Operationalizing Governance: The Path from Plan to Action

Barbara Filkins
Carl Stepnowsky
Mark Elson
The Workflow

Step One: Identify P&P (e.g. governance-related activities such as study participation request; recruitment; other)

Step Two: Develop P&P
- Develop: Assigned WG
- Review & Assess: GSC WG

Step Three: Operationalize
- Engage: Lead Actor(s)
- Facilitate: GSC WG
- Map to pSCANNER governance map that identifies supporting artifacts and needs
- Develop Plan of Action, obtain approval (if needed), and implement

Step Four: Evaluate (e.g. new or modified P&Ps, supporting artifacts)
- Operational modifications (e.g., SOPs, Portal updates)

Governance Plan Reference:
- Steps One and Two → Section 5.2
- Steps Three and Four → Section 5.3

pSCANNER Community Member

pSCANNER Community/Stakeholders

Executive Committee

Decision to proceed

pSCANNER P&Ps (Proposed Changes)

pSCANNER P&Ps (Proposed Original)

pSCANNER Community/Stakeholders

Outreach
Input / feedback

Present for approval
Definitions for Clarity

- **Policy:**
  - Establish the principle or rule to guide decisions
    - Enterprise (pSCANNER level)
    - Issue
    - System

- **Procedures:**
  - Describe actions that follow policy
    - Set of instructions that performs a certain task
    - Need at least one goal to accomplish
    - Should have a metric that defines success
Definitions for Clarity (cont.)

- **Plans:**
  - Coordination across P&Ps and related activities

- **Standard:**
  - Contains specific technical requirements
    - Encryption
    - Data elements for governance

- **Guideline(s):**
  - Recommends how to follow policy or procedure
    - Change the must to should in a policy -- you have a guideline!
Define the activity

› Determine defining policies (and agreements)
› Define workflow/approval process and develop the list of SOPs
› Establish roles and responsibilities
› Define metrics and rubrics to evaluate the activity and its outcomes
› Define data elements and standards for Portal implementation (if appropriate)
Operationalizing Governance

- Develop the Plan of Action
  - Decompose work effort into specific and granular actions
  - Map to a detailed project plan with milestones
- Perform the work
- Document outcomes as part of pSCANNER roadmap development
  - Supports strategic growth towards sustainability
Example: Study Request

- **Activities:** Request for Collaboration, Study/Research participation request
  - **Policies:** DSAs, participation, and evaluation policies (PCORnet, pSCANNER, sites, IRB)
  - **Workflow:** Evaluation and approval process for requests, study request completion instructions
  - **Roles & Responsibilities:** Evaluation, approval
  - **Rubrics:** Metrics to score study
  - **Data Elements:** FHIR specification (for example) and study request form
Example: Study Request

- **Plan of Action/Work Plan**
  - Complete study request form
  - Determine related workflows, SOPs, IRB review
  - Determine need for rubrics/metrics to evaluate requests (in support of eventual automation)
  - Work with Portal team to implement activity

- **Several GSC activities are coming together**
  - Review of data sharing agreements and policies
  - IRB streamlining, impact on study request process