PROTOCOL Title: Midwest TXTXT Scale up of an Evidence-Based Intervention to Promote HIV Medication Adherence

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Conducted at:

Ann & Robert H. Lurie Children's Hospital of Chicago
225 E. Chicago, Box 161
Chicago IL

Principal Investigator: Amy

K. Johnson, PhD MSW**Senior**

Investigators:

Robert Garofalo, MD
Lisa Kuhns, PhD MPH

Co-investigators

Ricardo Rivero, MD
Corina Wagner, M.Ed., MBA
Nanette Benbow, MS

Consultants:

N/A

CDC Project Officer:

Kimberly Evans, PhD, MPH

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ABBREVIATIONS AND ACRONYMS

AETC = AIDS Education and Training Center AIDS

= Acquired Immune Deficiency SyndromeART =

Antiretroviral Treatment

CAC = Cluster Auto-Correlation

CDC = Centers for Disease Control and Prevention

CDPH = Chicago Department of Health

Ce-PIM = Center for Prevention Intervention Methodology

CFAR = Center for AIDS Research

CFIR = Consolidated Framework for Implementation Research

DEBI = Diffusion of Effective Behavioral Interventions

EBI = Evidenced Based Interventions

EMR = Electronic Medical Record

GEE = Generalized Estimating Equation

GLM = Generalized Linear Model

HIPAA = Health Insurance Portability and Accountability Act

HIV = Human Immunodeficiency Virus

HRSA = Health Resources and Services Administration

ICC = Intra-Cluster Correlation

IS = Implementation Science

MATEC = Midwest AIDS Education Training Center

MIT = Massachusetts Institute of Technology

MPR = Medication Possession Ratio

MSM = Men Who Have Sex with Men

NHBS = National HIV Behavioral Surveillance System NIAID =

National Institute of Allergy and Infectious Diseases

NICHD = National Institute of Child Health and Human Development

NIDA = National Institute on Drug Abuse

NIH = National Institutes of Health

NIMH = National Institute of Mental Health

NIMHD = National Institute on Minority Health and Health Disparities

NINR = National Institute of Nursing Research

NUCATS = Northwestern University Clinical and Translational Sciences InstituteNUFSM =

Northwestern University, Feinberg School of Medicine

OR = Odds Ratio

PI = Principal Investigator

PID= Participant Identification

PWH = Persons with HIV

RCT = Randomized Control Trial

RE-AIM = Reach, Effectiveness, Adoption, Implementation, and Maintenance

SAMHSA = Substance Abuse and Mental Health Services Administration SES

= Socioeconomic Status

SD = Standard Deviation SMS

= Short Message ServiceUS =

United States

YLH = Youth Living with HIV

YYALH= Youth and Young Adults Living with HIV

YMSM = Young Men Who Have Sex with Men

PROTOCOL SUMMARY

In this study we propose to use implementation science (IS) to scale up and evaluate the TXTXT evidence-based intervention (EBI) as an effective strategy to increase ART adherence and retention in HIV care, ultimately leading to a suppression of viral load among Black/African American, Hispanic/Latino and other racial/ethnic minority youth and young adults living with HIV (YYALH) participating in the intervention. We hypothesize that those who complete the TXTXT intervention will demonstrate a clinically meaningful increase in ART adherence, viral suppression, and sustained retention in care. Additionally, we hypothesize that the implementation of TXTXT will reach ≥80% of the intended participants, will be fully adopted by ≥80% of clinic partners, and will achieve ≥90% ratings of satisfaction and acceptability. We will use mixed methods to complete our study aims: 1) determine the real-world efficacy of a regional scale up of an EBI – TXTXT -among poorly adherent racial/ethnicity minority YYALH, aged 16-35 years, on our primary outcomes: adherence and viral load suppression at 3-month post initiation of the intervention; and secondary outcome: retention in HIV care at 12-months post baseline, and 2) apply the Consolidated Framework for Implementation Research (CFIR) to describe the implementation process and identify barriers and facilitators needed to be addressed; and measure implementation outcomes of the TXTXT intervention using the RE-AIM framework (Reach, Efficacy, Adoption, Implementation, Maintenance). We will conduct a cluster randomized controlled trial to evaluate the intervention effectiveness (i.e., ART adherence, viral load suppression) at 3-months post-initiation of the intervention. Twelve clinic sites with the ability to enroll up to 50 participants at each site (N=600 participants total) will be trained to administer the TXTXT intervention. Sites will be randomized to either start the intervention immediately (i.e., intervention arm) or waitlisted to start at 3 months post baseline (i.e., comparison arm). In the comparison arm, the study will compare pre-post differences in adherence and viral suppression at 6 months post baseline. Last, we will evaluate retention in HIV care and sustained impact of the intervention at 12 months post baseline for all study participants.

RESEARCH TEAM

Dr. Amy Johnson, study Principal Investigator (PI) is a junior faculty member in the Division of Adolescent Medicine at Lurie Children's Hospital. Her research, evaluation and service career span a decade with established expertise in community-based participatory research and empowerment evaluation, specifically with engaging sexual, gender, and racial/ethnic minority youth in research andevaluation, as well as in developing and evaluating high-impact interventions for HIV prevention and care.

Dr. Johnson will be responsible for all aspects of the scientific integrity, daily operations, and implementation of study aims, as well as lead dissemination efforts. Data collection will occur at regional HIV clinic sites and will be submitted directly to Lurie Children's. Text message data (receipt, response) will be provided by Dimagi Commcare via encrypted data transfer. Dr. Johnson will supervise Ms. Cervantes (data manager) in all aspects of data cleaning, storage, and analysis. Dr. Johnson will build upon existing research collaborations with multidisciplinary Co-Investigators, Drs Garofalo, Kuhns, andRivero, and Ms. Benbow, Ms. Wagner. Dr. Johnson will convene standing monthly meetings with all investigators; and will meet with Dr. Garofalo bi- monthly.

Dr. Robert Garofalo will serve as the primary mentor to this project and will advise on overall study implementation; further Dr. Garofalo will provide learning opportunities, support, and critical feedback for success. Dr. Garofalo is the Potoski Family Professor of Pediatrics and Preventative medicine at Northwestern University's Feinberg School of Medicine, as well as the Director of the Research Center of Excellence for Gender, Sexuality, and HIV Prevention and the Division Chief of Adolescent Medicine at Lurie Children's Hospital. Finally, as Co- Investigator, Dr. Garofalo will contribute to the interpretation of findings, aid in the preparation and review of manuscripts and conference presentationsand assist in the dissemination of study findings.

Dr. Lisa Kuhns, study Co-Investigator (Co-I) is a Research Associate Professor in the Department of Pediatrics at the Feinberg School of Medicine and serves as the Associate Director for the Center for Gender, Sexuality, and HIV Prevention in the Division of Adolescent Medicine at Lurie Children's Hospital. Dr. Kuhns will serve as a content expert in app development and SMS deployment for HIV prevention among adolescents. Dr. Kuhns will attend project meetings, provide critical feedback on appdevelopment, contribute to the interpretation of findings, aid in the preparation and review of manuscripts and conference presentations, and assist in the dissemination of study findings.

Dr. Rivero, study Co-Investigator (Co-I), has been the Executive Director of MATEC for 17 years and currently serves as a member of the National Alliance of HIV Education and Workforce Development. His work has focused on HIV within the Latinx community.

Ms. Wagner, study Co-Investigator (Co-I), is currently the Research and Evaluation Manager for MATEC and oversees evaluation in addition to lending technical assistance and capacity building to the AETC.

Dr. Rivero and Ms. Wagner will oversee the TXTXT training, capacity building and technical assistance provided to HIV clinics across years 1-3 of the grant. Dr. Johnson will work with Dr. Rivero and Ms. Wagner to evaluate the implementation of TXTXT and engagement of clinic sites. A project coordinator will be hired and will report directly to Ms. Wagner.

Ms. Benbow, study Co-Investigator (Co-I) is current faculty at Northwestern University. Ms. Benbow also previously served as the Deputy Commissioner of the Chicago Department of Public Health. Additionally, she has worked collaboratively with MATEC for 20 years. Ms. Benbow will assist with cost analysis and sustainability planning by providing expertise to assist with the identification of barriers and facilitators and implementation outcomes to implement and scale-up the TXTXT intervention, as well as assess sustainability of the intervention. She will contribute to the oversight of the project, provide insight into implementation in a public health context, and provide input on dissemination products and manuscripts.

Kalob Gossett, research coordinator, will assist Dr. Johnson and Ms. Wagner with day-to-day study activities, coordinate communication with clinic sites, provide technical assistance to clinic sites, oversee data collection, assist with data management and data quality queries, and will attend all project meetings.

Marbella Cervantes, study data manager, will oversee data collection systems, data management, dataquality, and assist Dr. Johnson with initial and interim analysis.

Table 1. Research and Collaborator Team

Name	Role	Institution
Amy K Johnson, PhD	Principal Investigator, lead study & analyses; overseedata security	Lurie Children's Hospital
Robert Garofalo, MD	Senior Investigator, primary mentor; support PI on projectactivities	Lurie Children's Hospital
Lisa Kuhns, PhD	Co-Investigator, content area expert- mHealth	Lurie Children's Hospital
Ricardo Rivera, MD	Co-Investigator, oversee TA/CBA for TXTXT	MATEC- UIC
Corina Wagner, M.Ed., MBA	Co-Investigator, oversee TA/CBA for TXTXT	MATEC-UIC

Nanette Benbow, MS	Co-Investigator, content area expert – implementation science	Northwestern University

Kalob Gossett, MHA	Research Coordinator, oversee day-to-day activities,clinic engagement/communication	MATEC- UIC
Marbella Cervantes, MS	Data Manager, data collection/data management	Lurie Children's Hospital

INTRODUCTION

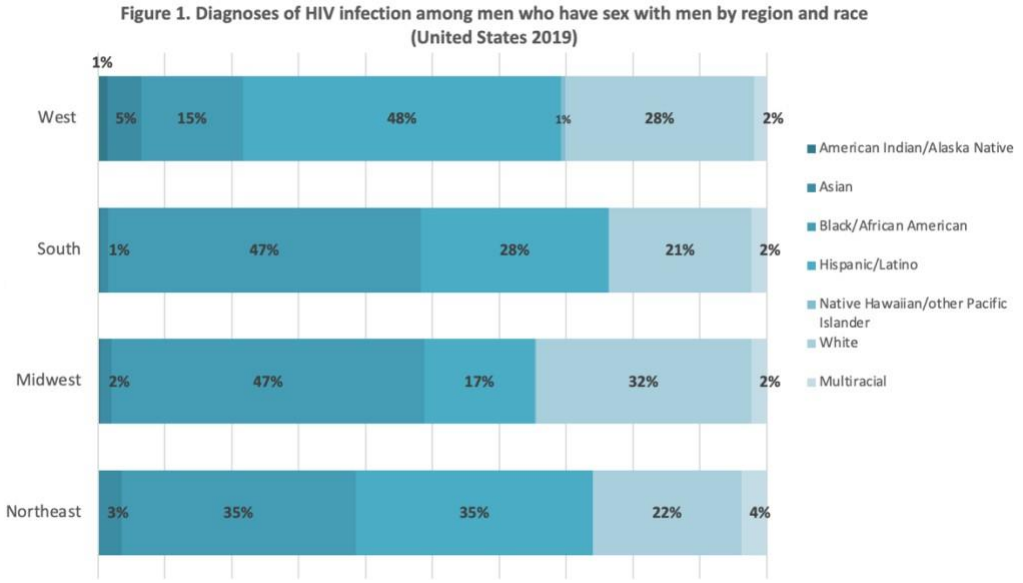
Literature Review

In the United States, at the end of 2019, there were an estimated 1.2 million people living with HIV.[1] Of those people, approximately 87% are aware of their status.[1] There are approximately 48,000 youth (aged 13-24) living with HIV, with 86% aware of their status.[1] Overall, 66.8% of young people aged 13 and older reach viral suppression within 6 months of HIV diagnosis.[1] Among young people, those who have the lowest rates of viral suppression include those who identify as Native Indian/Alaska Native (52.9%), Black/African American (62.9%), and Native Hawaiian/Other Pacific Islander (66.7%). Meanwhile, youth with the highest rates of viral suppression include those who identify as Multiple Races (69.3%), White (68.3%), Hispanic/Latino (71.0%) and Asian (76.7%).[1] New diagnoses have been decreasing since 2015, with 36,801 recorded in 2019.[1] Men who have sex with men (MSM) represent 69% of new HIV diagnoses in the United States and 6 dependent areas in 2019.[1] In terms of diagnoses by race and ethnicity, Black and African American people accounted for 45% and Latino people accounted for21.5% of all new HIV diagnoses in 2019.[1]

Black and Latino youth experience disproportionate rates of HIV compared to white youth. Accounting for only 14% of the US population, Black youth accounted for 51% of new HIV diagnoses in 2019, with Hispanic/Latino youth accounting for 30%.[1] Youth living with HIV (YLH) are also more likely to be racial/ethnic minorities. Young Black and Latino men who have sex with men (MSM) in the U.S. bear the disproportionate burden of HIV infection. HIV incidence is highest among young MSM (YMSM) aged 13-24 years, particularly Black and Latino YMSM.

Rates of infection among Black MSM are particularly relevant to the epidemiology of HIV in the Midwest, the region which has the second-highest rate of new HIV infections in Black residents, representing 47% of all new regional infections (Figure 1).[1] Despite the Midwest's relatively low national standing in terms of new diagnoses (only 7% of all new diagnoses of infections nationwide in 2019), there is an evident need for a more comprehensive approach to eliminating racial disparitiesin HIV infection in this region.[1] Rates of diagnoses in the Midwest decreased from 2015 to 2019 in addition to decreases in the South, Northeast, and West regions as well as 6 U.S. dependent areas (American Samoa, Guam, Northern Mariana Island, Puerto Rico, Republic of Palau, & U.S. Virgin Islands).[1] The Midwest region also contains several urban poverty areas sampled by the National HIV Behavioral Surveillance System (NHBS), including Chicago, Detroit, and St. Louis, which found very high prevalence rates of HIV among heterosexuals and an inverse relationship between HIV prevalence rates and socioeconomic status (SES). [2]

In addition to disproportionate risk for HIV infection, MSM and other YLH are less likely to be adherent to antiretroviral therapy (ART).[3] Low adherence is problematic because ART suppresses viral load and results in better long-term health.[4] A secondary benefit of viral suppression is that it prevents onward transmission, as people who are virally suppressed are extremely unlikely to transmit HIV.[5]



The effort to identify individuals with HIV infection, link and keep them engaged in care, support adherence to ARTand suppress viral replication isknown as the "HIV care continuum".[6] This project focuses on adherence to ART, a step in the HIV care continuum that has not been prioritized among youth and young adults to the same degree as earlier steps in the continuum. Correlates of ART adherence among youth include key psychosocial factors, such as co-morbid mental illness, substance use and HIV-related stigma, among other factors.[7] Youth and young adults living with HIV (YYALH) are more likely to disengage from care, delay initiation of ART, and have lower rates of virologic suppression compared to adult populations.[8-16] However, the most frequently cited reason for non-adherence among YLH is simply forgetting. In a study of youth living with HIV, (aged 12-24 years; n=217), 74% reported the reason for missing doses was that they "forgot".[17] These findings underscore the need for implementation of reminder interventions, including novel and proven effective intervention strategies such as the TXTXT intervention described herein.

The TXTXT intervention [18] will be adapted, pilot-tested, and scaled up in this project (Appendix A- https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/ma/cdc-hiv-text-messaging-txtxt-good-ma.pdf.). TXTXT uses a two-way daily text reminder and response system designed by Dr. Garofalo and colleagues, to improve ART adherence for 16-29 years old U.S. adolescents and young adults.[18] Both HRSA and the CDC have designated TXTXT as an effective HIV treatment intervention for ART adherence.[19] While the original TXTXT intervention focused exclusively on ART adherence, for the purposes of the proposed study, we will adapt the intervention to deliver SMS text reminders not only for ART adherence, but also to focus on criticalaspects of retention in care (e.g., clinic appointment and pharmacy refill reminders) as our primary outcome; viral suppression, is influenced by both. Further, we have expanded the age range up to 35 years to include young adults who often struggle with adherence as they transition into adulthood and face other developmental milestones.

Given the potential to accelerate progress towards no new HIV infections, the United States is at a critical point in the epidemic to support persons with HIV (PWH), particularly racial/ethnic minority youth, in achieving and sustaining viral suppression. [20] Deaths among PWH have decreased, resulting in an increasing prevalence; therefore**,** disparities in ART adherence in racial/ethnic minority youth must be the continued focus of these efforts in order to promote viral suppression and prevent onward transmission.[16,18,21,22] Evidence-based interventions for these youth across the HIV care continuum should be scaled up and widely disseminated to increase access to effective strategies.

The proposed implementation science research project "Midwest TXTXT" will focus on the Ending the HIV Epidemic Initiative *Treating people with HIV rapidly and effectively to reach sustained viralsuppression* by delivering an evidence-based intervention to improve ART adherence, retention in care and sustained viral suppression among racial/ethnic minority youth, inclusive of young gay, bisexual and other MSM, young cisgender women and young transgender women across multiple sites.[20]

Justification of the Study

The goal of the proposed project is to implement a scaled-up version of the existing TXTXT EBI in an effort to increase the rate of viral suppression among YYALH aged 16-35 years through medication adherence and retention in HIV medical care. In addition to disproportionate risk for HIV infection, racial and ethnic minority YYALH are less likely to be adherent to antiretroviral therapy (ART).[3] The most frequently cited reason for non-adherence among YYALH is simply forgetting .[17] The results of this study, if the adapted intervention proves to be an impactful and acceptable innovation, will be used to scale up this intervention further so that it can be used as a practical and sustainable tool at the regional level within clinic settings in the United States.

Innovation

This study is innovative for the following reasons:

1. **Scale-up and adaptation of a medication adherence intervention developed specifically for YYALH, only one of two such EBIs in the CDC Compendium**: Inaddition to the TXTXT intervention there is only one other intervention in the CDC Compendium that has been developed for youth, adolescents, or young adults (Red Carpet program). See https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html Of note, the Red Carpet program is a structural intervention that was evaluated in an international setting for YLH and consisted of fast tracked peer navigation to support linkage to and retention in care.
2. **Leverage of collaboration with a systems-level HIV/AIDS service partner, MATEC, to promote medication adherence among racial/ethnic minority youth, who have thelowest rates of viral suppression**: This widescale implementation of an EBI in conjunction with an already existing HIV service infrastructure is a novel approach to HIV care.

3. **Systems-level Implementation Science Approach**: Implementing this EBI at the systems-level or regional scale with MATEC has the possibility of broadening the reachof such an intervention.
4. **Targeting a diverse set of clinics who partner with MATEC across the Midwest region who serve Black and Latinx youth with poor adherence**: This initiative will allow us to test the intervention throughout MATEC's network of clinics but also allowus to compare different types of clinics within the network (i.e., Ryan White Care Act clinics versus non-Care Act clinics).

Conceptual Framework

Implementation Science

Implementation Science is a critical new area of HIV prevention and intervention science which provides the frameworks and methods to effectively translate evidence to practice in the next era of HIVprevention intervention for public health impact.[23] As articulated by the CDC, a set of lessons learned from 20 years of diffusion of effective behavioral interventions (DEBI) and EBI projects will influence the next wave of dissemination and interventioninitiatives. Implementation Science (IS) frameworks and methods provide the tools to incorporate theselessons into IS initiatives.[23] Furthermore, IS approaches allow us to measure systems-level HIV intervention implementation, a promising, but much rarer form of implementation.[24] By systematically studying the factors that influence implementation at higher levels of implementation, as well as evaluating specific implementation outcomes, we can shift our focus from intervention efficacy to public health impact among those populations most affected by the epidemic, including racial/ethnic minority youth.

IS approaches are necessary to understand and inform the roll out and scale up of effective strategiesto increase ART adherence. IS studies have highlighted the need for multilevel interventions and diverse models of dissemination. Implementation science also provides relevant conceptual and measurement frameworks to guide a hybrid trial of clinical outcomes and implementation factors.[25-28]

The Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework is an evaluation and reporting scheme commonly used to examine the potential public health impact of an intervention.[29] Reach represents the number and representativeness of patients who participate out of theeligible patient population. Effectiveness is the impact of the intervention on participant outcomes.
Adoption is the number and representativeness of eligible staff/settings that agree to deliver the intervention out of all eligible staff/settings. Implementation is the fidelity to the intervention. Maintenance is the degree to which the intervention is sustained overtime. RE-AIM provides a usefulmeasurement framework for capturing both clinical and implementation outcomes within the same study.

Implementation science also provides relevant conceptual and measurement frameworks to guide an assessment of factors which influence implementation outcomes. We will use the Consolidated Framework for Implementation Research (CFIR), which has been used to guide the implementation and evaluation of numerous evidence-based health programs, synthesizes the concepts of several available models into five inter-related domains: intervention characteristics, outer setting, inner setting, characteristics of individuals involved, and the process of implementation, with several constructs in each domain. [25] CFIR accounts for the non-linear process of implementation and incorporates consideration of the adaptation that is required for different context.

Theoretical Framework of TXTXT Intervention

TXTXT uses a two-way daily text reminder and response system designed by the mentor of the current PI, Dr. Garofalo, to improve ART adherence for 16-29 years old U.S. adolescents and young adults.[18] Both HRSA and the CDC have designated TXTXT as an effective HIV treatment intervention for ART adherence (Appendix A-Text Messaging TXTXT (cdc.gov)). TXTXT is a theory-based intervention that is grounded in social cognitive theory. Social cognitive theory specifies a core set offactors and mechanisms that influence health behavior with a primary emphasis on self-regulation (i.e., the accuracy and consistency of self-observation and self- monitoring) and self-reflection, including self-efficacy.[30] Social cognitive theory holds that cognition, behavior, and environmental influences interact and are reinforcing. Self-regulatory functions, for example, are enhanced by facilitative environmental conditions, such as reminder systems. A key developmental task for youth living with HIV is to take responsibility for management of their health care. Text messages are a supporting external influence, which is expected to enhance self-regulation, specifically the feeling of control over one's ability to take medications as prescribed. Self-efficacy is the foundation of motivation and action. Receipt of text messages is expected to help overcome a key barrier to adherence, forgetting to take medication, which may increase self-efficacy and thus, motivation. Among youth living with HIV, motivation and self-efficacy are strongly related to adherence; arelationship which is likely to be mutually reinforcing.

STUDY OBJECTIVES

There are two specific aims for this research:

Aim 1

Determine the real-world effectiveness of a regional scale up of an EBI- TXTXT- among poorly adherent racial/ethnic minority YYALH, aged 16-35 years on our primary outcomes: adherence and viral load suppression at 3-month post initiation of the intervention; and secondary outcome: retention in HIV care, at 12-months post baseline.

Aim 2

Apply the Consolidated Framework for Implementation Research (CFIR) to describe the implementation process and identify barriers and facilitators needed to be addressed; and measure implementation outcomes of the TXTXT intervention using the RE-AIM framework (Reach, Efficacy, Adoption, Implementation, Maintenance).

AIM 1: RESEARCH QUESTION AND OBJECTIVES

Aim 1: Determine the real-world effectiveness of a regional scale up of an EBI- TXTXT- among poorly adherent racial/ethnic minority YYALH, aged 16-35 years on our primary outcomes: adherence and viral load suppression at 3 months post initiation of the intervention; and secondary outcome: retention in HIV care at 12 months post baseline.

RESEARCH DESIGN

The proposed research uses a cluster randomized controlled trial design to evaluate the effectiveness of TXTXT intervention on adherence and viral load suppression at 3 months post intervention initiation. A total of 12 clinic sites in the Midwest will be randomly assigned to either a 3- month observation period (i.e., comparison arm) or a 3-month intervention period (i.e., intervention arm). At the 3-month mark, sites randomized to the intervention arm will continue with the intervention for an additional 3 months, and sites initially assigned to the comparison arm will switch to the intervention for the 3 months. We will assess initial impact of the intervention by comparing the primary outcomes (i.e., ART adherence and viral load suppression) of the intervention arm to the comparison arm at 3-months post initiation of the intervention. This timepoint (3 months post baseline) was selected based on the findings of the randomized control trial used to establish efficacy of TXTXT.[18] The study will also compare pre-post differences in adherence and viral load suppression for participants in the comparison arm at 6 months post baseline. Secondary outcomes of retention in HIV care and sustained impact of the intervention will be evaluated at 12 months post-baseline. At 3 months, 6 months, and 12 months post baseline, electronic medical record (EMR) data from participating clinics will be used to determine viral load and retention in care measures.

METHODS

Audience and Stakeholder Participation

The Midwest AIDS Training and Education Center (MATEC) is the ideal partner and stakeholder for us to carry out the proposed project. The partnership with MATEC will not only ensure the feasibility of this project but will also serve as a valuable partner in future work to increase dissemination of effective interventions throughout the Midwest and via strategic connections to the larger AIDS Training and Education Center (AETC) network. MATEC has a 32-year history as an AETC covering 7 jurisdictions across a 10-state region and oversees 8 different federally funded projects in the Midwest. Further, MATEC leads a practice transformation cohort consisting of 13 Ryan White funded clinics with the goal of advancing plans to End the Epidemic by increasing testing, identification of PWH, linkage to and retention in HIV care, and increasing viral suppression. We sought collaboration with MATEC specifically for this project because they are a regional hub for capacity development among HIV/AIDS service providers in the Midwest.

Study Population

Poorly adherent racial/ethnic minority youth living with HIV aged 16-35 years inclusive of all gender and sexual identities and orientations, including young gay, bisexual and other MSM, young cisgender women and young transgender women across multiple clinic sites in the Midwest US.

Inclusion and Exclusion Criteria

Clinic site inclusion criteria

MATEC affiliated clinics in the Midwest region are eligible to participate in Aim 1 if meeting these criteria: (1) Clinic must have at minimum 40 current patients who are: racial/ethnic minority AND have a 'detectable' viral load AND are aged 16-35 years; (2) clinic must be willing to commit at least one staff person as lead for registering clients to receive the intervention, completing consent, and administering research surveys; (3) clinic must be willing to provide deidentified individual-level data for registered TXTXT participants, including viral load, retention in care (dates of clinic visits) at least twice per year; (4) clinic must not be using a competing medication reminder text messaging system; (5) clinic must be willing and able to rely on Lurie IRB. Once sites sign a memorandum of commitment, the study coordinator will schedule a conference call to conduct a standard of care questionnaire (Appendix K). The standard of care questionnaire will document existing clinic approaches to support adherence as well as any ancillary services (e.g., transportation assistance). This information will form a descriptive profile for each clinic.

Study Inclusion

For inclusion in the TXTXT intervention individuals must meet the following criteria: 1) diagnosed with HIV-infection and on ART regimen for at least one month (not new to ART); 2) aged 16-35 years; 3) have a viral load ≥200c/mL and/or report poor adherence (<90% of pills taken in the last 30 days); 4) able to receive text messages; 5) provide informed consent for research component; and 6) are a patient of a participating clinic

Study Exclusion

Exclusion criteria includes: 1) those who are unable to give informed consent 2) those who are participating in other studies that impact primary and secondary outcomes.

Procedures for Recruitment and Informed Consent

Aim 1: Youth living with HIV (aged 16-35 years) who meet study inclusion criteria will berecruited by study staff from participating clinics. The EMR will identify potentially eligible patients who will be invited to complete further study screening and enrollment.

We will ask each clinic to construct a list of eligible patients and carefully track outreach, screening, and enrollment on an enrollment log provided. Clinics may enroll up to 50 participants (to account for 20% attrition, final sample of 40 participants per clinic).

Participants will be contacted either by phone or in-person by staff members at participating clinics using the recruitment script/screener (Appendix C). If potential participants are interested in enrolling in the study (Aim 1), staff members at participating clinics which have received Institutional Review Board (IRB) certification will conduct eligibility assessment and consent conferences with participants. Potentially eligible participants will be contacted by clinic staff who will screen them for eligibility and further consent and enroll them if eligible (Appendix C). Those individuals who are ineligible will be thanked for their time.

Lurie Children's IRB will ensure that the consent forms meet institutional and funding source standards. Lurie Children's requires that research participants review and sign an informed consent form. Participants aged 16-17 years will sign an assent form (a waiver of parental consent will be obtained prior to study start). Participants aged 16-17 years are eligible to provide assent in all participating clinics. The informed consent forms include information about the overall purpose of the study, study procedures, potential risks, potential benefits to participating for individuals and society, alternatives to participating in the study, confidentiality of data,and contact information for the site's Principal Investigator and the IRB (Appendix L). Once informed consent has been obtained, the clinic staff will have the form reviewed by a fellow team member, who will confirm that it is fully completed before it is filed in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

Project staff will inform participants that they have the right to skip any questions that make them feel uncomfortable. Participants will be informed that participation is completely voluntary and that they are free to stop their involvement in the study at any time without any negative consequences. Participants can stop their text messages by replying "STOP" at any time or by calling the participating clinic to unenroll in the study. Participants will be informed of their rights to privacy and confidentiality and willbe told that their answers to the survey (collected via computer-assisted self-interview [CASI]) will be kept confidential and not shared withothers outside of the research staff. They will be informed that no information about them or provided by them during the research will be disclosed to others without their written permission, except if necessary to protect their rights or welfare (for example, if they are injured and need emergency care) or if required by law (i.e., child or elder abuse, harm to self or others).

