StudySearch: a web-based application for posting and searching clinical research studies

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ABSTRACT

Participant accrual into research studies is critical to advancing clinical and translational research to clinical care. Without sufficient recruitment, the purpose of any research study cannot be realized; yet, low recruitment and enrollment of participants persist. StudySearch is a web-based application designed to provide an easily readable, publicly accessible, and searchable listing of IRB-approved protocols that are accruing study participants. The Regulatory, Recruitment and Biomedical Informatics Cores of the Center for Clinical and Translational Science (CCTS) at The Ohio State University developed this research study posting platform. Postings include basic descriptive information: study title, purpose of the study, eligibility criteria and study personnel contact information. Language concerning benefits and/or inducements is not included; therefore, while IRB approval for a study to be listed on StudySearch is required, IRB approval of the posted language is not. Studies are listed by one of two methods; one automated and one manual: (1). Studies registered on ClinicalTrials.gov are automatically downloaded once a month; or (2). Studies are submitted directly by researchers to the CCTS Regulatory Core staff. In either case, final language is a result of an iterative process between researchers and CCTS staff. Deployed in January 2011 at OSU, this application has grown to approximately 200 studies currently posted and 1500 unique visitors per month. Locally, StudySearch is part of the CCTS recruitment toolkit. Features continue to be modified to better accommodate user behaviors. Nationally, this open source application is available for use.

PROBLEM

Participant accrual into research studies is critical to advancing clinical and translational research to clinical care.[1] Clinical research cannot be successful without adequate recruitment and enrollment of human participants.[2] This dilemma is not unique to any one study-type, nor is it confined to academic institutions and/or health centers.[3] More than 80% of clinical trials are delayed as a result of low participant recruitment, and some studies are prematurely terminated.[4–8]

The consequences of low study participant accrual range from substantial financial costs to missed opportunities. Continuing such studies could be considered unethical as they promote undue risk to enrolled participants while not yielding the scientific benefit on which they had been premised. Kitterman *et al*[9] investigated the prevalence and economic impact of low enrolling clinical research studies at the Oregon Health and Science University (OSHU). The results of their work revealed that among 837 closed clinical research studies across 57 academic units between Fiscal Years 2006 and 2009, 260 studies (31.1%) demonstrated low enrollment which was defined as 0–1 participant(s) enrolled at the time that the study was terminated. Moreover, 53.6% of government funded studies had low enrollment as compared to 38% of studies sponsored by industry. The 'uncompensated economic impact' of these studies was estimated to be nearly $1 million for the OHSU Fiscal Year 2009; startup costs which include preparation of study materials, IRB initial review, preparation of study budgets, contract negotiation, awards set-up and study planning meetings accounted for 64.4% of that total.

Prior to StudySearch, a centralized listing of human subject research studies (ie, clinical research studies) at The Ohio State Univeristy (OSU) did not exist. Partial listings by various medical specialties on the OSU Medical Center website and a web-based listing of cancer-related clinical trials hosted by The James Cancer Hospital and Solove Research Institute at OSU existed. These were limited to drug or device intervention studies. A search of other institutional listings of clinical research studies revealed that such listings and content were limited to extractions from ClinicalTrials.gov. Such postings included dense text, and advanced technical vocabulary. Futhermore, ClinicalTrials.gov extractions did not always contain local site contact information. Most importantly, non-intervention clinical research studies are not always registered with ClinicalTrials.gov and therefore are not available to be extracted.

One of the strategic goals of the National Institutes of Health (NIH) National Center for Advancing Translational Science (NCATS) Clinical and Translational Science Award (CTSA) program has been to increase the efficiency, quality and safety of clinical and translational science.[10] As such, Federal support exists for the CTSA Consortium and individual sites to develop innovative tools that promote

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participation in research studies. In light of this strategic goal of NCATS and in response to general research study recruitment concerns as well as institutional regulatory compliance issues, the CCTS and the Department of Biomedical Informatics (BMI) at OSU have built a unique open source application to post and search clinical research studies that are open to accrual. StudySearch is a user-friendly search engine which makes information available to the general public about locally recruiting clinical research studies, that is accurate, succinct and in lay language.

