The Sentinel System
A Public-Private Partnership on Medical Product Safety
Initial Thoughts on Governance Issues

A Proposed Structure for Discussion

- General: Public-private partnership under nonprofit convener organization
- Convened under a charter that defines
    - Purpose: use electronic healthcare data for evaluation of medical product safety and performance in real world settings (maybe later amend to all FDA-regulated products)
    - Scope of activities
        - Establish infrastructure to optimize use of electronic healthcare data for this purpose
        - Perform evaluations and analyses
        - Perform research to develop best practices and methods
        - Provide opportunities for advanced training
        - Consider limiting activities of partnership to evaluations of product performance and outcomes of use; not to include, for example, assessments of quality of care
    - Membership parameters: consider how to define which entities may join partnership
    - Financial structure
        - How will core consortium activities be supported
        - How will the cost of various evaluations be supported
    - Organizational structure
        - Executive Board with broad stakeholder representation to oversee operations of consortium (under the direction of the nonprofit convener Board of Directors)
        - Role of Executive Board
            – Establish general procedures
            – Oversee fundraising efforts
            – Develop sustainable business model: to include evaluation of possible incentives for providers to participate
            – Establish management structure for the consortium

- – Establish initial distributed network infrastructure
- – Develop data and results communications policies
- – Develop policies for safeguarding patient and consumer privacy
- – Develop IP policies
- ▪ Scientific Advisory Board to provide input and oversight on scientific policies and procedures
- ▪ Executive director and program management staff to execute program, to include a query management structure
- ▪ Establish research program: academia; contracts; fellows

Policy Issues (to be elucidated and resolved via procedural and policy documents)

- Use of data
  - o What data sources are appropriate for inclusion?
  - o What existing and evolving data standards should be encouraged through this development?
  - o What are appropriate result communication policies?
- Queries
  - o Should the system initially only use a distributed network or should several configurations be evaluated?
  - o What is the process for deciding if a query can be run on the system?
  - o Who will have access to run queries?
  - o How is adherence to strict privacy protection ensured?
  - o How will it be determined that proposed queries are of appropriate design and employ proper methods?
  - o How will best practices be determined?
  - o How will the fitness of data for specific analyses, and for inclusion in the system, be determined? Who will decide?
  - o What are the advantages of the Sentinel System for all stakeholder groups?
  - o What impact would the Sentinel System have on existing practice and how can it complement existing efforts?