eSource

Advancement of digitization of clinical development for patients, sites, and sponsors by providing knowledge resources, tools and solutions, and industry engagement to enable eSource adoption

Project Life Cycle Phase:

Last Update: July 2020

Benefits:

- Develops best practices and call to action publications to create change
- Accelerates the maturity of EHR data through FHIR® as an eSource for Clinical Research to create a scalable solution
- Develops tools and solutions for stakeholders to evaluate readiness
- Engages with global regulatory agencies to understand expectations, raise awareness, and open conversations

Solutions:

Technology Considerations Paper (2020):

Technology considerations transcend technology issues —influencing regulatory, process, and ethical realms of clinical research

Accelerating Adoption of eSource in Clinical Research Paper (2020):

Adoption of eSource will improve data integrity by allowing direct data flow from the source to the sponsor's system, with minimal or no human intervention

CDISC Lab Semantics in FHIR® Implementation Guide (2019):

In partnership with HL7, eSource is working to bridge the gap between CDISC and HL7 standards, harmonizing existing standards, and advancing the maturity of HL7 FHIR® for use in clinical research

Site Capability Questionnaire (2019):

Form to help capture the site's use of technology during the site qualification process

Site Maturity Curve (Q3 2020):

Tool to help study sites determine their readiness for eSource implementation, by identifying their level and pathway to increasing interoperability