APPROACH

The first iteration of StudySearch was developed in late 2010 as a module for the Drupal Content Management System. It was launched January 2011 with 50 studies and 1100 unique visitors. As the system grew and more advanced features were deemed important, the decision was made to transition to Ruby on Rails. Ruby is a commonly used open source programing language. Rails is a web development framework built in Ruby. This transition allowed for a more flexible system that can easily accommodate the development of more advanced features.

The fundamental feature of StudySearch is the inclusion of all IRB approved research studies at OSU open to enrollment for the general public in an easy to use, readable and searchable listing. The criteria for posting content are limited to 'basic descriptive information' as defined by the Office for Human Research Protection (OHRP): study title, purpose of the study, basic eligibility criteria and study contact information. Language concerning benefits and/or inducements is not included; thus, any IRB approved study may be listed on StudySearch, however, IRB approval of the posted language is not required.

Studies are posted in one of two ways: either submitted directly by OSU research team personnel to CCTS staff; or by a monthly extraction of discreet information from ClinicalTrials.gov. The intake form from research teams includes study title, purpose, primary eligibility criteria, study type (ie, intervention, observation), study personnel contact information, up to five condition keywords, health category designation, if healthy volunteers are being recruited, name of the principal investigator, local study IRB number and approval date, and subject recruitment time period. Monthly data extractions from ClinicalTrials.gov include the following fields: ClinicalTrials.gov Study ID, study title, study type (interventional, observational, expanded use), study design(s), study phase (I, II, III, IV), short description/purpose, conditions (standardized and coded using Medical Subject Headings (MeSH) terms), interventions (standardized and coded using MeSH terms), study start date, estimated primary completion date, eligibility criteria, gender (male, female, both), age group (child, adult, senior), healthy volunteers, inclusion/exclusion criteria, site location and contacts (including name, email and/or phone number, as available), and first received date. Since the field extractions from ClinicalTrials.gov do not include language concerning inducements or benefits, and only OHRP defined 'basic descriptive language' is retained for posting into StudySearch, IRB approval is not required for these monthly extractions from Clinicatrials.gov for StudySearch. Once a study from ClinicalTrials.gov is extracted, then IRB approval for the study at the site location (ie, The Ohio State University) is verified as is a requirement for the study to be able to be posted at the site.

However, studies are submitted, CCTS staff are alerted via email, and then review and edit content. Once completed, CCTS staff emails the respective study contact person to either approve or reject the posting content. An email notice is then sent to CCTS staff for a final review and, as appropriate, studies are then posted for public viewing. It is expected of research teams that the postings have been reviewed and approved by the Principal Investigator. For multicenter clinical research studies, use of StudySearch is expected to have been included for the site as a method of recruitment. However, verification of this action has not been considered as a requirement in the process of posting studies.

The general public is able to access StudySearch at http://studysearch.osumc.edu/. At the landing page, users can browse studies using various filters, including diagnosis/condition and/or study intervention terms as well as gender and healthy volunteer criteria.

The primary search function for StudySearch is driven by MeSH which is a comprehensive terminology of medical terms maintained by the National Library of Medicine. Each study is annotated with a number of concepts from MeSH that allows end users to find studies based on keywords of their choosing. MeSH includes a set of supplemental terms which provides a set of layperson friendly synonyms in addition to its core set of concepts which are more scientific. This allows for a smarter search algorithm which will match the searched term to any study annotated with any synonym. Additionally, the terms within MeSH are organized into a tree structure which allows the search algorithm to look at more general or specific terms if the user's initial search yields no results.

The primary search function for StudySearch is driven by MeSH—a comprehensive terminology of medical terms maintained by the National Library of Medicine. Every study is tagged with a collection of terms from MeSH. This enables StudySearch to use a semisemantic search engine to bridge the gap in terminology from the technical language used by researchers and the common terms which research volunteers may use. MeSH specifically allows this in the following two ways. First, MeSH organizes medical concepts into a tree structure where each node represents a real world concept and contains a set of words which represent that concept. Words which are contained in the same concept are considered synonyms. Any concept which is a child of another concept can be considered a more specific example of its parent. Using this structure StudySearch matches users' search terms to concepts in the MeSH structure, then identifies studies which are tagged with those concepts or any child (more specific) concepts. Second, MeSH is better suited for a research volunteer oriented search engine than other terminologies because it provides a set of supplementary terms which contains lay-friendly words which map to more scientific terms which may be used by study teams. In this way, StudySearch can match a user's search for something like 'heart attack' to a study tagged with the more technical term 'myocardial infarction'.

