Technological Adjuncts to Streamline Clinical Research Processes: Recruitment, Informed Consent, and Data Management

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Submitted to: JMIR Formative Research
on: April 12, 2024

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Abstract

Background: Patient recruitment and data management are laborious, resource-intensive aspects of clinical research that often dictate whether the successful completion of studies is possible. Technological advances present opportunities for streamlining these processes, thus improving completion rates for clinical research studies.

Objective: This paper aims to demonstrate how technological adjuncts can enhance clinical research processes via automation and digital integration.

Methods: Using one clinical research study as an example, we highlight the use of technologic adjuncts to automate and streamline research processes across various digital platforms, including an enterprise data warehouse (EDW), a clinical research data management tool (REDCap), and a locally managed, HIPAA-compliant server. Eligible participants are identified through automated queries in the EDW, after which they receive personalized email invitations with digital consent forms. After digital consent, patient data is transferred to a single HIPAA-compliant server where each participant is assigned a unique QR code to facilitate data collection and integration. After the research study visit, data obtained is associated with existing EMR data for each participant via a QR code system that collated participant consent, imaging data, and associated clinical data according to a unique exam ID.

Results: Over a 19-month period, automated EDW queries identified 20,988 eligible patients, and 10,582 patients received personalized email invitations. 1000 patients (9.45%) signed consents to participate in the study. Of the consented patients, 549 unique patients completed 779 study visits; some patients consented to the study at more than one time period during their pregnancy.

Conclusions: Technological adjuncts in clinical research decrease human labor while increasing participant reach and minimizing disruptions to clinic operations. Automating portions of the clinical research process benefits clinical research efforts by expanding and optimizing participant reach while reducing the limitations of labor and time in completing research studies.

(JMIR Preprints 12/04/2024:58628)
DOI: https://doi.org/10.2196/preprints.58628

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Keywords: Digital Health, Patient Recruitment

INTRODUCTION

Clinical research processes are rife with logistical complexities that often determine the success or failure of a clinical trial [1]. Successful participant enrollment depends on organization, personnel, and participant factors, as well as the features of the clinical trial at hand [2-5]. McDonald cited reasons for research study failure as including heavy clinical and research workload of research team members, perceived imbalance between patient incentive and risk, and low-status typically conferred to recruitment work [6]. Of 114 studies in McDonald's review, only 31% met their original recruitment goals, while 53% required extended periods for completion [6].

The resource-intensiveness of recruitment activities often dictates whether studies are completed successfully [7]. Recruitment processes have traditionally relied heavily on trained manual labor [8, 9], which is costly. Moreover, these research personnel often face logistic barriers when recruiting in high-volume clinical settings, where their research activities may be restricted by clinical workflows and tight patient turnaround [10]. In general, in-person recruiting is personnel intensive, as it requires research staff to repetitively detail the research study to each potential participant accurately and representatively [11, 12]. Lastly, traditional methods for recruiting patients rely on collecting and filing printed paperwork especially in managing patient records and study results [2].

Following these observations, healthcare and federal institutions have increasingly demonstrated support for the integration of digital technological capabilities within clinical research [13-15], especially leveraging the capabilities brought about by automating clinical processes [16, 17]. In 2019, the National Heart, Lung, and Blood Institute, National Institutes of Health, and National Science Foundation hosted a workshop that called for the digitization of clinical research using advanced analytics to facilitate patient screening, data management, and to potentially increase the representation of diverse patient populations [18]. In a separate review of recruitment methods across 61 clinical trials, online recruitment was found to be 52% more effective than offline recruitment [19].

Such technological advancements present opportunities for overcoming the onerous complexities of clinical research workflows, while also reducing the operational costs of research (by reducing research staff labor-intensiveness and expanding potential participant reach) as well as the potential for human error in recruitment processes (by digitizing data management). In this paper, we share our experience using technological adjuncts to streamline participant identification, recruitment, consent, and data management processes for an observational clinical research study. These strategies allowed us to complete our study recruitment goal ahead of schedule, and in a cost-effective, resource-optimized way.

