RPS R2 DSTU

Technical Team Meeting
March 25, 2010
Introductions/Roles

- Scott Becker, Merck
- Bernadette Billet, Liquent
- Bob Birmingham, Johnson & Johnson
- Oliver Bojahr, Extedo
- Anita Coleman, Sanofi-Aventis
- Leslie Ferron-Smith, Sanofi-Aventis
- Joel Finkle, ISI
- Bill Friggle, Sanofi-Aventis
- Jill Geist, Abbott
- Mark Gray, FDA
- Harv Martens, Extedo
- Joe Montgomery, FDA
- Lenore Palma, Datafarm
- Ragunathan Pathmanathan, Abbott
- Jason Rock, Global Submit
- Kavitha Sivasubramanian, Independent
- Sriram Thiruvengadam, Datafarm
- Rich Ware, AstraZeneca
Identification of vendor tools

- RPS builders
- RPS viewers
- Availability/timing if known
Team Objective

• Identify and provide technical means to produce and review RPS message
• Not a tool analysis
Near-term Objectives

• Agreed interpretations
  – Data Model walkthrough
  – Implementation guide

• Testing protocols
  – Message creation
  – Message transmission
  – Message consumption
  – Technical acceptance criteria (Test Case team to develop business acceptance criteria)

• Content storage for source files an compiled messages (GForge)
Near-term Objectives

• Testing environments
  – Local installs, VMWare, remote access, etc.
  – Usage agreements (vendors not using other vendor's tools)

• Feedback and escalation mechanism
  – Interpretations/clarifications
  – Feedback/questions to other subteams
  – Capture for implementation guide
Known risks and dependencies

- Definition of the scope of test cases
- Draft/final test cases – iterative reviews
- Controlled vocabulary lists
- Agreed delivery format for controlled vocabularies
- Sample content for tests cases
- Availability of environments
Ongoing meeting scheduling

• Every 2 weeks?
• Same time/day?