REQUEST FOR PROPOSAL (RFP)
BioMedSA Clinical Trial Central Hub
Design and Development Through Launch

July 21, 2022

PROJECT OVERVIEW

Vision: To provide the most efficient, easy to implement, high quality, cutting-edge, accessible clinical trial system in the country to advance the healthcare of our people in the greater San Antonio region.

Problems to address:
The United States clinical trial enterprise has substantial challenges in efficiency and effectiveness that were documented within a 2012 Institute of Medicine of the National Academies Workshop Summary (Weisfeld, 2012). Most, if not all, of these challenges remain and are consistent with the state of the clinical trial enterprise in San Antonio as listed below.

- Low recruitment/enrollment in clinical trials
- Lack of diversity (ethnicity, age, environment) in clinical trials
- Shortage of clinical trial staffing
- Poor access to clinical trial resources
- Sponsor access to clinical trial sites and principal investigators is fragmented (personal relationships)
- Patient knowledge of and access to clinical trials is low
- Community healthcare providers understanding of clinical trials and the healthcare benefits they afford is low

BIOMEDSA

BioMedSA, a non-profit, membership-based organization supported in part by the City of San Antonio, was founded in 2005 to accelerate growth of the healthcare and bioscience sector, create regional economic benefit, and contribute to the health of San Antonio and beyond by establishing San Antonio as a leader in healthcare and bioscience. BioMedSA, as a neutral convener, is leading San Antonio's healthcare and bioscience industry in essential activities to create an environment of success for the sector and the community, connect people and resources to energize new ideas, facilitate collaboration, and advocate for the entire healthcare and bioscience ecosystem in the region.

The BioMedSA Clinical Trial Hub is a new initiative of BioMedSA. BioMedSA is hiring a Project Manager to manage the Clinical Trial Hub build-out and its long-term usefulness and sustainability.

GLOSSARY

Term	Definition
Community	The public, individuals, community or health advocacy groups, non-governmental agencies, businesses, and government agencies
Community Outreach Partner	individuals or entities that provide healthcare and/or wellness services to our underserved and least served population
Health Care Provider (HCP)	an individual health professional or a health facility organization licensed to provide health care diagnosis and treatment services, including medication, surgery, and medical devices. In the context of this proposal, these individuals are local to the region.

Hub Member	any individual, organization or entity electing to participate in the Clinical Trials Hub, selecting a membership level, and paying the membership fee.
Internal/External User	BioMedSA employees and representatives are internal users; all others are external users
Investigator (PI and Co-PI)	an individual who conducts a clinical trial; known as Principal Investigator (PI) when leading a site; Co-PI when not the lead.
Job Seekers	Individuals who are seeking employment in clinical trials
Participants	Individuals who volunteer to join a clinical trial
Service Provider	an entity that provides a service that supports the conduct of research
Solicitation	a sponsor's opportunity made to investigators and sites to participate in a trial
Sponsor	Clinical trial sponsors and other entities representing trial sponsors (e.g., Contract Research Organizations (CRO) or research networks.
Study Site	an entity that hosts a clinical trial
Volunteer Registry	a database of individuals who are interested in participating in clinical trials.

CLINICAL TRIAL HUB GOALS

1. Integrate our 90+ clinical trial entities that are currently working in silos
    - Promote clinical trial job creation and workforce development
    - Provide clinical trial access for our least served and underserved populations (e.g., rural, Latino)
    - Improve enrollment in clinical trials
2. Provide clinical trial access for our community healthcare providers (HCP)
    - Promote community understanding and engagement in clinical trials
3. Develop a network of healthcare providers that have a structure and system in place to tackle clinical problems together
    - Increase cost effectiveness and financial return to institutions/companies with clinical trial interests
4. Create differentiating value for clinical trial sponsors to conduct clinical trials in San Antonio region
    - Access to diversity of population
    - Access to HCPs, PIs and research sites
    - Access to efficient clinical trial implementation and completion
5. Create differentiating value for clinical trial sites
    - Access to HCPs
    - Access to diverse clinical trial participants
    - Access for collaboration with regional clinical trial sites
    - Access to service providers
6. Be financially self-sustaining within four years from launch.

SCOPE OF WORK AND DELIVERABLES

We envision inter-searchable databases comprising regional clinical trials (swept from clinicaltrials.gov, NIH), community people (e.g., Latinos, Blacks, Whites, Native Americans), community healthcare providers (e.g., doctors, nurses, physical therapists, dentists), clinical research sites (e.g., UTHealth San Antonio, Pinnacle Clinical Research), support services (e.g., The Geneva Foundation, Uber Health), and career development (e.g., training programs, jobs).

