FINAL PROGRESS REPORT

PI NAME AND TITLE, INSTIUTION:

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CO-PI NAME AND TITLE INSTITUTION:

TITLE OF PROPOSAL:

RE-Tool, Research Efficiency Tool

DOLLAR AMOUNT:

$13,491

SCOPE AND PURPOSE:

The focus of the project is development and use of REDCap, Research Electronic Data Capture, to improve the clinical research billing process at UTHealth. Specifically RE-Tool will allow clinical research study team members to communicate research patient appointments and charge entry directives using a single data entry point.

SUMMARY OF PROJECT GOALS AND OBJECTIVES:

1. Build a clinical trial management tool in REDCap. RE-Tool will allow clinical trial tracking from inception of the project to project closeout. The project involves multiple phases including tracking the protocol, budget development, coverage analysis, invoicing, and patient tracking.
2. Implement RE-Tool in three major divisions at UTHealth within one year. Physician leaders within Internal Medicine are supporters of this project. They agree to have their department beta test the system, which allows the implementation of the system without a mandate to use it. RE-Tool aims to be useful for the end-user, which contributes to a desire to use in lieu of a requirement.
3. Centralize scheduling for RE-Tool customers with the aim of increasing the use of research identifiers in GE Centricity. RE-Tool will include a patient level appointment form, which can be emailed to appropriate recipients from within the system. This eliminates the need to use Outlook email templates to notify various groups of a research patient status.

RESULTS:

1. Phase 1 of RE-Tool is complete, and it is currently in production. The development of this phase was sponsored by leaders of Internal Medicine. This module allows for protocol tracking, budget development, coverage analysis, and invoice tracking, and it assists with population of an internal routing document. The development of this phase was slowed by complex coding and calculations.

   Phase 2 of the RE-Tool, which was funded by the NCURA award is ready for implementation. This phase incorporates patient tracking, so that we can ensure compliance with clinical research billing policy. The module is based on the REDCap longitudinal project scheduling project.

   RE-Tool phase II accomplished the object of creating a CTMS in REDCap. This phase allows research coordinators to identify clinical trial patients and share their registration and scheduling data as needed with other key stakeholders.

   The patient tracking portion of RE-Tool is based on a template. The template is customized for each new clinical trial. The template includes a bridge to the patient registration system, so that patient basic demographics can be pulled into RE-Tool using the patient's medical record number (MRN). This feature accomplishes a key goal of reducing repetitive data entry. The patient's information is then saved through the life of the study, so it is not re-entered with each new visit.

   The patient appointment form is another key component of RE-Tool. This form allows research staff to request an appointment, and provide clinical research billing information with one entry. The patient demographic information is pulled into the form automatically when you select the patient name from the patient list. The research staff member then provides their contact information, selects study information from a dropdown list, communicates the desired appointment date and time, and selects the procedures from a dropdown list. Once all the information is selected the research staff member will then select "yes" to have the form emailed, and marks it complete. The form will then automatically route an email to the

individual that created it. The email outlines all the information in the form, and it can then be forwarded to both a scheduling office and the billing team.

The procedure options in the patient appointment form are derived from the studies coverage analysis. Each procedure dropdown provides the procedure description, CPT code, and designated payor. In addition to the prepopulated dropdown procedure list, the form provides two options for procedures not dictated in the study. This is necessary to provide options for adverse event visits as well as invoiceable options.

The appointment is repeated for each visit dictated by the study protocol and outlined in the coverage analysis. The study has a dashboard composed of a matrix that allows drilldown in to the appointment forms. The dashboard also includes three unscheduled visit options, which have appointment forms attached. These visits were created to allow flexibility in scheduling.

RE-Tool's patient tracking system is a simple way to communication clinical research patient information when a commercial CTMS system is not available. RE-Tool allows study teams to track patients for their purposes, and it provides an important means to share scheduling and billing data. You can view a demonstration of the patient tracking system by visiting YouTube.

2. Implementation of RE-Tool phase 1 has been a struggle. The RE-Tool faculty champion left UTHealth in late 2016. The result was a lack of traction at the research team level. There was no support to mandate RE-Tool at a central level, and the absence of a faculty champion left a void at the department level. Though the clinical research billing team has trained approximately 70 people across various clinical departments on the use of RE-Tool, the use of the system has not been widespread. Essentially RE-Tool has become a volunteer system, and most study teams lack the incentive to learn the new option.

3. The goal of centralized scheduling with RE-Tool has not be realized. Though the program is developed and ready to deploy, there is not support at an institutional level to centralize research scheduling. The

institution has undergone many staffing changes in leadership, and this has contributed to a dwindling of support.

RE-Tool is available for anyone to use. The alternative to central scheduling is to use the email functionality of the patient appointment form to generate an appointment request. The research team can then forward the request to the appropriate party. This functionality allows RE-Tool to retain the usefulness of the appointment form without the option of centralized scheduling.

