Evaluating automated electronic case report form data entry from electronic health records

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Abstract

Background: Many clinical trials leverage real-world data. Typically, these data are manually abstracted from electronic health records (EHRs) and entered into electronic case report forms (CRFs), a time and labor-intensive process that is also error-prone and may miss information. Automated transfer of data from EHRs to eCRFs has the potential to reduce data abstraction and entry burden as well as improve data quality and safety. *Methods:* We conducted a test of automated EHR-to-CRF data transfer for 40 participants in a clinical trial of hospitalized COVID-19 patients. We determined which coordinator-entered data could be automated from the EHR (coverage), and the frequency with which the values from the automated EHR feed and values entered by study personnel for the actual study matched exactly (concordance). *Results:* The automated EHR feed populated 10,081/11,952 (84%) coordinator-completed values. For fields where both the automation and study personnel provided data, the values matched exactly 89% of the time. Highest concordance was for daily lab results (94%), which also required the most personnel resources (30 minutes per participant). In a detailed analysis of 196 instances where personnel and automation entered values differed, both a study coordinator and a data analyst agreed that 152 (78%) instances were a result of data entry error. *Conclusions:* An automated EHR feed has the potential to significantly decrease study personnel effort while improving the accuracy of CRF data.

Introduction

The use of patient electronic health record (EHR) data for clinical trial data collection has been helpful in streamlining parts of the research process [1–4]. However, EHR data and data for clinical trials are collected for fundamentally different purposes. EHR data are collected primarily to inform clinical care and support hospital billing with little consideration for secondary research use. Clinical trials, on the other hand, require rigorous protocol-specific data collection with precise clinical context and timing parameters to enable controlled comparisons. While not all EHR data are beneficial for clinical studies, some, such as clinical lab results and vital signs collected in usual care clinical settings, can be repurposed for research by entering them into case report forms (CRFs) from the EHR. Reusing EHR data reduces participant burden by avoiding the duplication of patient testing and conserves valuable study resources by reducing study costs.

Historically, the process for using EHR data in study CRFs has relied upon research coordinators performing chart reviews on research participants, then manually transcribing data from the EHR into participants' CRFs in an electronic data capture (EDC) system such as REDCap (Research Electronic Data Capture) [5]. The process of chart review and transcribing data from the EHR to an EDC by research coordinators is labor intensive and prone to error [6]. Automated CRF completion using EHR data has the potential to improve the efficiency and accuracy of study data collection [7]. Researchers have shown that automatically transferring data from EHRs to CRFs can decrease data latency, transcription errors, database queries, monitoring activity, and staff time and effort [8,9]. Others have found that the added value for EHR-to-CRF transfer is limited by data missingness and a lack of contextual detail that is needed for research [10,11]. Nevertheless, guidance from the U.S. Food & Drug Administration (FDA) has encouraged the secondary use of EHR clinical data for research, emphasizing that the interchange between EHR and EDC systems should leverage interoperable standards [12,13].

This study assesses the potential benefit of automated EHR-to-CRF data transfer to augment coordinator chart review for an actual clinical trial. We measure coverage (the number of fields that automation could complete), concordance (the degree of agreement between human and machine-extracted data), and efficiency (the amount of coordinator time potentially saved by automating data transfer). We also outline a process for setting up EHR-to-CRF mapping to maximize concordance and coverage using this methodology for other clinical trials.

Materials and Methods

We used the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Host Tissue (A4-HT) platform as a test case for the EHR-to-CRF data transfer. A4-HT seeks to test various therapeutic medications for critically ill patients with COVID-19 [14]. A4-HT is a multisite trial platform with over 50 recruitment sites across the USA. In this study, we focused on data collected and managed by the study team at VUMC. A4-HT research coordinators assess outcomes based on EHR data collected for routine care and enter them into a REDCap study database daily. There are 28 CRFs in the A4-HT REDCap project. Most, such as eligibility criteria, medical history, and demographics, are only collected at baseline. Three CRFs – the daily inpatient form, clinical labs, and vital signs – must be completed for each day during which the participant is an inpatient at the hospital for up to 28 days during the study. The primary REDCap study database supporting A4-HT at VUMC is not currently configured for EHR-to-CRF data transfer. Thus, it serves as a reference database for comparing traditional CRF data entry and automated CRF extraction using REDCap's Clinical Data Interoperability Services module (CDIS). CDIS gives REDCap the ability to extract data from EHR Application Programming Interfaces (APIs) that comply with the HL7 Fast Healthcare Interoperability Resources (FHIR) standard [15].