Dependent on site randomization, intervention sites will sign up eligible participants to receive automated SMS messages from the DimagiCommCare platform. Participants will have the option to tailor the message content based on their own preferences and will be able to select to receive messages in English or in Spanish. The time the messages are delivered, and frequency will also be selected. Clinic staff will use the text message tailoring form to record tailored messages (Appendix D). Clinic staff will enter information from this form into the text messaging platform, and then test receipt of text messages by the participant before they complete this first intervention visit. If the participant choses a text message that discloses their HIV status, clinic staff will guide participants into selecting a discrete message and discuss options for alternate text. Participants at control sites will receive standard of care adherence counseling but will not enroll in text messaging until their site is eligible to receive the intervention. Messages used previously include, "Have you taken your vitamins

yet?" and "Don't forget!" The SMS platform is bi- directional and has an automated response system, so the participant is able to answer "1=yes" or "2=no"in response (press 1 or 2). When participants respond affirmatively, they will receive an encouraging message such as, "Great job!" However, when they respond with a "no" they will receive an acknowledging and encouraging message such as "You can do it!" (Appendix E).

Participants will be asked to complete a self-administered online survey at baseline, 3 months and 6 months post baseline. The survey will be hosted on REDCap and can be taken on a computer, tablet, or mobile phone. Participants will have the option of completing the survey remotely or coming to the clinic and taking the survey on-site (at a computer or tablet provided by the clinic). The online survey will be taken by both the intervention and comparison arm. The survey will measure demographics, self-reported ART adherence, HIV medication self-efficacy, barriers and facilitators of adherence, acceptability of TXTXT, and satisfaction (Appendix F). The survey CASI will be pilot tested with a small number of participants and adjusted as needed. Participants will also be asked to consent to release of specific EMR data to include viral load and attendance at HIV care visits.

At all study visits, staff will use the Fidelity Checklist to structure the visit and make sure that all procedures are followed (Appendix G). All study visits reflect the following general structure:

1. Complete intervention assessment
2. Complete standard-of care adherence counseling
3. Complete TXTXT Personalization form
4. Enter information into Dimagi platform (see Dimagi training, Appendix B)
5. Schedule date of next appointment
6. Build general rapport
7. Thank them for participation

As part of the initial visit, basic ART adherence education should be provided, based on the practices and/or protocols at each site. For example, if a site does not have a standard practicefor adherence counseling, at a minimum staff should review:

1. The current list of medications prescribed to each participant and how each medication should be taken (make sure they know how to take their prescribed medication).
2. In addition, basic facts on the importance of adherence should be reviewed with each participant, such as those described here: https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/54/hiv-medication-adherence

Retention

Retention will be facilitated through obtaining contact information for the participant during the initial stages of the enrollment process. To minimize participant and staff burden, the follow-up visits can be conducted virtually. Participants will be sent a personalized link to complete the follow-up survey via REDCap. Of note, there will not be financial reimbursement for participation in the

intervention as the goal of the project is to understand how TXTXT will work in the “real world” and inform wide scale routine implementation. Prior studies by Drs. Garofalo, Kuhns, and Johnson with vulnerable adolescent and other marginalized populations have maintained >80% retention. We will employ best practices in participant retention including: 1) collecting extensive locator information (multiple addresses/emails, phone numbers, social media profile names, etc.); 2) identification and discussion of difficult-to-reach participants and potential solutions during weekly team meetings; and 3) maintaining flexibility with mode of follow-up (e.g., in person options as well as internet based). Theinvestigative team and participating clinic staff will review the study team’s retention plans and will be asked for guidance on how to best keep YYALH engaged in the study for at least 6 months. No financial incentives will be provided to youth participating in the TXTXT intervention trial (Aim 1). At 3 months, 6 months, and 12 months post baseline, electronic medical record (EMR) data from participating clinics will be used to determine viral load; retention in care will be assessed for up to 12 months post baseline.

STUDY DESIGN AND DATA ANALYSIS

Study participation summary

1. 12 participating clinics randomized 1:1 into intervention or comparison arm
2. 50 participants at each clinic enrolled and complete baseline survey; baseline EMR data pulled
3. Participants at intervention clinics begin TXTXT after baseline survey and continue for 6 months
4. All participants complete a 3-month survey
5. Participants at comparison clinics begin TXTXT after 3-month survey and continue for 3 months
6. All participants complete a 6-month survey; 6-month EMR data pulled
7. TXTXT intervention stops at 6 months post baseline for all participants
8. 12-month EMR data pulled

Timepoint	Who	What	Data collected
zero	12 participating clinics	Randomized 1:1 intervention: comparison arm	
baseline	50 participants at each clinic	Participants at intervention clinics receive TXTXT Participants at comparison clinics do not receive TXTXT (i.e., standard of care)	EMR data Baseline survey
3 months	50 participants at each clinic	Participants at intervention clinics continue with TXTXT Participants at comparison clinics begin TXTXT	3-month survey
6 months	50 participants at each clinic	TXTXT stops for all participants	EMR data 6-month survey
12 months	50 participants at each clinic		EMR data

Sampling

We will ask each clinic to construct a list of potentially eligible patients and carefully track outreach, screening, and enrollment on an enrollment log provided. Participants (N=600, n=50 per each clinic site) will be enrolled.

The list of potentially eligible patients will be constructed from available EMR data and will be queried based on: (1) diagnosed with HIV; (2) age range (16-35 years); (3) most recent viral load obtained in past 12 months. If potential participants meet the first two criteria, they will be evaluated based on (#3) viral load data. The following scenarios are possible: 1) potential participant is virally suppressed; 2) potential participant is viremic (>200 copies/mL); 3) potential participant does not have viral load data available. Patients who are viremicand meet criteria 1-3 (HIV status, age) will be considered eligible for study inclusion and will be called by clinic staff to confirm eligibility and assess interest. Patients who meet criteria 1 and2 and are virally suppressed or missing viral load data will be contacted to assess eligibility - specifically, those who are virally suppressed will be queried about medication adherence (if <90% of pills taken in the past 30 days); for those who are missing viral load data they will be asked if they are willing to re-engage in HIV care and have labs drawn prior to enrollment (if so, they will follow steps outlined above for those with viral load

(VL) data). The list and eligibility assessment will be documented and reviewed on a weekly basis with individual sites to ensure timely enrollment into the study.

Data Analysis Plan and Variables

The data manager and study coordinator will review the Dimagi platform data reports,which include logs of all texts sent, received, responded to, as well as a log of "STOP" requests. These reports will be pulled by week and by clinic. The data manager and study coordinator will provide summary data to clinic sites as well as action items (e.g., follow up with "STOP" participants to inquire if they would like to discontinue from the study, or stop their messages for short time period). Summary statistics will be provided monthly as process data for the entire study team to review.

Sites in the control arm will continue the standard of care, which will include traditional adherence counseling. Data from the EMR will be gathered for both the control and intervention site participants to include viral load and visit attendance.

At baseline, univariate analyses will be used to characterize the sample; and bivariate analysis will be employed to explore any differences between groups (e.g., differences between clinics; age categories; sex). Fisher's Exact Test and χ^2 tests (for categorical variables) and t-tests (for continuous variables) will be used to identify demographic and behavioral factors associated with adherence and retention in care. Generalized linear models (GLMs) will be used to assess the effect of the intervention on the outcomes between the intervention and the control arm at 3 months and pre-post differences in the control arm after received the intervention at 6 months. GLMs can accommodate dependent variables with normal, binary, Poisson, and negative binomial distributions and can be adapted to incorporate random and fixed effects (generalized linear mixed models; GLMMs) to account for within-subject correlation among repeated measures over time.[31] The generalized estimating equation(GEE) can be used to compare 'average' population-level response to the intervention.[32] Potential confounding and effect modification by sociodemographic characteristics and location (defined by urban vs. rural residence) will be examined in exploratory analysis and these variables will be selected for inclusion in multivariable models based on statistical significance and conceptual importance. All models will account for correlation among repeated measures on individualsand within sites over time as appropriate. Inclusion of random effects for intercept and trend over time will be explored toassess subject-specific variability.

In order to assess feasibility, acceptability and satisfaction of the intervention we will use descriptive statistics using a combination of objective (e.g., rates of participation, intervention completion) and subjective measures (e.g., reported satisfaction, acceptability). In order to characterize adherence and retention in care throughout the course of the study, Kaplan-Meier survival curves will be used to measure time to adherence and retention, and Cox proportional hazard ratios will be used to assess whether individual-level factors are associated with shorter mean time to outcome. To measure reach ofthe intended participants, we will compare the study sample to those available in the sampling frame (proportion of those enrolled to those eligible). To measure adoption of clinic partners, we will evaluate the number of clinic partners who propose to continue with text messaging as adherence support post study (proportion of clinics who propose to continue TXTXT post study to total clinics). Satisfaction and acceptability will be measured by standard quantitative scales, summary total scores will be evaluated to determine whether or not ≥90% ratings were achieved.

Outcome definitions

Medication adherence**:** greater than or equal to 90% on self-reported visual analog scaler (non-adherence categorized at less than 90%)

Retention in care [33] : two visits 90 days apart in the past year will be considered retained in HIV care

Viral suppression [34] : VL < 200 copies/mL will be considered virally suppressed

Sample size, power calculation, and clinic scale up

A total of 12 clinics and up to N=600 YYALH will be enrolled in this study for evaluation purposes. Each clinic will be able to enroll up to 50 participants for a maximum total of 600 participants. We assume a 20% attrition rate, and therefore the sample size available for analysis will be N=480. Sites will be randomized to either a 3-month observation (i.e., comparison arm) or an immediate start intervention arm; at the end of the first 3-month period comparison arm sites will start the intervention for the 3 months and intervention sites will continue the intervention for an additional 3 months (6 months total). Pre-post EMR data, SMS data, and participant satisfaction data will be collected to determine efficacy, durability, maintenance and satisfaction (see expected outcomes). Rapid interim data analysis and interpretation will occur at 3 months. In Year 3, all clinics and participants (in both the initial control arm or intervention arm) will have their medical records abstracted In addition, de-briefing interviews will be conducted with clinic staff to assess implementation outcomes. Final analysis and sustainability plan will be conducted and elaborated.

This cluster randomized control study is powered to detect 20% difference in ART adherence (>90%) among participants receiving the TXTXT intervention and the control groups. . The power is calculated based on 3 levels hierarchical model design (i.e., randomization at the site level, two measures for each participant). The correlations between the participants within the site is assumed to be 0.05 and correlation within a participant is assumed to be 0.2. The proportion of participants with ≥ 90% ART adherence for the control group is assumed to be 25%, 35%, 45% and 55%. The effect size is assumed to be 10%, 20% and 25%. Given Type I error rate is 0.05, using the mixed model approach, the corresponding power is listed below.[35] The sample size with 6 sites in each arm and 50 participants from each site would have 80% power to detect 20% difference at 3 month post baseline.

Table 2: Power (6 sites in each arm, 40 participants from each site)

		proportion of participants with ≥ 90% ART adherence (Control)		
Effect Size	25%	35%	45%	55%
10%	0.30	0.29	0.28	0.29
20%	0.82	0.80	0.80	0.83
25%	0.95	0.94	0.94	0.96

Track Lessons Learned

Throughout the course of the project, all staff are encouraged to provide feedback and any "lessons learned" to the project coordinator or the investigative team (Johnson & Wagner). These lessons will help to improve the implementation of the TXTXT intervention for long term implementation and sustainability.

Track Costs

Clinic sites will be involved in the assessment of overall program costs to estimate the costs of implementing the intervention (Appendix M). Program costs will include personnel time, labor hours, wages, fringe benefits, materials and supply costs, office overhead and equipment costs, and the opportunity cost of any donated labor and in-kind services. Non-labor costs will include such costs as materials, supplies, travel, equipment, technology costs, and indirect or overhead costs that are attributed to the project. These overhead costs may include office rent, repair and maintenance, network connection and maintenance, telephone service, and shared office equipment. [36] The site-level data collection documents will be developed in consultation with IS experts (Ms. Benbow) and CDC SME (Carla Galindo) submitted for local IRB review and approval before data collection, fielding, and data analysis.

AIM 2: RESEARCH QUESTION AND OBJECTIVES

Aim 2: Apply the Consolidated Framework for Implementation Research (CFIR) to describe the implementation process and identify barriers and facilitators needed to be addressed; and measure implementation outcomes of the TXTXT intervention using the RE-AIM framework (Reach, Efficacy, Adoption, Implementation, Maintenance).

RESEARCH DESIGN

To explore the second aim qualitative data will be collected in the form of interviews fromparticipants and clinic staff members. The CFIR and RE-AIM frameworks will be used to evaluate the implementation of the TXTXT intervention.

METHODS

Audience and Stakeholder Participation

The Midwest AIDS Training and Education Center (MATEC) is the ideal partner and stakeholder for us to carry out the proposed project. The partnership with MATEC will not only ensure the feasibility of this project but will also serve as a valuable partner in future work to increase dissemination of effective interventions throughout the Midwest and via strategic connections to the larger AETC network. MATEC has a 32-year history as an AETC covering 7 jurisdictions across a 10-state region and oversees 8 different federally funded projects in the Midwest. Further, MATEC leads a practice transformation cohort consisting of 13 Ryan White funded clinics with the goal of advancing plans to End the Epidemic by increasing testing, identification of PWH, linkage to and retention in HIV care, and increasing viral suppression. We sought collaboration with MATEC specifically for this project because they are a regional hub for capacity development among HIV/AIDS service providers in the Midwest.

Study Population

Poorly adherent racial/ethnic minority youth living with HIV aged 16-35 years inclusive of all gender and sexual identities and orientations, including young gay, bisexual and other MSM, young cisgender women and young transgender women across multiple clinic sites in the Midwest US. Staff at the clinic sites will be asked to give feedback on the implementation of the EBI. Staff must be 18 years or older, currently employed at the clinic site, have participated in the implementation of the EBI, and speak and understand English.

Inclusion and Exclusion Criteria

Study Inclusion

CFIR Participant Feedback

To provide feedback on the intervention, individuals must meet the following criteria: 1) 16-35 years old;

2) current HIV care patient of clinic site; 3) HIV positive as identified by the EMR; 4) speak and understand English; 5) have aviral load >200c/mL; and 6) participated in the TXTXT intervention.

CFIR Staff Feedback

Staff are eligible to provide feedback if they are: 1) 18 years of age or older; 2) currently employed at theclinic site; 3) have participated in the implementation of the TXTXT; 4) speak and understand English.

Study Exclusion

Exclusion criteria includes: 1) those who are unable to give informed consent; and 2) those who are participating in other studies that impact primary and secondary outcomes.

Procedures for Recruitment and Informed Consent

Youth participants and clinic staff will be recruited to participate in implementation science surveys and interviews; youth participants will be referred to investigators from participating clinic staff; Ms. Wagner and Mr. Gosset will identify potential staff participants.

When potential participants are interested in enrolling in the study (Aim 2), members of the research team will conduct eligibility assessment and consent conferences with participants (Appendix K). Participants who are aged 16-17 years will complete informed assent; a waiver of parental consent will be obtained. Lurie Children's IRB will ensure that the assent/consent forms meet institutional and funding source standards. Lurie Children's requires that research participants review and sign an informed assent/consent form. The informed assent/consent forms include informationabout the overall purpose of the study, study procedures, potential risks, potential benefits to participating for individuals and society, alternatives to participating in the study, confidentiality of data, incentive for participation ($40), and contact information for the site's Principal Investigator and the IRB (appendix K). Once informed consent has been obtained, the clinic staff will have the form reviewed by a fellow team member, who will confirm that it is fully completed before it is filed in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

No identifying information is collected prior to informed assent/consent. Assent or consent is conducted in person, in a private room, by trained staff. Trained clinic staff will proceed through each component of the consent, written to Federal OHRP standards with 8th grade or below reading level. We will obtain a waiver of parental consent for participants aged 16-17 years. For potential participants aged 16-17 years, the staffreviews the assent to make a formal assessment of the youth's decisional capacity to consent prior to signing, using a 2-step process. First, the staff person determines if the person understands the study goals by asking "Can you tell me what this study is about?" In step 2, potential subjects will be asked questions designed to assess their capacity to understand, appreciate, reason with, and express a choice about participation in our specific protocol. We will use a modified version of the widely used Evaluation to Sign Assent/Consent Form: Subjects are asked to: (1) name things they will be expected to do during the study, (2) explain what they would do if they no longer wished to participate in the study, (3) explain what they would do if they experienced distress during the study and (4) identify potentialrisks for participating in the study. Respondents will be enrolled only if they are able to provide clear and correct answers to each of these items. If staff feel there is a question about the need for a more formal assessment of the decisional capacity of a potential participant, they will contact the principal investigator, who may refer the participant to medical or psychosocial services for evaluation.

Project staff will inform participants that they have the right to skip any questions that make them feel uncomfortable. Participants will be informed that participation is completely voluntary and that they are free to stop their involvement in the study at any time without any negative consequences. Participants can stop their text messages by replying "STOP" at any time or by calling the participating clinic to unenroll in the study. Participants will be informed of their rights to privacy and confidentiality and willbe told that their answers will be kept confidential and not shared with others outside of the research staff. They will be informed that no information about them or provided by them during the

research will be disclosed to others without their written permission, except if necessary to protect their rights or welfare (for example, if they are injured and need emergency care) or if required by law (i.e., child or elder abuse, harm to self or others).

Retention

Aim 2 participation is a single point in time, and therefore retention metrics will not be tracked.

Sampling

Feedback will be collected from up to 60 participants. The study coordinator based at MATEC will work with participating clinics to randomly select 4-5 participants from their enrollment log. Potential participants will be invited to participate in this additional interview (Appendix H & I). Participating individuals will complete a short open-ended questionnaire that collects information regarding the CFIR constructs (Appendix J). [37] The interview will last up to 30 minutes. Feedback will also be collected from up to 24 clinic staff at participating sites (1-2 staff per clinic). Staff are eligible to provide feedback if they are:1) 18 years of age or older; 2) currently employed at the clinic site; 3) speak and understand English.Clinic staff will be interviewed by the study coordinator or Dr. Johnson to determine what barriers and facilitators existed at each site that may have impacted the intervention. The interview will focus on the CFIR dimensions of inner setting, outer setting, intervention characteristics, individual characteristics, and process of implementation (Appendix J).The interview will last up to 60 minutes.

Data Analysis Plan and Variables

Analysis of qualitative interview data will be led by Dr. Johnson. Qualitative data will be audio recorded, transcribed verbatim then uploaded to Dedoose – a cloud-based flexible and adaptive qualitative analysis program. [38] After open coding 20% of the transcripts, Dr. Johnson will create a codebook providing clear definitions and examples for each code. Transcripts will be analyzed using a directed content analysis approach. [39] The coding team (Dr. Johnson, Ms. Cervantes) will establish and maintain high inter-rater reliability (80% agreement).[40] Expert consensus (Drs. Garofalo, Kuhns, & Rivero) will be used to address coder disagreements. This structured analysis uses existing theory and prior research to guide the identification of key concepts or thematic categories. After coding, Dedoose will be used to further categorize and visualize the data; organizing codes into frequency tables by participant and clinic descriptors to determine the occurrence and co-occurrence of codes in the sample.

Univariate analyses will be used to characterize and describe the sample and results from the quantitative survey.

RISKS TO HUMAN PARTICIPANTS (Aim 1 and Aim 2)

The largest risk to participants is a breach of confidential information.

In Aim 1, participants will be advised to delete the messages they receive from the Dimagi CommCare platform as a method of protecting the participant's HIV status. Participants will also be guided to select a personalized text message that does not disclose their HIV status ("remember to walk the dog", "you're your vitamins", "read your horoscope", etc.). Additionally, participants will walk through safe guarding their cell phones including how to activate passcodes and biometrics, as well as what to do if they lose their cell phone, get a new number, or switch providers (contact clinic study staff to update dimagi platform).Participants will also be advised that assessment questions may make them uncomfortable, howeverthey can skip any question they choose not to answer.

In Aim 2, we will follow best practices to maintain confidentiality of participants, inclusive of staff and youth participants. Further, we will report findings in aggregate and will not use identifiers in qualitative quotes to ensure the identities of our participants remain confidential. In reporting qualitative findings, inclusive of quotes, we will use only study ID. Finally, we will not report back to clinics which staff or participants have enrolled in Aim 2.

Potential Risks (Aim 1 and Aim 2)

Also see "data and safety monitory" subsection for details on adverse event reporting.

Potential risks to participants primarily consist of 1) feelings of discomfort or being upset as a result of the questions posed in the assessments and 2) breaches of confidentiality; however, the study does not involve any medical procedures, and the overall risk of harm to the participant is considered minimal. Participants are free to refuse to answer any question or not complete any intervention activity and mayterminate participation in the study at any time. All information disclosed to the research team (including clinic site staff) will remain confidential.

Adequacy of Protection against Risk

As in any study, there is always risk of inadvertent breach of confidentiality. Teams at Lurie Children's and MATEC have been involved with numerous local and national studies and have considerable experience implementing measures to protect confidentiality. Some of these steps include signed confidentiality agreements, in-service trainings on confidentiality, and the assignment of study ID numbers. Staff who conduct participant recruitment, screening, enrollment, and assessments are requiredto be trained in ethical human subject research and screening and interviewing techniques, to minimize participant risk as much as possible.

If an individual reports coercion, staff should report this to the PI (Dr. Johnson) within 24 hours. The PI will review the incident, and follow the standard protocol for handling such occurrences, including

notification to the local IRB, as warranted. See “Data and Safety Monitoring” section for additional detail on adverse events.

Because there is potential for psychological discomfort due to the research topic, we will make everyeffort to create a secure environment (ensuring privacy) prior to conducting baseline and follow-up assessments, participants will also be able to complete the brief follow-up assessment remotely.
Participants will be told that they do not have to answer any question they do not wish to. Participants experiencing mild distress during the assessments will be offered a small break or rescheduled to complete the assessment at a later date. In the unlikely event that a participant experiences considerabledistress we will make a referral (if needed) for clinical assessment and/or counseling. Participants will be given the names and office phone numbers of the study investigators and will be provided with referrals for mental health and support services.

Additionally, Dr. Johnson will be on-call for any serious problems that arise during assessments.

Incentive and risk of undue influence

Aim 2 participants will receive a $40 incentive for their participation. Aim 1 study participants will not receive a monetary incentive as the purpose of the study is to implement the EBI as a program todetermine if regional scale up is possible. Any study that pays an incentive may unduly influence participant behavior. Eliminating the all risk of undue influence by not awarding incentives would make it impossible to conduct many studies, and would shortchange subjects who provide time and energy, and may incur costs such as bus, train or car fares. The resolution to this problem is to ensure that incentives are not inappropriately large, to probe potential subjects to make sure they have not been influenced by the incentive, and to give persons who may have been coerced the opportunity not to enroll in the study in a manner that will protect them from retribution by the person coercing them. We believe we meet these conditions.The incentive we proposed is in use now in other studies at the lead site and has been reviewed by our own and other IRBs and deemed to not be unduly influential.

PROPOSED BENFITS TO PARTICPANTS

Individual participants may benefit from increased viral suppression, medication adherence and retention in care. Possible risks (i.e., discomfort answering questions, potential confidentiality breeches) are outweighed by the potential impact of sustained viral suppression among YYALH.

PRIVACY AND CONFIDENTIALITY

Certificate of Confidentiality
Consistent with Section 301(d) of the Public Health Service Act, a Certificate of Confidentiality (CoC) applies to this research because this research is funded, conducted, or supported by CDC and the following is true:

1. The activity constitutes biomedical, behavioral, clinical, or other research;and
2. The research involves information about an individual for which there is atleast a very small risk, that some combination of the information, a requestfor the information, and other available data sources could be used to deduce the identity of an individual

Therefore, CDC and any of its collaborators, contractors, grantees, investigators or collaborating institutions that receive "identifiable, sensitive information" as defined by subsection 301(d) of the Public Health Service Act shall not:

1. Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding "identifiable, sensitive information" that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
2. Disclose "identifiable, sensitive information" or provide ISI to any other person not connected with the research.

Disclosure is permitted only when:

3. Required by Federal, State, or local laws (e.g., as required by the Food, Drug and Cosmetic Act or required by state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
4. Made with the consent of the individual to whom the information,document, or biospecimen pertains; or
5. Made for the purposes of other scientific research that is in compliance withapplicable Federal regulations governing the protection of human subjects in research.

CDC and its collaborators and contractors conducting this research will establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the research is managed in compliance with subsection 301(d) of the Public Health Service Act. CDC will ensure: 1) that any investigator or institution not funded by CDC who receives a copy of identifiable, sensitive information protected by this Certificate, understands that it is also subject to the requirements of the Certificate; and 2) that any subrecipient that receives CDC funds to carry out part of this research involving a copy of identifiable, sensitive information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act. Therefore, all study staff will receive training on the importance of protecting the confidentiality of human research subjects and of personal information acquired, including the collection of biological specimens.

All research subjects will be informed of the protections and the limits to the protections provided by this Certificate through the informed consent process. All study staff who obtain consent from

study subjects will be trained on how the Certificate protects the information collected and the limitations ofthe Certificate's protections.

We have developed systematic protocols for data handling and storage over multiple cohort and intervention studies. We maintain both paper files and computer files for each participant. Paper files primarily include locator information and informed consent but may also contain other paper data collection forms. The first two have identifying information and are linked to the data by the patient identification number (PID). To protect the integrity of the participant's data, the study coordinator willassign each individual a unique PID at study enrollment. This code number will be used for all study data. We will maintain a list of participants with links between identifying information and PIDs for the purpose of avoiding any duplication in enrollment. Only research staff will have access to these lists, which will be kept behind double-locks or on a secure server with password-protected access. Consentswill be stored in a locked cabinet away from workstations and will only be accessed in the event of a consent amendment or an audit. Locator files are kept in a locked cabinet in the research area, separate from data files, and are updated monthly and at each research visit.

Computer files consist of the tracking database (locator information for study follow-up) and study datafiles.

Tracking files are maintained in a highly secure scheduling and monitoring database. This database contains all contact information and is used to schedule and track study visits; it is password protected and is not accessible via Internet or wireless devices. The tracking database stores contact preferences;all communications strictly follow the participants' contact guidelines(e.g., contact via text message only). The tracking database does not contain any clinical or research-based information; it only has information the participant agreed to provide for the purposes of tracking and communication.

Computer-assisted self-interview (CASI) study data will be collected by REDCap, a high-quality online survey software tool which uses Transport Layer Security (TLS) encryption (also known as HTTPS) forall transmitted data. Data files are securely exported from REDCap and imported into Stata databases for storage and analysis. Computer data files never have any identifying information and are encrypted for transfer between study sites. Data files do not include information that could be used to identify the participant from the data file alone.

Dimagi Commcare is HIPAA-compliant; no health information will be stored in the Dimagi platform. This is a secure system and will be further protected by login credentials for limited access, to protect confidentiality. Staff will only access Dimagi to register participants for text messages; Dr. Johnson, the data manager (Ms. Cervantes), and Co-Investigator Dr. Kuhns will have access to the SMS data (number of texts received; number responded) via encrypted, password protected files.

DATA AND SAFETY MONITORING PLAN

Lurie Children's (Ms. Cervantes, supervised by Dr. Johnson) will be responsible for computerized survey programming, data capture, management and analysis. All study information will be identified

through the PID on all forms and computerized files. Computer data files will never contain any identifying information and are encrypted prior to transfer between study sites. All SMS-related data will be securely stored by Dimagi per their HIPAA-compliant privacy policy.

Data entered into the Stata databases will not include any identifying information. Only authorized userswith a password will be able to open up the computerized survey, and only those with administrative privileges (i.e., login name and password) will be able to access data. The study staff will use a passwordto gain access to the software in order to administer it to a participant, but they will have no ability to access the saved data. The Data Manager will set up the database, check data quality, and prepare the data for use. In addition, the database, data structure, and data quality will be routinely reviewed by Dr. Johnson. Data quality will be examined before statistical analyses are conducted, including examinationof missing data, assessment of distributional assumptions, and identification of outliers.

All proposed staff have participated in the NIH required trainings for conduct of studies that involve human subjects, and any future study staff will do so upon hiring. Training for all staff includes (but is not limited to) Human Subjects, Informed Consent, Good Clinical Practice, Quality Management, and Confidentiality and Reporting of Adverse Events. If any study staff discovers an untreated condition in a patient (e.g., onset of physical or mental health condition),they will refer participants to appropriate treatment immediately.

Per guidance provided by the Office of Human Subjects Research at the NIH, an adverse event (AE) is any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent atbaseline, or, if present at baseline, appears to worsen. A serious adverse event (SAE) is defined as untoward medical occurrences that:

1. result in death
2. are life threatening
3. require (or prolong) hospitalization
4. cause persistent or significant disability/incapacity
5. result in congenital anomalies or birth defects or
6. are other conditions, which in the judgment of the investigators represent significant hazards.

Potential AEs that are unanticipated will be brought to the attention of the study PI and reported immediately to the IRB. All study staff will be trained to recognize and report AEs and SAEs. Possible adverse events will immediately (within 24 hours) be reported to the PIs by the study staff who identify the event. The study PIs will report the AEs and SAEs to the IRB in writing as soon as possible, but within 7 calendar days for death or life-threatening events, and within 15 calendar days for all other AEsor SAEs. The IRB will determine whether it is appropriate to stop the study protocol temporarily or will provide suggestions/modifications to the study procedures as necessary. Possible modifications include adding these possible adverse events to the consent form and re-consenting all study participants. The PIs will be responsible for monitoring participant safety on a monthly basis at regularly scheduled research meetings. They will keep a written log of all events and ensure that the IRB is contacted

immediately. They will also keep a log of the outcome of IRB decisions regarding AEs and apprise the research team of any changes that need to occur as a result of IRB decisions.

