# Supplement 1: Early Project Origination & Scoping Plans (Project Charter; Scoping Document)

**Document 1: Project Charter**

Overview

## Summary

Prior to November 2017 each of the individual Duke CTSA cores would provide the CTSA Administrative Director with success metrics related to their unique Core objectives**.** The CTSA Administrative Director compiled the submitted core metrics into a single document on a yearly basis as required by the Duke CTSA grant UL1TR002553. The Duke Planning, Evaluation, & Tracking Team (PET) conducted an in-depth needs assessment that documented the specific metrics for success for each of the CTSA Cores. The PET team then implemented a collection of REDCap forms unique to each of the specific CTSA cores. Each of the Cores entered their respective metrics into their REDCap form prior to the 2017 External Advisory Board meeting. The process of collecting, analyzing, and reporting core metrics has been (1) very time consuming, (2) subject to corrupted data, (3) difficult to glean meaningful success (both within and among cores), and (4) provided little tangible evidence for the development of measurable action items.

In order to reduce manual effort around this process, the CTSI, in collaboration with development resources from the Research Application Development Team, will build a comprehensive metric tracking relational database that is designed to allow authorized users to enter, update, and export CTSA operational data**.** The organization of the system will be based upon the Duke CTSA cores. Many of the operational activities are specific to individual Cores, however, a primary aim of this project is to bring consistency to the data and the associated definitions of core data where possible. This will enable the system to capture and link events and people that are common to multiple cores.

# Project Scope

The CTSA Metrics Tracker will be a multi-phase project beginning with the delivery of a Minimal Viable Product (MVP) in the initial Pilot Phase. The two Cores included in the first phase include Pilots and Community Engagement.

Features included in the first phase of the project will be:

* Security and Authorization
	+ Shibboleth multi-factor authentication
	+ System Administration functions
	+ Role based user access
* Custom System Navigation
	+ At-a-glance access to user-specific Cores and Projects
	+ Easy access to commonly used features, dependent on user role
* Core Module Design
	+ Add new and maintain existing Cores
	+ Assign common data elements to one or more Cores
	+ Allow addition of Core-specific data elements
* Project Design
	+ Create one or more projects within a Core
	+ Capture information about projects
	+ Create project-specific data entry forms
* Record Events
	+ Enter event information into forms using configurable data elements
* Search
	+ Search transactional records by person, department, date range, event type, project status
* Reports (including but not limited to)
	+ Data extract for all Cores
	+ Data extract for a single Core
	+ Data extract for one or more people

Subsequent phases of the Metrics Tracker could incorporate additional Cores and expand existing functionality. New features may include notifications, usage metrics, and data migration from legacy systems. Additionally, emerging initiatives within the CTSA could present opportunities for future enhancements. The project team will perform analyses of each iteration and recommend modifications to the existing functionality based on end user feedback.

Future phases of development and scope of that development will be subject to review and approval by the appropriate governing body.

# Project Stakeholders

|  |  |  |
| --- | --- | --- |
| **Department** | **Title** | **Personnel** |
| Duke CTSI | [role] | [name] |
| Duke CTSI | [role] | [name] |
| Duke CTSI | [role] | [name] |

# Project Team Members and Responsibilities

| **Role** | **Responsibilities** | **Personnel**  |
| --- | --- | --- |
| Business Owners | * Manages stakeholder communications
* Determines business and project priorities
* Track and report project risks and contingencies
* Schedule and organize focus group sessions
* Review and provide feedback for specifications and project artifacts
* Writes training documentation if needed
 | [names; Administration and Evaluation personnel] |
| Dev Analyst | * Manages application development process
* Manages development resources
* Communicates development status to team
* Conducts product demonstrations
* Assists with change control process as needed
* Coordinates Functional and User Acceptance Testing
 | [names; technical personnel] |
| Business Analyst | * Communicate project schedule and task assignments
* Reports project status to management
* Assists with stakeholder communications
* Manages project change process
* Manages change control process
* Documents functional requirements
* Writes KB articles
 | [names; technical personnel] |
| Developers | * Develop software that meets business requirements
* Conducts unit testing of software
* Provides status updates to Dev Analyst
 | [names; technical personnel] |

# Project Structure

The CTSA Metrics Tracker project will have a structure that includes a Steering Committee, Project Team and Core Focus Groups. The functions of the groups are described below.



## Steering Committee

The Steering Committee will provide project governance. The make – up of this group is as followings:

| **Department** | **Title** | **Personnel**  |
| --- | --- | --- |
| Duke Clinical & Translational Institute | [role] | [names] |
| Biostatistics & Bioinformatics, Basic Science | [role] | [names] |
| Office of Research Informatics | [role] | [names] |
| Duke Clinical & Translational Institute | [role] | [names] |
| Crucible, Duke Health | [role] | [names] |

# Project Objectives and Success Criteria

## Objectives

This project is being undertaken to streamline the process for gathering information related to CTSA-related activities and reporting Core-specific and aggregated metric data.

## Success Criteria

Successful execution of this project will be measured by completion of the project deliverables listed below. Progress will be reported in accordance with the Communication Plan.

