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Review

Review

HL7 FHIR-based tools and initiatives to support clinical research: a scoping review

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ABSTRACT

Objectives: The HL7® fast healthcare interoperability resources (FHIR®) specification has emerged as the leading interoperability standard for the exchange of healthcare data. We conducted a scoping review to identify trends and gaps in the use of FHIR for clinical research.

Materials and methods: We reviewed published literature, federally funded project databases, application websites, and other sources to discover FHIR-based papers, projects, and tools (collectively, "FHIR projects") available to support clinical research activities.

Results: Our search identified 203 different FHIR projects applicable to clinical research. Most were associated with preparations to conduct research, such as data mapping to and from FHIR formats ($n = 66$, 32.5%) and managing ontologies with FHIR ($n = 30$, 14.8%), or post-study data activities, such as sharing data using repositories or registries ($n = 24$, 11.8%), general research data sharing ($n = 23$, 11.3%), and management of genomic data ($n = 21$, 10.3%). With the exception of phenotyping ($n = 19$, 9.4%), fewer FHIR-based projects focused on needs within the clinical research process itself.

Discussion: Funding and usage of FHIR-enabled solutions for research are expanding, but most projects appear focused on establishing data pipelines and linking clinical systems such as electronic health records, patient-facing data systems, and registries, possibly due to the relative newness of FHIR and the incentives for FHIR integration in health information systems. Fewer FHIR projects were associated with research-only activities.

Conclusion: The FHIR standard is becoming an essential component of the clinical research enterprise. To develop FHIR's full potential for clinical research, funding and operational stakeholders should address gaps in FHIR-based research tools and methods.

Key words: fast healthcare interoperability resources (FHIR), health information interoperability, data management, health information management, electronic health records

BACKGROUND AND SIGNIFICANCE

The Health Level Seven International® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®)[1] specification has been rapidly adopted in healthcare to enable clinical data exchange. FHIR is a set of data models and aligned technologies that define data formats, data elements, and application programming interface (API) protocols to enable the exchange of healthcare-related information.[1] FHIR is built on modern computing standards (eg, JavaScript Object Notation [JSON], Secure HTTP [https]) and has data elements that are organized into data models called *Resources*. Data exchange rules, including additional data elements and constraints on the data model, are specified in *Profiles*. *Implementation Guides* serve as "recipes" or standard operating procedures for consistent use of FHIR Resources and APIs to support workflows in specified domains, thereby standardizing processes in addition to data.[2] Together, these core components of rules and procedures enable data exchange among a growing number of computer applications in healthcare. Integral to the adoption and development of FHIR has been the Substitutable Medical Applications and Reusable Technologies (SMART) API standard, which allows applications or "apps" to be used across a variety of health information systems without modification. A SMART on FHIR application implements standardized authorization and authentication protocols with the data interoperability specifications of FHIR.[3]

FHIR was first proposed in 2011[4] as a new specification from the HL7 standards development organization, based on emerging industry approaches and work accomplished in previous versions of HL7 standards development. Since then, federal agencies and insurers have begun promoting its use, particularly in response to the US 21st Century Cures Act of 2016 (Cures Act), which calls for simplified access, exchange, and use of healthcare information, via APIs, to support increased interoperability.[5] In March 2020, the Office of the National Coordinator for Health Information Technology (ONC) released a rule[6] by which interoperability provisions of the Cures Act[5] are to be implemented, providing a clearer path for health data interoperability. The National Institutes of Health (NIH) Strategic Plan for Data Science[7] and the National Library of Medicine (NLM) 10-year strategic plan[8] to ensure that research data are Findable, Accessible, Interoperable, and Reusable (FAIR)[9] have helped prioritize the development of standardized data exchange for research.[10,11] The current challenge is to implement modern data exchange standards for research in an industry that, so far, has focused on providers, payors, and patients.

In July 2019, NIH issued a notice (NOT-OD-19-122) to encourage investigators to explore applications of FHIR to "capture, integrate, and exchange clinical data for research purposes."[12] Vanderbilt University Medical Center was awarded a contract to pursue these goals with NLM support.[13] Because FHIR usage for research purposes is relatively new and growing at a rapid pace, no compilation currently exists of such projects. For this reason, we conducted a scoping review of FHIR-based papers, projects, and tools (collectively, "FHIR projects") available or in development that address the use of FHIR in support of clinical research. Our review differs from previous a review of FHIR use in clinical data exchange[14] as our review is focused on FHIR applications and projects in clinical research. This article presents a compilation and evaluation of our findings.

