Is Bruce’s email one of the questions you think we’ve already answered in the past?

Can I offer a suggestion? Could we possibly create a tracker on all the incoming questions/answers? I believe this might clarify the question and help get a quicker reply and keep everyone on the same page. Example below based on what Bruce requested today.

Thoughts?

<table>
<thead>
<tr>
<th>Question/Topic</th>
<th>Follow-Up Questions</th>
<th>Response/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cloud</td>
<td>• Are we getting the cloud correctly</td>
<td>• Document reference?</td>
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<tr>
<td></td>
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<td>• Strategy?</td>
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<td></td>
<td></td>
<td>• POC?</td>
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<tr>
<td>2. CIO</td>
<td>• Candidate Pool?</td>
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<td></td>
<td>• Key Qualifications?</td>
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<td></td>
<td>• Separation of roles?</td>
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<tr>
<td>3. Physician Input</td>
<td>• Patient Centric?</td>
<td></td>
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<td></td>
<td>• Physician Usability Scope?</td>
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<tr>
<td>4.</td>
<td></td>
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<tr>
<td>5. Apple Project</td>
<td>• Who is POC?</td>
<td></td>
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<tr>
<td></td>
<td>• Project update?</td>
<td></td>
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<td></td>
<td>• Mental Health Strategy and Portable EMR Solution that works with DOD &amp; VA &amp; Community?</td>
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<td>6.</td>
<td></td>
<td></td>
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<tr>
<td>7.</td>
<td></td>
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</tr>
</tbody>
</table>
To: Sandoval, Camilo J.
Subject: FW: [EXTERNAL] Fwd: EMR

Sent with Good (www.good.com)

From: David Shulkin
Sent: Tuesday, March 06, 2018 7:09:43 AM
To: Blackburn, Scott R.
Subject: [EXTERNAL] Fwd: EMR

Can we begin to address and then I'll respond back?

Sent from my iPhone

Begin forwarded message:

From: Bruce Moskowitz [ ] mac.com>
Date: March 5, 2018 at 6:49:58 AM EST
To: [ ] reagan.com
Cc: [ ] gmail.com, IP <@frenchangel59.com>, [ ] gmail.com
Subject: EMR

I would like to underscore the importance of getting the “Cloud” correctly and the other four issues with the new CIO’s. Also the composition of the physician input has to change immediately so that the EMR is patient-centric and usable from the physician perspective. Second this is going to take years to implement and especially in mental health we need a portable EMR solution that works with the DOD, the VA and the private sector. No one at the VA got back to me on what the Apple project can and cannot do in terms of solving this problem.

Sent from my iPad
Bruce Moskowitz M.D.
Good afternoon,

Thank you I can be there. I am including [redacted] on this email to ensure that the time/date is on my schedule.

Jacquie
Jacquelyn Hayes-Byrd, Deputy Chief of Staff
US Department of Veterans Affairs
Jacquelyn.Hayes-Byrd@va.gov
Cell: 202-817-5873

Hi Jacquie!
Great seeing you again today (briefly)! I spoke with Peter today about an effort around developing a Medical Device Registry, in collaboration with Bruce Moskowitz and his colleagues. We have a weekly call with the workgroup on Wednesdays at 7:30 am, and Peter suggested we hold tomorrow’s call at 7:30 am in his office, and if you have time, perhaps you could join? I’ll forward the invite to you. Let me know if you have any questions at all!

Thank you!
-Srey
(713-503-4274)

SreyRam Kuy, MD
Special Advisor to the Secretary
Veterans Health Administration
Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center
810 Vermont Avenue, NW, #1069
Washington, DC 20420
Mobile: 713-503-4274
Office: 202-461-4875
Dear Colleagues,

For our planning meeting on Medical Device Registry tomorrow morning, attached is a 1 pager (double sided), which can be used for discussion with outside stakeholders. Also, I’ve attached meeting minutes from both prior conference calls. The minutes are displayed chronologically, with the most recent at the end. I’ve also invited a few other colleagues to join the call, depending on their availability. And many apologies to our west coast colleagues for the very early time.

Conference call line: 800-767- Code
Wednesday March 14, 2018 at 7:30 am Eastern

Thank you so much for all your enthusiasm and support for this effort!

Warmly,
SreyRam

SreyRam Kuy, MD
Special Advisor to the Secretary
Veterans Health Administration
Associate Chief of Staff
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810 Vermont Avenue, NW, #1069
Washington, DC 20420
Mobile: 713-503-4274
Office: 202-461-4875
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:

- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- @va.gov

@va.gov
Meeting Objective: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

1. Welcome and introductions of participants and organization

2. Moderated Roundtable Discussion with Key Agency Leadership
   ✓ Panel Moderator – facilitates with questions
   ✓ Secretary of the VA
   ✓ FDA Commissioner (TBD)
   ✓ CMS leadership (TBD)
   ✓ HHS Leadership (TBD)

3. Topic Focused Presentations
   ✓ Why Registries Matter – Data about how it helps lower costs, improve outcomes – Subject Matter Expert TBD
   ✓ NEST – the next frontier in device surveillance and outcomes management – Speaker
   ✓ Other Key Topics

4. Closing Remarks, Thanks to Participants, Outline Key Next Steps
   ✓ Speaker TBD
Medical Device Registry Summit

February 21, 2018
Meeting Minutes

Meeting Objective: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

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<th>Last Name</th>
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<tr>
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<td></td>
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<tr>
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<td>Veterans Affairs</td>
<td>NCPS</td>
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<tr>
<td>Danica</td>
<td>Marinac-Dabic</td>
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<td>Kuy</td>
<td>Veterans Affairs</td>
<td>Special Advisor to the Secretary</td>
</tr>
<tr>
<td>Thomas</td>
<td>Concannon</td>
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2. Discuss current state of VA/UDI

Current state of VA
- Product recall office in the VA takes 0-10 days to initiate a recall, with an estimated 99% recall rate
- Bruce is conducting a stop-gap analysis focusing on implants, both biologic and non-biologic (mostly biological tissue in the VA population)
- Suggestion from Danica: expand stop-gap analysis to close calls

UDI
- CFR requires UDI manufacturers
- Getting information on the implanted devices, see if you can make that fast and easily go into patient medical records
- Track what gets implanted
- However, UDI has some push back from manufacturers, including:
  - Too expensive, small manufacturers who cannot afford it
  - Might not work for all devices because of packaging
  - Should be acquired by anyone purchasing a device
  - GUDID database
    - Need to bring in all these data sources and get an API to bring into your system

3. Discuss purpose and goals for the “Medical Device Registry”
Registry's Importance for Patients

- Patients do not know the manufacturer of devices or type of device
  - This becomes an issue if they do not know why their device needs to get a revision
- Need to capture this importation and develop a national registry to easily do recall
- Need tracking system and registry

4. Discuss purpose and goals for the “Medical Device Registry” Summit

Narrow the Focus to Make It Specifically about the Problem

- What people are interested in:
  - Cost benefit analysis
    - 400% price reduction for manufacturers
    - Implant registry improves cost and quality with a good system
  - Not just in case of error; the registry can act as an early detection system
  - Really hopes for longer standing registries where you get outcome reports from them, pull something from the market if quality or safety is lower (i.e. if the device is not doing its job)
  - The registry will be a valuable resource and tool
- Patient groups would love to use information to fund the study for feedback with people with devices
  - Many research opportunities
- Can give input to incorporate outcomes
- Can locate a device in an organization (RSLD) such as an IV pump, and can find a device in an organization
- Can help in the long term improve their product, become safer, and of better quality than the competitor

5. Determine Format of the “Medical Device Registry” Summit

Part 1

- Discuss the rational for the Medical Device Registry, including use cases, purpose, etc.
- Hear from each stakeholder, perspective, what is in it for them, barriers, SWAT analysis (better, faster, cheaper)

Part 2

- How to structure data capture; discuss stop gap analysis from NCPS and, potentially, the Mercy Hospital Study

6. Determine Panel of Speakers/Attendants

Summit invitees should include:
- Medtronic
- Johnson and Johnson
- Recommend smaller companies, like Titan
- Invite a portfolio of patient groups (Danica going to send to us)
  - Group, nice demonstration of organic collection of data to large roundtable
- Need to invite an additional voice, preferable a front-line provider
- Need to invite provider groups

7. Ideas for Medical Device Registry
Idea: Have a Patient Safety Device Score

- People need to report
  - Train and educate people, do a root cause analysis, consider reporting structures
- Learn from users’ experiences and use their issues (learning from the field, field is seeing this)
- Open database through NIH, can match with registries for global device

8. Next Steps Forward

1. Create agenda template: Danica
   - Draft agenda: SreyRam
2. Initiate contact with key stakeholders: Danica/Aaron
3. Reach out for speakers and attendance (e.g. patient advocacy groups, manufacturers, provider groups, Cerner, major medical journals, etc.): Danica/Aaron
4. Look for summit venues: Aaron (can help as well)
5. Create one-pager of summit or project, and modify for external audience: SreyRam
6. Pick a date, based on FDA’s calendar: February 28, 2018

February 28, 2018
Meeting Minutes

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<tr>
<td>SreyRam</td>
<td>Kuy</td>
<td>Veterans Affairs</td>
<td>Special Advisor to the Secretary</td>
</tr>
</tbody>
</table>

1. Discuss symposium speakers
   - For the symposium, it may be beneficial to have an unbiased third party speaker, such as an academic or consultant
   - A speaker who can talk about what already exists in terms of medical registries
   - Have a speaker on the UDI
2. Discuss outreach
   - Participants on this call, such as [redacted] and Aaron, are going to reach out to patient advocacy groups, provider groups, medical device groups, etc.
   - [redacted] will have informal calls to reach out to people; he wants a common message or paragraph we want to send out to experts
- SreyRam will reach out to Secretary Shulkin to reach out to counterparts
3. Discuss location
- DJS recommended we use the VA auditorium
4. Discuss dates
- Calendars - tell everyone to email potential conflicts
- However, Bruce noted that as long as we get CMS and VA leadership, others will send someone of important, won’t want to be left out with major players of the audience
5. Action Items
- One pager (vague without any promises for external use) with “common message” that can be used in informal phone calls: SreyRam
- Send one pager to experts/industry leaders to invite them into the conversation: Aaron, and Danica
Dear colleagues,

In preparation for our weekly Wednesday morning call, here's the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 3/21/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767-XXXX Code XXXXX

We've made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda, with locations, possible time and a slate of speakers. Several fantastic subject matter experts on board to participate! This is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

Again, many apologies to our west coast colleagues for the very early time.

Thank you so much for all your efforts!

Warmly,
SreyRam

Special Advisor to the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018 (TBD)
Location: VA Auditorium, #230

1. Welcome and Introductions of Participants and Organizations

2. Moderated Roundtable Discussion with Key Agency Leadership
   ✓ Panel Moderator – facilitates with questions (SreyRam Kuy, MD)
   ✓ Secretary David J. Shulkin, MD, Secretary of the VA
   ✓ Commissioner Scott Gottlieb, MD, FDA Commissioner
   ✓ CMS leadership (TBD)
   ✓ HHS Leadership (TBD)

3. Topic Focused Presentations (15 minutes each)
   ✓ “Why Registries Matter” – Data about how it helps lower costs, improve outcomes
     • Subject Matter Expert TBD
   ✓ NEST – the next frontier in device surveillance and outcomes management
     • Danica Marinac-Dabic, MD, PhD, MMSC, FISPE
       Director, Center for Devices and Radiological, FDA
   ✓ “Enabling Patient Participation in Device Registries” – Title TBD
     • Harlan M Krumholz, MD
       Director, Center for Outcomes Research and Evaluation, Yale University
   ✓ “Current Cardiac Device Monitoring in the VA”
     • Merrit H. Raitt, MD (TBD)
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   ✓ “Current VA Medical Device Registries in Place” - Maximo
     • Office of Healthcare Technology Management, Veterans Health Affairs
   ✓ “Building Future-State Model for VHA Implant Tracking”
     • Bruce McIntosh, PharmD
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   ✓ “Title TBD”
     • Frederic Resnic, MD
   ✓ Talks by other stakeholders (Amazon, Medtronic) TBD

4. Closing Remarks and Outline Key Next Steps
   ✓ “Pulling it All Together: Next Steps Working with Our Partners”
     • Carolyn Clancy, MD or Chris Vojta, MD, USH or PDUSH for VHA
National Medical Device Registry Summit

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Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
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Contacts:
- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [Redacted]@va.gov
Thank you!

Sent with Good (www.good.com)
Thank you everyone for your great input and effort on this project!

That’s a great question. Here is the double-sided one pager, as an editable word version (attached). I made it as “track-changes” enabled, so changes can be seen. I think it’s reasonable to share revisions and changes with the whole group.

Again, thanks for all your hard work and looking forward to a successful summit in June!

Warmly,
SreyRam

SreyRam Kuy, MD
Special Advisor to the Secretary
Veterans Health Administration
Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center
810 Vermont Avenue, NW, #1069
Washington, DC 20420
Mobile: 713-503-4274
Office: 202-461-4875

Hi Srey Ram: Thanks again for these conference calls with the group – exciting to see how wonderfully this is developing! Shall we make comments/edits to the one-pager you sent us in word version or are we waiting on another version from you? And are we sending back the document with comments to everyone in the group or just you- I ask for version control purposes.

--S
From: Kuy, SreyRam (HOU) [mailto:SreyRam.Kuy@va.gov]
Sent: Tuesday, March 13, 2018 18:08
To: GHLF <MI  @ghlf.org >; Bruce Moskowitz < @mac.com >; Aaron Moskowitz < @va.gov >; Thomas Concannon < @rand.org >; McIntosh, Bruce (NCPS) < @va.gov >; 'Marinac-Dabic, Danica' < @da.hhs.gov >; 'Atlas Research' < @atlasresearch.us >; 'dc-crd.com'; < @dc-crd.com >; Hayes-Byrd, Jacquelyn <Jacquelyn.Hayes-Byrd@va.gov >;
Subject: Medical Device Registry Summit - Planning Meeting, Wednesday March 14, 2018 at 7:30 am Eastern, Conference call line: 800-767- Code

Dear Colleagues,

For our planning meeting on Medical Device Registry tomorrow morning, attached is a 1 pager (double sided), which can be used for discussion with outside stakeholders. Also, I’ve attached meeting minutes from both prior conference calls. The minutes are displayed chronologically, with the most recent at the end. I’ve also invited a few other colleagues to join the call, depending on their availability. And many apologies to our west coast colleagues for the very early time

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   ✓ “Pulling it All Together: Next Steps Working with Our Partners”
      • Carolyn Clancy, MD or Chris Voita, MD, USH or PDUSH for VHA

Commented [S1]: if this is going to be a document we are circulating I was wondering if it may work better for this page to be page 2, and what is currently page 2, to be page 1- to provide more context and framing.

Commented [S2]: Since this is an introductory session (I’m assuming), wondering if the “Why registries matter” topic could also include “Perspectives on registries (thereby including a multi-stakeholder perspective) and spanning things like a) surveillance, b) post-market observation, c) Best practices sessions or models of current registries, d) Hurdles and obstacles e) Some kind of data on integrating clinical and PROs? The idea being that each topic could relate to a different stakeholder. Just a thought.
National Medical Device Registry Summit

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- RAND Corporation

Contacts:
- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [Redacted]@va.gov

Commented [S3]: Would be useful to add “Aims” as well to this- this will allow us to highlight the “multi-stakeholder” focus of the conference. It would also nicely lead into participating partners.
Ha, Richard

From: Kuy, SreyRam (HOU)
Sent: Tuesday, March 27, 2018 6:11 PM
To: Hayes-Byrd, Jacquelyn
Cc: 
Subject: RE: Medical Device Registry Summit - Planning Meeting: Conference call line: 800-767- [REDACTED] Code [REDACTED]

Jacquie,

Thank you!!!
-Srey

From: Hayes-Byrd, Jacquelyn
Sent: Tuesday, March 27, 2018 5:30 PM
To: Kuy, SreyRam (HOU)
Cc: 
Subject: RE: Medical Device Registry Summit - Planning Meeting: Conference call line: 800-767- [REDACTED] Code [REDACTED]

Hello!

I have reserved the 2nd floor conference room in this bldg. for the Summit. Let me know if I am off base.

Thanks,

Jacquie

From: Kuy, SreyRam (HOU)
Sent: Tuesday, March 27, 2018 5:05 PM
To: GHLF; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); [REDACTED]; Hayes-Byrd, Jacquelyn; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; 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[REDACTE
Thank you

Ok, this event is confirmed. I can reach out to Dr. SreyRam to identify the type of logistical support she will need (Power Point, Microphone, Banner, etc)

Monday, June 04, 2018
7:00 AM - 5:00 PM Medical Supply Conference (Web Confirmed) VACO RM 230/330

VA Core Values: Integrity, Commitment, Advocacy, Respect, and Excellence—I CARE

This Subject is the 2nd floor reservation title for June 4, 2018

Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:
Medical Device Registry Summit - Planning Call
Wednesday 3/28/2018  7:30 am – 8:00 am Eastern
Conference call line: 800-767- [____]  Code [____]

Thank you so much for all your efforts!

Warmly,
SreyRam

SreyRam Kuy, MD, MHS, FACS
Special Advisor to the Secretary
Senior Advisor to the PDUSH
Veterans Health Administration
Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 3/28/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767 [Redacted] Code [Redacted]

Attached are the minutes from last week’s call.

Again, thank you so much for all your efforts!

Warmly,
SreyRam

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810 Vermont Avenue, NW, #1069
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Mobile: 713-503-4274
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Medical Device Registry Symposium

March 28, 2018
Meeting Minutes

Meeting Objective: Bring together VA, FDA, and other federal agencies and key stakeholders for a national symposium about medical device registry efforts

1. Participants and organization

<table>
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<tr>
<th>First Name</th>
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<tr>
<td>Aaron</td>
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<tr>
<td>Thomas</td>
<td>Concannon</td>
<td>RAND</td>
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</table>

2. Discuss updates

Symposium Logistics
- Auditorium Secured
- SreyRam talking to DJS today to finalize date; DJS going to reach out to other leadership, such as HHS secretary and FDA commissioner (update: spoke with Chief of Staff, date finalized)

Danica Speaker
- Danica is going to reach out to Dr. and potentially add as speaker for return on investment for registries
- Danica going to send one of his past presentations
- Include a forum at the end; many “acronyms” we can invite to the forum
- Recommends that we consider , led pinnacle registry, and is part of the American association for orthopedic surgeon coordinating a registry
  - Lots of recent developments, need to invite speakers who can move the needle

DOD
- Bruce having trouble finding someone significantly involved in implant registry at DOD

Bruce Moskowitz
- Wants to invite major manufacturers, big players, to be there in attendance
- Bruce is going to invite the head of American Association of Surgeons to attend and relay info to their list serve
- Would there be controversy if J&J is asked to speak and metronics is not? Trying to avoid hot water
  - Move the needle vs. politics discussion
Shilpa
- Our focus topics should reflect the speakers in such a way that our speakers will complement all the topics
3. Action Item
4. Follow up with DOD - Bruce
5. Follow up with additional contacts she wants to include in this discussion - Danica
6. Reach out to orthopedics - SreyRam
7. Finalize dates - SreyRam
Ha, Richard

From: Kuy, SreyRam (HOU)
Sent: Tuesday, April 10, 2018 4:30 PM
To: GHLF'; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); (Atlas Research); 'Marinac-Dabic, Danica'; Hayes-Byrd, Jacquelyn

Subject: Medical Device Registry Summit - Planning Meeting Wednesday April 11, 2018 at 7:30 am; Conference call line: 800-767-

Attachments: Medical Device Registry Summit - 1 pager.docx

Dear colleagues,

Looking forward to catching up tomorrow for our weekly Wednesday morning call.