Protocol violations are any unapproved changes, deviations, or departures from the procedures of the research study that have not been reviewed and approved by the IRB. Major protocol violations are those that may affect participants' rights or safety, or the completeness, accuracy, and reliability of the study data.
Major violations will include any of the following:

1. The violation has harmed, or posed a significant or substantive risk of harm, to the research participant
2. The violation resulted in a change to the participant's clinical or emotional condition or status
3. The violation has damaged the scientific completeness or soundness of the data collected for the study
4. The violation is evidence of willful or knowing misconduct on the part of the investigator(s)
5. The violation involves serious or continuing noncompliance with federal, state or local regulations

Minor protocol violations are those that do not impact or harm participants, including:

1. The violation did not harm or pose a significant risk of substantive harm to the research participant
2. The violation did not result in a change to the participant's clinical or emotional condition or status
3. The violation did not damage the completeness, accuracy and reliability of the data collected for the study
4. The violation did not result from willful or knowing misconduct on the part of the investigator(s)

Study staff will be trained to identify and report all protocol violations to the study PI. The Study PI will determine if the violation is major or minor, will report to the IRB, and will follow up with a plan of corrective action in consult with the IRB.

Data Safety and Monitoring Board

There will not be an appointed data safety and monitoring board.

Data sharing

All data from the project will be made available as de-identified datasets to internal and external investigators requesting access. Data will be made available once primary analysis has been completed,to ensure data cleaning, accuracy, and completeness. The de-identification will include ensuring no protected health information or other potentially identifying information is available in the data set. Allthose who request data sets will be required to sign a confidentiality and data use agreement that will outline agreed upon use and storage of the de-identified data. The CDC will be provided a copy of the de-identified datasets as required at the end of the funding period. Finally, Dr Johnson will be responsible for maintaining a log of requests for data sharing and for sending data via encrypted and secure methods.

IMPORTANCE OF KNOWLEDGE TO BE GAINED

YYALH, particularly racial/ethnic minority youth, have the lowest rates of viral suppression among people living with HIV. Effective interventions exist to support adherence and should be scaled up to ensure equitable access. This proposal addresses these gaps and disparities by scaling up TXTXT, a CDC EBI, in the Midwest via a regional hub model with an established AIDS Education and Training Center (AETC), the Midwest AETC (MATEC). By using both a CDC EBI and HRSA AETC, we buildon existing infrastructure, to test an implementation approach with potential for nation-wide scale up. We will simultaneously evaluate effectiveness at the regional level, as well as both the implementation process and outcomes and will engage YYALH, health care providers, and other key stakeholders in theimplementation evaluation. This proposal is in line with the Ending the HIV Epidemic research agenda, specifically in efforts to reduce the incidence of HIV, advance cross cutting areas of research, and targeting high risk populations. This study combines behavioral and social science, implementation science, and information dissemination towards the ultimate goal of public health impact. Medication adherence is a key driver of viral suppression and this regional TXTXT initiative, with a longer-term objective of national dissemination and focused on patients at most risk of not achieving viral non- suppression will directly address local, regional, and national goals to End the Epidemic by 2030.

DISSEMINATION AND DATA ACCESS AND MANAGEMENT PLAN

Ann & Robert H. Lurie Children's Hospital of Chicago and the investigative team are committed to the open and timely dissemination of research outcomes. The investigative team has an extensive portfolioof publications, including peer-reviewed manuscripts and book chapters, and national and international conference presentations.

If effective, the scale up of TXTXT has the potential to impact viral load and HIV transmission among racial/ethnic minority youth and young adults in the United States. A multi-faceted dissemination and translation plan targeting various stakeholders is proposed. We will disseminate our findings to both clinical, community and academic audiences, via the following strategies:

1. Members of the research team will present the results of the study in a number of different venues targeting different audiences, including conferences such as the annual meeting of the American Public Health Association, at regional meetings such as HIV planning bodies and Departments of Public Health, and at ID week/grand rounds at regional academic institutions/hospitals.
2. We will present at CDC seminars, group site visits, and symposia to share interim findings
3. We plan to publish our results in appropriate high-impact peer reviewedacademic journals.
4. We will create a lay summary to publish on our website, disseminate to community partners, and circulate through the AETC network.

In addition, Lurie Children's maintains a website to disseminate relevant information about researchstudies conducted by Lurie Children's faculty. Summaries of the scientific presentations will be posted on this website on a regular basis, written primarily for a general audience. All final peer- reviewed manuscripts that arise from this proposal will be submitted to the digital archive PubMed Central.

In addition to disseminating project outcomes the study team will also develop an implementation strategy to integrate TXTXT into HIV clinical care. Guided by the Consolidated Framework for Implementation Research (CFIR), [37,41] we will meet with key staff from participating sites to review the de-identified/aggregated study data and to identify factors that will facilitate or impede the integration ofTXTXT and develop recommended procedures that will facilitate uptake and delivery (e.g., training, monitoring, supervision). In collaboration with MATEC, we will create and disseminate a recommended workflow that will facilitate ease of integration into clinics. Finally, we will create templates, tasks lists, and streamlined processes for patients and providers to guide integration of TXTXT into the clinic flow/care plan.

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APPENDICES

APPENDIX A: TXTXT Intervention Description

TEXT MESSAGING INTERVENTION TO IMPROVE ANTIRETROVIRAL ADHERENCE AMONG HIV-POSITIVE YOUTH (TXTXT)

Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Target Population
- HIV-positive adolescents and young adults with poor medication adherence

Goals of Intervention
- Improve adherence to antiretroviral therapy

Brief Description

Text Messaging Intervention to Improve Antiretroviral Adherence among HIV-Positive Youth (TXTXT) is an individual-level intervention for HIV-positive adolescents and young adults with poor medication adherence. The intervention consisted of daily youth-friendly 2-way text messages delivered over 6 months. Text messages were used to remind participants to take their medication and confirm that the medication was taken. Intervention participants tailored and personalized text message reminders to their medication regimen, including the number and time of dosages. Text message reminders and follow-up messages were also personalized to reflect content meaningful to their culture or other sources of identity. To protect confidentiality, intervention participants were encouraged to delete messages after taking medication, use messages that would not reveal their HIV status or mention medication, and received information about phone confidentiality (e.g., passcode protection). Message delivery was timed to coincide with the participant's dosing schedule. Youth-friendly motivational or encouraging follow-up messages were delivered that were based on the youth's responses to taking their medication (e.g., "Well done!" or "You can do it!"). All text messages were sent to participants' personal cell phones.

Theoretical Basis
- Social Cognitive Theory

Intervention Duration
- Daily text message reminders delivered over 6 months

Intervention Setting
- Anywhere participants had access to their cell phone

Deliverer
- Text messages delivered by Remedy Health Media

Appendix B Training Material

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TXTXT CommCare Platform Training

Brothers Health Collective

The Potocsnak Family Division of Adolescent and Young Adult Medicine

November 12th, 2019

Fundamentals

What is Dimagi and CommCare?

1. Dimagi is a software technologycompany that designs clinical interfaces and health information systems

2. 

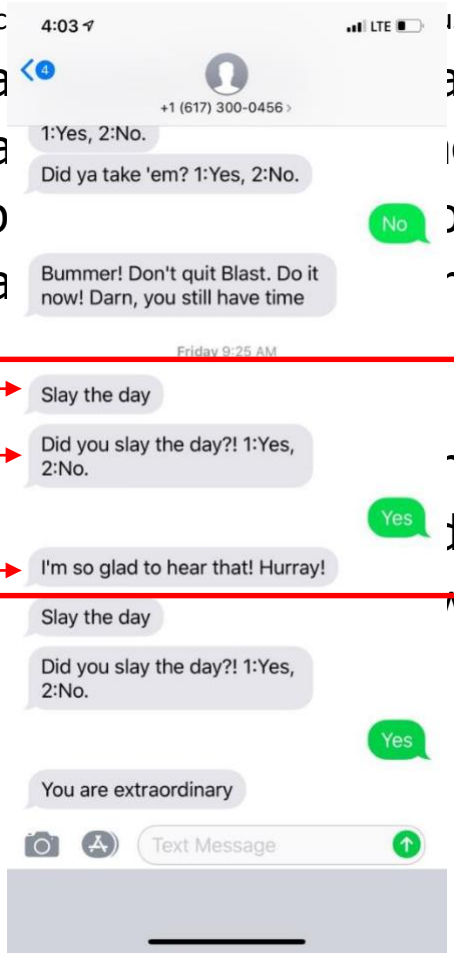
oroducts
ed tocreate apps for various purposes
ent management, decision support, etc.

3. o the text

What does the TXTXT App do?

1. Bidirec ised to address ART adherence. Registering a client in theapp means they:

1. receive a age
2. receive a ge 15m later
   1. resp ”
3. receive a nessage



1. lient:
   1. nder and question text
   2. daily texts
   3. weekly text

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Children's Hospital of Chicago®

Two User Roles

Two User Roles: App User and Admin

Mobile Worker: The TXTXT App

1. App User
2. Register a case (i.e., client/participant) to they can start receiving text messages
3. Revise text message preferences for a previously registered case

Web User: CommCareHQ

4. Admin
5. Monitor text message history for all cases
6. Download aggregate text message data
7. Manage Mobile Workers and Web Users
8. Managing the system and users

Two User Roles: App User and Admin

Mobile Worker: The TXTXT App

9. App User
10. Register a case (i.e., client/participant) to they can start receiving text messages
11. Revise text message preferences for a previously registered case

12. Anyone who will register clients into the system to receive messages will need aMobile Worker account

Web User: CommCareHQ

13. Admin
14. Monitor text message history for all cases
15. Download aggregate text messagedata
16. Manage Mobile Workers and Web Users
17. Managing the system and users

18. Only the few people who will monitor study progress, run data queries, and manage users need a Web User account

Two User Roles: App User and Admin

Mobile Worker: The TXTXT App

19. App User
20. Register a case (i.e., client/participant) to they can start receiving text messages
21. Revise text message preferences for a previously registered case
22. Anyone who will register clients into the system to receive messages will need aMobile Worker account

Anything other than registering a client or updating a client's preferences requires a Web User account

Web User: CommCareHQ

1. Admin
2. Monitor text message history for all cases
3. Download aggregate text messagedata
4. Manage Mobile Workers and Web Users
5. Managing the system and users
6. **Only the few people who will monitor study progress, run data queries, and manage users need a Web User account**

Two User Roles: App User and Admin

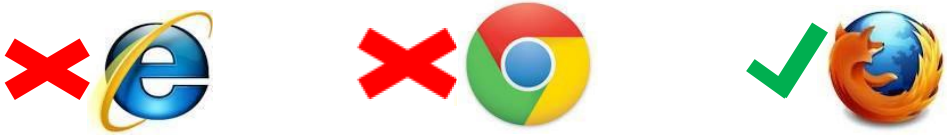
You log in as a Mobile Worker and Web User using the samelanding page, but with different credentials

1. Mobile Worker
    1. Username: created for you by Web User
    2. Password: created for you by Web User

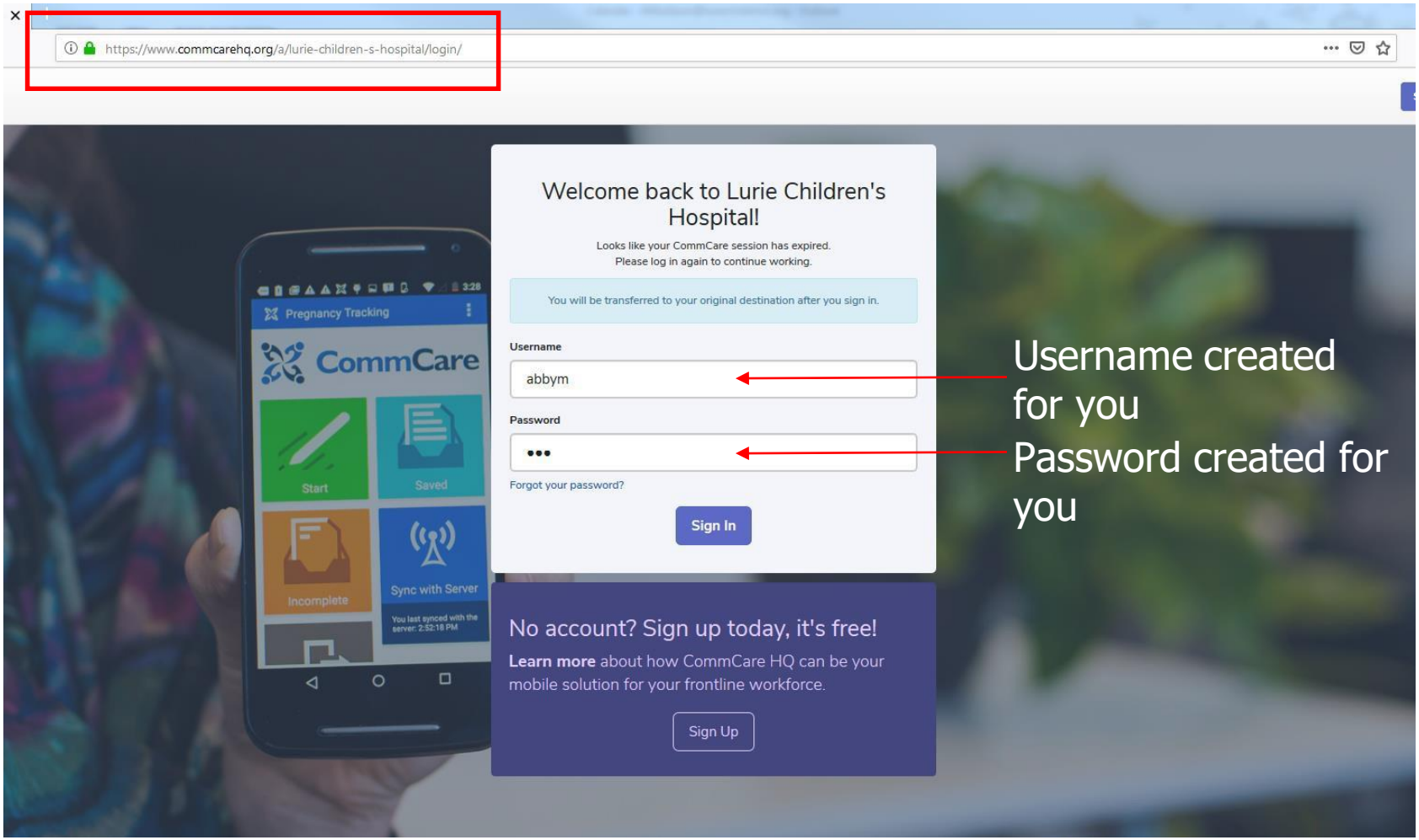
Logs into TXTXT App

1. Web User
    1. Username: Email
    2. Password: you set it up after youare invited via email to be a WebUser

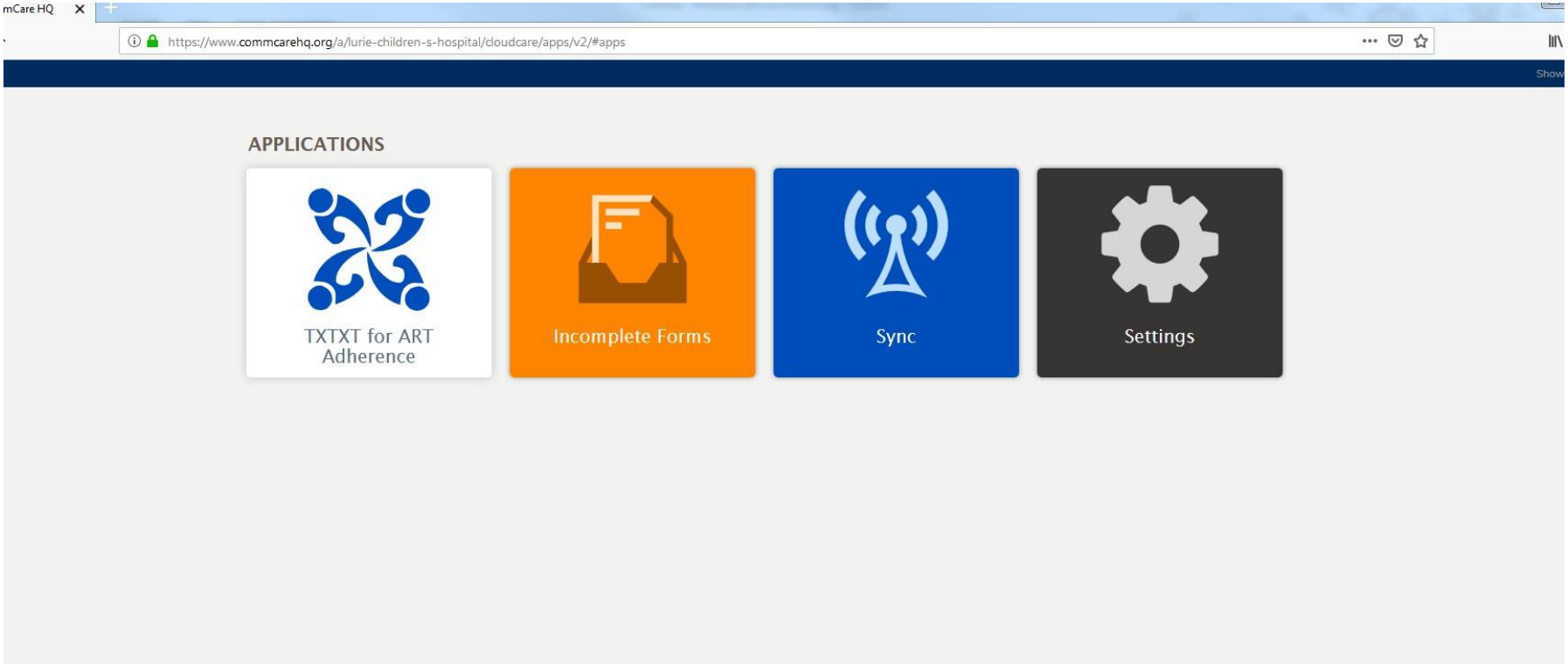
Logs into CommCareHQ



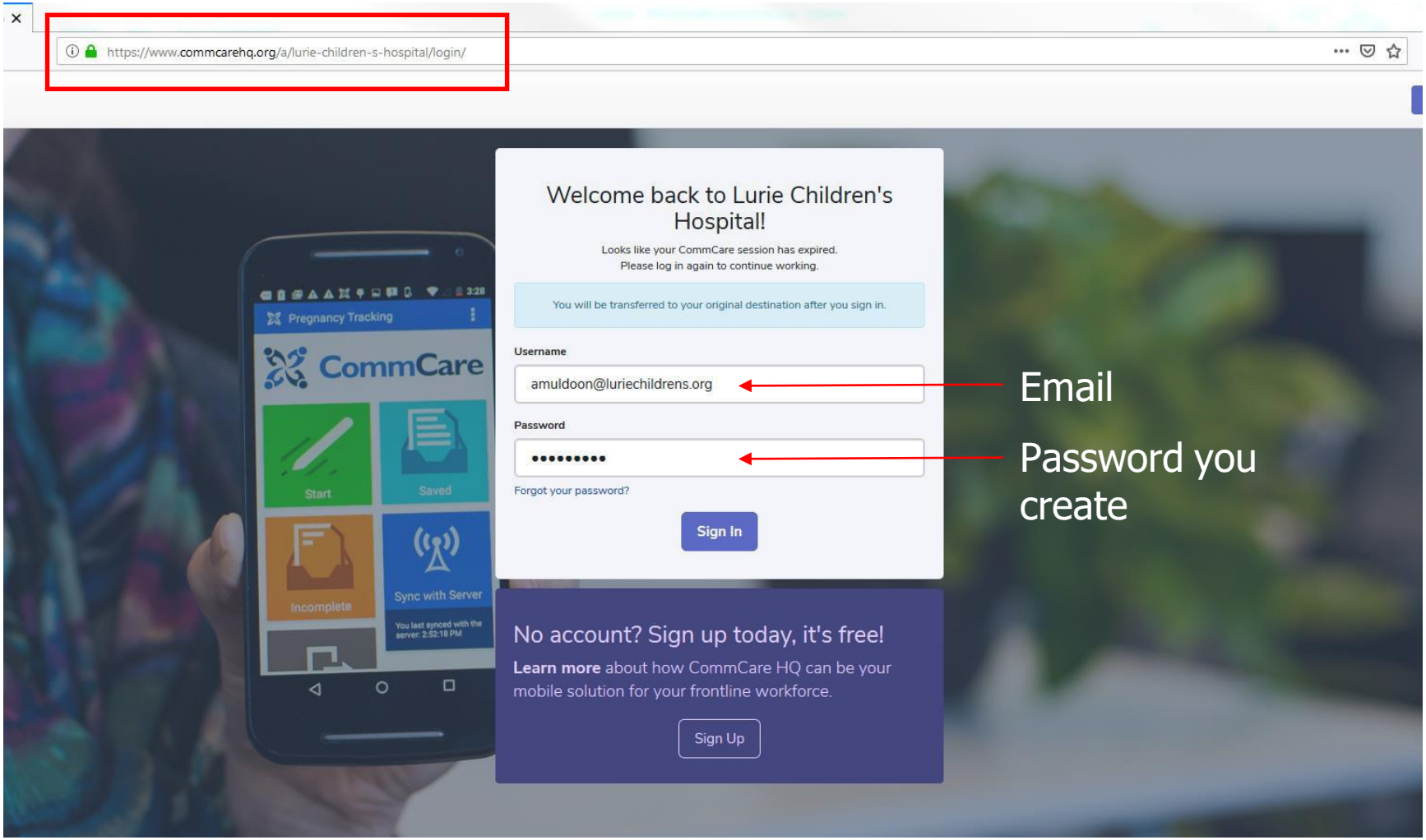
Two User Roles:
TXTXT App as a Mobile Worker



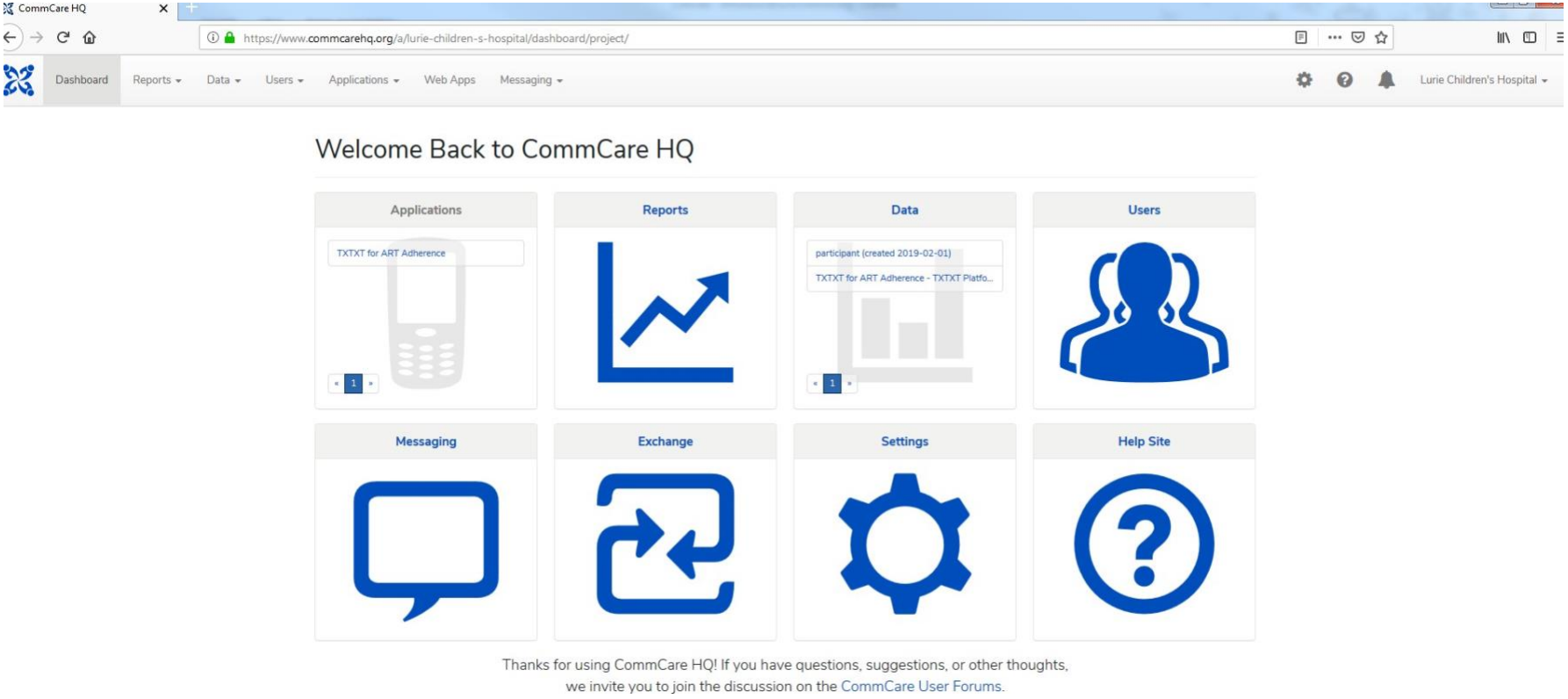
Two User Roles:
TXTXT App as a Mobile Worker



Two User Roles: CommCare HQ as a Web User



Two User Roles: CommCare HQ as a Web User



Two User Roles

1. Mobile Worker
    1. Logs you into the TXTXT App
    2. Deploy the system and use the app
    3. Register case to receive text messages
2. Web User
    1. Logs you into CommCareHQ
    2. Admin access to the system
    3. Manage all cases and access data

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Mobile Worker Task 1 of 2:Registering a case in the TXTXT App

The TXTXT App

1. Registration Form
    1. Collect essential participant information, including phone number
        1. PHONE NUMBER IS VERIFIED TO BE UNIQUE IN THE SYSTEM
    2. Set up daily and/or weekly SMS reminders
        1. Up to three times may be selected for daily reminders and one time for weekly
    3. Set-up the content of the initial message and of the follow-up question
2. Follow-Up Form
    1. Edit any information originally collected in the Registration form
        1. EXCEPT Participant ID

Two User Roles:
TXTXT App as a Mobile Worker

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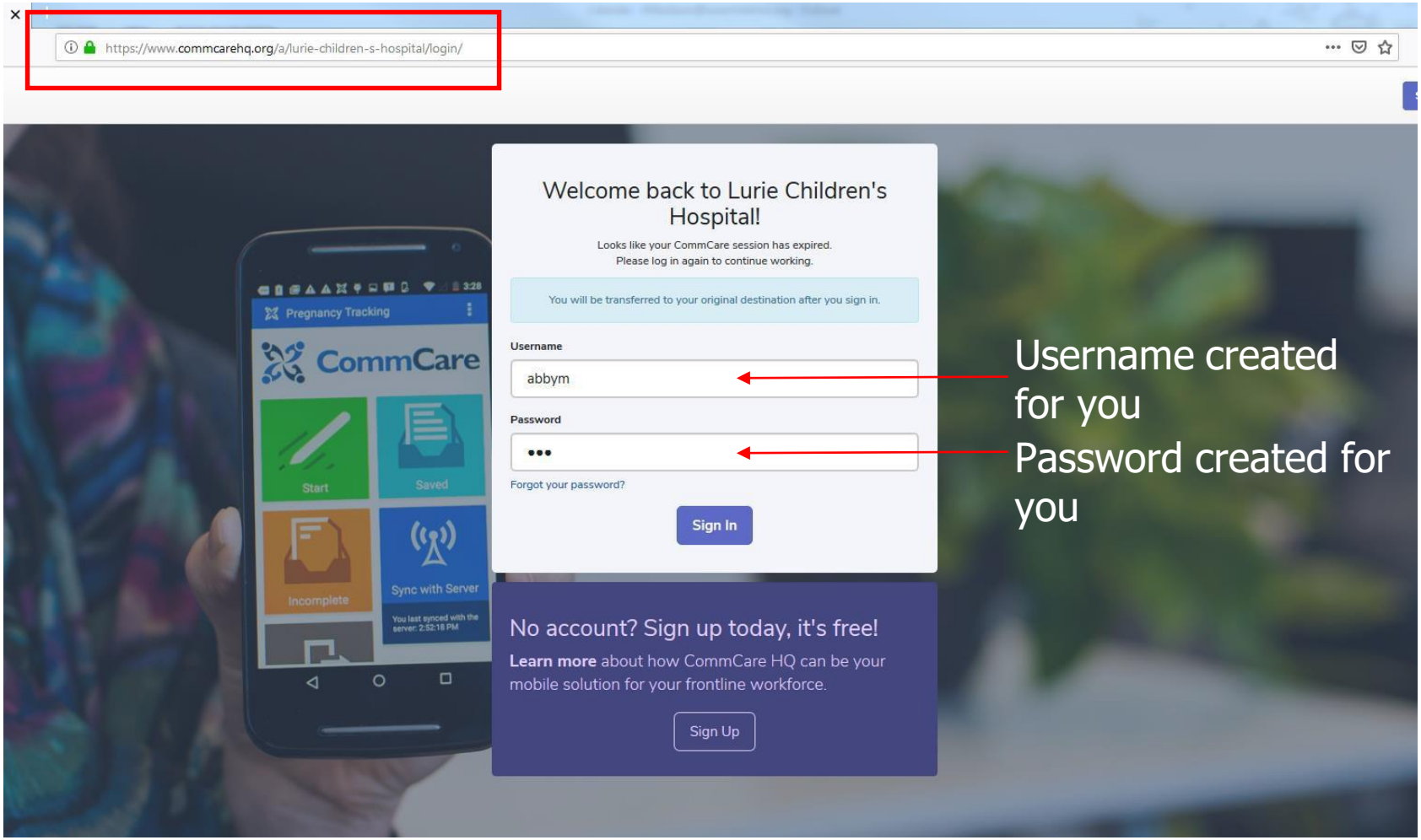

