Registry Assessment of Peripheral Interventional Devices (RAPID) Meeting

Phase 3 - Planning the Future: Coordinated Registry Network-based Clinical Trial Options: An Academic Perspective

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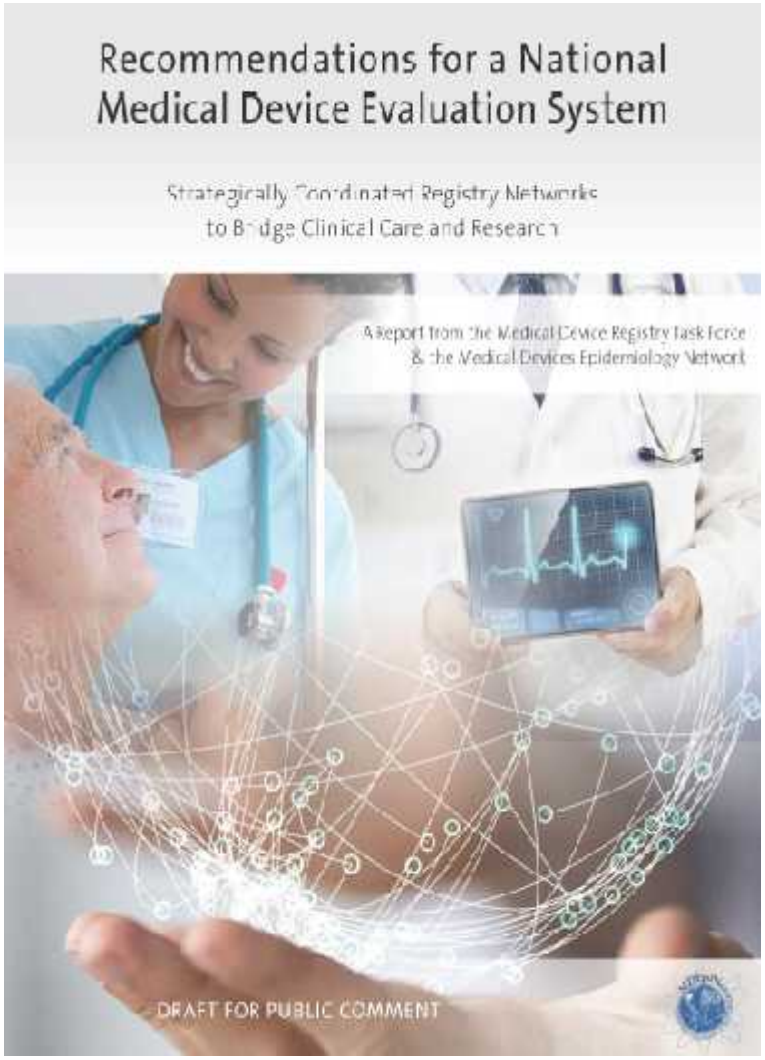

Recommendations for a National Medical Device Evaluation System

Coordinated Registry Networks

Medical Registry Task Force MDEpiNet

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Characteristics of a Coordinated Registry Network

- Ensure ability to identify medical devices
- Use standardized clinical vocabularies, common data elements, and outcome definitions as required
- Linkage across disparate data sources
- Create robust governance

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RAPID Vision in a Coordinated Registry Network

- **Phase 1:** RAPID core structured, standardized, interoperable data set, integration of the GUDID and implementation plans

- **Phase II:** Integrating Structured Data Sets and Supporting Data Extraction Interoperability