Here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 4/11/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767-

I don’t think I’ve been emailed any revisions to the agenda yet (many apologies if you did send and I missed!). So I’m attaching the agenda - welcome all your revisions! I added the Pew Trust as a tentative participant. Feel free to revise the editable word doc (it’s track changes enabled) and share with us all. Not too late to send in changes!

I owe Dr. Moskowitz a budget – Bruce and I are editing it.

Thank you so much for all your efforts! Much appreciated!

Warmly,
SreyRam

SreyRam Kuy, MD, MHS, FACS
Senior Advisor to the PDUSH
Veterans Health Administration
Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1022
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230

1. Welcome and Introductions of Participants and Organizations

2. Moderated Roundtable Discussion with Key Agency Leadership
   - Department of Veterans Affairs, SreyRam Kuy, MD (possible comments by Chief of Staff Peter O’Rourke TBD)
   - Food and Drug Administration Commissioner Scott Gottlieb, MD
   - CMS leadership (TBD)
   - HHS Leadership (TBD)

3. Topic Focused Presentations (15 minutes each)
   - “Why Registries Matter” – Data about how it helps lower costs, improve outcomes
     - Subject Matter Expert TBD
   - NEST – the next frontier in device surveillance and outcomes management
     - Danica Marinac-Dabic, MD, PhD, MMSC, FISPE
       Director, Center for Devices and Radiological, FDA
   - “Enabling Patient Participation in Device Registries” – Title TBD
     - Harlan M Krumholz, MD
       Director, Center for Outcomes Research and Evaluation, Yale University
   - “Current Cardiac Device Monitoring in the VA”
     - Merrit H. Raitt, MD (TBD)
       Director, National Cardiac Device Surveillance Program, Veterans Health Affairs
   - “Current VA Medical Device Registries in Place” - Maximo
     - Office of Healthcare Technology Management, Veterans Health Affairs
   - “Building Future-State Model for VHA Implant Tracking”
     - Bruce McIntosh, PharmD
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   - Talks by other stakeholders (Amazon, Medtronic) TBD

4. Closing Remarks and Outline Key Next Steps
   - “Pulling it All Together: Next Steps Working with Our Partners”
     - Carolyn Clancy, MD or Chris Vojta, MD, USH or PDUSH for VHA
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:
- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:
- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [Redacted]@va.gov
Hi Everyone!

Great conversation yesterday morning. Attached is the draft agenda, “Track changes enabled”. Please do revise and add to it, and circulate your additions to the whole group. All your efforts are greatly appreciated!

-SreyRam

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  SreyRam.Kuy@va.gov
- [Redacted]@va.gov
I edited two names for spelling and added two VA physicians as potential speakers: Dr. Nicholas Giori has an innovative approach to medical device registry outcome monitoring of orthopedic joint replacements, and Dr. Stephen Waldo who leads VA CART-CL (heart catheterizations- stents) where they have advanced to RTLS implant tracking and EHR integration for stent and cardiac device implants in the EP labs.

Thanks,

Bruce

---

Hi Everyone!

Great conversation yesterday morning. Attached is the draft agenda, “Track changes enabled”. Please do revise and add to it, and circulate your additions to the whole group. All your efforts are greatly appreciated!

-SreyRam

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  SreyRam.Kuy@va.gov
- [Redacted]@va.gov
Hi team,

In preparation for our weekly call tomorrow, here are a few reminders from last week’s action items.

1. Fill in the 3rd page of the agenda (agenda attached) with list of attendees/groups invited to the symposium—**Everyone**
2. Contact speakers for the title, topic, and content of their presentation (needed to ensure appropriate topics and no redundancy)—**Everyone**
3. Send us contact information for the speakers so we can coordinate a call with them all prior to the event—**Everyone**
4. Create a draft to operationalize the “formal and structured interaction between attendees”—**Everyone**
   a. Add this to the agenda draft—**Danica**
5. Create a draft to operationalize the “smaller discussion groups between or after the topic focused presentations”—**Danica**
   a. Add this to the agenda draft—**Everyone**
6. Edit agenda with track changes—**Everyone**

Thanks again everyone for all your hard work! Looking forward to our call tomorrow. Let us know if you have any questions.

All the best,

SreyRam and [Signature]
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  SreyRam.Kuy@va.gov
- [Redacted]
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List of Symposium Attendees/Groups:

<table>
<thead>
<tr>
<th>Name</th>
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For item 4 in the agenda, following is a draft plan for involving attendees actively in the summit. This plan follows from the meeting aims (stated in my own words):

- **Aim 1** is to unveil, learn about and discuss the VA national device registry plan
- **Aim 2** is to leverage the VA experience in the development and spread of other device registries

To accomplish both of these aims, we’ll need a systematic approach for identifying key stakeholder communities and finding a way to meaningfully involve them in the meeting.

**Identifying the stakeholder communities who can advance meeting aims.** If we want to keep the list of stakeholder communities contained for now, we could focus on the bolded groups that have already been mentioned during our planning calls. If this is the right list of stakeholder communities, the next step is to extend invitations to flesh each community out:

1. **The actors** – the developers of device registries in other settings. These include AAOS, ECRI, DCRI, and others
2. **Other stakeholders** – those whose decision-making depends on registries, including:
   - Policymakers who use registry data in regulatory decisions
   - Payers who use registry data in coverage determinations
   - Patient communities (GHLF, PPRNs, others) who use registries with patient-centered data to report and track health data and use it to plan care
   - Industry associations or representatives (Advamed, J&J, DePuy, others) who will increasingly use registries with RWD in device development
   - Clinicians who use registry-based evidence in clinical decision making
   - Researchers who use registries to produce new evidence
   - (and others)

**Involving actors and stakeholders meaningfully.** We need a quick plan that will not cost a lot of time and resources to organize. The most effective approach will be to structure stakeholder listening sessions that are aligned with the meeting agenda.

1. Danica is redrafting the agenda to group speaker sessions in some way. Presumably, this will give some shape to the two aims. I proposed to organize stakeholder listening sessions around aim 2 and related topics: how we leverage the VA experience in the development of device registries nationally.
2. The listening sessions should form a major part of any report and action plan that comes out of the summit. This is what will make the summit reflective of multi-stakeholder views and not just of the organizing committee.
3. We should allow for pre-meeting feedback from stakeholder representatives on the draft of the agenda, listening sessions, and proposed reporting and action plan.
From: "SreyRam (Atlas Research)" <va.gov>
Date: Tuesday, April 17, 2018 at 5:36 PM

Subject: Medical Device Registry Summit - Action Items

Hi team,

In preparation for our weekly call tomorrow, here are a few reminders from last week's action items.

1. Fill in the 3rd page of the agenda (agenda attached) with list of attendees/groups invited to the symposium—Everyone
2. Contact speakers for the title, topic, and content of their presentation (needed to ensure appropriate topics and no redundancy)—Everyone
3. Send us contact information for the speakers so we can coordinate a call with them all prior to the event—Everyone
4. Create a draft to operationalize the “formal and structured interaction between attendees”—
   a. Add this to the agenda draft—Danica
5. Create a draft to operationalize the “smaller discussion groups between or after the topic focused presentations”—Danica
   a. Add this to the agenda draft—Danica
6. Edit agenda with track changes—Everyone

Thanks again everyone for all your hard work! Looking forward to our call tomorrow. Let us know if you have any questions.

All the best,

SreyRam and
thanks for sharing!
great job with keeping us on track!
Danica, thanks for sending suggestions!

Sharing with everyone Danica’s great suggestions, attached.
Looking forward to hearing everyone’s great input tomorrow! - SreyRam

---

From: Marinac-Dabic, Danica [mailto: fda.hhs.gov]
Sent: Tuesday, April 17, 2018 5:03 PM
To: Kuy, SreyRam (HOU)
Subject: [EXTERNAL] Medical Device Registry Summit - 1 pager (005)DMD.docx

Dear SreyRam,
For your consideration I’ve attached my suggested revisions to the June 4th Medical Device Registry Summit Program. I look forward to tomorrow’s discussion.
Best,
Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/Room B-13
Silver Spring MD 20993; (301)796-1000

Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhccustomerservice?O=600&D=640&B=641&E=&S=E;
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230

Welcome and Introductions of Participants and Organizations- SreyRam Kuy

Session 1: Keynote Address: Leveraging the Medical Device Ecosystem
Rachael Fleurence PhD, Executive Director, National Evaluation System for Health Technologies (NEST)

Roundtable Discussion with Key Agency Leadership
Moderator: SreyRam Kuy, MD, PhD
✓ Department of Veterans Affairs, SreyRam Kuy, MD (possible comments by Chief of Staff Peter O’Rourke TBD)
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD
✓ CMS leadership (TBD)
✓ NIH Leadership (TBD) - Mike Lauer, MD
✓ CDC
✓ AHRQ
✓ HHS

Session 2. VA Landscape
Moderator: TBD
✓ Current Cardiac Device Monitoring in the VA
  • Merrit H. Raitt, MD (TBD)
    Director, National Cardiac Device Surveillance Program, Veterans Health Affairs
✓ Current VA Medical Device Registries in Place - Maximo
  • Office of Healthcare Technology Management, Veterans Health Affairs
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD
    VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion:
Session 3. Value of Registries for Partners/Stakeholders
Moderator: Titan Spine
- Enabling Patient Participation in Device Registries”, Harlan Krumholtz, MD, Yale
- Professional societies perspective – ACC/AOAS
- Hospital/system perspective - Kaiser
- Industry perspective – AdvaMed/MDMA
- Payer perspective- Blue Cross/CMS

Panel Discussion:

Session 4. Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health
- UDI implementation – Terrie Reed, FDA
- Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic
- Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell
- Methodology innovations – PhD – Medtronic
- Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH
- ONC- led efforts -TBD

Panel Discussion:

Session 5. Partnership Efforts/Sustainability Considerations
Moderator: Bruce Moscowitz, MD, BREF
- Return of Investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD
- FDA/CDRH
- PCORTF harmonization efforts - PhD, OS/ASPE
- Leveraging existing national informatics/standards efforts -

Panel Discussion:

Closing Remarks and Outline Key Next Steps
- “Pulling it All Together: Next Steps Working with Our Partners”
  - Carolyn Clancy, MD or Chris Vojta, MD, USH or PDUSH for VHA
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:
- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:
- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [Redacted]@va.gov
Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 4/25/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767- Code

Danica, Bruce, and I are having a call this afternoon to try to finalize the speaker schedule, and as soon as that’s done, will forward on to you all.

Thank you so much for all your efforts!

Warmly,
SreyRam

Senior Advisor
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875

SreyRam Kuy, MD, MHS, FACS

Senior Advisor to the PDUSH
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Dear Colleagues,

Wonderful discussion this morning! Thank you for everyone’s input & support, whether by phone or email or otherwise. I appreciate all your efforts!

Next steps and deliverables:
Danica — could you add the final closing panel (VA/FDA/Others) to the agenda
Bruce McIntosh/Danica (and anyone else) — could you add a patient perspective/speaker to the agenda
Everyone — could you please send a list of attendees to invite (see attached prelim, draft list)

Could I ask you to send to me this by end of tomorrow, Thursday 4/25/2018? Would like to get things the list of attendees vetted by our leadership, the agenda sent to communications, and the final list of speakers to invite for a planning conference call.

Thank you so very much!!!

-SreyRam

SreyRam Kuy, MD, MHS, FACS

From: Kuy, SreyRam (HOU)
Sent: Tuesday, April 24, 2018 4:07 PM
To: GHLF’; ‘Bruce Moskowitz’; ‘Aaron Moskowitz’; ‘Thomas Concannon’; McIntosh, Bruce (NCPS); (Atlas Research); ‘Marinac-Dabic, Danica’; ‘Hayes-Byrd, Jacquelyn’;
Subject: Medical Device Registry Summit - Planning Meeting 4/25/2018; Conference call line: 800-767- Code

Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

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Thank you so much for all your efforts!

Warmly,
SreyRam

Senior Advisor
Veterans Health Administration

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Quality, Safety & Value
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810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875

SreyRam Kuy, MD, MHS, FACS

Senior Advisor to the PDUSH
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1022
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Implant Registry Summit
DRAFT list of invitees
Date: June 4, 2018

This is a pre-decisional, working draft intended only for internal VA use

Invitees

Societies
AAMI
AORN
ECRI
American Academy of Orthopaedic Surgeons
Orthopedic Network News
Society for Vascular Surgery
The American Association for Vascular Surgery
American College of Surgeons
The American Society of General Surgeons
American Dental Association

VA
Acting USH/Executive in Charge
PDUSH
Acting ADUSH QSV: Dr. Saurabha Bhatnagar
Acting DUSH OE: Dr. Gerard Cox
ADUSH Operations Management: Dr. Steve Young
ADUSH Administrative Operations: Dr. Tammy Czarnecki
Deputy Chief Patient Care Services: Dr. Lucille Beck
National Surgery Office: Dr. William Gunnar
Office of Dentistry: Dr.
Office of Reproductive Health in Women’s Health: Dr.
of Gastroenterology: Dr.
Cardiology: Dr.
Ophthalmology: Dr.
National Program Office for Sterile Processing: Ms.
Prosthetic and Sensory Aids Service: Ms.
Procurement and Logistics Service: Mr.
NCPS: Ms. and Ms.
Salt Lake City VAMC: Mr.

Medical Device Companies
Abbot Laboratories
Academy Medical LLC
AMO Sales and Services
AvKare
Biotronik
Boston Scientific
Buffalo Supply
Depuy Synthes Joint Reconstruction
Depuy Synthes Spine
Depuy Synthes Trauma
Encore
Endologix
Howmedica
Medtronic USA
Nuvasive
Smith & Nephew
St. Jude Medical
Zimmer
Medical Implant Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230
8:30 – 4:00

8:30 Welcome and Introductions of Participants and Organizations-
SreyRam Kuy, MD

8:45 – 10:00 Session 1: Value for Stakeholders
Objective: To describe value of registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Needs
TBA – VA patient

Leveraging the Medical Device Ecosystem
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)

Value Roundtable Discussion
Moderator: SreyRam Kuy, MD, PhD
✓ Department of Veterans Affairs, SreyRam Kuy, MD (possible comments by Chief of Staff Peter O’Rourke TBD)
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD/ Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS leadership (TBD)
✓ Professional societies perspective – AMA – Kathy Blake
✓ Hospital/system perspective - Kaiser
✓ Industry perspective – AdvaMed/MDMA

10:00 – 11:30 Session 2. VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future
Panel Discussion:

Lunch: 11:30 – 12:30

12:30 – 2:00 Session 3. Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

- ONC Efforts - TBD
- UDI implementation efforts – Terrie Reed, FDA
- Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell
- Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH
- Patient-enabled evidence generation - Harlan Krumholz, MD, Yale
- Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic

Panel Discussion:

2:00 – 3:15 Session 4. From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Bruce Moscowitz, MD, BREF
Objective: Begin development of the framework for VA registry development

Panel: Jack Cronenwett, MD, Art Sedrakyan, MD; PhD, Mike Lauer, MD, PhD,

✓ Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S
✓ How to build in the sustainability: Return of Investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD FDA/CDRH
✓ Quality Management opportunities and compliance with standards – TBD
✓ Privacy/Ethics issues – TBD

Panel Discussion:

3:15 –4:00

Closing Remarks and Outline Key Next Steps
✓ “Pulling it All Together: Next Steps Working with Our Partners”
  • VHA Leadership
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:
- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:
- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [redacted]@va.gov
Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

**Medical Device Registry Summit - Planning Call**
Wednesday mornings 7:30 am – 8:00 am Eastern
Conference call line: 800-767- Code

Again, many apologies to our west coast colleagues for the very early time.

Attached is the program, a sample invitation letter with one pager, and a preliminary invitee list. Please feel free to add to the invitee list, edit the program and the invite letter, and share with us all.

Thank you so very much for ALL your hard work and efforts around this summit!

Warmly,
SreyRam

SreyRam Kuy, MD, MHS, FACS
Special Advisor
Office of the Secretary
Department of Veterans Affairs

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1022
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Implant Registry Summit
DRAFT list of invitees
Date: June 4, 2018

This is a pre-decisional, working draft intended only for internal VA use

Invitees

Societies
AAMI
AORN
ECRI
American Academy of Orthopaedic Surgeons
Orthopedic Network News
Society for Vascular Surgery
The American Association for Vascular Surgery
American College of Surgeons
The American Society of General Surgeons
American Dental Association
AMA – Kathy Blake

Agencies
Department of Veterans Affairs Leadership
Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
CMS Leadership
DOD Leadership
HHS Leadership

Health Systems
Kaiser -

VA
COS Mr. Peter O’Rourke
Deputy COS Ms. Jacquelyn Hayes-Byrd
Acting USH/Executive in Charge
PDUSH
Acting ADUSH QSV: Dr. Saurabha Bhatnagar
Acting DUSH OE: Dr. Gerard Cox
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National Surgery Office: Dr. William Gunnar
Office of Dentistry: Dr. 

of Reproductive Health in Women’s Health: Dr.
of Gastroenterology: Dr.
of Cardiology: Dr.
of Ophthalmology: Dr. and Dr.
National Program Office for Sterile Processing: Ms.
Prosthetic and Sensory Aids Service: Ms. and Mr.
Procurement and Logistics Service: Mr. and Mr.
NCPS: Ms. and Ms.
Salt Lake City VAMC: Mr.
VA Office of Healthcare Technology Management
Merrit H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health
Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety

FDA
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)
Terrie Reed, FDA
Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH
Vahan Simonyan, PhD (FDA)
Greg Pappas, MD, PhD FDA/CDRH

Medical Device Companies
Abbot Laboratories
Academy Medical LLC
AMO Sales and Services
AvKare
Biotronk
Boston Scientific
Buffalo Supply
Depuy Synthes Joint Reconstruction
Depuy Synthes Spine
Depuy Synthes Trauma
Encore
Endologix
Howmedica
Medtronic USA
Nuvasive
Smith & Nephew
St. Jude Medical
Zimmer
AdvaMed/MDMA

Others:
John Rumsfeld, MD (ACC)
Art Sedrakyan, MD, PhD, Cornell/MDEpiNet
Harlan Krumholz, MD, Yale
Fred Resnic, MD, Lahey Clinic
Jack Cronenwett, MD, Dartmouth, M2S
Rob Portman
Mike Lauer, MD (NIH)
Elise Berliner (AHRQ)
Thomas Concannon
EHR Vendor
DOD Representative for Session 2 panel
ONC Representative for Session 3 panel
May 1, 2018
From: SreyRam Kuy, MD
To: ----
Subj: Medical Implant Registry Summit

Dear Colleagues

The Department of Veterans Affairs is convening leaders to host a national healthcare summit on “Medical Implants Registry”. VA is partnering with sister agencies to ensure patient safety and implement the largest health system medical implant tracking program in the country.

