Statisticians Adding Value to HTA

Follow up to EFSPI Statistics Leaders Mtg 2014

June 2015

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Agenda

- Previous discussion at EFSPI Statistics Leaders forum June 2014
- Why HTA should be a core skills set for statisticians
- Example of HTA strategy for statisticians - Amgen
- Realising HTA strategy for statisticians in your companies
- Potential challenges you may face

Previous discussion at EFSPI Statistics Leaders forum June 2014

- We first discussed HTA at the EFSPI leaders meeting in 2010
- Agreement that HTA is a key area for statisticians and an area statisticians should engage in
- Companies have different organisational structures and mechanisms for analytical support to HTA
  - Sometimes, statisticians not given the opportunity to get involved in HTA activities
- HTA SIG have conducted numerous scientific meetings, trainings and developed materials to help statisticians understand HTA
- EFSPI Statistics Leaders in 2014 wanted to know "how do statisticians add value to HTA"

Why should HTA be a core skills set for statisticians?

Example of current statistical challenges in HTA

- Early dialogue between regulators and payers – building requirements of both in evidence generation plans and study designs and analysis of RCTs

- Subgroup analyses – analytical strategies enabling robust planning, conduct and reporting

- Treatment Switching in RCTs – design and analysis issues

- Evidence Synthesis – e.g. network meta-analysis, understanding the package of data and possible patterns and trends

- Extrapolation of RCTs – e.g. for economic modelling using survival analysis methods

- Analysis of heterogeneity of clinical evidence generated – measuring uncertainty in HTA decision making

Example of HTA Strategy for Statisticians - Amgen

Amgen's strategy for how statisticians add value to HTA

Goals and Aspirations?
- Global Statistical Leader (GSL) provides strategic contributions to HTA and is accountable for the statistical activities supporting HTA
- Widespread integration and engagement of GSLs in planning, resourcing and executing HTA statistical activities
- Global Biostatistical Science (GBS) is the best statistics function in terms of HTA skills and expertise
- GBS has strong partnerships with external HTA analytical experts and is collaborating in HTA statistical research

Where to play?
- GSL develops HTA statistical strategies and specifies analyses required in SAPs/Supplemental SAPs
- GSL partners with economic modelling team and supports statistical modeling activities
- Dedicated 'HTA Biostatistics' (HTAB) group advancing the skills and expertise in GBS on HTA analytics

How to win?
- Deliver statistical contributions at key milestones important to HTA (e.g. phase 3 design: choice of comparators, endpoints, subgroups; additional analyses; support to economic modeling; and network meta-analyses)
- Be a respected partner within Amgen leading statistical expertise for HTA
- Collaborate with external statistical experts in evolving HTA related statistical methodologies

What capabilities are required?
- Knowledge and understanding of HTA requirements from across multiple countries / payer associations
- Ability to deliver statistical contributions to HTA strategy and HTA dossiers
- Understanding the "value" of RCTs and observational evidence from a payer perspective to support HTA
- Good statistical modelling skills and HTA analytical expertise

What configuration of processes and people?
- Integrate GBS contributions to HTA analytics in product development activities
- Develop and maintain HTA analytics resource portal and establish HTA Biostatistics group
- Build knowledge, understanding and experience of HTA analytics across GBS and share case studies

Realising HTA Strategy in your companies

- Key HTA skills sets statisticians need for success
  - Understanding fundamentals of HTA – remit, processes, terminology, trends
  - Understanding analytical approaches used in HTA
  - Ability to generate robust evidence package and synthesize different sources of data – how RCT data can be used in HTA along with other data, how different data sources can fit together for a 'value' story
  - Critical data thinking and expertise, bringing solutions for problems - statisticians understand biases and how to manage these
  - Strong voice at the table in developing strategies for HTA and leading analytical components

Realising HTA Strategy in your companies

- Key HTA skills sets statisticians need for success (cont.)
  - Engaging in early dialogue meetings (e.g. scientific advice with payers) to understand HTA agency perspective and incorporating advice into design and analysis of evidence generation plans
  - Sharing internal experiences and learning from what others have done (external) – critiquing HTA submissions
  - Teamwork – working cross-functionally, respecting the views and perspectives of other colleagues
  - Willingness to learn – embracing HTA, adapting to different requirements, keeping abreast of trends in HTA

Potential challenges you may face

- Resources/Budget
  - Are statisticians able to support/be involved in HTA activities in the same manner they do regulatory activities?
  - Do your resource algorithms and budget estimates cover support for HTA activities?
  - Are you able to support HTA training and liaising with external HTA experts?

- Priorities
  - Does your company prioritise HTA activities?
  - Do you prioritise HTA activities in your statistics function?

- Timing of HTA activities
  - Can statisticians address HTA needs at the same time as regulatory needs?
  - Are statisticians able to partner with HE colleagues to work through conflicts?

- Evidence generation requirements for HTA
  - Are statisticians being involved in additional analyses of RCTs for HTA?
  - If your company have a separate group responsible for HTA analytics, how do statisticians partner with this group?