METHODS

Protocol

The Preferred Reporting Items of Systematic Reviews and Meta-Analysis (PRISMA) methodology extension for scoping reviews (PRISMA-ScR) was used to develop our review protocol, which is summarized below. The objective of this review was to systematically identify and categorize FHIR projects that self-identify as being designed for, useful for, or relevant to clinical research. The review was designed to address the following questions:

1. What FHIR projects currently exist or are being developed for clinical research preparation, planning, recruitment, management, or conduct, or for sharing and analysis of clinical research data?
2. What gaps are there in the landscape of FHIR projects for clinical research that have yet to be filled?

Eligibility criteria

Items eligible for inclusion in the review described a project, study, resource, method, tool, or application that uses or proposes to use FHIR to design, implement, or test tools, resources, and applications to advance clinical research. Publication years were restricted to 2015–2021. We excluded items unrelated to FHIR and ones that did not fit the conceptual framework of our review, including those describing clinical uses of FHIR with no research applications, those focusing on technology or computer science aspects, those using only features of the SMART on FHIR protocol that were not part of the HL7 FHIR specification (eg, user authentication), and general descriptive articles that did not reference practical methods or tools. We also excluded projects not written in the English language.

Information sources and search strategy

The following online bibliographic databases were searched for peer-reviewed publications: PubMed, ScienceDirect, and SpringerLink. For the search for federally funded projects, we queried NIH RePORTER[15] and the websites of the National Science Foundation (NSF),[16] the Agency for Healthcare Research and Quality (AHRQ),[17] and the Office of the National Coordinator for Health Information Technology (ONC).[18] For the tool search, we searched the app stores of leading electronic health record (EHR) vendors (Allscripts App Expo, Cerner App Gallery, Epic Apple Orchard, SMART App Gallery). In addition, we hand-searched the reference lists of relevant publications, reviewed project implementations listed on the FHIR website ("FHIR Applications Registry"). We also conducted a web search to locate any relevant gray literature on FHIR use for research, such as review papers, white papers, expert opinions, internet reports, government websites, and book chapters.

A research information specialist (N.K.) and informatics researcher (S.D.) developed the search strategies and conducted the searches. The proprietary online search engine provided by each database or website was employed when available. In most cases, the terms "FHIR" and "Fast Healthcare Interoperability Resources" were the terms searched. The full list of search strategies is presented in Table 1. We included papers published from January 1, 2015 (to avoid early concept papers irrelevant to our review), through September 15, 2021. Our search for funded projects and applications was conducted on September 15, 2021. We restricted our applications search to those apps that explicitly stated they were designed for research or could be used to facilitate research activities.

Selection of sources

All candidate records were deposited first into a reference manager software program and then compiled into a single Microsoft Excel spreadsheet. If a publication, funding award, and/or application and website referenced the same project, they were merged into a single

Table 1. Data sources and search strategies

Source	URL	Search strategy
PubMed	https://pubmed.ncbi.nlm.nih.gov/	(FHIR) OR (Fast Healthcare Interoperability Resources): filtered by 01/01/2015-09/15/2021
SpringerLink	https://link.springer.com/	FHIR OR "Fast Healthcare Interoperability Resources": filtered by 2015-2021 and English language
ScienceDirect	https://www.sciencedirect.com/	(FHIR OR "Fast Healthcare Interoperability Resources"): filtered by 2015-2021
NIH RePORTER	https://reporter.nih.gov/	FHIR
AHRQ	https://digital.ahrq.gov/ahrq-funded-projects/search	FHIR OR "Fast Healthcare Interoperability Resources"
NSF	https://www.nsf.gov/awardsearch/	FHIR OR "Fast Healthcare Interoperability Resources"
ONC	https://www.healthit.gov/topic/scientific-initiatives	All
Tool-Allscripts	https://storealpha.allscripts.com/	Category=FHIR Apps
Tool-Cerner	https://code.cerner.com/apps	FHIR
Tool-Epic	https://apporchard.epic.com/Gallery	FHIR & Categories=Research
Tool-SMART App Gallery	https://apps.smarthealthit.org/apps	Category=FHIR Tools
Website-FHIR	https://www.fhir.org/implementations/registry/	All
Google	https://www.google.com/search?q=%2Bfhir+%2Bresearch	"+fhir +research"

