# Perception, Ethical & Related Considerations

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**(on behalf of the Medical Device Registry Task Force)**

# KEY SUMMARY POINTS

- **Sustainability**
  - Stakeholders will contribute dollars, expertise, personal exposure, health information, infrastructure, or combinations thereof to CRNs
  - Governing entities must ensure that CRNs produce deliverables that are **valuable** to stakeholders' constituencies
  - **Inclusive** governance structures that allow **meaningful** participation are most likely to be successful

# KEY SUMMARY POINTS

- **Patients** Matter!
  - Patients value transparency relating to use of personal health data -**notice and consent** are important
  - Data security is essential – fear of breaches, hacking, publication
  - **Two way communication** is valued -patients want timely, relevant information from the research their data makes possible
  - Evolving **technology** makes direct patient data contribution and feedback possible
  - Patients (and other stakeholders) want the **best** outcomes possible

# KEY SUMMARY POINTS

- Clear definitions and requirements will promote collaboration and increase operational **efficiency**
  - What is **clinical research** in the context of a **learning** healthcare system?
  - For what uses of data is **informed consent** necessary?
  - Do **changing** uses of data require notification and/or updated consents?
  - How do HIPAA and HITECH impact **sharing** of EHR and claims data with registries or CRNs?
  - How do  IDE (and other) regulations apply to registries and registry data?

# KEY SUMMARY POINTS

- CRNs must manage information responsibly in order to earn the **trust** of stakeholders and the public
  - Differing stakeholder views about the definition and operational logistics of responsible data use and dissemination will be a governance **challenge**
  - Challenge to reconcile the **benefit** of registry data with the **dangers** posed by irresponsible use of centralized or linked databases
  - Information about patient safety, or device benefit/risk must not first appear in sensational headlines
  - **Collaborative** development of data access & dissemination policies essential

# 2 PILOT STUDIES

| Pilot I | |
|---|---|
| **Develop best practices for patient, industry, clinician, researcher and other stakeholder engagement in CRN design and operations. These practices will need to be tailored to different types of CRN designs:**<br>a. For hybrid systems (distributed and centralized) by leveraging existing models.<br>b. For systems created from data elements seamlessly extracted from EHR, using centralized data models. | |
| **1. disease/device focus** | Engage relevant stakeholders in developing a process that assures meaningful participation in the decision making process. Including explicit consideration of the likely cost and likely value of the outcome to stakeholders. Develop best practices that can be tested across different registry systems and for both disease and device specific registries. |
| **2. Immediate research question(s)** | Survey current practices used by existing registries, and public and private entities such as PCORI, NIH, and private foundations to determine research priorities. Using those resources, develop a process that will assure the meaningful engagement of relevant stakeholders in the processes of creating, reviewing and refining research questions that will produce information of value to diverse stakeholders. |
| **3. Stakeholders engaged** | Patients, healthcare institutions and healthcare providers are the minimum stakeholders for any effort to develop best practices relating to CRN design and operations. If applicable, industry, regulators, researchers, and others may be appropriately engaged in the 'best practices development' effort with the understanding that not every registry will include such stakeholders. |
| **4. Existing national resources leveraged** | AHRQ, PCORI, existing registries, PSOs, healthcare systems with significant registry experience (Kaiser), foundations (Pew Charitable Trust, Brookings), and other entities (IOM, AdvaMed) and as appropriate, existing international registries. |
| **5. Efficiencies promoted** | A process framework for stakeholder engagement that can be adopted for new registries will hasten the creation and use of registries. Creation of a repository of such processes would allow groups without extensive resources to accomplish the goals of this document. |
| **6. Applied national standards & definitions** | AHRQ |

| Pilot II | |
|---|---|
| **Re-examine the definitions of clinical research generally, and informed consent and privacy permissions specifically, to support the development of a CRN in the context of a learning health care system:**<br><br>a. Engage patients in a robust and meaningful review of research definitions with a special emphasis on informed consent requirements.<br>b. Engage product and research regulators in a review of regulatory definitions and the regulations governing the use of personal health information, whether or not collected specifically for research purposes, including from device or disease focused registries, and from EHRs or claims data for pre and post market regulatory applications, including availability for evaluation of benefit/risk and safety signals.<br>c. Engage organizations devoted to quality measurement in a review of HIPPA/HITECH requirements, and research definitions, to assure that information from PSOs and other quality related registries may be disclosed and used by stakeholders as contemplated by a CRN in the context of a learning health care system. | |
| **1. Disease/device focus** | Not specific to a particular device or disease. |
| **2. Immediate research question(s)** | May information from claims data, EHRs, and PSOs be used in clinical research relating to medical devices?<br>How can standards for informed consent be modified to account for new, interactive technologies and uses of data unforeseen at the time of data collection?<br>What changes will providers need to make to privacy permissions relating to EHRs & claims data to facilitate information sharing in a CRN?<br>What information about data uses, and medical devices/disease treatment outcomes, do patients desire in return for the contribution of personal data? |
| **3. Stakeholders engaged** | Patients, Providers, Payers, Physicians, Regulators, Ethicists, Privacy Experts, Data Security Experts. |
| **4. Existing national resources leveraged** | TBD |
| **5. Efficiencies promoted** | Seamless sharing of relevant health information across data sources with limited risk to all participants. |
| **6. Applied national standards & definitions** | TBD |