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?