century FDA

• Acts (Laws)
• Regulations
• Guidance
• Initiatives
• Consortia
• Foundations
• Memoranda of Understanding (MOUs)
• Non-Profit Organizations (NPOs)
Too Many Data, Too Little Time

- The Critical Path (CP)
- The Food and Drug Administration Amendments Act (FDAAA) and Prescription Drug User Fee Act IV (PDUFA IV)
The Critical Path Initiative Announced by FDA -- 2004

A serious attempt to focus attention on modernizing the evaluation of safety, efficacy and quality of medical products

Challenge and Opportunity on the Critical Path to New Medical Products

U.S. Department of Health and Human Services
Food and Drug Administration
March 2004

Murphy, 2007
Conceptual Framework

- Drug discovery and development in the 2000’s did not appear to be producing at the expected level
- Multiple explanations had been offered by various experts
- “Critical Path” offered a new one: lack of investment in development science

Woodcock, 2008
First Achievement of Critical Path: Defining (Naming) the Problem

- Most non-technical stakeholders (Congress, medical community, etc) did not grasp this issue
- FDA often blamed for development problems—undiagnosed safety issues as well as slowdowns of important drugs and devices
- Agency generally not funded for applied science to improve development
  - Biologics and device programs have (very modest) research funds
  - Drugs program does not have any significant funding

Woodcock, 2008
Reaching Agreement on Addressing the Problem

• Stakeholders such as patient advocacy groups, medical professional societies, and some academics rapidly on board

• Industrial representatives agreed with problem definition but not sure of its relative importance

• Slow buy-in by FDA staff (generally group-by-group as projects in their regulatory area are addressed)

• Consensus reached over time
  – Innovative Medicines Initiative (IMI) in Europe

Woodcock, 2008
Starting Point: 76 scientific projects

• Harnessing Bioinformatics -- Standards
• Streamlining Clinical Trials – Adaptive Designs, CDASH, CTTI
• Developing Products to Address Urgent Public Health Needs -- CAMD
• Better Evaluation Tools – Biomarkers, SAEC
Harnessing Bioinformatics – Data Standards
FDA Announces Standard Format That Drug Sponsors Can Use to Submit Human Drug Clinical Trial Data

FOR IMMEDIATE RELEASE
PD4-73
July 21, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Announces Standard Format That Drug Sponsors Can Use to Submit Human Drug Clinical Trial Data

The Food and Drug Administration (FDA) today announced a standard format, called the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium (CDISC), that sponsors of human drug clinical trials can use to submit data to the agency. It is expected that this step will lead to greater efficiencies in clinical research and FDA reviews of New Drug Applications (NDAs).

The announcement was made at the Secretarial Summit on Health Information in Washington, D.C. At the Summit, HHS Secretary Tommy G. Thompson brought together technology and health leaders and others to plan for nation-wide systems of health information technology, including clinical as well as research-oriented developments.

"The importance of a standard for the exchange of clinical trial data cannot be overstated," said Dr. Lester M. Crawford, Acting FDA Commissioner. "FDA reviewers spend far too much valuable time simply reorganizing large amounts of data submitted in varying formats. Having the data presented in a standard structure will improve FDA's ability to evaluate the data and help speed new discoveries to the public."

SDTM represents an important step by government, academia and industry in working together to accelerate research through the use of standards and health information technology. In addition, the adoption of the standard is consistent with the FDA's Critical Path initiative because it will help automate the largely paper-based clinical trials research process and foster easier communication and collaboration among clinical researchers. By providing a consistent framework and format for clinical trial information, this standard is expected to enhance data integration opportunities and thereby help to reduce data management barriers for sharing the latest clinical trial data.

