Stakeholder Engagement and Sustainability (SES) Committee Update

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SES Charter

- What defines an MDEpiNet "member" and "membership"
- What are the responsibilities of membership?
- What are the privileges/value of membership?
- What is the cost of membership?
- Sustainability model
- What stakeholders are engaged and what are their value priorities?
- What stakeholders are not engaged, what are their priorities and how do we reach out to them?

How to convert participants to members in 2016!

Introduction of Committee Members

- **Co-Chair – Elisabeth George (Philips)**
- **Co-Chair – Pam Plouhar (J&J Medical Device Companies)**
- **Members –**
  - Jesse Berlin (J&J)
  - Terrie Cowley (TMJ Association—patient advocate)
  - Bobbi Dressen (Independent)
  - Joseph Drozda (Mercy)
  - Blair Fraser (Smith & Nephew)
  - Ralph Hall (University of Minnesota Law School)
  - Elisa Hebb (Volcano)
  - Mitchell Krucoff (Duke University Medical School)
  - Janet McCauley (BCBS of North Carolina)
  - Kristi Mitchell (Avalere Health, LLC)
  - Bray Patrick-Lake (Duke Clinical Research Center—patient advocate)
  - Fred Resnic (Lahey)
  - Susan Robbins (Lahey)
  - Eve Ross (WL Gore & Associates)
  - Steve Rowland (OrbusNeich)
  - Ken Stein (Boston Scientific)
  - Robert Thatcher (CSI Cardiovascular Systems)
  - Gary Thompson (Abbott Laboratories)

SES Committee Work Products

– Work Products from Committee

- Stakeholder definition and strategy to insure representation of all stakeholder groups

- Definition of membership

- Development of dues proposal

- Development of value propositions for each stakeholder group

- Recruitment of members in 2016

Stakeholder Groups

- Academic groups
- Associations, Institutes, Foundations
- Clinical Research Industry (CROs)
- Consulting Groups
- Individuals
- Manufacturers
- Medical Society
- Not-for-Profits
- Patient Advocates
- Payers
- Provider/Health Systems
- Regulatory & Related Federal Agency
- Venture Capital
- Other (Benefit Management, Suppliers, Vendors)

Stakeholder Definitions

- **Payer stakeholders** are committed to ensure that their individual members receive safe, clinically and cost appropriate medical devices, and would thus benefit from enhanced processes to track member outcomes. Payers are also uniquely positioned to drive medical device population health management and cost effectiveness, through integration of clinical and financial data. Implementation of MDEpiNet serves to advance payer stakeholder objectives at both the individual and aggregate member levels.

- **Medical Societies**: These member organizations often address a specific condition or population through member education, public outreach, publications and advocacy. They are trusted sources of information about clinical evidence, practice guidelines and performance measures. Many are also stewards of clinical registries and make data available to conduct research, evaluate the risks and benefits of medical therapies, and promote rational dispersion of new technology. Medical societies and their members benefit if registry participation is integrated into the normal clinical workflow, fulfills regulatory, accreditation and licensing requirements, and promotes earlier access to critical information at the point of care.

- **Clinical Research Industry** A contract research organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, health services research including outcomes and economic research, clinical research including clinical trials design and execution, pharmacovigilance and non-interventional studies to study product effectiveness and safety. CROs may also support foundations, research institutions, universities, and governmental organizations.

- **Patient Advocate**/**Patient** Stakeholders represent those most at risk. They have the most to gain by successful collaboration to accomplish full implementation of the Mission of MDEpiNet. Patients also have the most to lose if vitally important and essential process improvements are not accomplished for improving Medical Device safety and effectiveness.

- **Consulting stakeholder group** represents those who, as individuals or as a part of an organization, interface with any and all stakeholders who are concerned by, directly impact, or are effected by medical devices. Such consultants offer strategic insight, technical support, and/or methodological guidance on developing, implementing, and evaluating approaches for medical device surveillance.

Membership Model

Who: All Medical Device Stakeholders

Responsibilities

- Provide support at appropriate funding level
- Commit to Committee, Workgroup or Think Tank Participation
- Commit to document development as requested
- Identify potential shared tools

VALUE of Membership—Develop value proposition for each stakeholder group

- Leadership roles (committees, thinktanks, projects etc)
- Protected web site & sharepoint community access
- Reduced registration fees for MDEpiNet events

Unresolved question

- **MDEpiNet members will be providing in-kind resources and dues payments toward development of infrastructure, methodology and projects that benefit all stakeholders. Is there a value of membership toward participating in this development beyond providing up front influence and participation in the design of these projects (e.g. data access priority to a distributed network, reductions in cost or invitation only to workshops/forums etc)**

Annual Dues Proposal by Stakeholder Group

Stakeholder Groups		Proposed Annual Dues	Current Representation
1) Academic		$1,000	11
2) Association, Institute & Foundation		$2,500	4
3) Benefit Management		TBD	0
4) Clinical Research Industry		$2,500	1
5) Consulting Groups	Individual	TBD	1
	Small	TBD	
	Medium	TBD	1
	Large	TBD	
6) Individuals		$10	0
7) Manufacturer	< 50 million	$5,000	1
	50-500 million	$20,000	2
	> 500 million	$35,000	11
8) Medical Society		$2,500	2
9) Non-Profit		$1	3
10) Patient Advocate		$1	4
11) Payer	< 1 million insured	$5,000	
	1-10 million insured	$20,000	1
	> 10 million insured	$35,000	
12) Provider/Health System	Small	TBD	
	Medium	TBD	2
	Large	TBD	
13) Regulatory & Related Federal Agency		$0	8
14) Suppliers		TBD	0
15) Vendors		TBD	3
16) Venture Capital		TBD	1

Key components to MDEpiNet Sustainability

- Must include immediate and long term value for stakeholder

- Must include something about access to other stakeholders early and often

- Must include tangible material (e.g.; access to data for submissions, early information on quality and safety)

- Must show that money and time will support regulatory strategy for shorter time to market and expanded indications

- Must include reference to regulatory conformance to pre and postmarket requirements

Elements of Industry Value Proposition

- Define evidence needs across the TPLC and improve access to data to enhance understanding of device performance
  - Promote pilot projects supporting faster, less expensive basis for regulatory decisions and more accurate means of safety surveillance
  - Shortened review and approval times, decreased cost to obtain required data, use of registry infrastructure and data to support product approvals, label expansion, fulfill post approval study requirement
- Evaluate the impact of expanded access to data from different sources to facilitate coverage and reimbursement decisions
  - Best practices for evidence development to support reimbursement
- Sponsor pilot projects to improve the quality of device data captured at the point of care
- Environment that fosters collaboration, improved understanding and professional trust across within the stakeholder community

Thank you!