Federated Deployment of Standards

A Case Study

July 7, 2017

Agenda

- Introduction

- Case Study

- Lessons Learned

Introduction

- **Everyone needs to work to CDISC standards**

- **Silo Challenges**
  - Work separately to manage their own standards
  - Not necessarily moving in same direction

- **Case Study on federating standards**
  - Assist client with developing a governance model – team, processes and documentation

Case Study

■ Review of existing documentation

– A lot in place – working instructions, process maps, CR forms

– Used SIPOC as a basis for the review of the documentation

– Outcome

- Streamline reviews

- Harmonise CR process based on five common steps

1. Identify need for change
2. Request Change
3. Review Change (including impact analysis)
4. Accept (move to 5) or Reject (back to 2)
5. Implement

– Single SOP to govern processes for all standard types, and for both global and study specific

Case Study

Standards Team

- Head of Standards Network was appointed
  - Global direction emerged
- Standards Charter
  - High level
  - Vision and Mission
  - Scope
  - Structure
  - Tasks and Responsibilities
  - Operating principles

Case Study

■ **Metrics and Compliance**

– Standards Network allows a clearer end to end vision

– Steering Committee workshop identified metric areas, including

- Standards Developed
- Cycle Times
- Compliance with HA
- Protocol Amendments and Deviations
- Data Capture

– Quarterly reviews of metrics allow for discussion of possible corrective action

Case Study

- ## Senior Management Buy-in
  - Aforementioned workshop held to sell the idea of implementing a federated standards governance model
  - Standards Head outlines vision and why their input was important
  - Managers could discuss how to prioritise actions and steer activities to meet this new end-to-end vision
  - Drive home message in fun way – use Lego
    - It is standard and resuable
    - Stop motion videos around performing a task – building a car without and then with standards

Standards Movie

[Click here for the movie](#)

Lessons Learned

■ Bigger picture thinking

– Lots done at the 'local' level, not much global

– Creating a standards network gives a vision across functions, improves communication, allows establishment of end-to-end metrics

■ Standards Charter

– Great way to frame the team structure, responsibilities, purpose and targets

– Those who interact with the team (in it and outside it) know what it is doing and why

– Helps to break down siloes and lead to true federated governance of standards

Questions?