We would like to respectfully invite you to participate in this national “Medical Implants Registry Summit”. The summit will be held on June 4, 2018 at the VA auditorium.

Medical Implant Registry Summit
Date: Monday, June 4, 2018
Location: VA Auditorium, room 230
Leadership Panel: 8:30 am - 4:30 pm

Attached is a one pager briefing on medical implant registry systems, and a draft of the “Medical Implant Registry Summit” program.

Warmly,

SreyRam Kuy, MD
Special Advisor
Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
A VA Medical Implant Registry: Why it Matters

The Vision
 ✓ A nationwide Implant Registry that enables VA to monitor the safety of implants in our veterans, track quality metrics and ensure the best possible care for VA patients

Current surveillance of medical implants is piecemeal
 ✓ Adverse Event Reports: mandatory for manufacturers & hospitals, but incomplete clinical data
 ✓ Insurance Claims data – lack clinical details
 ✓ Clinical Registries - operated by various groups & societies but not linked to VA’s Electronic Medical Records

Does VA need an Implant Registry?
 ✓ Yes!
   • Needed to monitor patient safety
   • Needed for recall of faulty medical implants
   • Needed to measure quality & compare outcomes of implants

Why is an Implant Registry important to the VA?
 ✓ A medical implant registry will:
   • Allow us to notify patients about safety recalls
   • Allows us to identify the exact device when patient shows up in ER with complications
   • Allows us to track clinical follow-up

What makes an Implant Registry effective for the VA?
 ✓ An effective medical implant registry will:
   • Link with the VA’s Electronic Medical Record to facilitate rapid identification
   • Easily accessible for VA clinicians, and from any VA medical center the veteran presents at
   • UDI barcode input automated (manual entry raises risk of error & patient safety)
   • Tracks both medical devices and biological implants (pending legislation will require VA to track biological implants)
   • Monitors veterans from the pre-registry era (comprises the majority of implants needing surveillance)
   • Implementable in the short-term via VA’s CPRS and VistA, and able to interface with Cerner in the long term

Collaboration
 ✓ As VA develops the nations’ largest implant registry, we welcome opportunities to collaborate with our sister agencies & the medical community in novel partnerships that advance this vision.

Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs

SreyRam.Kuy@va.gov
(713) 503-4274

Confidential - Working DRAFT, Informational Only, Pre-Decisional – VA Internal Use Only
Medical Implant Registry Summit

Date: June 4, 2018
Location: VA Auditorium
8:30 – 4:30 pm

8:30 Welcome and Introductions of Participants and Organizations
SreyRam Kuy, MD

8:45 – 10:00 Session 1: Value for Stakeholders
Objective: To describe value of medical implant registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Needs (15 min)
TBA – Patient perspectives

Leveraging the Medical Device Ecosystem (15 min)
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST) invited/available

Value Roundtable Discussion
Moderator: SreyRam Kuy, MD
✓ Department of Veterans Affairs Leadership
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS Leadership - TBD
✓ DOD Leadership - TBD
✓ HHS Leadership - TBD
✓ Professional societies perspective – AMA – Kathy Blake
✓ Hospital/system perspective - [Redacted] Kaiser
✓ Industry perspective – AdvaMed/MDMA
10:00 – 11:30 Session 2. VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future

Moderator: TBD
✓ Current Cardiac Device Monitoring in the VA
  • Merrit H. Raitt, MD
    Director, National Cardiac Device Surveillance Program, Veterans Health Affairs
✓ Current VA Medical Device Registries - Maximo
  • Presenter TBD, VA Office of Healthcare Technology Management
✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  • Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
✓ Medical Device Tracking in Cardiology: The integration of RTLS into CART-CL
  • Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD
    VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + MD (VA, Vanderbilt) and John Rumsfeld, MD (ACC) + EHR Vendor + DOD Representative

Lunch Break: 11:30 – 12:30

12:30 – 2:00 Session 3. Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

✓ ONC Efforts - TBD (10 min)
✓ UDI implementation efforts – Terrie Reed, FDA (10 min) – invited/available
✓ Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell/MDEpiNet (10 min) – invited/available
✓ Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH (10 min)
Patient-enabled evidence generation - Harlan Krumholz, MD, Yale (10 min) – invited/available
Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic (10 min) - invited/available

Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA) (invited/available),

2:00 – 3:15 Session 4. From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: TBD

Objective: Begin development of the framework for VA registry development

✓ Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S (10 min)
✓ How to build in the sustainability: Return of investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD FDA/CDRH (10 min)
✓ Quality Management opportunities and compliance with standards – (10 min)
✓ Privacy/Ethics issues –Rob Portman (10 min) JD

Panel Discussion: Speakers + Mike Lauer, MD (NIH), Elise Berliner (AHRQ)

3:15 –4:30
Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh - VA
Kaiser Permanente - NJRR
Art Sedrakyan – Weill Cornell Medical College
Danica Marinac-Dabic, MD, PhD - FDA
Rachael Fleurence, PhD – NESTcc
Patient (TBD)

Closing Remarks
• VA Leadership
Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 3/21/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767-4600  Code=  

We’ve made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda and a slate of speakers. Several fantastic subject matter experts on board to participate!

Attached is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

Again, many apologies to our west coast colleagues for the very early time.

Thank you so much for all your efforts!

Warmly,
SreyRam

Special Advisor
Office of the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center
810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-303-4274
Office: 202-461-4875
Medical Implant Registry Summit
DRAFT list of invitees
Date of Summit: June 4, 2018

This is a pre-decisional, working draft intended only for internal VA use

*These are planned invitees – they have not yet confirmed attendance, and may send a representative in their place.

Invitees*

Agencies
Department of Veterans Affairs Leadership
Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director,
Center for Devices and Radiological Health
FDA Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and
Radiological Health
CMS Administrator Seema Verma (tentative) or representative
HHS Secretary Alex Azar (tentative) or representative
DoD Secretary James Mattis or representative (tentative)

VA employees
COS Mr. Peter O’Rourke
Deputy COS Ms. Jacquelyn Hayes-Byrd
Secretary Wilkie (tentative) or Deputy Secretary Bowman (tentative)
Acting USH/Executive in Charge
PDUSH
Acting ADUSH QSV: Dr. Saurabha Bhatnagar
Acting DUSH OE: Dr. Gerard Cox
ADUSH Operations Management: Dr. Steve Young
ADUSH Administrative Operations: Dr. Tammy Czarnecki
Deputy Chief Patient Care Services: Dr. Lucille Beck
National Surgery Office: Dr. William Gunnar
Office of Dentistry: Dr.
Office of Reproductive Health in Women’s Health: Dr.
Office of Gastroenterology: Dr.
Cardiology: Dr.
Ophthalmology: Dr. and Dr.
National Program Office for Sterile Processing: Ms.
Prosthetic and Sensory Aids Service: Ms. and Mr.
Procurement and Logistics Service: Mr. and Mr.
NCPS: Ms. and Ms.
Salt Lake City VAMC: Mr. VA Office of Healthcare Technology Management
Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health
Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety
MD, VA, Vanderbilt

FDA
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)
Terrie Reed, FDA
Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH
Vahan Simonyan, PhD (FDA)
Greg Pappas, MD, PhD FDA/CDRH

Others:
John Rumsfeld, MD (ACC)
Art Sedrakyan, MD, PhD, Cornell/MDEpiNet
Harlan Krumholz, MD, Yale
Fred Resnic, MD, Lahey Clinic
Jack Cronenwett, MD, Dartmouth, M2S
Rob Portman
Mike Lauer, MD (NIH) AHRQ representative
PhD
Thomas Concannon PEW Trust

EHR Vendor
DOD Representative for Session 2 panel
ONC Representative for Session 3 panel - Donald Rucker, MD
Kristy Mitchel - Avalere
Christine Stake - Ann & Robert H. Lurie Children’s Hospital of Chicago
Societies/Nonprofits
Association for the Advancement of Medical Instrumentation (AAMI) leadership
- PhD
- FHIIMSS
- PhD
Association of peri-Operative Registered Nurses (AORN)
- MSHA, RN, CNOR, CSSM
- MHA, RN-BC, CNOR, CSSM
- MSN, RN, CNOR
- MSN, MBA, RN, ACNS-BC, CNS-CP, CNOR
Emergency Care Research Institute (ECRI)
- MD, PhD
- MS
American Academy of Orthopaedic Surgeons (AAOS)
- MD
- MD
- III MD
American College of Cardiology
- MD, FACC
- MD, FACC
- Jr., MD, MBA, FACC
- MD, FACC
American Association of Neurological Surgeons
- MD, PhD, FAANS, FACS
- MD, FAANS
- MD, MPH, FAANS, FACS
- MD, FAANS
American Neurological Association
- PhD, MS
- MD
Society for Vascular Surgery
- III, MD
- MD
American College of Surgeons
American Dental Association
- MD, DDS
- MD

AMA
- MD, MHA
- MD

Kathy Blake

AcademyHealth
- Dr.

Association for Healthcare Resources and Materials Management (AHRMM)
- Senior Supply Chain (aha.org)

Cognitive Health
- Julia Skapik, MD, PhD

Pew Charitable Trust
- MD

Henry J. Kaiser Family Foundation

Medical Device Companies (Tentative – pending OGC and ethics approval, would send invite to their government affairs contact)
- Abbot Laboratories
- Academy Medical LLC
- AMO Sales and Services
- AvKare
- Biotronik
- Boston Scientific
- Buffalo Supply
- Depuy Synthes Joint Reconstruction
- Depuy Synthes Spine
- Depuy Synthes Trauma
- Encore
- Endologix
- Howmedica
- Medtronic USA
Medical Device Registry Summit

VA Auditorium Room 230
810 Vermont Avenue, NW
Washington, DC 20420

June 4, 2018
8:30 a.m. – 4:30 p.m.

8:30 a.m. Welcome and Introductions of Participants and Organizations SreyRam Kuy, MD

8:45 a.m. – 10 a.m. Session 1: Value for Stakeholders
Objective: To describe value of medical device registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Perspective (10 min)
Christine Stake

Leveraging the Medical Device Ecosystem (15 min)
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)

Value Roundtable Discussion
Moderator: SreyRam Kuy, MD
✓ VA Secretary or Deputy Secretary
✓ FDA Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS Administrator Seema Verma (tentative)
✓ HHS Secretary Alex Azar (tentative) or representative
✓ DoD Secretary James Mattis or representative (tentative)
✓ Professional societies perspective – AMA – Cathy Blake

10 a.m. – 11:30 a.m. Session 2: VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future
Moderator: TBD
✓ Current Cardiac Device Monitoring in the VA
  • Merritt H. Raitt, MD
    Director, National Cardiac Device Surveillance Program, Veterans Health Affairs
✓ Current VA Medical Device Registries - Maximo
  • Presenter TBD
    VA Office of Healthcare Technology Management
✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  • Nicholas Giori, MD, PhD
    Chief of Orthopedic Surgery, VA Palo Alto Health Care System
✓ Medical Device Tracking in Cardiology: The integration of RTLS into CART-CL
  • Stephen Waldo, MD (or Paul Varosy, MD)
    Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD
    VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + MD (VA, Vanderbilt) and John Rumsfeld, MD (ACC) + EHR Vendor + DOD Representative

11:30 a.m. – 12:30 p.m. Lunch Break

12:30 p.m. – 2 p.m. Session 3: Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

✓ ONC Efforts – Don Rucker (10 min)
✓ UDI implementation efforts – Terrie Reed, FDA (10 min) – invited/available
✓ Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell/MDEpiNet (10 min) – invited/available
✓ Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH (10 min)
✓ Patient-enabled evidence generation - Harlan Krumholz, MD, Yale (10 min) – invited/available
✓ Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic (10 min) - invited/available
Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA) (invited/available),

2 p.m. – 3:15 p.m. Session 4: From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: TBD

Objective: Begin development of the framework for VA registry development

✓ Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S (10 min)
✓ How to build in the sustainability: Return of Investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD FDA/CDRH (10 min)
✓ Quality Management opportunities and compliance with standards – (10 min)
✓ Privacy/Ethics issues – Rob Portman, JD (10 min)

Panel Discussion: Speakers + Mike Lauer, MD (NIH), Elise Berliner (AHRQ), Julia Skapik, Cognitive Health (invited and available), Kristy Mitchel (Avalere)

3:15 p.m. – 4:30 p.m. Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh – VA
Kaiser Permanente – NJRR
Art Sedrakyan – Weill Cornell Medical College
Danica Marinac-Dabic, MD, PhD – FDA
Rachael Fleurence, PhD – NESTcc
Patient (TBD)

Closing Remarks
• VA Leadership

Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
The latest round of revisions.

1. [Redacted] from Kaiser – has a last minute conflict and I removed her – but she definitely wants to help with the effort in the next phase.
2. Added Julia Skapik, MD, PhD to the Panel (former ONC, currently with Cognitive Health)
3. Added Kristy Mitchel to the Panel – formerly ACC now Avalere
4. Still waiting to hear from [Redacted]
5. Still waiting to hear from AHRQ

Several people requested the agenda. Are we finalizing tomorrow?

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-
Silver Spring MD 20993; (301)796-

Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhccustomerservice?O=600&D=640&B=641&E=&S=E:

-----Original Appointment-----
From: Kuy, SreyRam (HOU) [mailto:SreyRam.Kuy@va.gov]
Sent: Tuesday, March 20, 2018 4:06 PM
To: Kuy, SreyRam (HOU); GHLF; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); (Atlas Research); Marinac-Dabic, Danica; Hayes-Byrd, Jacquelyn;
Subject: Medical Device Registry Summit - Planning Meeting
When: Wednesday, May 09, 2018 7:30 AM-8:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Conference call line: 800-767- [Redacted] Code [Redacted]
Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 3/21/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767- [redacted] Code [redacted]

We’ve made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda, with locations, possible time and a slate of speakers. Several fantastic subject matter experts on board to participate! This is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

Again, many apologies to our west coast colleagues for the very early time.

Thank you so much for all your efforts!

Warmly,
SreyRam

Special Advisor to the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875

<< File: Medical Device Registry Summit - 1 pager.docx >> << File: Medical Device Registry Summit - 1 pager.pdf >>
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230
8:30 – 4:30

8:30 Welcome and Introductions of Participants and Organizations-
SreyRam Kuy, MD, PhD

8:45 – 10:00 Session 1: Value of Registries for Stakeholders
Objective: To describe value of registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Needs (15 min)
TBA – VA patient

Leveraging Medical Device Ecosystem (15 min)
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NESTcc) - invited/available

Value Roundtable Discussion (45 min)
Moderator: SreyRam Kuy, MD, PhD
✓ Department of Veterans Affairs, SreyRam Kuy, MD (possible comments by Chief of Staff Peter O’Rourke TBD)
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS leadership (TBD)
✓ Professional societies perspective – AMA – Cathy Blake (invited and available)
✓ Hospital/system perspective – Kaiser
✓ Industry perspective – AdvaMed/MDMA (invited)
✓ ONC – Don Rucker

10:00 – 11:30 Session 2. VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future
Moderator: TBD
✓ Current Cardiac Device Monitoring in the VA
  • Merritt H. Raitt, MD
    Director, VA National Cardiac Device Surveillance Program
✓ Current VA Medical Device Registries - Maximo
  • Presenter TBD
    VA Office of Healthcare Technology Management
✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  • Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
✓ Medical Device Tracking in Cardiology: The integration of RTLS into CART-CL
  • Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD
    VA National Manager, National Center for Patient Safety

Panel Discussion: Speakers + MD (VA, Vanderbilt)

Lunch: 11:30 – 12:30

12:30 – 2:00 Session 3. Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

✓ UDI implementation efforts – Terrie Reed, FDA (10 min) – invited/available
✓ Harmonization Efforts with National/International Registries and Consortia- Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH (10 min) - invited/available
✓ Patient -enabled evidence generation - Harlan Krumholz, MD, Yale (10 min) – invited/available
✓ Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic (10 min) - invited/available

Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA) (invited/available),
2:00 – 3:15  Session 4. From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Bruce Moscowitz, MD, BREF

Objective: Begin development of the framework for VA registry development

- Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S (10 min) – invited/available
- Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources – Art Sedrakyan, MD, PhD, Cornell/MDEpiNet (10 min) – invited/available
- How to build in the sustainability: Return of investment (ROI) Multi-stakeholder Analysis – Greg Pappas, MD, PhD FDA/CDRH (10 min) – invited/available
- Quality Management opportunities and compliance with standards – invited/available (10 min) – invited/available
- Privacy/Ethics issues – Rob Portman (10 min) JD

Panel Discussion: Speakers + Julia Skapik, Cognitive Health (invited and available), Kristy Mitchel (Avalere) - invited and available

3:15 – 4:30

Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh - VA – invited/available
Art Sedrakyan – Weill Cornell Medical College – invited/available
Danica Marinac-Dabic, MD, PhD – FDA – invited/available
Rachael Fleurence, PhD – NESTcc – invited available
Bruce Moscowitz, MD – BREF – invited/available
Patient representative
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:

• Department of Veterans Affairs
• US Food and Drug Administration
• Biomedical Research and Education Foundation
• Global Healthy Living Foundation
• RAND Corporation

Contacts:

• SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
• [Redacted]@va.gov
Hi all,

I added the name of our patient speaker, Christine Stake, to the attached program. We are working with Chris on her comments so we can share them in the coming week. Since she’s probably not known to everyone, here’s her bio:

Chris has been a patient, caregiver and researcher for hip replacement. She is passionate about making sure that clinical decision making is a shared process between patients and health professionals and is particularly interested in health decision making at all ages due to her experience as a young person requiring joint replacement. She’s especially concerned about medical device safety and tracking, given that younger people may need revision surgery due to the early age of initial joint replacement. It’s important to her that the factors most important to patients, such as quality of life, are prioritized in both clinical care and research. Chris is currently employed at Ann & Robert H. Lurie Children’s Hospital of Chicago as the Research Operations Manager for Neuroscientific Aspects of Pain. She also serves as a Patient Governor for the ArthritisPower patient research registry and app (www.ArthritisPower.org).

