



CASE STUDY:

Increase usage of FHIR data standards to expand the breadth and depth of clinical research



Challenge

The data science department of a national government organization was assigned the task of providing a secure and reliable clinical IT infrastructure and a variety of IT and scientific computing services to its community in support of mission-critical clinical research.

To accelerate clinical research, it was essential for researchers to be able to securely share clinical data in standard formats that would enable large-scale analytics across many different clinical data sources. For this reason, they wanted to increase usage of the Fast Healthcare Interoperability Resources (FHIR) standard which defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems. In the context of FHIR, health data is not restricted to electronic health records but also includes genomics data, and data from mobile apps, sensors, and wearables. To understand how to improve its usage, the department hired BioTeam to assess the landscape of adoption, implementation, and use of FHIR in clinical research.

Approach

BioTeam partnered with the organization to approach the assessment from multiple angles:

- Evaluated the core FHIR technical documentation which defines data standards and mechanisms for sharing healthcare data with patients and with researchers.
- Reviewed the Final Rule released by the Office of the National Coordinator for Health Information Technology (ONC) that requires the use of FHIR for sharing patient data throughout the national healthcare system.
- Studied federal policies for data management and sharing.
- Conducted in-depth interviews with clinical researchers and technologists across the nation to evaluate familiarity with FHIR and the maturity of FHIR as a technology that could enable research.
- Studied a broad range of existing and emerging technologies that support FHIR infrastructure.
- Performed a demonstration of FHIR data loading and extraction using OMOP, a widely used clinical data warehouse schema to evaluate the maturity of this platform with respect to the FHIR data standard.
- Studied actual and hypothetical use cases for using FHIR in research and described the gaps between the ideal and the real implementations of FHIR technologies.

Outcome

BioTeam's assessment clearly indicated that FHIR adoption will be driven by a powerful combination of policy, data sharing, research, and interoperability needs. Also evident was the overwhelming support for data sharing through FHIR and the profound effect that the ONC directives will have on FHIR adoption in healthcare. We also found that a number of FHIR tools (e.g., databases, APIs for smart devices) are established, well-supported, and ready for broad production use. However, the FHIR standard itself is in need of continued attention since mature. Resources for a wide variety of biomedical data domains (e.g., genomics, proteomics) are not yet available, and significant work is needed in order to translate these abstract Resources into practical Implementation Guides for researchers and technologists. There is also a significant need for software that can translate biomedical content into FHIR format, starting with both structured and unstructured content.

Based on these findings, BioTeam made specific recommendations to the government to advance the use of FHIR in research:

- Offer specific funding opportunities that would create biomedical centers and hospitals that create and share data in FHIR format for use in research.
- Create government-funded initiatives that bring government agency and external technologists and researchers together to pilot remote sensing, pragmatic trial, and multi-site studies using FHIR.
- Fund awards or challenges that specifically address the need for Natural Language Processing code that creates FHIR-formatted content from unstructured text.
- Fund organizations specifically tasked with creating Implementation Guides due to the need for a wide variety of IGs addressing the many different possible uses for FHIR in healthcare, research, and registries.

The relevance of this work derives from the importance of FHIR itself: it is the only standard that structures clinical data content and specifies how this content can be shared, and this sharing will benefit patients, the healthcare system, and clinical research. As FHIR adoption spreads, driven both by federal policy and patient advocacy for their data, BioTeam will continue to work with researchers and organizations to implement systems and software that use FHIR and enable biomedical research on disease and biological mechanisms.

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