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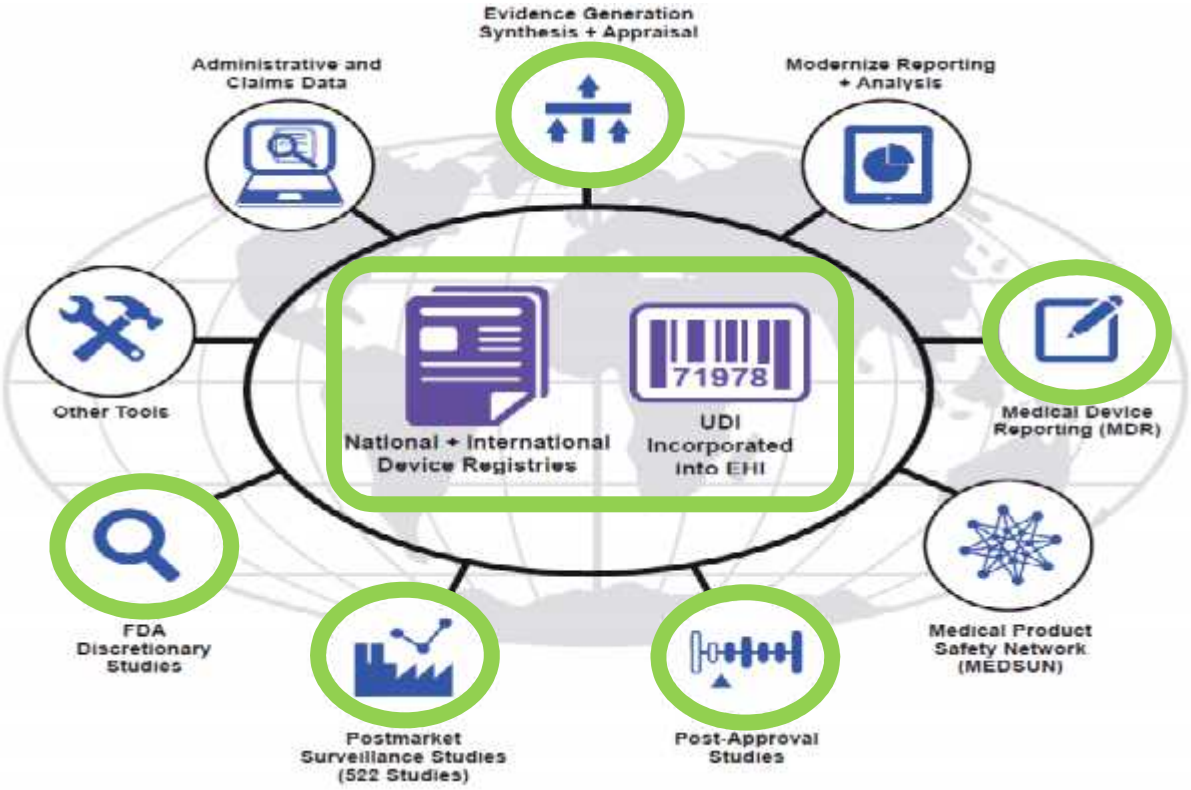
Strengthening National System for Medical Device Postmarket Surveillance



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RAPID Phase III

- Applications to improve device evaluation
- More efficient evaluation system where routinely collected interoperable structured data utilized for:
  - Discover new knowledge more quickly and seamlessly
  - Disseminate new knowledge more quickly into clinical practice
- Positive impact on public health

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THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

J Am Coll Cardiol 2015;65:931–41.

Evaluation and Treatment of Patients With Lower Extremity Peripheral Artery Disease

Consensus Definitions From Peripheral Academic Research Consortium (PARC)

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Peripheral Academic Research Consortium (PARC)

J Am Coll Cardiol 2015;65:931–41.

- PARC, FDA and Japanese PMDA developed consensus definitions for PAD patients affecting lower extremities.
- Definitions include the clinical presentation, anatomic depiction, interventional outcomes, surrogate imaging and physiological follow-up, and clinical outcomes of PAD patients.
- Use of definitions in RCTs evaluating novel revascularization technologies for more efficient regulatory evaluation and best practice guidelines to inform clinical decisions in PAD patients