Once displayed, maintenance of the posting is based on each study's respective IRB approval expiration date. Any posted study can be removed from public viewing at any time either on request by the study team or by CCTS StudySearch regulatory personnel. StudySearch includes an 'Expiring Studies' page managed by regulatory staff, which lists studies that are expiring in the next 30 days or those that are past expiration. The program automatically updates the 'days until expiration' daily. This feature contains a 'Notify Principal Investigator' button which sends out an email requesting updated IRB renewal information or confirmation that the study should be removed from StudySearch. CCTS Regulatory staff contacts each individual study via this method to alert the study team their study is due for verification of IRB Continuing Review approval. If they would like for the study to remain listed on StudySearch, they are asked to forward documentation of continued IRB approval.

StudySearch technical personnel requirements include 5 h/month of monthly IT maintenance and support. The primary tasks include ensuring security updates are applied to Ruby on Rails and addressing problems when they arise. Time devoted to the development of new features varies 10–15 h/month. Tasks include web development using Ruby on Rails and JavaScript (backbone.js), involving proper testing, source control and deployment of code.

OUTCOMES

Recruitment efforts for IRB approved research studies often come in the form of advertisements that require IRB review and approval. Since StudySearch posting content is restricted to 'basic descriptive information' as defined by OHRP the specific language does not have to be IRB approved. This allows for greater flexibility in the process for making modifications to posted study information, particularly as inclusion and/or exclusion criteria, and/or study personnel change. However, should revisions that alter substantive content to the posting, for example, changes in eligibility requirements, be requested, then verification of IRB approval for such content changes is required.

By utilizing two posting processes StudySearch broadens the breadth of research studies that are able to be included. The automated process extracts local studies that are required to be listed on ClinicalTrials.gov by either Federal Regulation or ICMJE criteria. Other types of research studies can be posted via a submission form process. All studies must have an active IRB approval to be posted on StudySearch. Those studies that have IRB approval to use social media networking can link to StudySearch.

StudySearch is a unique platform developed by the CCTS to improve efficiencies in and access to participation in clinical research. Initially launched in January 2011 StudySearch was adopted in November 2014 by the OSU Wexner Medical Center (OSUWMC) to serve its primary listing site for research studies open for recruitment at OSU. Currently, approximately 200 studies are made available for public viewing in easily readable 'basic descriptive' content (see figure 1). Initial dramatic increases of listed studies occurred when StudySearch went from being relatively unknown (having only 50 studies listed) to its current status of equilibrium (approximately 200 studies listed). Studies fall on and off StudySearch frequently as studies complete enrollment and IRB approval status changes. Currently listing studies on StudySearch is offered to researchers institution wide, but it is not a requirement. If listing enrolling studies became a requirement, there would be a substantial increase in studies listed. CCTS StudySearch staff are currently discussing this proposed requirement with leadership.

The site averages over 1500 unique visitors each month (see figure 2). Between March–July 2012 and July–August 2013 there appear to be large fluctuations in the number of hits, however, these fluctuations are the result of an interruption of the site's analytic gathering system. During these periods the number of hits on the site could not be tracked. Fluctuations in the number of hits to the site often correspond to popularity of listed studies highlighted in the local and national media. For instance, in January 2015 StudySearch had nearly 4000 hits due to a very popular listed study receiving national exposure which was marketed with a direct link to StudySearch.

Marketing of StudySearch could be added as part of a comprehensive campaign to increase public awareness of and participation in not only clinical trials as proposed by Probstfield[11] but also for potentially all clinical research endeavors conducted at any one institution (see figure 3). The CCTS's public awareness campaign is illustrated in figure 3. This table shows that StudySearch is currently the official listing of recruiting research studies at The Ohio State University Wexner Medical Center (OSUWMC) and is highlighted prominently on the 'Participate in Research' page on the Medical Center's website. Via this webpage the public can access additional information about the importance of participating in research and find currently enrolling studies at OSU. Other ways to connect to research study opportunities supported by the CCTS are shared on this page which include signing up on the national volunteer registry ResearchMatch.org, calling or emailing the general research participation HERO helpline at OSU, or connecting to the CCTS. The OSUMyChart, a secure interactive health record between patients and providers also links to the 'Participate in Research' page. StudySearch hyperlinks can be found on OSU and OSUWMC social media postings on Facebook and Twitter as well as online press releases and news articles about specific enrolling studies.