Hi all,

I added the name of our patient speaker, Christine Stake, to the attached program. We are working with Chris on her comments so we can share them in the coming week. Since she’s probably not known to everyone, here’s her bio:

Chris has been a patient, caregiver and researcher for hip replacement. She is passionate about making sure that clinical decision making is a shared process between patients and health professionals and is particularly interested in health decision making at all ages due to her experience as a young person requiring joint replacement. She’s especially concerned about medical device safety and tracking, given that younger people may need revision surgery due to the early age of initial joint replacement. It’s important to her that the factors most important to patients, such as quality of life, are prioritized in both clinical care and research. Chris is currently employed at Ann & Robert H. Lurie Children’s Hospital of Chicago as the Research Operations Manager for Neuroscientific Aspects of Pain. She also serves as a Patient Governor for the ArthritisPower patient research registry and app (www.ArthritisPower.org).
Sending updated Program with the names of confirmed speakers THIS MORNING. AHRQ is sending another speaker — as Elise Berliner has a conflict. Stay tuned.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-I.
Silver Spring MD 20993; (301)796-4311

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-----Original Appointment-----

From: Kuy, SreyRam (HOU) [mailto:SreyRam.Kuy@va.gov]
Sent: Tuesday, March 20, 2018 4:06 PM
To: Kuy, SreyRam (HOU); GHLF; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); Marinac-Dabic, Danica; Hayes-Byrd, Jacquelyn; va.gov

Subject: Medical Device Registry Summit - Planning Meeting

When: Wednesday, May 09, 2018 7:30 AM-8:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Conference call line: 800-767- Code

Dear colleagues,

In preparation for our weekly Wednesday morning call, here's the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 3/21/2018 7:30 am – 8:00 am Eastern
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We’ve made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda, with locations, possible time and a slate of speakers. Several fantastic subject matter experts on board to participate! This is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

Again, many apologies to our west coast colleagues for the very early time.
Thank you so much for all your efforts!

Warmly,
SreyRam

Special Advisor to the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230
8:30 – 4:30

8:30 Welcome and Introductions of Participants and Organizations-
SreyRam Kuy, MD, PhD

8:45 – 10:00 Session 1: Value of Registries for Stakeholders
Objective: To describe value of registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Needs (15 min)
Christine Stake, PhD, MA, Hip Replacement Patient
Global Healthy Living Foundation, ArthritisPower Patient Powered Research Network

Leveraging Medical Device Ecosystem (15 min)
Rachael Fleurence PhD, Executive Director, National Evaluation System for Health Technologies (NESTcc) - invited/available

Value Roundtable Discussion (45min)
Moderator: SreyRam Kuy, MD, PhD
✓ Department of Veterans Affairs, SreyRam Kuy, MD (possible comments by Chief of Staff Peter O’Rourke TBD)
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS leadership (TBD)
✓ Professional societies perspective – AMA – Cathy Blake (invited and available)
✓ Hospital/system perspective – Kaiser
✓ Industry perspective – AdvaMed/MDMA (invited)
✓ ONC – Don Rucker

10:00 – 11:30 Session 2. VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future
Moderator: TBD

✓ Current Cardiac Device Monitoring in the VA
  • Merritt H. Raitt, MD
    Director, VA National Cardiac Device Surveillance Program

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  • Presenter TBD
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Panel Discussion: Speakers: Merritt H. Raitt, MD (VA, Vanderbilt) and John Rumsfeld, MD (ACC) + EHR Vendor + DOD Representative

Lunch: 11:30 – 12:30

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Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

✓ ONC Efforts - TBD (10 min) –
✓ UDI implementation efforts – Terrie Reed, FDA (10 min) – invited/available
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Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA) (invited/available),

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Moderator: Bruce Moscowitz, MD, BREF

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- Who should be at the table: What can we learn from VQI?—Jack Cronenwett, MD, Dartmouth, M2S (10 min) – invited/available
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- Quality Management opportunities and compliance with standards— (10 min) – invited/available
- Privacy/Ethics issues –Rob Portman (10 min) JD

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3:15 – 4:30

Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh - VA
Kaiser Permanente - NJRR -
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Danica Marinac-Dabic, MD, PhD - FDA - invited/available
Rachael Fleurence, PhD – NESTcc
Bruce Moscowitz, MD – BREF
Patient
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

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Current Participating Partners:

- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
Cathy Blake – confirmed; Jack Cronenwett - confirmed; Elsie Berliner – sending another person from AHRQ; still waiting for AdvaMed speaker and confirmation for [redacted] and ONC – speaker. I updated the agenda with the confirmed speakers (I called them invited/available). Sending further updates as I receive them.

Danica

-----Original Appointment-----

From: Kuy, SreyRam (HOU) [mailto:SreyRam.Kuy@va.gov]
Sent: Tuesday, March 20, 2018 4:06 PM
To: Kuy, SreyRam (HOU); [redacted] GHLF'; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); [redacted] Atlas Research; [redacted] Marinac-Dabic, Danica; [redacted] Hayes-Byrd, Jacquelyn;
Cc: [redacted]
Subject: Medical Device Registry Summit - Planning Meeting
When: Wednesday, May 02, 2018 11:30 AM-12:00 PM.
Where: Conference call line: 800-767-0383

Dear colleagues,

In preparation for our weekly Wednesday morning call, here's the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday mornings 7:30 am – 8:00 am Eastern
Conference call line: 800-767-## Code ##

Again, many apologies to our west coast colleagues for the very early time.

Thank you so very much for ALL your hard work and efforts around this summit!

Warmly,
SreyRam

SreyRam Kuy, MD, MHS, FACS
Special Advisor
Office of the Secretary
Department of Veterans Affairs

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1022
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230
8:30 – 4:30

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TBA – VA patient

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✓ CMS leadership (TBD)
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2:00 – 3:15 Session 4. From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Bruce Moscowitz, MD, BREF

Objective: Begin development of the framework for VA registry development

- Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S (10 min) – invited/available
- How to build in the sustainability: Return of Investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD FDA/CDRH (10 min) – invited/available
- Quality Management opportunities and compliance with standards – (10 min) – invited/available
- Privacy/Ethics issues – Rob Portman (10 min) JD

Panel Discussion: Speakers + Mike Lauer, MD (NIH), Elise Berliner (AHRQ)

3:15 – 4:30

Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh – VA
- Kaiser Permanente - NJRR -
- Art Sedrakyan – Weill Cornell Medical College- invited /available
- Danica Marinac-Dabic, MD, PhD - FDA - invited/available
- Rachael Fleurence, PhD – NESTcc
- Bruce Moscowitz, MD – BREF
- Patient
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:

- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
Subject: Medical Device Registry Summit - Planning Meeting
Location: Conference call line: 800-767-M Code [redacted]

Start: Wed 5/2/2018 7:30 AM
End: Wed 5/2/2018 8:00 AM
Show Time As: Tentative

Recurrence: Weekly
Recurrence Pattern: every Wednesday from 7:30 AM to 8:00 AM

Meeting Status: Not yet responded

Organizer: Kuy, SreyRam (HOU)
Required Attendees: GHLF; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); Marinac-Dabic, Danica; Hayes-Byrd, Jacquelyn;

Optional Attendees: [redacted]
Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday mornings 7:30 am – 8:00 am Eastern
Conference call line: 800-767- [ ] Code [ ]

Again, many apologies to our west coast colleagues for the very early time.

Thank you so very much for ALL your hard work and efforts around this summit!

Warmly,
SreyRam

SreyRam Kuy, MD, MHS, FACS
Special Advisor
Office of the Secretary
Department of Veterans Affairs

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1022
Washington, DC 20420
Medical Implant Registry Summit
DRAFT list of invitees
Date: June 4, 2018

This is a pre-decisional, working draft intended only for internal VA use

Invitees

Societies
AAMI
AORN
ECRI
American Academy of Orthopaedic Surgeons
Orthopedic Network News
Society for Vascular Surgery
The American Association for Vascular Surgery
American College of Surgeons
The American Society of General Surgeons
American Dental Association
AMA – Kathy Blake

Agencies
Department of Veterans Affairs Leadership
Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director,
Center for Devices and Radiological Health
CMS Leadership
DOD Leadership
HHS Leadership

Health Systems
Kaiser - [Redacted]

VA
COS Mr. Peter O’Rourke
Deputy COS Ms. Jacquelyn Hayes-Byrd
Acting USH/Executive in Charge
PDUSH
Acting ADUSH QSV: Dr. Saurabha Bhatnagar
Acting DUSH OE: Dr. Gerard Cox
ADUSH Operations Management: Dr. Steve Young
ADUSH Administrative Operations: Dr. Tammy Czarnecki
Deputy Chief Patient Care Services: Dr. Lucille Beck
National Surgery Office: Dr. William Gunnar
Office of Dentistry: Dr. [Redacted]
of Reproductive Health in Women's Health: Dr. [Redacted]
Gastroenterology: Dr. [Redacted]
Cardiology: Dr. [Redacted]
Ophthalmology: Dr. [Redacted] and Dr. [Redacted]
National Program Office for Sterile Processing: Ms. [Redacted] and Dr. [Redacted]
Prosthetic and Sensory Aids Service: Ms. [Redacted] and Mr. [Redacted]
Procurement and Logistics Service: Mr. [Redacted] and Mr. [Redacted]
NCPS: Ms. [Redacted] and Ms. [Redacted]
Salt Lake City VAMC: Mr. [Redacted]
VA Office of Healthcare Technology Management
Merrit H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health
Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety
MD, VA, Vanderbilt

FDA
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)
Terrie Reed, FDA
Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH
Vahan Simonyan, PhD (FDA)
Greg Pappas, MD, PhD FDA/CDRH

Medical Device Companies
Abbot Laboratories
Academy Medical LLC
AMO Sales and Services
AvKare
Biotronik
Boston Scientific
Buffalo Supply
Depuy Synthes Joint Reconstruction
Depuy Synthes Spine
Depuy Synthes Trauma
Encore
Endologix
Howmedica
Medtronic USA
Nuvasive
Smith & Nephew
St. Jude Medical
Zimmer
AdvaMed/MDMA

Others:
John Rumsfeld, MD (ACC)
Art Sedrakyan, MD, PhD, Cornell/MDEpiNet
Harlan Krumholz, MD, Yale
Fred Resnic, MD, Lahey Clinic
Jack Cronenwett, MD, Dartmouth, M2S
Rob Portman
Mike Lauer, MD (NIH)
Elise Berliner (AHRQ)
Thomas Concannon
EHR Vendor
DOD Representative for Session 2 panel
ONC Representative for Session 3 panel
May 1, 2018
From: SreyRam Kuy, MD
To: ----
Subj: Medical Implant Registry Summit

Dear Colleagues

The Department of Veterans Affairs is convening leaders to host a national healthcare summit on “Medical Implants Registry”. VA is partnering with sister agencies to ensure patient safety and implement the largest health system medical implant tracking program in the country.

We would like to respectfully invite you to participate in this national “Medical Implants Registry Summit”. The summit will be held on June 4, 2018 at in the VA auditorium.

Medical Implant Registry Summit
Date: Monday, June 4, 2018
Location: VA Auditorium, room 230
Leadership Panel: 8:30 am -4:30 pm

Attached is a one pager briefing on medical implant registry systems, and a draft of the “Medical Implant Registry Summit” program.

Warmly,

SreyRam Kuy, MD
Special Advisor
Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
A VA Medical Implant Registry: Why it Matters

The Vision
✓ A nationwide Implant Registry that enables VA to monitor the safety of implants in our veterans, track quality metrics and ensure the best possible care for VA patients

Current surveillance of medical implants is piecemeal
✓ Adverse Event Reports: mandatory for manufacturers & hospitals, but incomplete clinical data
✓ Insurance Claims data – lack clinical details
✓ Clinical Registries - operated by various groups & societies but not linked to VA’s Electronic Medical Records

Does VA need an Implant Registry?
✓ Yes!
  • Needed to monitor patient safety
  • Needed for recall of faulty medical implants
  • Needed to measure quality & compare outcomes of implants

Why is an Implant Registry important to the VA?
✓ A medical implant registry will:
  • Allow us to notify patients about safety recalls
  • Allows us to identify the exact device when patient shows up in ER with complications
  • Allows us to track clinical follow-up

What makes an Implant Registry effective for the VA?
✓ An effective medical implant registry will:
  • Link with the VA’s Electronic Medical Record to facilitate rapid identification
  • Easily accessible for VA clinicians, and from any VA medical center the veteran presents at
  • UDI barcode input automated (manual entry raises risk of error & patient safety)
  • Tracks both medical devices and biological implants (pending legislation will require VA to track biological implants)
  • Monitors veterans from the pre-registry era (comprises the majority of implants needing surveillance)
  • Implementable in the short-term via VA’s CPRS and VistA, and able to interface with Cerner in the long term

Collaboration
✓ As VA develops the nations’ largest implant registry, we welcome opportunities to collaborate with our sister agencies & the medical community in novel partnerships that advance this vision.

Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs

SreyRam.Kuy@va.gov
(713) 503-4274

Confidential - Working DRAFT, Informational Only, Pre-Decisional – VA Internal Use Only
Medical Implant Registry Summit
Date: June 4, 2018
Location: VA Auditorium
8:30 – 4:30 pm

8:30 Welcome and Introductions of Participants and Organizations
SreyRam Kuy, MD

8:45 – 10:00 Session 1: Value for Stakeholders
Objective: To describe value of medical implant registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Needs (15 min)
TBA – Patient perspectives

Leveraging the Medical Device Ecosystem (15 min)
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST) invited/available

Value Roundtable Discussion
Moderator: SreyRam Kuy, MD
✓ Department of Veterans Affairs Leadership
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS Leadership - TBD
✓ DOD Leadership - TBD
✓ HHS Leadership - TBD
✓ Professional societies perspective – AMA – Kathy Blake
✓ Hospital/system perspective - Kaiser
✓ Industry perspective – AdvaMed/MDMA
10:00 – 11:30 Session 2. VA Landscape

Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future

Moderator: TBD

✓ Current Cardiac Device Monitoring in the VA
  - Merrit H. Raitt, MD
    Director, National Cardiac Device Surveillance Program, Veterans Health Affairs

✓ Current VA Medical Device Registries - Maximo
  - Presenter TBD, VA Office of Healthcare Technology Management

✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  - Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System

✓ Medical Device Tracking in Cardiology: The integration of RTLS into CART-CL
  - Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)

✓ Building Future-State Model for VHA Implant Tracking
  - Bruce McIntosh, PharmD
    VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + MD (VA, Vanderbilt) and John Rumsfeld, MD (ACC) + EHR Vendor + DOD Representative

Lunch Break: 11:30 – 12:30

12:30 – 2:00 Session 3. Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term

Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

✓ ONC Efforts - TBD (10 min)

✓ UDI implementation efforts – Terrie Reed, FDA (10 min) – invited/available

✓ Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell/MDEpiNet (10 min) – invited/available

✓ Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH (10 min)
✓ Patient-enabled evidence generation - Harlan Krumholz, MD, Yale (10 min) – invited/available
✓ Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic (10 min) - invited/available

Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA) (invited/available),

2:00 – 3:15 Session 4. From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: TBD

Objective: Begin development of the framework for VA registry development

✓ Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S (10 min)
✓ How to build in the sustainability: Return of investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD FDA/CDRH (10 min)
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✓ Privacy/Ethics issues – Rob Portman (10 min) JD

Panel Discussion: Speakers + Mike Lauer, MD (NIH), Elise Berliner (AHRQ)

3:15 – 4:30
Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh - VA
Kaiser Permanente - NJRR
Art Sedrakyan – Weill Cornell Medical College
Danica Marinac-Dabic, MD, PhD - FDA
Rachael Fleurence, PhD – NESTcc
Patient (TBD)

Closing Remarks
✓ VA Leadership
Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
Made the correction - time is now consistent on the first page and in the last session – ending at 4:30.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-66
Silver Spring MD 20993; (301)796-
FDA
U.S. FOOD & DRUG ADMINISTRATION
fda.hhs.gov;

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Bruce and the Team,
Do you think we need to invite someone from DOD?

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-66
Silver Spring MD 20993; (301)796-
Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhcuserservice?0=600&D=640&B=641&E=&S=E;

From: McIntosh, Bruce (NCPS) [mailto va.gov]
Sent: Thursday, April 26, 2018 9:28 PM
To: Marinac-Dabic, Danica fda.hhs.gov; Kuy, SreyRam (HOU); GHLF'; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); (Atlas Research); Hayes-Byrd, Jacquelyn; <Jacquelyn.Hayes-Byrd@va.gov>
Subject: RE: Medical Device Registry Summit - Planning Meeting

Nice work Danica!

Attached are edits to Agenda for VA section. I am waiting to receive who will cover for presentation (still TBD). Don’t hold up locking this in though if we have to leave as TBD.

Regarding a VA patient to present, I think we may be making this too complicated. To find a VA patient who is comfortable presenting with a story to tell effectively and with proper HIPAA release and clearance will likely be complicated, especially without funding for travel. Perhaps we should use one of the previous non-VA patients presented earlier with a known story, or remove this.

Thanks,
Bruce

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Subject: [EXTERNAL] RE: Medical Device Registry Summit - Planning Meeting

Colleagues,

The updated document is attached. Please note that I added additional names of potential speakers, panelists and moderators for your consideration. In addition I marked the names of those speakers who have been already tentatively invited/available (pending the VA Senior leadership approval). Please review and revise as needed.

Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-314
Silver Spring MD 20993; (301)796-0403

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-----Original Appointment-----

From: Kuy, SreyRam (HOU) [mailto:SreyRam.Kuy@va.gov]
Sent: Tuesday, March 20, 2018 4:06 PM
To: Kuy, SreyRam (HOU); GHLF; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); Marinac-Dabic, Danica; Hayes-Byrd, Jacquelyn
Subject: Medical Device Registry Summit - Planning Meeting
When: Wednesday, April 25, 2018 7:30 AM-8:00 AM (UTC-05:00) Eastern Time (US & Canada).

Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 3/21/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767- [redacted] Code [redacted]

We’ve made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda, with locations, possible time and a slate of speakers. Several fantastic subject matter experts on board to participate! This is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

Again, many apologies to our west coast colleagues for the very early time.

Thank you so much for all your efforts!

Warmly,
SreyRam

Special Advisor to the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230
8:30 – 4:30

8:30 Welcome and Introductions of Participants and Organizations-SreyRam Kuy, MD, PhD

8:45 – 10:00 Session 1: Value of Registries for Stakeholders
Objective: To describe value of registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Needs (15 min)
TBA – VA patient

Leveraging Medical Device Ecosystem (15 min)
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NESTcc) - invited/available

Value Roundtable Discussion (45min)
Moderator: SreyRam Kuy, MD, PhD
✓ Department of Veterans Affairs, SreyRam Kuy, MD (possible comments by Chief of Staff Peter O’Rourke TBD)
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS leadership (TBD)
✓ Professional societies perspective – AMA – Kathy Blake
✓ Hospital/system perspective – Kaiser
✓ Industry perspective – AdvaMed/MDMA

10:00 – 11:30 Session 2. VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future

Moderator: TBD
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  • Merritt H. Raitt, MD
    Director, VA National Cardiac Device Surveillance Program
✓ Current VA Medical Device Registries - Maximo
  • Presenter TBD
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  • Bruce McIntosh, PharmD
    VA National Manager, National Center for Patient Safety

Panel Discussion: Speakers + MD (VA, Vanderbilt) and John Rumsfeld, MD (ACC) + EHR Vendor + DOD Representative

Lunch: 11:30 – 12:30

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Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

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3:15 – 4:30

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Current Participating Partners:

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- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:

- SreyRam Kuy, MD  
  SreyRam.Kuy@va.gov
- [Contact information redacted]
Just added a placeholder on the VA session Panel for DOD panelist. Another option would be to have DOD speaker. I was given (by a colleague) as a suggestion the name of Col. John Smith who works with FDA on another collaborative project; not sure if you know him and if he is the right person.