There are five implementation areas designed to:

1) Connect clinical trial sponsors with local study sites (e.g., non-profit, for-profit, institutional, community).
2) Connect Principal Investigators (PIs) with community healthcare providers and community participants.
3) Connect study sites with businesses offering needed services (e.g., trial management, laboratory services, study subject identification and recruitment, remote monitoring of study subjects, transportation).
4) Connect the community and healthcare providers with current clinical trial opportunities.
5) Connect individuals making career choices with training/development and career opportunities.

The Clinical Trial Hub will require full-stack development and hosting, including a secure front-end web interface, a middle-ware layer supporting advanced queries, reporting, 3rd party API integration, and updating, and a back-end database. Integrating existing, off-the-shelf solutions for components of the hub is encouraged.

Development of the Clinical Trial Hub will span 3 years with alpha and beta functional prototype deliverables in years 1 and 2, respectively, along with a final version in year 3.

Goal #1 - Study Placement Service

The first goal of this project is to create a hub for Hub Members where PI/Study Sites can share their clinical trial expertise and capabilities with Sponsors, Contract Research Organizations and Research Networks (Sponsors) seeking collaborators. The hub will consist of a **Study Placement Service** and an online repository of information.

The scope of this goal is to plan, design, build and implement a **Study Placement Service** with administrative support (Administrator) and an online database system. Azure cloud is preferred for all workloads: database, basic storage, security, AD (active directory, interface/applications, etc.) A virtual platform will be used by PI/Study Sites to share their clinical trial capacity with Sponsors looking to collaborate. The system will be accessible from common browsers, (e.g. Chrome, Safari) secure and have a user-friendly interface. Sponsors will be able to search the database (MS SQL preferred) for PI/Study Sites

according to predefined search criteria. Sponsors will have the option of contacting the PI/Study Sites directly using contact information provided or request assistance from the Administrator with finding an interested PI/Study Sites by providing a brief description of the study (solicitation). These interactions will be stored and logged in the system.

Goal #2 - Site Placement Service and Patient Referral

This goal will create a hub where local community Healthcare Providers (HCPs) can share their clinical expertise, practice capabilities and degree of interest in collaborating with Hub Member PIs who are planning to conduct a trial and are seeking collaborators (co-PIs). The hub will consist of a **Site Placement Service** and an online repository of information that enables HCPs to refer patients to participate in a study.

The scope of this goal is to plan, design, build and implement a **Site Placement Service** with administrative support and an online database system. A virtual platform will be used by local HCPs to share their willingness and capacity with PIs looking to collaborate or receive patient referrals. The system will be accessible from any browser, secure and have a user-friendly interface. PIs will be able to search the database for local HCPs according to predefined search criteria. PIs will have the option of contacting the HCP directly using contact information provided or request assistance from the Administrator with finding an interested HCP by providing a brief description of the study (solicitation).

Goal #3 - Study Recruitment Service and Volunteer Registry

This goal will create a hub where Hub Member PI/Study Sites can share information about their active, enrolling clinical trials with the public (Community) seeking to participate.

The scope of this goal is to plan, design, build and implement a **Study Recruitment Service** with administrative support and an online database of information. The virtual platform will be used by PI/Study Sites to share information about their active and enrolling clinical trials with the Community. Public facing & internal sites must be secured. PI/Study Sites will be able to use existing study descriptions from ClinicalTrials.Gov, use a modified version of CT.GOV, or input/upload their own. The system will be accessible from any browser, be secure and have a user-friendly interface. Community members will be able to search the database for trials according to predefined search criteria modeled after ClinicalTrials.Gov. Community members will have the option of contacting the PI/Study Sites directly using contact information provided or request assistance from the Administrator to find a qualified study by providing a brief description of their study interests (**Volunteer Registry**). Community members can request hub credentials to join the Volunteer Registry or sign-up to receive email notification for studies of interest by practice area/disease.

Goal #4 - Support Services Assistance Program

This goal will create a hub where Hub Member businesses providing clinical trial related services (herein **Service Providers**) can share information with Hub Member PI/Study Sites seeking to contract for services.

The scope of this goal is to plan, design, build and implement the **Support Service Assistance Program** with the administrative support and an online database system to connect Service Providers and PI/Study Sites. The virtual platform will be used by Service Providers to share information about their services with PI/Study Sites. The system will be accessible from any browser, secure, and have a user-friendly interface. The PIs/Study Sites will be able to search the database for Service Providers with services according to predefined search categories of support. The PI/Study Site will have the option of contacting the Service Provider directly using contact information provided or request assistance from the Administrator with finding a service provider by providing a brief description of their study service needs. Service Providers will have the ability to promote their services.