project listing that included all relevant citations. The items extracted for each record included, as applicable: title, first author or funding award recipient, journal, URL, publication or award year (where specified), abstract, and source. After excluding duplicates, the first authors (S.D. and N.K.) independently screened each record's title, abstract, description, or summary, as applicable, depending on whether the project was a paper, funded award, or application. We excluded those records not related to FHIR and those for which the full text could not be retrieved. For the remaining records, the full text was reviewed. Records were excluded that were not related to a specific FHIR clinical research use such as those with only a technology focus, only about the potential promise of FHIR, or only about SMART on FHIR. Disagreements regarding inclusion or exclusion were resolved through discussion between the two adjudicators (S.D. and N.K.), who together approved the final list of included projects.

Data items and charting

The same authors (S.D. and N.K.) independently reviewed all included projects and labeled them according to how FHIR was being proposed or used to support research (eg, to extract data from an EHR, map data between formats, or standardize genomic data formats). Each project could receive more than one label.

To support consistent labeling, we used a flowchart defined by Marquis-Gravel et al[19] that outlines opportunities for leveraging EHRs for clinical trials. This trial-oriented framework, applicable to clinical research studies in general, was also useful as a foundation for organizing and synthesizing many of the FHIR projects discovered in our search, as FHIR is a principal means of extracting and repurposing EHR data. The Marquis-Gravel framework includes the major EHR-based elements capable of supporting a clinical trial, such as cohort identification, consent procedures, recruitment and retention, study management, and data collection. Within the established framework, we added categories for collecting data from patients (eg, surveys, patient-reported outcomes [PROs]), collecting data from devices such as wearables and monitors, and sharing and coordinating regulatory documentation. Given that research uses for FHIR extend beyond the conduct of a single study, we extended this framework to include a clinical research preparation stage that encompasses such organization-level activities as establishing data pipelines and infrastructure, or mapping between FHIR and other data formats (eg, Observational Medical Outcomes Partnership[20] Common Data Model to FHIR, FHIR to Clinical Data Interchange Standards Consortium[21] formats, custom datasets to FHIR Resources). We also extended the framework beyond study conduct, to include post-study activities such as preparation of analysis datasets, research data sharing, and depositing data in registries or repositories. These added categories were determined through prior reviews of the literature and discussion with all authors. If the reviewers determined a need for additional categories during the labeling process, they were discussed with the other authors and added to the categorization system.

Synthesis of results

The lead authors (S.D. and N.K.) independently assigned each of the FHIR projects identified in the search to one or more of these research use categories and then compared and harmonized the selection of labels for each FHIR project based on discussion. Each project could receive multiple labels to describe its use of FHIR for research. Categorization differences were resolved through a joint re-review of the materials and discussion. Any persisting conflicts in labeling were to be resolved by a third author (P.H.). We calculated the counts and frequencies of each label, as well as the number of projects with labels in each study phase (eg, Preparation, Recruitment, Study Conduct).

RESULTS

Selection and characteristics of sources of evidence

Our searches identified 1572 candidate FHIR projects through searches of publication databases ($n = 1285$), funding libraries ($n = 120$), tool/app stores ($n = 41$), citation searches ($n = 43$), and other websites and search engines ($n = 83$). We dropped 135 duplicate records and screened out an additional 907 records after a review of the title, abstract, or other preview material. Of the 530 records sought for retrieval, 16 could not be obtained, primarily due to expired web links that could not be located elsewhere. A total of 530 candidate FHIR projects were reviewed in depth, of which 311 were dropped after review, which were mostly projects not addressing a research use for FHIR ($n = 148$) or papers that were not actually about FHIR, often mentioning FHIR only once in a background text or citation ($n = 76$). Of the original 1572 candidate projects,

