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

White paper

Deliverable

- Advanced research and content development for the white paper
- Consolidated initial findings on digital health technologies in clinical trials and regulatory submissions
- Recovery plan initiated to address slower progress, low engagement and inconsistent meeting cadence.

Key Achievements This Quarter:

- Complete draft of the white paper
- Submit draft to PHUSE Leadership Team for review and feedback
- Establish consistent meeting cadence and secure stronger contributor engagement to bring the workstream back on track

Deliverables & Targets Planned for the Next Quarter:

Vijay Pasapula & Unnat Patel

Leads

Project Status: Amber
Accepting New Members

- Progress remains slower than planned
- Actively engaging additional contributors to accelerate completion of the white paper
- DHTs was specifically identified in the Q2 ET&I updates as lagging behind schedule; the current focus is on executing the recovery plan and improving engagement discipline.

Project Status

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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 Working Group 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 Working Group 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

Two white papers under review. Substantial feedback has been received and is being incorporated into the white paper work. The team has streamlined the Omics group by removing inactive members and is targeting white paper updates within the month. The group will present at the PHUSE EU Connect 2026, and FDA engagement and workshop planning are underway.

Key Achievements This Quarter:

Pending discussion. Next-quarter priorities include incorporating feedback into the white papers, advancing regulatory alignment, preparing for the PHUSE EU Connect 2026, progressing FDA engagement and workshop planning, and exploring collaboration with CDISC, PSI/PHUSE, BioCompute and Pistoia-linked governance discussions.

Deliverables & Targets Planned for the Next Quarter:

Adrian Czaban, Bron Kisler & Jonathon Keeney

Leads

Project Status: Green
Accepting New Members

- Second white paper received substantial feedback; authors planning discussion on which feedback to incorporate. Feedback is now being incorporated, with white paper updates targeted within the month.
- 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. The workstream continues to identify CDISC gaps and strengthen regulatory alignment as part of the broader Omics deliverables.
- External collaboration is expanding, including engagement with CDISC and proposed PSI/PHUSE collaboration; BioCompute and Pistoia-related governance discussions remain linked to the workstream.
- FDA engagement and workshop planning are underway, with the group also preparing to present at the PHUSE EU Connect 2026.
- Additional activities:

-Stakeholder list cleanup planned to remove inactive participants, with opt-in confirmation. The Omics group has now been streamlined, with inactive members removed.
-Awareness of PHUSE EU Connect Call for Papers opening (early April), with intent to submit if feasible. Presentation at the PHUSE EU Connect 2026 is planned.

Project Status

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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.

Q3 2026

Proposed End Date

White paper

Deliverable

Geoff Low

Lead

- Implementation Guide finalised and ballot opened; the ballot period was active through to 11 May, with limited comments received at the time of the May update.
- Continued discussions with implementation partners, including MSKCC and The Synergist, to support practical implementation planning.
- FHIR team is working through the next round of ballots in collaboration with Vulcan.

Key Achievements This Quarter:

- Complete the current ballot cycle, review and resolve feedback, and progress the next round of ballot activities with Vulcan.
- Advance implementation proof-of-concept discussions with MSKCC and/or The Synergist and plan for a virtual connectathon at the start of July.

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- The project remains on track. The V2 Schedule of Activities FHIR Implementation Guide has entered ballot, with feedback being monitored and addressed. The team is continuing discussions with implementers, including MSKCC and The Synergist, and is planning a virtual connectathon for early July. In parallel, the team is working through the next ballot round with Vulcan and exploring further alignment with the Utilizing the Digital Protocol team.

Project Status

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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.

Proposed End Date

Q1 2027

Deliverable

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

Key Achievements This Quarter:

- PHUSE US Connect 2026 presentation completed with good engagement and feedback from the workshop.
- Workshop at the PHUSE US Connect used as a foundation for the next phase of work, including EU Connect workshop planning and white paper development.
- Literature review integration is advancing and will be used as a core input to shape the future direction of the project.

Deliverables & Targets Planned for the Next Quarter:

- Submit EU Connect 26 HoW abstract and continue progressing the EU Connect workshop proposal.
- Revamp membership for phase 2 through active membership reassessment and confirmation of contributors for the next phase.
- Organise and consolidate output from the US Connect workshop and paper to support development of a strong white paper, incorporating both PHUSE US Connect feedback and the literature review.
- Identify new technologies on which to focus the next stage of research, including how AI and other modern approaches may influence future QC workflow models.

Leads

Caroline Phares, Matthew Finnemeyer & Korak Datta

Project Status

Project Status: Amber
Accepting New Members

- Last quarter was focused primarily on getting the deliverables ready for PHUSE. We will need to kick off the next phase, given we have taken a breather since the US Connect. Literature review work is progressing in the background. The workstream reset is now in progress, with membership reassessment ongoing. The team is building on PHUSE US Connect feedback, incorporating the literature review as a core input, and advancing the EU Connect workshop proposal to shape the future direction of the project.

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

Eleanor Sparling & Kieran Martin

Leads

PHUSE US Connect workshop/presentation completed with good engagement and follow-up work ongoing.

Key Achievements This Quarter:

Draft introductory chapter of the white paper and continue consolidating outcomes from PHUSE US Connect and EU Connect workshop planning.

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Workstream reset in progress, with membership reassessment ongoing and active contributors being reviewed.
- EU Connect workshop proposal and literature review integration are advancing, building on PHUSE US Connect feedback and incorporating the literature review as a core input to shape the future direction.
- Engagement remains mixed; the most recent meeting had no agenda topics raised and ended early, highlighting the need to re-energise participation and clarify next steps.

Project Status