Career paths for statisticians in pharmaceutical industry

EFSPi Statistical Leaders Meeting
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Stefan Driessen, Chrissie Fletcher, Christoph Gerlinger, Michael Branson

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Overview

• Discussion on career paths for and future of statisticians in Europe at last two meetings
• Two questionnaires sent out
• Results summarized in a white paper (distributed before the meeting)
• White paper
  – To summarize current situation
  – To outline future opportunities for statisticians
  – To outline what we can help
Overview

• Introduction
• Overview on current situations
• Opportunities
• Where we can add
• Summary
Introduction: Times of change

- **Pharma industry under pressure**
  - Development costs new treatments still increasing
  - Revenues are going down (public pressure)
  - Many effective treatments on market
  - Block buster model is out

- **Resource model is changing**
  - Operational activities outsourced to CROs
  - Introduction low cost sites in Emerging Countries

- **University output**
  - Significant less students in Statistics in some EU countries
Threats and Opportunities

• Increase in pressure to outsource work including statistics work
  – Cost effective CROs
  – Sites with better cost structure

• Differentiation between operational and strategic work. Chance that statistics end up as operational support function with limited strategic impact
Threats and Opportunities

- Increase of strategic role of statistician
- Increase of areas of interest with link to statistics
  - Preclinical and technical, HTA, Benefit Risk, Personalized Medicine, …
- Drug development moves away from blockbuster models and to diversified portfolio (Pharma 2.0)
  - Generics, OTC, vaccines, consumer products, animal health, …
- From developing drugs to delivering health outcomes
  - Managing patient outcomes
  - Expanding access to health care
  - Meeting unmet medical needs
Threats and Opportunities

• When we concentrate on the threats instead onto opportunities we may loose…
• We have to think about future as a large opportunity

And:

There are more opportunities than threats!
Current situation

- Established function in pharmaceutical industry
- Strategic impact increasing over time
- Career opportunities beyond classical biometrics roles in many companies and examples for successful career paths beyond biometrics available
# Current situation

Results EFSPi questionnaire: Biostatistics responsibilities

<table>
<thead>
<tr>
<th>Area:</th>
<th>% (N=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-clinical studies</td>
<td>63%</td>
</tr>
<tr>
<td>Pre-clinical safety assessments</td>
<td>63%</td>
</tr>
<tr>
<td>Modeling and Simulation</td>
<td>50%</td>
</tr>
<tr>
<td>Clinical studies</td>
<td>100%</td>
</tr>
<tr>
<td>Drug safety</td>
<td>75%</td>
</tr>
<tr>
<td>Biomarker</td>
<td>75%</td>
</tr>
<tr>
<td>Epidemiology</td>
<td>75%</td>
</tr>
<tr>
<td>Risk benefit assessment</td>
<td>75%</td>
</tr>
<tr>
<td>Marketing studies</td>
<td>75%</td>
</tr>
<tr>
<td>Pricing/economics</td>
<td>25%</td>
</tr>
<tr>
<td>Statistical methodology</td>
<td>50%</td>
</tr>
<tr>
<td>Port-folio management</td>
<td>13%</td>
</tr>
</tbody>
</table>