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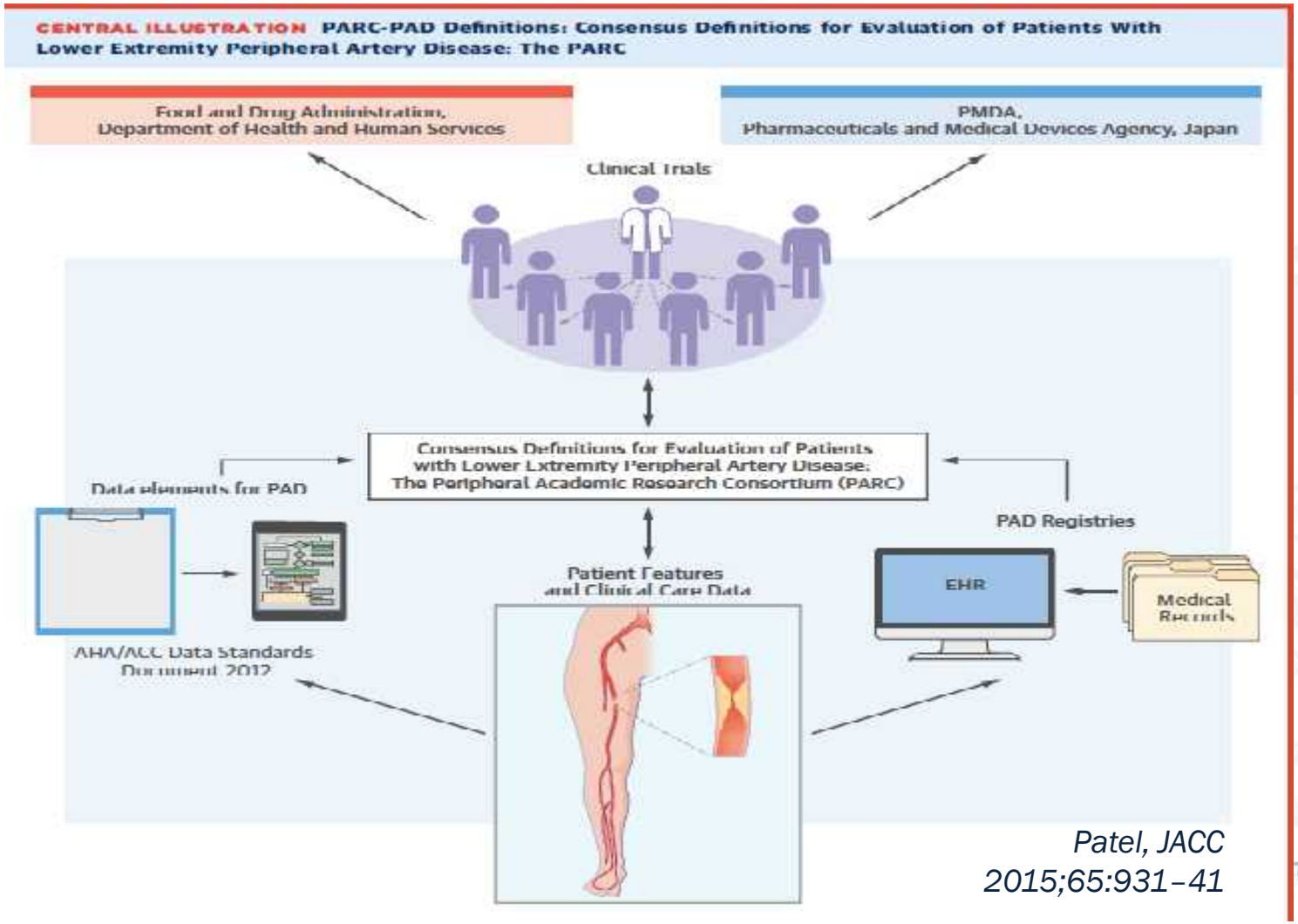