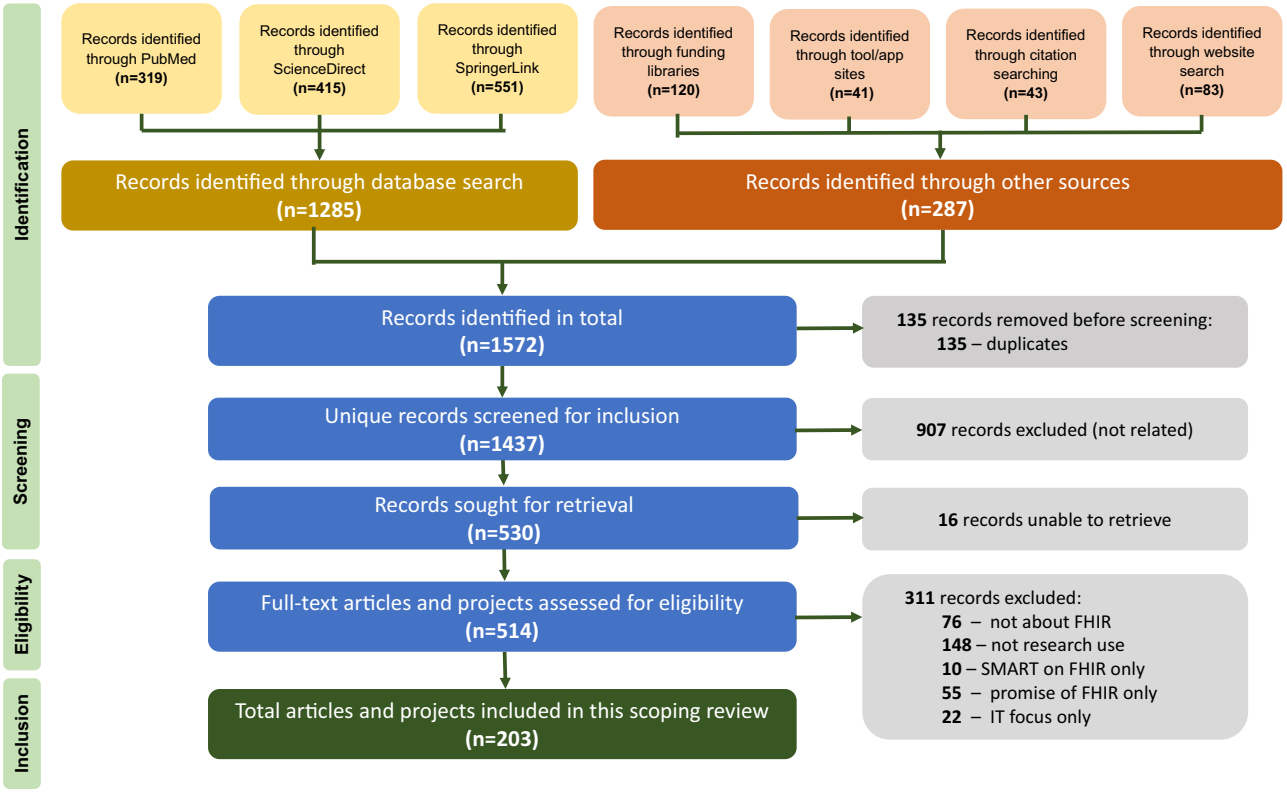

Figure 1. PRISMA flowchart identification of FHIR projects related to clinical research. Figure acronyms: FHIR, fast health interoperability resources; IT, information technology; SMART, Substitutable Medical Applications and Reusable Technologies.

203 (12.9%) were selected for inclusion in the scoping review (Figure 1). Note that our search found 16 projects that included more than one source, such as a paper and tool, funding award and tool, website and tool, or paper and website. For these 16 cases, we classified the search source as the one through which we originally found the project. The final 203 projects are thus represented by 125 articles from publication databases (plus their associated tools and websites),[11,22–155] 29 projects from funding award libraries (plus their associated tools),[156–187] 12 standalone tools from app stores,[188–199] and 37 items from website and citation searches (plus their associated tools or websites).[200–238]

Thirty-eight different labels were available using the expanded Marquis-Gravel categories to categorize how each project used FHIR to contribute to research activities (Figure 2). Reviewer 1 used an average of 1.64 labels per item and reviewer 2 an average of 1.66 labels. Approximately, one-third of FHIR projects were labeled identically between reviewers ($n = 73$, 36%) and 40 did not match (19.7%), with the remainder overlapping with some or most categories. All categorization differences were resolved through joint review of the materials and discussion and did not require intervention of the third reviewer. After the harmonization of the labels, projects had a mean of 1.8 labels, with 89 projects receiving only one label and two projects with five labels.