Danica

Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhcUSTOMERSERVICE?O=600&D=640&B=641&E=E&S=E;

Yes very important

Sent from my iPad
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Veterans Health Administration

Associate Chief of Staff  
Quality, Safety & Value  
Michael E. DeBakey VA Medical Center
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  • Bruce McIntosh, PharmD
    VA National Manager, National Center for Patient Safety

Panel Discussion: Speakers + MD (VA, Vanderbilt) and John Rumsfeld, MD (ACC) + EHR Vendor + DOD Representative

Lunch: 11:30 – 12:30

12:30 – 2:00 Session 3. Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

✓ ONC Efforts - TBD (10 min)
✓ UDI implementation efforts – Terrie Reed, FDA (10 min) – invited/available
✓ Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell/MDEpiNet (10 min) – invited/available
✓ Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH (10 min)
✓ Patient -enabled evidence generation - Harlan Krumholz, MD, Yale (10 min) – invited/available
✓ Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic (10 min) - invited/available
Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA) (invited/available),

2:00 – 3:15 Session 4. From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Bruce Moscowitz, MD, BREF

Objective: Begin development of the framework for VA registry development

✓ Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S (10 min)
✓ How to build in the sustainability: Return of Investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD FDA/CDRH (10 min)
✓ Quality Management opportunities and compliance with standards – (10 min)
✓ Privacy/Ethics issues – Rob Portman (10 min) JD

Panel Discussion: Speakers + Mike Lauer, MD (NIH), Elise Berliner (AHRQ)

3:15 – 4:30

Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh - VA
Kaiser Permanente - NJRR
Art Sedrakyan – Weill Cornell Medical College
Danica Marinac-Dabic, MD, PhD - FDA
Rachael Fleurence, PhD – NESTcc
Bruce Moscowitz, MD – BREF
Patient
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:
- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:
- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
Regarding Bruce McIntosh's comment below, we have a non-VA patient who could fill this role. She was part of our PCORI-funded arthroplasty engagement project (BeTTER SAID) where patients identified device selection/tracking as a critical concern. I’ll check with her about her interest and availability. Then I’ll get back to everyone with more info about the patient so we can collectively make a decision.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE

Improving the lives of people with chronic disease through better access to care, education, support, advocacy and patient-centered research.

TY.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhcustomerservice?O=600&D=640&B=641&E=S=E

From: Bruce Moskowitz [mailto:mac.com]
Sent: Friday, April 27, 2018 7:50 AM
To: Marinac-Dabic, Danica <fda.hhs.gov>
Cc: McIntosh, Bruce (NCPS) <va.gov>; Kuy, SreyRam (HOU) <SreyRam.Kuy@va.gov>; GHLF <ghlf.org>; Aaron Moskowitz <me.com>; Thomas Concannon <rand.org>; Atlas Research <atlasresearch.us>; dc-crd.com; Hayes-Byrd, Jacquelyn <Jacquelyn.Hayes-Byrd@va.gov>; va.gov;

Subject: Re: Medical Device Registry Summit - Planning Meeting

Will ask

Sent from my iPad
Bruce Moskowitz M.D.

On Apr 27, 2018, at 7:45 AM, Marinac-Dabic, Danica <fda.hhs.gov> wrote:

Any suggestions?

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-=
Silver Spring MD 20993; (301)796-8

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From: Bruce Moskowitz [mailto:mac.com]
Sent: Friday, April 27, 2018 5:27 AM
To: Marinac-Dabic, Danica <fda.hhs.gov>
Cc: McIntosh, Bruce (NCPS) <va.gov>; Kuy, SreyRam (HOU) <SreyRam.Kuy@va.gov>; GHLF <ghlf.org>; Aaron Moskowitz <me.com>; Thomas Concannon <rand.org>; Atlas Research <atlasresearch.us>; dc-crd.com; Hayes-Byrd, Jacquelyn <Jacquelyn.Hayes-Byrd@va.gov>; va.gov;
Yes very important

Sent from my iPad

Bruce Moskowitz M.D.

On Apr 26, 2018, at 11:29 PM, Marinac-Dabic, Danica <fda.hhs.gov> wrote:

Bruce and the Team,

Do you think we need to invite someone from DOD?

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-15
Silver Spring MD 20993; (301)796-3317

Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: McIntosh, Bruce (NCPS) [mailto va.gov]
Sent: Thursday, April 26, 2018 9:28 PM
To: Marinac-Dabic, Danica <fda.hhs.gov>; Kuy, SreyRam (HOU) <SreyRam.Kuy@va.gov>; Bruce Moskowitz <mac.com>; Aaron Moskowitz <me.com>; Thomas Concannon <rand.org>; GHLF <ghlf.org>; Bruce Moskowitz <mac.com>; Aaron Moskowitz <me.com>; Hayes-Byrd, Jacquelyn <Jacquelyn.Hayes-Byrd@va.gov>; <va.gov>; <va.gov>; <va.gov>

Subject: RE: Medical Device Registry Summit - Planning Meeting

Nice work Danica!

Attached are edits to Agenda for VA section. I am waiting to receive who will cover for presentation (still TBD). Don’t hold up locking this in though if we have to leave as TBD.

Regarding a VA patient to present, I think we may be making this too complicated. To find a VA patient who is comfortable presenting with a story to tell effectively and with proper HIPAA release and clearance will likely be complicated, especially without funding for travel. Perhaps we should use one of the previous non-VA patients presented earlier with a known story , or remove this.

Thanks,
Bruce
Colleagues,

The updated document is attached. Please note that I added additional names of potential speakers, panelists and moderators for your consideration. In addition I marked the names of those speakers who have been already tentatively invited/available (pending the VA Senior leadership approval).

Please review and revise as needed.

Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-III
Silver Spring MD 20993; (301)796-7354

Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

-----Original Appointment-----

From: Kuy, SreyRam (HOU) [mailto:SreyRam.Kuy@va.gov]
Sent: Tuesday, March 20, 2018 4:06 PM
To: Kuy, SreyRam (HOU); GHFL'; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); (Atlas Research); Marinac-Dabic, Danica; Hayes-Byrd, Jacquelyn;

Subject: Medical Device Registry Summit - Planning Meeting

When: Wednesday, April 25, 2018 7:30 AM-8:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Conference call line: 800-767-4042 Code 755

Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 3/21/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767-4042 Code 755
We've made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda, with locations, possible time and a slate of speakers. Several fantastic subject matter experts on board to participate! This is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

Again, many apologies to our west coast colleagues for the very early time.

Thank you so much for all your efforts!

Warmly,
SreyRam

Special Advisor to the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Further revisions added to the version Bruce had sent last night.

Talk to you at 7:30.
Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-10
Silver Spring MD 20993; (301)796-0559
to participate! This is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

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Warmly,
SreyRam

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Quality, Safety & Value
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810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018
Location: VA Auditorium, #230
8:30 – 4:00

8:30 Welcome and Introductions of Participants and Organizations-
SreyRam Kuy, MD, PhD

8:45 – 10:00 Session 1: Value for Stakeholders
Objective: To describe value of registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Needs
TBA – VA patient

Leveraging the Medical Device Ecosystem
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)

Value Roundtable Discussion
Moderator: SreyRam Kuy, MD, PhD
✓ Department of Veterans Affairs, SreyRam Kuy, MD (possible comments by Chief of Staff Peter O’Rourke TBD)
✓ Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS leadership (TBD)
✓ Professional societies perspective – AMA – Kathy Blake
✓ Hospital/system perspective - Kaiser
✓ Industry perspective – AdvaMed/MDMA

10:00 – 11:30 Session 2. VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future
Moderator: TBD
✓ Current Cardiac Device Monitoring in the VA
  • Merrit H. Raitt, MD (TBD)
    Director, National Cardiac Device Surveillance Program, Veterans Health Affairs
✓ Current VA Medical Device Registries - Maximo
  • TBD
    Office of Healthcare Technology Management, Veterans Health Affairs
✓ “Title TBD” – Nicholas Giori, MD
✓ “Title TBD” – Stephen Waldo, MD (or Paul Varosy, MD)
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD
    VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion:

Lunch: 11:30 – 12:30

12:30 – 2:00 Session 3. Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
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✓ Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell
✓ Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH
✓ Patient-enabled evidence generation - Harlan Krumholtz, MD, Yale
✓ Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic

Panel Discussion:

2:00 – 3:15 Session 4. From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Bruce Moscowitz , MD, BREF
Objective: Begin development of the framework for VA registry development

Panel: Jack Cronenwett, MD, Art Sedrakyan, MD, PhD; Mike Lauer, MD, PhD,

✓ Who should be at the table: What can we learn from VQI?— Jack Cronenwett, MD, Dartmouth, M2S
✓ How to build in the sustainability: Return of Investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD, FDA/CDRH
✓ Quality Management opportunities and compliance with standards—
✓ Privacy/Ethics issues – TBD

Panel Discussion:

3:15 –4:00

Closing Remarks and Outline Key Next Steps
✓ “Pulling it All Together: Next Steps Working with Our Partners”
  • Carolyn Clancy, MD or USH or PDUSH for VHA
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:

- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov

- [Redacted]@va.gov
Dialing in a few minutes. Sorry – had a phone issue.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-M
Silver Spring MD 20993; (301)796-

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-----Original Appointment-----

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Medical Device Registry Summit - Planning Call
Wednesday 3/21/2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767-

We’ve made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda, with locations, possible time and a slate of speakers. Several fantastic subject matter experts on board to participate! This is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.
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Warmly,
SreyRam

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810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Can this be added to my schedule?

Sent with Good (www.good.com)

From: Kuy, SreyRam (HOU)  
Sent: Tuesday, March 20, 2018 1:05:15 PM  
To: GHLF'; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); (Atlas Research); 'Marinac-Dabic, Danica'; Hayes-Byrd, Jacquelyn;  
Subject: Medical Device Registry Summit - Planning Meeting  
When: Occurs every Wednesday from 7:30 AM to 8:00 AM effective 3/21/2018 until 6/11/2018. (UTC-05:00) Eastern Time (US & Canada)  
Where: Conference call line: 800-767= Code  

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SreyRam
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Quality, Safety & Value
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810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit
Draft Agenda
Date: June 4, 2018 (TBD)
Location: VA Auditorium, #230

1. Welcome and Introductions of Participants and Organizations

2. Moderated Roundtable Discussion with Key Agency Leadership
   ✓ Panel Moderator – facilitates with questions (SreyRam Kuy, MD)
   ✓ Secretary David J. Shulkin, MD, Secretary of the VA
   ✓ Commissioner Scott Gottlieb, MD, FDA Commissioner
   ✓ CMS leadership (TBD)
   ✓ HHS Leadership (TBD)

3. Topic Focused Presentations (15 minutes each)
   ✓ “Why Registries Matter” – Data about how it helps lower costs, improve outcomes
     • Subject Matter Expert TBD
   ✓ NEST – the next frontier in device surveillance and outcomes management
     • Danica Marinac-Dabic, MD, PhD, MMSC, FISPE
       Director, Center for Devices and Radiological, FDA
   ✓ “Enabling Patient Participation in Device Registries” – Title TBD
     • Harlan M Krumholz, MD
       Director, Center for Outcomes Research and Evaluation, Yale University
   ✓ “Current Cardiac Device Monitoring in the VA”
     • Merrit H. Raitt, MD (TBD)
       Director, National Cardiac Device Surveillance Program, Veterans Health Affairs
   ✓ “Current VA Medical Device Registries in Place” - Maximo
     • Office of Healthcare Technology Management, Veterans Health Affairs
   ✓ “Building Future-State Model for VHA Implant Tracking”
     • Bruce McIntosh, PharmD
       VA National Manager, Product Recall Office, National Center for Patient Safety
   ✓ “Title TBD”
     • Frederic Resnic, MD
   ✓ Talks by other stakeholders (Amazon, Medtronic) TBD

4. Closing Remarks and Outline Key Next Steps
   ✓ “Pulling it All Together: Next Steps Working with Our Partners”
     • Carolyn Clancy, MD or Chris Vojta, MD, USH or PDUSH for VHA
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

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Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [redacted]
  [redacted]@va.gov
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Contacts:

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  SreyRam.Kuy@va.gov
- [Redacted] va.gov
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SreyRam

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Veterans Health Administration

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Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420
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Draft Agenda
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Contacts:
- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [Redacted] va.gov
Medical Device Registry Summit
Draft Agenda
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- RAND Corporation

Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
Dear colleagues,

For our planning meeting on Medical Device Registry tomorrow morning, attached is a 1 pager (double sided), which can be used for discussion with outside stakeholders. Also, I’ve attached meeting minutes from both prior conference calls. The minutes are displayed chronologically, with the most recent at the end. I’ve also invited a few other colleagues to join the call, depending on their availability. And many apologies to our west coast colleagues for the very early time

Thank you so much for all your enthusiasm and support for this effort!

Warmly,

SreyRam

Hi Everyone,

We’ll have our next Medical Device Registry Summit planning meeting next week, Wednesday March 14 at 7:30 am eastern. I’ll send out a calendar invite.

Thank you for all your help on this effort!

SreyRam Kuy, MD
Special Advisor to the Secretary
Department of Veterans Affairs

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

Mobile: 713-503-4274
Office: 202-461-4875
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Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov
- [Redacted]@va.gov
Medical Device Registry Summit

Month, Day, 2018
Draft Agenda

Meeting Objective: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

1. Welcome and introductions of participants and organization

2. Moderated Roundtable Discussion with Key Agency Leadership
   ✓ Panel Moderator – facilitates with questions
   ✓ Secretary of the VA
   ✓ FDA Commissioner (TBD)
   ✓ CMS leadership (TBD)
   ✓ HHS Leadership (TBD)

3. Topic Focused Presentations
   ✓ Why Registries Matter – Data about how it helps lower costs, improve outcomes – Subject Matter Expert TBD
   ✓ NEST – the next frontier in device surveillance and outcomes management – Speaker
   ✓ Other Key Topics

4. Closing Remarks, Thanks to Participants, Outline Key Next Steps
   ✓ Speaker TBD
National Medical Device Registry Summit

Subject: Medical Device Registry Summit

Purpose: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

Current Participating Partners:

- Department of Veterans Affairs
- US Food and Drug Administration
- Biomedical Research and Education Foundation
- Global Healthy Living Foundation
- RAND Corporation

Contacts:

- SreyRam Kuy, MD
  SreyRam.Kuy@va.gov

- [Redacted] va.gov
Medical Device Registry Summit

Month, Day, 2018
Draft Agenda

Meeting Objective: Bring together VA, FDA, and other federal agencies and key stakeholders for a national summit about medical device registry efforts

1. Welcome and introductions of participants and organization

2. Moderated Roundtable Discussion with Key Agency Leadership
   ✓ Panel Moderator – facilitates with questions
   ✓ Secretary of the VA
   ✓ FDA Commissioner (TBD)
   ✓ CMS leadership (TBD)
   ✓ HHS Leadership (TBD)

3. Topic Focused Presentations
   ✓ Why Registries Matter – Data about how it helps lower costs, improve outcomes – Subject Matter Expert TBD
   ✓ NEST – the next frontier in device surveillance and outcomes management – Speaker
   ✓ Other Key Topics

4. Closing Remarks, Thanks to Participants, Outline Key Next Steps
   ✓ Speaker TBD
Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday May 9, 2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767- Code

Attached is the latest version of the agenda and the invitee list. Please use this version, dated 5/8/2018. Please review the invitee list, and add as appropriate. If a name is not on this list, they will **not** be able to clear security to attend the summit.

Thank you so much for all your efforts! It’s phenomenal how much has been accomplished with your incredible work! I really appreciate it. Looking forward to a fantastic summit!

Warmly,

SreyRam

SreyRam Kuy, MD, MHS, FACS
Special Advisor
Office of the Secretary
Veterans Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Implant Registry Summit
DRAFT list of invitees
Date of Summit: June 4, 2018

This is a pre-decisional, working draft intended only for internal VA use

*These are planned invitees — they have not yet confirmed attendance, and may send a representative in their place.

Invitees*

**Agencies**
Department of Veterans Affairs Leadership
Food and Drug Administration Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
FDA Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
CMS Administrator Seema Verma (tentative) or representative
HHS Secretary Alex Azar (tentative) or representative
DoD Secretary James Mattis or representative (tentative)

**VA employees**
COS Mr. Peter O'Rourke
Deputy COS Ms. Jacquelyn Hayes-Byrd
Secretary Wilkie (tentative) or Deputy Secretary Bowman (tentative)
Acting USH/Executive in Charge
PDUSH
Acting ADUSH QSV: Dr. Saurabha Bhatnagar
Acting DUSH OE: Dr. Gerard Cox
ADUSH Operations Management: Dr. Steve Young
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Deputy Chief Patient Care Services: Dr. Lucille Beck
National Surgery Office: Dr. William Gunnar
Office of Dentistry: Dr.
Office of Reproductive Health in Women’s Health: Dr.
Office of Gastroenterology: Dr.
Cardiology: Dr.
Ophthalmology: Dr.
National Program Office for Sterile Processing: Ms.
Prosthetic and Sensory Aids Service: Ms.
Procurement and Logistics Service: Mr.
NCPS: Ms. and Ms.
Salt Lake City VAMC: Mr. VA Office of Healthcare Technology Management
Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health
Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety
MD, VA, Vanderbilt

FDA
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)
Terrie Reed, FDA
Danica Marinac-Dabic, MD, PhD, MMSc, FISPE – FDA/CDRH
Vahan Simonyan, PhD (FDA)
Greg Pappas, MD, PhD FDA/CDRH

Others:
John Rumsfeld, MD (ACC)
Art Sedrakyan, MD, PhD, Cornell/MDEpiNet
Harlan Krumholz, MD, Yale
Fred Resnic, MD, Lahey Clinic
Jack Cronenwett, MD, Dartmouth, M2S
Rob Portman
Mike Lauer, MD (NIH)
AHRQ representative
PhD

Thomas Concannon
PEW Trust

EHR Vendor
DOD Representative for Session 2 panel
ONC Representative for Session 3 panel - Donald Rucker, MD
Kristy Mitchel - Avalere
Christine Stake - Ann & Robert H. Lurie Children’s Hospital of Chicago
Societies/Nonprofits
Association for the Advancement of Medical Instrumentation (AAMI) leadership
- PhD, FACHE, FIMSS
- PhD

Association of peri-Operative Registered Nurses (AORN)
- MSHA, RN, CNOR, CSSM
- MHA, RN-BC, CNOR, CSSM
- MSN, RN, CNOR
- MSN, MBA, RN, ACNS-BC, CNS-CP, CNOR

Emergency Care Research Institute (ECRI)
- MD, PhD
- MS

American Academy of Orthopaedic Surgeons (AAOS)
- MD
- MD
- III MD

American College of Cardiology
- MD, FACC
- MD, FACC
- Jr., MD, MBA, FACC
- MD, FACC

American Association of Neurological Surgeons
- MD, PhD, FAANS, FACS
- MD, FAANS
- MD, MPH, FAANS, FACS
- MD, FAANS

American Neurological Association
- PhD, MS
- MD

Society for Vascular Surgery
- III, MD
- MD

American College of Surgeons
American Dental Association

AMA

AcademyHealth

Association for Healthcare Resources and Materials Management (AHRMM)

Cognitive Health

Pew Charitable Trust

Henry J. Kaiser Family Foundation

Medical Device Companies (Tentative – pending OGC and ethics approval, would send invite to their government affairs contact)

Abbot Laboratories

Academy Medical LLC

AMO Sales and Services

AvKare

Biotronik

Boston Scientific

Buffalo Supply

Depuy Synthes Joint Reconstruction

Depuy Synthes Spine

Depuy Synthes Trauma

Encore

Endologix

Howmedica

Medtronic USA
Medical Device Registry Summit

VA Auditorium Room 230
810 Vermont Avenue, NW
Washington, DC 20420

June 4, 2018
8:30 a.m. – 4:30 p.m.