The following deliverables will be produced during the course of this project:

* Detailed functional/user requirements
* Creation of wireframes that visually represent functional requirements
* Scalable Minimum Viable Product (MVP) that rapidly delivers critical functionality
* Plan for building out additional functionality
* Plan for transitioning the application to an operational state

# Key Milestones

Progress of the overall project will be measured against significant pre-defined milestone events. These milestones are driven by the gated project process followed by the Office of Research Informatics. Below are the key milestones and estimated delivery dates.

| **Description** | **Estimated Date** |
| --- | --- |
| Functional Specification | 12/15/218 |
| Charter Approval | 1/11/2018 |
| Demo Proof of Concept to Focus Groups | 2/22/2019 |
| Completed Proof of Concept | 3/1/2019 |
| Deploy MVP to Production | 5/1/2019 |

# Communication Plan

## Project Schedule Updates

Project deliverables and issues will be tracked in Smartsheet and posted to the ORI Project Wiki page. The Business Analyst is responsible for updating the schedule weekly.

## Meetings

| **Meeting Name** | **Purpose** | **Frequency** | **Owner/Organizer** | **Attendees** |
| --- | --- | --- | --- | --- |
| Steering Committee Meeting | Provide high level project governance | Monthly or as needed | [name] | Steering Committee members |
| Project Team Meeting | Working meeting to share feedback and plan | Bi-weekly | [name] | Project Team members |
| Weekly Check-in  | Plan and track project deliverables | Weekly | [name] | Analysts and Developers (as needed) |
| Development Team Meeting | Discuss issues and work related to development  | Weekly | Kellie Browning | RAD team members as needed |
| User Focus Group meetings | Gather input and feedback on detailed requirements, test/demo | Periodic, dependent on phase | Doug Chartrand | Core Champions |

# Project Risks and Constraints

| **Risk** | **Impact** | **Likelihood** | **Mitigation**  |
| --- | --- | --- | --- |
| Availability of business owners to provide feedback may be limited | High | Medium | Schedule meetings far in advance and consistently.  |
| CTSI competing priorities | Medium | High | Leadership commitment to project goals and timelines within the CTSI framework |

# Approvals

This document was approved by [names; CTSI leadership] on 1/8/19.

**Document 2. Project Scope**

##

**Project Scope**

# Overview and Scope

The process of collecting, analyzing, and reporting core metrics has been (1) very time consuming, (2) subject to limited and missing data, (3) difficult to glean meaningful success (both within and among cores), and (4) **provided little benefit in understanding the impact and value of measurable action items.**

Many operational activities are specific to individual Cores, however, **a primary aim of this project is to bring consistency to the data and the associated definitions of core data where possible**. This will enable management and linking of events and people common across multiple cores.

Initial Scope of the Product

The initial scope of the envisioned system is to create a centralized datastore and front end for capturing minimum information required for CTSA metrics reporting. These include required data points about **projects, people, accomplishments, educational activities, consults and collaborations**. As the product is being developed we will architect a load mechanism which will enable loading of data from CSV or automatically from REDCap into the datastore. This will enable individual CTSA cores to continue to use current and future core specific vertical system solutions such as excel, smartsheet and REDCap.

Included in the scope will be to create an initial set of dashboards, queries and standard reports desired for management insight, core management and impact measurements.

## The diagram below represents the anticipated architectural framework of the initial product scope:



Not included in the scope are core specific functions and reporting of core specific data points, although to the extent possible we will map core specific data to more inclusive, broadly reported CMT elements.

Once the initial product is near completion, direction future could be set to include many functions and enhancements. Some potential platform enhancements include:

* Functionality required for KL2 and TL1 Scholar tracking
* Incorporation of Translation Science Benefits Model (TSMB) into the platform to better allow the mapping of activities onto impacts and outcomes.
* Integration with other central administration systems such as:
	+ The Internal Review Board System (iRIS): [https://iris.duke.edu](https://iris.duke.edu/)
	+ Sponsored Projects System (SPS): <https://radapps.duke.edu/sps>
	+ Faculty Profile(Scholars@Duke): <https://scholars.duke.edu/>
	+ The MyRESEARCHhome Portal: <https://myresearchhome.duke.edu/>

# General Requirements

Ability capture and view **common** data elements about Projects, People, accomplishments, Consults, Collaborations, Educational Activities

Ability to bulk load of Projects, People, accomplishments, Consults, Collaborations, Educational Activities from a specified format

Ability to manage central drop down lists

Ability to export information about Projects, People, accomplishments, Consults, Collaborations, Educational Activities

The system should be architected to enable maximum flexibility in adding new data points needed as CTSA reporting requirements change or progress.

# Critical Success Factors

**Below is a list of assumptions and critical succeeds factors in order to achieve project success:**

* There will need to be an agreed upon input format or ontology for bulk data input
* Creation of a process for loading data from the cores will need to be agreed upon specified and documented
* The role of a data curator will be to be clearly defined. This person from each core submitting data will be responsible for submission and the overall integrity of the data being uploaded or coalesced.
* The system will required a flexible data store and architecture to meet changing needs.

# Supplement 2. Additional TRACER Platform Images

**A. Projects – General Tab**



**B. Projects – People Tab**



**C. Projects – Project Details Tab**

 

**D. Projects – Project Status**



**E. Projects - Milestones**



**E1. Fields for Milestone Publication & Presentations**



**F. TSBM Fields for Benefits**



Directions on how to fill out the TSBM benefits tab are embedded on the page. Defined options are given for each TSBM benefit, including dates when potential and demonstrated benefit are realized. To describe the relationship of the benefit to the project users are given an open text field.

**G. New Ongoing Activity Fields**



**H. New Educational Activity Fields**



**I. New Consult Fields**



**J. Custom Search Builder, Reports**



A custom search builder is built into each report where users have the option to filter data by hierarchical status, start / end date, project PI, and project status.