Characteristics of sources and synthesis of results

Two-thirds of FHIR projects were funded or published in the most recent 3 years, with 41 in 2019 (20%), 44 in 2020 (22%), and 43 projects through mid-September of 2021 (21%). The remaining third of the projects were older, with 26 in 2018 (13%), 23 in 2017 (11%), 13 in 2015–2016 (6%), and 13 with no date specified (6%).

Across the trajectory of clinical research activities, most projects focused on general research preparation including infrastructure and development of data pipelines ($n = 152$, 74.9%). The second major category for research-related FHIR projects was post-study activities ($n = 93$, 45.8%), including analyzing data, managing specific types of collected data, and sharing data, followed by study conduct ($n = 52$, 25.6%). The individual categories with the most research-related FHIR projects involved mapping data to and from FHIR formats ($n = 66$, 32.5% of projects), managing ontologies for FHIR ($n = 30$, 14.8%), sharing data through FHIR-enabled repositories or registries ($n = 24$, 11.8%), research data sharing including personal health records ($n = 23$, 11.3%), managing genomic data ($n = 21$, 10.3%), and cohort phenotyping ($n = 19$, 9.4%). FHIR projects appeared less common among prestudy feasibility assessment activities ($n = 27$, 13.3%), study setup ($n = 29$, 14.3%), and recruitment ($n = 5$, 2.5%) (Table 2). All FHIR projects and their labels are listed in Supplementary Table S1.

Unused labels from the Marquis-Gravel categorization included two prestudy activities (cohort's interaction profiles with the health system, recruitment plan), two study setup activities (feasibility dashboard, embed study instructions in EHR), one recruitment task (EHR health portals with patient opt in/opt out), and one study activity (extracting data to facilitate the work of the study coordinator.)

DISCUSSION

Summary of evidence

Our landscape assessment revealed a growing number of FHIR-related projects, but limited penetration of FHIR in current research operations, especially compared to its more robust use in clinical