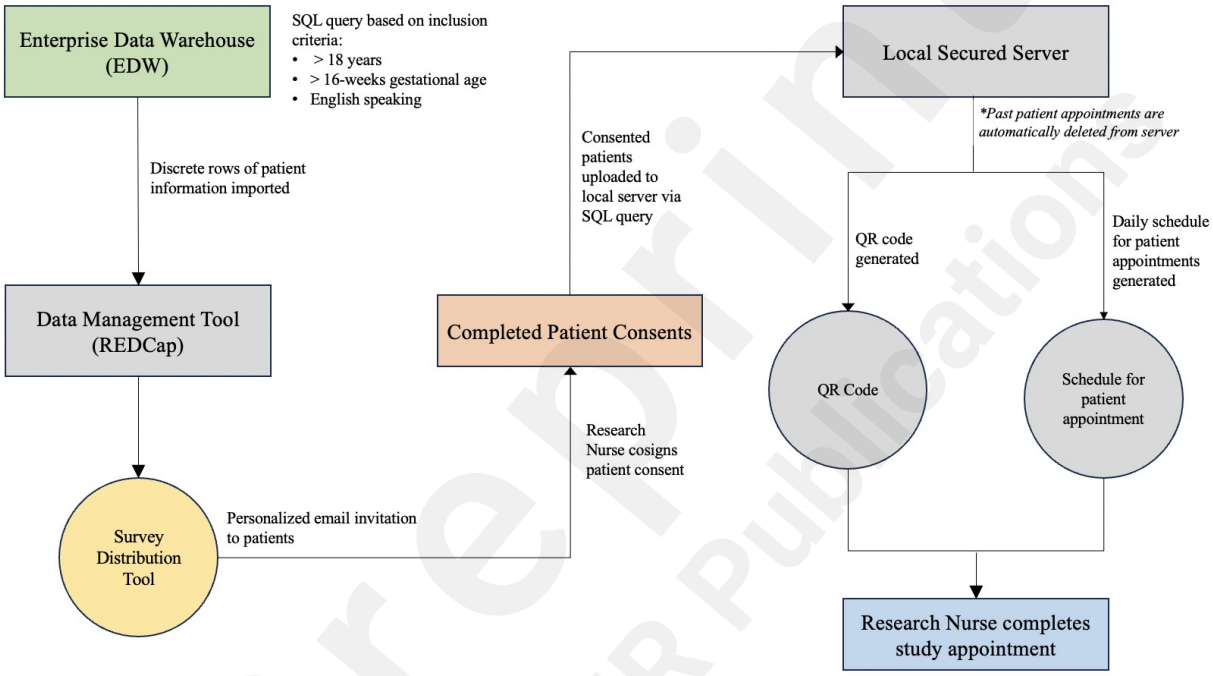
METHODS

Purpose of broader research study

The clinical research processes that we describe in this paper are part of a prospective, observational research study, approved by our university's Institutional Review Board. The research study's primary aim is to develop a database of ultrasonography images for use in the development of artificial intelligence technology with specific applications to perinatal care. To fulfill this goal, we planned to consent 1000 patients across various time periods of pregnancy from within a single institution. To accomplish this task, we designed and executed a digitized process of patient recruitment and data management.

Given the ultimate goal to build algorithms that address, diagnose, and predict various maternal and fetal health outcomes, we engaged in strategic and targeted patient recruitment to ensure an appropriate number of patients with specific health conditions while abiding by constraints including a temporally bounded funding structure. Our clinical research processes relied on three main technologic adjuncts: an Enterprise Data Warehouse (EDW), a research data management tool (REDCap), and a locally managed, HIPAA-compliant QR-code-based system that allowed us to coordinate all patient information, data, and enrollment-related documentation on a single, secured server. An overview of our clinical research processes is depicted in Figure 1. Each step of these processes is further detailed below.

Figure 1: Workflow for clinical research processes across digital adjuncts.



Identifying eligible patients using the EDW

The patient recruitment process leveraged access to patient medical records collated from EPIC using a local EDW to identify eligible patients for the study. In doing so, we performed a SQL query, filtering for the inclusion and exclusion criteria and limited to participating clinical sites. The inclusion criteria were patients 18-years old and older, English-speaking, and at least 16 weeks of gestational age. This query derived multiple rows of eligible patients to be invited to participate in our study. We set up this query function as an automated process with the list of eligible patients refreshed every 24 hours. This query generated a list of patient appointments that had been scheduled within the next 30 days across participating clinics.

