

Blue-button Integrated Clinical Trial Matching Pilot Study Grant Program Request for Proposals (RFP)

I. Background and Program Overview

The American Cancer Society Cancer Action Network (ACS CAN) is pleased to announce an opportunity to partner with health sites to execute a pilot of an integrated cancer clinical trial screening functionality to evaluate its impact on the overall number and demographic makeup of cancer clinical trial referrals and enrollments.

Problem statement: Increasing cancer clinical trial opportunities and enrollments requires increasing the number of patients screened and/or the number of trials they are screened against.

Plans are for grants to between one and four sites to execute and evaluate the pilot. Proposals can be for either a comprehensive evaluation or for a high-level evaluation (as noted below), and sites can submit proposals for one or both evaluation plans. ACS CAN intends to examine the impact of the functionality in sites with significant existing research infrastructure/activity (“academic”), as well as sites that have more limited existing research infrastructure/activity (“community”). While there is no formal definition for these categories, in general “academic” sites will have higher levels of NCI funding, high patient volume, and serve as a tertiary referral center. Ultimately it is up to the applicant to self-identify in one of these categories.

Comprehensive evaluation

- Academic Site—1
- Community Site-1

High-level evaluation

- Academic Site—1
- Community Site-1-2

Tool design:

ACS CAN, through a collaboration with the MITRE [Corporation](#) and the [CodeX FHIR Accelerator](#), is developing open-source integrated clinical trial screening functionality to address a lack of in-workflow tools for providers to prescreen cancer patients for cancer clinical trials. This functionality will work within existing electronic health records (EHRs) to enable patients or providers to initiate a prescreen for relevant trials for a given patient within a specified radius of the practice. This is done by automatically extracting and sending limited, deidentified single-patient data elements to existing trial matching services which return potential trial matches via a SMART on FHIR application (Figure 1). The patient data elements will be extracted and sent to partner clinical trial matching services using FHIR and the open standard language for cancer data, [minimal Common Oncology Data Elements](#) (mCODE). The partner clinical trial matching services (Trialjectory, Ancora.ai, and BreastCancerTrials.org) will receive the patient data in the mCODE FHIR format, analyze the data, and return the results using the FHIR ResearchStudy resource. The [eight patient data elements](#) used for prescreening include age, cancer type, cancer subtype, presence of metastasis, stage, biomarkers, prior treatments, and performance

status. Recognizing that not all data elements will always be available in a structured format, the tool shows the user the extracted data elements and allows for addition or correction prior to transmitting the data to matching services (see screenshot in the Appendix). This novel functionality, referred to as “Blue Button,” will enable one-button clinical trial prescreening not only by providers, but eventually also by patients who use a patient portal to access their medical record.

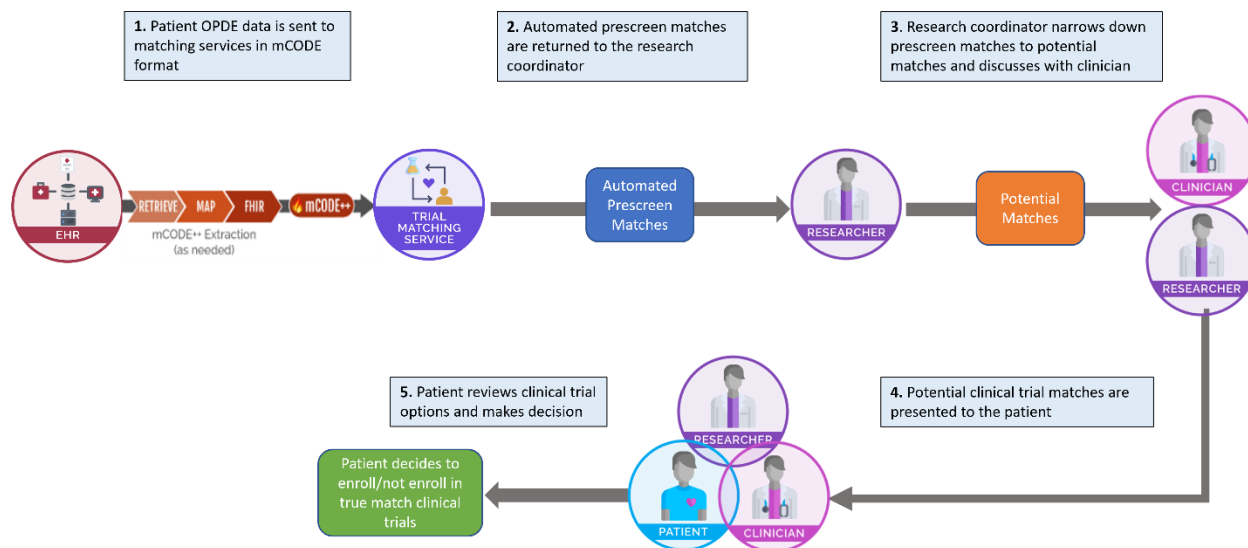


Figure 1: Data flow from EHR to 3rd-party matching services

The goal of this project is to provide trial screening to patients who are either not currently being pre-screened or are only screened against limited onsite trials. It is built upon the hypothesis that by making clinical trial eligibility screening part of routine care, requiring little effort, and making that screening site agnostic, the Blue-Button matching functionality will not only increase overall cancer clinical trial enrollment, but it will also result in more diverse clinical trial participants that better reflect the U.S. cancer population.