# Supplement 3: Sample Aggregate Report

**TRACER Aggregate Example Report: Counts of Overall Process and Achielvement Outcomes, by Core**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Core** | **Active Projects, Total Count** | **Milestone: Collaborat-ions, Total Count** | **TSBM *Potential* Benefits, Total Count** | **TSBM *Demonstrated* Benefits, Total Count** | **Consults, Total Count** | **Educational Activities, Total Count** | ***Timeframe*** |
| Duke Core 1 | 7 | 9 | 39 | 20 | 13 | 42 | *06/02/23 –03/14/24* |
| Duke Core 2 | 23 | 10 | 21 | 16 | 39 | 45 | *06/02/23 –03/14/24* |
| Duke Core 3 | 42 | 35 | 12 | 20 | 21 | 11 | *06/02/23 –03/14/24* |
| Duke Core 4 | 24 | 38 | 32 | 23 | 29 | 31 | *06/02/23 –03/14/24* |

NOTE: This is an example of a potential report. Reports can take varying forms and include a wide array of data depending on the specific user intent. Full versions of a report could include a cumulative count for each individual milestone and individual TSBM benefit indicator, including both demonstrated and potential. TRACER Users would have the option to filter by varied data elements included in TRACER including Pillar, Core, Program, and timeframe. Reports can also focus on individual specific Projects. Next steps include noted in the manuscript include dashboards with enhanced data visualization potential. The manuscript also referenced that data can be exported in a raw data spreadsheets for more advanced statistical analyses.