We obtained permission to conduct this evaluation from the A4-HT principal investigator, the VUMC site principal investigator, and the VUMC Institutional Review Board (study #220069). First, we assessed which A4-HT CRF instruments contained fields where data are available from the EHR. Next, we invoked a 'copy project' procedure in REDCap to clone the original A4-HT REDCap project, thereby creating a new REDCap study database with identical CRFs, data fields, and events, but no study data. We then used REDCap's researcher-facing CDIS mapping tools to map data from the EHR to each of the CRF fields where mapping was feasible.

Once our new FHIR-enabled REDCap database was established and all data mappings were configured by our study team, we began collecting and comparing the automated EHR data. We chose the first 10 of the 40 A4-HT participants who had completed the study at VUMC by January 24, 2022 for comprehensive data comparison. For these 10 participants, we extracted medical record numbers (MRN) and randomization date and time from the original REDCap study database and inserted them into the FHIR study database. The REDCap CDIS module then extracted all mapped EHR data into participants' CRFs.

Since the FHIR REDCap project was a clone of the original A4-HT REDCap project with the same variable and event names, statisticians were able to use R to query the REDCap API and compare the values in the two projects. For the 10-participant subset, a A4-HT study coordinator and REDCap analyst reviewed and discussed data discrepancies between the two projects and modified REDCap CDIS mappings to better align with the original data wherever appropriate and possible. We iteratively reapplied the mapping rules, refreshed the EHR data, and compared the data between the two projects until we could no longer make any additional improvements. As part of our assessment of efficiency, we documented personnel efforts for the coordinator and analyst to conduct these mapping tasks.

Finally, using data from the remaining 30 A4-HT participants (total of 40 participants), we tested whether our findings could be extrapolated to a larger data set. For this set of data, we did not perform an in-depth comparison with a research coordinator but did characterize both coverage and high-level (exact match only) concordance. We also estimated the amount of time spent entering data using results from Nordo *et al.*, which timed the abstraction of demographic data from the EHR into REDCap by research personnel [9]. That study found that coordinators spent an average of 15 seconds filling out each demographic field in REDCap from the EHR. Estimating 15 seconds per field provides a conservative estimate of time spent completing CRFs since demographic information is easier to find and transcribe than clinical information and because the 15 seconds does not include initiation tasks such as opening the EHR browser and CRFs.

Results

Coverage

In assessing which instruments and fields were most appropriate for automated EHR data exchange, we eliminated instruments related to randomization, blinding, and compliance. We considered EHR data for adverse events but deemed that creating phenotypes for adverse events from EHR codes was outside the scope of this work. Medical history and concomitant medications seemed feasible by scanning for condition and medication names in the problem list and medication lists, respectively. However, our testing with the first few patients proved difficult to generate a complete list of conditions and medications that fit into the various categories. Additionally, these data only have one status (i.e., active, or inactive) per condition or medication, which made it difficult to determine retroactively which conditions and medications started before the trial started.

We utilized six CRFs for which to test FHIR data pull: Demographics, Eligibility Criteria, COVID-19 Testing/Vaccination, Daily Inpatient Form, Clinical Labs, and Vital Signs. The Demographics and COVID-19 Testing/Vaccinations CRFs had FHIR data types, known as resources, that addressed those instruments well (the *Patient* and the *Immunizations* FHIR resources, respectively). The Daily Inpatient Form, Clinical Labs, and Vital Signs instruments all relied primarily on the *Observation* FHIR resource. These three forms presented the greatest opportunity to address coordinator burden since they had to be completed on each day of participants' inpatient stays during the study. In total, we mapped data for 85 CRF fields out of 100 possible fields on these six forms.

At the time we collected data for this study, 40 participants had enrolled in and completed the A4-HT study at VUMC. Coordinators entered 11,952 values in six CRFs for these 40 participants. The data from FHIR were able to populate 10,081 (84%) values. Table 1 summarizes the coverage results. Our analysis found that the study could have saved 42 hours of personnel time by using only the automated EHR extraction for the six CRFs of these 40 participants. The study coordinator and analyst expended approximately 42 hours to review and optimize the mapping rules.