8:30 a.m. Welcome and Introductions of Participants and Organizations SreyRam Kuy, MD

8:45 a.m. – 10 a.m. Session 1: Value for Stakeholders
Objective: To describe value of medical device registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Perspective (10 min)
Christine Stake

Leveraging the Medical Device Ecosystem (15 min)
Rachael Fleurence PhD, Executive Director, National Evaluation System for health Technologies (NEST)

Value Roundtable Discussion
Moderator: SreyRam Kuy, MD
✓ VA Secretary or Deputy Secretary
✓ FDA Commissioner Scott Gottlieb, MD/Jeff Shuren, Director, Center for Devices and Radiological Health
✓ CMS Administrator Seema Verma (tentative)
✓ HHS Secretary Alex Azar (tentative) or representative
✓ DoD Secretary James Mattis or representative (tentative)
✓ Professional societies perspective – AMA – Cathy Blake

10 a.m. – 11:30 a.m. Session 2: VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future
Moderator: TBD
✓ Current Cardiac Device Monitoring in the VA
  • Merritt H. Raitt, MD
    Director, National Cardiac Device Surveillance Program, Veterans Health Affairs
✓ Current VA Medical Device Registries - Maximo
  • Presenter TBD
    VA Office of Healthcare Technology Management
✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  • Nicholas Giori, MD, PhD
    Chief of Orthopedic Surgery, VA Palo Alto Health Care System
✓ Medical Device Tracking in Cardiology: The integration of RTLS into CART-CL
  • Stephen Waldo, MD (or Paul Varosy, MD)
    Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD
    VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + MD (VA, Vanderbilt) and John Rumsfeld, MD (ACC) + EHR Vendor + DOD Representative

11:30 a.m. – 12:30 p.m. Lunch Break

12:30 p.m. – 2 p.m. Session 3: Infrastructure/Methodology Opportunities for Standing Up the VA Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, Harvard Medical School/Harvard School of Public Health (invited/available)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of VA registry; present short- and long-term opportunities

✓ ONC Efforts – Don Rucker (10 min)
✓ UDI implementation efforts – Terrie Reed, FDA (10 min) – invited/available
✓ Strategically Coordinated Registry Networks (CRNs) – Linking Registries with other data sources - Art Sedrakyan, MD, PhD, Cornell/MDEpiNet (10 min) – invited/available
✓ Harmonization Efforts with National/International Registries Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH (10 min)
✓ Patient-enabled evidence generation - Harlan Krumholz, MD, Yale (10 min) – invited/available
✓ Active Surveillance via DELTA in National Registries – Fred Resnic, MD, Lahey Clinic (10 min) - invited/available
Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA) (invited/available),

2 p.m. – 3:15 p.m. Session 4: From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: TBD

Objective: Begin development of the framework for VA registry development

✓ Who should be at the table: What can we learn from VQI? – Jack Cronenwett, MD, Dartmouth, M2S (10 min)
✓ How to build in the sustainability: Return of Investment (ROI) Multi-stakeholder Analysis - Greg Pappas, MD, PhD FDA/CDRH (10 min)
✓ Quality Management opportunities and compliance with standards – (10 min)
✓ Privacy/Ethics issues – Rob Portman, JD (10 min)

Panel Discussion: Speakers + Mike Lauer, MD (NIH), Elise Berliner (AHRQ), Julia Skapik, Cognitive Health (invited and available), Kristy Mitchel (Avalere)

3:15 p.m. – 4:30 p.m. Panel: Pulling it All Together/Next Steps
Objective: To summarize key recommendations and prioritize the next steps toward building VA Medical Device Registry

Moderator: Harlan Krumholz, MD

Panel: Bruce McIntosh – VA
Kaiser Permanente – NJRR
Art Sedrakyan – Weill Cornell Medical College
Danica Marinac-Dabic, MD, PhD – FDA
Rachael Fleurence, PhD – NESTcc
Patient (TBD)

Closing Remarks
• VA Leadership

Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
Subject: Medical Device Registry Summit - Weekly Planning Meeting - Wednesdays 7:30 am
Location: Conference call line: 800-767- Code
Start: Wed 5/16/2018 7:30 AM
End: Wed 5/16/2018 8:00 AM
Show Time As: Tentative
Recurrence: Weekly
Recurrence Pattern: every Wednesday from 7:30 AM to 8:00 AM
Meeting Status: Not yet responded
Organizer: Kuy, SreyRam (HOU)
Required Attendees: GHLF; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce
(Atlas Research); ‘Marinac-Dabic, Danica’; Hayes-Byrd, Jacquelyn
Optional Attendees

Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday 7:30 am – 8:00 am Eastern
Conference call line: 800-767- Code

We’ve made great headway with fleshing out the Medical Device Registry Summit details, and attached is a much more detailed agenda and a slate of speakers. Several fantastic subject matter experts on board to participate!

Attached is a draft - welcome all your input, ideas, revisions! Feel to revise the editable word doc and share with us all.

Again, many apologies to our west coast colleagues for the very early time.

Thank you so much for all your efforts!

Warmly,
SreyRam

Special Advisor
Office of the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1069
Medical Implant Registry Summit
DRAFT list of invitees
Date of Summit: June 4, 2018

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*These are planned invitees – they have not yet confirmed attendance, and may send a representative in their place.

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Ophthalmology: Dr.
National Program Office for Sterile Processing: Ms.
Prosthetic and Sensory Aids Service: Ms.
Procurement and Logistics Service: Mr.
NCPS: Ms.

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- MD

American College of Surgeons
American Dental Association
  - MD, DDS
  - Henry J. Kaiser Family Foundation
  - MD, MHA
  - Kathy Blake

AcademyHealth
  - Dr.

Association for Healthcare Resources and Materials Management (AHRMM)
  - Senior Supply Chain

Cognitive Health
  - Julia Skapik, MD, PhD

Pew Charitable Trust
  - MD

Henry J. Kaiser Family Foundation
  - MD

Medical Device Companies (Tentative – pending OGC and ethics approval, would send invite to their government affairs contact)
  - Abbot Laboratories
  - Academy Medical LLC
  - AMO Sales and Services
  - AvKare
  - Biotronk
  - Boston Scientific
  - Buffalo Supply
  - Depuy Synthes Joint Reconstruction
  - Depuy Synthes Spine
  - Depuy Synthes Trauma
  - Encore
  - Endologix
  - Howmedica
  - Medtronic USA
Medical Device Registry Summit

VA Auditorium Room 230
810 Vermont Avenue, NW
Washington, DC 20420

June 4, 2018
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Art Sedrakyan – Weill Cornell Medical College
Danica Marinac-Dabic, MD, PhD – FDA
Rachael Fleurence, PhD – NESTcc
Patient (TBD)

Closing Remarks
• VA Leadership

Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
Ha, Richard

From: Hutton, James
Sent: Friday, May 11, 2018 10:29 AM
To: Hayes-Byrd, Jacquelyn
Cc: 
Subject: FW: Medical Device Registry Summit - June 4

Jacque,

This is an event that will likely attract media. We intend to provide public affairs coverage including media escort.

Any objections? I was told you had some concerns.

James

James Hutton
Deputy Assistant Secretary
Office of Public and Intergovernmental Affairs
Department of Veterans Affairs
810 Vermont Ave, NW
Washington, D.C. 20420
Office: 202-461-7558
Email: james.hutton@va.gov
Twitter: @jehutton
VA on Facebook . Twitter . YouTube . Flickr . Blog

Hi James, just following up on our conversation about you sending an email to inform Ms. Hayes-Byrd about OPIA’s recommendation that media attend the event.

Hi James, just following up on our conversation about you sending an email to inform Ms. Hayes-Byrd about OPIA’s recommendation that media attend the event.

Sharing all the information with you. Please follow up with [redacted] if you have questions and need more background.
Good morning,

Please see below and let me know if you one of you should take the lead for providing the following support: news media invite and escort, press releases, and web posting.

Thanks,

From: Kuy, SreyRam (HOU)
Sent: Tuesday, May 01, 2018 6:06 PM
To: [redacted]; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; McIntosh, Bruce (NCPS); [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]
Subject: Medical Device Registry Summit - Planning Call, 5/2/2018 Wednesday 7:30 am Eastern, 800-767- Code

Dear colleagues,

In preparation for our weekly Wednesday morning call, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesday mornings 7:30 am – 8:00 am Eastern
Conference call line: 800-767- Code

Again, many apologies to our west coast colleagues for the very early time.

Attached is the program, a sample invitation letter with one pager, and a preliminary invitee list. Please feel free to add to the invitee list, edit the program and the invite letter, and share with us all.

Thank you so very much for ALL your hard work and efforts around this summit!

Warmly,
SreyRam Kuy, MD, MHS, FACS
Special Advisor
Office of the Secretary
Department of Veterans Affairs

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1022
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Ha, Richard

From: Kuy, SreyRam (HOU)
Sent: Tuesday, May 15, 2018 9:47 AM
To: Hayes-Byrd, Jacquelyn
Cc: 
Subject: RE: Summit Monday June 4, 2018
Attachments: Medical Device Registry Briefing - SecVA - Dr. SreyRam Kuy - 5-14-2018.docx

Jackie,

Thank you and great idea! Prepared remarks by the SecVA would be fantastic.

Let me know if I can help in any way, including giving a short briefing if needed, or working with his speech writers.

Attached is a short double sided one-pager briefing document on the summit.

Thanks!
-Srey

---------------
From: [redacted]
Sent: Tuesday, May 15, 2018 9:09 AM
To: Kuy, SreyRam (HOU) <SreyRam.Kuy@va.gov>; <Jacquelyn.Hayes-Byrd@va.gov>
Cc: <va.gov>
Subject: RE: Summit Monday June 4, 2018

Will discuss this with SecVA ASAP. Perhaps he’d be better suited to give brief welcoming remarks?

---------------
From: Kuy, SreyRam (HOU)
Sent: Thursday, May 10, 2018 3:23 PM
To: Hayes-Byrd, Jacquelyn
Cc: 
Subject: Summit Monday June 4, 2018

Hi and [redacted]

I wanted to check if this was on the Secretary’s schedule. Under COS Peter O’Rourke’s leadership, VA is hosting a healthcare summit about Medical Device Registries. There’ll be panel on Monday June 4, at 8:45 - 10 am, that will include leadership from the various agencies, and the plan was to have SecVA on the panel too. I think the DepCoS Jacque Hayes-Byrd had mentioned her staff would facilitate getting it on the SecVA’s calendar, but wanted to double check if you needed anything else.

Attached is the summit program. And please let us know who else we should keep in the loop.

Thank you!

SreyRam Kuy, MD, MHS, FACS
Special Advisor
Office of the Secretary

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #1022
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
To: Acting Secretary Wilkie  
From: SreyRam Kuy, MD  
Subj: Medical Device Registry Summit

Does VA Need a Medical Device Registry?
✓ Yes!
  • Allows us to notify patients about safety recalls
  • Allows us to identify the exact device when patient shows up in ER with complications
  • Allows us to track & compare outcomes of implants

Why Registries Matter to VHA:
✓ Legislation:
  H.R. 28: Rep Roe, unanimous vote Jan 2017 (408-0)  
  S. 23: Senator Cassidy, SVAC hearing 5/2017

  "Biological Implant Tracking and Veteran Safety Act"
  ✓ Focused on biological implants only
  ✓ Adopt UDI for biologicals & a tracking system that enables recall notification
  ✓ 6 months for VA to implement

✓ VHA doesn’t have a standardized system. Multiple databases capturing only about 60% of patients with implants.

Past VA Efforts
✓ Several VA funded initiatives over past 10 years, $5.5 million spent on trying to build our own product
✓ VITAS (Veterans Implant Tracking and Alert System) and ITR (Implant Tracking Registry)
✓ Now efforts focused on COTS based solution

The Summit
✓ VA convenes leaders on medical device tracking;
✓ Partners with sister agencies FDA and CMS to ensure patient safety;
✓ Highlights efforts of VA to implement largest health system device tracking program and FDA NEST

Stakeholders
Federal
✓ Rep Roe & Senator Cassidy
✓ FDA
  • Unique Device Identifiers (UDI) in 2007 to enable tracking
• Registry efforts contracted out
  ▪ $3 million to “Medical Device Innovation Consortium” in 2016
  ▪ Establish post market surveillance system NEST (National Evaluation System for Health Technology)\(^1\)

✓ CMS & HHS – 2017 MEDPAC recommendation to require device identifiers on claims forms\(^2,3\)
✓ VA
✓ DoD

Private Interests
✓ American Association of Tissue Banks
  • Focus on biological implants
  • Accredits organizations for a fee (125 tissue banks)
✓ Bruce Moskowitz, MD
  • Founder of nonprofit “Biomedical Research and Education Foundation” (BREF)
  • Son (Aaron) serves as executive director of BREF

\(^3\)http://www.access.gpo.gov/nara/cfr/waisidx_08/21fr17561.htm
Hello Colleagues,

Attached please find the CLOSE TO FINAL DRAFT of the AGENDA (in a slightly changed format—we hope you’d like it)) and the WORKING DRAFT OF THE SPEAKERS BIOS (the ones we had on file).

Please send the outstanding bios to [copied] today if possible or early next week.

Have a great weekend!

Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-319
Silver Spring MD 20993; (301)796-1974

FDA U.S. FOOD & DRUG ADMINISTRATION
fda.hhs.gov;
Medical Device Registry Summit
June 4, 2018

Brief Biographical Sketches for Moderators and Presenters

Kathleen Blake, MD, MPH
Kathleen Blake is Vice President, Healthcare Quality, at the American Medical Association where she works to ensure that physicians have the information and tools they need to successfully participate in new payment programs.

Jack L. Cronenwett, M.D.
Jack L. Cronenwett is Professor of Surgery and The Dartmouth Institute for Health Policy and Clinical Practice at Dartmouth-Hitchcock Medical Center, and Chief Medical Officer for Medstreaming/M2S, which provide...

Rachael L. Fleurence, PhD
Dr. Rachael L. Fleurence is the Executive Director for the NEST Coordinating Center and...
Harlan Krumholz M.D

Harlan Krumholz is a cardiologist, health care scientist, and health care improvement expert at Yale University where he is the Harold H. Hines, Jr. Professor of Medicine and the Director Emeritus of the National Clinician Scholars Program, formerly the Robert Wood Johnson Foundation Clinical Scholars Program, a postdoctoral training program that he co-directed from 1996-2017. He is the Director of the Center for Outcomes Research and Evaluation (CORE) at Yale-New Haven Hospital. He has led

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE

Danica Marinac-Dabic is the Director of the Division of Epidemiology at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). She has over

0479
Gregory Pappas, MD, PhD

Gregory Pappas is the Associate Director for National Devices Surveillance at the FDA’s Center for Devices and Radiological Health (CDRH). He previously served as the

Terrie Reed, MSc

Terrie Reed works as a Senior Advisor for UDI Adoption at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Formerly, Terrie worked as a

Art Sedrakyan, MD, PhD

Art Sedrakyan is a Professor at Weill Cornell Medical College and leads the FDA Medical Device Epidemiology (MDEpiNet) Coordinating, Science and Infrastructure Center. At Cornell, he directs the
Vahan Simonyan, Ph.D.

Vahan Simonyan has solid scientific background in varied academic disciplines: MS in Physical Organic Chemistry, PhD in Quantum Physics and Mathematics, post-doctoral training in Nanotechnology and Quantum Statistical Thermodynamics. After 2001 he switched his expertise to...

Julia Skapik, M.D., M.P.H.

Julia Skapik a board-certified Internist and Clinical Informaticist and Chief Health Information Officer at Cognitive Medical Systems. Currently, she is focused on...
Kathleen Blake, MD, MPH

Kathleen Blake is Vice President, Healthcare Quality, at the American Medical Association where she works to ensure that physicians have the information and tools they need to successfully participate in new payment programs.

Jack L. Cronenwett, M.D.

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Rachael L. Fleurence, PhD

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Danica Marinac-Dabic is the Director of the Division of Epidemiology at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). She has over
garnered experience in obstetrics, gynecology, and epidemiology in the academic and hospital settings as well as teaching experience in academic environment.

**Gregory Pappas, MD, PhD**

Gregory Pappas is the Associate Director for National Devices Surveillance at the FDA’s Center for Devices and Radiological Health (CDRH). He previously served as the

**Terrie Reed, MSc**

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Sorry – did not attach the AGENDA/PROGRAM – attaching it now. Made formatting changes and added the times for each presentation/panel discussion.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-1
Silver Spring MD 20993; (301)796-

Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhcUSTOMerservice?O=600&D=640&B=641&E=&S=:

Hello Colleagues,
Attached please find the CLOSE TO FINAL DRAFT of the AGENDA (in a slightly changed format – we hope you’d like it)) and the WORKING DRAFT OF THE SPEAKERS BIOS (the ones we had on file).
Please send the outstanding bios to (copied) today if possible or early next week.