FDA's Critical Path initiative is focused on identifying both the problems and potential solutions to the daunting task of ensuring that the unprecedented breakthroughs in medical science are demonstrated to be safe and effective for patients as quickly and inexpensively as possible. FDA launched the Critical Path initiative on March 16, 2004, with the release of a major report entitled "Innovation or Stagnation? -- Challenge and Opportunity on the Critical Path to New Medical Products."
Example of the Problem: Locate Relevant Data and Merge/Concatenate/Subset

- Prior Medical History data here
- Adverse Event data here
- Lab data here
- Demographic data here
- Concomitant Meds data here
3 Weeks of Data Manipulation – 36 pages taped together to explore one question

Demographic data here from DEM dataset

Past Medical History data here from MEDH dataset

Laboratory data here from LAB dataset

Concomitant Meds data here from Conmed dataset

Adverse Event data here from AE dataset
To Drill Down on Data...
...hold face closer to page
Assessing Potential Liver Injury by Analyzing Increases in Serum Alanine Aminotransferase (ALT) and Total Serum Bilirubin (TBILI) IN ONE STEP

Wonderdrug NDA - ISS Data

Subject: XXXXXX - Age: 23 - Sex: M - Race: Hispanic

Drug experience Data

Adverse Event Data

Concomitant Drugs

Laboratory Data

Cooper, 2008
5-Years Down the Path: Standards

- CDISC – SDTM, ADaM, Lab, SEND, SHARE, CDASH, etc.
- HL7/CDISC – RIM, BRIDG, CaBIG, RPS, SPL, etc.
- Tools – iReview, JMP, SAS, WebSDM, R, etc.
- CDER Computational Science Center (CSC)
- PDUFA IT Plan & Data Standards Plan
- Three weeks ago – “First” Annual FDA/DIA Computational Science Meeting in Bethesda
Analysis Data Model (ADaM)

• Analysis Data Model, Version 2.1
  – …fundamental principles that apply to all analysis datasets, with the driving principle being that the design of analysis datasets and associated metadata facilitate explicit communication of the content of, input to, and purpose of submitted analysis datasets.
  – …describes ADaM metadata, the subject-level dataset ADSL, and a new multiple-record-per-subject data structure: the ADaM Basic Data Structure (BDS).
  – The Analysis Data Model supports efficient generation, replication, and review of analysis results.

• ADaM Implementation Guide, Version 1.0

• www.cdisc.org
The FDAAA or FDA$^3$-- Standards

- *From the Goals Statement:* …electronic data standards, including the associated Standards Development Organization, are being considered for adoption or development. (Note: … FDA participates in international Standards Development Organizations and supports global harmonization of data standards through open structured processes.)
- SDOs – ISO, ANSI, HL7, CDISC, LOINC, etc.
Streamlining Clinical Trials – Adaptive Designs, CTTI, CDASH
FDAAA/PDUFA IV: Expediting Drug Development

• Publish for comment new draft guidances to clarify current FDA thinking on certain critical trial design issues
  - Clinical Hepatotoxicity - FY2008
  - Non-inferiority Trials – FY2008
  - Adaptive Trial Designs – FY2008
  - End of Phase 2(a) Meetings – FY2008
  - Multiple Endpoints in Clinical Trials – FY2009
  - Enriched Trial Designs – draft by end of FY 2010
  - Imaging Standards as End Point in Clinical Trials - FY2011

• Work to clarify regulatory pathways in 3 important areas
  - Predictive toxicology
  - Biomarker qualification
  - Missing clinical trial data
Guidance for Industry
Non-Inferiority Clinical Trials

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments...
A Shameless Plug

4th Annual FDA/DIA Statistics Forum
Integrating Knowledge in Clinical Development: Meta-analysis, Non-Inferiority, and Related Topics

April 19-21, 2010       Tutorials: April 18, 2010
Marriott Bethesda North Hotel & Conference Center
Bethesda, MD, USA

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Adaptive Design Draft Guidance
February 2010

Guidance for Industry

Adaptive Design Clinical Trials for Drugs and Biologics

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
CDASH Initiative
CDASH
Clinical Data Acquisition Standards Harmonization

• CDISC-led project, initiated by ACRO (Association of Clinical Research Organizations)

• Announced by Janet Woodcock, FDA, at the 2006 DIA Annual meeting-- FDA Critical Path Opportunity #45,

• Sixteen organizations: ACRO, ACRP, AMIA, Baylor College of Medicine, CDISC, Clinical Research Forum, FDA, NCI, NCRR, NIH, NLM, C-Path Institute, PhRMA, BIO, SCDM and Duke Clinical Research Institute.
The project goal is to develop a set of "content standards" (element name, definition, and related metadata) for a basic set of global data collection fields (also known as CRF, or Case Report Form, variables) that will support clinical research studies.