Inviting and consenting patients using REDCap

We used a REDCap specific Application Programing Interface (API) to import the rows of eligible patient appointments generated from the EDW into the REDCap database. Each discrete row provided all necessary details for patient identification and recruitment including patient MRNs, personal and clinical information, contact information, and details including patient notes on

upcoming appointments. Within REDCap, we conducted an additional manual check on the list of eligible patients against our inclusion criteria using a filtering function. This was done to mitigate any errors that may have been made as a result of data compatibility issues during transfer between platforms. Given that patients are exclusively electronically recruited for this study, we also filtered patients based on presence of an email address on file. Lastly, we filtered to exclude patients who previously indicated disinterest in participating in this study, resulting in a narrowed list of eligible patients to recruit.

We utilized REDCap's Survey Distribution Tool function to distribute invitations to eligible patients. We sent personalized emails with patient names as designated in their charts followed by all relevant information pertaining to the study including the title and purpose of clinical research, risks and benefits of participation, participant expectations for the study, and contact information for any inquiries. Patients were provided unique links that directed them to their personalized electronic consent forms embedded in REDCap. The email invitation text may be reviewed in Appendix A.

Enrolling patients

As the research nurse on the team cosigned patient consent forms, using a second SQL query, we uploaded the list of consented patients onto a local server managed by members of the project team. On the server, expired patient appointments were removed to minimize the memory space taken up by past appointments.

To prepare the research nurse for data collection appointments, we deployed a third script that generated a daily schedule for all appointments using the list of consented patients on the server. These lists of appointments were organized by time and facilitated the nurse's data collection schedule throughout the day, especially as data collection occurred in multiple clinic locations. Simultaneously, this script also generated a unique QR code for each patient to associate the collected data with the patient's EMR on the lab server and in REDCap.

Data management, transfer and de-identification using unique QR codes

As is standard for most data collection studies, the study workflow must culminate in generating a fully deidentified database. Alongside generating the QR code, a unique research exam ID that is not present in the patient's medical record is generated as a function for identifying collected data without associating it with any PHI.

At the beginning of each data collection appointment, a research nurse would scan the unique QR code that indicates where the collected ultrasound scans will be routed and stored on the local server. The folders on the server are labelled using the unique exam ID. This system allows the QR code to serve as a means for identification and reference as we link de-identified patient files with the associated ultrasound scans. Aside from a single "master list" linking the patient's "real" (PHI) information to their study information (as is standard in data collection studies), routing and parsing relevant data points is fully automated and relies on research-specific identifiers (unique exam ID) and QR codes, thus reducing the risk of study documentation being lost or otherwise mishandled. This contrasts current, manual approaches that oftentimes rely on names and/or date-of-births written on documents to associate data to a patient, which subsequently must be shredded and disposed of.

RESULTS

Between December 1, 2021 and June 13, 2023 (19 months), we achieved our study goal of consenting 1000 patients for the study. Our automated EDW queries identified 20,988 eligible patient appointments across 3 obstetric clinics throughout that time period. Each query was automatically run every 24 hours and generated between 1000 - 2000 eligible patient appointments.

Logistic constraints including limited study personnel (1 research nurse on the project) and limited work schedule availability to collect data resulted in only 50.4% of identified eligible patients receiving an invitation to participate in the study. We also restricted invites to 2 or 3 potential patients with overlapping appointment times across all clinical sites. Data collection appointments were only scheduled on weekdays between 8am and 4pm.

Based on these constraints, personalized email invitations were subsequently issued to 10,582 potential participants. 1000 patients consented to participate, yielding a 9.5% consent rate over 19 months. Among those who consented, 779 patients completed the research study visit. The difference between consented patients and those with successful data collection was attributed to rescheduling of patient appointments. A total of 549 unique individual patients participated in the study; some patients participated more than once during their pregnancy.

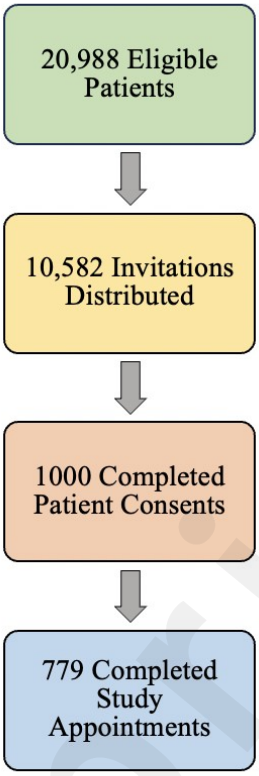
Table 1 presents the descriptive demographics of participating patients for race, ethnicity, age, gestational age, parity, and insurance payor. The patient recruitment and enrollment process are summarized in Figure 2.

Table 1: Demographic data of the consented patient population.

