The Role of the
Pre-Clinical Statistician

PSI Toxicology SIG
Webinar Overview

• Background
• SWOT Analysis
• Summary of Core TOX SIG Discussions
• Open Discussion
Background

• PSI Tox Sig Workshop held in April 2018.
• Interesting and thought provoking session looking at a SWOT analysis of roles of statisticians in the PSI Tox SIG group.

• Action: Go back to our respective companies and have a discussion on “What is the role of a pre-clinical statistician now and how do we see this changing in the future”.

• This webinar presents the summary of our findings with approx. a 40 minute group discussion at the end on how can we influence our future.
SWOT Analysis

SWOT analysis is a framework used to evaluate an organization's competitive position by identifying its **Strengths**, **Weaknesses**, **Opportunities** and **Threats**.

SWOT analysis groups key pieces of information into two main categories:

- **Internal factors** — the *strengths and weaknesses* internal to the organization
- **External factors** — the *opportunities and threats* presented by the environment external to the organization
<table>
<thead>
<tr>
<th>INTERNAL Origin</th>
<th>Strengths</th>
<th>Negative/ Harmful/ Risks to achieving the goal</th>
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<tbody>
<tr>
<td>Facts/ factors of the organization</td>
<td>Things that are good now, maintain them, build on them and use as leverage.</td>
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<th>EXTERNAL Origin</th>
<th>Opportunities</th>
<th>Threats</th>
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<tbody>
<tr>
<td>Facts/ factors of the environment in which the organization operates</td>
<td>Things that are good for the future, prioritize them, capture them, build on them and optimize.</td>
<td>Things that are bad for the future, put in plans to manage them or counter them.</td>
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Strategy

• Goal: Define where we are and where we are going.

• **SWOT** Analysis

• Evaluate: Webinar with open discussion to extrapolate our analysis.

• Action: Publish our findings.
Strengths
Strengths

Knowledge
Wide Knowledge: encompass many different scientific areas/techniques/methods
Scientific knowledge of Statistical techniques; Scientific Integrity; Experts
Programming knowledge (SAS)
Highly Focused/Deliver Quickly
High demands in statistics, scientific areas. **Innovative**

Role
Flexibility and Variety of Work: Less-regulated
Open to change, Adaptable
Neutrality (to organisation and Business decisions)
Independent and Objective (results)
Team orientated: Team work and Interdisciplinary (working cross-teams)
Work with scientists; integral part scientific team.
Weaknesses

- Resource
- Input and Oversight
- Weak Links
- Methods and Methodology
**Resource:**
- Resource constraints dependent on those who might not see our value directly.
- At the mercy of others – customers, business needs, guidelines.
- Customers and management will not pay for/support new methods unless there is a regulatory need.
- Preclinical is not as highly funded and there can be severe restrictions on sample size and design.
- Statistical results are usually not obligatory.

**Input and Oversight**
Concerns over:
- How data is collected and stored
- How studies/experiments are designed
- How studies/experiments are carried out
- How data is analysed
- What decisions are made based on the analysis
- Lack of input into study reports (i.e. are stats results interpreted and reported appropriately)
- Lack of oversight of overall compound development
- Lack of visibility within companies and across industry
- Lack of understanding, acceptance and appreciation from business

**Weak Links**
- Weak connection to clinical statisticians and scientists
- Lack of collaboration with clinical statisticians
- The tendency to be isolated (preclinical stat is a small group and it is less connected to other statistics groups)
- In any one institution preclinical statisticians tend to be few in number and can feel isolated.
- Late or missing involvement wrt design, analysis and interpretation
- Statistical contributions are sometimes time-consuming and cautious.

**(Technical) Methods**
- Some statistical methods are extremely old
- Lack of innovation - many methods currently used have been around for a long time
- Lack of (recent) publications from CRO and Pharma statisticians (academics only)

**Methodology**
- Stats terminology can be difficult for scientists to understand
- The jargon and science can be difficult to comprehend
- Given the wide variety of data and experiments it is not always easy to understand all the biological details
- Limited in depth knowledge of science – No training.
Opportunities

**CURRENT WORK**
Improve Statistical interpretation of results: Move away from p-values
Be more involved in interpretation of results in reports
More input into design of non-standard studies
Improve reproducibility of results
Earlier Involvement: Earlier Identification of poor/unsafe compounds

**NEW AREAS**
More Research: Statistical Input to 3R, Statistical input to Regulatory documents
Involved in New Areas: Alternatives to animal experiments, Big Data, Machine Learning and data-mining, Modelling, Bioinformatics, Bayesian, predictive toxicology

**ORGANISATION**
Visibility within organisation and outside: Improve contacts in scientific areas
Training Scientists
Educate on Value of Statistics
Threats

Being Replaced
- Data Scientists
- Automation
- Out-Sourcing

Undervalued
- Under Resourced
- Underestimated
Threats

Being Replaced

Data Scientists
- We must adapt and learn to use the new technologies so as not to get “left behind”

Automation
- Stats can be seen to be a bottleneck so faster more efficient technologies are being created. Uncritically Used Software is a threat to our reputation.

Outsourcing
- Pharma employees

Under Valued

Statistics: Unimportant or Irrelevant
- Lack of understanding amongst scientists of stats in general

Underestimated:
- Knowledge: Scientists/researchers/toxicologists do their own statistical analysis

Under resourced:
- Spread too thinly. Declining numbers across industry?

Increased Regulation
Too many areas/topics to be an expert/specialist
SWOT

STRENGTH
WEAKNESS
OPPORTUNITY
THREAT

Webinar: 18 September 2018
Open Discussion

Recurring common themes from our respective discussions
Now, we want to take this a step further with input from as many people on the line as possible

Discussing:

• Do you agree with what we have presented here, is anything missing?
• Where do you see yourself (if a pre-clinical Statistician) or us in 5-10 years time?
• How can we influence what happens?
Online References

• https://www.mindtools.com/pages/article/newTMC_05.htm
• https://en.wikipedia.org/wiki/SWOT_analysis
• https://rapidbi.com/SWOTanalysis/
Future Webinars

• 11\textsuperscript{th} December 2018  \textbf{Big Data}: Thomas Steger-Hartmann
• 19\textsuperscript{th} February 2019  \textbf{Data Quality and Pre-Clinical Research}: Malcolm Macleod
• 16\textsuperscript{th} April 2019  tbc
• 18\textsuperscript{th} June 2019  tbc

All run at 1400-1500 (UK Time)

If you would like to present at an upcoming webinar, please get in touch 
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