Have a great weekend!
Medical Device Registry Summit
June 4, 2018
GV (Sonny) Montgomery Veterans Auditorium, Room 230
810 Vermont Avenue, NW
Washington, DC 20420

<table>
<thead>
<tr>
<th>Registration</th>
<th>Presenter/Affiliations</th>
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<tr>
<td>8:30-8:45</td>
<td>Welcome and Introduction of Participants and Organizations</td>
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<tr>
<td><strong>8:45-10:00</strong></td>
<td><strong>Session 1: Value for Stakeholders</strong></td>
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<td>Objective:</td>
<td>To describe value of medical device registries to major stakeholders, identify the gaps and prioritize the opportunities</td>
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<td>Moderator:</td>
<td>SreyRam Kuy, MD - VA</td>
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<td>8:45-9:00</td>
<td>Patient Perspective</td>
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<td>9:00-9:15</td>
<td>Leveraging the National Medical Device Ecosystem</td>
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<td>9:15-10:00</td>
<td>Value Roundtable Discussion:</td>
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<td>- Veterans Affairs (VA) Chief of Staff Peter O’Rourke</td>
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<td>- Food and Drug Administration (FDA)</td>
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<td>- Scott Gottlieb, MD, FDA Commissioner</td>
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<td></td>
<td>- Jeff Shuren, MD, PhD, Director, Center for Devices and Radiological Health</td>
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<td>- Centers for Medicare and Medicaid Services Administrator Seema Verma (tentative)</td>
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<td>- Secretary of Health and Human Services Alex M. Azar (tentative)</td>
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<td>- Secretary of Defense James N. Mattis (tentative)</td>
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<td></td>
<td>- American Medical Association, Kathleen Blake, MD</td>
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<tr>
<td></td>
<td>- National Coordinator for Health Information Technology - Donald Rucker, MD</td>
</tr>
</tbody>
</table>

**10:00-11:30 Session 2: VA Landscape**
**Objective:** To share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future

**Moderator:** Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA

10:00-10:10  Current Cardiac Device Monitoring in the VA  
Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health Affairs (VHA)

10:10-10:20  Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data  
Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System

10:20-10:30  Medical Device Tracking in Cardiology: The integration of Real Time Locations System into The Clinical Assessment, Reporting, and Tracking System (CART) for Cardiac Catheterization Laboratories  
Paul Varosy, MD Director, CART Program

10:30-10:50  Building Future-State Model for VHA Implant Tracking  
Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety

10:50-11:30  **Panel Discussants:** Speakers & Julia Skapik, MD, PhD - Cognitive Medical Systems

11:30-12:30  Lunch

12:30-2PM  **Session 3: Infrastructure/Methodology Opportunities for Standing Up a Medical Device Registry – Short and Long-Term**

**Objective:** To identify key national and international efforts in the device space that can be leveraged for the development of a Medical Device Registry; present short- and long-term opportunities

**Moderator:** Sharon-Lise Normand, PhD - Harvard Medical School/Harvard School of Public Health

12:30-12:40  Strategically Coordinated Registry Networks – Linking Registries with other data sources  
Art Sedrakyan, MD, PhD - WCMC MDEpiNet

12:40-12:50  Unique Device Identifier implementation efforts  
Terrie Reed, FDA

12:50-1:00  Harmonization Efforts with National/International Registries  
Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA
1:00-1:10  Patient-enabled evidence generation  
Harlan Krumholz, MD - Yale University

1:10-1:20  Active Surveillance via DELTA in National Registries  
MD - Lahey Clinic

1:20-2:00  **Panel Discussants:** Speakers & Vahan Simonyan, PhD - FDA

2:00-3:15  **Session 4: From the Conceptual Framework to the Developmental Efforts and Sustainability**

**Objective:** How to begin development of the framework for a VA Medical Device Registry

**Moderator:** Thomas Concannon, PhD – RAND

2:00-2:10  Device Evaluation in a Quality Improvement Registry: Lessons learned from VQI.  
Jack Cronenwett, MD - Dartmouth

2:10-2:20  How to Build in the Sustainability: Return of Investment Multi-stakeholder Analysis  
Greg Pappas, MD, PhD - FDA

2:20-2:30  Privacy/Ethics Issues  
Robert M Portman, JD - Powers, Pyles, Sutter and Verville PC

2:30-3:15  **Panel Discussants:** Speakers & Kristi Mitchell - Avalere Health

3:15-4:30  **Panel: Pulling it All Together**

**Objective:** To summarize key points in the next steps toward building a VA Medical Device Registry

**Moderator:** Harlan Krumholz, MD - Yale University

**Panel Discussants:** Bruce McIntosh, PhD - VA  
Art Sedrakyan, MD, PhD - WCMC  
Danica Marinac-Dabic, MD, PhD - FDA  
Rachael Fleurence, PhD - NEST

5:00  **Closing Remarks**  
VA Leadership – Dr. Carolyn

**Contact:**  
SreyRam Kuy, MD  
Special Advisor, Office of the Secretary  
Department of Veterans Affairs  
SreyRam.Kuy@va.gov  
(713) 503-4274
Dear Colleagues,

I have updated the list of attendees with couple of additional FDA, NIH staff/leadership and other experts from other organizations (please see attached). Please note that I used the version dated 5-8 and made updates and save it as 5-25. Please advise if we need to merge some other versions to this one.

Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-2
Silver Spring MD 20993; (301)796-

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Thanks Danica,

I like the new format. I also changed myself from PhD to PharmD for the last panel discussion and removed Dr. title. Regarding timing for the first session, I want each of the VA speakers to have at least 15 minutes, that leaves 30 minutes for the panel discussion (I changed times for presentations for panel and this session).

Also, I think SreyRam mentioned Dr. would be added to the last panel. Srey Ram is in clinic today and will review this later.
Thanks and enjoy the holiday everyone.

Bruce

Removed FDA Commissioner’s name (in the attached) version as just confirmed by Dr. Shuren’s office that he will represent the FDA/CDRH. Still working on Don Rucker’s confirmation.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
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Sorry – did not attach the AGENDA/PROGRAM – attaching it now. Made formatting changes and added the times for each presentation/panel discussion.

<< File: PROGRAM VA Medical Device Registry Summit FINAL DRAFT .docx >>
Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhccustomerservice?O=600&D=640&B=641&E=&S=E:

From: Marinac-Dabic, Danica  
Sent: Friday, May 25, 2018 12:47 PM  
To: 'Kuy, SreyRam (HOU)' <SreyRam.Kuy@va.gov>; GHLF <ghlf.org>; Bruce Moskowitz <ghlf.org>; Aaron Moskowitz <me.com>; Thomas Concannon <rand.org>; McIntosh, Bruce (NCPS) <va.gov>; Bruce Moskowitz <me.com>; McIntosh, Bruce (NCPS) <va.gov>; Hayes-Byrd, Jacquelyn <Jacquelyn.Hayes-Byrd@va.gov>  
Cc: fda.hhs.gov  
Subject: MOST RECENT AGENDA + BIOS - VA MEDICAL DEVICE REGISTRY SUMMIT

Hello Colleagues,
Attached please find the CLOSE TO FINAL DRAFT of the AGENDA (in a slightly changed format – we hope you’d like it)) and the WORKING DRAFT OF THE SPEAKERS BIOS (the ones we had on file).
Please send the outstanding bios to fda.hhs.gov (copied) today if possible or early next week.

<< File: VA Medical Device Summit Final.docx >>  << File: 2018 VA Registry Summit Bios Final.docx >>

Have a great weekend!
Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE  
Director, Division of Epidemiology  
Center for Devices and Radiological/OSB  
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-I  
Silver Spring MD 20993; (301)796-  
<< OLE Object: Picture (Device Independent Bitmap) >>
Medical Implant Registry Summit
DRAFT list of invitees
Date of Summit: June 4, 2018

This is a pre-decisional, working draft intended only for internal VA use

*These are planned invitees – they have not yet confirmed attendance, and may send a representative in their place.

Invitees*

Agencies
Department of Veterans Affairs Leadership
Food and Drug Administration Commissioner Scott Gottlieb, MD/ Jeff Shuren, Director, Center for Devices and Radiological Health
FDA Commissioner Scott Gottlieb, MD/ Jeff Shuren, Director, Center for Devices and Radiological Health
CMS Administrator Seema Verma (tentative) or representative
HHS Secretary Alex Azar (tentative) or representative
DoD Secretary James Mattis or representative (tentative)

VA employees
COS Mr. Peter O’Rourke
Deputy COS Ms. Jacquelyn Hayes-Byrd
Secretary Wilkie (tentative) or Deputy Secretary Bowman (tentative)
Acting USH/Executive in Charge
PDUSH
Acting ADUSH QSV: Dr. Saurabha Bhatnagar
Acting DUSH OE: Dr. Gerard Cox
ADUSH Operations Management: Dr. Steve Young
ADUSH Administrative Operations: Dr. Tammy Czarnecki
Deputy Chief Patient Care Services: Dr. Lucille Beck
National Surgery Office: Dr. William Gunnar
Office of Dentistry: Dr. 
Office of Reproductive Health in Women’s Health: Dr. 
Office of Gastroenterology: Dr. 
Cardiology: Dr. 
Ophthalmology: Dr. 

National Program Office for Sterile Processing: Ms. 
Prosthetic and Sensory Aids Service: Ms. 
Procurement and Logistics Service: Mr. 
NCPS: Ms. and Ms. 

Putting Veterans First
Diffusion of EXCELLENCE
Diffusing Best Practices
AUGSS VHA
U.S. Department of Veterans Affairs
0493
Salt Lake City VAMC: Mr. [redacted]
VA Office of Healthcare Technology Management
Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health
Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
Stephen Waldo, MD (or Paul Varosy, MD), Director, VA Clinical Assessment, Reporting and Tracking Program (CART)
Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety
[redacted], MD, VA, Vanderbilt

FDA
Terrie Reed, FDA/CDRH
Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA/CDRH
Vahan Simonyan, PhD - FDA/CBER
Greg Pappas, MD, PhD FDA/CDRH
[redacted], MD, MPH, FDA/CDRH
PhD – FDA/CDRH on detail to HHS

National Evaluation System for health Technologies Coordinating Center /MDIC
Rachael Fleurence, PhD, Executive Director

Medical Device Epidemiology Network (MDEpiNet)
Art Sedrakyan, MD, PhD, Weill Cornell Medical College, MDEpiNet Coordinating Science and Infrastructure Center
Sharon-Lise Normand, PhD, Harvard medical School/Harvard School of Public Health/MDEpiNet Methodology Center
Fred Resnic, MD, Leahy Clinic
Jack Cronenwett, MD, Dartmouth
Julia Skapik, MD, PhD – Cognitive Health
Kristy Mitchell – Avalere

John Rumsfeld, MD (ACC)
Harlan Krumholz, MD, Yale
Rob Portman
Michael Lauer, MD (NIH)
Elise Berliner - AHRQ (sending replacement)
Thomas Concannon
PEW Trust
EHR Vendor
DOD Representative for Session 2 panel
ONC Representative for Session 3 panel - Donald Rucker, MD
Kristy Mitchel - Avalere
Christine Stake - Ann & Robert H. Lurie Children's Hospital of Chicago

Societies/Nonprofits
Association for the Advancement of Medical Instrumentation (AAMI) leadership
- PhD
- FHIIMSS
- PhD

Association of peri-Operative Registered Nurses (AORN)
- MSHA, RN, CNOR, CSSM
- MHA, RN-BC, CNOR, CSSM
- MSN, RN, CNOR
- MSN, MBA, RN, ACNS-BC, CNS-CP, CNOR

Emergency Care Research Institute (ECRI)
- MD, PhD
- MS

American Academy of Orthopaedic Surgeons (AAOS)
- MD
- MD
- MD

American College of Cardiology
- MD, FACC
- MD, FACC
- Jr., MD, MBA, FACC
- MD, FACC

American Association of Neurological Surgeons
- MD, PhD, FAANS, FACS
- MD, FAANS
- MD, MPH, FAANS, FACS
American Neurological Association
PhD, MS
MD
Society for Vascular Surgery
III, MD
MD
American College of Surgeons
MD
American Dental Association
DDS
AMA
MD, MHA
MD
Kathy Blake
AcademyHealth
Dr.
Association for Healthcare Resources and Materials Management (AHRMM)
Senior Supply Chain
Cognitive Health
Julia Skapik, MD, PhD
Pew Charitable Trust
MD
Henry J. Kaiser Family Foundation
Medical Device Companies (Tentative – pending OGC and ethics approval, would send invite to their government affairs contact)
Abbot Laboratories
alphabetical list of companies:

- Academy Medical LLC
- AMO Sales and Services
- AvKare
- Biotronk
- Boston Scientific
- Buffalo Supply
- Depuy Synthes Joint Reconstruction
- Depuy Synthes Spine
- Depuy Synthes Trauma
- Encore
- Endologix
- Howmedica
- Medtronic USA
- Nuvasive
- Smith & Nephew
- St. Jude Medical
- Zimmer
- AdvaMed/MDMA
Thank you for all of your hard work in making this event happen.

Jacquie

Sent with Good (www.good.com)

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Dear colleagues,

Nearing the finish line! Thank you ALL for your phenomenal efforts pulling together this national summit on Medical Device Registries! We’ve got a fantastic line-up of amazing speakers! Thanks for making this possible.

For our weekly Wednesday morning calls, here’s the call-in information:

Medical Device Registry Summit - Planning Call
Wednesdays 7:30 am – 8:00 am Eastern
Conference call line: 800-767- Code

I’ve attached the latest version of the agenda, the speaker ready packet, and the RSVP list (as of 5/29/2018 at 2 pm). Could you look over, and if the speakers you’ve been in contact with aren’t on the list, please have them RSVP as soon as possible to the office of protocol at rsvp@protocol@va.gov. This is the list that will go to security, allowing them to enter the building. Thank you!

Thank you so much for all your incredible efforts! So proud of your work and this wonderful summit.

Warmly,
Dear colleagues,

For our weekly Wednesday morning calls, here’s the call-in information:

**Medical Device Registry Summit - Planning Call**

Wednesdays 7:30 am – 8:00 am Eastern
Conference call line: 800-767- \ Code

Thank you so much for all your efforts!

Warmly,
SreyRam

SreyRam Kuy, MD, MHS, FACS

Special Advisor
Office of the Secretary

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW, #858
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit

GV (Sonny) Montgomery Veterans Auditorium, Room 230
810 Vermont Avenue, NW
Washington, DC 20420

June 4, 2018
8:30 a.m. – 4:30 p.m.

8:30 a.m. Welcome and Introduction of Participants and Organizations
   SreyRam Kuy, MD

8:45 a.m. – 10 a.m. Session 1: Value for Stakeholders
   Objective: To describe value of medical device registries to major stakeholders; identify the gaps; prioritize opportunities

   Patient Perspective
   Christine Stake, Patient Governor, the ArthritisPower Patient Research Registry

   Leveraging the Medical Device Ecosystem
   Rachael Fleurence Ph.D., National Evaluation System for Health Technologies

Value Roundtable Discussion
   Moderator: SreyRam Kuy, MD
   - Veterans Affairs (VA) Chief of Staff Peter O’Rourke
   - Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD
   - Jeff Shuren, MD, PhD, Director, Center for Devices and Radiological Health
   - Centers for Medicare and Medicaid Services Administrator Seema Verma (tentative)
   - Secretary of Health and Human Services Alex M. Azar (tentative)
   - Secretary of Defense James N. Mattis (tentative)
   - American Medical Association, Kathleen Blake, MD
10 a.m. – 11:30 a.m. Session 2: VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future

Moderator: Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA
✓ Current Cardiac Device Monitoring in the VA
  • Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health Affairs (VHA)
✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  • Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
✓ Medical Device Tracking in Cardiology: The integration of Real Time Locations System into The Clinical Assessment, Reporting, and Tracking System (CART) for Cardiac Catheterization Laboratories
  • Stephen Waldo, MD or Paul Varosy, MD Director, CART Program
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + John Rumsfeld, MD, American College of Cardiology

11:30 a.m. – 12:30 p.m. Lunch Break

12:30 p.m. – 2 p.m. Session 3: Infrastructure/Methodology Opportunities for Standing Up a Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, PhD (Harvard Medical School/Harvard School of Public Health)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of a Medical Device Registry; present short- and long-term opportunities

✓ Efforts of the Office of the National Coordinator (ONC) for Health Information Technology
  • Don Rucker, MD (ONC)
✓ Unique Device Identifier implementation efforts
  • Terrie Reed (FDA)
✓ Strategically Coordinated Registry Networks – Linking Registries with other data sources
  • Art Sedrakyan, MD, PhD (Cornell/MDEpiNet)
✓ Harmonization Efforts with National/International Registries
  • Danica Marinac-Dabic, MD, PhD, MMSC, FISPE (FDA/Center for Devices and Radiological Health (CDRH))
✓ Patient -enabled evidence generation
Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA)

2 p.m. – 3:15 p.m. Session 4: From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Thomas Concannon, PhD (RAND)

Objective: How to begin development of the framework for a Medical Device Registry

✓ Who should be at the table: What can we learn from Vascular Quality Initiative?
  • Jack Cronenwett, MD (Dartmouth)
✓ How to build in the sustainability: Return of Investment Multi-stakeholder Analysis
  • Greg Pappas, MD, PhD (FDA/CDRH)
✓ Privacy/Ethics issues
  • Robert M Portman, JD (Powers, Pyles, Sutter and Verville PC)

Panel Discussion: Speakers + Mike Lauer, MD (National Institute of Health), Elise Berliner, PhD (Agency for Healthcare Research and Quality), Julia Skapik, MD (Cognitive Medical Systems), Kristi Mitchell (Avalere Health)

3:15 p.m. – 4:30 p.m. Panel: Pulling it All Together
Objective: To summarize key points in the next steps toward building a Medical Device Registry

Moderator: Harlan Krumholz, MD (Yale University)

Panel: Bruce McIntosh, PharmD (VA)
  Art Sedrakyan, MD (Weill Cornell Medical College)
  Danica Marinac-Dabic, MD, PhD (FDA)
  Rachael Fleurence, PhD (National Evaluation System for Health Technology Coordinating Center)

Closing Remarks
  VA Leadership – Dr. Carolyn Clancy

Questions?

Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov
(713) 503-4274
May 2018

VA Medical Device Registry Summit

Every day, doctors and nurses at VA medical centers across the country are innovating: creating ground breaking cures, developing novel procedures and performing lifesaving treatments. They do this because serving our nation’s heroes with excellence is their commitment. Today, we’re shining the spotlight on one example of this VA excellence.

VA is convening thought leaders on medical device tracking, and partnering with sister agencies, FDA, CMS, HHS and DoD to ensure patient safety. Medical Device Registries are critically important because they allow us to notify patients about safety recalls, identify the exact device when patient shows up in ER with complications, and track & compare outcomes of implants. Partnering with these medical experts and sister agencies, VA is working to implement the largest health system device tracking program in the nation.

On June 4, 2018, VA will be hosting a summit of thought leaders and sister agencies. The public is invited to participate.

Medical Device Registry Summit
GV (Sonny) Montgomery Veterans Auditorium, Room 230
810 Vermont Avenue, NW, Washington, DC 20420
June 4, 2018, 8:30 a.m. – 4:30 p.m.

Interested parties may RSVP to attend in person, with space limited to the first 150 who RSVP. RSVP at rsvpprotocol@va.gov.

The summit will also be broadcast live in two parts. The public can also register to watch online here:
Link for the Medical Device Registry Summit Morning Session 1:
https://www.webcaster4.com/Webcast/Page/89/25950
Link for the Medical Device Registry Summit Afternoon Session 2:
https://www.webcaster4.com/Webcast/Page/89/25951
Of course. Will do right now.

Jack
Can you provide Pete’s?