Goal #5 – Career Development Service

This goal will create a hub where individuals and organizations can share information regarding career development and training in clinical trial related jobs. The hub will promote related training and career development opportunities and an online repository. This resource will support the growth of clinical trials in the greater San Antonio region.

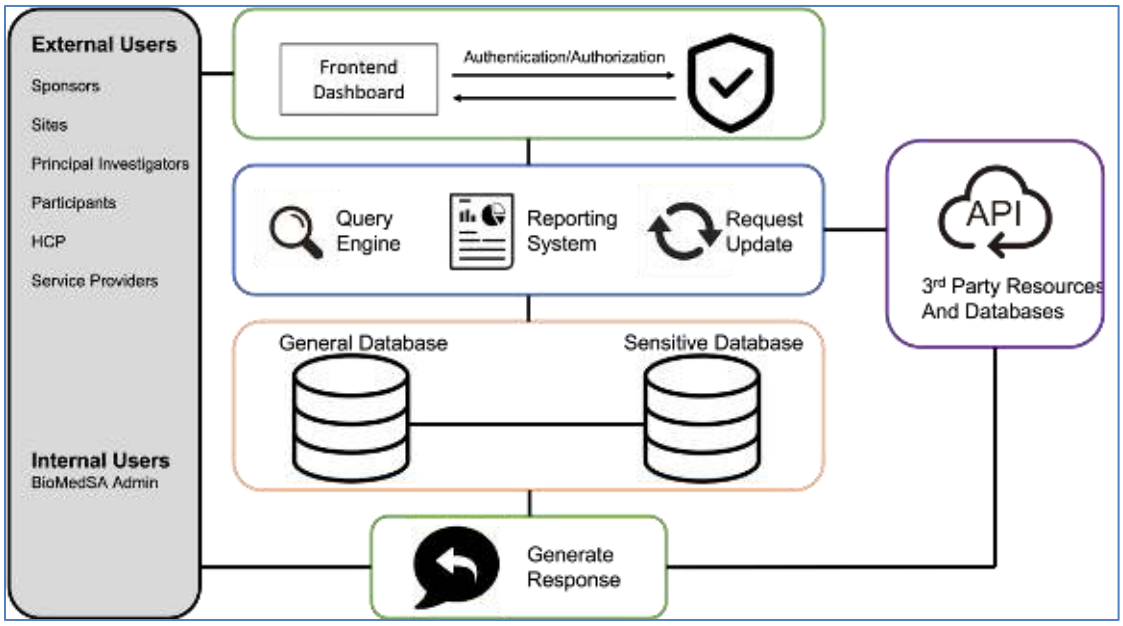
The scope of this goal is to plan, design, build and implement a **Career Development Service** with the administrative support and an online database system to connect individuals (Job Seekers) and Community with Hub Members that offer training, jobs, and other career development related services. The virtual platform will be used by Sponsors, Service Providers, and PI/Study Sites to share information about their training programs and job opportunities. The system will be accessible from any browser, secure and have a user-friendly interface. Community members will be able to search the database for training opportunities and job opportunities that meet their individual needs. Each party will have the option of contacting the other directly using contact information provided or request assistance from the Administrator to find a training provider by providing a brief description of their needs.

TECHNICAL REQUIREMENTS

Common Requirements

- A secure, user-friendly website that can be accessed by Hub Members through authenticated log in and a publicly facing interface for user searches and request for administrative support.
    - Hub member accounts with ability to designate proxy users
    - Hub members will receive credentials that will allow them to manage their profiles and run reports, queries, and searches.
    - Hub members access will be assigned according to membership type/tier

- Hub membership types/tiers:
    1) Sponsors/Contract Research Organizations (CRO)
    2) PI/Study Sites
    3) Service Providers
    4) Career Development Entities
    5) Community Health Care Providers (HCPs)
    6) Community members who join the volunteer registry
- Hub Members will be able to edit their information.
- A BioMedSA Administrator will be able to add/delete/archive institutional profiles, create/manage access for Hub Members.
- A database that is searchable and allows for easy import and export of data.
- Data will be stored by an off-site web hosting service.
    - Hosting service will include backups (both cloud redundancy and local backups), recovery, and data encryption both at-rest and in-transit.
- A user guide which outlines user expectations and provides step-by-step instructions on how to use the system.
- A troubleshooting guide which will provide corrective steps to users of all permission levels for all anticipated problems.
- An IT help desk that can assume user profiles for the purpose of troubleshooting
- Administrative support
- Provisions for protecting private information and allowing users to determine the level and form of disclosure to other users.
- Public access – the public (Community Members) will have read only access to designated areas of the website (generally marketing and informational sections) with English and Spanish versions of publicly accessible sections