OUTCOME:

The success of RE-Tool implementation will be measured in two ways. The first measurement is the change in satisfaction with the clinical research billing process at UTHealth. Prior to completion of phase 1, we surveyed our research community to determine satisfaction with our current procedure. The second poll results of after the rollout of RE-Tool did not show significant improvement in clinical research billing satisfaction. Though there was slight improvement in the level of satisfaction, the difference was marginal.

The stagnant satisfaction is attributed to the lack of a faculty champion and reduced central support for centralization. System change is not easily embraced, and it is necessary to have buy in and support to encourage change. This failure does not negate the successful development of RE-Tool.

The second measurement is improvement in compliance with our internal clinical research billing policy. We have tracked the use of patient identifiers at the time of scheduling for a year. Compliance with our clinical research billing policy has not be measurably impacted by RE-Tool. This is primary due to a lack of active users.

RE-Tool possesses the ability to positively impact clinical research billing compliance. A shift is leadership support is needed to create the desired change. To strongly impact this compliance RE-Tool should be mandated, and central scheduling should be implemented.

CONCLUSION:

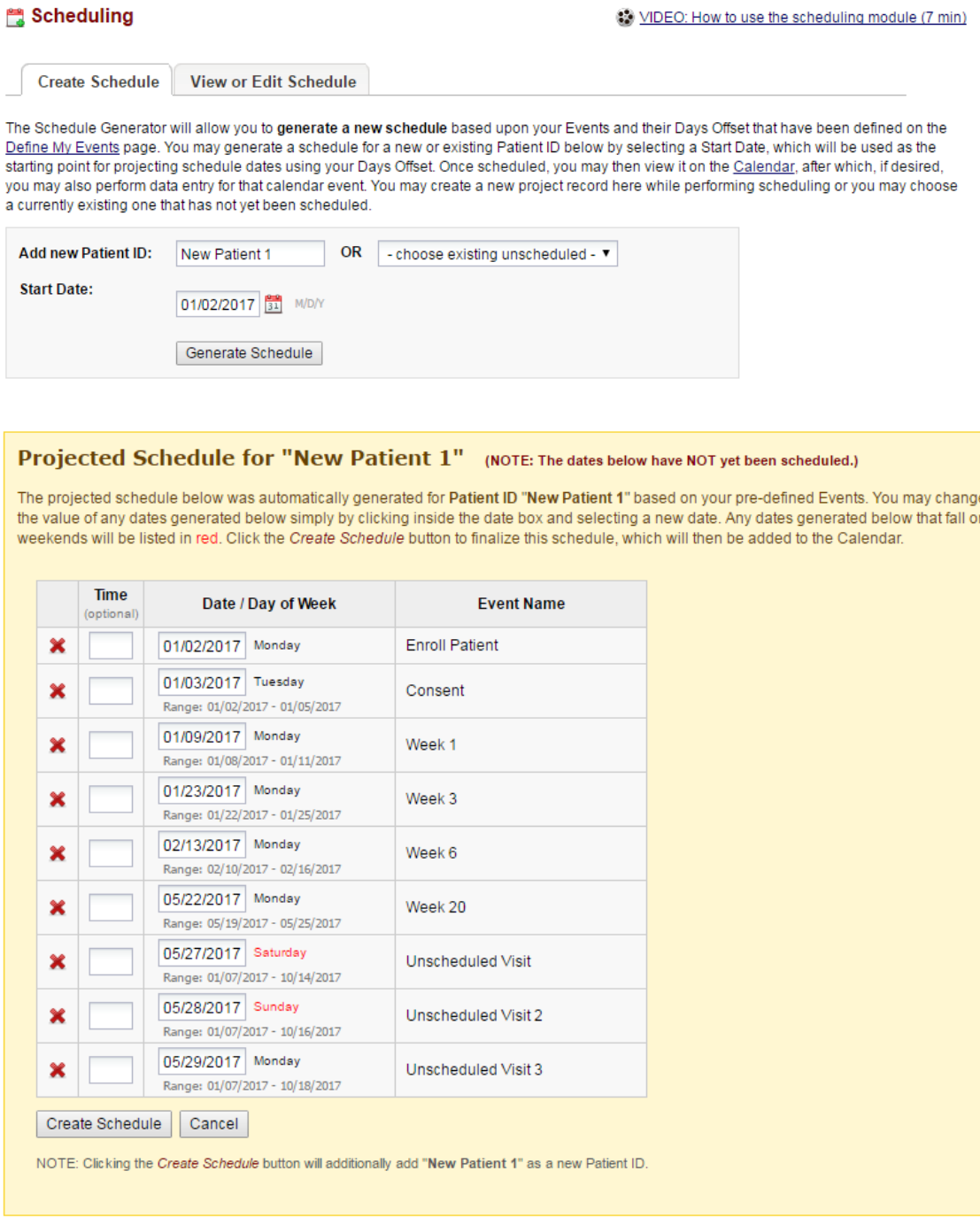
Replication of RE-Tool's functionality in REDCap is possible. Most of the functionality of the patient capture module was built on the base features of REDCap. The bridge to UTHealth's patient registration system was a customization developed by REDCap developers in the School of Biomedical Informatics. RE-Tool's functionality is streamlined with this option, but it not a necessary component of the tracking system. The remaining features of the system are built per the general system capabilities.

