
A LEGACY OF SCIENTIFIC LEADERSHIP
75
BARDS

Statistics in 2013

- International year of statistics
- ASA celebrates 175th Anniversary
- Merck Quantitative Sciences celebrates 75th Anniversary

The Year 1938

- In the U.S.
  - Franklin D. Roosevelt was president
  - Events leading up to World War II escalated
  - Benny Goodman and jazz orchestra performed at Carnegie Hall
  - Cartoon featuring Bugs Bunny premiered
- In statistics
  - Rank correlation (Kendall, Biometrika 30: 81-93)
  - ANOVA (Pitman, Biometrika 29: 322-335)
  - ASA established Biometrics Section

Origin of BARDS at Merck

- In 1938, Joe Ciminera was hired by Sharp & Dohme as a research pharmacist for $22.50 per week.
- Biometrics Research department established under Joe in 1952 with the merger of Merck with Sharp & Dohme. Joe had job title Biometrician.
- Biostatistics in the pharmaceutical industry grew after 1962 when the U.S. Congress amended the Federal Food, Drug and Cosmetic Act requiring clinical trials for both safety and efficacy.
- Quantitative Sciences has grown over the years to meet the growing complexity and challenge of drug and vaccine R&D.
  - Biometrics Research
  - Clinical Biostatistics
  - Epidemiology
  - Health Economics
  - Scientific Programming

BARDS 2013

- Series of celebrations and activities commemorating our 75th Anniversary.
  - Articles and news items
  - Invited speaker series
  - One-day symposium
  - Articles on importance of statistics in science
  - External articles and scientific meetings
- Key message: Our history has formed the foundation for our current and future scientific capabilities.

Success in Biopharmaceutical Industry

Biopharmaceutical industry has had remarkable on a number of dimensions.

- Improvements in patient health
- Cost benefits for patients and health care systems
- Growth in important economic sector
- Research and technology development
- Statistics and statistical methodology
  - Societies
  - Journals
  - Professional society meetings
  - Academic programs

Keys to success

- It's all about the collaboration
  - Industry-Government-Academia
  - Industry-Industry
  - Interactions among various disciplines in medical and technological sciences
- Development of guidances and best practices
- Connection with related societies e.g., AAAS, medical associations, health economics
- It's about thinking in a rigorous statistical framework especially understanding uncertainty and risk.

Perspective on Statisticians (3 C's)

Capability is the ability to perform actions.
It implies that the person has the attributes required to accomplish a task.
…The "What"
The capable statistician gets hired.

Competency is the ability to perform a specific task or function successfully alone and in a team environment.
…The "How"
The competent statistician gets to keep his job.

Critical Thinking is the ability to apply without bias methods of logical inquiry and reasoning to problems to reach well thought-out conclusions.
…The "Why"
The critical thinking statistician gets to works in different areas (scientific and strategic) and at different leadership levels.

Communication: Shared Understanding

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Communication is the process by which ideas are exchanged in an attempt to create shared understanding.
The statistician who communicates well advances his/her "3C" career.

Looking ahead

- In biopharmaceutical sciences look at other areas of the business e.g., manufacturing, marketing, operations, etc.
- Causes of Phase III failures?
- Portfolio approaches to drug and vaccine development
- These are all Small data problems that may be informed through BIG data information.
- Know you audience and satisfy the needs of the stakeholders
- Define statistics as a framework for problem solving rather than a defined set of methods and tools
- Don’t forget the fundamentals.