

Emerging Trends & Innovation

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Cloud Adoption in the Life Sciences Industry

Scope

In some areas, multi-tenant cloud solutions have become ubiquitous. [Salesforce.com](https://www.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 for overcoming the barriers to pharma adopting cloud-based technology.

Q4 2025

Proposed
End Date

Finished paper
regarding cloud exit
strategy and completed
industrial review

PHUSE to publish cloud
exit strategy paper

White paper

Deliverable
Type

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Anders Vidstrup

Leads



Project Status: Green

- Having delivered and updated five papers since 2014, we suggest closing the Working Group project (with the papers remaining on the PHUSE website). A core group of old members should form an editorial group to update documents if needed.

Project Status

Digital Health Technologies (DHTs)

Scope

The project will introduce and identify the current state of topics relating to the usage of digital health technologies in clinical trials and regulatory submissions. The project will also provide a common platform to discuss regulatory guidance around DHT.

Q2 2026

Proposed
End Date

White paper

Deliverable
Type

Vijay Pasapula &
Unnat Patel

Leads

Paper review in progress

Key Achievements
This Quarter:

Send white paper draft
to leadership team

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Timeline is not moving as anticipated because of leads' regular work
- Preliminary draft of white paper is there. Need to update it with current AI advancements.

Project Status

Integration of Omics Data into Clinical Drug Development

Scope

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

First stage Q4 2025. Proceed with new deliverables after.

Proposed End Date

White paper

Deliverable Type

Adrian Czaban, Jonathon Keeney & Bron Kisler

Leads

- Webinar Wednesday presentation
- Pistoia Alliance presentation
- 2 white papers ready for review
- PHUSE EU Connect 2025 presentation

Key Achievements This Quarter:

Pending discussion

Deliverables & Targets Planned for the Next Quarter:



Project Status: Green
Accepting New Members – *looking for clinical data scientists with experience of working with omics data*

- 2 white papers in review - one of which was published for the PHUSE EU Connect 2025. Team to discuss future deliverables before the end of Q4 2025.

Project Status

Investigating the Use of FHIR in Clinical Research

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.

Q3 2026

Proposed
End Date

White paper

Deliverable
Type

Geoff Low

Leads

Working on the plan and implementation for dynamic structures in the Protocol SoA
Preparing the narrative for the IG
Revealed plans for dynamic actions to UDP and SDC/CDS stakeholders

Key Achievements
This Quarter:

January Connectathon, targeting the May ballot for the next release

Deliverables & Targets Planned for the Next Quarter:



Project Status: Amber
Accepting New Members - *looking for individuals with experience of HL7 FHIR, JSON, protocol design, protocol-led research, site operations and experience*

- Deliverable draft in progress. Testing planned for January/February

Project Status

QC Workflow Optimisation

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?

Q2 2027

Proposed
End Date

- PHUSE US Connect 2026
- Presentation & PHUSE
Advance Session
- PHUSE EU Connect 2026
- Workshop
- White paper

Deliverable
Type

Caroline Phares,
Matthew
Finnemeyer &
Korak Datta

Leads

Acceptance of paper
and workshop for the
PHUSE US Connect 2026
Development of industry
survey

Key Achievements
This Quarter:

Finalise paper for the
PHUSE US Connect 2026
Deliver presentation and
workshop at the PHUSE
US Connect 2026

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green

- Survey being drafted
- Workshop being developed
- Paper being drafted

Project Status

The Use of Git in Statistical Programming

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.

Q4 2026

Proposed
End Date

An abstract for the
PHUSE US Connect has
been approved

PHUSE US Connect
presentation

Guidance
document

Deliverable
Type

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Eleanor Sparling &
Kieran Martin

Leads



Project Status: Green
Accepting New Members

- **Blog Post Development:** Multiple blog topics 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 consolidating best practices.
- **Conference Preparation:** preparing presentation for the PHUSE US Connect
- **Training & Change Management:** Discussions are ongoing about how members started their Git journeys, what resources were helpful, and how to promote adoption among colleagues.

Project Status