Public-facing Website Requirements

1. Home Page
2. Community Engagement page: FAQs, Blog posts, google searches within the Clinical Trial Hub. Access to Study Recruitment Service and Volunteer Registry.
3. Industry page: Access to Study Placement Service, Site Placement Service, Study Recruitment Service, Support Services Assistance Program; FAQs, google searches within the Clinical Trial Hub, Advertisements, Blog posts, text, graphics/photos.
4. Hub Membership page: list of Hub Member Sponsors, Study Sites, Service Providers; membership information text/graphics; membership request form with paypal connection; profile creation/update/delete access.
5. Career Development page – promotes clinical trial related careers (graphic/text information). Access to Career Development Service.
6. The graphics/front-end of the website should be editable via Word Press by competent, technical BioMedSA staff (IT), enabling staff to update advertisements, blog posts, pictures, displayed text and FAQs.

Goal-Specific Requirements

The descriptions below outline key internal and external users involved in these business processes, and how they will interact with the system.

Goal #1 - Connect Sponsors with PI/Study Sites (**Study Placement Service**)

User	Hub Member: **Sponsor** (External User)
Access	Read and Edit Access

User Needs	• Complete membership application (levels TBD) and pay via paypal or request invoice so I can receive Hub Member login credentials and access.
	• Search the database so that I can find and read about the experience, qualifications, access to target patient populations, and clinical trial conduct capacity (Table A) of:
	  ○ Hub Member PI/Study Sites that are potential candidates for study placement
	  ○ Research HCPs to develop new investigators (network development)
	• Filter and sort my search results so that I can easily narrow the results to entities of interest.
	• Select PI/Study Sites of interest and export the related data from the system so that I can use this information at my home organization (e.g., make contact).
	• Request assistance from the Administrator in finding an interested PI/Study Site or have the option of sending the solicitation directly to the PI/Study Site.
	  ○ I will complete a brief description of the study to assist with the search and share with interested PI/Study Sites (Table C). I will have the option of uploading a study summary document.

	• Search the database so that I can find and read about clinical trials open to enrollment *(same as Goal 2)* for purpose of determining local competitive landscape (competing trials) • Search the database so that I can find and read about Service Providers (community outreach partners) to bring access to trials • Search the Volunteer Registry (database) to get an overview of potential participants using de-identified information from Table B

User	Hub Member: **PI/Study Site** (External User)
Access	Read and Edit Access
User Needs	PI/Study Site will perform all the same functions as the Sponsor, plus the following: • Complete membership application (levels TBD) and pay via paypal or request invoice so I can receive Hub Member login credentials and access. • Upon membership approval, post my institution's profile. • Enter my experience, qualifications, and my site's capacity to conduct clinical trials (i.e., profile) into the system so that I can share this information with Sponsors (Table A). • Review, edit or remove my profile. • Receive notifications when a new study summary (solicitation) is created by a Sponsor. • Search the database so that I can find and read about the studies seeking a PI/Study Site for study placement. • Filter and sort my search results so that I can easily narrow the results to entities of interest. • Select studies of interest and export the related data from the system so that I can use this information at my home organization (e.g., make contact). I can export this information from the system.

User	Hub Member: **HCP** (External User)
Access	Read and Edit Access
User Needs	HCP interested in being a PI or collaborator will perform the following: • Complete membership application (levels TBD) and pay via paypal or request invoice so I can receive Hub Member login credentials and access. • Upon membership approval, enter my experience, qualifications, and my practice's capacity to participate in clinical trials (i.e., profile) into the system so that I can share this information with Study Sites and Sponsors (Table A). • Review, edit or remove my profile. • Receive investigator development solicitations from a Sponsor and/or PI/Study Site • Search the database so that I can find and read about the studies seeking a PI/Study Site for study placement.

	• Filter and sort my search results so that I can easily narrow the results to entities of interest. • Select studies of interest and export the related data from the system so that I can use this information at my home organization (e.g., make contact). I can export this information from the system.

