

# Emerging Trends & Innovation

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# 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 use of DHT in the clinical space
- Continuous data flow from telemedicine and telehealth platforms, mobile health (mHealth), wearable/implantable devices, software as a medical device (SaMD)
- Clinical and analytical validation of medical devices
- Digital biomarkers, digital interventions and digital medicine

The project will also provide a common platform to discuss regulatory guidance around DHT.

Q4 2026

Proposed  
End Date

White paper

Deliverable  
Type

Vijay Pasapula  
& Unnat Patel

Leads

- Advanced research and content development for the white paper
- Consolidated initial findings on digital health technologies in clinical trials and regulatory submissions

Key Achievements  
This Quarter:

- Complete draft of the white paper
- Submit draft to the PHUSE Leadership Team for review and feedback

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Amber  
Accepting New Members

- Progress remains slower than planned
- Actively engaging additional contributors to accelerate completion of the white paper

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.

Q4 2026

Proposed  
End Date

White papers  
x2

Deliverable  
Type

Adrian Czaban,  
Bron Kisler &  
Jonathon Keeney

Leads

2 white papers under  
review

Key Achievements  
This Quarter:

- Second white paper received substantial feedback; authors planning discussion on which feedback to incorporate.
- Meeting scheduled with a George Washington University professor to explore use of an academic biomarker knowledge base in pharma settings.
- Third white paper planned; potential authors contacted but writing not yet started.

Deliverables &  
Targets Planned for  
the Next Quarter:



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

- Stakeholder list cleanup planned to remove inactive participants, with opt-in confirmation
- Awareness of PHUSE EU Call for Papers opening (early April), with intent to submit if feasible

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

Lead

Implementation Guide  
finalised for ballot  
Identified two partners  
for implementation  
(MSKCC and The  
Synergist)

Key Achievements  
This Quarter:

- Successful ballot
- Implementation PoC with either of the two partners

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Green  
Accepting New Members

- We are currently in the ballot period for V2 of the Schedule Of Activities FHIR Implementation Guide. We will be watching for and addressing any feedback received as part of the ballot process. Aiming to have further discussions with the Utilising the Digital Protocol team to see how they are using the IG.

Project Status

# QC Workflow Optimisation

## Scope

The scope will include the following topics:

- 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?

Q1 2027

Proposed  
End Date

PHUSE US Connect  
2026 presentation &  
workshop, EU Connect  
2026 workshop, white  
paper Q1 2027

Deliverable  
Type

Caroline Phares,  
Matthew Finnemeyer  
& Korak Datta

Leads

PHUSE US Connect 2026  
presentation and  
workshop

Key Achievements  
This Quarter:

1. Submit EU Connect 26  
HoW abstract
2. Revamp membership for  
phase 2
3. Organise and  
consolidate output from  
the US Connect  
workshop and paper
4. Identify new  
technologies to focus on  
in the next stage of  
research

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Amber

Accepting New Members - *Specific experience in using AI in coding & Experience in cross/novel technology QC processes (AI in QC, GIT use, Shiny implementation for QC, etc.)*

- Last quarter was focused on getting the deliverables ready for PHUSE. We will need to kick off the next phase, since we have taken a breather since the US Connect. Literature review work is progressing in the background.

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. The introduction of Git has increased the complexity of a statistical programmer's tasks, which has led to challenges in uptake and in 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

PHUSE US Connect 2026  
presentation

Key Achievements  
This Quarter:

Draft introductory  
chapter of the white  
paper

Deliverables &  
Targets Planned for  
the Next Quarter:

Guidance  
document

Deliverable  
Type

Eleanor Sparling  
& Kieran Martin

Leads



Project Status: Green  
Accepting New Members

- **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 started,** with the aim of consolidating best practices
- **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