

Objectives of Meeting and Logistics ROI of the National System

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17 June 2016, at FDA White Oak

Objective

- Demonstration that NES will create a platform for better, faster and cheaper (less expensive) studies and data for regulatory decision making
 - Won't really focus on what we mean by "better"
 - Cost is the topic for the day (more from Greg on that) (Much more)

ROI

- Return on investment
 - It's about costs (Greg will get into details) of doing a study the “traditional way” compared with embedding a study within a registry or network of registries
 - The white paper will have a section describing (high-level) OTHER benefits of a national system for various stakeholders
- Roi in French means “king”

Session 1: Where are we? 8:30 – 10:15

(at FDA in White Oak)

- **Moderator:** Provide overview regarding need for this meeting as it developed out of value proposition work – Danica Marinac-Dabic
- 1) Value proposition of NESMD set out in Planning Board report and status update – Heather Colvin (10 Minutes)
- 2) Report from ROI on UDI work group (what we learned about framing the analysis) – Kade Etter (10 Minutes)
- 3) Framing the ROI for better evidence generation by the National Evaluation System – Gregory Pappas (10 Minutes)

- **Discussion (1 Hour, 15 Minutes)**
- **Then a BREAK (just when you needed it)**

Session 2: 10:30 to 12:30

- **Session 2: Case studies of ROI**
- **Moderator:** Mitchell Krucoff
- 1) TVT case study: evidence for better, faster, cheaper – TBA (10 minutes)
- - **Discussion (20 minutes)**
- 2) VQI case study: evidence for better, faster, cheaper – Philip Goodney (10 minutes)
- - **Discussion (20 minutes)**
- 3) Ortho case study: evidence for better, faster, cheaper – Patricia Franklin (10 minutes)
- - **Discussion (20 minutes)**
- 4) Coronary case study: evidence for better, faster, cheaper – David Kong (10 minutes)
- - **Discussion (20 minutes)**

Working Lunch: 12:30 to 13:30

- 1) Creation of small groups (volunteers)
- 2) Review questions that will guide small groups
- 3) Introduction of chairs and rapporteurs for each small group (chairs will be presenters of case studies)

- Rapporteurs: TVT group: Perry Bridger, VQI group: Gary Thompson, Ortho group: Paul Haisman, Coronary group: Mitchell Krucoff

Session 3: 13:30 to 14:30

- Small group discussion: The purpose is to reach agreement on questions posed by the meeting. Example, come to consensus about what investments should be included in the studies in question. Each group should internally select a chair person and a rapporteur
- 1) TVT
- 2) VQI
- 3) Ortho
- 4) Coronary
- **THEN A BREAK**

Session 4: Report out: 14:45 - 16:30

- 1) Report out of small groups on consensus and further questions.
- 2) Discussion of cross cutting questions
- 3) Discussion of draft work plan for proposed manuscript – writing teams for each section identified

Closing Session: 16:30 to 17:00

- 1) Finalization of plans to compete work of small groups, as needed
- 2) Review of proposed outline for a White Paper
- 3) Discussion
- 4) Creation of work group to develop first draft of White Paper
- 5) Note how the output from this meeting feeds into the broader work on value propositions

The White Paper (with a version for publication)

- Why we need a NES and vision for NES,
- Framing the ROI (investments from whom, returns for whom) focus on cost of evidence generation studies using linked registries compared to traditional
- Review of case studies that have been done (linked registry studies of devices)
- Analysis of case studies – review information on how they are better, faster, and cheaper, summarize
- Lessons learned
- Discussion – benefits of the NES beyond direct ROI – financial and others
 - Example pre-post market shift
 - Faster to market
 - Less exposure to big recalls and law suits by finding problems faster
- Conclusion

Value Proposition

- The ROI work done in this meeting supports broadly value propositions for the national system
 - MDEpiNet has also developed value propositions to promote investment
- This meeting and the proposed paper are welcome because they will provide a baseline for both traditional studies and for what our current prototype linked registry studies cost