User	BioMedSA Administrator (Internal User)
Access	All Functions
User Needs	Administrators will perform all the same functions as the Sponsor, PI/Study Site, and HCP, plus the following: • Create accounts for new users. I can create accounts for a Hub Member or Administrator roles. I can create accounts for delegates from any Hub Member. • Review new account requests for any institution or individual. I can approve or deny a new account request. • Approve or deny membership applications • Edit and/or deactivate the accounts of existing users. I can edit all fields associated with an account. I can modify accounts for all members. • Edit, copy, renew, archive, reactivate or delete study summaries from the system. I can edit, copy, renew, archive, reactivate or delete study summaries submitted by any sponsor. • Edit the Help page of the site to update frequently asked questions and/or the document library so that training and guidance materials are up to date. • Manage pre-defined lists within the site (e.g., therapeutic area, HCP clinical trial expertise) to keep data selections up to date. I want to be able to add new entries, modify existing entries, and/or delete entries that are no longer needed. • Query the system using reports and dashboards • Present automatically gathered metrics, such as number of sponsor queries, what types of queries, number of sponsor-initiated emails to potential sites/PIs, etc.

Goal #2 - Connect Local PI/Study Sites with Community HCPs interested in being a Co-PI or referring patients (**Site Placement Service and Patient Referral)**

User	Hub Member: **PI/Study Site** (External User)
Access	Read and Edit Access
User Needs	PI/Study Site looking for collaborators will perform the following: • Enter my login credentials • Search the database so that I can find and read about the quality, experience, qualifications and capacity (Table A) of experienced HCPs that may be interested in collaborating on a study I am planning. • Filter and sort my search results so that I can easily narrow the results to HCPs of interest. • Select HCPs of interest and export the related data from the system so that I can use this information at my home organization (e.g., make contact). • Request assistance from the Administrator in finding an interested HCPs or have the option of sending the solicitation directly to the HCP. I will complete a brief description of the study to assist with the search. I will have the option of uploading a study summary document.

User	Hub Member: **HCP** (External)
Access	Read and Edit Access
User Needs	HCP interested in being a co-PI or referring patients will perform the following: • Enter my login credentials • Receive notifications when a new study summary (solicitation) is created by a PI/Study Site • Search the database so that I can find and read about the studies seeking an HCP for study placement. • Search the database so that I can find and read about the studies pertinent to my patients. • Filter and sort my search results so that I can easily narrow the results to entities of interest. • Select studies of interest and export the related data from the system so that I can use this information at my home organization (e.g., make contact). I can export this information from the system.

User	BioMedSA Administrator (Internal)
Access	All Functions
User Needs	Administrators will perform all the same functions as the Sponsor and Member, plus the following: • Create accounts for new users. I can create accounts for the member or administrator roles. I can create accounts for members from any institution. • Review new account requests for any institution. I can approve or deny a new account request. • Edit and/or deactivate the accounts of existing users. I can edit all fields associated with an account. I can modify accounts for all members. • Edit, copy, renew, archive, reactivate or delete study summaries from the system. I can edit, copy, renew, archive, reactivate or delete study summaries submitted by any sponsor. • Edit the Help page of the site to update frequently asked questions and/or the document library so that training and guidance materials are up to date. • Manage pre-defined lists within the site (e.g., therapeutic area, phase) to keep data selections up to date. I want to be able to add new entries, modify existing entries, and/or delete entries that are no longer needed. • Query the system using reports and dashboards • Present automatically gathered metrics, such as number of sponsor queries, what types of queries, number of sponsor-initiated emails to potential sites/PIs, etc.

Goal #3 - Connect Community Members with Trials (**Study Recruitment Service**)

User	Community (External Users)
Access	Read and if a given user credentials, Edit Access
User Needs	• Search the database (Table C) so that I can find and read about clinical trials open to enrollment *(same as Goal 1 Sponsors*). • Filter and sort my search results so that I can easily narrow the results to studies of interest (e.g., age, conditions, diseases). • Select trials of interest and export the related data from the system so that I can use this information (e.g., make contact). • Request assistance from the Administrator in finding a trial of interest or have the option of sending a message directly to the PI/Study Site. • I will have the option of joining the Volunteer Registry so that my information can be used by PI/Study Sites in the future. I can choose to provide my contact information with or without details on the types of trials I'm interested in (Table B). I will complete a contact form and a brief description of the types of trials I'm interested in to assist with future searches. I will be provided with log-in credentials so that I can update or opt-out of the registry in the future.