# Supplement 4. TRACER Data Dictionary, as of February 2024

|  |  |  |
| --- | --- | --- |
| **Field Label**  | **Field Description** | **Field Type** |
| **TRACER Interface Page: Home** |
| Search for Projects, Cores, or People  | Search for Projects, Cores, or People  | List Lookup |
| **TRACER Interface Page: New User/ User** |
| Search for person by name: | Person  | List Lookup |
| First Name | First Name of TRACER user | Auto Fill Text |
| Last Name | Last Name of TRACER user | Auto Fill Text |
| Primary Core | Name of users’ primary core | Auto Fill Text |
| NetID | Duke net ID | Auto Fill Text |
| Department | Duke Department | Auto Fill Text |
| Title | Duke Title | Auto Fill Text |
| Work Email | Duke e-mail | Auto Fill Text |
| Secondary Email | E-mail #2 | Auto Fill Text |
| Work Phone | Duke Phone number | Auto Fill Text |
| Phone (Secondary) | Other Phone number | Numerical |
| Role | Type of TRACER access | Radio Button |
| **TRACER Interface Page: User** |
| User Status | TRACER account access | Radio Button |
| **TRACER Interface Page: New Core /Update Core** |
| Name | Short informal name of project | Free Text |
| Official Name | Long formal NIH name | Free Text |
| Description | Description of Core | Free Text |
| Funded by CTSA | Program is funded by the CTSA | Radio Button |
| New Aim | Core Aims | Button |
| Aim Description | Aim description | Free Text |
| Pillar | Associated pillar to Core | Drop-down List  |
| **TRACER Interface Page: Update Core** |
| Program | Programs associated with Core | Button |
| Key Core Membership | Team members associated with Core | List Lookup |
| **TRACER Interface Page: Cores** |
| Search for existing Core | look up Cores already entered | List Lookup |
| **TRACER Interface Page: New Program / Update Program** |
| Program Name | Program Name | Free Text |
| Primary Core | Associated primary Core | Drop-down List  |
| Collaborating Cores | Cores collaborating with Program | List Lookup |
| Funded by CTSA | Program is funded by the CTSA | Radio Button |
| **TRACER Interface Page: Update Program** |
| Program Status | Status of program (Active, Deactivated) |  |
| **TRACER Interface Page: Contacts - Internal** |
| Title | Title | Auto Fill Text  |
| E-Mail | E-Mail | Auto Fill Text  |
| Degree | Degree | Auto Fill Text  |
| Department | Department | Auto Fill Text  |
| Phone | Phone | Auto Fill Text  |
| Cores | Primary Core | Auto Fill Text  |
| Projects | Associated projects | Auto Fill Text  |
| **TRACER Interface Page: New Contacts - External** |
| First Name | External Contact First Name | Free text |
| Last Name | External Contact Last Name | Free text |
| middle initial | External Contact middle initial | Free text |
| Organization Affiliation  | Organization Affiliation of external contact | Free text |
| Work Email | Work Email | Free text |
| Role | Role in project | Drop-down List  |
| Title | Professional Title of external contact | Free text |
| Work Phone | Work phone | Free Text |
| Notes | Any additional information about the contact | Free text |
| **TRACER Interface Page: Projects - General** |
| Project Short Title | Short informal name of project | Free Text |
| Project Formal Title | Long formal NIH name | Free Text |
| Project Status | Most current standing of project | List Lookup |
| Start Date | Date project was approved to begin | Calendar  |
| End Date | Date project was closed | Calendar  |
| Development Stage | Stage of development project is on | Drop-down List  |
| Lead Duke Project Investigator | PI owner of project | List Lookup |
| Project Lead | Lead team member for project | List Lookup |
| Parent Core | Lead Core for the project | List Lookup |
| Cooperating Duke Cores | Collaborating Cores for project | List Lookup |
| Summary | Overview of project and goals | Free Text |
| Notes | Supplementary project information  | Free Text |
| **TRACER Interface Page: Projects - Details** |
| Program | Parent Program for the project | List Lookup |
| Has Associated Funding? | Initial funding of project if applicable  | Radio Button |
| Funding Source Type | Source of funding for project | Drop-down List  |
| Grant Number | Supporting Grant (If applicable) | Free Text |
| Contract Number | Related to contract (If applicable) | Free Text |
| Budget | Amount available for project | Free Text |
| Seeding funding | Related / not related to seed funding | Radio Button |
| Associated with CTSA Funding? | Related/ not related to CTSA funding | Radio Button |
| Approve IRB? | Related/ not Related to IRB  | Radio Button |
| IRB # | IRB # | Free Text |
| IRB Title | Title of IRB | Free Text |
| IRB Approving Institution | Institution that approved IRB | Drop-down List  |
| Initial IRB Approval Date | Approval date of IRB | Calendar |
| IRB Documentation on File | If IRB is documented outside of TRACER | Radio Button |
| IRB Documentation URL | URL to IRB documentation | Free Text |
| Approved IACUC? | Related / not related to IACUC | Radio Button |
| IACUC # | IACUC # | Free Text |
| IACUC Title | Title of IACUC | Free Text |
| IACUC Approving Institution | Institution that approved IACUC | Drop-down List  |
| Initial IACUC Approval Date | Date IACUC was approved | Calendar |
| IACUC Documentation on File | IACUC is documented outside of TRACER | Radio Button |
| IACUC Documentation URL | URL to IACUC documentation | Free Text |
| Keywords | Keywords describing the Project | Free text |
| **TRACER Interface Page: Projects - People - Internal** |
| Search for internal people to add by name:  | Search for Duke people to add to Project | List Lookup |
| Name | First/last name of contact | Read Only |
| Title | Title | Read Only |
| Email | Email | Read Only |
| Role | Role in project | Drop-down List  |
| External People | Non-Duke people supporting project | List Lookup |
| **TRACER Interface Page: Projects - Progress** |
| Project Status | Current status of the project  | Drop-down List  |
| Description | Description of status | Free Text |
| Comments | Any other relevant information about project status | Free Text |
| **TRACER Interface Page: Project - Milestones - Publication & Presentations - Publications** |
| Search MySCHOLARS@DUKE | Link to MySCHOLARS@DUKE | Button |
| PMID | PubMed ID Number | Free Text |
| PMCID | PubMed Central reference number | Free Text |
| NLM Citation | NLM Citation | Free Text |
| DOI | DOI | Free Text |
| Title | Formal Title of Paper | Free Text |
| Publication Date | Official Publication Date | Free Text |
| Authors | All authors listed on the paper | Free Text |
| Notes | Any additional information about the publication | Free Text |
| Comments | Any additional information about the publication | Free Text |
| Funding source cited | Was the CTSA listed as a funding source for this publication? | Check Box |
| **TRACER Interface Page: Project - Milestones - Publication & Presentations - Academic Presentations, Abstracts, Posters** |
| Presentation Type  | How project was presented | Drop-down List  |
| Title | Title of presentation | Free Text |
| Conference or Setting | Name of conference or setting presentation took place in | Free Text |
| Presentation Date | Date of presentation | Calendar |
| Comments  | Any additional information about the presentation | Free Text |
| **TRACER Interface Page: Project - Milestones - Publication & Presentations - Public Scholarships** |
| Media Type | Type of scholarship | Drop-down List  |
| Title | Title of scholarship | Free Text |
| Description | Description of scholarship | Free Text |
| Scholarship Date | Date of scholarship | Calendar  |
| Comments | Any additional information about the scholarship | Free Text |
| **TRACER Interface Page: Project - Milestones - Grants & Funding - Follow on Funding** |
| Funding Status | Funding Standing | Drop-down List  |
| Funding Source Type | Source of funding supporting the project | Drop-down List  |
| Grant Number | Grant Number | Free text |
| Project Title | Title of project | Free text |
| Principal Investigator | Principal Investigator | Free text |
| Amount | US Dollar amount of grant | Free text |
| Start Date | Start date of grant | Calendar  |
| End Date | End date of grant | Calendar  |
| Evidence in file? | Supporting documentation | Button |
| SPS Proposal Record? | If SPS Proposal is recorded outside of TRACER | Free Text |
| Comments | Any additional information about the follow-on funding | Free Text |
| Funding Status | Status of LOI | Drop-down List  |
| Funding Source Type | Funding source type of LOI | Drop-down List |
| **TRACER Interface Page: Project - Milestones - Grants & Funding - Letters of Intent** |
| Project Title | LOI Title | Free Text |
| Principal Investigator | LOI Principal Investigator | Free Text |
| Submission Date | Submission date of LOI | Calendar |
| SPS Proposal Record? | If SPS Proposal is recorded outside of TRACER | Free Text |
| Comments | Any additional information about LOI | Free Text |
| **TRACER Interface Page: Project -Milestones- Invention Disclosure Forms** |
| IDF Number  | IDF Number | Free text |