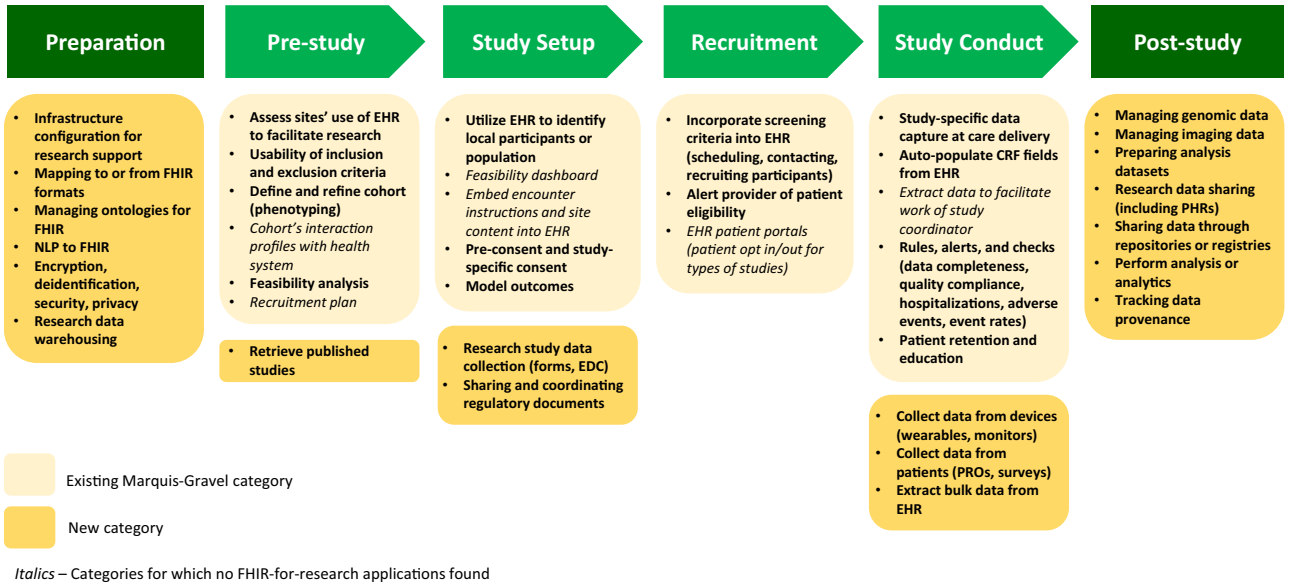

Figure 2. Expanded Marquis-Gravel categorization[19]—major components of clinical research facilitated by FHIR capabilities. CRF, case report form; EDC, electronic data collection [system]; EHR, electronic health record; NLP, natural language processing; PHR, personal health record; PRO, patient-reported outcomes.

applications for direct patient care.[14] Most FHIR projects to date appear focused on the two ends of our clinical research trajectory: the development of FHIR-based data infrastructure and pipelines or the storage, analysis, or sharing of data generated from the study. This may reflect the relative newness of the FHIR specification; researchers and software developers are still building the foundations and working on transmitting data in FHIR. Moreover, many of the remaining research- and FHIR-related projects we did find were linked to clinical systems such as EHRs, patient-facing data systems, and registries, a situation possibly driven by patient, provider, or payor needs. We found relatively few projects associated with prestudy research activities, such as participant recruitment, consenting, and management of study documents.

Among the published papers that describe FHIR-based research application projects, a fair number of examples fall into the realm of demonstration projects, single-purpose applications, or concept ideas for FHIR tool development.[89,93,112,128,225] Similarly, while various funded projects are developing FHIR infrastructure and tools to achieve their research aims, few are actively engaged in the development of FHIR-based research tools as their primary objective.

Limited adoption to date of FHIR for research may also be due to gaps in the FHIR specification. Essential enhancements to FHIR and its accompanying Implementation Guides are needed, including additional research-related FHIR Resources and protocols for study document management and participant consent. Many of these projects are in formative phases, and the ever-expanding FHIR implementer community is continually working to evaluate proposed additions to the specification and broaden the range of research use cases for FHIR. Connectathon events, organized regularly by HL7, engage participants from industry and academia in hands-on development and testing of new FHIR-based software solutions, including solutions benefiting research.[239] The HL7 FHIR Accelerator program comprises a growing list of defined user communities across the spectrum of healthcare to improve data interoperability, including CodeX (data exchange for cancer research), the Da Vinci Project (payor–provider data interoperability), and the Gravity Project (social determinants of health).[240] Of particular interest is HL7's Vulcan FHIR Accelerator, a recently formed, multistakeholder program to advance the development, refinement, and use of the FHIR standard to bridge gaps between healthcare and clinical research by fostering collaborations, maximizing shared resources, and developing FHIR Research Resources.[241]

Despite gaps in project coverage and the FHIR specification itself, FHIR usage in the research context is evolving quickly. The body of literature reporting on FHIR-related projects for clinical research is growing steadily; most manuscripts included in this review were published between 2019 and 2021, demonstrating growing interest in this topic among researchers. Funding by NIH for developing FHIR tools to support research is also increasing.[13] Notably, a priority of the recently released Policy and Development Agenda on National Health IT Priorities for Research promulgated by ONC is to improve the interoperability of healthcare data and the underlying documentation to enable investigators to more productively exploit FHIR-based APIs for research.[242,243] The ONC Cures Act Final Rule also confirms the adoption of the FHIR Bulk Data Access implementation specification, providing a mandate for prioritizing further development and use of this technology.[6] This specification may be transformative in enabling clinical research data retrieval to be both timely and efficient. In addition, a December 31, 2022, compliance deadline for the Cures Act components in the ONC Health IT Certification Program[244] requires FHIR R4.0.1, US Core profiles, and SMART on FHIR. This will likely lead to further adoption of FHIR in EHRs, especially at academic medical centers, thereby accelerating the network effect and allowing researchers to develop FHIR applications and benefit from the data interoperability.