User	Hub Member: **PI/Study Site** (External User)
Access	Read and Edit Access
User Needs	PI/Study Sites will perform all of the following: • Enter my login credentials • Use the ClinicalTrials.Gov description, use a modified version of CT.GOV, or enter my own description of clinical trials into the system so that I can share this information with the Community and Health Care Providers (HCPs). If the study is not available from CT.Gov, I can enter this information manually into the system using a webform or CSV file upload. (Table C1 - Study Description) ○ I can choose whether to manually insert other information about the trial (Table C2 - Other Info) • Review, edit or remove a study description. • Receive notifications when a community member or HCP expresses interest in a study. • Search the Volunteer Registry database so that I can find individuals who have expressed interest in participating in the type of clinical trial I am conducting. • Filter and sort my search results so that I can easily narrow the results to individuals of interest. • Select volunteers of interest and export the related data from the system so that I can use this information at my home organization (e.g., make contact). I can export this information from the system.

User Type	BioMedSA Administrator (Internal)
Access Level	All Functions
User Needs	Administrators will perform all the same functions as the Community Member/HCP and Member, plus the following: As an Administrator, I want to: • Create accounts for new users. I can create accounts for anyone. • Review new account requests. I can approve or deny a new account request. • Edit and/or deactivate the accounts of existing users. I can edit all fields associated with an account. I can modify accounts for all users. • Edit, copy, renew, archive, reactivate or delete study summaries from the system. I can edit, copy, renew, archive, reactivate or delete study summaries submitted by any member. • Edit the Help page of the site to update frequently asked questions and/or the document library so that training and guidance materials are up to date. • Query the system using reports and dashboards • Present automatically gathered metrics, such as community participants diversity, age range, and medical condition – and number of community participants.

Goal #4 - Connect Study Sites with Businesses Providing Needed Services (**Support Services Assistance Program**)

User	Hub Member: **Service Providers** that provide support services (External)
Access	Read and Edit Access
User Needs	• Complete membership application (levels TBD) and pay via paypal or request invoice so I can receive Hub Member login credentials and access. • Upon membership approval, enter my login credentials. • Provide information about services. • Search the database for PI/Study Sites searching for services my business provides. • Filter and sort search results to narrow to desired PI/Study Sites. • Export this information from the system.

User	Hub Member: **PI/Study Site** seeking support services (External)
Access	Read and Edit Access
User Needs	PI/Study Site seeking a Service Provider will perform all of the following: • Enter my login credentials so that I can post the support service needs for my studies (Table C.3). • Review, edit or remove a services description for each study. • Receive notifications when a Service Provider responds to a service request. • Search the Service Provider database for relevant companies that provide the service a specific clinical trial I am conducting. • Filter and sort search results so that I can easily narrow the results to Service Providers of interest. • Select Service Providers of interest and export the related data from the system so that I can use this information at my home organization (e.g., make contact). I can export this information from the system.

User	BioMedSA Administrator (Internal)
Access	All Functions
User Needs	Administrators will perform all the same functions as the Businesses and Member, plus the following: • Create accounts for new users. Businesses, Hub Member or administrator roles. • Review new account requests. I can approve or deny a new account request. • Edit and/or deactivate the accounts of existing users. I can edit all fields associated with an account. I can modify accounts for all users.

	• Edit, copy, renew, archive, reactivate or delete business descriptions from the system. I can edit, copy, renew, archive, reactivate or delete service request descriptions submitted by any member. • Edit the Help page of the site to update frequently asked questions and/or the document library so that training and guidance materials are up to date. • Query the system using reports and dashboards • Present automatically gathered metrics, such as number of public queries, what types of queries, number of public-initiated emails to potential sites/PIs, etc.

Goal #5 – Connect Individuals seeking career development with Research Training and Career Advancement Opportunities (**Career Development Service**)

User	Job Seeker, HCP, Community (External)
Access	Read Access
User Needs	• Search the database so that I can find and read about research job or training opportunities. • Filter and sort my job search results so that I can easily narrow the results to career paths/qualifications. Filters should include position type (e.g., investigator, coordinator, etc.) • Search and select training programs of interest and export the related data from the system so that I can use this information (e.g., make contact). I can export this information from the system.