Identification of potential trial opportunities, however, is only the first barrier to trial enrollment, so within the comprehensive evaluation we also propose an additional examination of barriers subsequent to the identification of relevant trials. At a minimum this will involve documenting patient-level barriers that prevent enrollment of patients with identified trials, and providing basic navigation services to address logistical challenges, answer questions, and connect patients to existing resources (e.g., third-party financial assistance, rides, or lodging).

Protocol Details:

This study will analyze how using the Blue-button integrated trial matching functionality performs in a real-world clinical setting integrated into a site EHR. It will be integrated into providers workflows for 3-8 cancer types from the following list: breast, lung, prostate, bladder, primary brain, colon, bladder, and multiple myeloma. The sample size for a participating site will depend on site resources and the number of patients who typically receive care at the site over a given time period. Accrual to the study will

contribute to the overall evaluation of the effectiveness of the intervention which will be performed by ACS CAN. The intervention will be used as a primary pre-screening method on eligible patients. Based on a modified “Zelen” design (Figure 2), patients will be randomized prior to consent, with consent sought only in the patients randomized to intervention. No consent will be sought for patients randomized to a control arm in which care is “business as usual.” Patients on both arms will then be followed to assess the proportion who end up participating in a clinical trial.

For patients randomized to the intervention arm, a list of potential trials will be generated through automated pre-screening. These trials will be further evaluated manually by study staff using publicly available eligibility criteria for selected trials and the patient’s medical record. Patients on the intervention arm will be offered additional basic clinical trial navigation support provided by site study staff that will include

- Basic educational material about clinical trials and availability to answer questions
- Assistance contacting study coordinator
- Assistance transferring any medical records to confirm eligibility
- Confirmation of insurance coverage at referral site
- Evaluation of specific patient needs (e.g., transportation, lodging, financial support, translation, etc.)
- Connecting patients with identified needs to existing resources (e.g., ride programs, financial support)

Data Sharing: Deidentified study data will be shared with ACS CAN and combined with data from other sites for central analysis.

