



Project Orchid: A Conceptual 3D Open Science Collaboration Platform for Multi-National Clinical Innovation Programs

Abstract

The U.S., and its clinical research stakeholders in the global drug discovery and public health research domains that address infectious and chronic diseases, genomic data modeling and maternal and child health care innovation, have chronically suffered great disparities in the adoption and advancement of clinical trial and population health data management capabilities; this is significantly apparent between U.S. based research organizations in rural and low-income urban areas, and emerging and low income markets, due to unsustainable IT infrastructure costs and the inability to consistently demonstrate compliance to data management requirements for U.S. supported GxP systems. As a result, this directly impedes the ability to mature these collaborative partnerships within the U.S. and abroad. However, based on the International Conference on Harmonization (ICH) Final Concept Paper Q10: Pharmaceutical Quality Systems) and the December 12, 2013 presentation from the Center for Drug Evaluation and Research, on the FDA's perspective on international clinical trials, there are clear signs that the global market have been ready adopt methods to overcome these barriers of collaborative innovation due to:

- _Heightened advocacy regarding disparities of underrepresented patient populations in clinical trials
- _Increased global strategies for international policy harmonization
- _Increased global acceptance of imported clinical data sets, and sustainable Open Source Health IT platforms
- _Access to timely patient and population-level clinical intelligence, process transparency and agile data capacity management solutions

The primary aim of Project Orchid, a conceptual Open Source/Open Science platform, is to bridge those gaps, by providing capabilities that align to ICH and FDA GCP guidelines for collaborative research. For Phase I, the goal is to develop and test a proof of concept that will simulate the following use cases:

- _TB/HIV Disease Management & Clinical Trial Drug Discovery
- _Maternal and Child Health Innovation Program Modeling using mHealth and Smart Card technology for Population Health Tethering Practices
- _Clinical Imaging Trial Research in Radiology
- _Population Health & Clinical Trial Digital Library, Clinical Registry and Virtual Knowledge



Management Network

Project Orchid is unique in its conceptual design as a Platform-As-A-Service offering; it consists of Collaboration Maturity Model, a 3D Open World Virtual Lab, a genomic avatar design center, and a Global Health Learning Engine and Digital Library, which enables virtual innovation partnerships between multi-national research teams, using basic Internet access, smart card and mobile technology. The following technology standards will be used to develop the Enterprise Reference Architecture: Web3D Consortium X3D standards, HL7, DICOM, IEEE, Smart Card Alliance, U.S. Dept. of Health and Human Services Health IT Standards and Interoperability Framework, Agency for Healthcare Quality and Research Registry of Patient Registry Framework, and The Open Group Architecture Framework. This will provide an implementation model that will support a secure and sustainable IT infrastructure that can integrate with pre-existing clinical and medical device IT platforms, and minimize operational cost and care management disruption within care settings.