The initial scope of the project is focused on the "safety data domains" (i.e. Adverse Events, Prior and Concomitant Medication, Demographics and Subject Characteristics, Medical History, etc.).
Critical Path Activities
Collecting the Data

CTTI

• Clinical Trials Transformation Initiative
• Collaboration with Duke University, Industry, NIH, FDA, law firms
• Focus on clinical research as a quality system to support efficient product development
• More efficient clinical trial designs
• More efficient monitoring of clinical trials using novel technological and statistical tools

Throckmorton, 2009
Big CP Innovation: Consortia
CTTI Mission/Scope

• To generate evidence about how to improve the design and execution of clinical trials
• To focus on principles that can be generally applicable to all clinical trials
• To identify clinical trials practices that, when adopted broadly, will increase the quality and efficiency of clinical trial

Throckmorton, 2009
Example of CTTI Project Concepts

Improving the System of Reporting and Interpreting Serious Adverse Events (SAEs)

• Focus: SAEs that must be reported in an expedited manner

• Goal: to improve ability of system, including investigators, institutional review boards, industry and FDA, to identify and communicate SAEs in a more efficient and informative manner

Throckmorton, 2009
Example of CTTI Activities: SAE Reporting (cont)

• Current regulations (21 CFR 312.32) require IND sponsors to notify investigators of all unexpected SAEs associated with the drug

• Common practice is to provide all unexpected SAEs as individual expedited reports
  - Go to overburdened IRBs and investigators
  - Individual reports often lack context and detail, making interpretation difficult

• Result is significant investigator investment for little-to-no gain in understanding investigational product risk-benefit
  - Risks distracting from direct study participant care and more meaningful safety data communications

Throckmorton, 2009
CTTI Efforts on SAEs (cont)

• Project will:
  – Assess resource utilization and value of current system
  – Develop proposal for possible modification of the current system

• Improving reporting of SAEs to investigators will:
  – More efficiently and effectively inform investigators of safety events
  – Improve protection of study participants

Throckmorton, 2009
Developing Products to Address Urgent Public Health Needs -- CAMD
Critical Path Activities
Disease Focus

CAMD

• Coalition Against Major Diseases
• Focus on Parkinson’s and Alzheimer’s
• Collaboration: CPath and Brookings Institutes, Academia and Industry
• Aims to clarify natural history using shared data from placebo use (aim: natural history of the disease)
• Support disease modeling and improved trial efficiency

Throckmorton, 2009
Coalition Against Major Diseases (CAMD)

One of the greatest challenges facing biomedical sciences in the 21st century is the development of fundamentally better treatments for neurodegenerative diseases. The two most prevalent of these, Alzheimer's disease and Parkinson's disease, are the initial focus of the Coalition Against Major Diseases.

OUR PURPOSE

The CAMD's focus is to develop new tools and methods that can be applied during the development of new treatments for these diseases that have remained beyond the reach of drug discovery and continue to result in added costs for treatment, chronic suffering, and the loss of lives.
Better Evaluation Tools – Biomarkers, SAEC
Biomarkers

• Collaborative research on the anti-coagulant drug warfarin – label change

• The Predictive Safety Testing Consortium, a public–private partnership, led by the non-profit Critical Path Institute (C-Path)
  – FDA and the European Medicines Evaluation Agency (EMEA).
  – May 2008, FDA and EMEA announced that they had reviewed and accepted seven new biomarkers – laboratory tests on urine that signal kidney injury.
  – Predict the safety of experimental drugs, enabling drugs to reach market faster and with greater confidence in their safety
Predictive Safety Testing Consortium (PSTC)

The PSTC is a unique public-private partnership, led by the non-profit Critical Path Institute (C-Path), that brings together pharmaceutical companies to share and validate each other’s safety testing methods under advisement of the Food and Drug Administration (“FDA”) and its European counterpart, the European Medicines Agency (“EMA”). The 16 corporate members of the consortium share internally developed pre-clinical safety biomarkers in five workgroups: carcinogenicity, kidney, liver, muscle and vascular injury.

“Today, the FDA gives approval for a new drug or device, but there has previously been no way to obtain approval for a new and better way to test a drug or device for its safety.”