User	Hub Member: PI/Study Site, Sponsor, HCP or Service Provider (External)
Access	Read and Edit Access
User Needs	PI, Study Site, Sponsor, or Service Providers will perform all of the following: • Enter my login credentials so that I can post my research career development, job opportunities or training opportunities. • Review, edit or remove a posting. • Set a date for a posting to be automatically deleted. • Receive notifications when an individual responds to a posting. • Search the career development database for potential staff

User	BioMedSA Administrator (Internal)
Access	All Functions
User Needs	Administrators will perform all the same functions as the Job Seeker and Member, plus the following: • Create accounts for anyone. • Review new account requests. I can approve or deny a new account request. • Edit and/or deactivate the accounts of existing users. I can edit all fields associated with an account. I can modify accounts for all users. • Set timelines for job postings to be automatically deleted that will override other user settings. • Edit the Help page of the site to update frequently asked questions and/or the document library so that training and guidance materials are up to date. • Query the system using reports and dashboards • Present automatically gathered metrics, such as number of public queries, what types of queries, number of public-initiated emails to potential sites/PIs, etc.

User Profile and Access Specification Examples:

Table A. PI/Study Site or HCP Profile

A. Engagement Tiers*:
    a. Willing to refer patients to the local PI
    b. Willing to conduct limited study procedures (standard of care procedures & assessments)
    c. Willing to be an Associate/Sub Investigator or Principal Investigator
B. Individual name*
C. Clinic/business name*
D. Telemedicine Capabilities – platform
E. Early Phase Research Capabilities
    a. First in Human Y or N
        i. Dose escalation phase Y or N
        ii. Dose expansion phase Y or N
    b. Extended serial sample collection capabilities (X hours post dose)
    c. Overnight stay – number of beds
F. Contact Information* (option for more than one contact)
G. Admin Contact (option for more than one)
H. Specialty*
I. Therapeutic areas of interest*
J. Board Certifications
K. HCP/PI sex, age, race & ethnicity
L. Catchment area
        i. Map (underserved or targeted patient populations) - color coded for race
        ii. Counties

M. Patient Demographics - sex, age, race, - with numbers ideal (they will be on TriNetx) – percentage
    i. Insured - uninsured -if possible -percentage (TriNetx)
    ii. Underserved populations
N. Languages other than English
O. Years of clinical trial experience* - 0; 1-4; 5-9; 10+
P. Equipment - check list - high level (PET, DEXA, X Ray) - updated every 2 years
Q. Upload CV
R. Upload practice description including usual types of procedures performed)
S. Interest in DCT (remote visit capabilities)
T. Site attributes of interest to potential participants (in addition to above):
    a. Visual/hearing challenged
    b. Days/Hours of operation
    c. Closest public transportation
    d. Closest parking & costs

* - required

Table B. Community/Volunteer Participant Profile

1. Interested in research involving the following medical conditions* (multiselect CT.Gov list)
2. Interested in following types of trials* (select all applicable): prevention, diagnosis, treatment
3. Interested in studies enrolling healthy individuals*
4. Sex* (single select: 1, male; 2, female; 0, prefer not to answer)
5. Age*
6. Race* (single select: 1, White or Caucasian; 2, Black or African American; 3, Asian; 4, Hawaiian or Pacific Islander; 5, American Indian or Alaska Native; 7, Unknown; 0, prefer not to answer)
7. Ethnicity* (single select: 1, Hispanic or Latino: 2, Not Hispanic or Latino; 0, Unknown, not reported)
8. Preferred language* (single select: 1, English; 2, Spanish; 3, Chinese;……)
9. Highest education level (single choice: 1, less than secondary/high school; 2, secondary/high school diploma; 3, some post-secondary education; 4, Post-secondary diploma/degree)
10. Address
11. Phone(s)
12. email
13. Preferred method of contact* (single select: cell phone, home phone, smart device texting, email, mail)
14. How far are you willing to travel? (single select: 5, 10, 15, 20+ miles)
15. Internet or smart phone access?

* - required

Table C. Study Description Profile

1. Fields based on ClinicalTrials.Gov data structure with the intention of retrieving the data via an API interface
    a) Brief Title*
    b) Brief Summary*
    c) Study Type*
    d) Study Phase*

e) Study Design*
f) Condition*
g) Study Arms*
h) Intervention*
i) Eligible Criteria*
j) Sex/Gender*
k) Ages*
l) Accepts Healthy Volunteers*
m) Sponsor*

2. More trial information (manual):
   a) Participant payments
   b) Number of visits
   c) Length of participation
   d) Major procedures
   e) Type of visit - remote or office visits
   f) Languages available
   g) File upload the Sponsor's study summary document
   h) File upload a read-only copy of the consent
3. Services Needed (manual):
   a. Statistical Support
   b. Marketing/Awareness
   c. Healthcare staffing
   d. Participant Transportation
   e. Translation services
   f. Home Healthcare
   g. Recruitment/Enrollment/Retention
   h. Data Safety Monitoring
   i. Sponsor Monitoring
   j. Webhosting, Smartphone applications
   k. Electronic Data Capture
   l. Regulatory Affairs
   m. Imaging
   n. Laboratory