Limitations

Our scoping review has several limitations. FHIR usage in the research domain is changing rapidly and our review was conducted within a finite timeframe. Our search of the gray literature was not exhaustive and may have missed research-related work presented in other forums. Indeed, we may have missed FHIR-related tools for "the middle" of the research trajectory (prestudy, study setup, recruitment) if such tools are only presented in closed EHR vendor conferences. We also excluded FHIR projects designed strictly for

Table 2. Synthesis of results—research-related FHIR projects by category

Categories	Count	% projects	Category total
Preparation			152 (74.9%)
Mapping to or from FHIR research formats	66	32.5	
Managing ontologies for FHIR	30	14.8	
Infrastructure configuration for research support	17	8.4	
NLP to FHIR	16	7.9	
Research data warehousing	14	6.9	
Encryption, deidentification, security, privacy	9	4.4	
Prestudy			27 (13.3%)
Define and refine cohort (phenotyping)	19	9.4	
Assess sites' use of EHR to facilitate research	3	1.5	
Usability of inclusion and exclusion criteria	2	1.0	
Retrieve published studies	2	1.0	
Feasibility analysis	1	0.5	
Study setup			29 (14.3%)
Research study data collection (forms, EDC)	12	5.9	
Preconsent and study-specific consent	7	3.4	
Utilize EHR to identify local participants or population	6	3.0	
Sharing and coordinating regulatory documents	3	1.5	
Model outcomes	1	0.5	
Recruitment			5 (2.5%)
Incorporate screening criteria into EHR (scheduling, contacting, recruiting participants)	4	2.0	
Alert provider of patient eligibility	1	0.5	
Study conduct			52 (25.6%)
Collect data from patients (PROs, surveys)	14	6.9	
Collect data from devices (wearables, monitors)	13	6.4	
Autopopulate CRF fields from EHR	12	5.9	
Extract bulk data from EHR	8	3.9	
Rules, alerts, and checks	2	1.0	
Study-specific data capture at care delivery	2	1.0	
Patient retention and education	1	0.5	
Post-study			93 (45.8%)
Sharing data through repositories or registries	24	11.8	
Research data sharing (including PHRs)	23	11.3	
Managing genomic data	21	10.3	
Preparing analysis datasets	12	5.9	
Managing imaging data	5	2.5	
Perform analysis or analytics	5	2.5	
Tracking data provenance	3	1.5	
Total labels	358 (for 203 projects)		

CRF, case report form; EDC, electronic data collection [system]; EHR, electronic health record; NLP, natural language processing; PHR, personal health record; PRO, patient-reported outcomes.

clinical use, although we recognize such tools may be repurposed for research in appropriate circumstances.

The Marquis-Gravel schema provided an essential framework for our labeling of projects, but the categories were designed to describe EHR use in clinical trials and did not reflect all the possible uses of FHIR in a clinical research context. We attempted to remedy this by the development of additional categories. Our assignment of categories was also subjective; although we had two authors independently reviewing the citations, discussion and additional review of the material was necessary for almost two-thirds of the projects. While useful for this scoping review, we recognize this organizational framework is an approximation of the clinical research process, that not all research studies require all categories, and that some research activities may span individual process steps. Nevertheless, our review revealed gaps and opportunities in the application of FHIR for research that may inform future development and implementation efforts.

CONCLUSIONS

Despite significant interest in FHIR among investigators and the potential of the FHIR standard to transform the clinical research landscape, relatively few FHIR projects that address research needs are fully operational. Moreover, FHIR specifications for research operations, while developing at a fast pace, are not yet mature. Although more FHIR-enabled apps for research are entering the marketplace, a scattershot approach is unlikely to create a truly interoperable research ecosystem. Promoting and investing in the further development and use of FHIR Implementation Guides to support research through programs such as Vulcan will encourage the broad and substantial base needed to ensure that interoperability is accessible and attainable for all researchers.

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AUTHOR CONTRIBUTIONS

S.D. and N.K. contributed equally to the manuscript. P.H., T.Z.-C., N.K., D.C., and S.D. conceived the study. N.K. and S.D. conducted the searches, reviewed and classified the findings, and drafted the manuscript. All authors revised the manuscript and approved the final submission.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

DATA AVAILABILITY

No new data were generated or analyzed in support of this research.

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