| EIR Number | EIR Number | Free text |
| Title | Title of IDF | Free text |
| Date submitted | Date IDF submitted | Calendar  |
| CTSA Cited? | If CTSA was cited in IDF | Check Box |
| Evidence in file? | Evidence is documented outside of TRACER | Check Box |
| Comments | Any additional information about IDF | Free Text |
| Inventors | Name of inventors affiliated with Duke | List Lookup |
| **TRACER Interface Page: Project -Milestones- Intellectual Property - Patent** |
| Patent Number | Patent Number | Free Text |
| Title | Patent title | Free Text |
| Provisional Date | Patent provisional date | Calendar |
| Non-provisional date | Patent non-provisional date | Calendar |
| Converted? | If patent is converted | Check Box |
| Comments | Any additional information about patent | Free Text |
| **TRACER Interface Page: Project -Milestones- Intellectual Property - Non-patents & Copyrights** |
| Title | Non-patents & copyrights title | Free Text |
| Description | Description of non-patent & copyrights | Free Text |
| Date | Date of non-patent & copyrights | Calendar |
| Comments  | Any additional information about non-patent & copyrights | Free Text |
| Inventors | Inventors of non-patent & copyrights | List Lookup |
| **TRACER Interface Page: Project - Milestone - Agreements & Licenses - Licenses** |
| License Type | Type of license | Drop-down List  |
| Company Name | Name of company  | Free text |
| Description | Description of license | Free text |
| Created Date | Date license was created | Calendar |
| License Exclusive? | If the license was exclusive | Radio Button |
| Comments | Any additional information about license | Free Text |
| **TRACER Interface Page: Project - Milestone - Agreements & Licenses - Business Development** |
| Business Development Type | The type of business development | Drop-down List  |
| Company Name | Name of company  | Free text |
| Description | Description of business development | Free text |
| Created Date | Date business development was created | Calendar |
| Comments | Any additional information about business | Free Text |
| **TRACER Interface Page: Project - Milestone - Agreements & Licenses - Transfers** |
| License Type | Type of license transferred | Drop-down List  |
| Description | Description of transfer | Free text |
| Transfer Agreement in place | If there is a transfer agreement in place | Radio Button |
| How shared | How the transfer was shared | Free Text |
| Completed Date | Date transfer was completed | Calendar |
| Comments | Any additional information about transfer | Free Text |
| **TRACER Interface Page: Project - Milestone - Agreements & Licenses - Agreements** |
| Agree Type | Type of agreement | Drop-down List  |
| Company or Institution Name | Name of institution agreement is associated with | Free Text |
| Description | Description of agreement | Free Text |
| Created Date | Date agreement was created | Calendar |
| Comments | Any additional information about agreement | Free Text |
| **TRACER Interface Page: Project - Milestone - Regulations & Compliance - Federal Agency Interactions** |
| Agency Type | Type of Agency | Drop-down List  |
| Description | Description of agency | Free Text |
| Completed Date | Date interaction was completed | Calendar |
| Comments | Any additional information about agency | Free Text |
| **TRACER Interface Page: Project - Milestone - New Clinical Study - IACUC** |
| Protocol Title | Title of protocol | Free Text |
| IACUC Number | IACUC Number | Free Text |
| Select IACUC | Institute of IACUC | Drop-down List  |
| IACUC Approval Date | Date IACUC was approved | Calendar |
| Evidence in file? | Evidence is documented outside of TRACER | Radio Button |
| Study Type | Type of study | Drop-down List |
| Date Animal work began | Date Animal work began | Calendar |
| Date animal work completed | Date animal work completed | Calendar |
| Comments | Any additional information about IACUC | Free Text |
| **TRACER Interface Page: Project - Milestone - New Clinical Study - IRB Studies** |
| Protocol Title | Protocol Title | Free Text |
| IRB Number | IRB Number | Free Text |
| Select IRB | IRB Institute  | Drop-down List  |
| Approval Date | IRB Approval Date | Calendar |
| Date First participated entered | Date First participated entered | Calendar |
| Date Clinical Trail Completed | Date Clinical Trail Completed | Calendar |
| Comments | Any additional information about study | Free Text |
| **TRACER Interface Page: Project - Milestone - Software & Devices - Software** |
| Select Software Type | Type of software | Drop-down List |
| Description | Description of software | Free text |
| Date completed | Date software was completed | Calendar |
| Comments | Any additional information about software | Free Text |
| **TRACER Interface Page: Project - Milestone - Software & Devices - Devices** |
| Select Device Type | Device type | Drop-down List  |
| Description | Description of device | Free text |
| Date completed | Date device was completed | Calendar |
| Comments | Any additional information about device | Free Text |
| **TRACER Interface Page: Project - Milestone - Research & Educational Aids - Methods & Improvement** |
| Select Method Type | Method Type | Drop-down List  |
| Description | Description of method | Free text |
| Date completed | Date method was completed | Calendar |
| **TRACER Interface Page: Project - Milestone - Research & Educational Aids - Educational Aid** |
| Comments | Any additional information about method | Free Text |
| Select Educational Aid | Educational Aid type | Drop-down List  |
| Description | Description of educational aid | Free text |
| Date completed | Date educational aid was completed | Calendar |
| Comments | Any additional information about educational aid | Free Text |
| **TRACER Interface Page: Project - Milestone - Workforce Development - Scholar Outcomes** |
| Trainee Type | Scholar level | Drop-down List  |
| Outcome as of | Date outcome was reported | Drop-down List  |
| Time Point Data Represents | Pre-set time points to enter scholar information after graduation | Free Text |
| Stayed in Research | # of scholars who stayed in research after graduation | Free Text |
| Stayed in Health Sciences | # of scholars who stayed in health sciences after graduation | Free Text |
| Did not stay in Research | # of scholars who did not stay in research after graduation | Free Text |
| Did not stay in Health Science | # of scholars who did not stay in health sciences after graduation | Free Text |
| **TRACER Interface Page: Project - Milestone - Collaborations** |
| Collaborating Institution | Collaborating Institution | Free Text |
| Description | Description of collaboration | Free Text |
| Start Date | Start date of collaboration | Calendar |
| Collaborating Type | Type of collaboration | Drop-down List  |
| Comments | Any additional information about collaboration | Free Text |
| People | External people associated with collaboration | List Lookup |
| **TRACER Interface Page: Project - Milestone - Other Translational Advancements** |
| Select Achievement Type | Achievement Type | Drop-down List  |
| Description | Description of achievement | Free text |
| Date | Date of achievement | Calendar |
| Comments | Any additional information about achievement | Free Text |
| **TRACER Interface Page: New Consult** |
| Title | Title of Consult | Free text |
| Consultee | Person coming to your group for a consult | List Lookup |
| Additional Consultees | Other members of the group requesting consult | List Lookup |
| Consultants | People in the Core/CTSI providing consult | List Lookup |
| Consult Open Date | Consult Open Date | Calendar |
| Consult Close Date | Consult Close Date | Calendar |
| Notes | Notes of the consult | Free Text |
| Primary core | Core consult associated with consult | List Lookup |
| Project | The project the consult is connected with (If applicable) | List Lookup |
| Program | If applicable, the program associated with the consult | List Lookup |
| Keywords | List of words that describe content of the consult | List Lookup |
| Outcomes | Short description of the results of the consult | Free text |
| **TRACER Interface Page: Educational Activities** |
| Title | Name of educational activity | Free Text |
| Project | Name of the project related to this event | Drop-down List  |
| Program | Name of the program related to this event | Drop-down List |
| Event Date | Date of event | Calendar |
| Event Type | Type of Educational Activity | Drop-down List |
| Audience | Target audience for the event | Free Text |
| Primary Core | Primary Core conducting the event | List Lookup |
| Collaborating Cores | Cores helping primary Core with activity  | Free Text |
| Keywords | List of words that describe content of the Educational Activity | List Lookup |
| Attendee Count | How many people attended / participated in the event | Numerical |
| Frequency | Frequency of activity | Button |
| Location | Location of activity | Drop-down List  |
| Description | Description of activity |  |

