

Emerging Trends & Innovation

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Digital Health Technologies (DHTs)

Description

This Working Group project aims to explore the current use of digital health technologies (DHTs) in clinical trials and regulatory submissions, providing a structured overview of key concepts and applications. Areas of focus include telemedicine, mobile health, wearable and implantable devices, software as a medical device, and the generation of continuous data streams, as well as the clinical and analytical validation of these technologies.

The project will also examine the role of digital biomarkers, digital interventions and digital medicine within the broader DHT ecosystem, recognising that these cannot be considered in isolation. In addition, it will establish a platform for discussion of evolving regulatory guidance and expectations.

With the rapid growth of DHTs - accelerated by increased adoption of remote healthcare - this initiative seeks to support organisations in navigating regulatory complexity and improving understanding of how these technologies can be effectively integrated into clinical development.

Q4 2026

Proposed
End Date

No update

Finalise white paper

White paper

Deliverable

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Vijay Pasapula
& Unnat Patel

Leads



Project Status: Amber

- Progress with finalising the white paper has been slow.

Project Status

Integration of Omics Data into Clinical Drug Development

Description

This project aims to advance the adoption of omics data in clinical drug development by addressing key challenges in data integration, quality, analysis and standardisation. Current limitations, including the inability of CDISC standards to fully accommodate complex omics data types and workflows, highlight the need for complementary approaches.

The project will focus initially on the implementation of the BioCompute standard, developed in collaboration with the FDA to document bioinformatics workflows. Activities will include defining best practices, developing guidance for creating and validating BioCompute Objects, and outlining submission considerations. The project will also support knowledge sharing and community engagement to improve understanding and adoption.

In the longer term, the initiative will explore broader topics such as data integration frameworks, regulatory guidance, quality control, and training. Establishing this project early will support consistent adoption, provide industry feedback and help prepare for increasing regulatory use of omics data.

Q4 2026

**Proposed
End Date**

**White papers
x2**

Deliverable

**Adrian Czaban,
Bron Kisler &
Jonathon Keeney**

Leads

- Significant progress was made on defining a new SDTM biomarker domain to better support high-dimensional omics and biomarker data. The team continued engaging with CDISC, who expressed interest in discussing the proposed domain.
- Work focused on multi-component biomarkers, biomarker modelling, biomarker knowledge base integration, and collection of real-world example datasets.
- The related white paper progressed towards publication, aligned with the planned Pistoia project launch and FDA engagement activities.

**Key Achievements
This Quarter:**

Obtain additional biomarker examples, hold a CDISC scoping call, invite Raja Mazumder to review the proposed approach, and evaluate protein terminology coverage.

**Deliverables &
Targets Planned for
the Next Quarter:**



**Project Status: Green
Accepting New Members**

- On track

Project Status

Investigating the Use of FHIR in Clinical Research

Description

Interest in eSource continues to highlight the persistent challenge of integrating data between research systems (e.g. EDC, CTMS, CDMS) and healthcare systems (e.g. EHRs). Despite repeated efforts, scalable and widely adopted solutions have not been achieved. Historically, concerns have centred on the perceived limitations of healthcare data quality for research, slow and costly adoption of electronic systems at investigative sites, and a focus on operational rather than clinical data capture. Additionally, implementation of required interfaces has been resource-intensive, and the lack of a universally supported electronic exchange standard has created fragmentation.

However, these barriers are gradually being addressed. Government initiatives have accelerated the adoption and accessibility of electronic health records, while industry collaborations are prioritising the integration of healthcare data into research. Notable efforts include the TransCelerate eSource Initiative and the HL7 Vulcan Accelerator, both aiming to support more efficient and standardised data exchange.

Project work complete, project will close after publication

Proposed End Date

White paper

Deliverable

Geoff Low

Lead

- Deliverables and the Implementation Guide have been approved, with publication dependent on the final FHIR R6 release.
- A successful connectathon and ballot activities were completed, and project closure planning is underway.

Key Achievements This Quarter:

Publication, project closeout documentation, and optional dissemination/presentation activities.

Deliverables & Targets Planned for the Next Quarter:



Project Status: Green

- Awaiting publication

Project Status

QC Workflow Optimisation

Description

This Working Group project aims to evaluate the current clinical study analysis and reporting QC process, which has remained largely unchanged for decades despite recognised inefficiencies, particularly with double programming. The project will assess whether existing approaches remain fit for purpose in a modern context and identify opportunities to improve efficiency and better use programming resources.

A key focus will be understanding how the QC process impacts the adoption of Git and other modern technologies, and how current expectations - including those of regulators - may influence acceptable QC practices. The project will analyse industry-wide approaches, challenges introduced by double programming, and potential alternative models. It will also explore the impact of agile methodologies, insights from other regulated industries, cost considerations, and the potential role of AI.

The outcome will provide a comprehensive, evidence-based view of how QC processes can evolve to better support modern statistical programming practices.

Q1 2027

Proposed
End Date

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

Deliverable

- Membership reassessment following a scope change and plans to attract contributors with experience in modern tools and technologies.
- Work is focused on literature review activities and preparation of a Hands-on Workshop proposal for the EU Connect, using feedback from previous workshops.

Key Achievements
This Quarter:

Literature review activities and preparation of a Hands-on Workshop proposal for the EU Connect, using feedback from previous workshops.

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Amber
Accepting New Members

- Recruitment and industry outreach activities remain.

Caroline Phares,
Matthew Finnemeyer
& Korak Datta

Leads

Project Status

The Use of Git in Statistical Programming

Description

This Working Group project aims to support the pharmaceutical industry in adopting Git for statistical programming by identifying the most beneficial features and addressing common challenges. While interest in Git is growing and some organisations have begun implementation, uptake remains inconsistent due to the added complexity it introduces to established workflows.

The project will provide practical guidance, tools and examples to help statistical programmers understand and effectively use Git, enabling them to realise its benefits in areas such as version control, collaboration and traceability. By reducing barriers to adoption and clarifying how Git can be integrated into existing processes, the initiative seeks to improve efficiency, consistency and confidence in its use across the industry.

Q4 2026

Proposed
End Date

Guidance
document

Deliverable

- The group continued development of the Git white paper, with a target full draft by the end of September and finalisation later in the year.
- August discussions focused on AI-assisted development, GitHub Copilot, QC guidance, code-review practices, and how AI should be referenced in the paper.
- Consensus emerged that AI should be discussed where relevant but not become a dedicated section in the initial beginner-focused paper.

Key Achievements
This Quarter:

Complete the Benefits chapter, add the Git tools appendix, review pull requests, and finalise contributor authorship.

Deliverables &
Targets Planned for
the Next Quarter:

Eleanor Sparling
& Kieran Martin

Leads



Project Status: Green
Accepting New Members

- On track

Project Status