Emerging Trends & Innovation

Project Lead:
Anders Vidstrup

Proposed Project End Date:
Q4 2025

Project Scope:

In some areas, multi-tenant cloud solutions have become ubiquitous.
Salesforce.com claim >150k customers use cloud technology, and its use of multi-tenant app solutions is increasing the capabilities of life sciences solutions and reducing IT infrastructure costs through the sharing of infrastructure and investment cross-industry. Many use their platform for customer relationship management. And many rely on cloud services associated with their computer backups and data services associated with their mobile phones. Nonetheless, the perceptions and interpretations of the regulations by which the life sciences industry must conduct its business still leave many uncertain about whether they can (or should) pursue cloud solutions for GxP applications.
The goal of this project has been to provide a practical, usable framework to overcome those barriers. It is envisaged that using this framework will address the barriers to pharma adopting cloud-based technology.

Deliverable:
Cloud framework

Cloud Adoption in the Life Sciences Industry

Project Status:
Amber

Project Accepting New Members: N/A – Project Closing

Key Achievements This Quarter:

In public review

Deliverables & Targets Planned for the Next Quarter:

Finalise document

Project Leads:
Vijay Pasapula &
Unnat Patel

Deliverable:
White paper

Key Achievements This Quarter:

Draft white paper to send to leadership team for review

Proposed Project End Date:
Q4 2025

Digital Health Technologies (DHTs)

Project Scope:

Limited to the use of digital health technologies in the clinical space

Project Status:
Green

Project Accepting New Members: No

Deliverables & Targets Planned for the Next Quarter:

Finalise white paper

Project Leads:
Adrian Czaban, Jonathon Keeney & Bron Kisler

Deliverable:
White paper

Key Achievements This Quarter:

Ongoing work on white paper(s)

Proposed Project End Date:
First stage till Q4 2025. Proceed with new deliverables after.

Integration of Omics Data into Clinical Drug Development

Project Scope:

The team proposes an initial short-term smaller scope of the WG focused on BioCompute and its implementation. This would ensure a focused short to mid-term delivery. The scope would entail:

- Establishing best practices when working with BioCompute
- Guide for creating and validating BioCompute Objects
- Submission considerations for BioCompute Objects
- Sharing of BioCompute Objects across the industry.

Project Status:
Green

Deliverables & Targets Planned for the Next Quarter:

Draft white paper(s) by end of October

Project Accepting New Members: Yes

Investigating the Use of FHIR in Clinical Research

Project Lead:
Geoff Low

Proposed Project End Date:
Q2 2026

Deliverable:
HL7 FHIR Implementation Guide (IG)

Project Scope:

Increasing interest in eSource keeps the issue of data integration between research systems (EDC, CTMS, CDMS, etc.) and healthcare systems (EHR etc.) a consistent want for sponsors of clinical investigators and regulators. Previous efforts to make this a repeatable, scalable solution have not met with wide-scale adoption, for a variety of reasons. Common points of view include:

- That the quality of the data retrieved from the healthcare sites is insufficient to meet research needs
- That uptake of electronic systems at investigative sites is slow, expensive, and doesn't deliver real value to healthcare practices
- Types of data captured in healthcare are more operational than clinical
- Enabling the necessary interfaces is expensive and process-heavy
- There is no suitable electronic exchange format with standard representations supported.

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Connectathon
- Based on our discussions with the Clinical Decision Support Group, we elected to defer the ballot to develop a new approach (not bound to expectations around base capabilities of an EHR system)

Deliverables & Targets Planned for the Next Quarter:

- Developing content in line with new assumptions to support clinical research activity scheduling
- Regularly meeting with Clinical Decision Support and Structured Data Capture teams to verify assumptions and develop extensions to add to updated Implementation Guide
- Aiming for updated IG Q1 2026

QC Workflow Optimisation

Project Leads:
Caroline Phares, Matthew Finnemeyer & Korak Datta

Proposed Project End Date:
Q4 2026

Project Scope:

- State of the union: how QC is broadly performed across the industry
- What obstacles does double programming introduce when it comes to accelerating and making use of modern technology and techniques?
- Alternatives to the current process
- What impact does the adoption of Agile methodology have on the current QC process?
- What are other regulated industries, such as banking and insurance, doing?
- What is the cost of QC, and does changing the process impact on the cost positively or negatively?
- How might the increasing use of AI change the QC process?

Deliverables:
PHUSE US Connect 2026 presentation, and white paper submission to coincide with the EU Connect 2026

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Charter finalised and locked
- PHUSE US Connect abstract submitted
- Research fully underway

Deliverables & Targets Planned for the Next Quarter:

- PHUSE US Connect presentation preparations

Project Leads:
Eleanor Sparling & Kieran Martin

Deliverable:
Guidance document

Proposed Project End Date:
Q4 2026

The Use of Git in Statistical Programming

Project Scope:

What features are most beneficial to stat programming? What are the benefits of Git? There is interest across the pharmaceutical industry in using Git for statistical programming. Some companies have already incorporated Git, or are attempting to, and there are common challenges being faced. In these cases, the introduction of Git has increased the complexity of a statistical programmer's tasks, which has led to challenges in uptake and to taking advantage of the benefits Git offers. The purpose of this Working Group project is to provide the industry with tools and guidance for addressing and overcoming this common challenge.

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- **Blog Post Development:** Multiple blog topics have been proposed and are in progress, covering areas such as commit message best practices, Git workflows, branching strategies, and common mistakes.
- **White Paper Foundation:** The accumulated blog content will underpin a future white paper, aiming to consolidate best practices.
- **Conference Preparation:** An abstract for the PHUSE US Connect has been submitted
- **Training & Change Management:** Discussions are ongoing about how members started their Git journeys, what resources were helpful, and how to promote adoption among colleagues.

Deliverables & Targets Planned for the Next Quarter:

- PHUSE US Connect presentation preparation
- White paper first outlines