

Registry Trials Project Expert Interview Results

Ted Lystig, Ph.D.

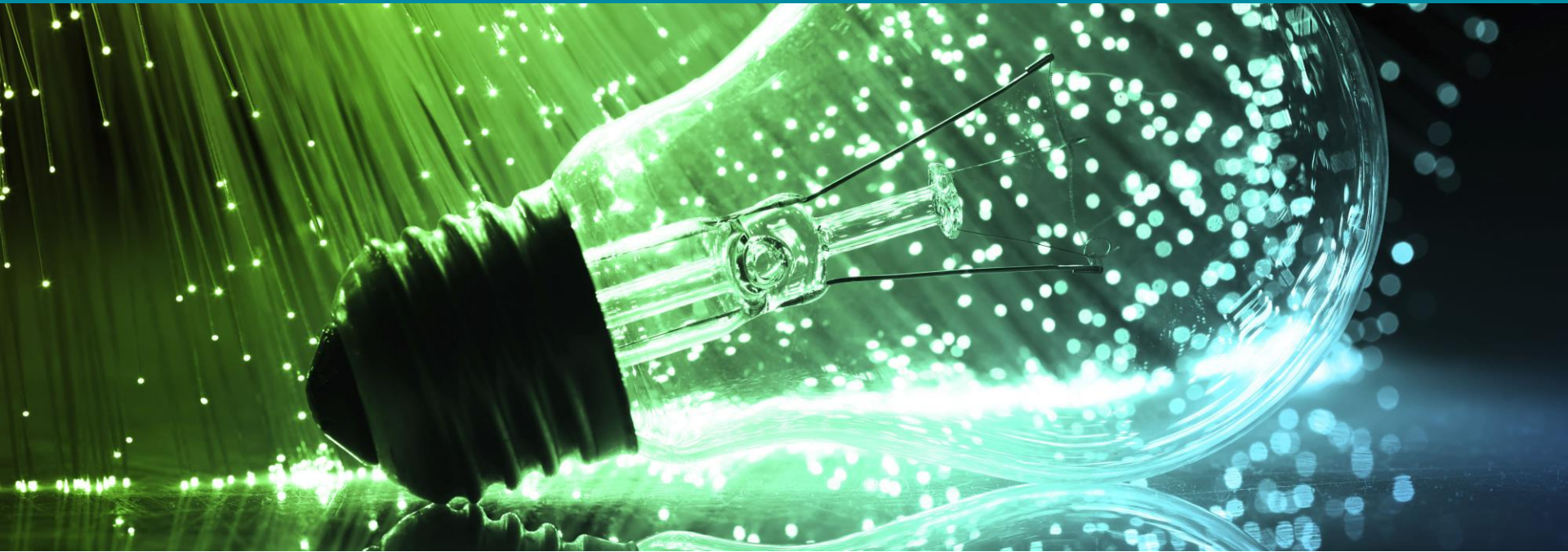
Director, Corporate Biostatistics

Medtronic

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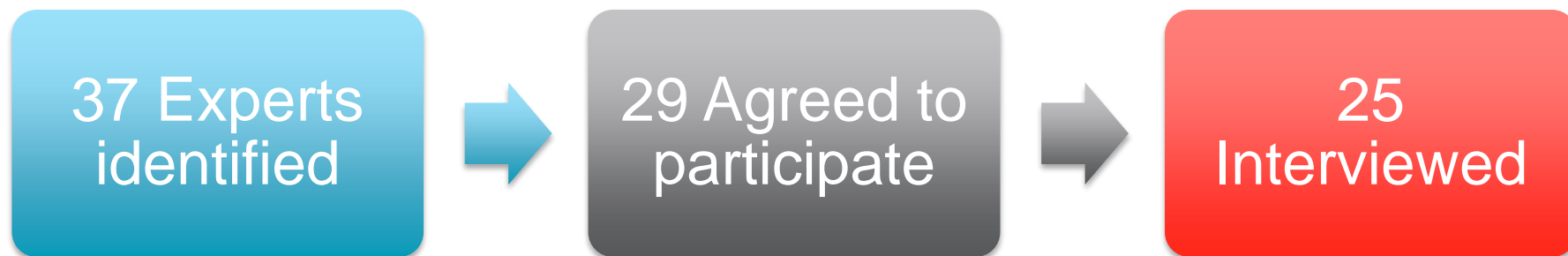
The presenter is an Employee of Medtronic.