– Raymond Woosley, MD, PhD
Biomarker Qualification

• Dr. Margaret Hamburg, AAAS-The Future of Personalized Medicine October 26, 2009

• “We know for developers to make a substantial investment in this still-evolving arena, they need clear guidelines setting out our expectations and approval standards. One important step in that direction is likely to come before the end of this year when we issue a draft guidance on biomarker qualification. This will enable developers to gain a clear picture of the criteria the FDA will use to vet the usefulness of biomarkers in the evaluation of clinical trial data.”
Key Initiatives

The Foundation for NIH, as part of its portfolio, manages several large biomedical research partnerships or *Key Initiatives*. These partnerships leverage the resources of the National Institutes of Health with the public and private sectors, including government agencies, industry, academia, foundations, associations, and the philanthropic community.

**The Biomarkers Consortium**

This groundbreaking initiative expands the science of personalized medicine. The study of biomarkers creates the potential to individualize medical treatment by determining how a drug works in the body and identifying patients likely to respond to targeted medicines and therapies.

**Grand Challenges in Global Health**

Funded by the Gates Foundation, Grand Challenges in Global Health encompasses 43 project across 33 countries, working toward scientific breakthroughs to prevent, treat, and cure diseases that kill millions each year.

**Observational Medical Outcomes Partnerships (OMOP)**

An exciting initiative designed to improve the safety of drugs on the market, OMOP utilizes information drawn from patient medical record databases and health insurance claims to develop and test methods to detect and evaluate drug safety issues over time.
The Biomarkers Consortium Launches I-Spy 2 Breast Cancer Clinical Trial

• **Groundbreaking Public-Private Collaboration Combines Personalized Medicine and Novel Trial Design to Develop Potentially Life Saving New Breast Cancer Drugs**

• **BETHESDA, MD – March 17, 2010 –** [The Biomarkers Consortium](#), a unique public-private partnership that includes the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), and major pharmaceutical companies, led by the Foundation for the National Institutes of Health (FNIH), today announced the launch of a highly anticipated clinical trial to help screen promising new drugs being developed for women with high risk, fast-growing breast cancers — women for whom an improvement over standard treatment could dramatically change the odds of survival.
Home

The International Serious Adverse Event Consortium (iSAEC) is a nonprofit organization founded in 2007. It is comprised of leading pharmaceutical companies, the Wellcome Trust, and academic institutions; with scientific and strategic input from the U.S. Food and Drug Administration (FDA) and other international regulatory bodies. The mission of the iSAEC is to identify DNA-variants useful in predicting the risk of drug-related serious adverse events (SAEs).

Patients respond differently to medicines and all medicines can have side effects, in some people. The iSAEC’s work is based on the hypothesis that these differences have (in part) a genetic basis, and its research studies examine the impact genes can have on how individuals respond to a large variety of medicines. The iSAEC’s initial studies have successfully identifying genetic variants associated with drug-related liver toxicity (DILI) and Serious Skin Rashes (SSR). The majority of the iSAEC’s genetic findings to date have been specific to a given drug versus across multiple drugs. However, a number of cross drug genetic alleles are starting to
Funding Support for the CPI

• Appropriated funding from Congress each of the last three years ($8 million, $16 million, and $18 million in 2008, 2009, and 2010, respectively) to support project activity areas across all FDA centers.

• These activities contribute to transforming the processes through which FDA-regulated products are developed, evaluated, manufactured, and used.

• Some of this funding has been awarded to collaborative organizations through grants and contracts; some has gone to support projects in the centers, often encompassing extensive collaborations.

• FDA is also fostering many CPI projects that are part of an overall, decades-long effort to enable FDA to manage electronically the massive amounts of information submitted to the agency.
The FDA-NIH Collaboration
February 2010

• This new collaboration between FDA and the National Institutes of Health (NIH) — announced by HHS Secretary Sibelius on February 24, 2010 — will help focus additional funding on developing and applying the new tools, standards, and approaches we need to properly assess the safety, effectiveness, and quality of products currently in development.

• The collaboration will leverage NIH’s breadth of experience as a leader in biomedical sciences to help make the regulatory review process at FDA as seamless as possible.

