

Sage Bionetworks will build the platform that tests whether AI digital twins are ready for the ICU

Twin-TECC will test ICU digital twins against FDA guidance, give CIRCLE teams a shared sandbox, and help prepare models for regulatory review

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received a contract award from the Advanced Research Projects Agency for Health (ARPA-H), an agency within the U.S. Department of Health and Human Services, to build Twin-TECC (Testing, Evaluation, Clinical alignment, and Compliance of Digital Twin Models). The platform will evaluate the patient digital twins developed across ARPA-H's new Critical Illness Immunological Reprogramming and Control Point Learning Engine ([CIRCLE](#)) program and help facilitate their readiness for regulatory review. CIRCLE is awarding Sage Bionetworks up to \$18.3 million over five years to serve as the program's independent evaluation partner.

A digital twin is a computational model of an individual patient that predicts the patient's response to interventions. CIRCLE teams are building real-time datasets of how critical illness progresses, creating patient-specific models of the immune system that predict a patient's response to interventions in the ICU, and testing ways to act on those predictions. Sage's team answers the question that sits between the model and the bedside: can a clinician trust it?

The obstacle is not a shortage of models. The research teams that build digital twins tend to evaluate their own models on their own data, making it nearly impossible to compare one model against another or to know which are ready to inform care.

"For critical illness, the question goes beyond whether we can build a digital twin. It is whether it is ready for regulatory review, and whether a clinician should trust one to inform care," says Jineta Banerjee, PhD, Associate Director of Advanced Data Analytics at Sage Bionetworks and Principal Investigator for the project. "Digital twins have enormous potential, but sophistication is not the same as trustworthiness. Before these models can inform clinical decisions, we need

to know where they work, where they fail, for whom they work, and within what bounds we can rely on them."

Sage's role has two halves. The first is independent: each model developed as part of the CIRCLE program is assessed against FDA guidance and established validation standards, using stratified patient data the model's developers never see. The second is collaborative. Twin-TECC gives every CIRCLE research team a shared place to bring in a model, test it in a sandbox, run simulations using patient data, simulate clinical trials, and generate the documentation regulators will expect. Models are accepted in the formats the field already uses, and the developer controls access, so a model can be evaluated rigorously while respecting intellectual property needs.

"Open, governed infrastructure is how a field learns to check its own work," says Luca Foschini, PhD, President & CEO of Sage Bionetworks. "Sage has spent 15 years building places where sensitive biomedical data can be shared and evaluated on terms everyone can see. Digital twins in the ICU are a use case that can benefit a lot from that approach."

Sage Bionetworks develops and operates Synapse, one of the NIH-listed generalist repositories, managing more than 4.5 petabytes of biomedical research data. Twin-TECC builds on 15 years of Sage's experience developing governed infrastructure for biomedical data, on infrastructure for running model evaluations through more than 20 DREAM Challenges, and on tools created for the [ARPA-H Biomedical Data Fabric Toolbox](#). As prime awardee, Sage is building Twin-TECC with multidisciplinary subawardees InSilicoTrials Technologies, the NYU Grossman School of Medicine, and The Jackson Laboratory. Modeling teams and clinical partners interested in the platform can contact the Sage Bionetworks team at CIRCLE_AP2@sagebionetworks.org.

About Sage Bionetworks

Sage Bionetworks is a Seattle-based 501(c)(3) nonprofit research organization founded in 2009 to drive a new age of discovery through open science and radical collaboration. Sage develops and operates Synapse, an NIH-listed generalist data repository, and has spent 15 years building governed data commons for sensitive biomedical data on behalf of the research community. Learn more at <https://sagebionetworks.org>.

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