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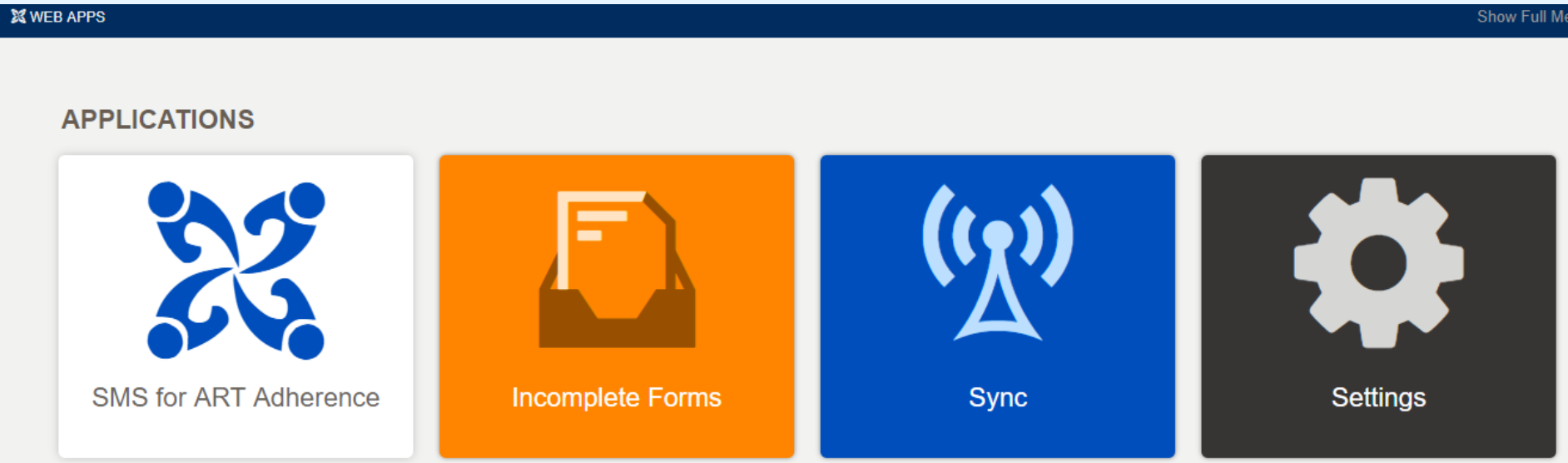

Click this Icon to begin using the application

Forms that a Mobile worker began, but did not

Ensures that information/forms filled out on Web

Where a mobile workers goes to clear user data,

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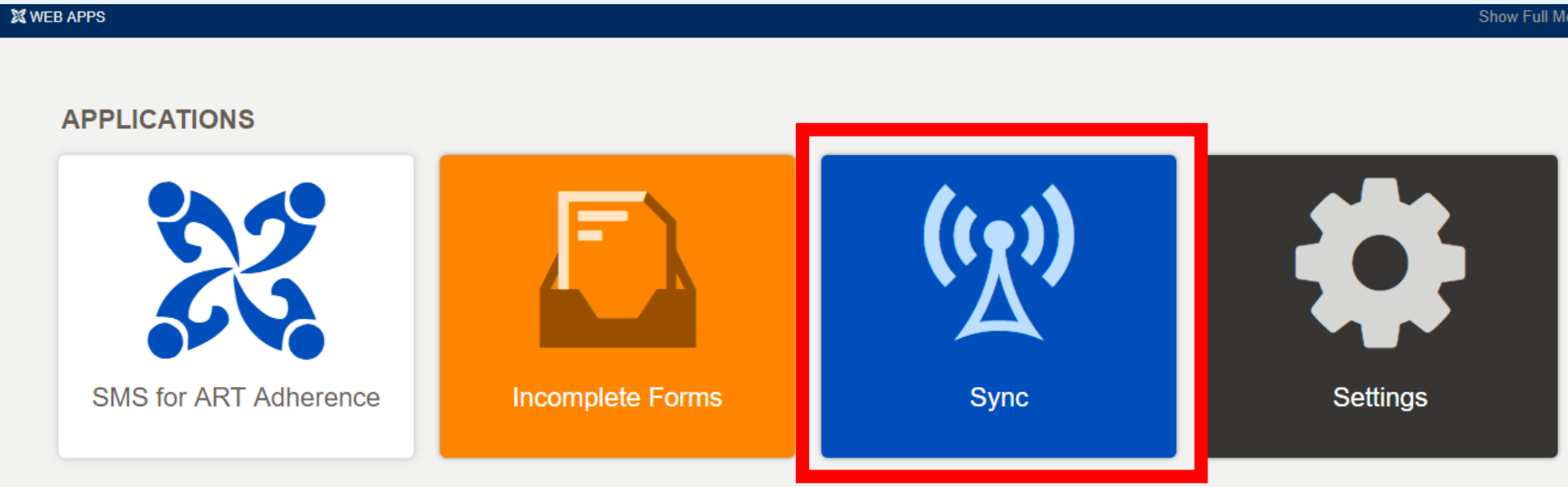

Click this Icon to begin using the application

Forms that a Mobile worker began, but did not

complete and submit

Ensures that information/forms filled out on Web

Apps is sent to CommCareHQ and that app updates are sent to Web Apps

Where a mobile workers goes to clear user data,

which is only important when you have deleted cases

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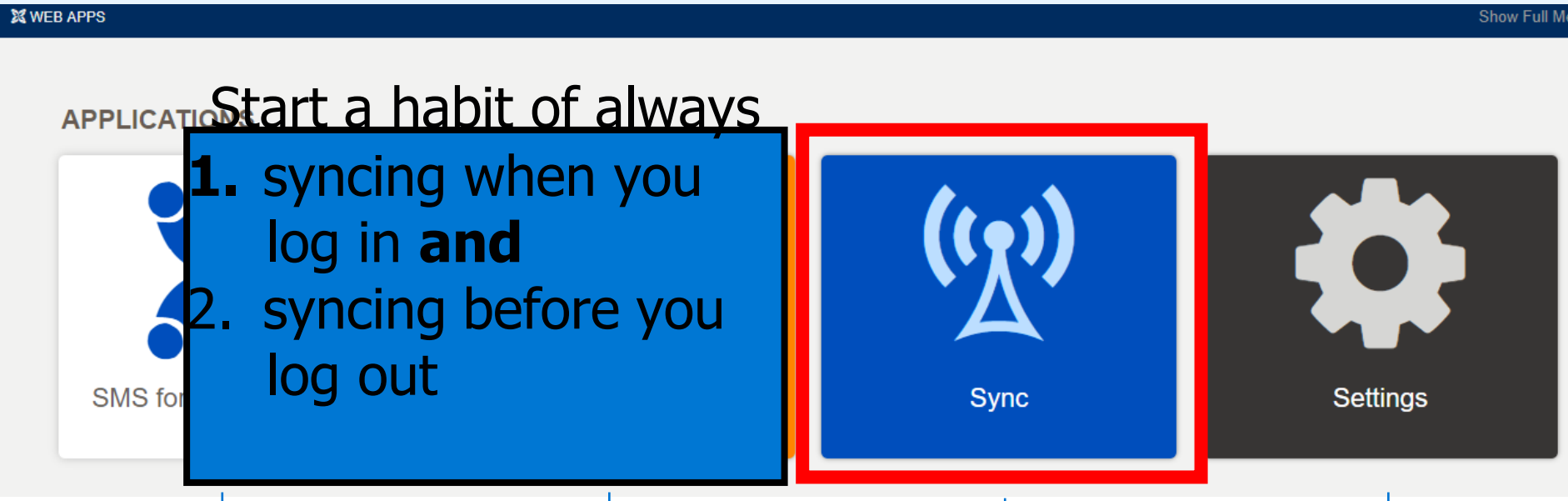

Start a habit of always

1. syncing when you log in **and**
2. syncing before you log out

Click this Icon to begin using the application

Forms that a Mobile worker began, but did not

complete and submit

Ensures that information/forms filled out on Web

Apps is sent to CommCareHQ and that app updates are sent to Web Apps

Where a mobile workers goes to clear user data,

which is only important when you have deleted cases

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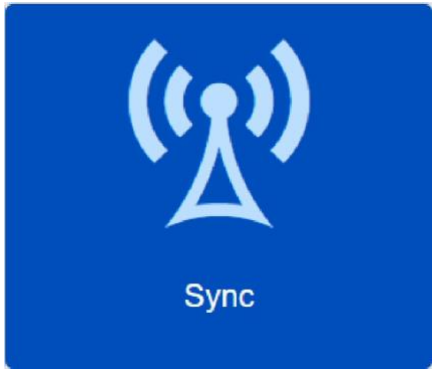
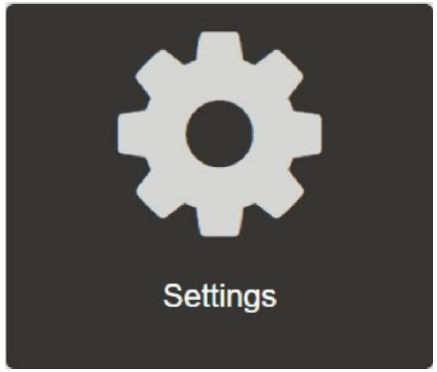
APPLICATIONS

SMS for ART Adherence

Incomplete Forms





HEAT TXTXT FOR ART ADHERENCE

TXTXT Platform

Formplayer Version: 2.43 App Versfon: 18

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HEAT TXTXT FOR ART ADHERENCE

TXTXT Platform

Fon yer Version: 2.43 App Versfon: 18

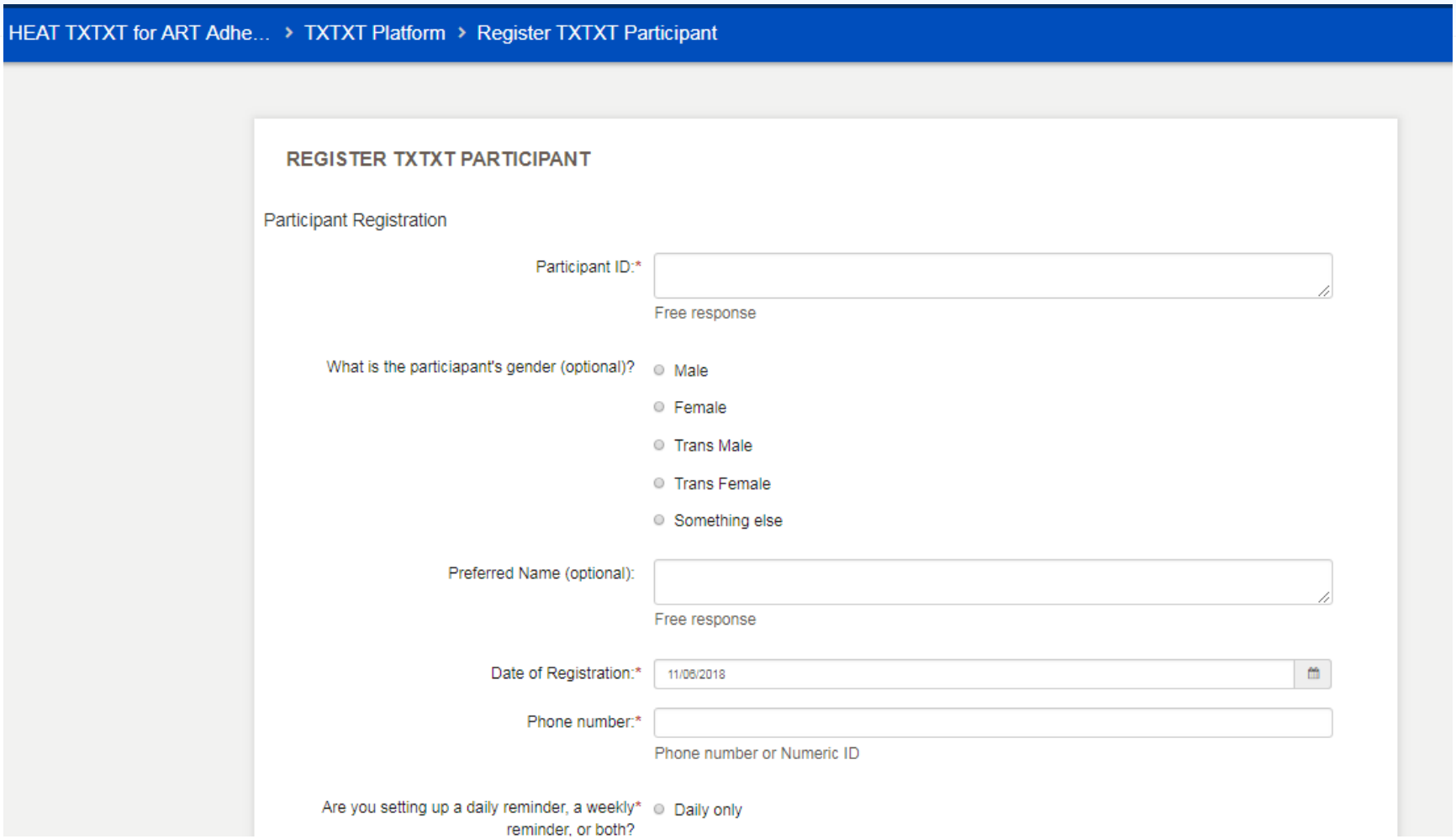
TXTXT PLATFORM

Register TXTXT Participant

Update Existing TXTXT Participant

Formplayer Version: 2.43, App Version: 18


TXTXT PLATFORM
Register TXTXT Participant
Update Existing TXTXT Participant
Formplayer Version: 2.43, App Version: 18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REGISTER TXTXT PARTICIPANT
Participant Registration
Participant ID:*
Free response
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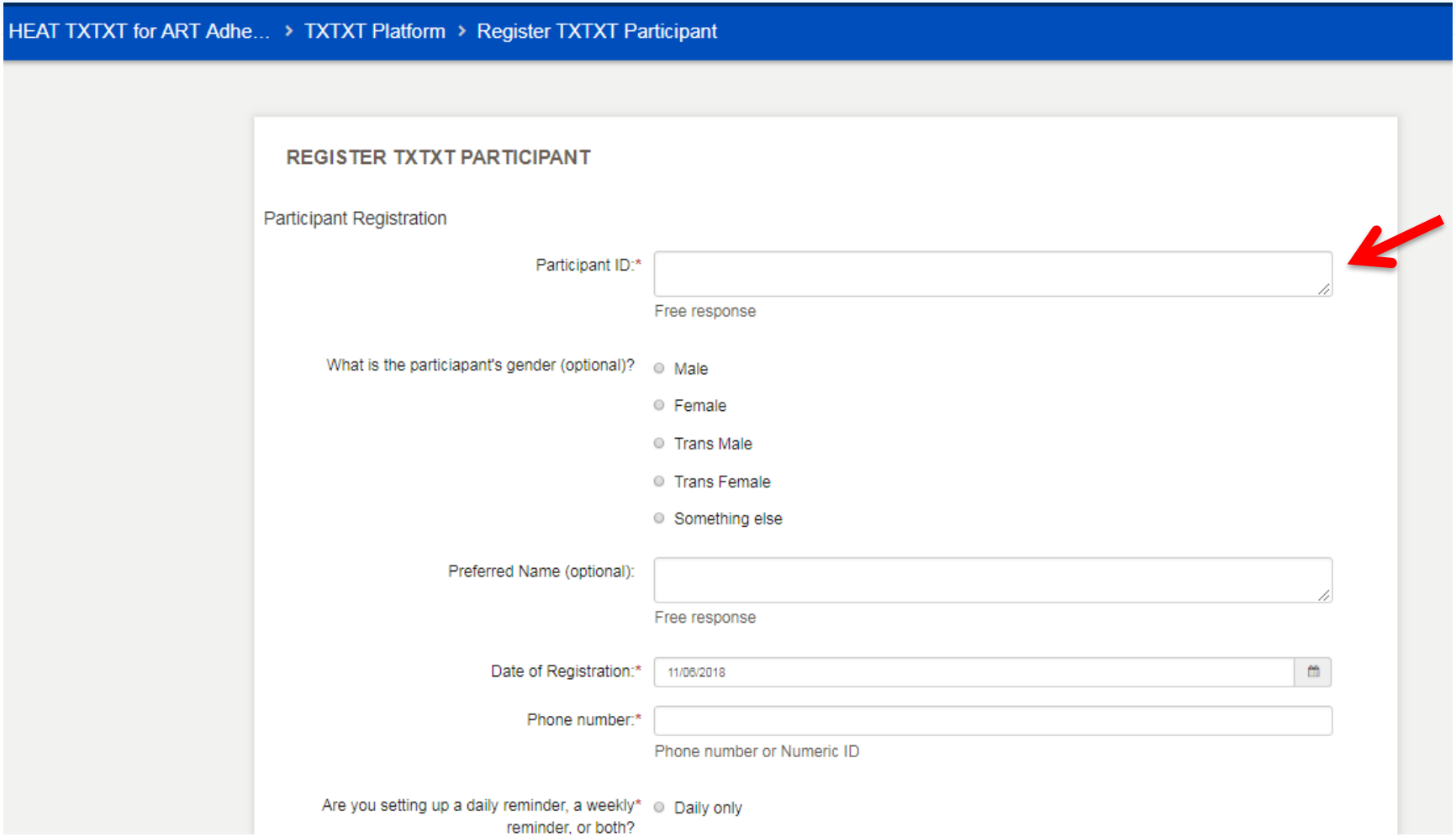
Something else
Preferred Name (optional):
Free response
Date of Registration:*
11/06/2018
Phone number:*
Phone number or Numeric ID
Are you setting up a daily reminder, a weekly* reminder, or both?
Daily only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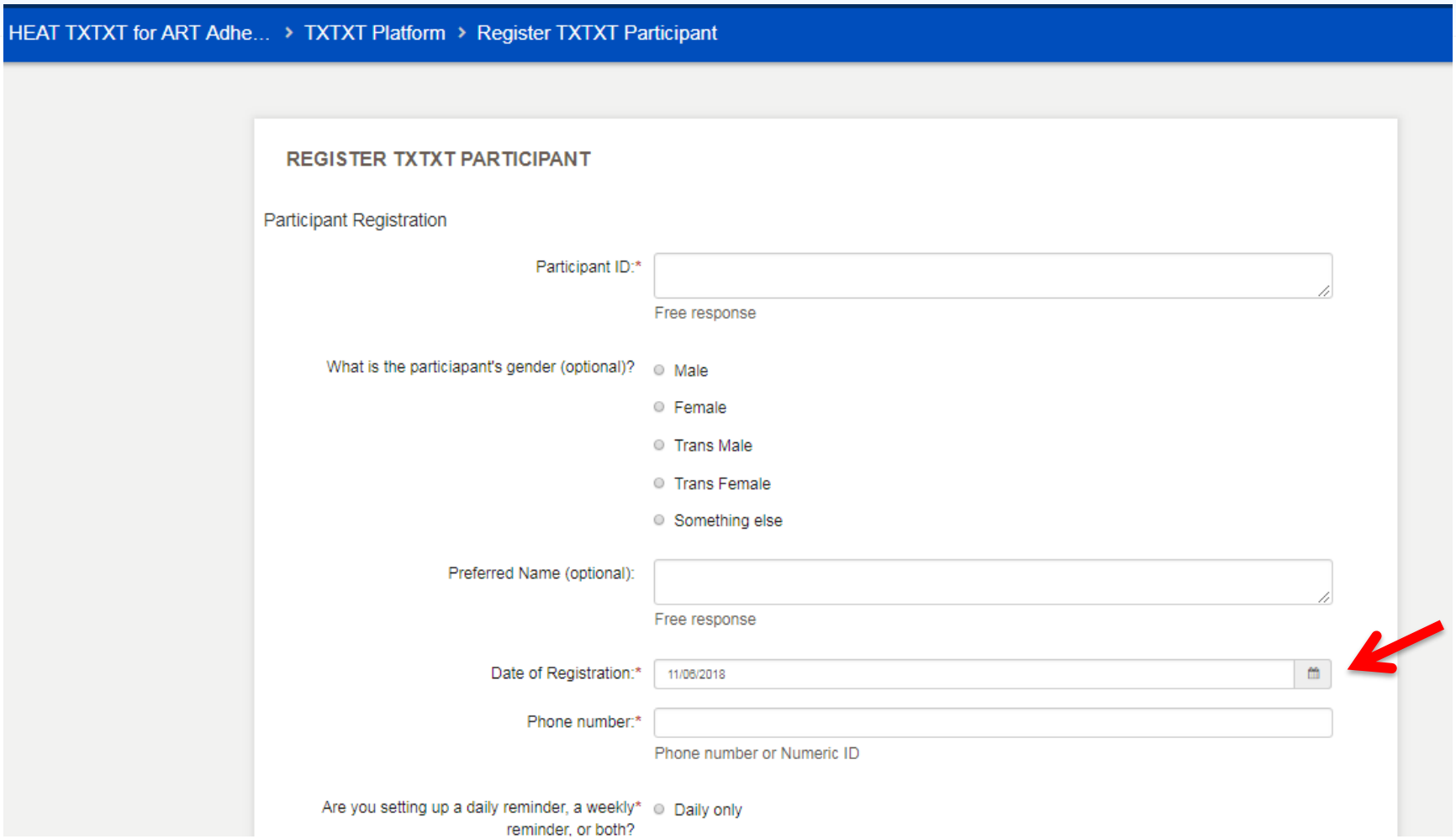
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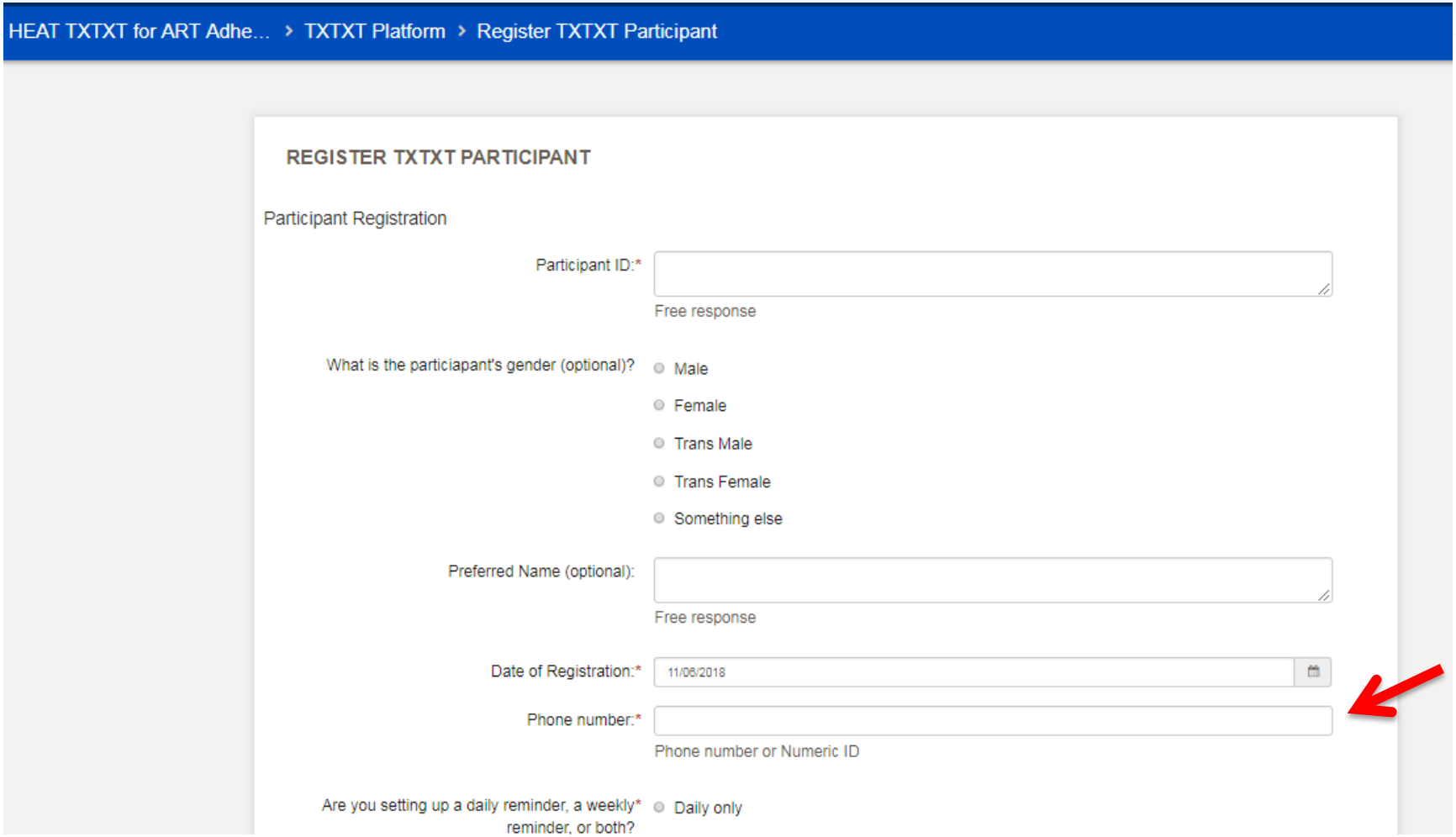
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What is the particiapant's gender (optional)?
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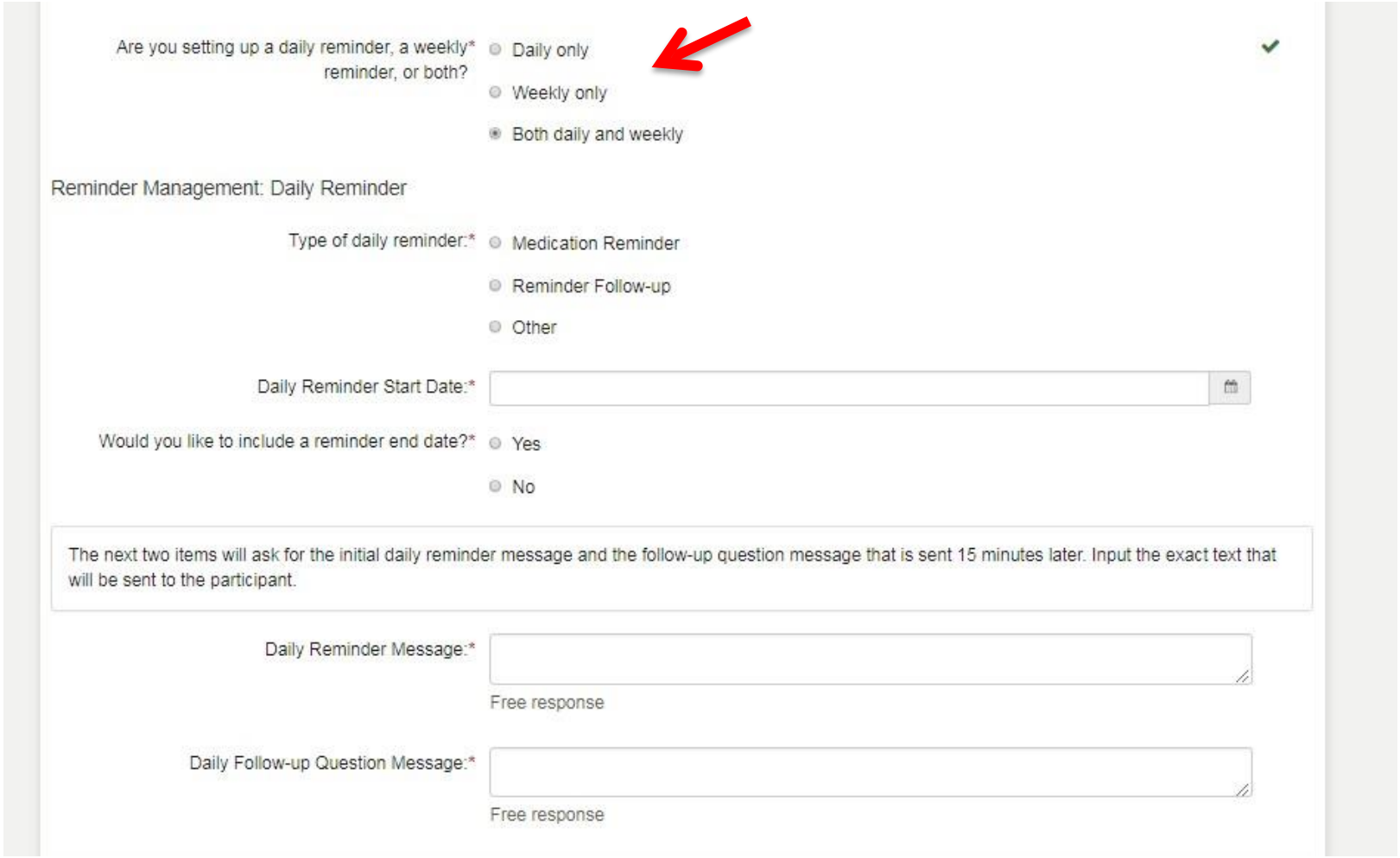
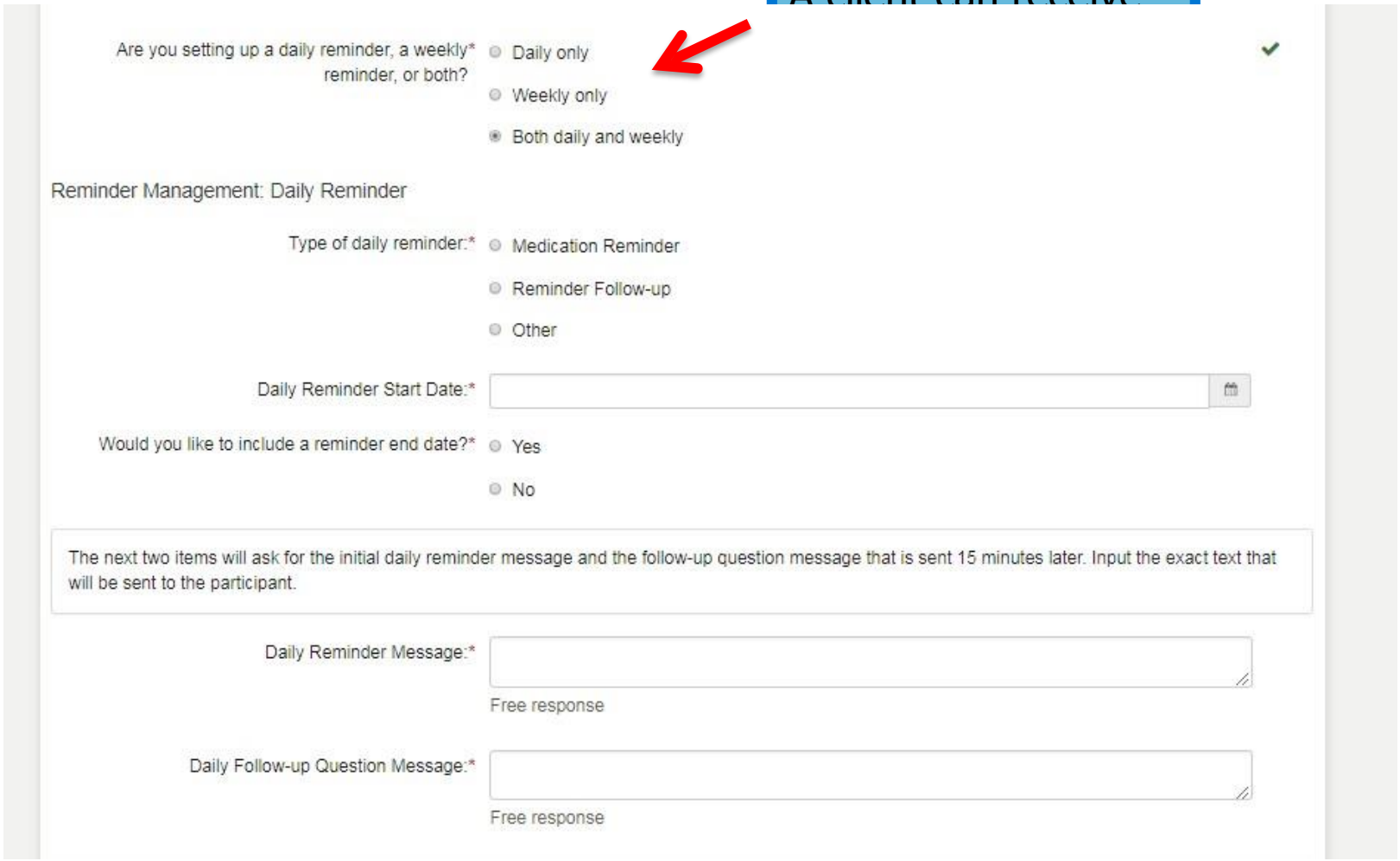
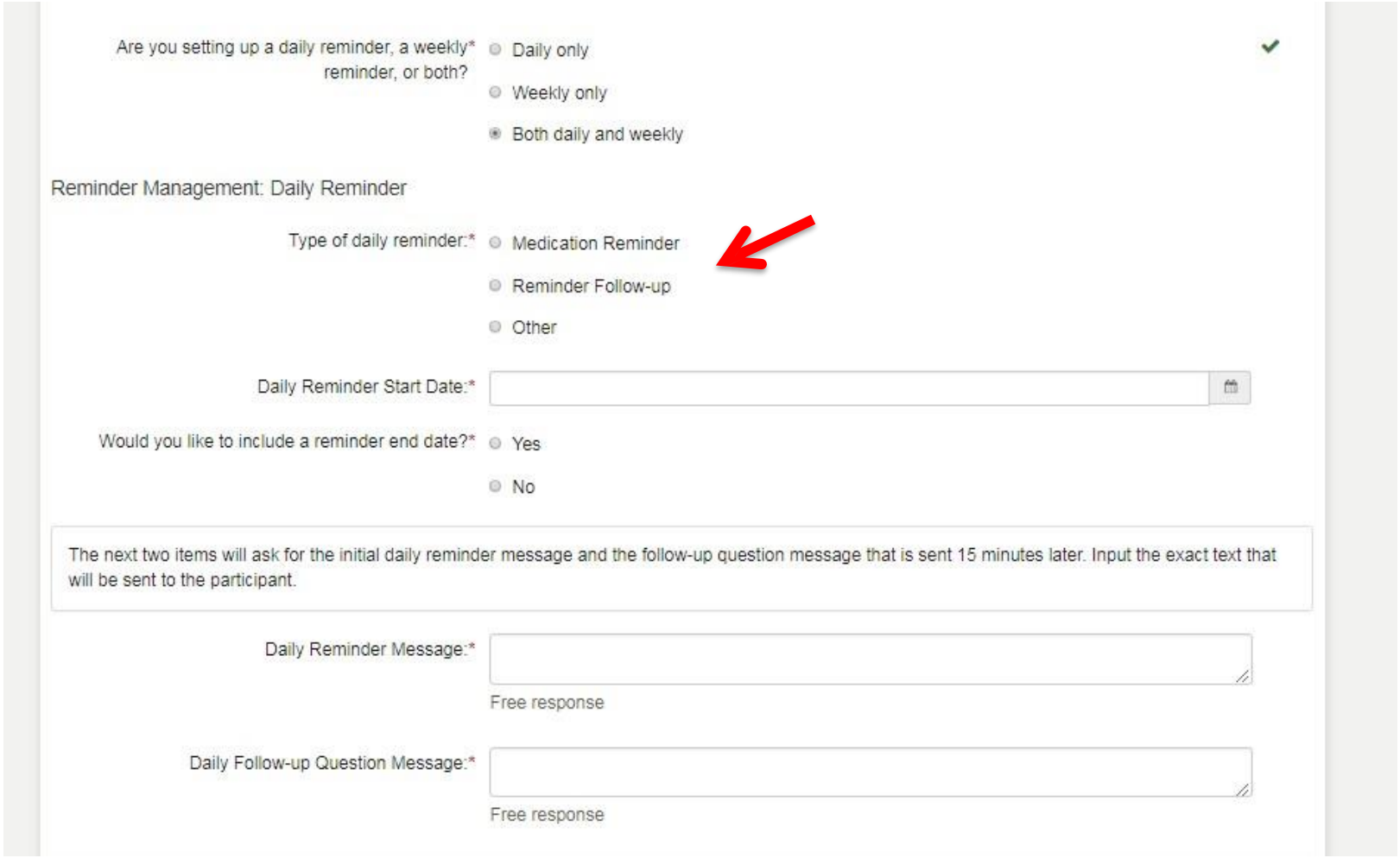
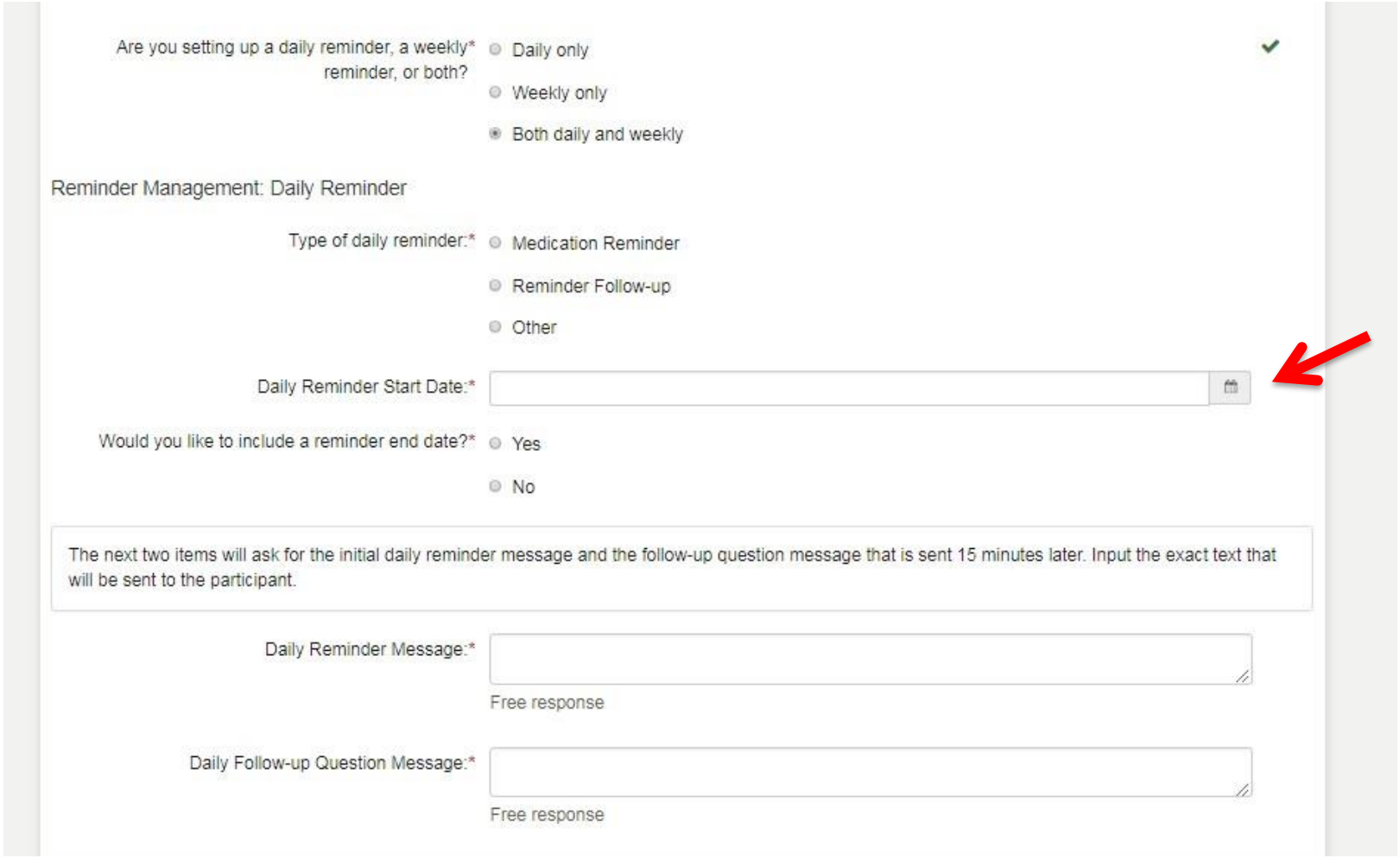
Are you setting up a daily reminder, a weekly* reminder, or both?
Daily only