Expert Interviews Overview

- ▶ **Purpose:** Gather expert opinions regarding the feasibility of using clinical registries for prospective clinical trials
- ▶ Interviews conducted for CTTI by RTI International
 - From October 13, 2015 to November 23, 2015

Interviewee Selection and Recruitment

- CTTI project team identified experts
 - Inclusion: knowledge regarding the use of registry data in clinical trials
- CTTI Project Manager sent email invitation
- RTI followed up to schedule interviews



Who was interviewed?

Sector	n
Academia	9
Other*	6
Government	4
Patient Groups	4
Pharm Industry	1
CRO	1
Total	25

- ▶ Patient Advocates
- ▶ Physicians
- ▶ Clinical Trial Investigators
- ▶ Statisticians
- ▶ Epidemiologists
- ▶ Lawyers
- ▶ Existing Registry Managers/Sponsors
- ▶ Regulators

*Professional Society=3, Professional Services=2, Policy Org=1

Thank you Interviewees

Ron Bartek	Sharon-Lise Normand	Rich Platt
Elise Berliner	Stefan James	Sunil V. Rao
Ralph Brindis	Javier Jimenez	Kristen Rosati
Greg Daniel	Jeffrey S. Kasher	John Rumsfeld
Chris Dowd	Mitchell Krucoff	Bob Temple
Nancy Dreyer	Beverly Lorell	Carol Ann Wallace
Ole Frobort	Danica Marinac-Dabic	Bram Zuckerman
Sharon Hesterlee	Evan Myers	
Louis Jacques	Bray Patrick-Lake	

Interview Guide and Process

- 14 question structured guide
 - Many open-ended questions
 - Questions could be skipped if covered in response to previous question or not relevant to interviewee
 - Probe questions to gain more detail when applicable
- Verbal informed consent provided
- Interviews recorded, transcribed, and coded to summarize responses and identify themes

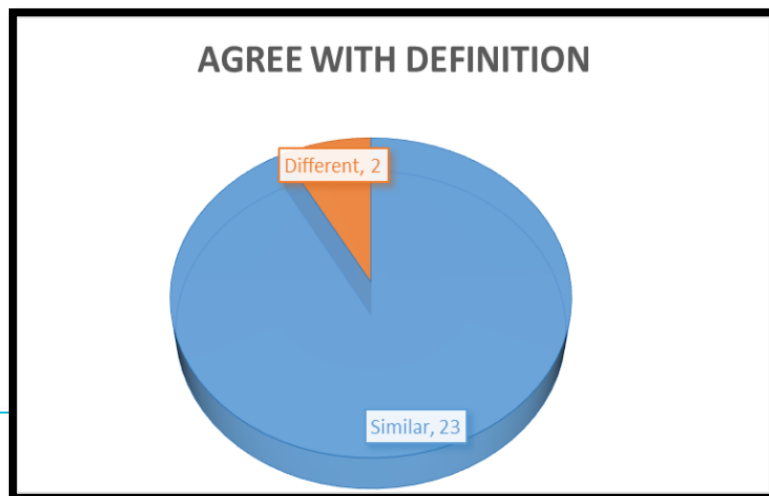
Topics Covered

- Confirming Registry Definition
- Feasibility of Using Registries for Embedded Clinical Trials
- Strengths and Weaknesses of Registries
- Barriers and Potential Solutions (divided into 2 tiers of priority)
- Device Registries and Trials: Experience, Differences between Drug and Device Trials
- Adapting Registry (Tools, Experience, Regulations) for drug or device Trials
- Operational Adjustments for Registries to be Used in Clinical Trials
- Prioritized Issues
- Actionable Items: Near-term and Long-term

Items with broad agreement

➤ Definition of registry

- An adapted version of the EMA's definition of registry is being used for this project: *“An organized system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition or exposure. A registry can be used as a data source within which studies can be performed. Entry in a registry is generally defined either by diagnosis of a disease (disease registry) or prescription of a drug, device, or other treatment (exposure registry).”* [Source: EMA: Guideline on good pharmacovigilance practices (GVP). The majority of the interviewees agreed with this definition.