Concordance: Detailed Evaluation of 10 Participants

Our detailed assessment of concordance was performed on data from 10 participants (Fig. 1). Of the 2659 values entered by the coordinator with data from the automation, 2463 (93%) matched exactly. The remaining 196 instances were discrepancies that could not be resolved by modifying the mapping or REDCap calculations. There were 152 instances in which the automated data from

Table 1. Coverage of FHIR to complete data filled by coordinator by CRF for 40 participants

CRF name	# Fields in source project	# Fields with FHIR data mapped	# Values entered by coordinator	# Values entered by FHIR	% Values entered by FHIR	Potential hours saved with FHIR*
Demographics	13	9	349	120	34	0.5
Eligibility criteria	23	20	920	800	87	3.3
COVID-19 testing/vaccination	4	4	160	159	99	0.7
Daily inpatient form	14	9	2040	1270	62	5.3
Vital signs	17	14	3433	2946	86	12.3
Clinical labs	29	29	5050	4785	95	19.9
Total	100	85	11,952	10,080	84	42

*Based on Nordo et al. mean of 15 seconds per value entered by coordinator [9].
CRF, case report form; FHIR, Fast Healthcare Interoperability Resources; COVID-19, coronavirus disease of 2019.
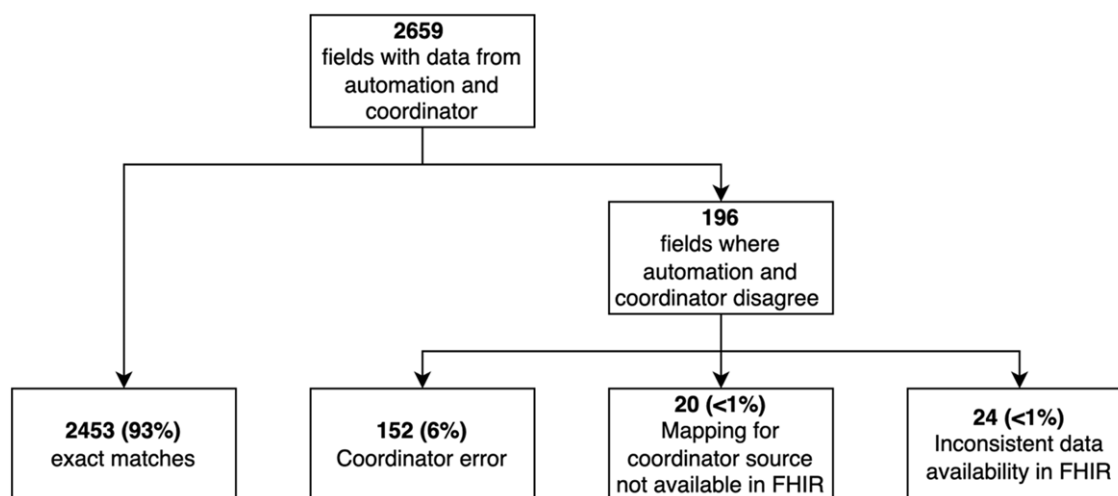
Fig. 1. Summary of data concordance for the first 10 participants in the trial at Vanderbilt University Medical Center. FHIR, Fast Healthcare Interoperability Resources.

the EHR was correct and the data hand-entered by the coordinator was incorrect as mutually agreed by the coordinator and analyst. Data entry errors included recording the first value after 8:00 am instead of the value closest to 8:00 am, entering data for the wrong day (i.e., 1 day ahead of or behind the actual study day), entering values into the wrong field adjacent to the correct field, and other simple typos. In 20 discrepancies, FHIR lacked mapping to some source fields in the EHR that the coordinators used. For example, we were able to map "pulse" in the EHR feed, but the coordinators typically selected "heart rate" from another tab in the EHR. For these 20 discrepancies, neither human nor machine were technically incorrect. Finally, 24 of the discrepancies were due to other limitations in the EHR data. For example, fever was not consistently documented in patients' problem lists and therefore was not always available for determining eligibility criteria.

Concordance: Larger Participant Sample (40 Participants)

In examining all 40 records, we found that over 90% of values with both automation and coordinator values matched exactly except in the vital signs form which had 79% concordance (Table 2). As we discovered in our detailed analysis of the first 10 records, many of the vital signs data had several sources and multiple measurements

to choose from on any given study day, which may have led to these discrepancies.

Discussion

While superiority of EHR-to-CRF data transfer over manual methods in accuracy and efficiency has been assumed, the only prototype or proof-of-concept studies that have attempted to map real-world EHR data to CRFs using FHIR resources have met with mixed success [11,16–19]. A major limitation of these attempts has been the limited array of data elements that can be extracted from EHR to CRF via FHIR, because of fields that are semantically nonequivalent or lack coverage in FHIR resources. Garza et al. [19], for example, performed mapping from EHR to CRF using FHIR resources in three diverse multisite clinical trials to evaluate FHIR coverage in support of data collection and transformation across a wide range of study data elements and found 45–80% of elements were covered in FHIR resources.