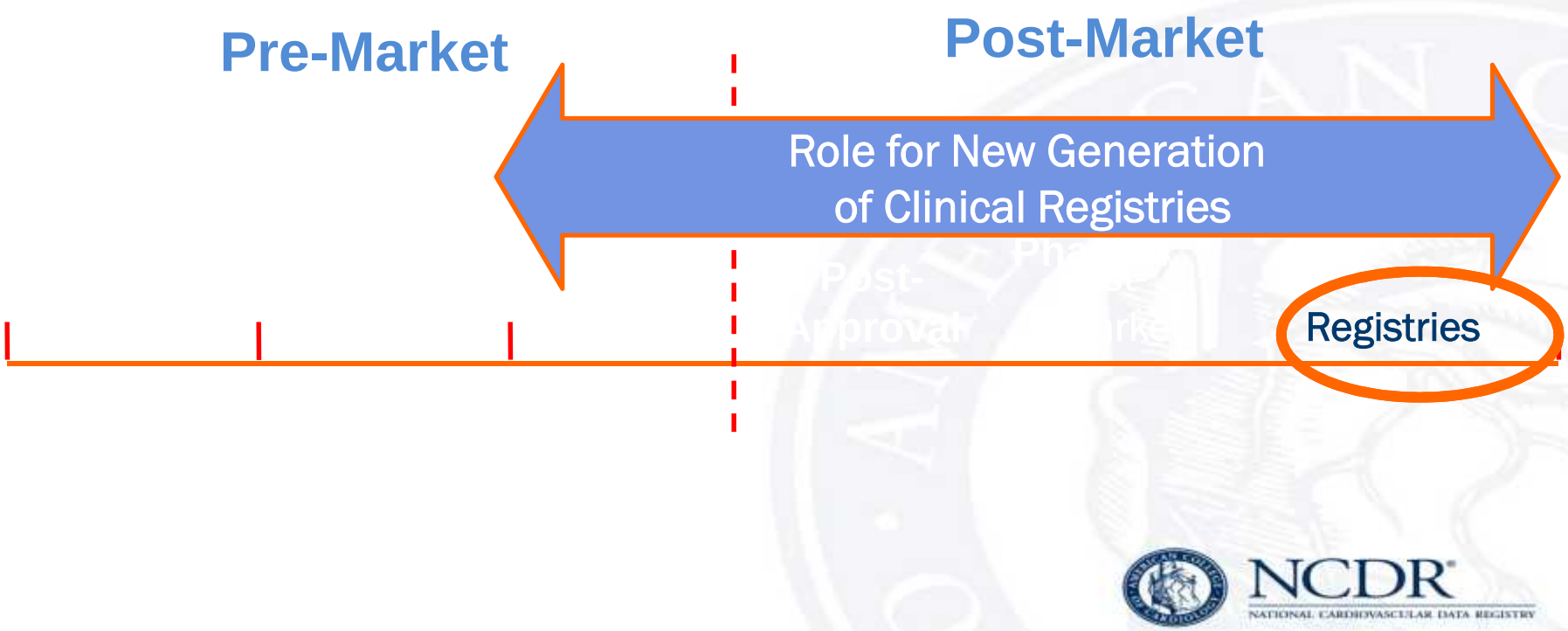
Patel, JACC 2015;65:931–41

Evidence Generation

- **PASSION/RAPID Registry platform as a viable infrastructure for:**

  CV Device Randomized Clinical Trials

The Potential Breadth of RAPID CRN



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	Traditional Approach	Novel Approach
	$$$ Longer	$ Shorter
	Scalable Approaches	
Recruitment	select among existing participants	
Site Training Support	build upon existing training structures	
IRB/Informed Consent	traditional	modified
Site Monitoring	onsite and remote monitoring	registry completeness & select audits
Data Capture	registry + more	registry only
Adjudication	clinical event committee	algorithmic

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Traditional Clinical Research Studies

Benefits	Limitations
• Industry “Gold Standard” • Rigorous • Controlled and Monitored • Levels of randomization • High Data Quality • Regulatory Requirements • Useful tool for investigating new drugs and devices	• Expense • Strict inclusion/exclusion criteria • Often restricted to “research ready” specialized study centers and experienced Investigators known as “thought leaders” • Lengthy timeframe • Often requires industry sponsorship • Increasing number of visits, procedures and data collection requirements • Difficult to identify low frequency safety signals

National Cardiovascular Research Infrastructure (NCRI)

- **Initiated in 2009 by DCRI and ACCF**
- **Four goals to improve cardiovascular research**

Replace the repetitive assembly and disassembly of short-lived clinical investigator networks with a stable and enduring operational infrastructure for clinical research;	Standardize and harmonize cardiovascular data to achieve complete syntactic and semantic interoperability throughout the network;	Coordinated and facilitate the transfer of selected, standardized cardiovascular data into existing and future national registries; and	Develop an enduring library of content for education and training of clinical investigators and site personnel.

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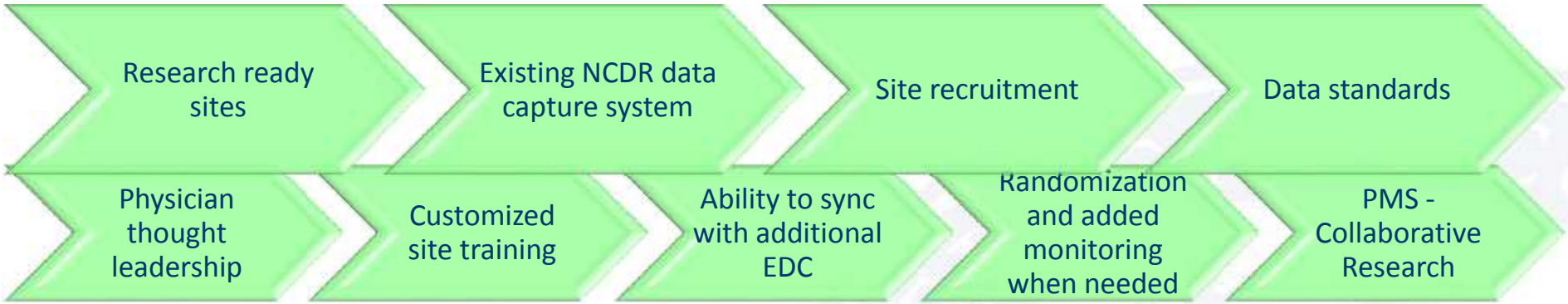
Registry Platform
Clinical Research Studies



- Economical
- Reduces data entry burden
- Real world population
- Consecutive patients
- Larger patient volumes
- Can use central randomization mechanism
- Ongoing data capture

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Maintaining and Improving the Quality of Data for CV Devices Registries