Caveats: Different from AHRQ definition (esp. predetermined purpose); ties to demographic information, communication, and recruitment

Items with broad agreement

- ▶ Registries can be more widely used to facilitate embedded clinical trials



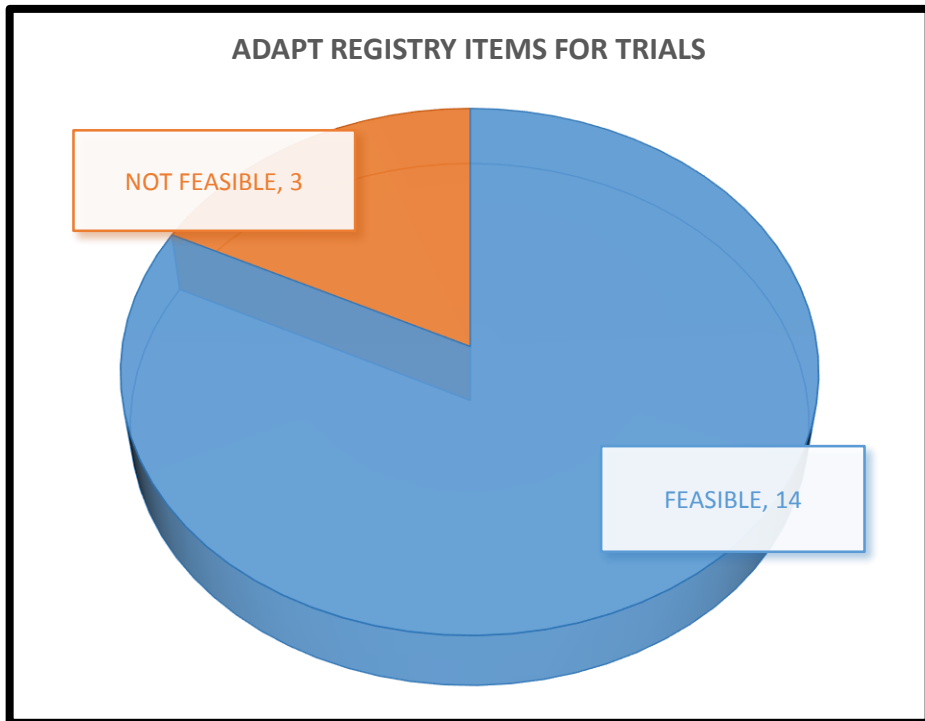
Comments:

Primarily valuable for recruitment
Ideal to better design a study
Help to track long term outcomes

Some concern with bias and variability, esp. for rare diseases

Items with broad agreement

Some adaption of registry items would work for clinical trials



Comments:

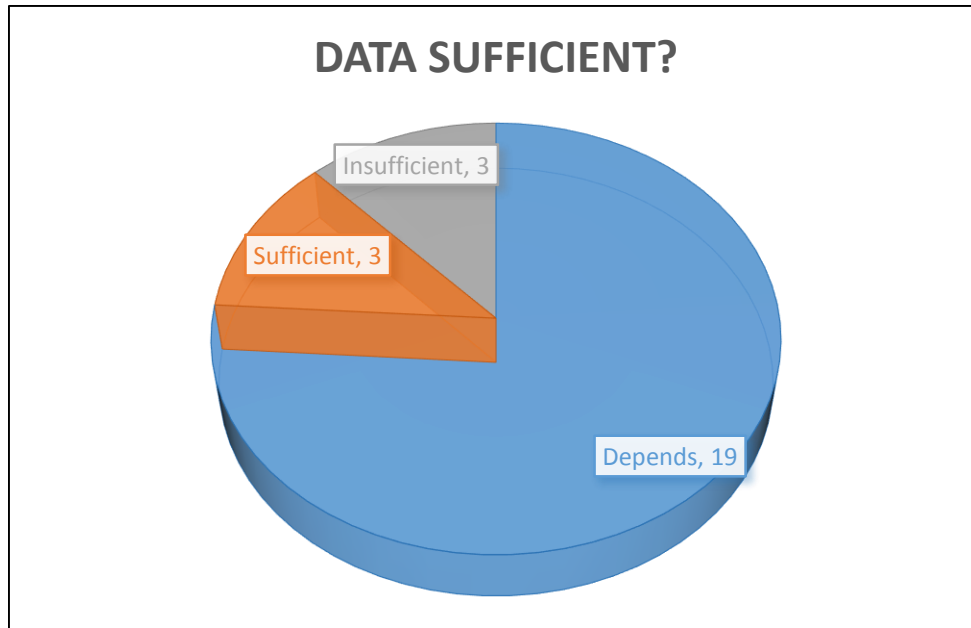
Concerns about quality of data (including monitoring related issues)

Registries should be set up from the beginning to support trials

Regulatory guidance, appropriate informed consent, IRB and DMC operations, and contractual niceties are all potential considerations

Items with broad agreement

▸ Sufficiency of data (answer: it depends)



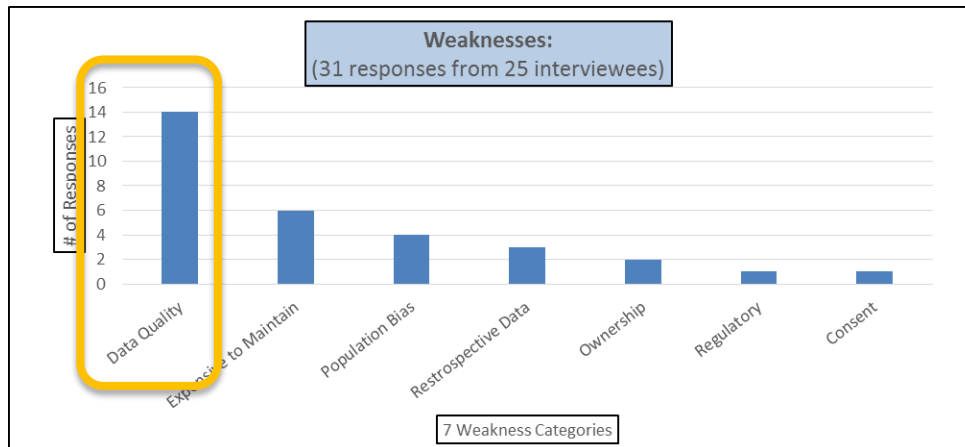
Comments:

Concerns about the extent to which the design of the registry adequately supports the research question