# Supplement 5. TRACER Overview (A) and Onboarding Form (B)

1. **TRACER: Onboarding Overview**

**What is TRACER, and why are we using it?**

TRACER was created to address previous challenges to the process of collecting, analyzing, and reporting information about project activities because of this TRACER aims to:

* Assist in the ease of reporting burden.
* Enable the ability to document accomplishments such as consults, project milestones, translation benefits, etc.
* Facilitate the ability to view and aligned information within and across CTSI entities to answer critical questions.
* Provide valuable information for communications and fundraising.

**What resources are available to get me started?**

The following is a list of resources to help you get started using TRACER:

1. TRACER User Guide: A detailed guide on how to use TRACER, includes directions on how to run reports.
2. TSBM One Pager: Brief explanation of the Translational Science Benefits Model
3. TSBM Indicators: Detailed definitions and rationales of all TSBM indicators.
4. TRACER Onboarding Form: The Onboarding form found in the shared folder is a sample for the form we will ask you to complete prior to onboarding your team to the production website. Feel free to use this form to take notes, however in order to complete onboarding the official form on Smartsheet must be filled out.

All resources can be found in the shared box folder: [TSBM\_Onboarding\_docs\_and\_resources.](https://duke.box.com/s/qkte29hpnmz40pylcw28cooaour4zdsa)

**I am new to this. How do I get started?**

1. Get familiar with the platform.
	* You can request access to a [test version of TRACER](https://tracer-test.duhs.duke.edu/) by sending an email with your Duke netID to CTSI-TRACER@duke.edu. A member of our team will notify you when access is added.
	* Explore the platform a bit. Feel free to create a “mock” project and save the information.
	* While exploring the platform keep in mind which fields / elements make sense for your team. TRACER team is happy to meet with you to help determine this. You will be sharing this perspective back via the TRACER Onboarding Form (step 4, below).
2. Think about user permissions.
	* While getting familiar with the platform we ask you to think about which team members will need access to TRACER, as well as their permission levels. Below is a list and description of the various permission levels we can grant. Team members who will be the person / people directly entering data into TRACER will automatically be enrolled as a Core Administrator(s).

User Types:

* + Core Administrator (TRACER Champions)
		- Core Administrator will be granted to the main users entering data in TRACER.
		- Core Administrators can create projects, assign roles to users, enter, save data, and run reports. All permissions of the general and view only user.
	+ General Users
		- Ability to create, edit and delete data. Can generate reports. All permissions of the view only user.
	+ View Only
		- View / search transactions.
1. Review the Translation Science Benefits Model (TSMB)
	* Material explaining the TSBM can be found [here](https://duke.box.com/s/qkte29hpnmz40pylcw28cooaour4zdsa).
	* While reviewing this information please think about if you would like the ESP team’s help on understanding how to use the model or clarification on any of the domains / indicators. If so, please get in touch with the ESP team – they will be happy to meet with you.
2. Complete and share back out the TRACER Onboarding Form
	* After reviewing the TRACER User Guide and exploring the platform fill out the onboarding form. Please only fill out the form **once per team**.
	* The propose of this form is for you to share (1) which milestones are related to your team’s activities, (2) if there are any data fields missing related to your program’s measures/metrics that make sense to include on TRACER, (3) which databases and data sources you are currently using. This is all intended to make TRACER as appropriate for your team as possible within the overall CTSI use.
	* The TRACER Onboarding Form cannot be saved while in progress. Make sure to allow yourself plenty of time to fill out the form. To be prepared please make sure you do the following before filling it out:
		+ Review TRACER with an idea of which sections do or don’t make sense for your team.
		+ Review the TSBM materials.
		+ Have a list of team members who will need access to TRACER including their emails and duke IDs.
		+ Have TRACER open while filling out the TRACER Onboarding Form.
	* To preview or fill out the Onboarding Form use the following link: <https://app.smartsheet.com/b/form/3d12b7ad89b94ae7915e5ab5a108298a>
3. Next Steps
	* The ESP team will review what you shared and invite the point-person/people to the production version of the TRACER platform.