* - required

Hub Member Permissions

Access/ User	PI	Site	Sponsor	Volunteer	HCP	Service Provider	Reports
PI	Edit own	Read	Read	Read	Read	Read	Read
Site	Edit own	Edit own	Read	Read	Read	Read	Read
Sponsor	Read	Read	Edit own				Read
Volunteer	Read	Read		Edit own			Read
HCP	Read	Read			Edit Own		Read
Service Provider	Read	Read				Edit own	Read
BioMedSA Admin	All	All	All	All	All	All	All

The "Reports" column represents the level of access of each hub member (row) to aggregate, de-identified information about the Clinical Trial Hub (e.g., number of community participants currently opted-in to participate in trials).
The other columns represent the level of access of each hub member (row) to individual, identified information on the specified hub member (column).

PROJECT TIMELINE

Milestone	Date Due	Deliverables	Responsibility
RFP release	July 21, 2022	RFP	BioMedSA
Proposers' Conference	Aug 1, 2022	E-mail notification	BioMedSA
Proposals due	Aug 26, 2022	Proposals	Suppliers
Shortlisting candidates for interviews	Sep 9, 2022	E-mail notification	BioMedSA
Final interviews	Sep 16, 2022	Zoom	BioMedSA
Demonstration (Selected providers)	Sept 30, 2022	Written notification	BioMedSA
Contract execution	Q1 2023*	Contract, purchase order	BioMedSA, supplier
Project kick-off	Q1 2023	Kick-off meeting	BioMedSA, supplier

Pre-Alpha Demonstration 1	Q2 2023	Product roadmap, software development plan, wireframes, data management plan	Supplier
Pre-Alpha Demonstration 2	Q3 2023	Updated plans, interactive (tappable) prototype	Supplier
Pre-Alpha Demonstration 3	Q4 2023	Updated prototype	Supplier
Alpha prototype due	Q1 2024	Functional prototype with core features, hosted on a platform accessible to BioMedSA, and initial user guide	Supplier
Beta prototype due	Q1 2025	Functional prototype that accomplishes goals 1-5, hosted on a platform accessible to the public, and refined user guide	Supplier
Final deliverable due	Q2 2026	Functional prototype that integrates feedback from beta-testing, hosted on a platform accessible to the public, further refined user guide, and source code for the application	Supplier

* Contract execution is dependent upon grant funding expected Q1 2023.

BUDGET

The expected budget is $3 million to $5 million. This project will be paid per agreed-upon deliverables.

SELECTION CRITERIA

1. Commitments
2. Scope of work
3. Technical and operational solution of the project
4. Proposed methodologies
5. Domain knowledge and relevant experience in similar projects
6. Pricing and payment terms

7. Data security guarantees
8. Compliance with current regulations
9. Ongoing support for maintenance and improvements

SUBMISSION REQUIREMENTS

1. Proposals must be received by August 26, 2022, via email to info@biomedsa.org with CLINICAL TRIAL HUB PROPOSAL in the subject line.
2. **Maximum proposal length (not including budget) is 15 pages (10-12 pt font).**
3. Proposal format must include the following sections:

   Section 1: Company Information
   - Company name
   - Short company description
   - Company location
   - Ability to work remotely and/or on-site in San Antonio

   Section 2: Planned project team
   - Planned team members and their qualifications
   - Relevant corporate experience, case studies, client testimonials

   Section 3: Project Plan
   - High-level project activities and milestones
   - Time/cost breakdown
   - Project Management plan

   Section 4: Proposed Scope of Work and Technical Details
   - Technical approach and methodologies with trade-offs
   - Technical risks and mitigations
   - Suggestions for project improvements and features (as appropriate)
   - Data and cyber security provisions

   Section 5: Budget and High- Level Terms
   - Labor and material cost breakdown by quarter and high-level task
   - High-Level or critical contract terms

   Section 6: Additional Services
   - Training, maintenance, etc., as appropriate

4. Email completed proposals in pdf form to:

POINT OF CONTACT AT BIOMEDSA

If you have any questions and concerns regarding this project, please submit an email to: info@biomedsa.org with CLINICAL TRIAL HUB in the subject line or call 210-468-1829 to speak with Heather Hanson, President, BioMedSA.

To receive the link to the Proposers' Conference, please send an email to info@biomedsa.org with CLINICAL TRIAL HUB in the subject line to request the link by July 29, 2022.