Statisticians in Pharmaceutical Industry

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Objectives

- History of biostatisticians in pharmaceutical industry
- Important roles and tasks in drug development
- Opportunities for statisticians in pharmaceutical industry
- Career opportunities
- Pharmaceutical industry: A changing environment
History of biostatisticians in pharmaceutical industry

• Started in the 70’s
  – 70’s and 80’s: Statisticians to a large extent employed as consultants
  – To calculate sample sizes for studies and write related sections in the protocol
  – No impact on analysis and trial interpretation

• 90’s:
  – Take on reporting safety and efficacy
  – Start to become integrated in development teams

• Last decade:
  – Becoming more strategic
  – Move from a statistician working in drug development to a drug developer with biostatistics background
History of biostatisticians in pharmaceutical industry

- Drug development today organized globally
  - Many sites
  - Many therapeutic areas to work on

- Biostatistics usually part of a larger organization frequently called biometrics
  - Data management and statistical programming separate

- Biostatistics works in a metric structure on development teams together with
  - Pharmacology and medical Scientist
  - Operations
  - Regulatory
  - Research
  - Business and production
Important roles and tasks in drug development

- Planning
  - Designing drug development plans
  - Protocol writing
  - Strategy discussions
- Reporting
  - Programming and analysis
  - Interpretation and CSR writing
- Others:
  - HA interactions and registration
  - Drug safety
  - Biomarker
  - Experimental studies
  - ...
Important roles and tasks in drug development

• Important roles
  – Statisticians on individual studies (usually larger phase III trials)
  – Project lead statistician for an early program
  – Project lead statistician for a late program
  – Technical specialists
  – Therapeutic area leads

• Important is
  – Not to be seen as a support function only but as an integral part of drug development
  – To be seen as a strategic player
Important roles and tasks in drug development

• Three core competencies
  – Statistical knowledge
    • Key principles to control confounding factors
    • Statistical procedures and competence to apply
    • Good understanding of variability
    • Drug development experience
  – Personal competence
    • Integrity, passion and courage
  – Communication
    • Ability to speak the language of our “costumers”
    • Willing to speak up with confidence
    • Networking
Further opportunities in pharmaceutical industry

- Non-clinical statistics
- Quality assurance in pharma technical (production)
- Marketing
  - Pricing and health economics
  - Marketing trials
- Epidemiology
  - Disease pattern and population definition
  - Analysis of observational studies
- Portfolio management
Opportunities in pharmaceutical industry (II)

• Note:
  Scientific backbone of clinical studies and other experimental settings frequently of statistical nature: This concerns as well
  – Understanding of key principles
  – Interpretation of data and underlying variability

• Statisticians needed!

• Word of caution:
  These opportunities are primarily for pharma. CROs as by today may offer different opportunities

• Note:
  Methodology is important but not necessarily in the foreground
Really important: Data interpretation

This is where we started to draw taller bars to please you guys.
## Biostatistics activities
### Clinical development

<table>
<thead>
<tr>
<th>Level 1 deliverables: Documents and analyses</th>
<th>Level 2 deliverables: Strategic Input in</th>
<th>Methodological excellence Input and standards for</th>
<th>Strategic excellence Input and standards for</th>
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</table>
| - Protocol writing including sample size determination  
  - DAP writing  
  - Output control and QA  
  - Adhoc programming  
  - SRS and report writing  
  - HA response analyses and writing  
  - Analysis of pre-clinical experiments | -Protocol design  
  - Design of development program  
  - Data interpretation  
  - Regulatory strategy  
  - Program conclusions  
  - Defining key features of pre-clinical experiments  
  - Result interpretation of pre-clinical experiments | -Defining optimal analyses  
  - Stat. Procedures  
  - Defining optimal designs  
  - Special methods  
  - Adaptive designs  
  - Bayesian designs | -Protocol design  
  - Analysis strategies  
  - Program development strategies  
  - Portfolio strategies  
  - Biomarker analyses  
  - PTS and portfolio decision making  
  - Risk benefit strategies |
Example: Career paths (Roche)

- **Cross functional path**
  - LCTL

- **Technical path**
  - Senior technical expert
  - Technical expert

- **Team lead initiatives**
  - Team leader for technical teams
  - Team leader for SOP/processes teams

- **Management path**
  - GH
  - TAGH
  - Site head
  - Deputy GH
  - FLM

- **Study Statistician**

- **Technical expert**
  - Senior technical expert

- **Team leader for cross functional strategies**
  - Project team lead (SH)

- **Team leader for cross functional strategies**
  - BR

- **Team leader for cross functional strategies**
  - DSTL

- **Team leader for cross functional strategies**
  - BSTL
Career opportunities in clinical development

- Career opportunities usually within statistics
- There are impressive careers starting in statistics and then ending in leadership roles outside statistics
- Important is a decent motivation and the willingness to work independently and take on ownership
- An entrepreneurial mindset to go into new areas for statistics may be specifically important
- Career opportunities are not only in management. Leadership roles are not only in management
- Most important for statisticians in future probably are strategic leadership!
Changing environment

Today:
- Business model for whole pharma industry put in question
- Raising cost pressure
- Good CRO infrastructure
- Increasingly good infrastructure in low cost countries
- Outsourcing models starting everywhere to
  - CROs with better cost structure
  - Other sites with better cost structure
- Increased pressure why we would need statisticians at main, expensive sites
- Development more advanced and more critical for clinical data management and programming due to smaller strategic abilities
Changing environment

- How should statisticians react?

⇒ Diversification:

Think about where statisticians could be needed

⇒ Strategic component:

Think about how we can show best value to an organization
Participate in driving the strategy for a study, for a whole project and for the company
Changing environment

- In today's pharmaceutical industry, statisticians who just like operational work may not have job security.
- Statisticians have to become largely strategic.
- Methodology ≠ Strategy.
- What does this mean for the education:
  - Focus not only on methodology and how to do things.
  - Focus on why we do things and what are the key principles.
  - Do nothing without having understood why we need to do it!
  - Challenge continuously current practice.
Most important: Strategic impact

“Stay with me now, people, because in Step C, things get a bit delicate.”

“Seriously?! No one saw this coming?!”
Thank you!