Digital Health Technologies (DHTs)

Project 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.

Problem Statement
Digital biomarkers cannot be explained without providing context to the larger eco-system of digital health technology (DHT). Digital health technology has been growing rapidly in recent years, and this trend is expected to continue. The COVID-19 pandemic has also accelerated the adoption of digital health technologies as people have become more accustomed to receiving healthcare services remotely.

Problem Impact
We are requesting to change the Digital Biomarker Working Group project with Digital Health Technology. Navigating the regulatory landscape for digital health technologies can be challenging. Companies need to be proactive in understanding the regulatory requirements that apply to their products and work closely with regulators to ensure they are meeting these requirements in a timely and efficient manner.

Project Leads	Email
Vijay Pasapula, *Cerus*	VPasapula@cerus.com
Unnat Patel, *AnalysisMate*	unnat.patel@analysismate.com
Kerry Robson, *PHUSE Project Assistant*	kerry@phuse.global

Objectives & Deliverables	Timelines
Produce a poster / paper for US Connect	Q1 2024
Produce a White Paper	Q3 2024
Deliver a presentation at a PHUSE Single Day Event on DHTs	Q3 2023

CURRENT STATUS Q1 2024
White paper on digital health technologies