



# Career paths for statisticians in pharmaceutical industry

EFSPI Statistical Leaders Meeting

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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 block buster 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

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

N = number of companies completing the survey



# Current situation

## Results EFSPi questionnaire:

### Strategic contributions and impact of statisticians

Cross functional leadership responsibilities	(N=8)
Companies with cross functional leadership roles for statisticians	50%
Companies with less than three statisticians taking this role	25%
Companies with three to ten statisticians taking this role	25%
Involvement of statisticians in cross functional teams	(N=8)
Study management teams	100%
Member of pre-clinical teams	63%
Member of clinical teams	75%
Member of project teams	88%
Member of internal advisory boards	88%
Involvement of statisticians in decision making	(N=8)
Candidate selection pre-clinical	50%
Protocol planning	100%
Planning of development program	88%
End of phase II decisions	75%
Filing decisions	75%
Port folio decisions	50%

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 ?

# Where we can add

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