Several concerns about various aspects of data quality

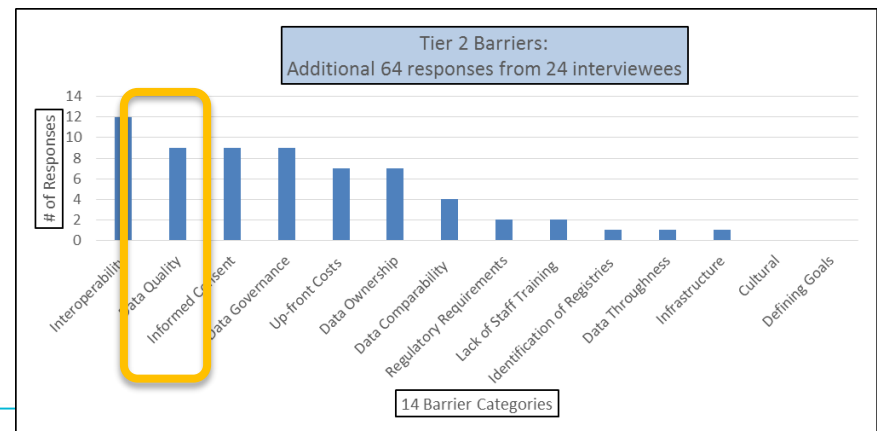
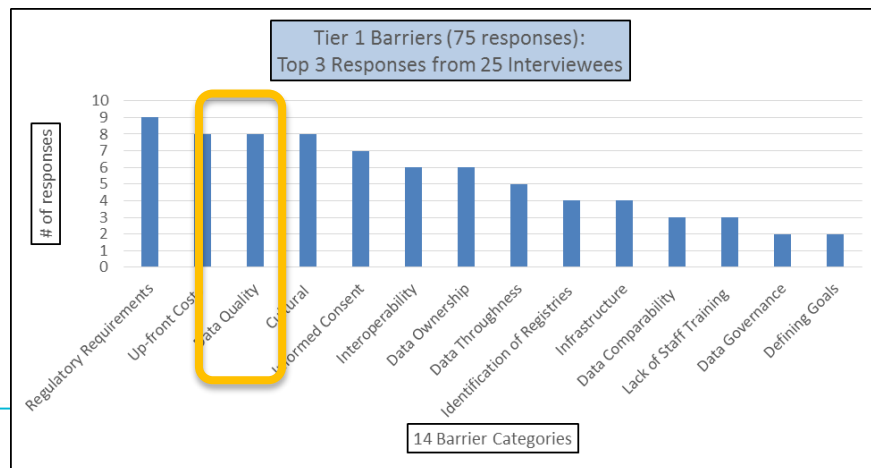
Items with broad agreement

▶ Data quality is a potential weakness for registries



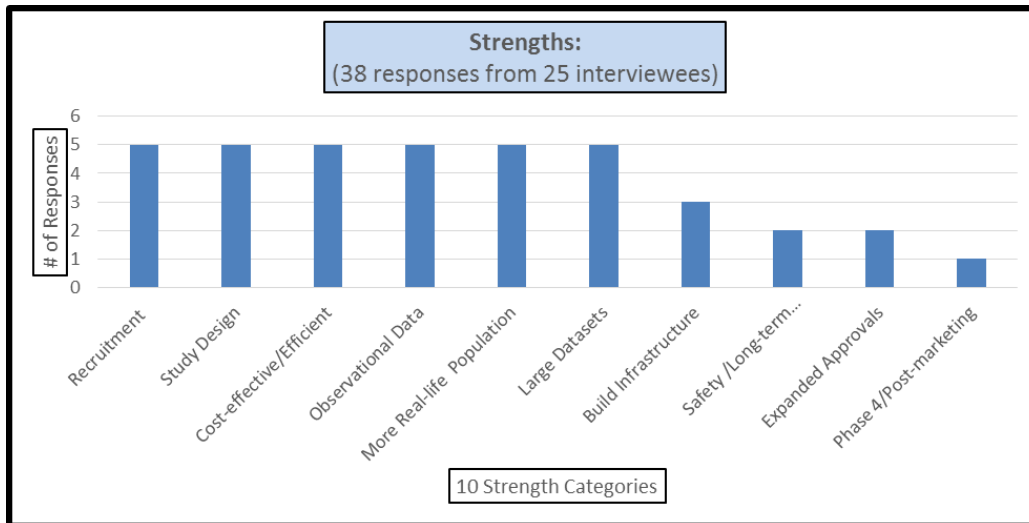
Comments:

This is a recurring concern, and is also present in responses to tier 1 and tier 2 barriers, as well as the earlier question on sufficiency of data



