

Update on the Scientific Oversight Committee (SOC)

Greg Pappas, FDA

Jesse Berlin, Johnson & Johnson

Presented to MDEpiNet Annual Meeting

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Committee charge (from the MDEpiNet Charter)

- Convening, oversight and facilitation body for MDEpiNet Working Groups
- Review and approving Working Group proposals
- Oversee Working Group roadmap implementation plans
- Identify strategic priorities for think tanks
- Facilitate and evaluate the progress of the individual Working Groups
 - alignment of objectives with the MDEpiNet mission;
 - practicality of the implementation plan, including access to resources, leadership, expertise and timelines for deliverables;
 - the impact of specific proposed deliverables
- Details about membership criteria

Committee membership considerations

- Willing to donate time
- Tried to balance with respect to:
 - Industry, FDA, Academia, Payers
 - Clinician vs. methodologist
- Willing to donate time

Committee Members

Berlin	Jesse	J & J
Bhandari	Mohit "Mo"	McMaster University
Brindis	Ralph	American College of Cardiology
Dahm	Philip	University of Minnesota Law School, Food and Drug Law
Dwight	Schrag	Consumer Representative, Washington Advocates for Patient Safety (Seattle)
Hakim	Rosemarie	CMS
Helwig	Amy	AHRQ
Jacques	Louis	ADVI
Kessler	Larry	University of Washington
Kong	David	Duke Clinical Research Institute
Krucoff	Mitchell	Duke University Medical Center
Lystig	Theodore	Medtronic
Mack	Michael	Baylor Health
Marinac-Dabic	Danica	FDA
Murray	Sheldon	FDA
Normand	Sharon-Lise	Harvard Medical School
Pappas	Gregory	FDA
Sedrakyan	Art	Cornell Medical Center
Tcheng	James	Duke Clinical Research Institute
White	Roseann	Abbott and Abbott Laboratory

WWMS (what would Mitch say?)

- “Shedding the more ubiquitous expectations of NIH-like review is the first objective of the PPP—we want to encourage proposal submissions to MDEpiNet, even if as great ideas, without the expectation that there is an 87% likelihood we will reject the effort outright. Since we do not fund projects *per se*, this is doubly important, as no one in their right minds would submit project with high likelihood of going nowhere to an organization that is at best a partner, not a funder, *per se*.
- Being perceived as too easy or meaningless will not be nearly the problem.

Reviewer Guidelines

- **Does the working group proposal contribute to building the national health data infrastructure network or related tools for post market surveillance are related use?**
- **Does the proposal contribute to implementation of UDI?**
- **How might this proposal be funded? By whom?**
- **Are there additional partners or other similar proposals that might be suggested for collaboration that would improve the project?**
- **Design review (Please make constructive comments that would improve the likelihood of funding)**
- **Methods review (Please make constructive comments that would improve the likelihood of funding)**

Approved projects

- PASSION 1: Registry Assessment of Peripheral Interventional Devices (RAPID)
- PASSION 2: The Study of Access site For Enhancement of ST-Elevation MI for Seniors: SAFE-STEMI for Seniors (FUNDED)
- PASSION 3: Optimal integration of procedural and Medicare claims data for regulatory and reimbursement decision making involving innovative transcatheter mitral valve implants
- SMART A. Extension of UDI Implementation Pilot
- SMART B. An Internal Hospital Unique Device Identifier Registry: Workflow and Infrastructure Redesigns
- SMART C. EHR Minimum Data Set and Structured Data Capture for Registries
- SMART D. Electrophysiology structured reporting providing UDI for Leads and devices using industry Standards to Electronic Health Records and CVIS systems (EPulse)
- SMART E. Medical Device Data Capture and Exchange: Leading Practices and Future Directions
- SMART F. Society of Interventional Radiology (SIR) VANGUARD (Venous Access: National Guidelines and Registry Development) initiative

Endorsement: what does it mean, how does it help?

- This endorsement may be included in your external grant proposals or other funding efforts, if you find it useful
- MDEpiNet PPP will be happy to work with you to coordinate your project's working group activities with introductions to novel partners, conduct of think tank sessions or any means at the PPP's disposal to assist with your efforts.
- An SOC function includes getting updates on progress of the project. One of the fruits of such updates is that participants may stimulate ideas, solutions, new directions, etc., that would never blossom through other means.
- Use of our SharePoint space for your project to store and share materials between the partners working on this endorsed project.
- **Nurturing the projects is an ongoing process of partnering.**

In conclusion

- The SOC is a work in progress
 - E.g., small changes to the review criteria
- We welcome suggestions on how to take full advantage of the broad MDEpiNet community to encourage collaborations
- Alignment with disease specific/device specific projects combining immediate impact with generalizable “use/re-use” predicates - AND
- Alignment with the pilot-project orientation of the National Device Evaluation System
- *“If you want to go fast, go alone. If you want to go far, go together.”*
 - African Proverb