**Ok, I’m in! How do I add information?**

* How do I add information?
	+ Once you have access you are free to start adding data for your team and projects!
		- Please review the TRACER User Guide in the shared folder for directions about data entry.
	+ For manual data entry:
		- Enter information directly.
	+ For teams importing data:
		- You will work with the TRACER Development Team to develop a plan.
		- Your team may have to do a combination of importing and data entry if you don’t currently collect all required information in TRACER.
		- We ask, even for teams fully importing data, that you check the data for accuracy monthly.
* How often do I add my information?
	+ We expect TRACER to be updated monthly.
* What happens if I encounter an error? Or I have a question on how to use TRACER?
	+ Reach out to us! We can help navigate any errors, missing information, or general questions that you encounter. We can be reached at CTSI-TRACER@duke.edu.

**Can I generate reports for my team? What reports are there?**

*For a full overview of how to run reports and export data please see the TRACER User Guide located in the* [*TSBM\_Onboarding\_docs\_and\_resources*](https://duke.box.com/s/qkte29hpnmz40pylcw28cooaour4zdsa) *shared folder.*

The following is a summary of the built in reports:

1. Project Overview

A report pulling major data points for projects.

Includes information from the progress tab (success tracking).

Includes a count of all milestones found under the milestones tab as well as associated a count of associated consults and educational activities.

1. Publications & Presentations

Includes information entered under the Publications & Presentations milestone (Publications; Academic presentations, abstracts, posters; Public scholarships) and associated subfields.

1. Follow On Funding

Includes information entered under the Grants & Funding milestone (Follow-on funding) and associated subfields.

1. Intellectual Properties

Includes information entered under the Intellectual Properties milestone (Invention disclosure forms; Patents; Non-patents & Copyrights) and associated subfields.

1. Agreements & Licenses

Includes information entered under the Agreements & licenses milestone (Licenses; Business developments; Transfers) and associated subfields.

1. Regulations, IACUC & IRB

Includes information entered under the Regulations & Compliance, New Pre-Clinical Study, and New Clinical Study milestone.

1. Other Deliverables

Includes information entered under the milestones: Software & Devices; Research & Educational Aids; Collaborations; Translation Advancements and their associated subfields.

1. Consults

Include information entered under the consults tab including, consultee; open / closed data; consultee department; etc.

**I have other questions!**

We’re happy to answer more! Please reach out to us at CTSI-TRACER@duke.edu, and we can help or answer questions.

**B. Onboarding Form Content**

\*Note that the information below shows the text, but the format as received by onboarding Cores is adapted into a Smartsheet format.

*[Introduction] Thank you for taking the time to review TRACER.*

*As a next step, we are now asking you to share: (1) which milestones are related to your team’s activities, (2) if there are any data fields missing related to your program’s measures/metrics that make sense to include on TRACER, (3) which databases and data sources teams are currently using. This is all intended to make TRACER as appropriate for your team as possible within the overall CTSI use.*

*We are also using this as an opportunity to remind or introduce teams to the Translational Science Benefits Model (TSBM), provide resources, and set expectations.*

*Information type in form is only saved on submission. Please make sure you have sufficient time to complete this before starting***.**

**Team Background**

1. Please enter the name of the team you are filling this out for: [Open text box or drop down]
2. Please enter the contact information for all team members that should be included in follow up conversations. [Open text box]
3. Please enter the names / emails for any other team members who will need access but will not be entering data. [Open text box]

**General, Project Details, People and Progress Tabs**

*[Directions] For this section we ask that you create a mock project on the TRACER test website located here:* [*https://tracer-test.duhs.duke.edu/*](https://tracer-test.duhs.duke.edu/)

*The test website is made for users to learn TRACER, it is fine for you to enter fake information and / or save the project.*

 *Please review each of the areas asked and report any content that is required but does not make sense to your team’s projects or any information that is not collected but is important to track your projects.*

**General Tab Question 1**

*The General tab is where basic information of teams’ projects is stored such as name of project, status, associated Core, start date, and a summary of the project.*

1. Please review the general tab. Are there any required (indicated with \*) data fields that do not make sense for your program? [ [Multiple choice]
	1. Status
	2. Start Date
	3. Parent Core
	4. All DO make sense for us

**General Tab Question 2**

1. Is there any information that is not collected that is important to your projects? [Open text box]

**Project Details Tab Question 1**

*Project details is where projects can be linked to programs as well as store funding related information.*

1. Please review the project details tab. Are there any required (indicated with \*) data fields that do not make sense for your program? [Multiple choice]
	1. Does this project already have associated funding?
	2. Does this project already have an approved IRB protocol?
	3. Does this project already have an approved IACUC protocol?
	4. All DO make sense for us