Previous efforts to "eSource" data from the EHR for clinical trials used a standard called Retrieve Form Data Capture (RFD) which allowed systems such as REDCap to extract EHR data [9]. RFD has since been supplanted by FHIR [20] as the de facto standard for exchanging healthcare data between systems.

Table 2. *Concordance results by form*

CRF name	Fields with both coordinator and EHR data	Exact matches	% Exact matches
Demographics	120	113	94
Eligibility criteria	800	728	91
COVID-19 testing/ vaccination	159	149	94
Daily inpatient form	1270	1168	92
Vital signs	2946	2316	79
Clinical labs	4785	4484	94
Total	10,080	8958	89

CRF, case report form; EHR, electronic health record; COVID-19, coronavirus disease of 2019.

Although adoption of the FHIR standard has accelerated progress in automating data pipelines for randomized clinical trials and mitigating the need for manual data transcription, the semantic interoperability across systems has continued to impede efforts at more complete automation [4].

Another limitation in EHR-to-CRF automation has been the lack of accessibility for researchers without significant IT budgets or available informatics experts. Leveraging REDCap, however, enables researchers at over 6000 institutions in 147 countries to access EHR FHIR API data and to seamlessly collect data for clinical and translational research [21]. Currently, 40 institutions in the United States and Canada have integrated REDCap with either Epic or Cerner EHR systems. Local use of CDIS is strong at Vanderbilt University Medical Center (VUMC) and is offered at no cost to VUMC research teams for projects meeting IRB and Privacy Office requirements.

This study provides strong evidence that automated CRF completion using EHR FHIR API data has the potential to improve the accuracy, consistency, and efficiency of clinical trial data collection. This could also translate into significant resource savings in a clinical trial by not requiring the coordinator to manually extract and enter these data. These benefits are particularly true for data where there is just one value for a given patient, such as demographics, and where a single value needs to be extracted at a particular time from the EHR, such as labs and vitals. Results where the data collector needs to search through EHR records over a time period, such as concomitant medications, medical history, or eligibility criteria, are more challenging to automate with EHR data, but still feasible with text searches and calculated fields.

After project setup, the automated EHR data extraction can be initiated in less than 5 minutes of personnel effort. Therefore, the A4-HT study team might have saved 42 hours of personnel time if they had automated EHR data extraction for the first 40 participants in the study. The combined 40 hours that the coordinator and analyst spent design mapping and validating the data coming from the EHR must be taken into account when designing future studies using this automation. The amount of time it takes to set up the project may vary depending on the clinical and informatics expertise of the team members. We therefore recommend that both a study coordinator, with knowledge of the research, and an analyst, with knowledge of the EHR and REDCap be involved in the mapping and testing. While this setup time is considerable, we believe project-level implementation mapping and data validation exercises will decrease over time as study personnel become more versed with the data availability in the EHR and the mapping process. Moreover, the value of automated EHR extraction will be maximized for large trials with many participants and many EHR data points. Smaller trials with few participants and data points are unlikely to benefit from automation.

Future EHR-to-CRF Work with Additional A4-HT Sites

A4-HT was an ideal trial to test the EHR-to-CRF interface because the study team had already planned to use REDCap for collecting and managing abstracted EHR data. REDCap has existing functionality allowing rapid export and reuse of study data dictionaries and mapping files for sharing with other sites. Going forward, we are working to find additional A4-HT sites to externally test our coverage, concordance, and setup time results. Additional sites would receive a REDCap XML project setup file, a mapping file, and an API query and analysis R script to recreate the calculations we did at VUMC. Since EHR data structure is highly variable at different institutions, some modifications to the EHR mapping and associated calculations may be necessary. Characterizing this congruence or noncongruence will be a secondary finding. Our primary analysis will demonstrate that the automated CRF completion works at a diverse group of health systems with a variety of EHR vendors. We also plan to demonstrate that there is minimal effort needed from the adopting sites once the study mapping has been performed at one institution (e.g. data coordinating center) and shared with other site institutions. We anticipate, based on anecdotal work, that meaningful sharing of implementation-ready field mappings will be straightforward for sites where standardized codes (e.g. Logical Observation Identifiers Names and Codes LOINC) are well characterized in the local EHR system. In other cases, individual sites would have to perform their own mapping with local codes to adopt EHR-to-CRF automation. Smaller domestic sites with older EHR systems and international sites with diverse coding standards would likely be more difficult to onboard.