Topics without broad consensus

Strengths of registries

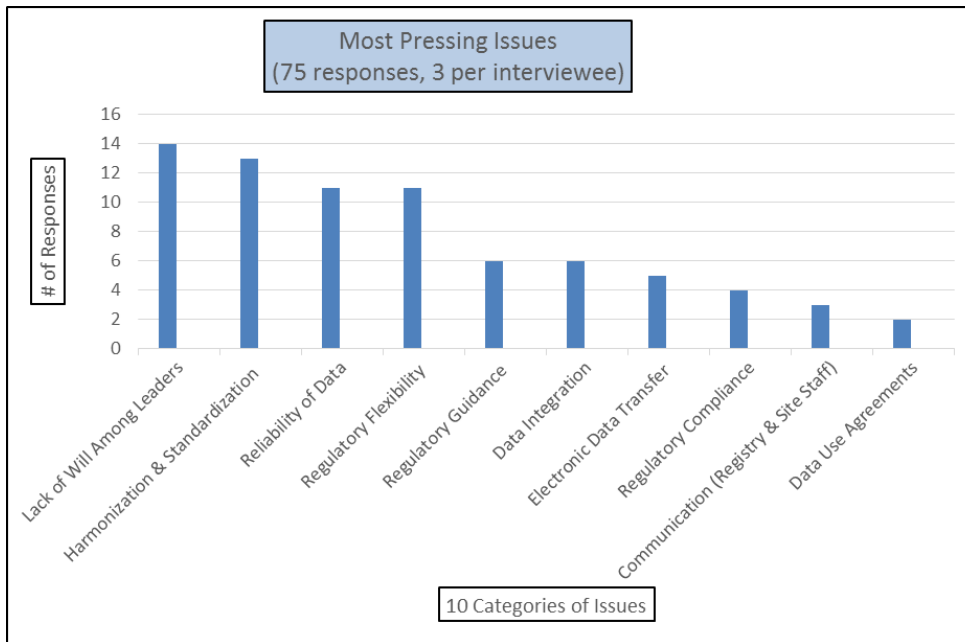


Multiple strengths seen, but spread across several broad categories

Not necessarily an item for which we need to achieve broad consensus

Topics without broad consensus

Determining the most pressing issues for registries



Lack of will question could be chicken and egg scenario

Harmonization and standardization are related data issues, though distinct from quality

Reliability of data may be a facet of data quality

We will address data quality, registry design, regulatory, and governance issues in breakout groups later today

Suggested items for further discussion

- ▶ What should we encourage for near term actionable items?
 - Variety of suggestions from experts
 - Mostly around how to improve using registry data from trials
 - Also some specific items around data and regulations

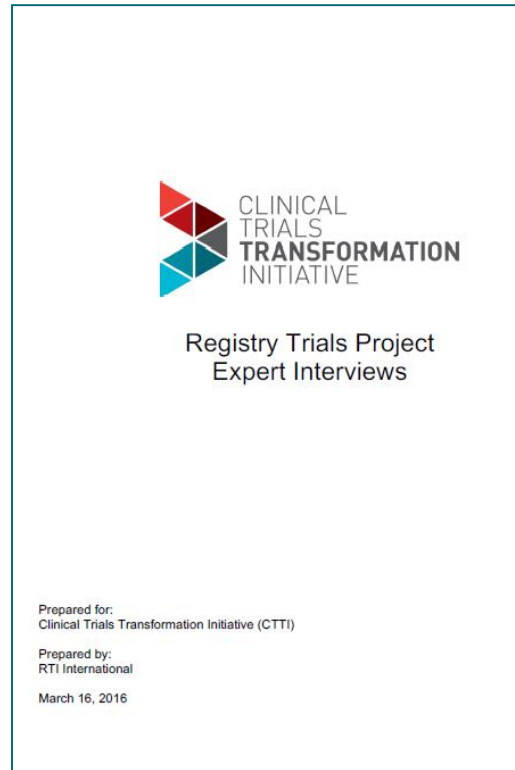
- ▶ What should nature of these items be?
 - Publications
 - Consensus building/meetings
 - Infrastructure
 - Other
 - Coordinated or dispersed

Suggested items for further discussion

- What should we encourage for longer term action items?
 - Three major themes from expert interviews: development of registries, costs, and data issues
- Development: domestic or international? Legislative mandate or voluntary cooperation? Organized by CTTI, MDEpiNet, professional societies, other?
- Costs: Elements of a sustainable, scalable business model?
- Data issues: drive change or leverage change? Relationship to other initiatives?

Reference

- ▶ For additional details, please refer to “Interview report” item
 - Link from meeting materials email from Kimberly Smith at CTTI



Thank you.



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theodore.lystig@medtronic.com