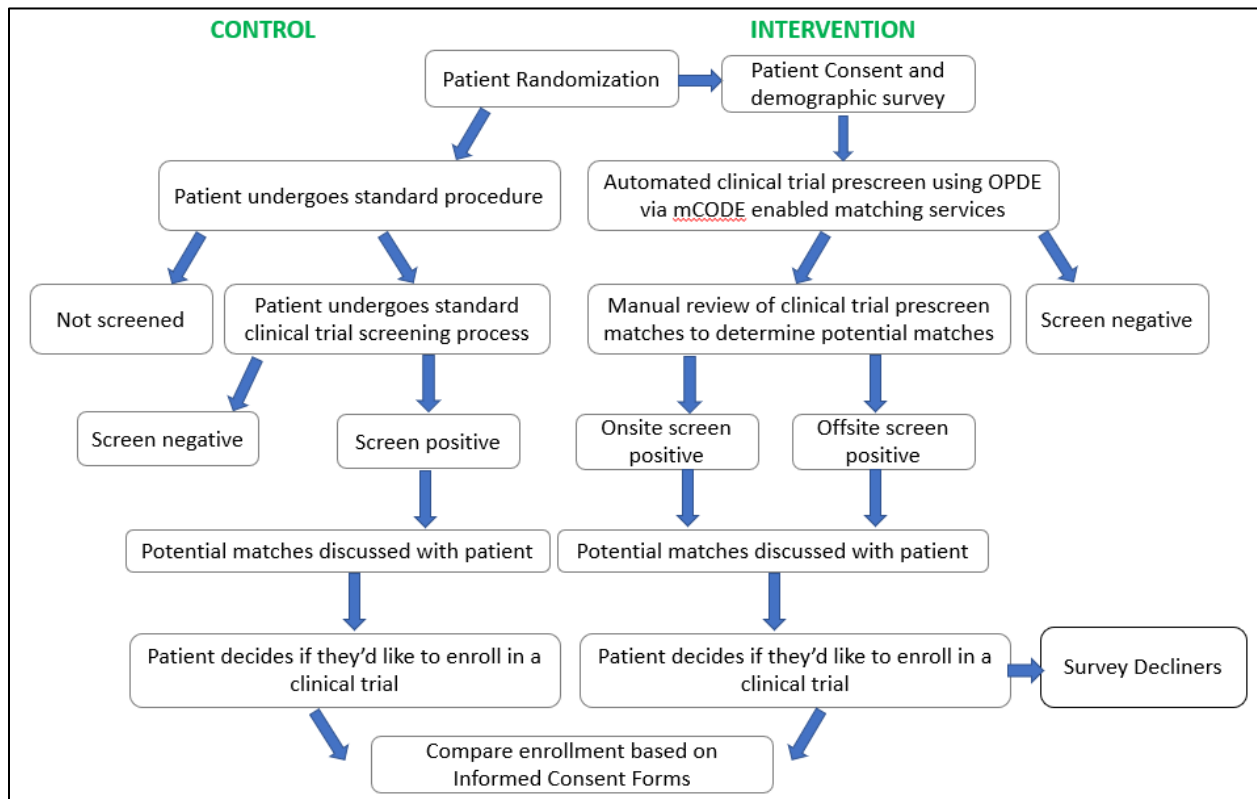


Figure 2: Option for using Integrated Clinical Trial screening functionality in place of site's traditional screening method

Data collection is designed to enable analysis of the primary endpoints of changes in overall enrollment and changes in demographics of enrollment (Table 1 and Appendix of Survey Instruments).

Based on the data collected (Table 1), the primary objective will be to examine:

- Differences in the proportion of patients between arms who enroll in a clinical trial

Secondary objectives

- To compare the 8-week retention rates between arms of those enrolled in trials
- To evaluate (via survey) the ease of use and time and effort of the automated prescreening tool by providers and research coordinators.
- To describe reasons that patients do not enroll in clinical trials among those for whom a trial is available, and the patient is offered participation.
- To evaluate the performance of the clinical trial matching tool for returning quality matches for patients (percentage of trials returned from prescreening that are ultimate matches after manual review).
- To assess the utilization of navigation resources when patients enroll and/or participate in a clinical trial.

Exploratory Objectives

- To compare demographic characteristics between patients identified as eligible for clinical trial participation in the intervention group versus site historical data.
- To compare social determinants of health data between patients who enroll in clinical trials onsite versus offsite at another institution.

Table 1: Variable data collection across pilot sites

| | Academic Comprehensive | Community Comprehensive | Academic High Level | Community High Level |
|---|------------------------|-------------------------|---------------------|----------------------|
| Evaluation Patients (intervention) | 200-300 | 100-300 | 100-200 | 100-200 |
| Navigation? | Yes | Yes | Optional | Optional |
| Control Arm? | Yes | Yes | Historical | Historical |
| <u>Data collected/Analyses</u> | | | | |
| Race/ethnicity | X | X | X | X |
| Income (likely binary +/- \$70k family income) | X | X | X | |
| Employment status | X | X | | |
| Education level | X | X | | |
| Native Language | x | x | | |
| Insurance type | X | X | | |
| Transportation mode utilized | X | X | | |
| Dependence on support for visits | X | X | | |
| Patient distance from cancer center | X | X | | |
| Clinical characteristics (primary diagnosis, stage) | X | X | | |
| Number of trials returned from blue-button screening | X | X | X | Optional |
| Provisionally positives among screen positive trials | X | X | | |
| Enrollment resulting from blue-button screening (onsite/offsite) | X | X | X | X |
| Distance of trial from original site | X | X | X | Optional |
| Crosstabs (demographics and clin characteristics) for enrollment resulting from Blue-button | X | X | X | X |
| Reasons for non-enrollment | X | X | X | Optional |
| Retention 8 weeks post trial identification | X | X | X | Optional |
| Provider feedback on tool | X | X | X | X |

Publishing: ACS CAN seeks to publish study findings in the peer-reviewed literature and invites participation of grantees in this process as co-authors.

Technical Implementation:

The automatic matching functionality is open-source and available free of charge. However, health sites must commit resources to install the functionality and maintain it throughout the study. Currently, only EPIC sites will be considered due to software limitations. Details on the technical implementation requirements can be found in the Requirements table below.

II. Program Eligibility

| | |
|---------------------------------------|---|
| Geographic Scope | United States |
| Applicant Eligibility Criteria | Use Epic EHR software |
| Referral Options | Additional institutions offering interventional clinical trials within 50 miles and site commitment to supporting referrals of all trial-matched patients |

Sites wishing to clarify their eligibility for the grant can contact Mark Fleury <mark.fleury@cancer.org> for more info.

