

# Workshop Plan

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# Sentinel Implementation Issues: Governance and Infrastructure

- Who will be responsible for various aspects of Sentinel, and how will they be coordinated?
- Who will be able to use the Sentinel infrastructure, and under what conditions?
- How will it be sustained financially?

# Sentinel Implementation Issues: Data and Scientific Operations

- What data are needed?
- What methods will be used to assure consistent aggregation of data, and effective statistical analysis?
- How can standard processes for querying be developed that can be applied against multiple, different data environments?
- What are current best practices?
- What new analytic methods are needed, and how can their development be supported?

# Sentinel Implementation Issues: Communication with Consumers and Providers

- What do consumers, patients, and providers need to know about Sentinel?
- How can the public be better educated about risks and benefits of medical products – particularly in light of the information developed by Sentinel?

# Sentinel Implementation Issues: Legal and Privacy

- What are the necessary protections to ensure data privacy?
- Whose responsibility is it to ensure privacy is protected?

# Overview of Today's Workshop

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# Objectives of Today's Workshop

- To provide an update on the current status of the Sentinel Initiative and allow for comment from all stakeholders
- To discuss potential governance models and their implications
- To discuss approaches to ensuring continued involvement of all stakeholders as the initiative evolves

# Agenda

**9:45 – 10:00 Overview of Governance Options**

**Rachel Behrman  
Janet Marchibroda**

**10:00 – 10:15 Break**

**10:15 – 11:55 Perspectives on the Potential Functions and Structures of Sentinel**

10:15 – 10:30	Data and Informatics	Lead: Shawn Murphy
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10:30 – 10:40	Participant Discussion and Views
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10:40 – 10:55	Legal and Privacy	Lead: Marcy Wilder
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10:55 – 11:05	Participant Discussion and Views
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11:05 – 11:20	Communications	Lead: Marc Boutin
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11:20 – 11:30	Participant Discussion and Views
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11:30 – 11:45	Scientific Operations	Lead: Rich Platt
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11:45 – 11:55	Participant Discussion and Views
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**11:55 – 12:00 Recap of Charge for the Day**

**Mark McClellan**



# Agenda

**12:00 – 12:45 Break for Lunch**

**12:45 – 1:45 Breakout Groups**

1. What is your vision for a nation-wide safety network in the short term (1-2 years) and the long term (10 or more years)? Please discuss who might use it and under what “rules,” predicated on the following:
  - FDA will build Sentinel to support its statutorily mandated functions
  - Medical product safety is a multi-stakeholder national concern
  - Privacy and security are paramount
2. Given there are a spectrum of options for governance, how do you best feel that this vision could be accomplished?
3. As FDA continues to work toward establishing Sentinel, what are some major risks that you can foresee and how would you guard against them?
4. What are the most productive ways to engage stakeholders in establishing Sentinel? Does this differ depending on the stakeholder group?

**1:45 – 2:00 Break**

# Agenda

## **2:00 – 3:20 Report-out of Breakout Groups**

**Mark McClellan**  
(Facilitator)

2:00 – 2:20	Discussion of Question 1
2:20 – 2:40	Discussion of Question 2
2:40 – 3:00	Discussion of Question 3
3:00 – 3:20	Discussion of Question 4

## **3:20 – 3:30 Summary and Next Steps**

**Janet Woodcock**

# Housekeeping

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