NEXT STEPS

The CCTS developed StudySearch to serve as a novel web-based application in the toolkit of recruitment resources to address and help resolve the challenge of recruitment of human participants into clinical research protocols. It is not an entirely automated system. Manual postings, and content and IRB continuing review updates require CCTS personnel commitment. IT support is necessary to maintain the system and develop new features to better address user behaviors. One such feature is the development of an online portal where investigators and/or coordinators will be able to edit current postings. Such changes will be reviewed by StudySearch support staff before moving any posting content changes into production. Ways to automate the posting process are constantly being sought. Additional efforts are underway to make more user friendly viewing of StudySearch by programing it to be more responsive to

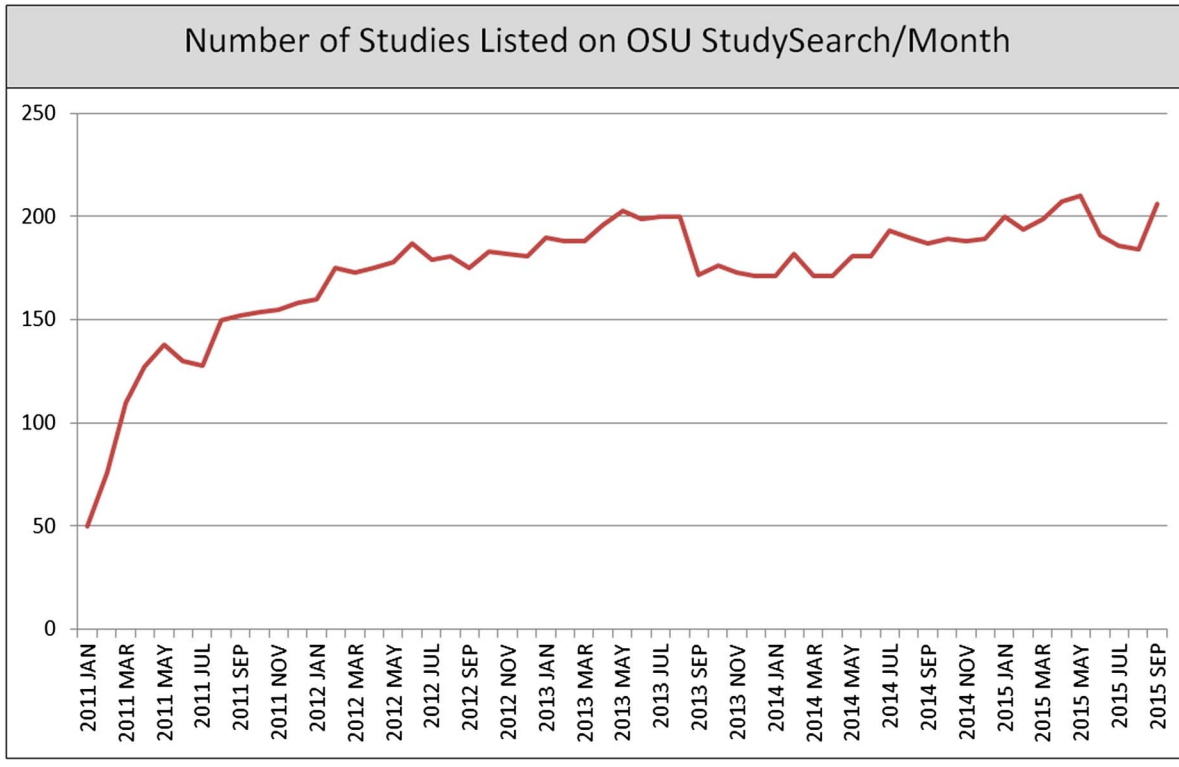

Figure 1 Number of listed studies: January 2011 thru September 2015.

the device on which it is being used. This has great advantages not only for patient populations but also for members of healthcare teams to access local research opportunities for their patients during patient–provider interactions.