III. Requirements

| | |
|---|--|
| Area of Interest for this RFP | <p>The goal of this initiative is to study the effect of implementing the Blue-button clinical trial matching functionality on the overall number and demographic makeup of cancer clinical trial referrals and enrollments.</p> <p>The intent of the grant project is to support proposals in several different site settings (urban, rural, academic, community, etc.) to explore how this clinical trial matching functionality works in different settings.</p> <p>It is expected that health systems applying for funding demonstrate their commitment to clinical trials and making cancer care accessible to all patients.</p> <p>All grantees will be expected to work closely with ACS CAN and the CodeX Initiative/MITRE throughout the study process.</p> |
| Gaps in Care and Barriers | Pre-screening cancer patients for clinical trials can be a manual and ad hoc process. We have created an in-workflow tool that may be used to quickly and efficiently pre-screen many patients for locally available clinical trials. |
| Study Approval, Staffing and Oversight | Sites will be responsible for securing IRB approval for the conduct of the study and will ensure that all research activities are compliant with applicable laws and regulations. Upon discussion, ACS CAN may secure central IRB approval with sites deferring to the central IRB. Sites will receive funding to support any local IRB submissions and clinical personnel needed to conduct the study. ACS CAN and MITRE will provide IT, technical, analytical, and administrative support, but will not interact with patients in any way. |

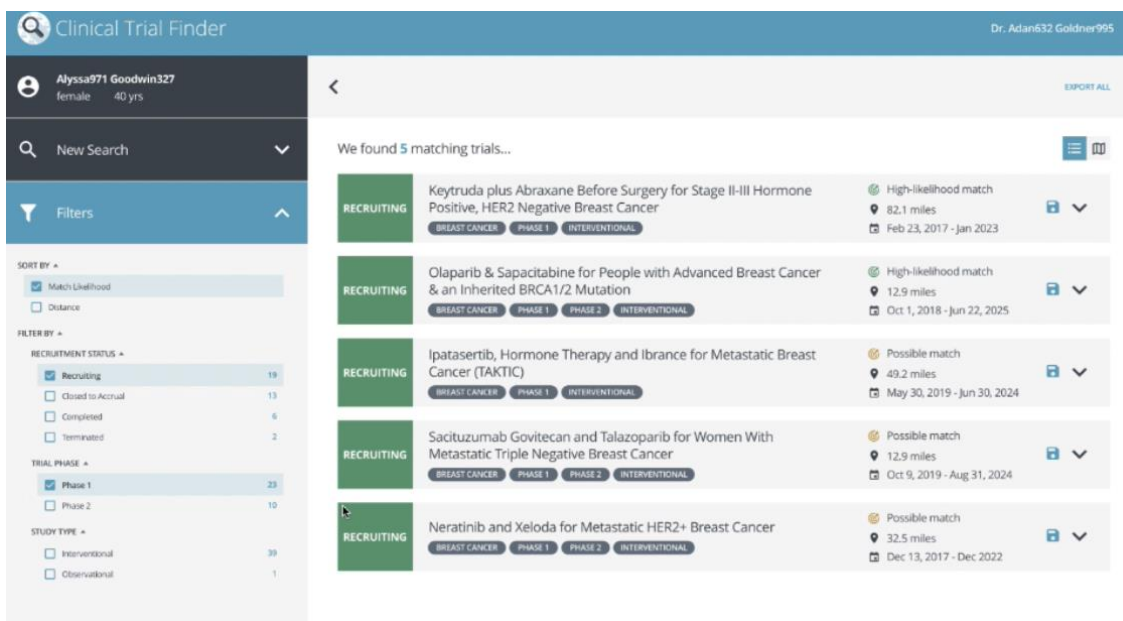
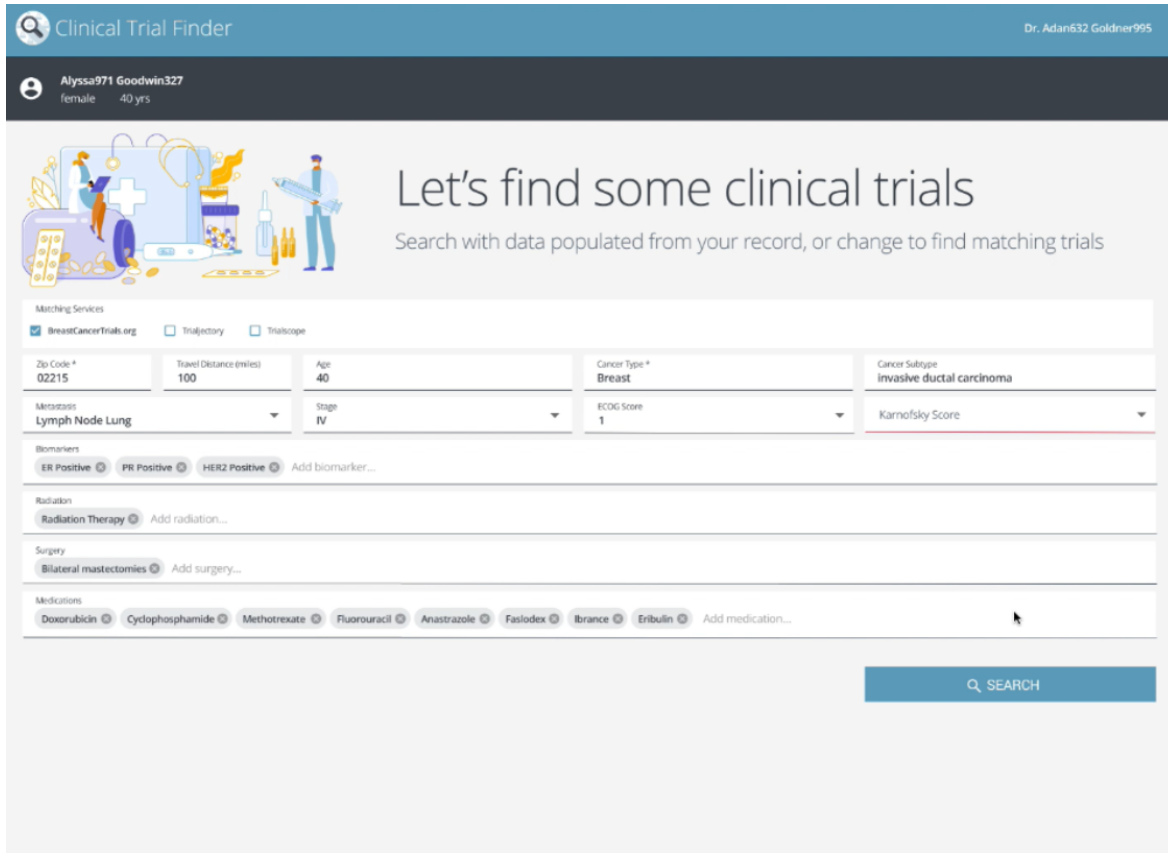
| | |
|---|---|
| <p>Technical/IT Requirements</p> | <p>Sites will need a server that is capable of running either a Docker image or a virtual machine. The server will also need to be able to run Node and npm for installing and starting up the application and wrappers. The code for trial matching application and trial matching service wrapper will be provided.</p> <p>The health site needs to create a FHIR client ID for the app so that it can access the EHRs. Most operating systems should be usable for installation.</p> <p>Sites will be required to install application and wrappers used a preconfigured package. Although the installation and maintenance is required by the health site, the MITRE team can deliver a preconfigured package as a .vdk or a docker file for ease of implementation.</p> <p>Link to the GitHub repositories - GitHub - mcode/clinical-trial-matching-app: Smart on FHIR application for matching patient records with clinical trials Scrolling down on this webpage will display 7 repositories for this project.</p> |
| <p>Data Required with Submission</p> | <p>Target Audience: Please describe the patient population/catchment area. Describe the overall population size, including the number of cancer patients you see per year and the number of patients in each clinic/with a specific cancer type.</p> <p>Please describe your current practice for pre-screening for clinical trial eligibility. Include whether or not you offer onsite trials and how often you send patients offsite for clinical trials. Please list the research centers/other clinical trial locations within 20, 50, and 100 miles of your clinic. Please describe your relationship with any of these sites for referring patients for clinical trials. Include any barriers to referring patients to other sites for clinical trials.</p> <p>Please describe the percentage of cancer patients that enroll onto clinical trials at your site. If known, include your overall screen positive rate as well as for each cancer type/clinic.</p> <p>Project Design and Methods: There will be up to 6 cancer types studied: breast, lung, prostate, bladder, primary brain, colon, and multiple myeloma. Please indicate which of the cancer types you would conduct the pilot in (minimum of two).</p> <p>Patients will be offered additional clinical trial navigation support that will include</p> <ul style="list-style-type: none"> • Basic educational material about clinical trials and availability to answer questions • Assistance contacting study coordinator • Assistance transferring any medical records to confirm eligibility • Confirmation of insurance coverage at referral site |