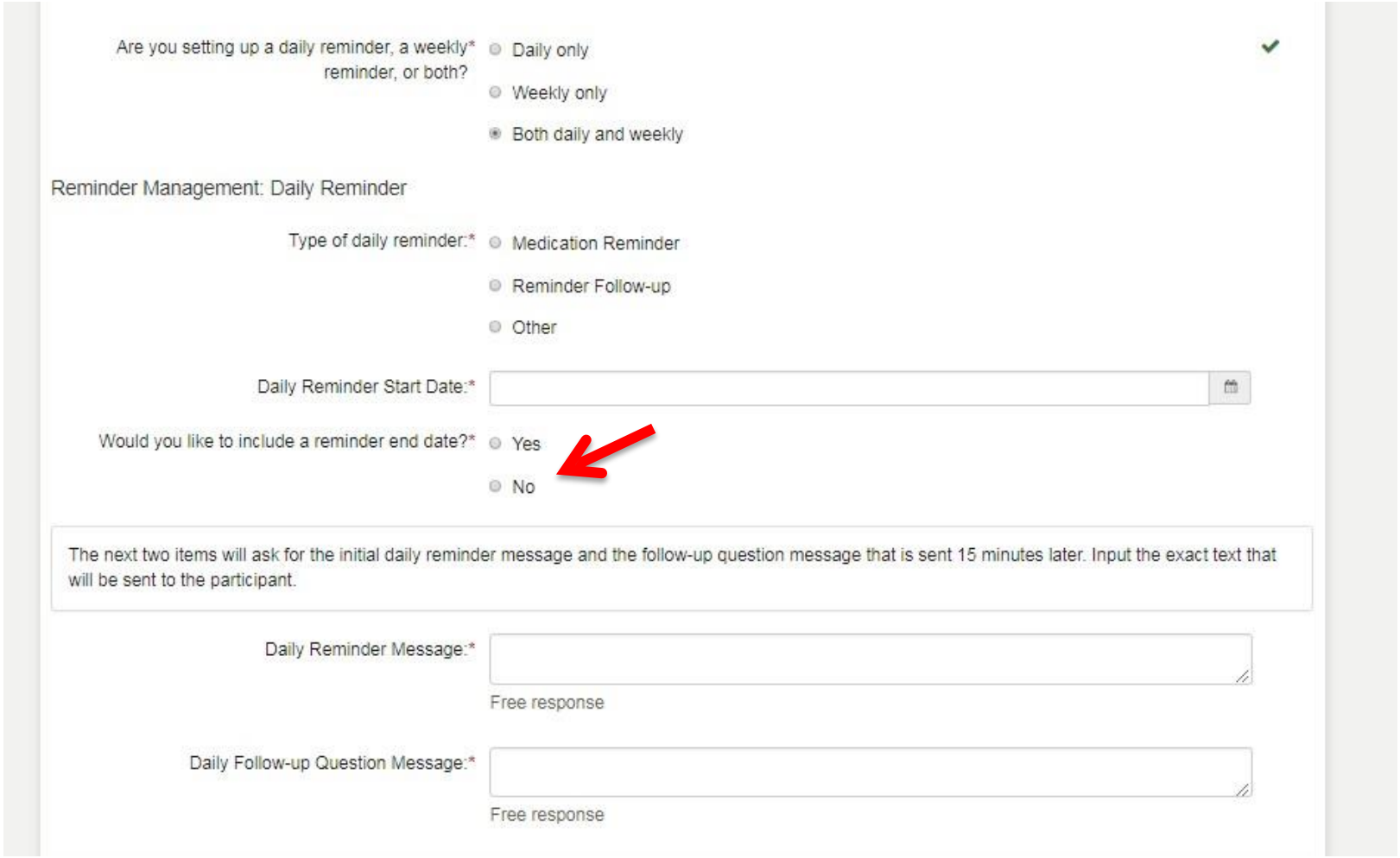

Are you setting up a daily reminder, a weekly reminder, or both?*
Daily only
Weekly only
Both daily and weekly
Reminder Management: Daily Reminder
Type of daily reminder:*
Medication Reminder
Reminder Follow-up
Other
Daily Reminder Start Date:*
Would you like to include a reminder end date?*
Yes
No
The next two items will ask for the initial daily reminder message and the follow-up question message that is sent 15 minutes later. Input the exact text that will be sent to the participant.
Daily Reminder Message:*
Free response
Daily Follow-up Question Message:*
Free response

A client can receive




Are you setting up a daily reminder, a weekly reminder, or both?*
Daily only
Weekly only
Both daily and weekly
Reminder Management: Daily Reminder
Type of daily reminder:*
Medication Reminder
Reminder Follow-up
Other
Daily Reminder Start Date:*
Would you like to include a reminder end date?*
Yes
No
The next two items will ask for the initial daily reminder message and the follow-up question message that is sent 15 minutes later. Input the exact text that will be sent to the participant.
Daily Reminder Message:*
Free response
Daily Follow-up Question Message:*
Free response


Are you setting up a daily reminder, a weekly reminder, or both?*
Daily only
Weekly only
Both daily and weekly
Reminder Management: Daily Reminder
Type of daily reminder:*
Medication Reminder
Reminder Follow-up
Other
Daily Reminder Start Date:*
Would you like to include a reminder end date?*
Yes
No
The next two items will ask for the initial daily reminder message and the follow-up question message that is sent 15 minutes later. Input the exact text that will be sent to the participant.
Daily Reminder Message:*
Free response
Daily Follow-up Question Message:*
Free response


Are you setting up a daily reminder, a weekly reminder, or both?*
Daily only
Weekly only
Both daily and weekly
Reminder Management: Daily Reminder
Type of daily reminder:*
Medication Reminder
Reminder Follow-up
Other
Daily Reminder Start Date:*
Would you like to include a reminder end date?*
Yes
No
The next two items will ask for the initial daily reminder message and the follow-up question message that is sent 15 minutes later. Input the exact text that will be sent to the participant.
Daily Reminder Message:*
Free response
Daily Follow-up Question Message:*
Free response

Are you setting up a daily reminder, a weekly reminder, or both?* ○ Daily only ✔
○ Weekly only
◉ Both daily and weekly

Reminder Management: Daily Reminder

Type of daily reminder:* ○ Medication Reminder
○ Reminder Follow-up
○ Other

Daily Reminder Start Date:*

Would you like to include a reminder end date?* ○ Yes
○ No

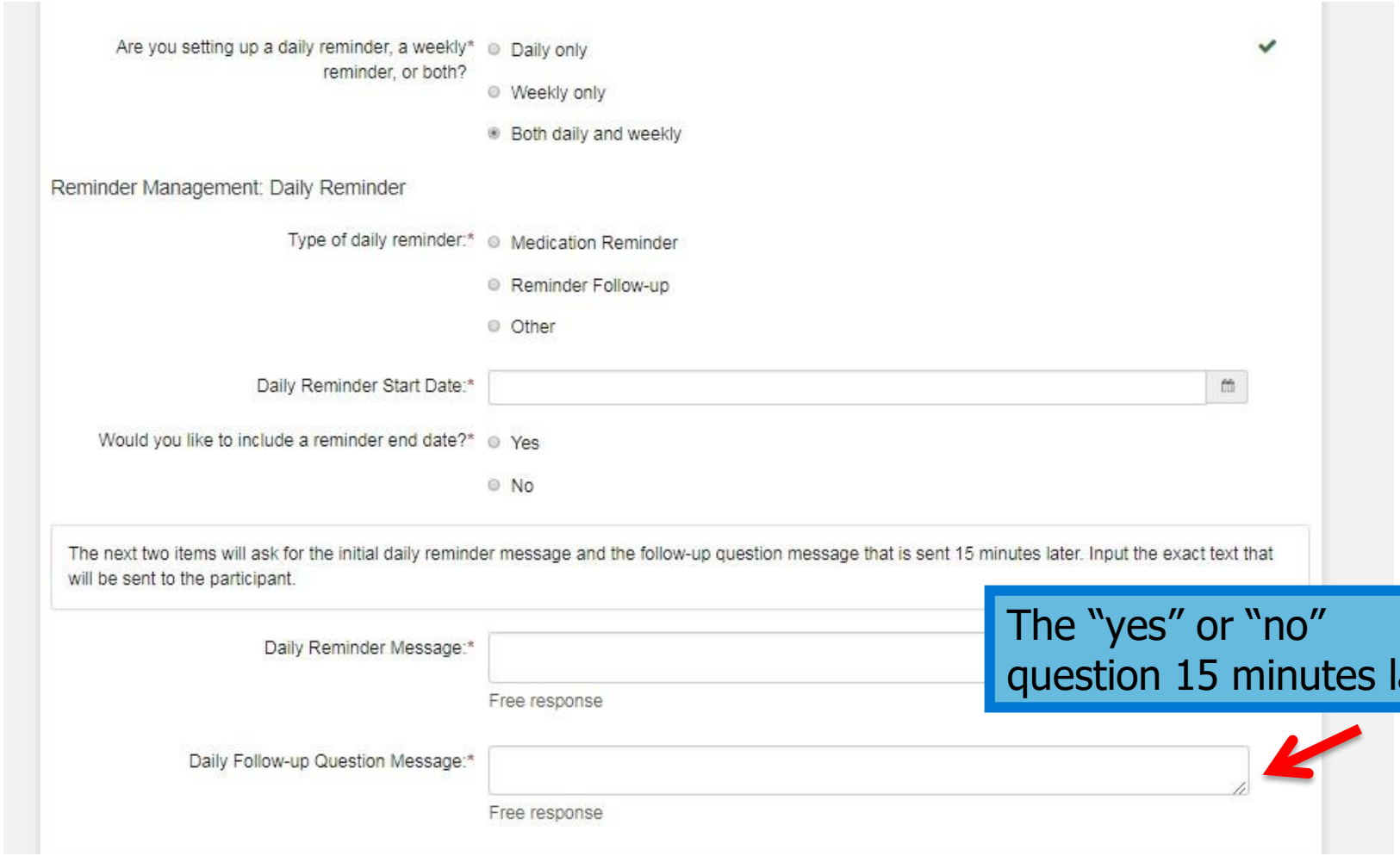
The next two items will ask for the initial daily reminder message and the follow-up question message that is sent 15 minutes later. Input the exact text that will be sent to the participant.

Daily Reminder Message:*

Free response

Daily Follow-up Question Message:*

Free response


Are you setting up a daily reminder, a weekly reminder, or both?*
Daily only
Weekly only
Both daily and weekly
Reminder Management: Daily Reminder
Type of daily reminder:*
Medication Reminder
Reminder Follow-up
Other
Daily Reminder Start Date:*
Would you like to include a reminder end date?*
Yes
No
The next two items will ask for the initial daily reminder message and the follow-up question message that is sent 15 minutes later. Input the exact text that will be sent to the participant.
Daily Reminder Message:*
Free response
Daily Follow-up Question Message:*
Free response
The "yes" or "no" question 15 minutes later

Daily Reminder Message: *

Free response

Daily Follow-up Question Message: *

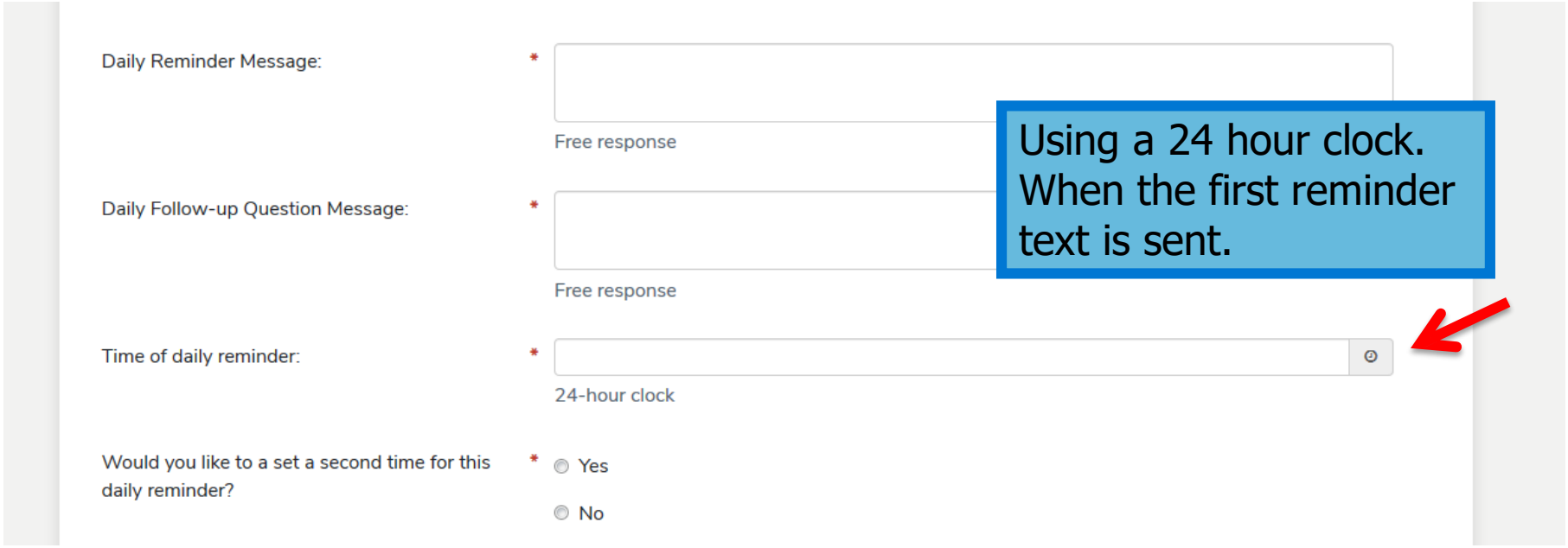
Free response

Time of daily reminder: *

24-hour clock

Would you like to a set a second time for this daily reminder? *

- Yes
- No


Daily Reminder Message:
*
Free response
Daily Follow-up Question Message:
*
Free response
Time of daily reminder:
*
24-hour clock
Would you like to a set a second time for this daily reminder?
*
Yes
No
Using a 24 hour clock. When the first reminder text is sent.

Daily Reminder Message: *

Free response

Daily Follow-up Question Message: *

Free response

Time of daily reminder: *

24-hour clock

Would you like to a set a second time for this daily reminder? *

- Yes
- No

Daily Reminder Message: *

Free response

Daily Follow-up Question Message: *

Free response

Time of daily reminder: *

24-hour clock

Would you like to a set a second time for this daily reminder? *

- Yes
- No

Can send up to 3 texts a day for 3 daily doses

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Free response

Time of daily reminder: *

24-hour clock

Would you like to a set a second time for this daily reminder? *

- Yes
- No

Your daily reminder has been successfully created!

Submit

Free response

Time of daily reminder: *

24-hour clock

Would you like to a set a second time for this daily reminder? *

- Yes
- No

Your daily reminder has been successfully created!

Don't forget to click "Submit!"

