

# Digital Data Flow\*

- This initiative is aiming to develop a **solution framework** to share with technology entities enabling them to innovate and create technical solutions that allow the industry to move to a **future state with full end-to-end data flow**, making **fully-automated study start-up asset readiness achievable**.

## Initiative Status

Last Update: September 2018



### Deliverables:

- ✓ Planning, Analysis & Design Phase will deliver:
  - ❑ Robust Landscape Analysis
  - ❑ A Framework & Considerations (will include defined data elements to enable innovative technical capabilities to emerge)
    - *Data Standards\* (developed through standards setting bodies) & User Requirements*
    - *Design Patterns, Principles, & Requirements*
    - *Value Assessment Tool*
    - *Stakeholder, Communication & Execution Phase Plans*
- ✓ Execution Phase will deliver:
  - ❑ Proof of Concept / Proof of Concept Paper
  - ❑ Applicable Communications (*i.e. conference presentations, publications*)

## Value for Stakeholders

### Near-term:

- Accelerate study start-up asset readiness
- Reduction in cycle times
- Reduction in study costs
- Improve consistency and quality of the study startup through data traceability

### Long-term:

- Enable platform trial design and set-up
- Facilitate digital / remote trials
- Promote the use of machine learning / artificial intelligence to automate and reduce clinical trial startup cycle times

*\*Initiative is being executed in collaboration with CDISC*