| | |
|-----------------------|---|
| | <ul style="list-style-type: none"> • Evaluation of specific patient needs (e.g., transportation, lodging, financial support, translation, etc.) • Connecting patients with identified needs to existing resources (e.g., ride programs, financial support) <p>Please describe your current navigation/clinical trial support system and what aspects might be missing for the scope of this project.</p> <p>Site Details: Please describe the size, setting, and network participation of your site. Please describe any patient demographic information you currently collect. (See appendix and draft information for types of information to be collected) Please describe your current method(s) for electronic data capture. Please describe the FHIR resources available at your site.</p> <p>Evaluation and Outcomes: Variable levels of data collection and analysis will happen based on site capabilities. Please describe which type of pilot site you would prefer to participate as (see Table 1 and Appendix of Survey Instruments for more information on Site levels).</p> <p>Core metrics will be required for this project that will be combined with similar data from other sites</p> <ul style="list-style-type: none"> • Difference in enrollment and 8-week retention between arms • Comparison of demographic information of patients who enroll in clinical trials after using the automated pre-screening tool and the cancer patient population (by cancer type) • Refusal reasons in interventional arm • Positive-predictive value of automated clinical trial pre-screening searches • Proportion of patients with at least one potential positive when using the automated clinical trial pre-screening tool • Distance to potential-positive trials • Provider/research coordinator feedback on usability • Description of navigation resources requested and used |
| Funding Amount | <p>Proposals shall not exceed the following amounts: Comprehensive evaluation \$300,000, High-level evaluation \$225,000. Proposals may include multiple options but should specify level of evaluation and number of patients.</p> <p>Proposed projects may request up to 20% indirect costs. Amounts over this will not be considered.</p> |