Submit

Phone Number Confirmation

3. The client should immediately receive a test text message reading "Testing"
    1. If they do not receive one, double check the phone number was entered correctly, check the number with the client, confirm the client can receive messages, or reach out to Lisa and Abby
4. Their daily and weekly texts will begin immediately

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Time to try!

https://www.commcarehq.org/a/txtxt/dashboard/project/

1. Login to CommCare as a Mobile Worker
2. Create a new case in the TXTXT App

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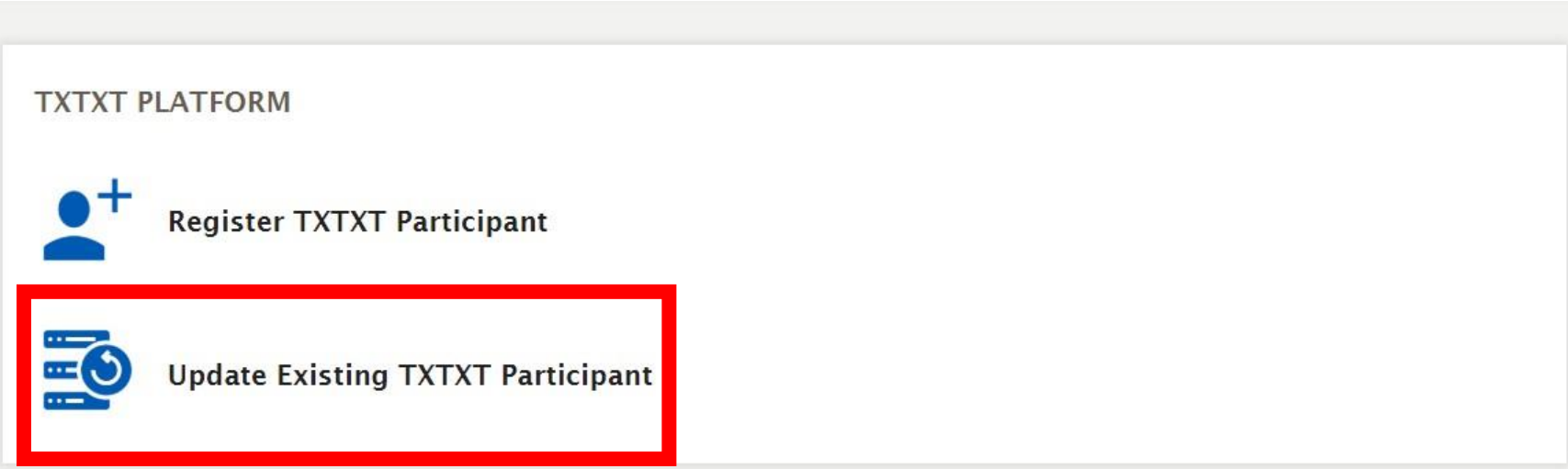
Mobile Worker Task 2 of 2:Updating a case in the TXTXT Application

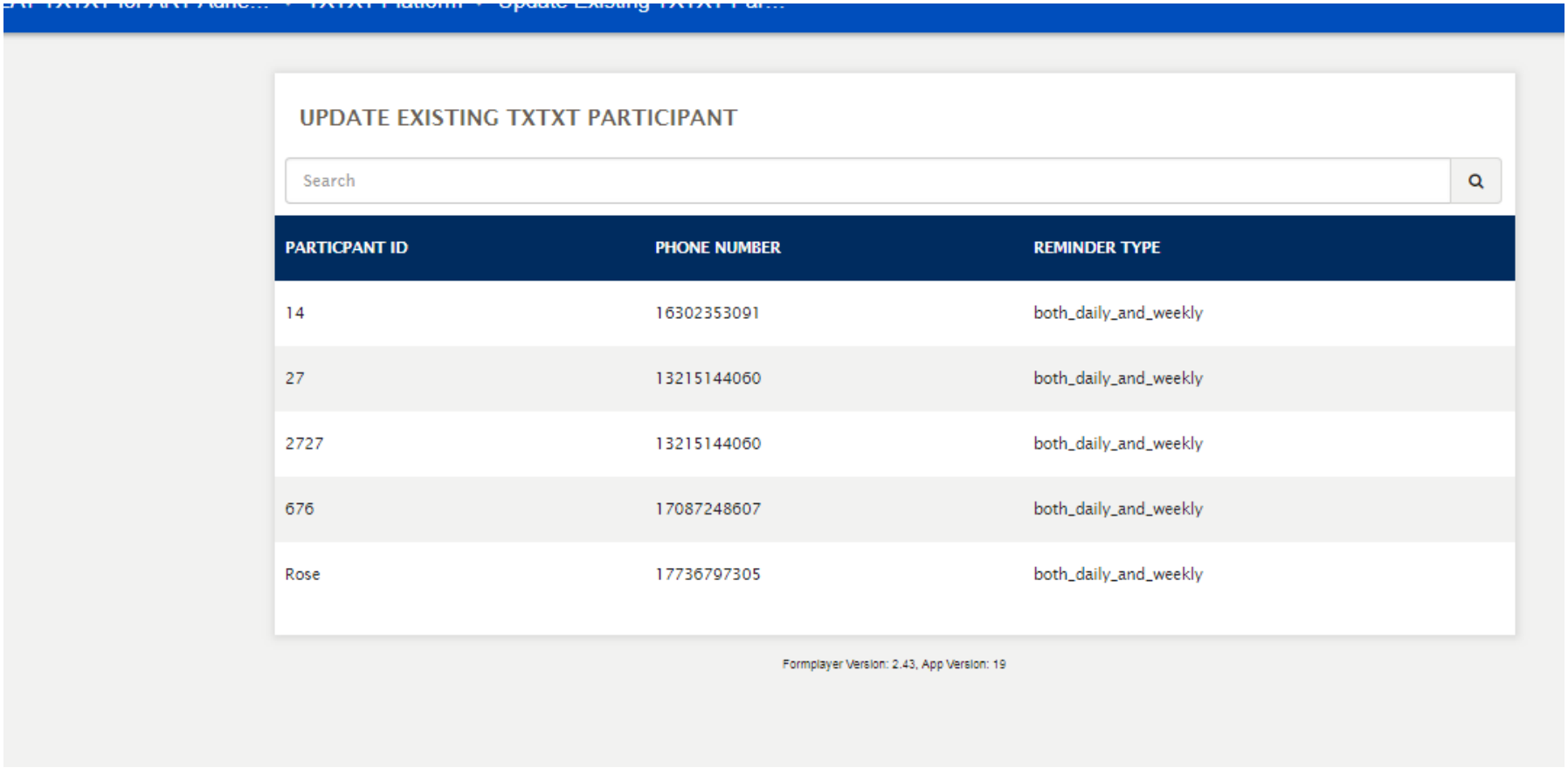
TXTXT PLATFORM

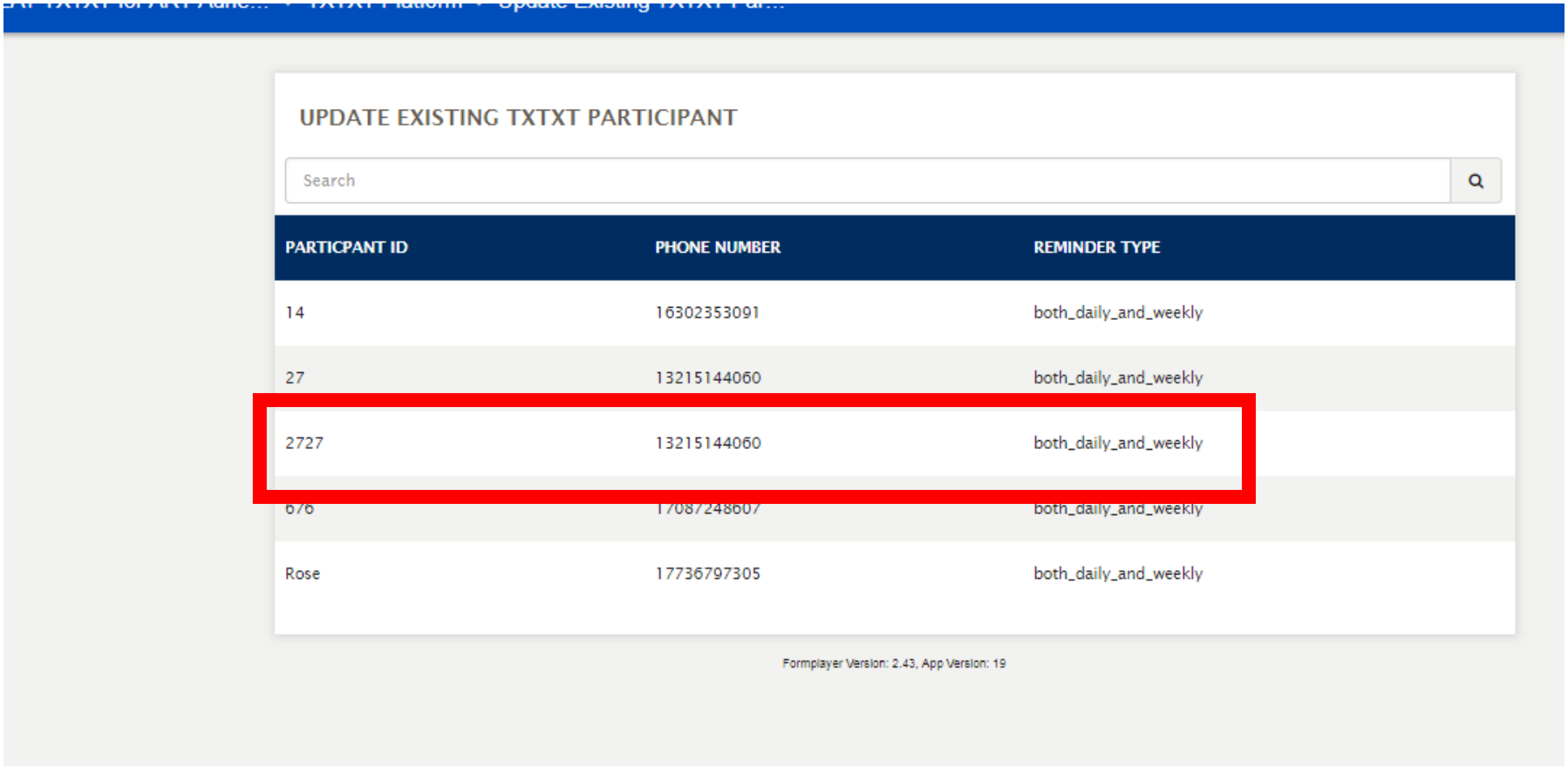
Register TXTXT Participant

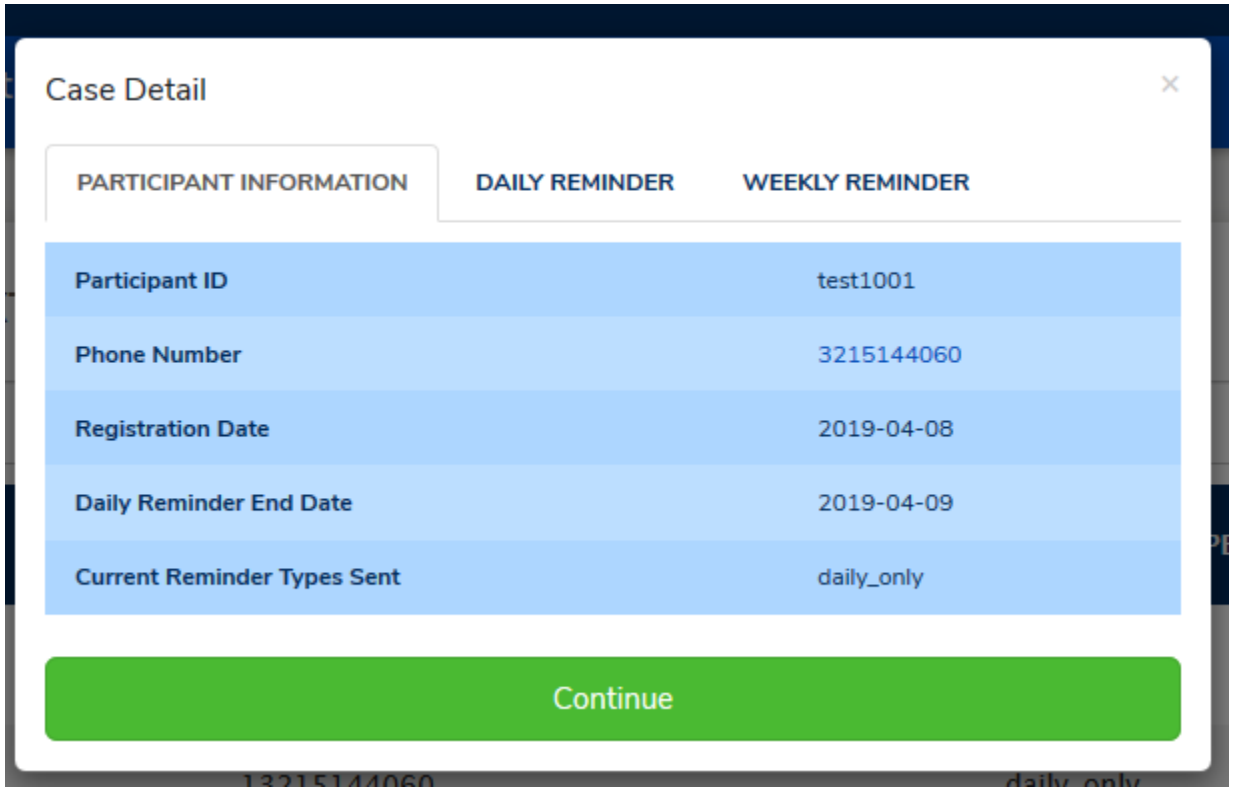
Update Existing TXTXT Participant

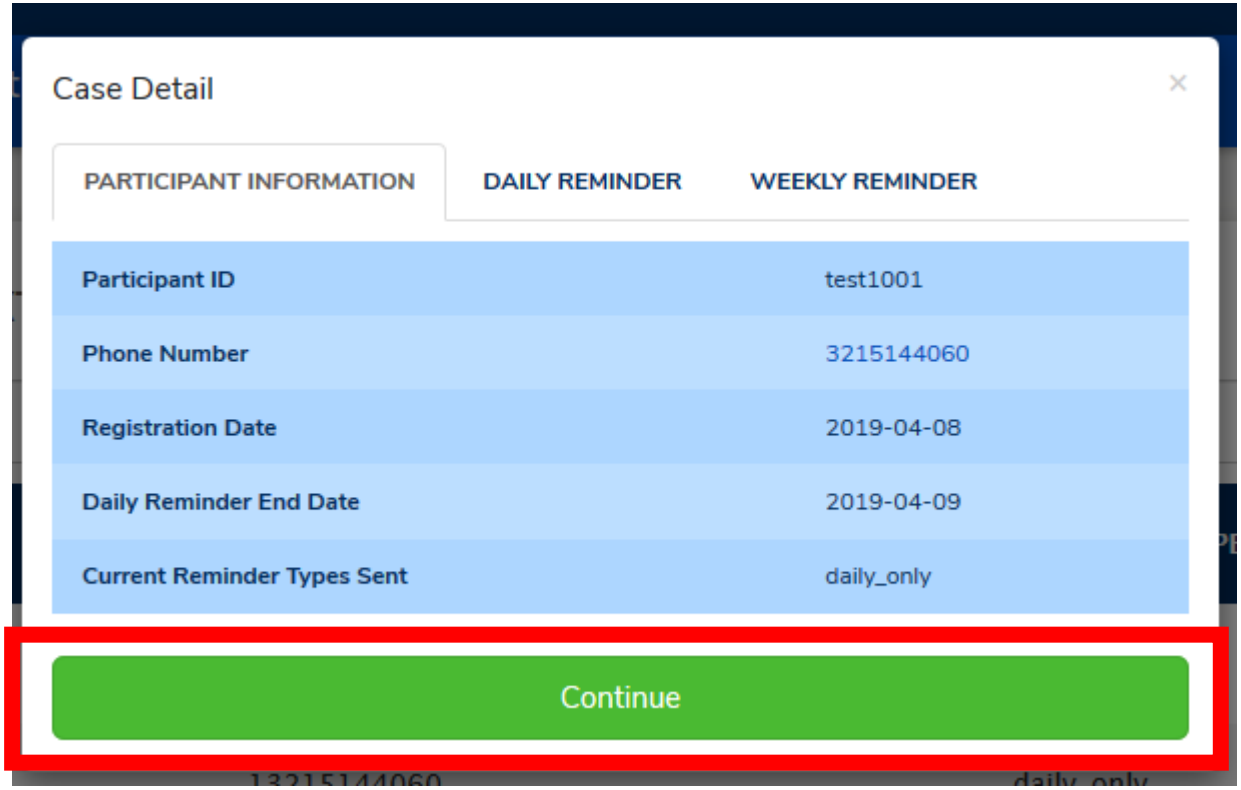
Formplayer Version: 2.43, App Version: 18


TXTXT PLATFORM
Register TXTXT Participant
Update Existing TXTXT Participant
Formplayer Version: 2.43, App Version: 18


UPDATE EXISTING TXTXT PARTICIPANT
Search
PARTICPANT ID
PHONE NUMBER
REMINDER TYPE
14
16302353091
both_daily_and_weekly
27
13215144060
both_daily_and_weekly
2727
13215144060
both_daily_and_weekly
676
17087248607
both_daily_and_weekly
Rose
17736797305
both_daily_and_weekly
Formplayer Version: 2.43, App Version: 19


UPDATE EXISTING TXTXT PARTICIPANT
Search
PARTICPANT ID
PHONE NUMBER
REMINDER TYPE
14
16302353091
both_daily_and_weekly
27
13215144060
both_daily_and_weekly
2727
13215144060
both_daily_and_weekly
676
17087248607
both_daily_and_weekly
Rose
17736797305
both_daily_and_weekly
Formplayer Version: 2.43, App Version: 19


Case Detail
PARTICIPANT INFORMATION
DAILY REMINDER
WEEKLY REMINDER
Participant ID
test1001
Phone Number
3215144060
Registration Date
2019-04-08
Daily Reminder End Date
2019-04-09
Current Reminder Types Sent
daily_only
Continue


Case Detail
PARTICIPANT INFORMATION
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Daily Reminder End Date
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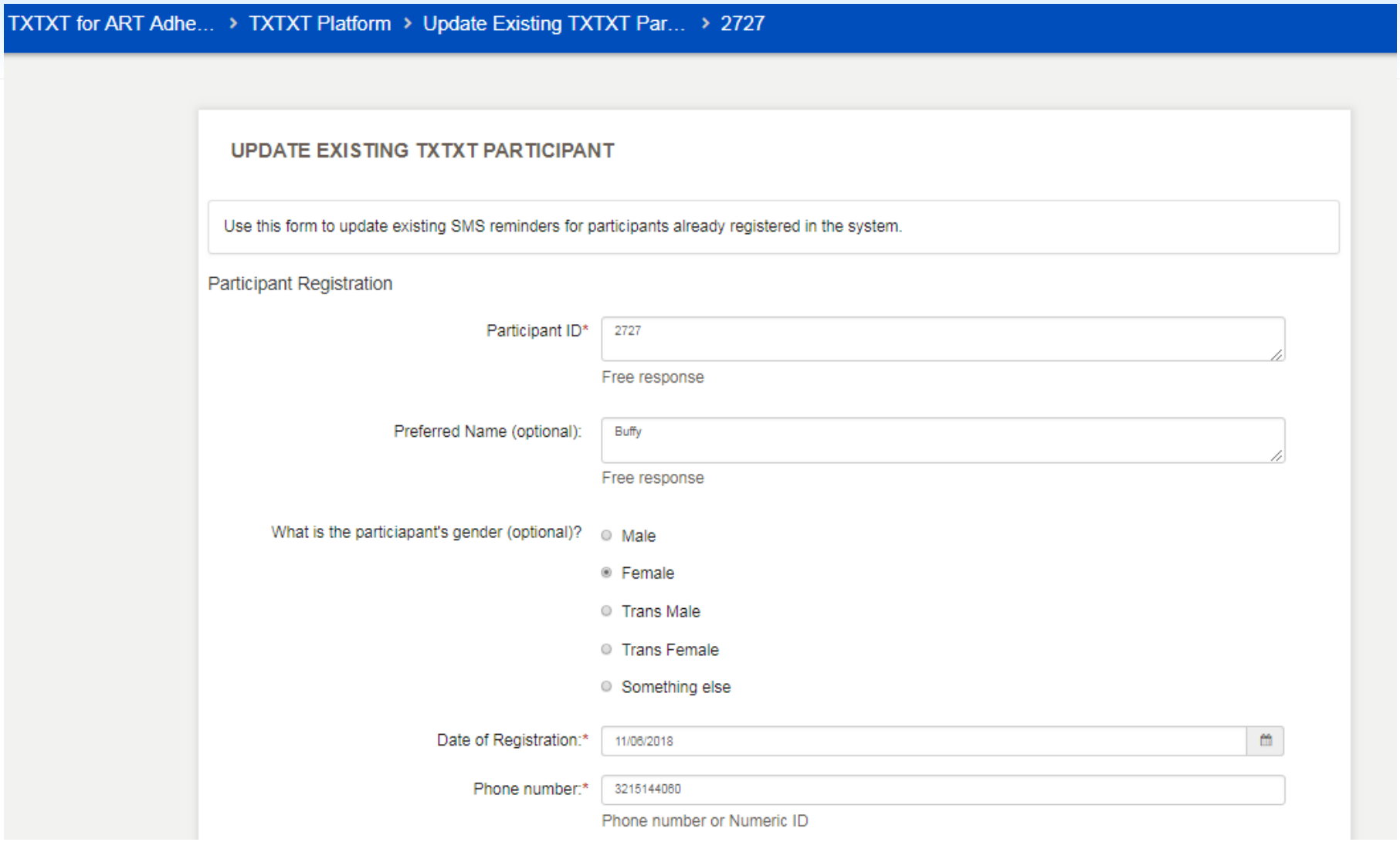
Current Reminder Types Sent
daily_only
Continue


TXTXT for ART Adhe... › TXTXT Platform › Update Existing TXTXT Par... › 2727
UPDATE EXISTING TXTXT PARTICIPANT
Use this form to update existing SMS reminders for participants already registered in the system.
Participant Registration
Participant ID*
2727
Free response
Preferred Name (optional):
Buffy
Free response
What is the particiapant's gender (optional)?
Male
Female
Trans Male
Trans Female
Something else
Date of Registration:*
11/06/2018
Phone number:*
3215144060
Phone number or Numeric ID

This participant currently receives: both_daily_and_weekly

Moving forward, does this participant want to receive daily reminders, a weekly reminder, or both?*
- (•) Daily only ✔
- ( ) Weekly only
- ( ) Both daily and weekly

If the client changes any setting,
Confirm the rest of the information
In this form is correct before submitting

Reminder Management: Daily Reminder

Type of daily reminder:*
- (•) Medication Reminder
- ( ) Reminder Follow-up
- ( ) Other

Daily Reminder Start Date:* 11/06/2018

Would you like to include a reminder end date?*
- ( ) Yes
- (•) No

The next two items will ask for the initial daily reminder message and the follow-up question message that is sent 15 minutes later. Input the exact text that will be sent to the participant.

Daily Reminder Message:* Walk Tennie

Free response

Daily Follow-up Question Message:* Did you walk Tennie?

Free response

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Time to try!

https://www.commcarehq.org/a/txtxt/dashboard/project/

1. Login to CommCare as a Mobile Worker
2. Update an existing case in the TXTXT App

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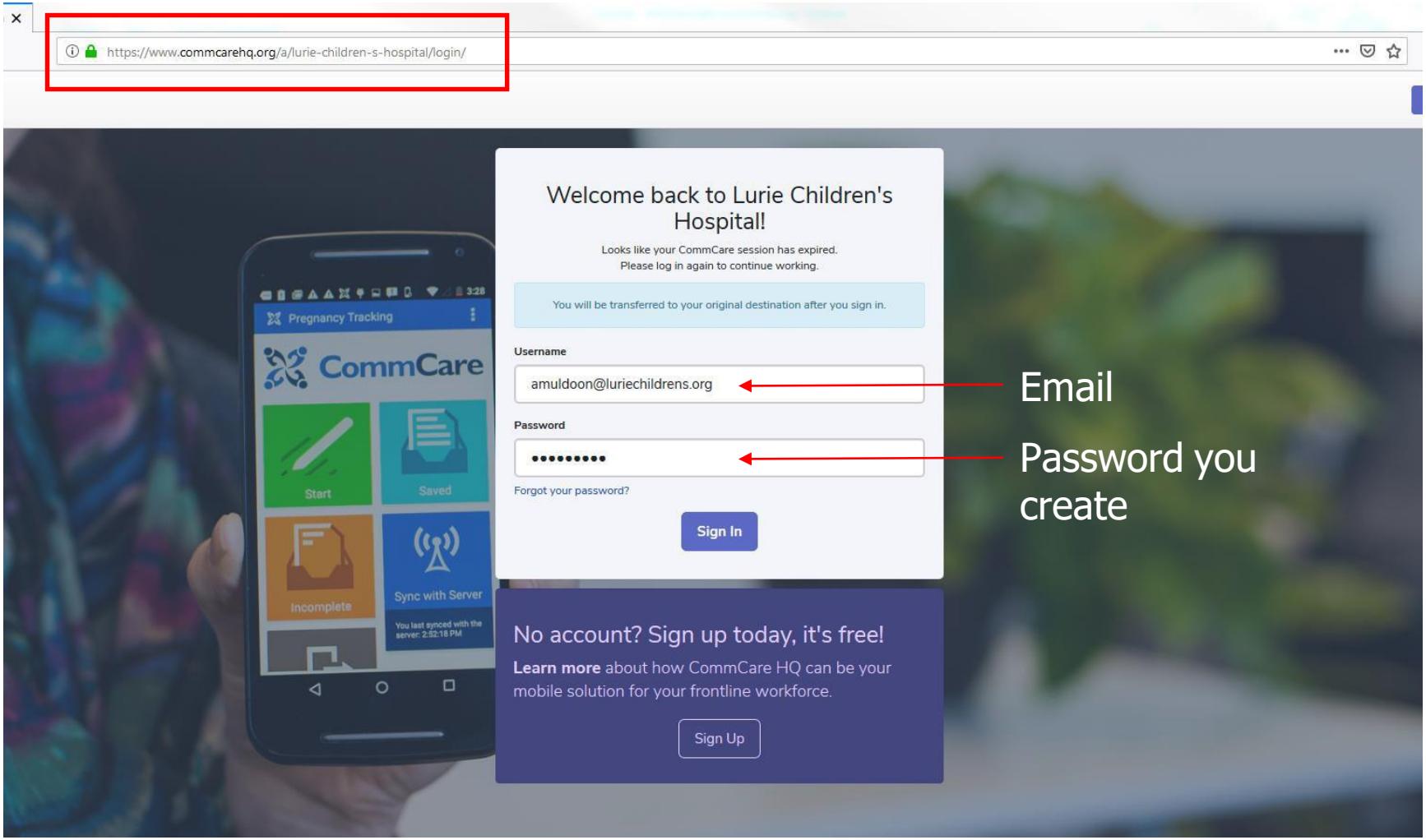
Web User MonitoringTexts

Two User Roles: CommCare HQ as a Web User



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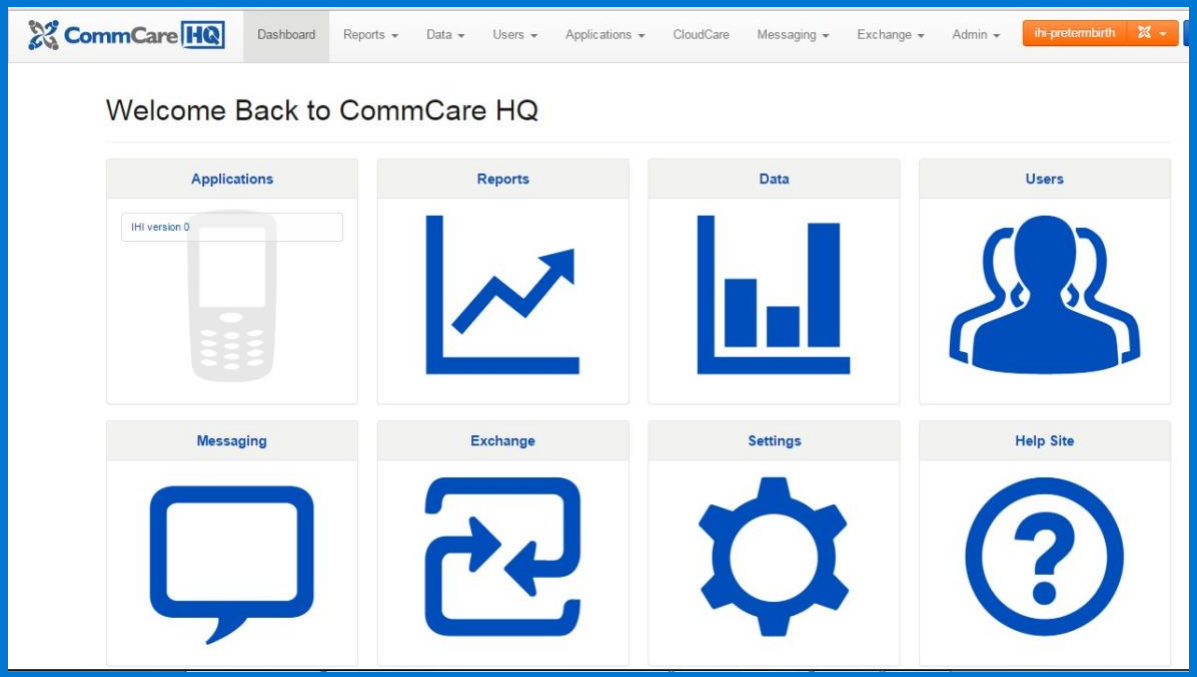
Basics of CommCareHQ: Sections of HQ



Links to learn more:

1. https://www.commcarehq.org/home/
2. https://help.commcarehq.org/display/commcarepublic/Beginner+Tutorial+Part+1

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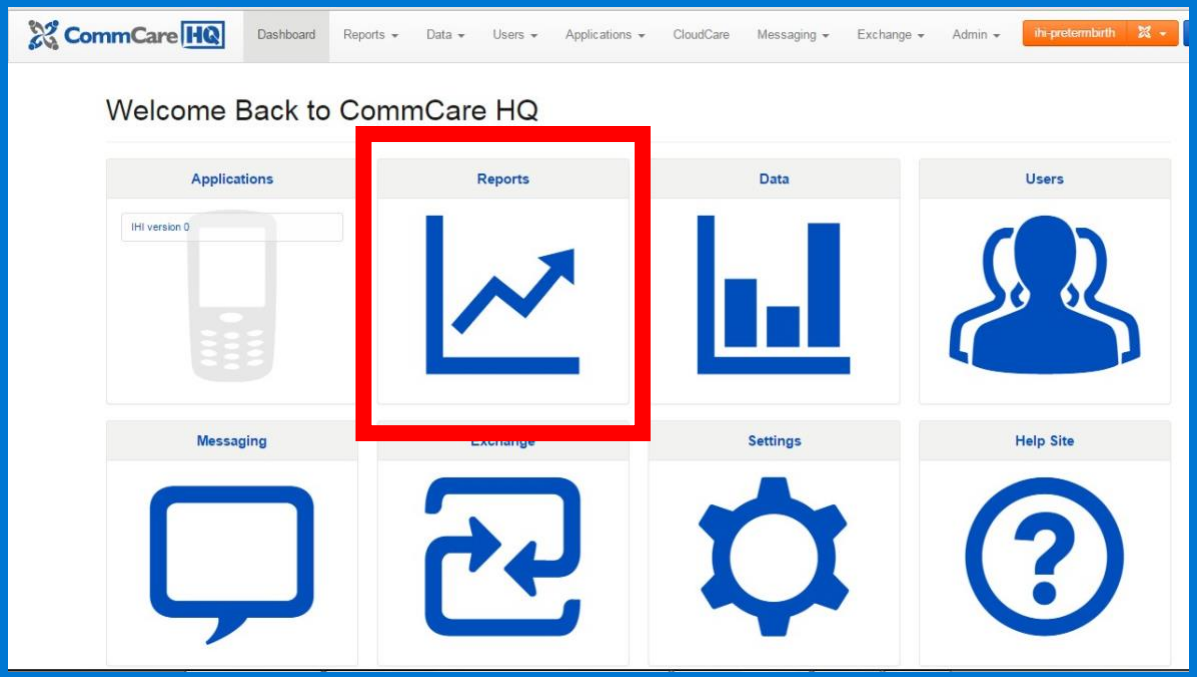
Basics of CommCareHQ: Sections of HQ



Links to learn more:

1. https://www.commcarehq.org/home/
2. https://help.commcarehq.org/display/commcarepublic/Beginner+Tutorial+Part+1

Basics of HQ: Reports

In the Reports section of HQ you can:

1. the TXTXT app
2. 