The development of RE-Tool was a success, but the project did not meet the expected implementation results. RE-Tool is still active and available for use, so the long-term success of the project is still unknown. The implementation failure was a result of many factors familiar in research administration.

Successful research administration projects involve many champions. A successful project should have the support of leaders in both central administration as well as faculty spokesperson. Though the clinical research finance team generated demand and interest in RE-Tool it failed to translate to active users. The lack of support for RE-Tool made its use optional. Optional tools, even those that streamline and create efficiency, are just that, optional. Given the choice between change and status quo, we often choose the later without a mandate to implement change.

Exhibit A:

Add a New Patient



Successfully Scheduled "New Patient 1"

Patient ID "**New Patient 1**" was successfully scheduled for the dates and times below and has been added to the Calendar. You may now edit this schedule or add more information, such as changing the status (e.g., 'Cancelled', 'Confirmed') or adding descriptive notes, by clicking the *View or Edit Schedule* tab above.

Schedule for "New Patient 1" Edit Print

Time	Date	Event Name
	01/02/2017 Monday	Enroll Patient
	01/03/2017 Tuesday	Consent
	01/09/2017 Monday	Week 1
	01/23/2017 Monday	Week 3
	02/13/2017 Monday	Week 6
	05/22/2017 Monday	Week 20
	05/27/2017 Saturday	Unscheduled Visit
	05/28/2017 Sunday	Unscheduled Visit 2
	05/29/2017 Monday	Unscheduled Visit 3

Study Dashboard:

Patient ID	DDP New items from SBMI CDW	Patient/Subject Enroll Patient	Enroll Patient Enroll Patient	Appointment Consent	Appointment Week 1	Appointment Week 3	Appointment Week 6	Appointment Week 20	Appointment Unscheduled Visit	Appointment Unscheduled Visit 2	Appointment Unscheduled Visit 3
EX PAT 1	None view	●	●	●	○	○	○	○	○	○	○
New Patient 1	None view	○	○	○	○	○	○	○	○	○	○
Study Pat 1	2 view	●	●	●	○	○	○	○	○	○	○

Patient Demographics Pull:

Patient ID	EX PAT 1
New or Returning Patient	Return
MRN:	2676892
Last Name:	CODY
First Name:	HEATHER
Address:	3722 QUAIL MEADOW DR
Apartment/Suite (if, applicable):	
City:	MISSOURI CITY
State:	TX
ZIP Code:	77459
Phone:	(512) 426-6557
Phone (alternate):	
Date of Birth:	08-09-1976
Gender:	Female
Race:	Caucasian
Ethnicity:	Non-Hispanic or Latino
Marital Status:	MARRIED

Study Status:

Subject Study Status	
Date of Consent	12-21-2016 Today M-D-Y
(Estimate) Date of Completion	05-31-2017 Today M-D-Y
Patient Status	Enrolled/Active
MHH MRN	0987654321
Case Number:	0123456
Form Status	
Complete?	Complete

Coverage Analysis Summary:

Procedures per Coverage Analysis

Visit	Procedure	CPT	SOC/RES	Unit Cost
Enroll	Clinic Visit Level 1	99211	SOC	
	ECG 12/15 Lead	93010	SOC	
Week 1	Echo 2D M Mode Comp	93325	SOC	
	PTT	85730	RES	$150
Week 3	Clinic Visit Level 1	99211	RES	$50
	CBC	85025	RES	$25
Week 6	Echo Doppler	93306	RES	$100
Week 20	Clinic Visit Level 1	99211	SOC	

Attachment: Phase 2 Sample (5) (1).xlsx (0.01 MB)

Appointment Form:

Appointment

Editing existing Patient ID **EX PAT 1** — No new items from source system (View)

Event Name: **Consent**

Patient ID	EX PAT 1
MRN# 2676892	
MHH MRN: 0987654321	
Last Name: CODY	
First Name: HEATHER	
Address: 3722 QUAIL MEADOW DR	
City: MISSOURI CITY	
State: TX	
Zip Code: 77459	
Phone: (512) 426-6557	
Alt Phone: _____	
DOB: 08-09-1976	
Gender: Female	
Ethnicity: Non-Hispanic or Latino	
Marital Status: MARRIED	
Patient Case Number: 0123456	

Study Contact Information:	
Coordinator Last Name:	Jones
Coordinator First Name:	Janet
Coordinator Email:	Jones.Janet@uth.tmc.edu
Office Phone:	500-7856
Coordinator Phone Alt:	
PI Last Name:	Smith
PI First Name:	John
Study Information	
IRB Number:	HSC-MS-17-0001
NCT Number:	01234567
Study EG Account:	098765432

Email Options

Do you want to email this form? Mark form as "Complete" and save in order to send auto email.	(H) (C) ◉ Yes ○ No reset

Post Appointment Documentation

Did the patient arrive to appointment?	(H) (C) ◉ Yes ○ No reset
Patient arrived mark appoint form as complete and save. Patient did NOT arrive, reschedule	(H) (C) Expand Comments

Form Status

Complete?	(H) (C) Complete ▾