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|----------------------|---|
| | <p>Up to four health systems/sites will be awarded depending on budget and available funds. Proposals not awarded immediately may be awarded at a later date if additional funds become available.</p> <p>Payments will be made on a milestone basis as follows: 20% On contract signing 25% First patient enrolled 25% 50% enrollment 20% Last patient enrolled 10% Final data transfer and protocol close-out</p> <p>Failure to evaluate patients with the integrated tool within six months of contract execution will nullify contract as will failure to pursue external referrals for matched patients. Either failure will require refund of any paid funds.</p> |
| Key Dates | <p>RFP release date: October 7th, 2022 Applications due: November 11, 2022 Decision notification date: Anticipated December 9 Startup date: Negotiable. First patients should be enrolled no later than June 2023</p> |
| How to Submit | <p>Submit proposals via email to mark.fleury@cancer.org</p> |
| Questions | <p>We will host webinars for interested sites to learn more about the project and ask any relevant questions. Webinars will cover overall project design and specific IT needs.</p> <p>These webinars will be held: Overall project webinars: October 18, 12:30-1:30 Eastern, November 1, 1-2 Eastern IT needs webinars: October 20, 2-3 Eastern, November 2, 3-4 Eastern</p> <p>General questions about the RFP can be directed to mark.fleury@cancer.org</p> <p>A compilation of questions and answers will be regularly updated at https://www.fightcancer.org/blue-button-integrated-trial-screening-pilot</p> |

IV. Appendices

Screenshots of user interface (see also <https://www.fightcancer.org/blue-button-integrated-trial-screening-pilot> for video of interface use)



Appendix of Draft Survey Instruments:

Demographic Information Survey (questions also available in Spanish)

We are asking you to participate in a survey about cancer patients. This survey does not involve any medical treatment and will not influence what treatment you may receive for your cancer. We would like to ask you questions about your race/ethnicity, income status, educational background, and a few other questions about travel, employment, and caretaking responsibilities. You may decline to answer any of the particular questions if you wish. Completing these questions will take less than 10 minutes of your time and will be answered before you meet with your physician. Your answers will be treated in a confidential manner.

- 1) Are you of Hispanic, Latino, or Spanish origin?
 - a. Yes
 - b. No
 - c. Don't know
 - d. I prefer not to answer

- 2) Which of these groups best describes you? You may choose more than one.
 - a. Black or African American
 - b. Native Hawaiian or other Pacific Islander
 - c. American Indian or Alaska Native
 - d. White
 - e. Asian
 - f. Other, specify: _____
 - g. Don't know
 - h. I prefer not to answer

- 3) What is the highest grade or level of school you have completed?
 - a. Less than high school
 - b. Some high school, no diploma
 - c. High school diploma or GED
 - d. Some college
 - e. Associate degree
 - f. Trade degree
 - g. Bachelor's degree (e.g. BA, AB, BS)
 - h. Graduate or Professional degree (e.g. MA, MS, PhD, EdD, MD, JD)
 - i. Don't know
 - j. I prefer not to answer

- 4) Thinking about all family members living in your household, what is your combined annual income from all sources?
 - a. \$35,000 or less
 - b. \$35,001 to \$70,000
 - c. \$70,001 to \$125,000

- d. \$125,001 or more
 - e. I prefer not to answer
- 5) Are you employed?
- a. Yes—full time
 - b. Yes—part time
 - c. No—including retired, homemaker, or student
 - d. Job Seeker
- 6) What type of health insurance do you have? Select all that apply.
- a. Privately purchased insurance
 - b. Employer-provided insurance
 - c. Medicare
 - d. Medicare plus a supplemental policy
 - e. Medicaid
 - f. Military/VA
 - g. None/uninsured
 - h. Other, specify: _____
 - i. Don't know
 - j. I prefer not to answer
- 7) Which best describes your current method of transportation to your appointments?
- a. Drive a personal vehicle that is not shared
 - b. Drive a personal vehicle that is shared with others
 - c. Get rides from a family member or friend
 - d. Get rides with other in a carpool or vanpool
 - e. Use public transportation
 - f. Use rideshare services
 - g. Walk
 - h. Other, Specify: _____
- 8) Have you delayed getting care in the past 12 months because you did not have transportation?
- a. Never
 - b. Rarely
 - c. Sometimes
 - d. Often
- 9) When you go to health care appointments, do you typically have someone else come with you?
- a. No, I typically go alone
 - b. Yes, for moral support or company
 - c. Yes, for transportation to my appointment
 - d. Yes, for the person who accompanies me helps to manage my care
 - e. Yes, for mobility assistance

- 10) Are you a primary caregiver for a young child or other household or family member requiring care?
- Yes
 - No

Spanish Language Version of Demographic Survey

Encuesta de Información demográfica

Le pedimos que participe en una encuesta sobre pacientes con cáncer. Esta encuesta no supone ningún tratamiento médico y no influirá en el tratamiento que pueda recibir para su cáncer. Nos gustaría hacerle preguntas sobre su raza/origen étnico, estado de ingresos, antecedentes educativos y algunas otras preguntas sobre viajes, empleo y responsabilidades de cuidado. Si lo desea, puede negarse a responder a cualquiera de las preguntas en particular. Completar estas preguntas le tomará menos de 10 minutos de su tiempo y se completará antes de que se reúna con su médico. Sus respuestas se tratarán de manera confidencial.