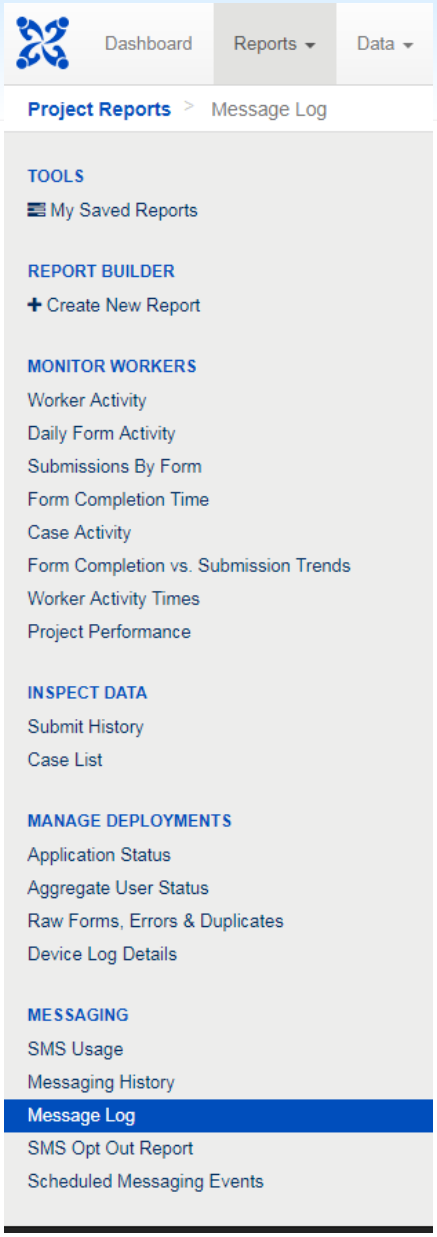
3. g Events
   eports (not all will beuseful for this project)

Reports: Message Log

Reports > Messaging > Message Log

Manage all **individual** messages

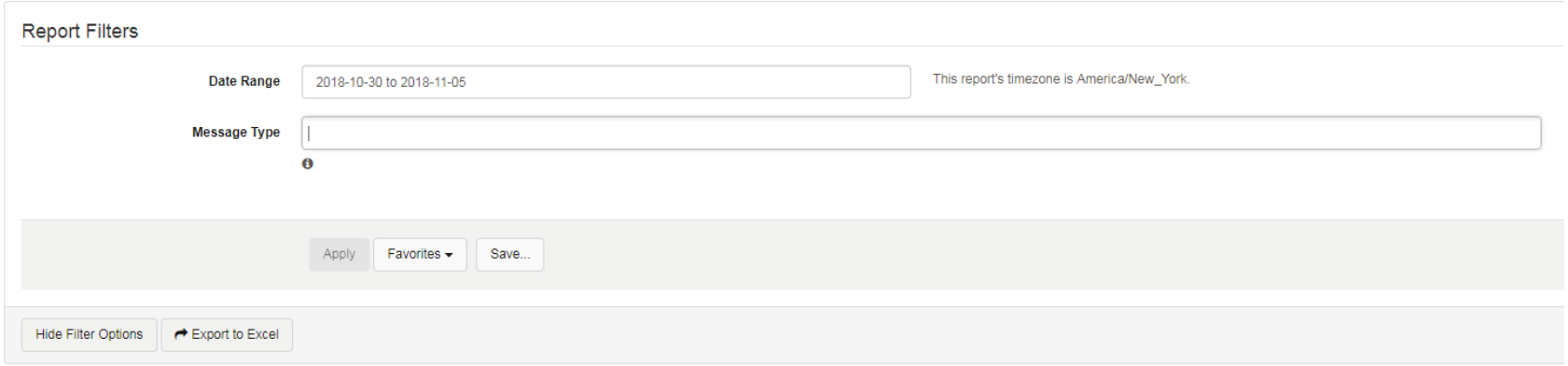
1. incoming or outgoing,
2. in order sent or received
3. displays message content,
4. displays status,
5. displays type of message.



Reports: Message Log

Establish a date range

Drill down by message type (optional)



Reports: Message Log

1. incoming or outgoing,
2. in order sent or received
3. displays message content,
4. displays status,
5. display type of message
6. one row of data per text

Manage all **individual** messages

Message Log

Timestamp	User Name	Phone Number	Direction	Message	Status	Event	Type
2019-11-12 13:34:14	test1001	+13215144060	Outgoing	You have opted-in to receive messages from CommCareHQ. To opt-out, reply to this number with STOP	Sent	-	other
2019-11-12 13:34:13	test1001	+13215144060	Incoming	Start	Received	-	other
2019-11-12 13:34:11	test1001	+13215144060	Incoming	Stop	Received	-	other
2019-11-12 13:34:06	test1001	+13215144060	Incoming	Yes	Received	SMS Message	default
2019-11-12 13:16:06	test27	+13215144060	Outgoing	Walk Tennie!	Sent	First Daily Reminder	other
2019-11-12 13:15:06	test27	+13215144060	Outgoing	Testing	Sent	1. Welcome Test Message	other

Showing 1 to 6 of 6 entries 100 per page

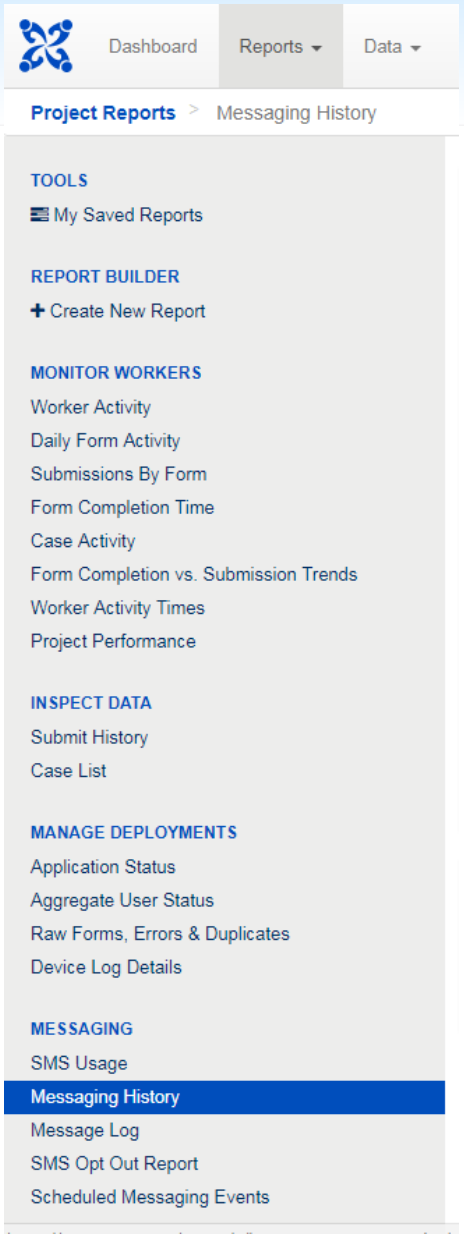
Previous 1 Next

Reports: Message History

Reports > Messaging > Message History

Manage **all** messages grouped by type

1. Completed or incomplete or error
2. Does not display message content
3. Groups two-messaging for the question text
4. Gives more details on errors



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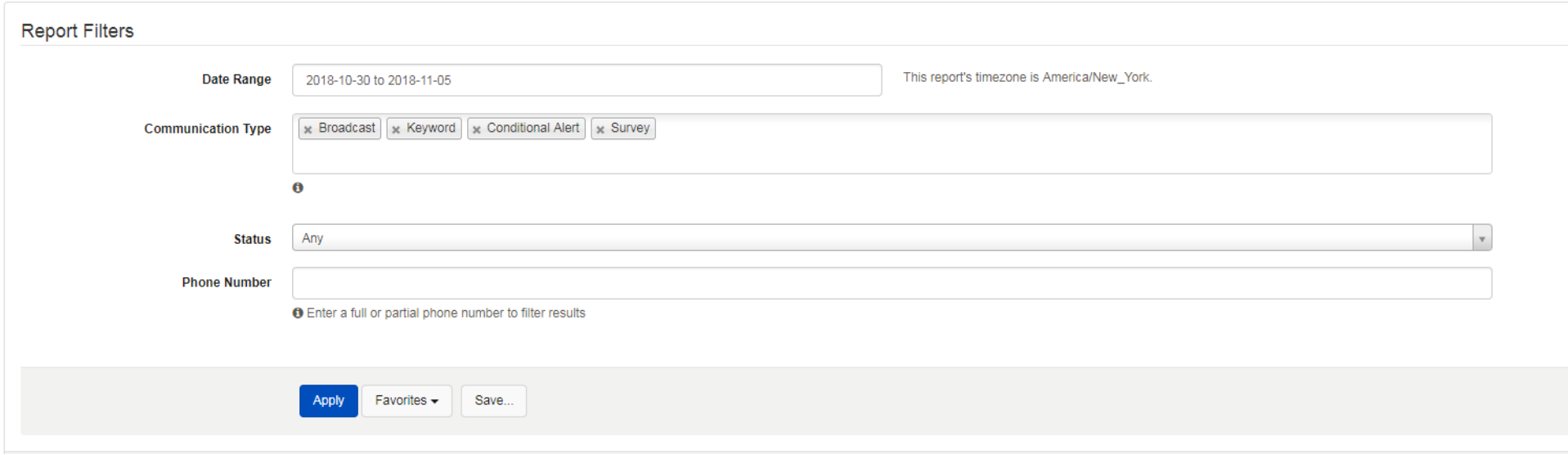
Reports: Message History

Establish a date range

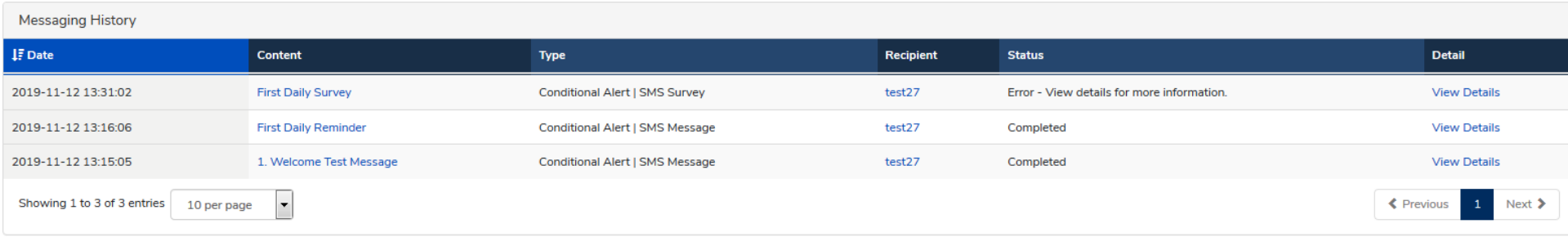
Add/delete communication type, select status, enter in a phone number (optional)



Reports: Message History

Manage **all** messages grouped by type

1. Completed or incomplete or error
2. Does not display message content
3. Groups two-messaging for the question text
4. Gives more details on errors


Messaging History

Date	Content	Type	Recipient	Status	Detail
2019-11-12 13:31:02	First Daily Survey	Conditional Alert | SMS Survey	test27	Error - View details for more information.	View Details
2019-11-12 13:16:06	First Daily Reminder	Conditional Alert | SMS Message	test27	Completed	View Details
2019-11-12 13:15:05	1. Welcome Test Message	Conditional Alert | SMS Message	test27	Completed	View Details

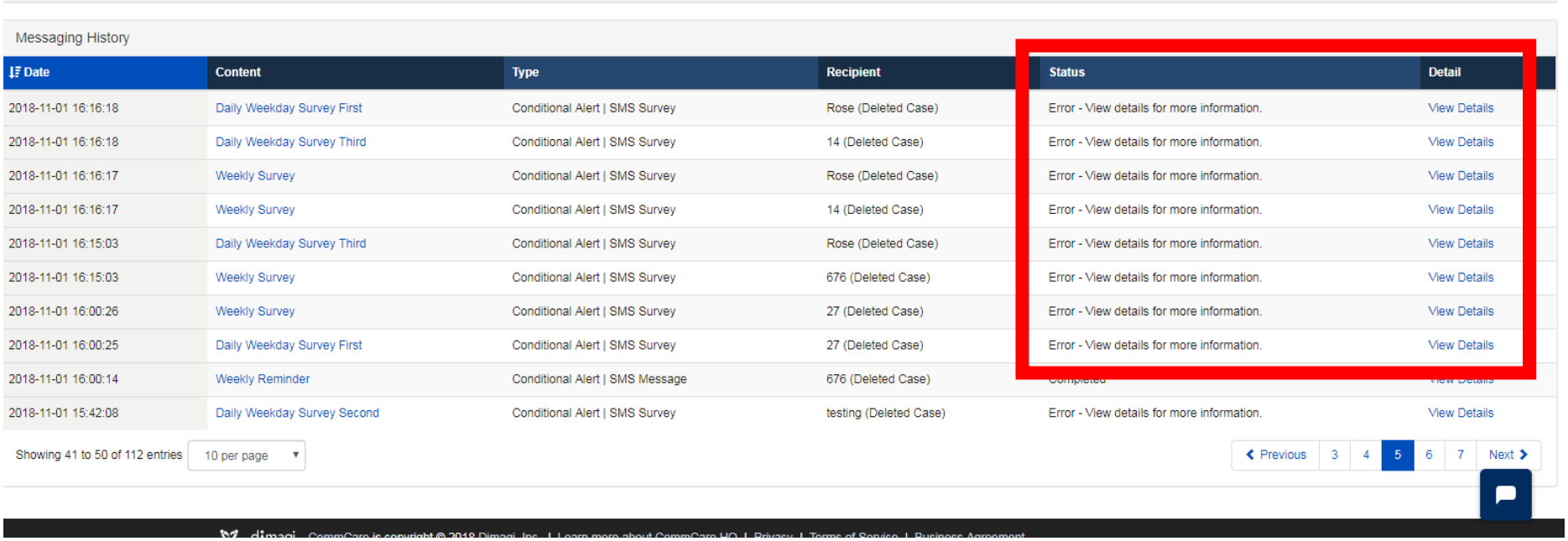
Showing 1 to 3 of 3 entries 10 per page

Previous 1 Next

Reports: Message History

If there are messages failing to send, click, "View Details" and either

1. troubleshoot with the client or
2. submit a bug report to Dimagi



Messaging History

Date	Content	Type	Recipient	Status	Detail
2018-11-01 16:16:18	Daily Weekday Survey First	Conditional Alert | SMS Survey	Rose (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:16:18	Daily Weekday Survey Third	Conditional Alert | SMS Survey	14 (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:16:17	Weekly Survey	Conditional Alert | SMS Survey	Rose (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:16:17	Weekly Survey	Conditional Alert | SMS Survey	14 (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:15:03	Daily Weekday Survey Third	Conditional Alert | SMS Survey	Rose (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:15:03	Weekly Survey	Conditional Alert | SMS Survey	676 (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:00:26	Weekly Survey	Conditional Alert | SMS Survey	27 (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:00:25	Daily Weekday Survey First	Conditional Alert | SMS Survey	27 (Deleted Case)	Error - View details for more information.	View Details
2018-11-01 16:00:14	Weekly Reminder	Conditional Alert | SMS Message	676 (Deleted Case)	Completed	View Details
2018-11-01 15:42:08	Daily Weekday Survey Second	Conditional Alert | SMS Survey	testing (Deleted Case)	Error - View details for more information.	View Details

Showing 41 to 50 of 112 entries | 10 per page | Previous | 3 | 4 | 5 | 6 | 7 | Next

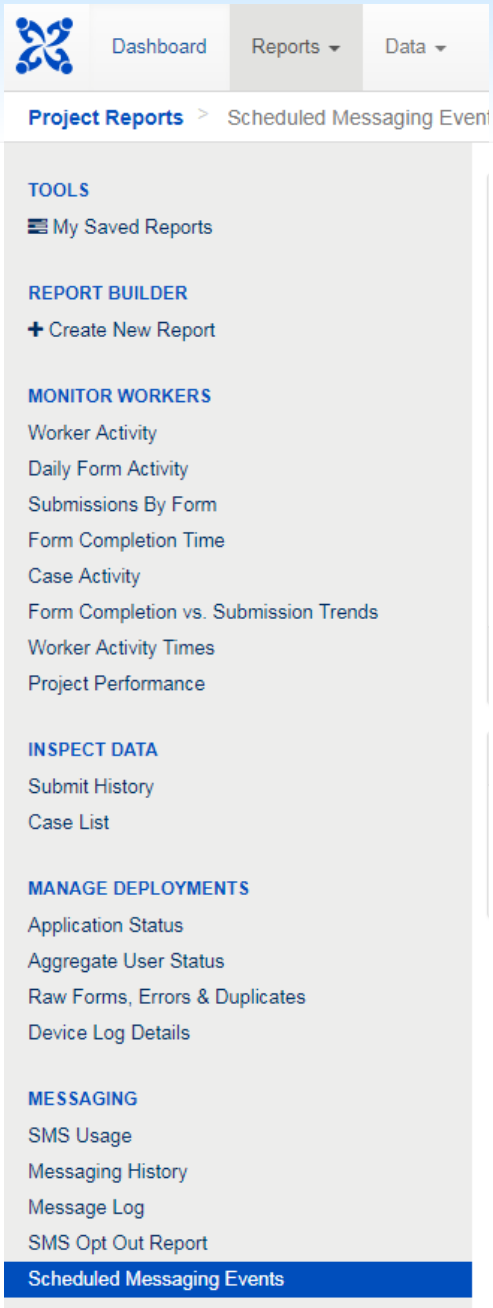
Reports: Other

SMS Opt Out Report

3. Has a client opted out/back in of the messages

Scheduled Messaging Events

4. View all upcoming types of messages scheduled tobe sent



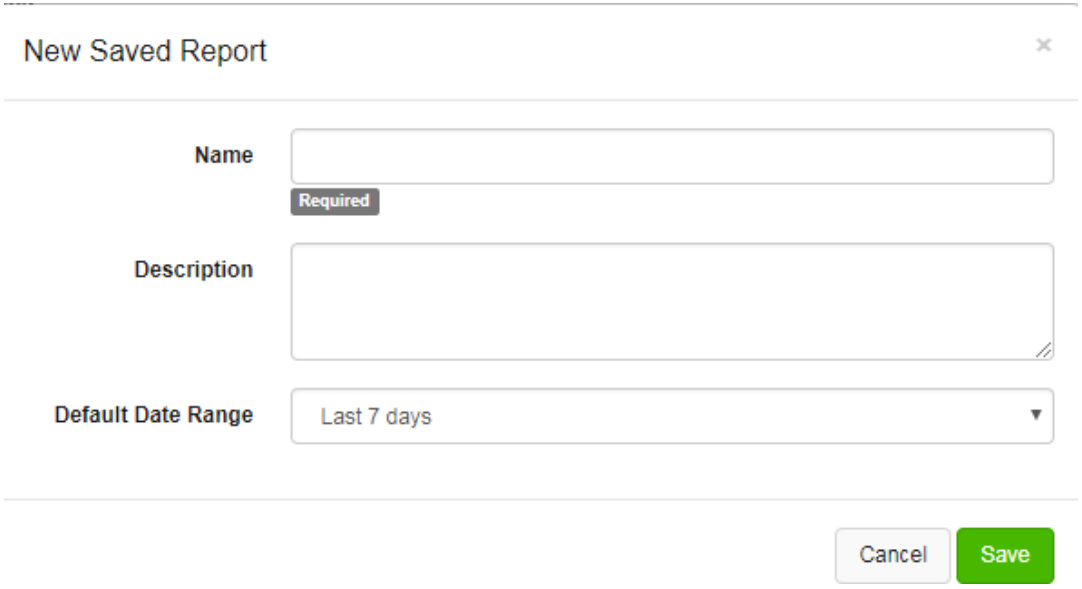
Reports: Saving

You can save any reports for easy access

Name the report, add a description, and establish a date range

Reports will be saved under

Reports > Tools > My Saved Reports



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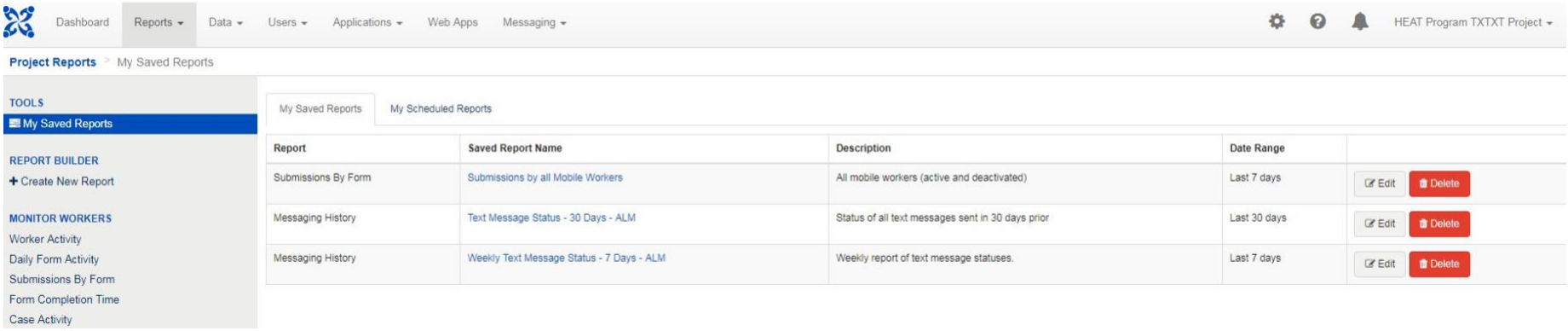
Reports: Saved Reports

Easy access

Delete or edit

Use "My Scheduled Reports" to create automatic emails



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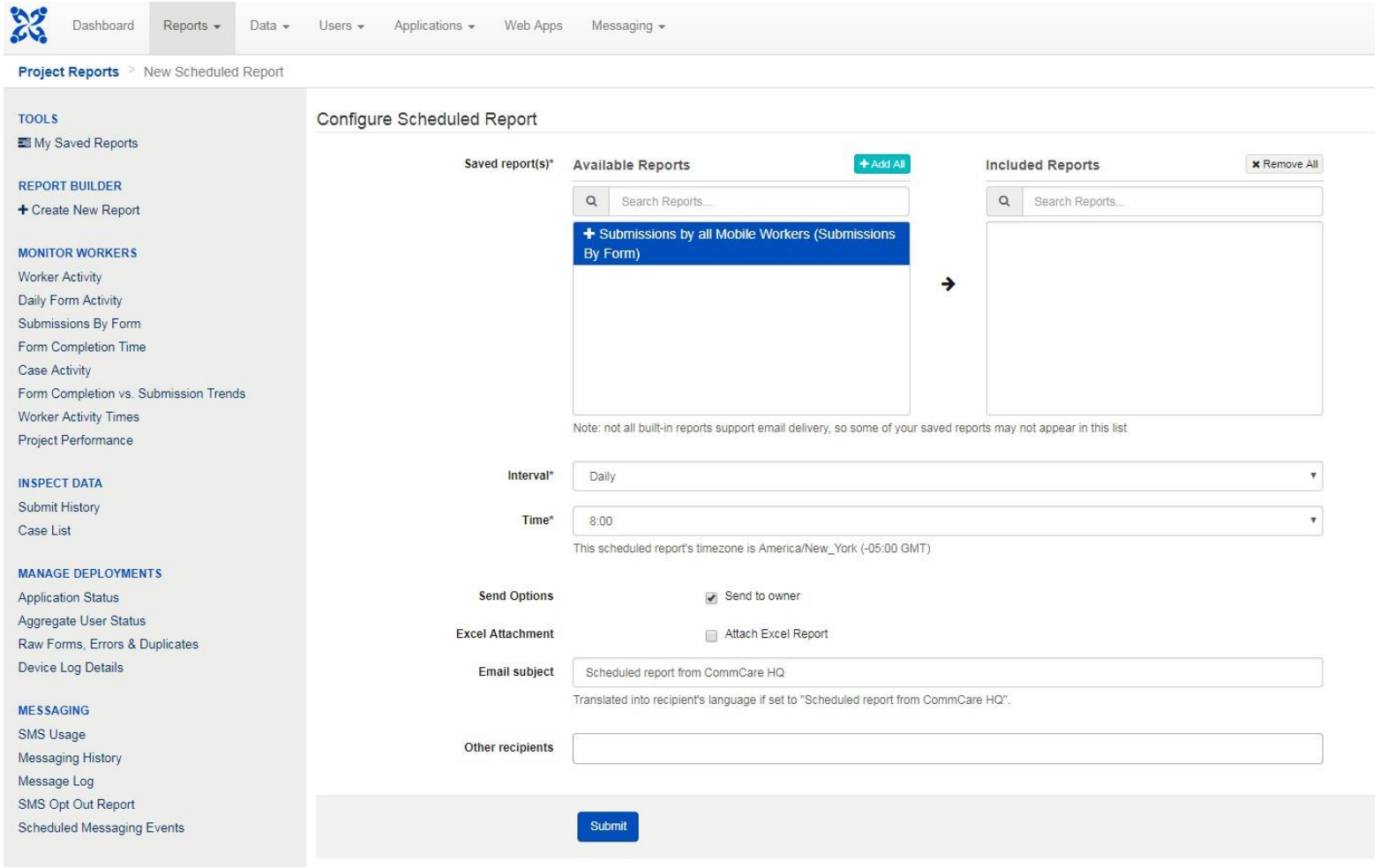
Reports: My Scheduled Reports



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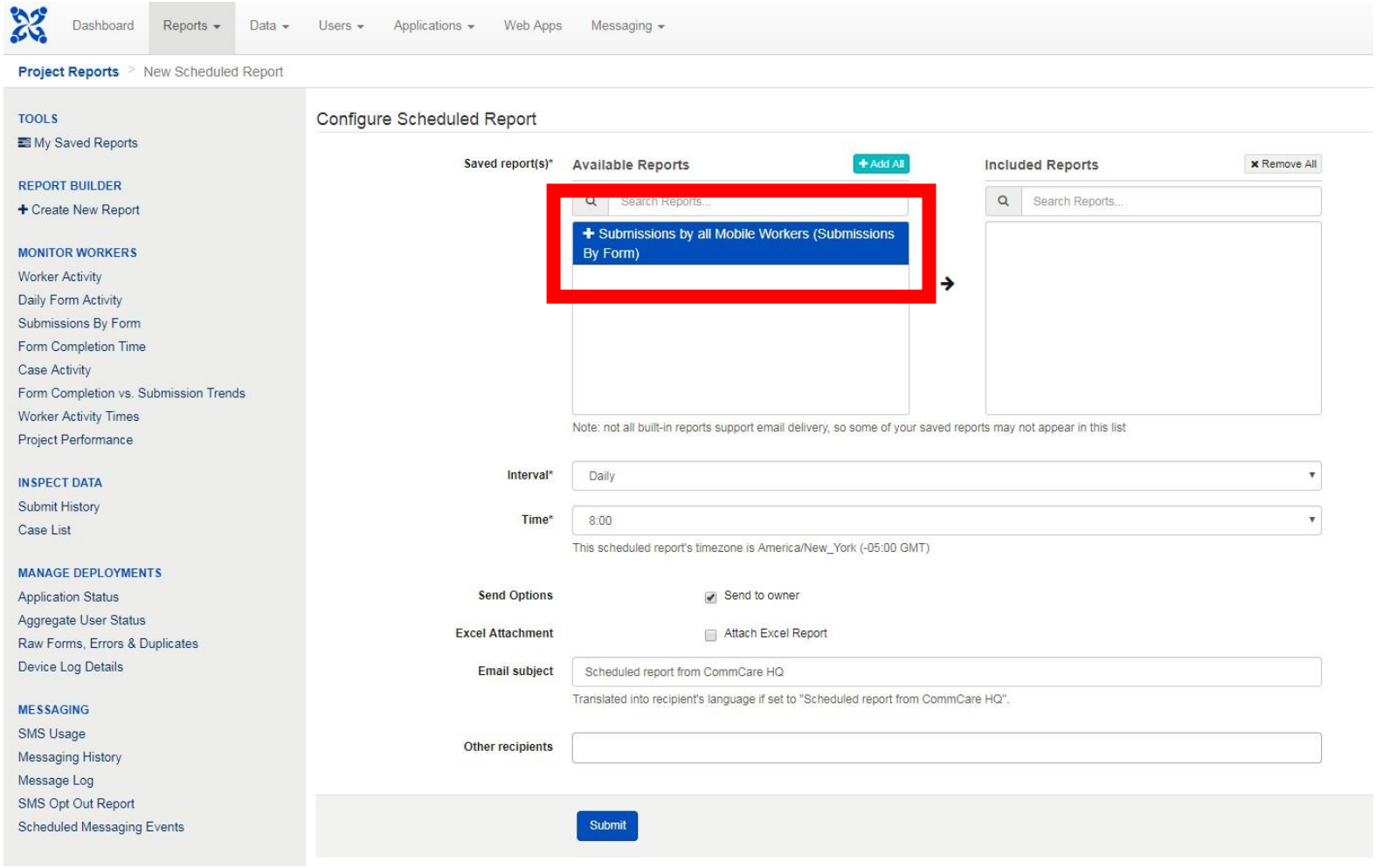
Reports: My Scheduled Reports