**Project Details Tab Question 2**

1. Is there any information that is not collected that is important to your projects? [Open text box]

**People Tab Question 1**

*The People tab is used to link lead investigator(s).*

1. Please review the people tab. Is there any collected information that does not make sense for your program?

**People Tab Question 2**

1. Is there any information that is not collected that is important to your projects? [Open text box]

**Progress Tab**

*The progress tab is* ***optional****. It can be used as a tool to manage projects, if desired.*

1. Do you plan to use the Progress Tab? [Yes/ no /unsure]

Milestones

*[Directions] Milestones are major events that are linked to entered projects. For the following section please select “yes” if your team currently has projects, or foresees that you will have projects, that could lead to a milestone and its subcategories. Only select “no” if this milestone has no relation to the type of projects your team hosts. If the milestone is relevant to your work but is missing important data fields please select "with modification"*

*[All questions will have a yes/ no / with modification option]*

* **Publications & Presentations.**
	+ Associated publications, academic presentations, abstracts, posters, and public scholarships.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Grants & Funding**
	+ Associated follow-on funding.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Intellectual Property**
	+ Associated invention disclosure forms, patents, non-patents & copyrights.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Agreement & Licenses**
	+ Associated project’s licenses, business developments, and transfers.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Regulation & Compliance**
	+ Associated federal agency interactions.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **New Pre-Clinical Study**
	+ Associated new pre-clinical study associated and contains IACUC information.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **New Clinical Study**
	+ Associated clinical study and contains IRB information.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Software & Devices**
	+ Associated software or device.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Research & Educational Aids**
	+ Associated methods and educational aids.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Collaborations**
	+ Associated external collaborations.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?
* **Other Translational Advancements**
	+ Associated other translational advancement, this may include major milestones related to patient and community engagement, and training and workforce development, etc.
	+ *[Display logic: with modification]:* What modification would be beneficial to your team?

Consults and Educational Activities

*[Directions] Consults and Educational Activities are tracked by Core, not by project. A project can be linked to both consults and educational activities but that is not required.*

*For this section please exit out of the mock project and instead use the tabs on the left of the screen labeled “Educational Activities” and “Consults”. Please review both the consult and educational activities form while answering the questions.*

*Please read the following definitions of each section and let us know if either consults or educational activities are a service your team provides or would conceivably provide in the future. There is no frequency requirement.*

*[All questions will have a yes/ no option]*

1. Consults: Offered by Cores/teams, any type of consulting or advising services internally or externally to Duke. Consults are linked by Core.
2. Educational Activities: Hosted by Cores/teams, any type of educational activity. There is no requirement for the number of times an educational activity is held or its frequency. Types of educational activities include presentations, training tools, online events, other. Educational activities are linked by Core.

Follow-up Questions

1. After reviewing the fields in TRACER, are there any missing major milestones that you think would be helpful to capture at the program level? [Open textbox]
2. Regarding the way TRACER captures information, is there any other feedback you would like to share? [Open textbox]

Data Entry

*[Directions] One of our main priorities when developing TRACER was to help reduce the reporting burden, so we are working on various ways to import data. We are working with the Development team to target the most used data sources within CTSI teams.*

*When answering the following questions please think of the data sources your team currently uses that are applicable to TRACER. Applicable data sources contain measurements that overlap with fields already tracked in TRACER.*

1. Does your team currently collect/store data that is applicable to TRACER in another platform/source (e.g., Excel files, Redcap, Qualtrics)?
	1. Yes
	2. No
2. [Display logic; yes applicable to TRACER] How do you currently collect/store data? Indicate all that apply. [multiple choice]
	1. Excel / CVS worksheet
	2. Redcap
	3. Qualtrics
	4. Other
3. *[Display logic: other]* What other mechanism(s) do you use to collect/store program data? [Open textbox]
4. [Display logic; yes applicable to TRACER] Does your data source contain PHI?
	1. Yes
	2. No
5. *[Display logic: No PHI;* yes applicable to TRACER*]* If your team is interested in importing data from an external source into TRACER it will be required for you to work with the TRACER development team to prepare your data.

Please include a copy of the data dictionary (if Redcap) or an example spreadsheet from your data source. If you currently collect data using **multiple sources, upload all files here.** [File upload]

Translation Science Benefits Model

*[Introduction] The Translational Science Benefits Model (TSBM) was developed and released for use in 2018\* as a new approach for demonstrating the impact of science to the broader community. Moving beyond bibliometric measures; the TSBM focuses on clinical and community health impacts with 30 indicators that reflect benefits in 4 different domains.*

*The Translational Science Benefits Model is* ***required******for all teams*** *to report on for* ***each project****. We understand that learning a new model can be time consuming and complex which is why we have provided resources here for you. TSBM resources are located* [*here*](https://duke.box.com/s/x7b4l4lq0tpmzjlvdmi6v5kxd7tb3h7o)*.*

*After reviewing the TSBM, please select one of the following options:*

1. I understand the TSBM and require no further training. (Checkbox)
2. Our team would like to request a meeting to review the TSBM model with the ESP team. (Checkbox)

**Closing Statement**

*Thank you for taking to complete the TRACER onboarding form.*

*The ESP team will follow up with your team with next steps to onboard your team to the production version of TRACER.*

*If you have any questions, email:* *CTSI-TRACER@duke.edu*

*If you would like to change your submission answers at any time, please resubmit the form.*