- ¿Es usted de origen hispano, latino o español?
 - Sí
 - No
 - No sé
 - Prefiero no responder
- ¿Cuál de estos grupos lo(a) describe mejor? Puede escoger más de una opción.
 - Raza negra o afroamericano(a)
 - Hawaiano(a) nativo(a) o de otra isla del Pacífico
 - Indígena Americano(a) o Nativo(a) de Alaska
 - Raza blanca
 - Asiático(a)
 - Otra, explique en detalle: _____
 - No sé
 - Prefiero no responder
- ¿Cuál es el grado o nivel académico más alto que ha completado?
 - Menor que la escuela secundaria/preparatoria (high school)
 - Algo de la escuela secundaria/preparatoria (high school), no obtuvo diploma
 - Título secundario/preparatoria (high school) o Diploma de Equivalencia General (GED)
 - Estudió en la universidad pero no se graduó
 - Título de Asociado (Associate degree)
 - Formación profesional/Oficio (Trade)
 - Licenciatura (p.ej. licenciatura en Humanidades (B.A., A.B.), licenciatura en Ciencias (B.S.))
 - Título de especialización profesional (p.ej. maestría en Humanidades (M.A.), maestría en Ciencias (M.S.), doctorado (Ph.D.), doctorado en Educación (Ed.D.), doctorado en Medicina (M.D.), doctorado en Jurisprudencia (J.D.)
 - No sé
 - Prefiero no responder

4. Considerando a todos los miembros de la familia que viven en su hogar, ¿cuál es su ingreso anual combinado de todas las fuentes?
 - a. \$35,000 o menos
 - b. \$35,001 a \$70,000
 - c. \$70,001 a \$125,000
 - d. \$125,001 o más
 - e. Prefiero no responder
5. ¿Está usted empleado?
 - a. Sí—a tiempo completo
 - b. Sí—a tiempo parcial
 - c. No—incluidos los jubilados, amas de casa o estudiantes
 - d. Busco empleo
6. ¿Qué tipo de seguro médico tiene? Seleccione todas las opciones que correspondan.
 - a. Seguro adquirido de forma privada
 - b. Seguro provisto por el empleador
 - c. Medicare
 - d. Medicare más una póliza complementaria
 - e. Medicaid
 - f. Militar/Veteranos (VA)
 - g. Ninguno/sin seguro médico
 - h. Otro, explique en detalle: _____
 - i. No sé
 - j. Prefiero no responder
7. ¿Qué opción describe con mayor frecuencia su principal método de transporte [a sus citas médicas]?
 - a. Conduce un vehículo personal que no sea compartido
 - b. Conduce un vehículo personal que es compartido con otros
 - c. Lo lleva un familiar o amigo
 - d. Lo llevan junto con otras personas en un automóvil o una camioneta compartida
 - e. Usa el transporte público
 - f. Usa servicios de viajes compartidos (rideshare)
 - g. Camina
 - h. Otro, explique en detalle: _____
8. ¿Se ha demorado en recibir atención en los últimos 12 meses porque no tenía transporte?
 - a. Nunca
 - b. Pocas veces
 - c. A veces
 - d. A menudo
9. Cuando va a las citas médicas, ¿normalmente alguien lo acompaña?
 - a. No, por lo general voy solo(a)
 - b. Sí, para contar con apoyo moral o compañía
 - c. Sí, para que me lleve a mi cita
 - d. Sí, porque la persona que me acompaña me ayuda a gestionar mi cuidado
 - e. Sí, para contar con asistencia a la movilidad
10. ¿Es usted el cuidador principal de un niño pequeño o de otro miembro del hogar o de la familia que requiere atención?
 - a. Sí
 - b. No

Draft Refusal to Enroll Survey (*Comprehensive evaluation*)

We are asking you to participate in a survey about cancer clinical trials. This survey does not involve any medical treatment and will not influence what treatment you may receive for your cancer. We would like to ask you questions about your choice not to enroll in a clinical trial. You may decline to answer any of the particular questions if you wish. Completing these questions will take less than 5 minutes of your time. Your answers will be treated in a confidential manner.

- 1) What was the main reason you did not enroll in a clinical trial? (free response)

- 2) Is there anything else you would like to add?