Sent with Good (www.good.com)

Still missing:
SreyRam Kuy, MD - VA
Peter O’Rourke
Bruce McIntosh, PharmD
Robert M Portman
Kristi Mitchell
Carolyn Clancy
Seema Verma (tentative)
James N. Mattis (tentative)

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From: McIntosh, Bruce (NCPS) [mailto va.gov]
To: Marinac-Dabic, Danica <fda.hhs.gov>; Kuy, SreyRam (HOU) <SreyRam.Kuy@va.gov>; GHLF' ghlf.org; 'Bruce Moskowitz' mac.com; 'Aaron Moskowitz' me.com; 'Thomas Concannon' rand.org; Hayes-Byrd, Jacquelyn <Jacquelyn.Hayes-Byrd@va.gov>; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov;
Subject: RE: [EXTERNAL] RE: MOST RECENT AGENDA/PROGRAM for VA Medical Device Registry Summit

I attached the Bios and pictures for:

Merritt H. Raitt, MD,
Nicholas Giori, MD, PhD
Paul Varosy, MD
Bruce McIntosh, PharmD

Thanks,
Bruce

From: [mailto fda.hhs.gov]
To: McIntosh, Bruce (NCPS) va.gov; Marinac-Dabic, Danica fda.hhs.gov; Kuy, SreyRam (HOU) SreyRam.Kuy@va.gov; GHLF ghlf.org; 'Bruce Moskowitz' mac.com; 'Aaron Moskowitz' me.com; 'Thomas Concannon' rand.org; Hayes-Byrd, Jacquelyn jacquelyn.Hayes-Byrd@va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov; va.gov;
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Dear all,
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Peter O’Rourke
Bruce McIntosh, PharmD MD
Robert M Portman
Kristi Mitchell
Carolyn Clancy
Seema Verma (tentative)
James N. Mattis (tentative)

Best Regards,

MSc
Office of Surveillance and Biometrics | CDRH | FDA
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-
Silver Spring MD 20993 | Tel: 301-796-
E-mail: fda.hhs.gov

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From: McIntosh, Bruce (NCPS) [mailto va.gov]
Sent: Friday, May 25, 2018 2:53 PM
To: Marinac-Dabic, Danica; Kuy, SreyRam; Bruce Moskowitz; Aaron Moskowitz; Thomas Concannon; (Atlas Research); Hayes-Byrd, Jacquelyn
Cc: 4
Subject: RE: [EXTERNAL] RE: MOST RECENT AGENDA/PROGRAM for VA Medical Device Registry Summit

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Also, I think SreyRam mentioned Dr. would be added to the last panel. SreyRam is in clinic today and will review this later.

Thanks and enjoy the holiday everyone.

Bruce

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Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R
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<mac.com>; 'Aaron Moskowitz'
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Cc: va.gov
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<< File: PROGRAM VA Medical Device Registry Summit FINAL DRAFT.docx >>

Danica Marinac-Dabic, MD, PhD, MMS, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-11111
Silver Spring MD 20993; (301)796-5050

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Cc: fda.hhs.gov

Subject: MOST RECENT AGENDA + BIOS - VA MEDICAL DEVICE REGISTRY SUMMIT

Hello Colleagues,
Attached please find the CLOSE TO FINAL DRAFT of the AGENDA ( in a slightly changed format – we hope you’d like it)) and the WORKING DRAFT OF THE SPEAKERS BIOS ( the ones we had on file).
Please send the outstanding bios to (copied) today if possible or early next week.

<< File: VA Medical Device Summit Final.docx >> << File: 2018 VA Registry Summit Bios Final.docx >>

Have a great weekend!

Danica

Danica Marinac-Dabic, MD, PhD, MMS, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-11111
Silver Spring MD 20993; (301)796-5050

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fda.hhs.gov;
Thanks Marta.

I have the bios and pictures for four VA speakers highlighted below and will add these to the document Danica started Friday and send over to you today.

Bruce

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Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-M
Silver Spring MD 20993; (301)796-3051

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Have a great weekend!
Danica

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Director, Division of Epidemiology
Center for Devices and Radiological/OSB
White Oak Campus, 10903 New Hampshire Avenue, Bldg 66/R-4
Silver Spring MD 20993; (301)796-1010
Dear colleagues,

This is our FINAL 7:30 am planning call! Chance to tie up loose ends and finalize.

Here’s the call-in information:

Medical Device Registry Summit - Planning Call
Friday June 1, 2018 7:30 am – 8:00 am Eastern
Conference call line: 800-767- Code

Thank you SO MUCH for all your PHENOMENAL efforts!

Warmly,
SreyRam

SreyRam Kuy, MD, MHS, FACS
Special Advisor
Office of the Secretary
Veterans Health Administration

Associate Chief of Staff
Quality, Safety & Value
Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Dear colleagues,

This is our FINAL 7:30 am planning call! Chance to tie up loose ends and finalize. I attached up updated agenda (some changes in order in the beginning to accommodate Secretary/Agency Leadership schedules. Also attached is the latest RSVP list as of 5/31/2018 at 2:50 pm.

Powerpoints:
We’re received 9 PowerPoints so far, from:
Fleurence, Giori, Majithia, McIntosh, Pappas, Raitt, Reed, Stake and Varosy.

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Michael E. DeBakey VA Medical Center

810 Vermont Avenue, NW
Washington, DC 20420

Mobile: 713-503-4274
Office: 202-461-4875
Medical Device Registry Summit

GV (Sonny) Montgomery Veterans Auditorium, Room 230
810 Vermont Avenue, NW
Washington, DC 20420

June 4, 2018
8:30 a.m. – 4:30 p.m.

8:30 a.m. Welcome
   SreyRam Kuy, MD

8:35 a.m. Keynote Address
   Acting Secretary of Veterans Affairs Peter O’Rourke

8:45 a.m. – 10 a.m. Session 1: Value for Stakeholders
   Objective: To describe value of medical device registries to major stakeholders; identify the gaps; prioritize opportunities

Value Roundtable Discussion
   Moderator: SreyRam Kuy, MD
   - Veterans Affairs (VA) Acting Secretary Peter O’Rourke
   - Food and Drug Administration (FDA) Jeff Shuren, MD, PhD, Director, Center for Devices and Radiological Health
   - Centers for Medicare and Medicaid Services Administrator Seema Verma (tentative)
   - American Medical Association, Kathleen Blake, MD

Patient Perspective
   Christine Stake, Patient Governor, the ArthritisPower Patient Research Registry

Leveraging the Medical Device Ecosystem
   Rachael Fleurence Ph.D., National Evaluation System for Health Technologies, FDA

10 a.m. – 11:30 a.m. Session 2: VA Landscape
   Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future
Moderator: Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA

✓ Current Cardiac Device Monitoring in the VA
  • Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health Affairs (VHA)

✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  • Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System

✓ Medical Device Tracking in Cardiology: The integration of Real Time Locations System into The Clinical Assessment, Reporting, and Tracking System (CART) for Cardiac Catheterization Laboratories
  • Paul Varosy, MD CART Program

✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + Kristi Mitchell (Avalere Health)

11:30 a.m. – 12:30 p.m. Lunch Break

12:30 p.m. – 2 p.m. Session 3: Infrastructure/Methodology Opportunities for Standing Up a Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, PhD (Harvard Medical School/Harvard School of Public Health)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of a Medical Device Registry; present short- and long-term opportunities

✓ Unique Device Identifier implementation efforts
  • Terrie Reed (FDA)

✓ Strategically Coordinated Registry Networks – Linking Registries with other data sources
  • Art Sedrakyan, MD, PhD (Cornell/MDEpiNet)

✓ Harmonization Efforts with National/International Registries
  • Danica Marinac-Dabic, MD, PhD, MMSC, FISPE (FDA/Center for Devices and Radiological Health (CDRH))

✓ Patient -enabled evidence generation
  • Harlan Krumholz, MD (Yale University)

✓ Active Surveillance via DELTA in National Registries
  • MD (Lahey Clinic)

Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA)
2 p.m. – 3:15 p.m. Session 4: From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Thomas Concannon, PhD (RAND)

Objective: How to begin development of the framework for a Medical Device Registry

✓ Who should be at the table: What can we learn from Vascular Quality Initiative?
  • Jack Cronenwett, MD (Dartmouth)
✓ How to build in the sustainability: Return of Investment Multi-stakeholder Analysis
  • Greg Pappas, MD, PhD (FDA/CDRH)
✓ Topic TBD
  • [Name] MD, PhD, FCCM (United Healthcare)

Panel Discussion: Speakers + Julia Skapik, MD (Cognitive Medical Systems)

3:15 p.m. – 4:30 p.m. Panel: Pulling it All Together
Objective: To summarize key points in the next steps toward building a Medical Device Registry

Moderator: Harlan Krumholz, MD (Yale University)

Panel: Bruce McIntosh, PharmD (VA)
  Art Sedrakyan, MD (Weill Cornell Medical College)
  Danica Marinac-Dabic, MD, PhD (FDA)
  Rachael Fleurence, PhD (National Evaluation System for Health Technology Coordinating Center, FDA)

Closing Remarks
  VA Leadership – Dr. Carolyn Clancy

Questions?

Contact:
SreyRam Kuy, MD
Special Advisor, Office of the Secretary
Department of Veterans Affairs
SreyRam.Kuy@va.gov  (713) 503-4274
May 2018

VA Medical Device Registry Summit

Every day, doctors and nurses at VA medical centers across the country are innovating: creating ground breaking cures, developing novel procedures and performing lifesaving treatments. They do this because serving our nation’s heroes with excellence is their commitment. Today, we’re shining the spotlight on one example of this VA excellence.

VA is convening academic leaders on medical device tracking, and partnering with sister agencies, FDA, CMS and DoD to ensure patient safety. Medical Device Registries are critically important because they allow us to notify patients about safety recalls, identify the exact device when patient shows up in ER with complications, and track & compare outcomes of implants. Partnering with these medical experts and sister agencies, VA is working to implement the largest health system device tracking program in the nation.

On June 4, 2018, VA will be hosting a summit of thought leaders and sister agencies. The public is invited to participate.

Medical Device Registry Summit
GV (Sonny) Montgomery Veterans Auditorium, Room 230
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June 4, 2018, 8:30 a.m. – 4:30 p.m.

Interested parties may RSVP to attend in person, with space limited to the first 150 who RSVP. RSVP at rsvpprotocol@va.gov by Friday June 1, 2018.

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<td>VA National Center for Patient Safety</td>
<td>McIntosh</td>
<td>Bruce A.</td>
<td>Bruce A. McIntosh</td>
<td>National Manager, Product Recall Office</td>
<td>703-488-4722</td>
<td><a href="mailto:bmcintos@va.gov">bmcintos@va.gov</a></td>
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<td>Director, Division of Epidemiology</td>
<td>301-922-3050</td>
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<td>VA Office of Quality, Safety and Value</td>
<td>Samsel</td>
<td>William</td>
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<td>Senior Manager, Product Safety</td>
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<td>Hines</td>
<td>Harold H.</td>
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<td>National Manager, Product Recall Office</td>
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<td>Miller</td>
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<td>Executive Director</td>
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<td>Nicholas</td>
<td>Nicholas Reynolds</td>
<td>Chief of Orthopaedic Surgery, M.D., Ph.D.</td>
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<td><a href="mailto:nreynolds@vma.org">nreynolds@vma.org</a></td>
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<td>Dr.</td>
<td>Merrih H. Raitt MD</td>
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<td>Dr.</td>
<td>Raitt MD</td>
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<td>Dr.</td>
<td>Ashwini Zenoox</td>
<td>Chief Medical Officer (CMO), VA Electronic Health Record Modernization (EHRM)</td>
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<td>Speaker</td>
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<td>Dr.</td>
<td>Ashwini Zenoox</td>
<td>Chief Medical Officer (CMO), VA Electronic Health Record Modernization (EHRM)</td>
<td>202-382-4992</td>
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Sir,

Attached and below are brief opening remarks (5 mins.) for the Medical Device Registry Summit, Monday morning, at 8:30, in Room 230.

The audience will consist of about 75 medical experts from federal agencies and the healthcare community. About one third will be from VA. The purpose of the summit is to advance collaborative efforts to create a national management and tracking system to unify, expand, and improve existing medical device registries. The main objectives of your remarks are:

(a) to stress the importance of the collaboration and VA’s commitment to its success, and

(b) to thank our public and private partners for their participation in the summit and the effort.

Internal and external media will be present. Dr. SreyRam Kuy will introduce you. You will speak from the podium and depart immediately afterwards.

The summit’s program is also attached. Jackie will have hardcopies for you.

V/r

Good morning. Thank you, Doctor [SreyRam Kuy, MD], for that introduction and for taking charge of this summit.
I’d also like to thank our key partners in this effort:

- Dr. Danica Marinac-Dabic [dan-NEE-sa Ma-RIN-ac DA-bic] of FDA,
- Dr. Thomas Concannon at RAND,
- Dr. [redacted] and Dr. [redacted] from the Global Healthy Living Foundation.
- Also VA’s Dr. Bruce McIntosh, [redacted] and Acting COS Jacquelyn Hayes-Byrd and her team, who have all worked very hard to make this summit a success.
Finally, I’d like to thank two people who are not here but who have been driving forces in the development of medical device registries — Dr. Bruce Moskowitz and Mr. Aaron Moskowitz of the Biomedical Research & Education Foundation.

A few days ago, we announced a major decision:

- to move forward with a multi-billion-dollar contract to modernize VA’s electronic health records,
- by adopting the same EHR platform used by DoD,
- with a few additional functions to accommodate the special needs of Veterans.

Today we’re here to talk about one way to make the most out of the new EHR system.
In the past few years, VA has worked with DoD to develop a Joint Patient Safety Reporting program to learn from reported healthcare system vulnerabilities, including the inability to identify specific patient implants.

- Now we’re looking to expand that collaboration to include the Food & Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), as well as our Community Care partners.

- So we have organized this summit to bring together industry and academic leaders and sister-agency experts to map out a strategy for launching the largest medical device-implant tracking program in the Nation.

Medical devices are a $170 billion business, accounting for 6 percent of U.S. health spending in 2013.

- Implantable device sales are estimated to have been $43 billion in 2011 and are expected to reach $74 billion this year.

But for all that money, it’s hard to know what works best for patients — and what puts them at greater risk.

- Current tracking systems don’t provide enough clinical detail, or they aren’t linked to VA’s EHR system.

- Adverse Event Reports are mandatory for hospitals and manufacturers, but they don’t provide enough information for us to tell which patients are affected.

The solution is a nationwide medical implant registry that enables us to identify and manage patients with implanted medical devices and biological implants, no matter where they receive their care.
Such a system would enable us to —

- measure quality & compare outcomes,
- monitor patient safety,
- recall faulty devices,
- notify patients about safety recalls,
- know the exact device in question when patient shows up in ER with complications,
- and track clinical follow-up.

The system must be implementable in the short term via VA’s CPRS and VistA, and able to interface in the long term with VA’s new EHR system.

With a well-managed medical device tracking system, and a fully integrated EHR system linking VA and DoD and our Community Care providers:

- We will know, from day one, what implants a Veteran has received on active duty, so nothing is lost when a Veteran enters our care.
- We will know how those implants have performed for each Veteran.
- We will also know how the same implants have performed for all other Veterans and active-duty servicemembers.
- We will be able to identify and address the concerns of individual Veterans about their implants.
- We will also be able to see whether other patients have experienced the same issues, to better assess the risk.
And we will be able to share that information with other providers and with device manufacturers, which will mean both better design and better use of implants.

The result will be safer, more efficient, more patient-centered care — not just for Veterans, but for all implant recipients.

Congress has mandated that we track medical implants, and this administration is committed to fielding the very best, inclusive, patient-centered implant tracking system.

We can’t do that without the collaboration of our sister agencies and nongovernmental partners.

So we greatly appreciate your participation in this summit.

Thank you for being here. I look forward to hearing about your discussions later.

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###
Medical Device Registry Summit

GV (Sonny) Montgomery Veterans Auditorium, Room 230
810 Vermont Avenue, NW
Washington, DC 20420

June 4, 2018
8:30 a.m. – 4:30 p.m.

8:30 a.m. Welcome and Introduction of Participants and Organizations*
   Acting Secretary of VA Peter O’Rourke

8:45 a.m. – 10 a.m. Session 1: Value for Stakeholders
Objective: To describe value of medical device registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Perspective
Christine Stake, Patient Governor, the ArthritisPower Patient Research Registry

Leveraging the Medical Device Ecosystem
Rachael Fleurence Ph.D., National Evaluation System for Health Technologies

Value Roundtable Discussion
Moderator: SreyRam Kuy, MD
- Veterans Affairs (VA) Acting Secretary Peter O’Rourke
- Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD
- Jeff Shuren, MD, PhD, Director, Center for Devices and Radiological Health
- Centers for Medicare and Medicaid Services Administrator Seema Verma (tentative)
- American Medical Association, Kathleen Blake, MD
10 a.m. – 11:30 a.m. Session 2: VA Landscape
Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future

Moderator: Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA
✓ Current Cardiac Device Monitoring in the VA
  • Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health Affairs (VHA)
✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
  • Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
✓ Medical Device Tracking in Cardiology: The integration of Real Time Locations System into The Clinical Assessment, Reporting, and Tracking System (CART) for Cardiac Catheterization Laboratories
  • [Redacted] MD
  • [Redacted] Program
✓ Building Future-State Model for VHA Implant Tracking
  • Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + Kristi Mitchell (Avalere Health)

11:30 a.m. – 12:30 p.m. Lunch Break

12:30 p.m. – 2 p.m. Session 3: Infrastructure/Methodology Opportunities for Standing Up a Medical Device Registry – Short and Long-Term
Moderator: Sharon-Lise Normand, PhD (Harvard Medical School/Harvard School of Public Health)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of a Medical Device Registry; present short- and long-term opportunities

✓ Unique Device Identifier implementation efforts
  • Terrie Reed (FDA)
✓ Strategically Coordinated Registry Networks – Linking Registries with other data sources
  • Art Sedrakyan, MD, PhD (Cornell/MDEpiNet)
✓ Harmonization Efforts with National/International Registries
  • Danica Marinac-Dabic, MD, PhD, MMSC, FISPE (FDA/Center for Devices and Radiological Health (CDRH))
✓ Patient-enabled evidence generation
  • Harlan Krumholz, MD (Yale University)
✓ Active Surveillance via DELTA in National Registries
  • [Redacted] MD (Lahey Clinic)
Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA)

2 p.m. – 3:15 p.m. Session 4: From the Conceptual Framework to the Developmental Efforts and Sustainability
Moderator: Thomas Concannon, PhD (RAND)

Objective: How to begin development of the framework for a Medical Device Registry

✓ Who should be at the table: What can we learn from Vascular Quality Initiative?
  • Jack Cronenwett, MD (Dartmouth)
✓ How to build in the sustainability: Return of Investment Multi-stakeholder Analysis
  • Greg Pappas, MD, PhD (FDA/CDRH)
✓ Privacy/Ethics issues
  • Robert M Portman, JD (Powers, Pyles, Sutter and Verville PC)
✓ Topic TBD
  • [Redacted] MD, PhD, FCCM (United Healthcare)

Panel Discussion: Speakers + Julia Skapik, MD (Cognitive Medical Systems)

3:15 p.m. – 4:30 p.m. Panel: Pulling it All Together
Objective: To summarize key points in the next steps toward building a Medical Device Registry

Moderator: Harlan Krumholz, MD (Yale University)

Panel: Bruce McIntosh, PharmD (VA)
  Art Sedrakyan, MD (Weill Cornell Medical College)
  Danica Marinac-Dabic, MD, PhD (FDA)
  Rachael Fleurence, PhD (National Evaluation System for Health Technology Coordinating Center)

Closing Remarks
  VA Leadership – Dr. Carolyn Clancy

Questions?

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