Currently, there is not a mechanism in place for the system to respond in real time to updates and warnings from ClinicalTrials.gov to Principal Investigators for a study that is posted for public viewing on StudySearch. The only automated regulatory monitoring mechanism in place is the IRB

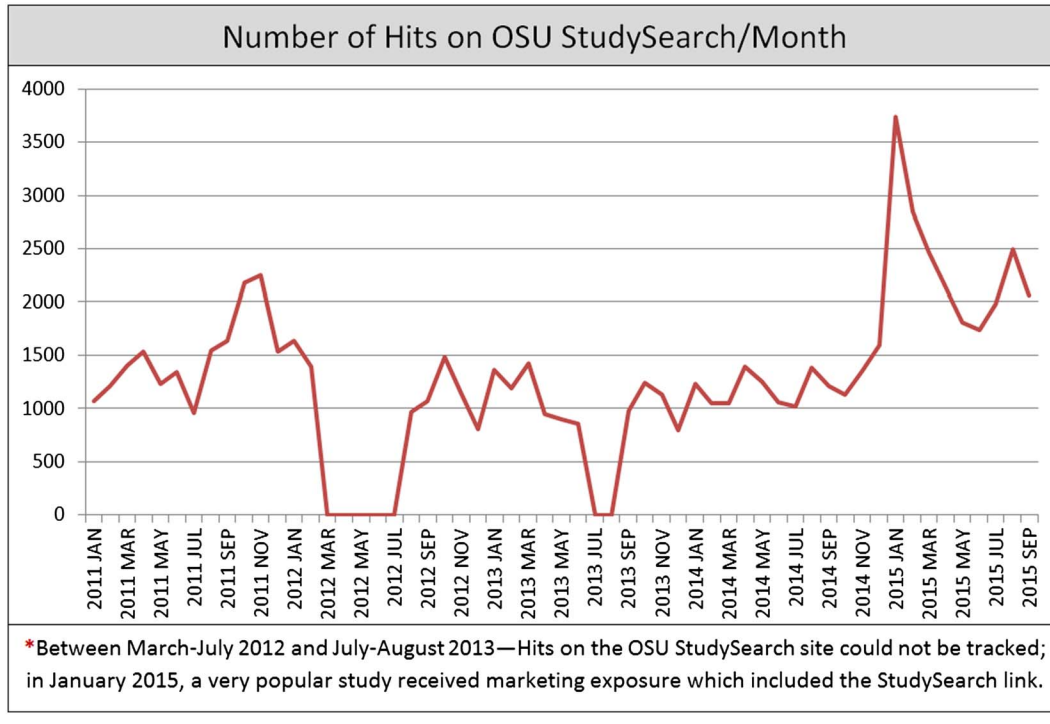

Figure 2 Average hits to site per month: January 2011 thru September 2015.

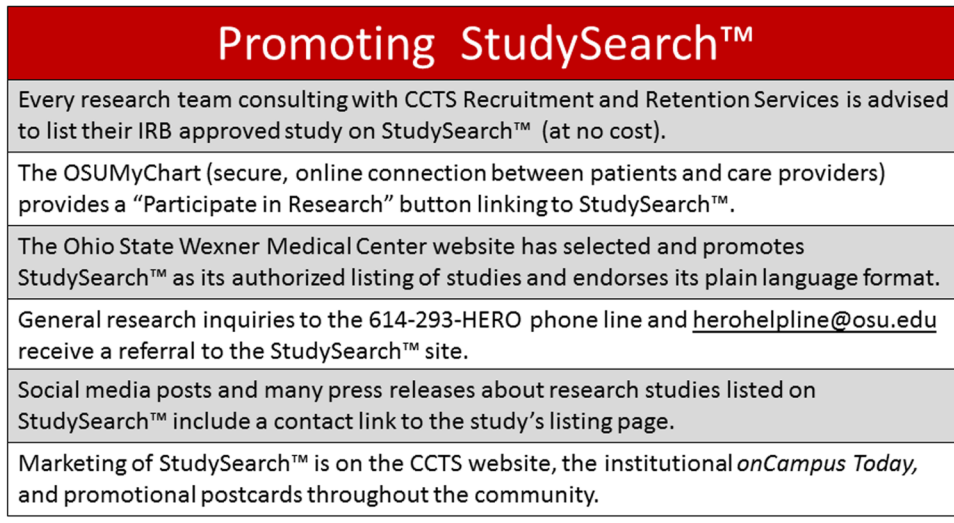

Figure 3 Public awareness campaign to promote research study participation via StudySearch. CCTS, Center for Clinical and Translational Science.

