Early adopters' minimum criteria for success in implementing eSource

Background: The European Institute for Innovation through Health Data (i~HD) has launched the eSource Scale Up Task Force, to transform clinical trial data collection. This task force, comprising select industry and healthcare members, aims to revolutionize clinical trial execution by scaling eSource technology globally. Building on initiatives like EHR4CR, EHR2EDC and EU-PEARL , the task force focuses on advancing impartial recommendations across vendors, pharmaceutical companies, and hospitals.

The first in a series of deliverables is the "Early Adopters' Minimum Criteria for Success", offering guidance for scaling eSource technology for different stakeholders. Future deliverables will include eSource assessment criteria, the eSource PLAYBOOK, and Guiding Principles for Preparing, Planning, Setup, and Execution of eSource Implementation. These will be informed by insights from workshops and webinars involving hospitals, sponsors, vendors, and regulators.

Contents

1.1 Health Care Organisations

a. Routinely or planned to conduct high number of clinical trials requiring high volume of data entry
b. Structured data entry into electronic EHR, ensuring
    I. complying with published guidance to capture data provenance (ISO 18308, ALCOA and EMA reference) and have robust audited version tracking
    II. availability in structured and coded form of Vital Signs (VS) and Local Lab (LL) data
c. Utilization of a certified EHR system, meeting regional requirements such as ONC
d. Adoption of FHIR® with action plans for incorporating research FHIR® resources into the system roadmap ensuring ongoing support and commitment from senior staff through a periodic review process.
e. Utilization of common clinical coding ontologies such as LOINC and/or SNOMED.
f. Demonstrated or willing to commit capacity from the EHR eSource Team including clinical informatics resources.
g. Additional requirements such as privacy and security approval, will be a part of the Commitment and Capacity Team's initial work.

Recommendations:

1) Expanding structured data entry into EHR such as Medications and Adverse Events (AE)
2) Assessment of site processes and technology systems to ensure readiness for integration with an eSource vendor or existing vendor compliant with consortium requirements and approved by the Sponsor. Long-term considerations of the taskforce include the development of a maturity matrix for sites and middleware certification.

1.2 Middleware EHR2EDC vendors

a. Utilization of FHIR® and EHR-agnostic approach.
b. Demonstrated site acceptability with evidence of user acceptance.
c. Study set up activities must be vendor independent and relying on ODM as a standard
d. Vendor implementation at sites must be technology/vendor agnostic allowing multiple vendors to be implemented with no additional efforts and costs
e. Adherence to Vulcan Implementation Guidelines
f. Conversion of data from site LOINC and/or SNOMED codes to FHIR® to ODM, shared freely with the sponsor.
g. Establishment of a clear end-to-end data flow where the EHR2EDC vendor is not the data controller.
h. Capability to transfer key data domains: Vital Signs, Local Lab, and Concomitant Medications (with future considerations for AE and mCode for oncology data).
i. Data use is limited to transfer to the trial sponsor exclusively, with no other permissible usage outside data required by the study protocol
j. Compliance with GDPR/HIPAA and CFR 21 Part 11 standards regarding data processing roles.
k. Implementation of a change management process to handle EHR site changes, FHIR setup modifications, middleware solution updates, and protocol amendments.
l. Evidence of a realistic roadmap addressing both structured and unstructured data requirements for typical clinical trial protocols.
m. Fulfillment of End-to-End traceability and audit trail providence, including the ability to detect and alert changes to EHR data.
n. Implementation of user access controls, with considerations for Single Sign-On (SSO) in the long term.

1.3 EDC vendors

a. Implement a unified study eCRF capable of accommodating both manual and EHR2EDC data entry.
b. Integrate laboratory ranges using FHIR® resources to ensure consistency and accuracy.
c. Develop eCRF forms through seamless integration with EHR systems.
d. Enable data entry directly through integration channels for enhanced efficiency.
e. Provide real-time status updates for integrated data to facilitate monitoring and management.
f. Implement robust audit trail mechanisms to track changes and maintain data integrity across integrated platforms.

1.4 EHR vendors

a. Provide FHIR® access to essential clinical research data elements such as LB, VS, and ConMed.
b. Offer native functionality tailored for research purposes, with ongoing development to enhance research capabilities.
c. Enable the creation of research-specific forms (e.g., AE forms) within the EHR system to streamline data collection and reporting processes.
d. Ability to collect data from external sources such as wearables and process them to be data research ready.

Recommendations:

Have a clear roadmap for exposing additional FHIR® research resources (e.g., subject ID, subject status, protocol, schedule of activities, study AE), including capabilities for using AI to abstract structured data from unstructured health records (text, images, sound...)