Adjudication and Auditing Processes

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SAFE-PCI for Women

In a nutshell…	Programmatic outcomes…

• NCRI proof of concept
• First multicenter randomized trial comparing radial with femoral access in U.S.
• First randomized trial comparing interventional strategies in women
• Sponsored by DCRI
• Used NCDR CathPCI Registry platform
• Estimated 65% per patient workload reduction
	• $750 per patient reimbursement
	• ~ $5 million budget
	• Study start up time cut in half
	• Included research naive sites
	• Wider enrollment spread
	  • 90% sites enrolled at least 1 patient
	  • > 70% sites enrolled at least 10 patients

Phase III RAPID Strawman

- **Modeling the accomplishments and methodology of ICOR** (International Consortium of Orthopedic Registries)**:**
  - **Integrated approach to more efficient device surveillance creating the ability to report unexpected problems with device (now UDI-enabled!) through the CRN.**

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Phase III RAPID Strawman

- **Utilization of the CRN for FDA mandated Post Approval Studies of new Peripheral devices**

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Defining RAPID/CRN Collaboration Success

Academic/Professional Society Goals:

- The Registry should maintain the traditional goals of the professional societies:
  1) Patient Care 2) Education, 3) Research, 4) Members' interests.
- Are the professional societies governing boards still supportive of the CRN
- Are other professional societies being included or do they feel excluded?

Governance Goals:

- Does the present/proposed structure work?

Cost/Benefit Goal: The CRN must provide benefits by meeting all goals at a reasonable cost with ideally an overall cost reduction.

Scientific Integrity Goals:

- Objective, bias-free, and scientifically based reports?
- Is the CRN in compliance of COI policies?

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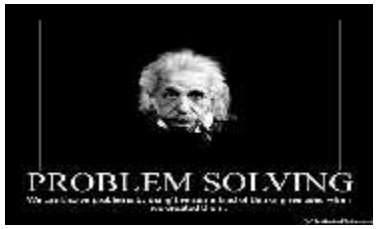
Regulatory Goals

New infrastructure for PAS and IDE studies

- Replacement of “off-label” use without data collection and lack of pathway to expand label indications.
- Leveraging costs and maximizing “quantity” of patient data

Medical Device Surveillance Goal

- All implanted devices should be monitored with periodic assessments of expected device-related adverse events and identification of any unanticipated adverse events.
- **Device Efficacy and Safety**: Sharing of the responsibility by more than FDA and Industry. Public-Private Partnership- MDEpiNet-
  - **PASSION/RAPID**



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Medical Device Industry Goals:

Does the medical industry view the CRN as an improvement versus the prior system?
What do they see as the benefits versus the losses/sacrifices?

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Financial Goals

Is the RAPID CRN Financially Viable and Sustainable?
Have We Created a More Cost-Effective Infrastructure for all ?
Are Costs Being Shifted to Hospitals or CMS for Expanded Indications Studies?

Key Alignment of CMS, Pre-Market and Post-Market FDA and the RAPID CRN

- Will be a continuous work in evolution
- Constant alignment of stakeholder's aims and goals
- Sensitivity and maintaining focus to hospital/clinician burden of data collection and costs
- Acknowledgement and sensitivity to Industry needs
  - Issues of availability to patient level vs. aggregate data, timeliness, industry independent analytical capabilities, and their own regulatory needs
  - Requirements for PMS, PAS and IDE studies
- Patient's needs and rights – informed consent and IRB issues for both IDE and PAS studies

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RAPID CRN Formula for Success:
Working Collaboratively with FDA and CMS

- Realizing that we are all in the “Same Boat”
- Avoidance of “Turf Wars” – SVS, ACC, and SIR and …. “holding hands”
- Promotion of true transparency and “blame free” environment – working towards solutions
- Communication, communication and communication
  - Extemporaneous leadership calls
- Documentation

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Highest Priority

- EMR integration
- 100% data availability
- Global Reach – Global Registry harmonization
- Patient Consent
- Governance
- PAS studies and IDE labeling extensions – helps strike right balance between pre and post market evaluations

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Highest Priority

- National Consortium- **PASSION (Predictable and Sustainable Implementation of National Registries for CV Diseases)**
  - **RAPID CRN** arm focused on PAD
  - Advisory body for registry derived RCTs with all potential stakeholders - NHLBI, FDA, CMS, PCORI, AHRQ, patient groups, Industry, academia, etc.
- Real-time analysis of data captured
- Stable funding and sustainable registry and registry derived RCT model
- Eliminate systematic redundancy
- Clinical registries become the standard infrastructure for conducting pre and post market research.

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