Continuing Review Approval process. As such, any such notices and/or changes to postings including requests to remove the posting, (have) come from notifications by research teams with IRB approval verification required as applicable. It may be advantageous to implement such a monitoring system in order for the system to be able to be timely in its response to such instances as they occur, that is, revise or remove a posting on StudySearch from public viewing.

As user behaviors are understood, modifications to better accommodate preferences will be made. Currently, a search categories feature is being added. This feature will allow for searches of studies by medical specialty rather than strictly by disease, medical condition and/or intervention. This change should allow users to obtain a more comprehensive search of studies. Further optimization of the Keyword feature will include a drop down box of terms to match users typed-in search terms, offering a prefilled term list. This feature should minimize vacant searches due to search-term misspellings. A redesign of the home page will include a 'Recently Added Studies' section to post the 10 most recently added studies.

The ultimate question to determine the value of StudySearch is: how many visitors actually enroll in research? We know from anecdotal reports that this platform has been successful as a recruitment service; however, to date we have yet to develop a useable tracking system to answer this question. As a proxy metric for this, we have recently begun tracking whether users click or copy the study contact's email address. This action can be thought of as intent to contact the study team, though we currently have no way of tracking if they truly do contact the team or enroll. We are considering other methods of measuring the impact of StudySearch such as integration with our institutional Clinical Trials Management System (CTMS) to track referrals from StudySearch. This measure would help clarify the value of StudySearch in the clinical research studies recruitment to enrollment toolkit.

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REFERENCES

1 Sung NS, Crowley WF Jr, Genel M, *et al*. Central challenges facing the national clinical research enterprise. *JAMA* 2003;289:1278–87.
2 Nasser N, Grady D, Balke CW. Commentary: Improving Participant Recruitment in Clinical and Translational Research. *Acad Med* 2011;86:1334–5.
3 Pierre C. Recruitment and retention in clinical trials: what works, what doesn't and why. *Paper presented at 2006 Drug Information Association Annual Summit*; June 2006; Philadelphia, PA.
4 CenterWatch. *An industry in evolution: a sourcebook of charts and statistics*. Boston, MA: Thomson CenterWatch, 2006.
5 Cheng SK, Dietrich MS, Dilts DM. A sense of urgency: evaluating the link between clinical trial development time and the accrual performance of cancer therapy evaluation program (NCI-CTEP) sponsored studies. *Clin Cancer Res* 2010;16:5557–63.
6 Durivage H, Bridges K. Clinical trial metrics: protocol performance and resource utilization from 14 cancer centers. *J Clin Oncol* 2009;27(15 Suppl):6557.
7 Go R, Meyer C, Mathiason M, *et al*. Nature and outcome of clinical trials conducted by the Eastern Cooperative Group (ECOG) from 1977 to 2006. *Poster presented at: American Society of Clinical Oncology*; 2010; Chicago, Ill. Abstract 6069.
8 Schroen AT, Petroni GR, Wang H. Preliminary evaluation of factors associated with premature trial closure and feasibility of accrual benchmarks in phase III oncology trials. *Clin Trials* 2010;7:312.
9 Kitterman DR, Cheng SK, Dilts DM, *et al*. The prevalence and economic impact of low-enrolling clinical studies at an academic medical center. *Acad Med* 2011;86:1360–6.
10 Reis SE, Berglund L, Bernard GR, *et al*. Reengineering the national clinical and translational research enterprise: the strategic plan of the National Clinical and Translational Science Awards Consortium. *Acad Med* 2010;85:463–9.
11 Probstfield JL, Frye RL. Strategies for recruitment and retention of participants in clinical trials. *JAMA* 2011;306:1798–9.