• Initially, $6.5 million is being made available to award eligible applicants with relevant project proposals in a variety of areas related to regulatory science. (The application deadline is April 27, 2010.)

• Collaboration inviting the best minds and research institutions to help develop and apply the new

• 21st-century tools, standards, and approaches we need to properly assess the safety, effectiveness, and quality of medical products currently in development
FDA-NIH Collaboration and the Critical Path Initiative

• The FDA-NIH collaboration is aligned with CPI's goals and collaborative approach.
• The FDA-NIH collaboration will help focus additional funding ($6.5 million in 2010) on many of the areas CPI has identified to support the development and evaluation of human medical products and ensure their safety and effectiveness.
• The funding will go to applicants, awarded through an NIH competitive grant process.
• A key goal of the FDA-NIH collaboration is to identify ways that FDA and NIH can work together to support common goals.
The Advancing Regulatory Science Initiative (ARSI*)

- Broad, FDA scientific initiative
- Many cross-agency components
- Building on existing efforts like the Critical Path Initiative and Food Safety.
- FDA is requesting an additional $25 million (including more than $4 million to support CPI) for fiscal year 2011 to fund the Advancing Regulatory Science Initiative.
- Expand its work with partners to transform the culture and science of product research, development, and evaluation.

* Not to be confused with the The Advanced Rutabaga Studies Institute
ARSI – Broad Areas

• Speeding therapies to patients
• Setting standards for products with unmet public health needs
• Enhancing safety and health through informatics (information technology)
• Protecting our food supply
• Modernizing toxicology and hazard assessment
• Meeting the challenges for regulating tobacco
• Advances in regulatory science will help modernize product development to provide better tools, standards, assays, disease models, and science-based pathways to improve the efficiency, predictability, capacity, and quality of FDA-regulated products, as well as to support safety surveillance of FDA-regulated products once they reach the market.
The CPI and the ARSI

• The CPI is one of the many programs underway on which the Advancing Regulatory Sciences Initiative is building. Since 2004, FDA has been working to bring together multiple partners to spur the transformation of processes through which FDA-regulated products are developed, evaluated, manufactured, and used.

• CPI has helped support constructive partnerships, engaging academia, non-profits, and industry to address major regulatory science questions that cut across multiple interests.

• Examples include validation of new biomarkers that better predict product safety or efficacy, new approaches to improve the quality and conduct of clinical studies, and new ways to monitoring the safety of approved products, the Sentinel Initiative and the DAPT Trial, mentioned in the question above being two examples. For more information on specific projects, see the CPI Reports from 2006, 2007, and 2008.
Critical Path Website

http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm
Innovative Medicines Initiative Joint Undertaking

The IMI is a unique partnership between the European Community and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The aim of IMI is to support the faster discovery and development of better medicines for patients and to enhance Europe’s competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector.

More...

IMI Objectives

The vision of IMI is to create Biomedical Research & Development leadership for Europe to benefit patients and society.

More...

Why IMI Matters to You

IMI will drive the creation of a vibrant and dynamic scientific environment and ensure a strong European biomedical science base.

More...
SO, WHAT IS THE PLAN?
Visioning and Planning: How Do “We” Do This Right?
Too Many Data, Too Little Time: Where Do Statisticians Fit?

• Common complaints:
  
  – “They don’t understand us.”
  
  – “Academics don’t think about what we really need to make decisions.”

• It’s All About Us …

• Regulatory, Industry, Academia Collaboration or Confusion?

• Can we statistician’s Work Together to Actually Plan for the future/progress?

• What would this look like?
Too Many Data, Too Little Time Many More Decisions to Come!

• **Science** is concerned with understanding variability in nature

• **Statistics** is concerned with making decisions about nature in the presence of variability

Too Many Data, Too Little Time
Do We Need a Strategic Plan?

• Process of defining its strategy or direction
• Making decisions on allocating its resources to pursue this strategy
• Strategic planning is the formal consideration of an organization's future course.
• In order to determine where it is going, the organization needs to know exactly where it stands, then determine where it wants to go and how it will get there.
• Should we do this? Are we capable as an “organization” (profession) of actually doing this?
• My Opinion: This is important stuff … we owe it to the public and ourselves to try
Thank You for Your Attention!!

stephen.wilson@fda.hhs.gov