	Percentage (Raw)
Race	
White	52% (284)
Black	13% (74)
Asian	8% (44)
Other	6% (40)
Not specified	21% (107)
Ethnicity	
Hispanic	15% (80)
Not Hispanic	72% (396)
Not specified	13% (73)
Age	
Under 20	1% (4)
20-30	18% (101)
30-40	73% (404)
Over 40	8% (40)
Gestational Age	
Under 16	0% (2)
16 - 20	17% (167)
21-25	16% (163)
26-30	20% (196)
31-35	31% (315)

36-40	16% (157)
Above 40	0% (0)
Insurance Payor	
Public	23% (126)
Private	77% (423)

Figure 2: Overview of patient recruitment data across the recruitment and enrollment process.



DISCUSSION

Overall, relying on digital adjuncts in this study helped us to achieve our study goal in less than 19 months (as compared to an initial projection of 24 months) while optimizing operational costs and minimizing disruptions to participating clinical sites. For this study, utilizing SQL automation within the EDW allowed us to accurately identify and regularly update lists of eligible participants without ongoing human input or intervention. Digitizing recruitment and consent expanded our reach to many more eligible participants than one research nurse could have realistically approached via in-person recruitment, thereby shifting the research nurse's efforts and availability to collecting ultrasound scans and ensuring positive patient experience participating in the study. Finally, utilizing a digital interface simplified and contained data management for the study to a single server which reduced the human burden of data management and consequently improved data integrity.

Strengths

Consistent with the existing literature, we found digitizing clinical research processes to be effective in attaining goal recruitment rates, minimizing disruptions to clinic workflows, and ensuring transparency of information regarding research studies [9, 19, 20]. We also experienced the benefits of integrating the technological capabilities of the electronic health record for broad-based identification of eligible participants [21-23].

Digitizing patient recruitment and enrollment allowed us the flexibility to strategically target patients with specific outcomes or appointments in specific locations. This also meant that our recruitment data was available to be analyzed frequently as a means for providing real-time feedback to improve our recruitment methods. Based on this feedback, we adjusted the time interval between sending an invitation and the scheduled appointment date to optimize participant consent rates.

Reducing aspects of clinical research that are highly dependent on human-labor helped to alleviate financial constraints that have previously crippled clinical research[24] and instead focused efforts on participant experience throughout the study. Over 19 months of active patient recruitment with only one research nurse, we were able to complete data collection appointments with up to 5 participants per day in 3 different participating clinics. In comparison, a study looking at consent rates using traditional in-person recruitment found that 9 recruiters were needed to approach 2498 patients over a 1-year period in a primary care physician office [24]. If we extended those ratios to our study, we would have needed 18 recruiters over 2 years to approach the 10,582 patients we reached by personalized email invitation.

In clinic settings where multiple clinical research studies are conducted concurrently, front-loading recruitment activities and consent limited disruption to the clinic workflows and minimized patient recruitment fatigue or coercion. We found that limiting research personnel presence in clinics with high volumes of patients and quick patient turnaround increased clinics' willingness to collaborate as recruitment sites for our study.

From a patient's perspective, shifting recruitment processes onto digital platforms allowed participants relatively unbounded time to review holistically all the information pertaining to the study, their participation, and address data privacy concerns. Digitizing patient recruitment inherently standardized the information shared with all eligible participants, giving us confidence in the ethical execution of informed consent.

Finally, our QR code system alleviated pressures on research nurses to maintain cumbersome paperwork associated with data management and instead focus on collecting data and the patient's experience in the study. Additionally, digitizing data management leveraged the compatibility between already digitized patient information (on EPIC) and routed relevant study data, thus simplifying the deidentification process of PHI, especially when sharing data with external parties.

Limitations

A limitation of patient recruitment via digital platforms is the potential for selection bias, in our case by restricting recruitment to patients with an associated email address. To mitigate this, research teams may wish to complement digital recruitment activities with telephone or in-person outreach to directly target groups at risk of exclusion.

We recognize that our study was minimally invasive and posed no risk to participants. As such, our results using technological adjuncts for clinical research processes may not be generalizable to clinical research with different study features.

Lastly, employing digital adjuncts in clinical research inherently means that research teams must include team members well-versed in the technical skills and know-how for setting up digitized recruitment systems and troubleshooting when needed. This option may not be readily available for all research programs or may require consideration of the costs of such expertise.