Guidance for Use of REDCap CDIS Services in Single or MultiSite Trials

This study and other pragmatic clinical trials demonstrate that researchers can confidently use EHR data embedded in CRFs to augment or streamline several clinical trial processes. For example, a screening form could extract a patient's problem list and medication list from the EHR so that the coordinator could review them quickly for eligibility criteria without having to open the EHR. EHR-to-CRF methods could also be used to assist with data monitoring. In our in-depth review of 10 participants' data to compare the coordinator-entered and automation-entered data, our results showed that most of the discrepancies were a result of human error. These data had already been audited by a study monitor. Therefore, the EHR was able to identify many cases of incorrectly entered data that two humans had previously reviewed. This suggests we could use EHR-to-CRF integration to make risk-based monitoring more efficient. Instead of asking monitors to check all or a sample of CRF entries with the EHR, they could run a discordance report of all instances where the automated EHR data and the coordinator-entered data disagree and focus efforts on those entries.

Based on our experience in this study and working with investigator teams at VUMC implementing EHR data mapping and transfer services using REDCap CDIS, we have developed a set

Table 3. *Process for planning and executing a trial with automated EHR-to-CRF data collection*

Task	Personnel
Form hypothesis, design study, write clinical protocol	Investigator, statistician
Create CRFs in EDC system	Investigator, coordinator, statistician, analyst
Identify 1–2 example patients and map data from EHR-to-CRF	Investigator, coordinator, analyst
Reorganize CRFs based on data available from EHR	Investigator, coordinator, statistician, analyst
Write a workflow for pulling EHR data into protocol	Investigator, coordinator, analyst
Obtain regulatory approvals, launch trial	Investigator, coordinator, statistician
Perform BOTH manual and automated EHR data entry for first 10 participants in study	Coordinator
Compare manual and automated data for discrepancies. Modify mapping, calculations, and workflow as necessary	Investigator, coordinator, analyst
Obtain regulatory amendment (if necessary) and proceed with only EHR data entry	Investigator, statistician

CRF, case report form; EDC, electronic data capture; EHR, electronic health record.

of recommendations that should generalize across institutions and studies. Future studies that will use EHR data should consider what data can be automated from the EHR during the study design phase. After defining the study goals, EHR analysts, statisticians, and coordinators should work together to ensure that the EHR data obtained meets the intended purpose for the study. When mapping EHR data, study personnel should identify a few real patients that would qualify for the study as examples of what data is available using the CDIS mapping helper feature. Fields that are automated with EHR data should be segregated into forms separate from fields that are coordinator-entered. Table 3 outlines the process for designing and running a study with automated EHR-to-CRF data collection.

Conclusions

Based on our assessment in this study, we believe automated CRF completion with EHR data has a strong potential for increasing timeliness, accuracy, and efficiency of data-related clinical trial tasks, including participant screening, data collection, and data monitoring. For the A4-HT study, we found that the majority of coordinator data entry burden for demographics, eligibility criteria, vaccine, and daily labs and vital signs could be reduced through automation. The automation would have also reduced the number of data abstraction errors. Future work evaluating resource investment for study start-up versus downstream benefit is needed to inform the total value proposition for diverse single and multisite studies.