- 3) Please rank the broad categories of reasons for not enrolling in a clinical trial in order from most influential (1) to least influential (8).
 - _____ Concerns over cost to me
 - _____ Challenges getting to needed appointments/tests)
 - _____ Concerns about safety of proposed treatment
 - _____ Desire to retain control over treatment
 - _____ Lack of interest in specific trial offered
 - _____ Insurance would not cover the trial or the facility where the trial was held
 - _____ Doctor advised against enrolling
 - _____ After further screening, I was deemed ineligible

Refusal to enroll—Spanish language version

Encuesta sobre la negación a inscribirse

Le pedimos que participe en una encuesta sobre estudios clínicos. Esta encuesta no implica ningún tratamiento médico y no influirá en el tratamiento que pueda recibir para su cáncer. Nos gustaría hacerle preguntas sobre su elección de no inscribirse en un estudio clínico. Si lo desea, puede negarse a responder a cualquiera de las preguntas en particular. Completar estas preguntas le llevará menos de 5 minutos de su tiempo. Sus respuestas se tratarán de manera confidencial.

1. ¿Cuál fue el motivo principal por el que no se inscribió en un estudio clínico? (respuesta libre)
2. ¿Hay algo más que le gustaría agregar?
3. Clasifique las categorías generales de razones para no inscribirse en un estudio clínico en orden desde la más influyente (1) hasta la menos influyente (8).
 - _____ Preocupaciones sobre el costo que tiene para mí
 - _____ Dificultades para llegar a las citas/pruebas necesarias
 - _____ Inquietudes sobre la seguridad del tratamiento propuesto
 - _____ Deseo de mantener el control sobre el tratamiento
 - _____ Falta de interés en el estudio clínico específico ofrecido

 - _____ El seguro no cubriría el estudio ni el centro donde se llevaría a cabo el estudio
 - _____ El médico aconsejó no inscribirse

_____ Después de una evaluación adicional, se consideró que no era elegible

Draft User Experience Survey (All Sites)

- 1) What is your role/position
- 2) Approximately how many patients have you screened using this tool in the last 3 months?
 - a. 0 patients
 - b. 1-10 patients
 - c. 11-20 patients
 - d. 21-50 patients
 - e. 51-100 patients
 - f. >100 patients
- 3) On a scale of 1 to 5, how would you rate the amount of time it takes to prescreen patients for clinical trials using your typical procedure, with 1 being very time consuming and 5 being not very time consuming?
 - a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
- 4) On a scale of 1 to 5, how would you rate the level of difficulty prescreening patients for clinical trials using your typical procedure, with 1 being very difficult and 5 being not difficult at all?
 - a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
- 5) On a scale of 1 to 5, how would you rate the quality of clinical trial matches using your typical procedure, with 1 being very excellent matches and 5 being not very good matches?
 - a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
- 6) On a scale of 1 to 5, how would you rate the amount of time it takes to prescreen patients for clinical trials using the integrated clinical trial matching tool, with 1 being very time consuming and 5 being not very time consuming.
 - a. 1
 - b. 2
 - c. 3

- d. 4
 - e. 5
- 7) On a scale of 1 to 5, how would you rate the level of difficulty prescreening patients for clinical trials using the integrated clinical trial matching tool, with 1 being very difficult and 5 being not difficult at all?
- a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
- 8) On a scale of 1 to 5, how would you rate the quality of matches with the integrated clinical trial matching tool compared to the matches from your typical prescreening procedure, with 1 being very excellent matches and 5 being not very good matches?
- a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
- 9) Did using the integrated clinical trial matching impact your relationship with your patient(s)?
- a. Yes
 - b. No
- 10) If yes, how so?
- 11) If this tool was readily available outside this pilot study, would you use it regularly for your patients?
- a. Yes
 - b. No

Appendix of Technical Responsibilities:

| MITRE Responsibilities | Site Requirement / Responsibilities: |
|---|---|
| Code for trial matching application and trial matching service wrappers | Server capable of running either a Docker image or a virtual machine |
| Preconfigured package as .vdk or Docker file for installation of application and wrappers | Creation of FHIR client ID for application so it can access EHRs |
| Support in installation and maintenance of application and wrappers | Installation of application and wrappers, using preconfigured package |
| | Site specific configuration of application/wrappers |
| | Ongoing maintenance of application and wrappers |

Link to the GitHub repository <https://github.com/mcode/clinical-trial-matching-app>

About ACS CAN

ACS CAN makes cancer a top priority for policymakers at every level of government. ACS CAN empowers volunteers across the country to make their voices heard to influence evidence-based public policy change that saves lives. We believe everyone should have a fair and just opportunity to prevent, find, treat, and survive cancer. Since 2001, as the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN has successfully advocated for billions of dollars in cancer research funding, expanded access to quality affordable health care, and made workplaces, including restaurants and bars, smoke-free. As we mark our 20th anniversary, we're more determined than ever to stand together with our volunteers and save more lives from cancer. Join the fight by visiting www.fightcancer.org.