CONCLUSION

Digital adjuncts are promising tools that can assist in streamlining patient identification, recruitment, and enrollment in clinical research studies. In our experience, digital adjuncts allowed us to reach out to many more patients than would have been possible with traditional one-on-one,

in-person-based recruitment. Additionally, we believe the benefit of private reflection without time constraints, or in-person influences optimizes an ethical consent process. Finally, streamlining the data management necessary for our imaging-based observational study has reduced the personnel and resources required for completion of the study. Employing these digital tools could ease research and make it more equitable, leading to higher chances of study completion.

Acknowledgements:
All authors contributed equally to the development of this paper. SC and DM were responsible for building the digitized patient recruitment process. SC, DM, KH, and AS were responsible for providing data for this paper. The study in which this digitized patient recruitment and enrollment process is for is funded by the Bill and Melinda Gates Foundation and Google.

Ethical Statements:
Patient consent for publication: Not applicable.

Ethics approval: The portion of the study involving patient recruitment to carry out the goals of our study was approved by Northwestern University's Institutional Review Board Office (Study ID: STU00215717).

Conflicts of Interest: No authors have any competing interests to report.

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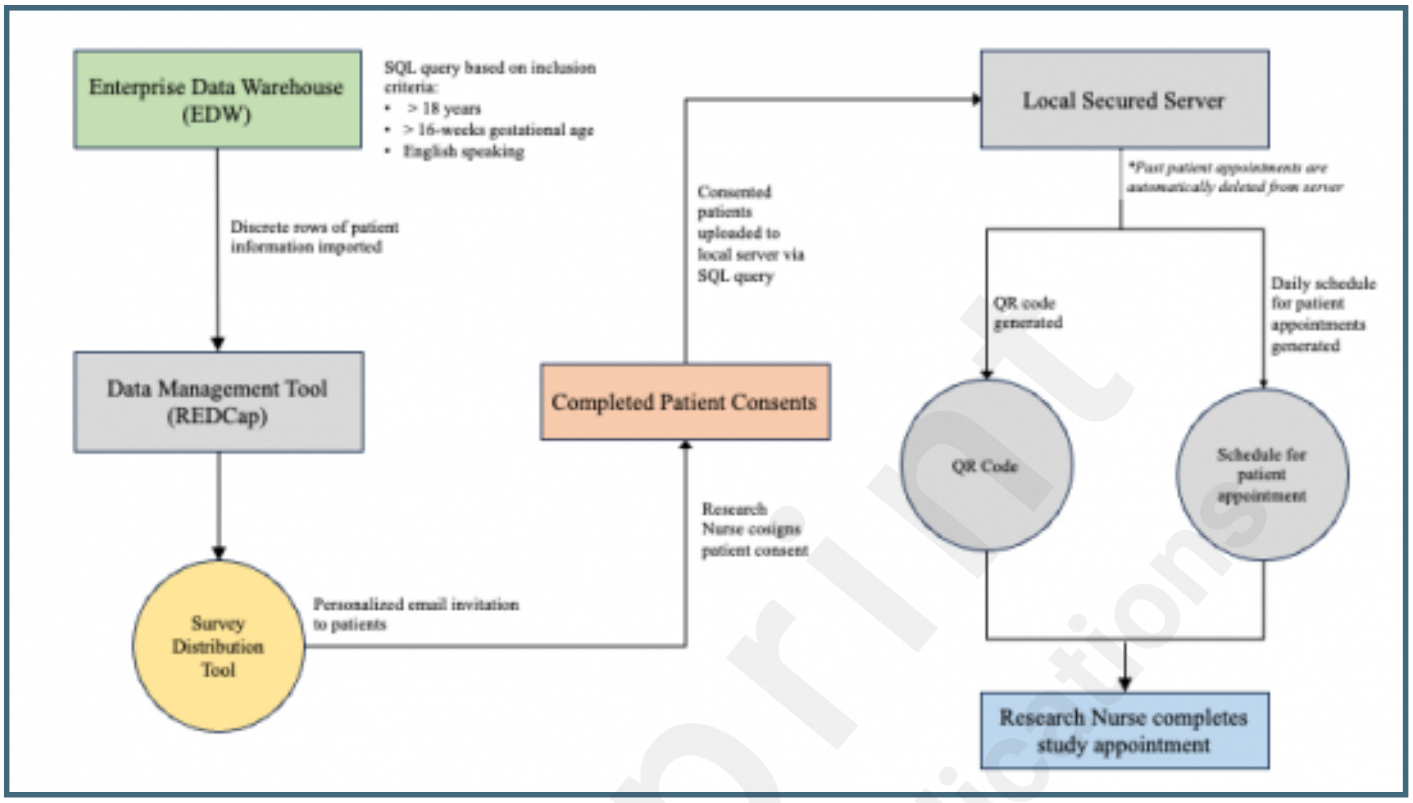
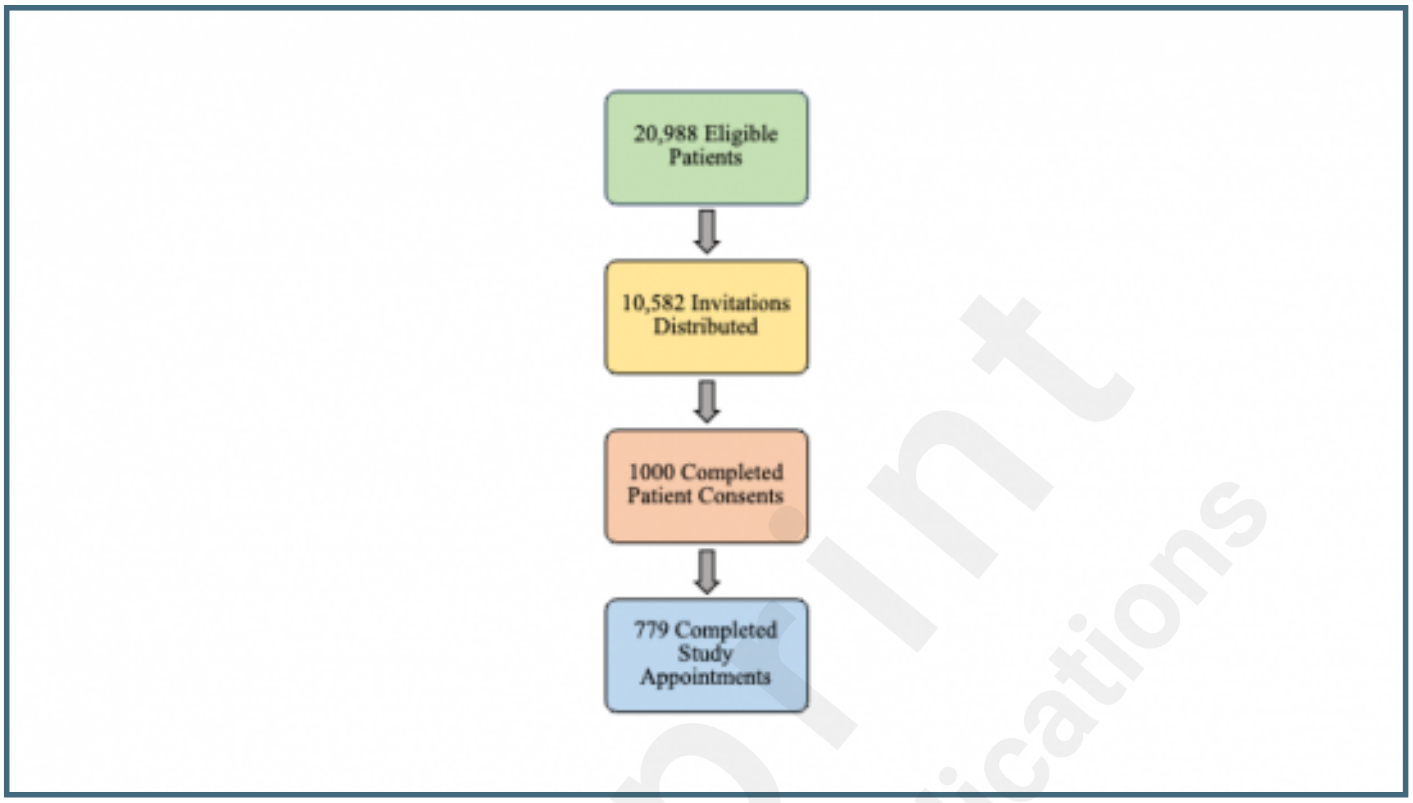
Supplementary Files

Figures

Workflow for clinical research processes across digital adjuncts.



Overview of patient recruitment data across the recruitment and enrollment process.



Multimedia Appendixes

Personalized invitation sent to patients to participate in study.
URL: http://asset.jmir.pub/assets/af4da50960b06f198364332d28c36fbd.docx