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References

1. **Laird-Maddox M, Mitchell SB, Hoffman M.** Integrating research data capture into the electronic health record workflow: real-world experience to advance innovation. *Perspectives in Health Information Management* 2014; **11**(Fall): 1e.
2. **McCowan C, Thomson E, Szmigielski CA**, *et al.* Using electronic health records to support clinical trials: a report on stakeholder engagement for EHR4CR. *BioMed Research International* 2015; **2015**: e707891. DOI: 10.1155/2015/707891.
3. **Mc Cord KA, Hemkens LG.** Using electronic health records for clinical trials: Where do we stand and where can we go? *Canadian Medical Association Journal* 2019; **191**(5): E128–E133. DOI: 10.1503/cmaj.180841.
4. **Nordo AH, Levaux HP, Becnel LB**, *et al.* Use of EHRs data for clinical research: historical progress and current applications. *Learning Health Systems* 2019; **3**(1): e10076. DOI: 10.1002/lrh2.10076.
5. **Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG.** Research Electronic Data Capture (REDCap) – a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics* 2009; **42**(2): 377–381. DOI: 10.1016/j.jbi.2008.08.010.
6. **Mays JA, Mathias PC.** Measuring the rate of manual transcription error in outpatient point-of-care testing. *Journal of the American Medical Informatics Association* 2019; **26**(3): 269–272. DOI: 10.1093/jamia/ocy170.
7. **Marsolo K.** Informatics and operations–let's get integrated. *Journal of the American Medical Informatics Association* 2013; **20**(1): 122–124. DOI: 10.1136/amiajnl-2012-001194.
8. **Buckley M, Vattikola A, Maniar R, Dai H.** Direct data extraction and exchange of local labs for Clinical Research Protocols: a partnership with sites, biopharmaceutical firms, and clinical research organizations. *Journal of the Society for Clinical Data Management* 2021; **1**(1): 1–5. DOI: 10.47912/jscdm.21.
9. **Nordo AH, Eisenstein EL, Hawley J**, *et al.* A comparative effectiveness study of eSource used for data capture for a clinical research registry. *International Journal of Medical Informatics* 2017; **103**: 89–94. DOI: 10.1016/j.ijmedinf.2017.04.015.
10. **Bots SH, Groenwold RHH, Dekkers OM.** Using electronic health record data for clinical research: a quick guide. *European Journal of Endocrinology* 2022; **186**(4): E1–E6. DOI: 10.1530/EJE-21-1088.
11. **Zopf R, Abolafia J, Reddy B.** Use of Fast Healthcare Interoperability Resources (FHIR) in the generation of real world evidence (RWE). In: Proceedings of PhUSE, 2017 [cited November 17, 2022]. (https://www.cdisc.org/sites/default/files/resource/Use_of_Fast_Healthcare_Interoperability_Resources_in_the_Generation_of_Real_World_Evidence.pdf)
12. **Rocca M, Asare A, Esserman L, Dubman S, Gordon G.** Source data capture from EHRs: using standardized clinical research data, 2019 [cited November 17, 2022]. (https://aspe.hhs.gov/source-data-capture-electronic-health-records-using-standardized-clinical-research-data)
13. **U.S. Department of Health and Human Services Food and Drug Administration**. Use of electronic health record data in clinical investigations: guidance for industry, 2018 [cited November 17, 2022]. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/

use-electronic-health-record-data-clinical-investigations-guidance-industry)

14. **Moskowitz A, Shotwell MS, Gibbs KW**, *et al.* Oxygen-free days as an outcome measure in clinical trials of therapies for COVID-19 and other causes of new-onset hypoxemia. *Chest* 2022; **162**(4): 804–814. DOI: 10.1016/j.chest.2022.04.145.

15. **Cheng AC, Duda SN, Taylor R, Delacqua F, Lewis AA, Bosler T, Johnson KB, Harris PA**. REDCap on FHIR: Clinical Data Interoperability Services. *Journal of Biomedical Informatics* 2021; **121**: 103871. DOI: 10.1016/j.jbi.2021.103871.

16. **Hume S, Abolafia J, Low G.** *Use of HL7 FHIR as eSource to pre-populate CDASH case report forms using a CDISC ODM API*, 2018 [cited November 17, 2022]. (https://www.lexjansen.com/phuse/2018/rw/RW02.pdf)

17. **Zong N, Stone DJ, Sharma DK**, *et al.* Modeling cancer clinical trials using HL7 FHIR to support downstream applications: a case study with colorectal cancer data. *International Journal of Medical Informatics* 2021; **145**: 104308. DOI: 10.1016/j.ijmedinf.2020.104308.

18. **Zong N, Wen A, Stone DJ**, *et al.* Developing an FHIR-based computational pipeline for automatic population of case report forms for colorectal cancer clinical trials using electronic health records. *JCO Clinical Cancer Informatics* 2020; **4**: 201–209. DOI: 10.1200/CCI.19.00116.

19. **Garza MY, Rutherford M, Myneni S**, *et al.* Evaluating the coverage of the HL7® FHIR® standard to support eSource data exchange implementations for use in multi-site clinical research studies. *AMIA Annual Symposium Proceedings* 2021; **2020**: 472–481.

20. **HL7 FHIR, Release 4**. [cited November 17, 2022]. (https://www.hl7.org/fhir/)

21. **Harris PA, Taylor R, Minor BL**, *et al.* The REDCap consortium: building an international community of software platform partners. *Journal of Biomedical Informatics* 2019; **95**: 103208. DOI: 10.1016/j.jbi.2019.103208.