N = number of companies completing the survey
## Current situation

Results EFSPI questionnaire: Strategic contributions and impact of statisticians

<table>
<thead>
<tr>
<th>Cross functional leadership responsibilities</th>
<th>(N=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Companies with cross functional leadership roles for statisticians</td>
<td>50%</td>
</tr>
<tr>
<td>Companies with less than three statisticians taking this role</td>
<td>25%</td>
</tr>
<tr>
<td>Companies with three to ten statisticians taking this role</td>
<td>25%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Involvement of statisticians in cross functional teams</th>
<th>(N=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study management teams</td>
<td>100%</td>
</tr>
<tr>
<td>Member of pre-clinical teams</td>
<td>63%</td>
</tr>
<tr>
<td>Member of clinical teams</td>
<td>75%</td>
</tr>
<tr>
<td>Member of project teams</td>
<td>88%</td>
</tr>
<tr>
<td>Member of internal advisory boards</td>
<td>88%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Involvement of statisticians in decision making</th>
<th>(N=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candidate selection pre-clinical</td>
<td>50%</td>
</tr>
<tr>
<td>Protocol planning</td>
<td>100%</td>
</tr>
<tr>
<td>Planning of development program</td>
<td>88%</td>
</tr>
<tr>
<td>End of phase II decisions</td>
<td>75%</td>
</tr>
<tr>
<td>Filing decisions</td>
<td>75%</td>
</tr>
<tr>
<td>Port folio decisions</td>
<td>50%</td>
</tr>
</tbody>
</table>

N = number of companies completing the survey
Opportunities

• History of biostatistics in pharmaceutical industry is going along with increasing strategic impact

• Responsibilities of statistics also broadened over time
  – Sample size calculation and consultancy
  – Analysis planning and reporting
  – Interpretation and decision making
Opportunities

• Concentration on strategic tasks over operational activities
• Broader impact on decision making
  => Statistics: Core group involved from candidate selection to marketing in all key development areas
• Broadening scope for statistics to all areas where we deal with uncertainty
Opportunities
Areas for broadening scope

– Disease modeling
– Non-clinical statistics
– Biomarkers development
– Drug safety
– Epidemiology
– Risk-benefit assessments
– Market access, health economics and outcomes research
Opportunities
Areas for broadening scope

– Port-folio management
– Business and marketing
– Devices, diagnostics and nutrition
– New technologies
Where we can add

• Important:
  Statisticians in cross functional leadership roles
• Are all of us prepared for this?
• Do all of us like it?
• What can we do as statistics communities to support?
## Changes in the environment for statisticians in pharmaceutical industry

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there plans to differentiate between operational and strategic activities for statisticians (Yes/No)</td>
<td>(N=8) 50%/50%</td>
</tr>
<tr>
<td>Are the plans to outsource statistics activities more than in the past to (Yes/No) CROs Other sites being with better cost structure No plans</td>
<td>75%/25% 63%/37% 13%/87%</td>
</tr>
<tr>
<td>Expecting an increase in strategic tasks requiring more strategic thinking</td>
<td>75%</td>
</tr>
<tr>
<td>Are all of statisticians prepared for the environmental change in pharmaceutical industry ? (YES/NO)</td>
<td>0%/100%</td>
</tr>
<tr>
<td>Do all statisticians recognize the need to shift towards more strategic work ? (YES/NO)</td>
<td>12%/88%</td>
</tr>
</tbody>
</table>
| If no, how many statisticians would not appreciate a shift ? Less than 10% 10 to 25% More than 25% | 13% 50% 25%      

N = number of companies completing the survey
Where we can add

• Leadership in cross functional teams comes with a mind shift change
  – Not only statistics knowledge counts but also how to reach the partners
  – Understanding of whole environment, not only those aspects where statistics is needed

• Success in cross functional teams will be decisive for statistics future

• Success in cross functional teams needs to be reflected in internal career paths for statisticians
Where can we add
Companies

• What kind of internal training is required?
• What kind of career paths should be laid out?
• How could an ideal career path map for statisticians in pharmaceutical industry look like?
• How can we support an environment within a development organization to support such activities?
Where can we add
Support by statistical communities

• Offer special training how to work in a matrix structure

• Do not concentrate training only on methodological aspects
  – Training on understanding disease areas
  – Training on development from a statistical perspective
  – Training to support statisticians in taking leadership
Summary

• Next 10 years we will see a changing environment, also within statistics

• There are threats
  – Outsourcing
  – Concentration on operational tasks

• But also many more opportunities
  – Broadened applications of statistics
  – Increased strategic impact
Summary

• We need to think how to support this period of change
  – Not all of our staff will like
  – Not all of our staff will manage it

• What support is needed within companies?
• What support is needed from statistical communities?