EFSPPI/PSI SIG on data transparency

Hans Ulrich Burger, Sally Hollis
EFSPPI leadership meeting Brussels 1. July 2015
Overview

• Short overview on status of data sharing SIG

• Discussion round on data sharing: How can we utilize this further?
  – Internal data sharing?
EFSPI/PSI working group on data sharing

• Lead Sally Hollis and Uli Burger
• Objectives:
  – To identify and prospectively prioritize statistical issues in data transparency
  – To co-ordinate statistical contributions across Europe to the data transparency debate
  – To disseminate relevant information on the topic across the statistical community
  – To develop and share a vision of the potential longer term impact of data transparency.
EFSPI/PSI working group on data sharing

- Five work streams
  - Providing continuous input in EMA/EFPIA
    (Christoph Gerlinger, Bayer, Chrissie Fletcher, Amgen)
  - Recommendations for minimal analysis practices
    (Sally Hollis, AstraZeneca, Chrissie Fletcher, Amgen)
  - Future impact on biostatistics
    (Nick Manamamley, Amgen)
  - Minimal requirements for data sharing
    (Rebecca Sudlow, Roche, Janice Branson, Novartis)
  - Ensuring patient data confidentiality
    (Katherine Tucker, Roche)
• Status:
  – All subgroups close to finalization
  – Four manuscript in preparation (first work stream never anticipated publication)
  – Goal: To publish all four manuscripts together with an accompanying introduction during this year
General activities

• Data sharing is still a very important topic in the statistical community
  – One day BBS/EFSPi meeting in Basel Nov 14
  – Many sessions at statistical conferences
• Data sharing implemented in most companies and becoming reality
• Requests coming but perhaps still at lower level than anticipated
Update on data sharing requests

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<th>Number of research proposals</th>
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Ref: https://www.clinicalstudydatarequest.com/Metrics.aspx
General status

• Data sharing is helping to provide transparency
• Reputation of Pharma has increased, at least partly (quick implementation, data sharing pretty extensive)
• But impact on Pharma beyond these early gains still not evaluable
Potential impact

• Data sharing activities in companies often driven by biostatistics

• High integrity of biostatistics helped companies to handle transparency
  – Impact of biostatistics highlighted

• Still to be seen: Impact on companies when results of data sharing comes back. Not all companies are prepared for that
Potential impact

Some opportunities:
• More internal and cross-industry sharing
• Increased credibility
• More interactions with academia
• Job security
• Interesting new role for some statisticians
• Biostatistics influence could grow further in marketed products

Some threats:
• More work to assess resulting publications
• Biostatistics not prepared for investigation of resulting publications
• Need more resources and different profile of statisticians
• Quality of resulting research could be poor with confusing impact on societies
Discussion

• What is the status at your company and the impact for statistics?
• Are you preparing for further work coming out of data sharing?
• Are you thinking about opportunities for internal and cross-industry sharing?
• Should EFSPi stay heavily involved in this topic? Or have we done the work?