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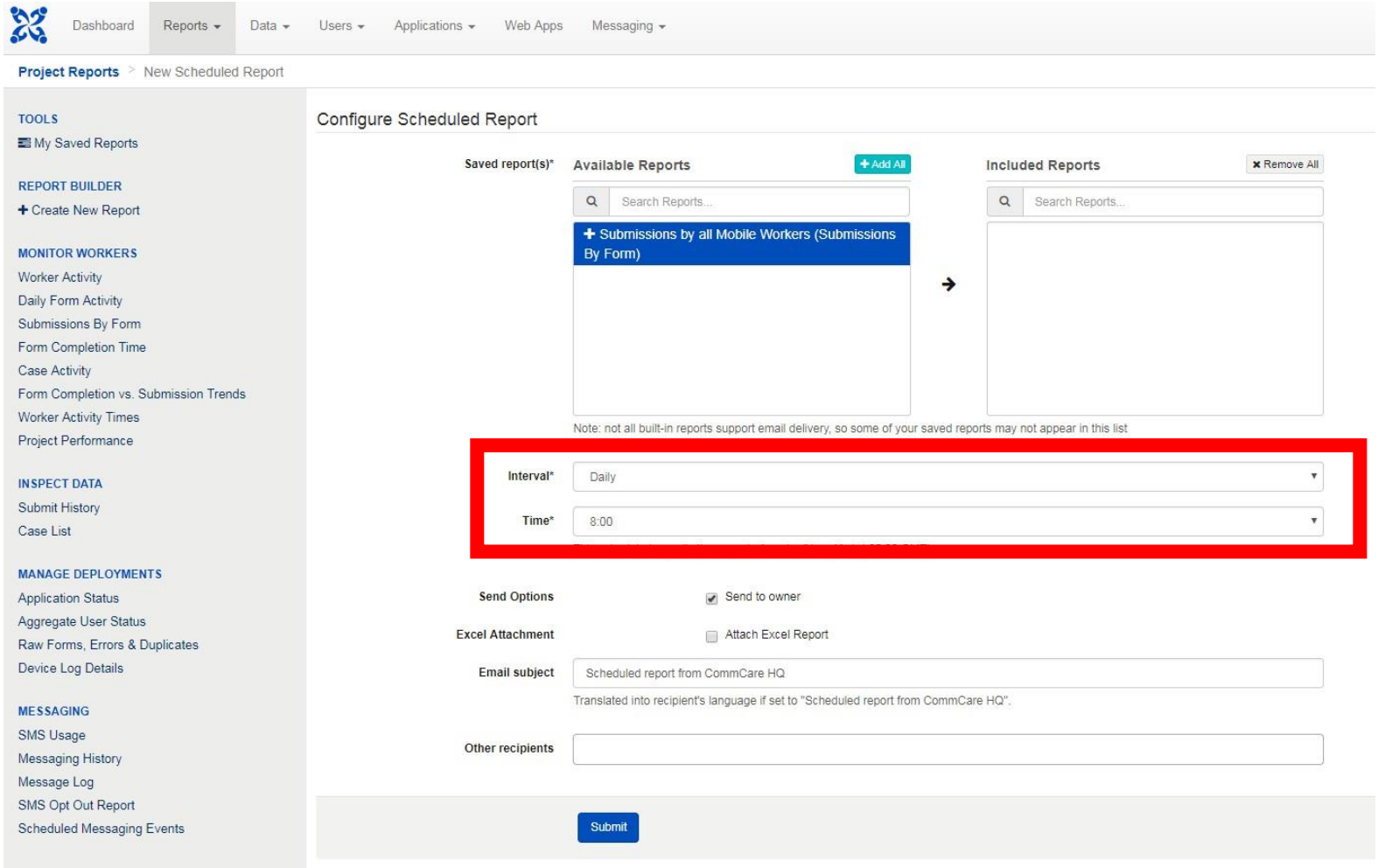
Reports: My Scheduled Reports



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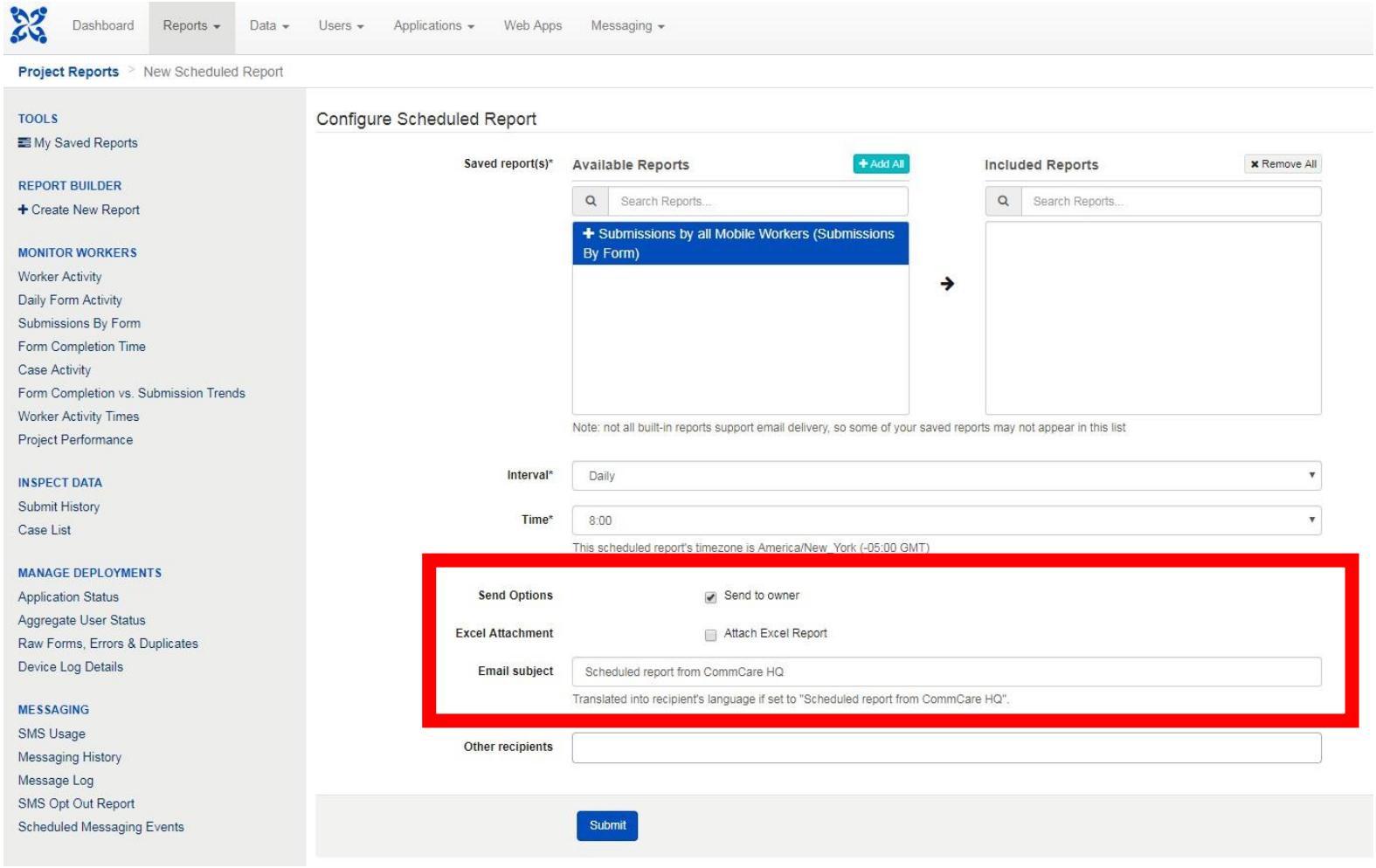
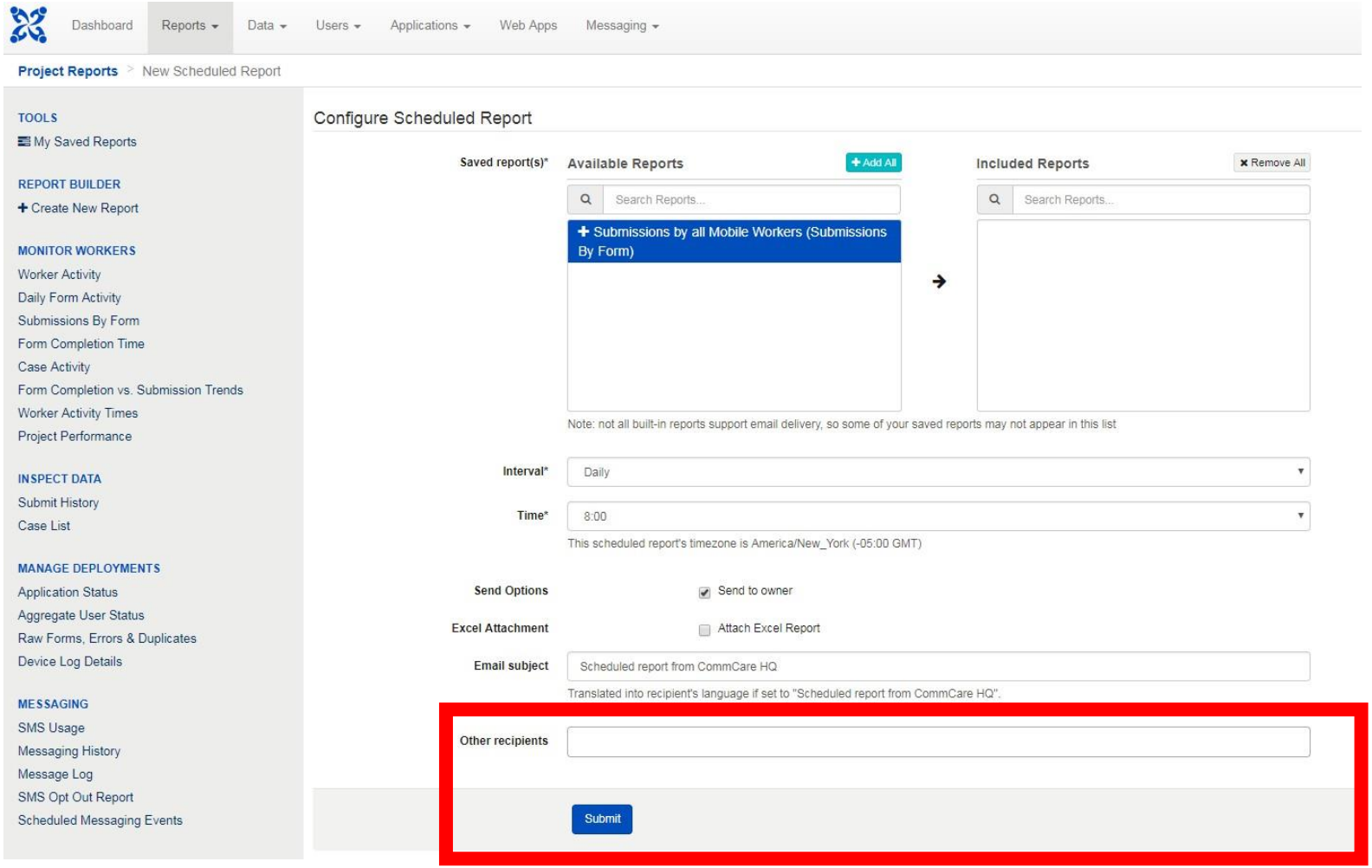
Reports: My Scheduled Reports



Ann & Robert H. Lurie Children's Hospital of Chicago®

Reports: My Scheduled Reports



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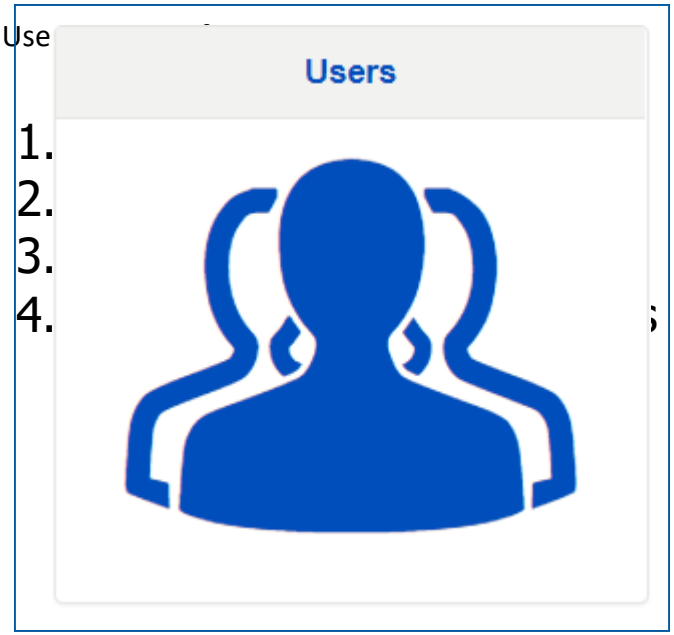
Children's Hospital of Chicago®

Web User

Creating a Mobile Worker

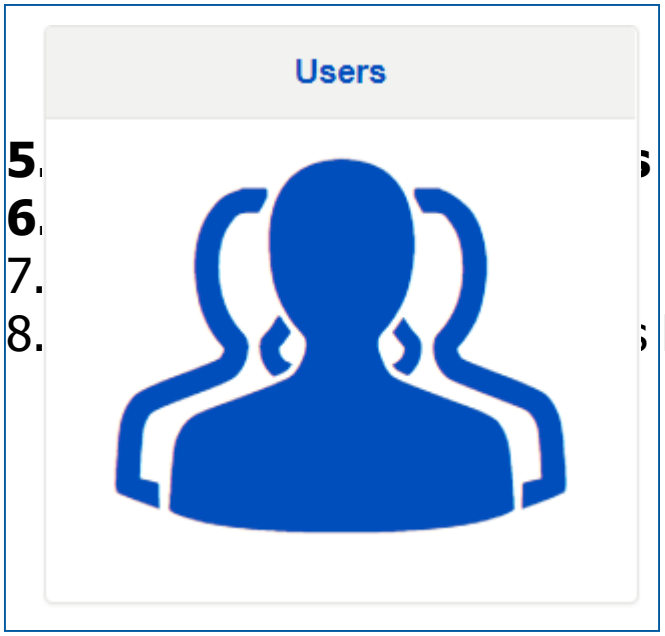
Basics of HQ: Users

In the Use



1.
2.
3.
4. ; have access to

Basics of HQ: Users



In the Users section of HQ you can:

5. **s**
6.
7.
8. s have access to

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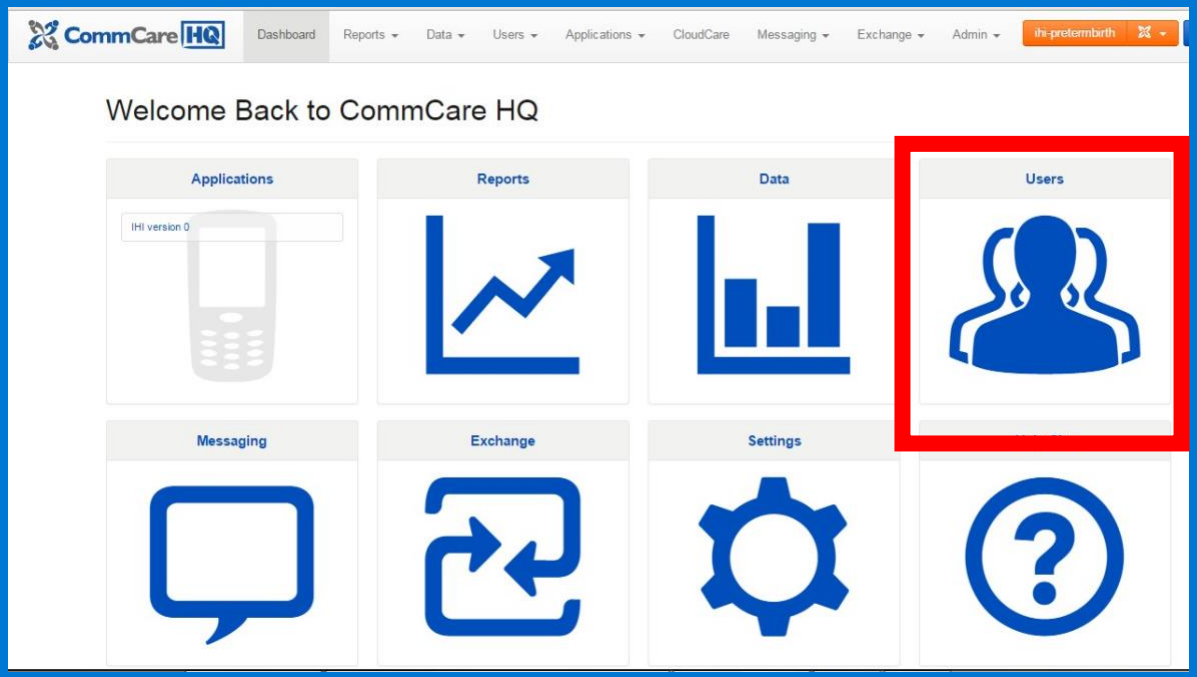
Basics of CommCareHQ: Users

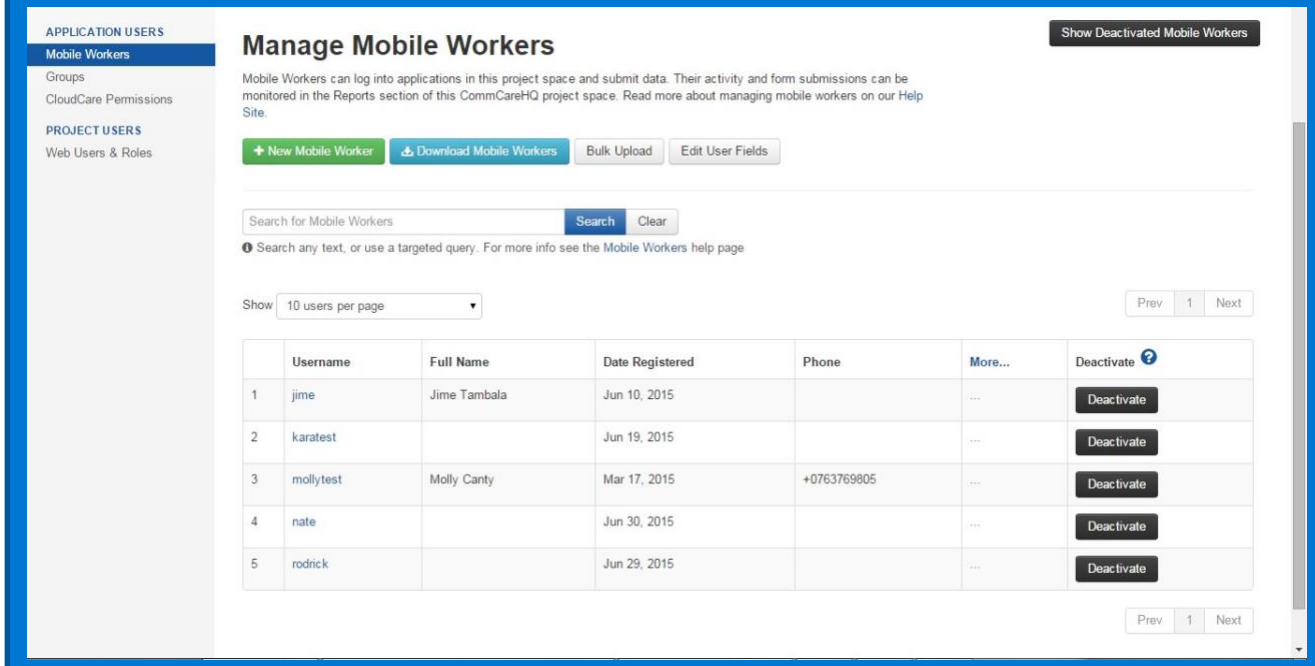


Links to learn more:

https://help.commcarehq.org/display/commcarepublic/CommCare+Fundamentals+-+Web+and+Mobile+Users

https://help.commcarehq.org/display/commcarepublic/Create+and+Manage+CommCare+Mobile+Workers

User Management: Mobile Users



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https://help.commcarehq.org/display/commcarepublic/Create+and+Manage+CommCare+Mobile+Workers

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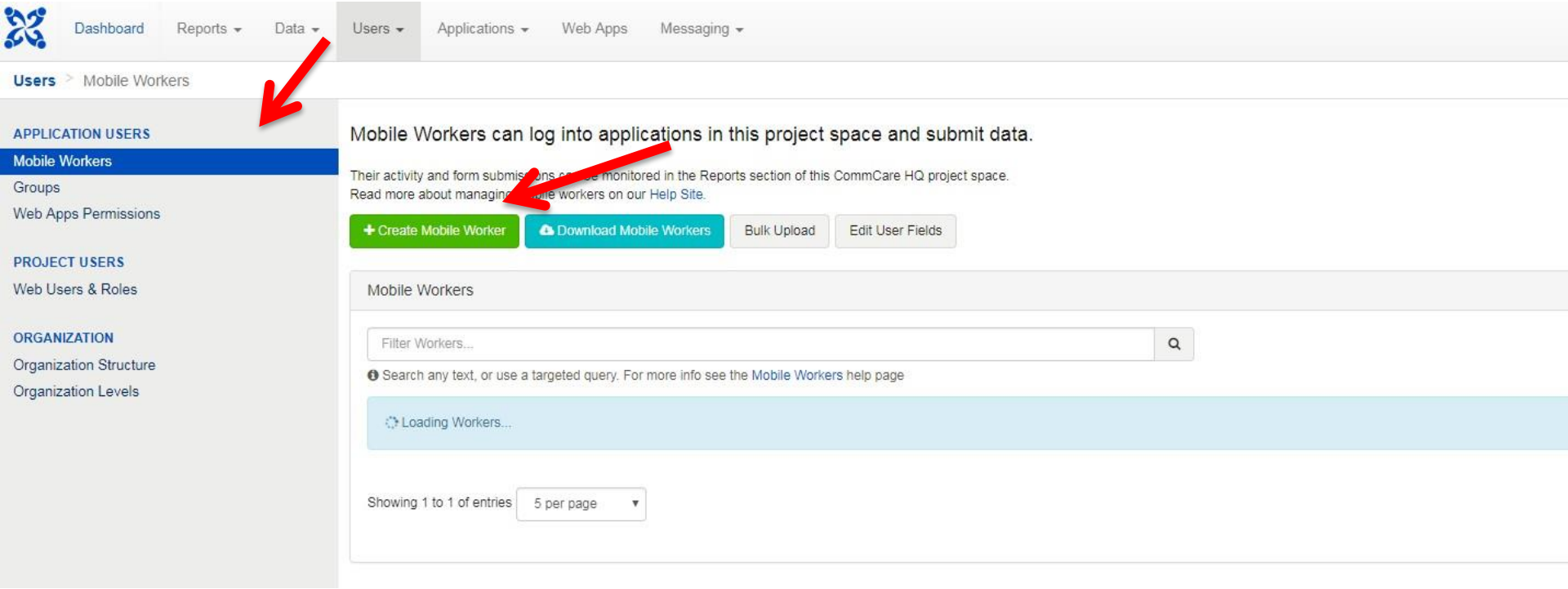
Managing Mobile Workers: Creating



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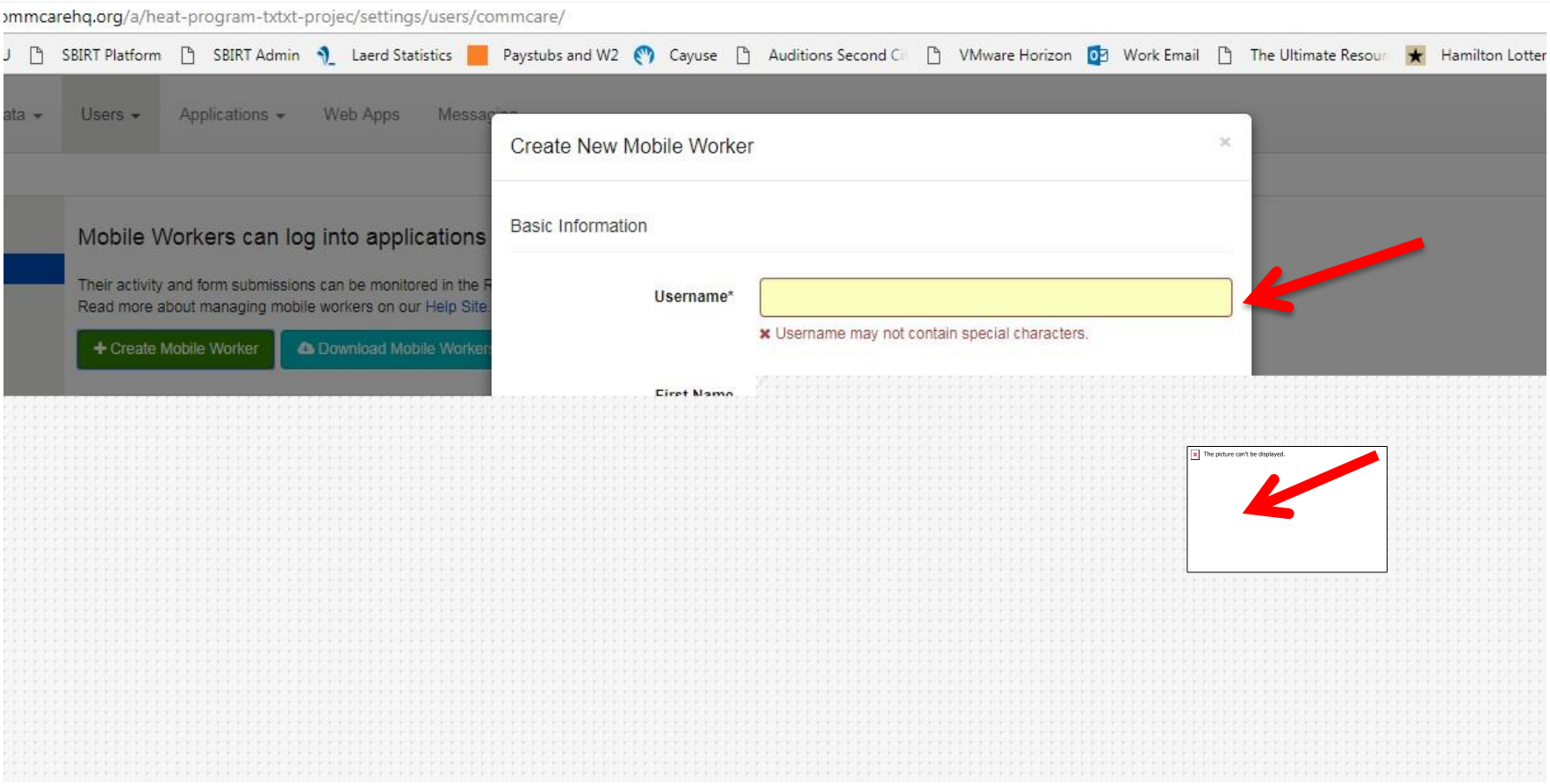
Managing Mobile Workers: Creating



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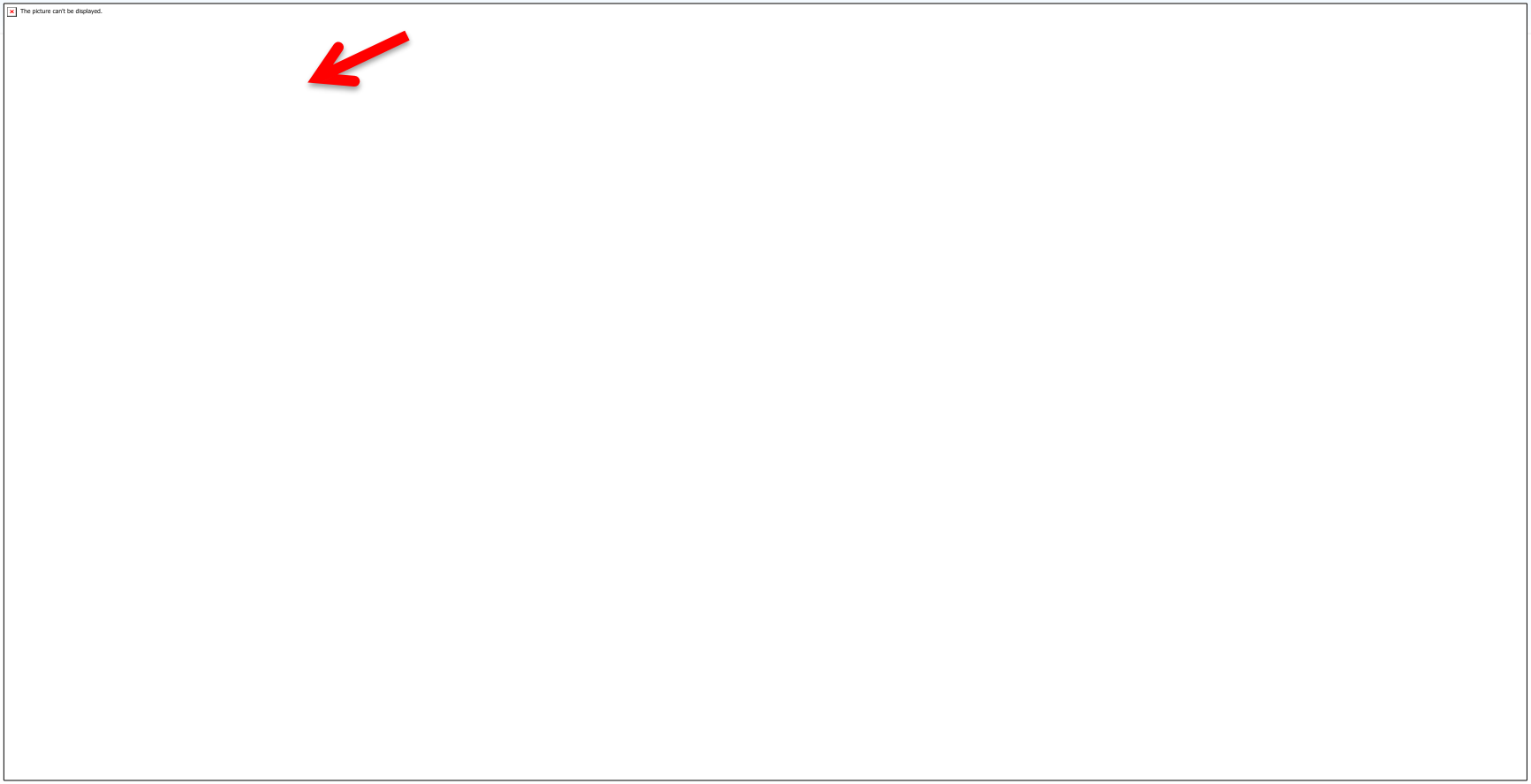
Managing Users: Edit Mobile Workers



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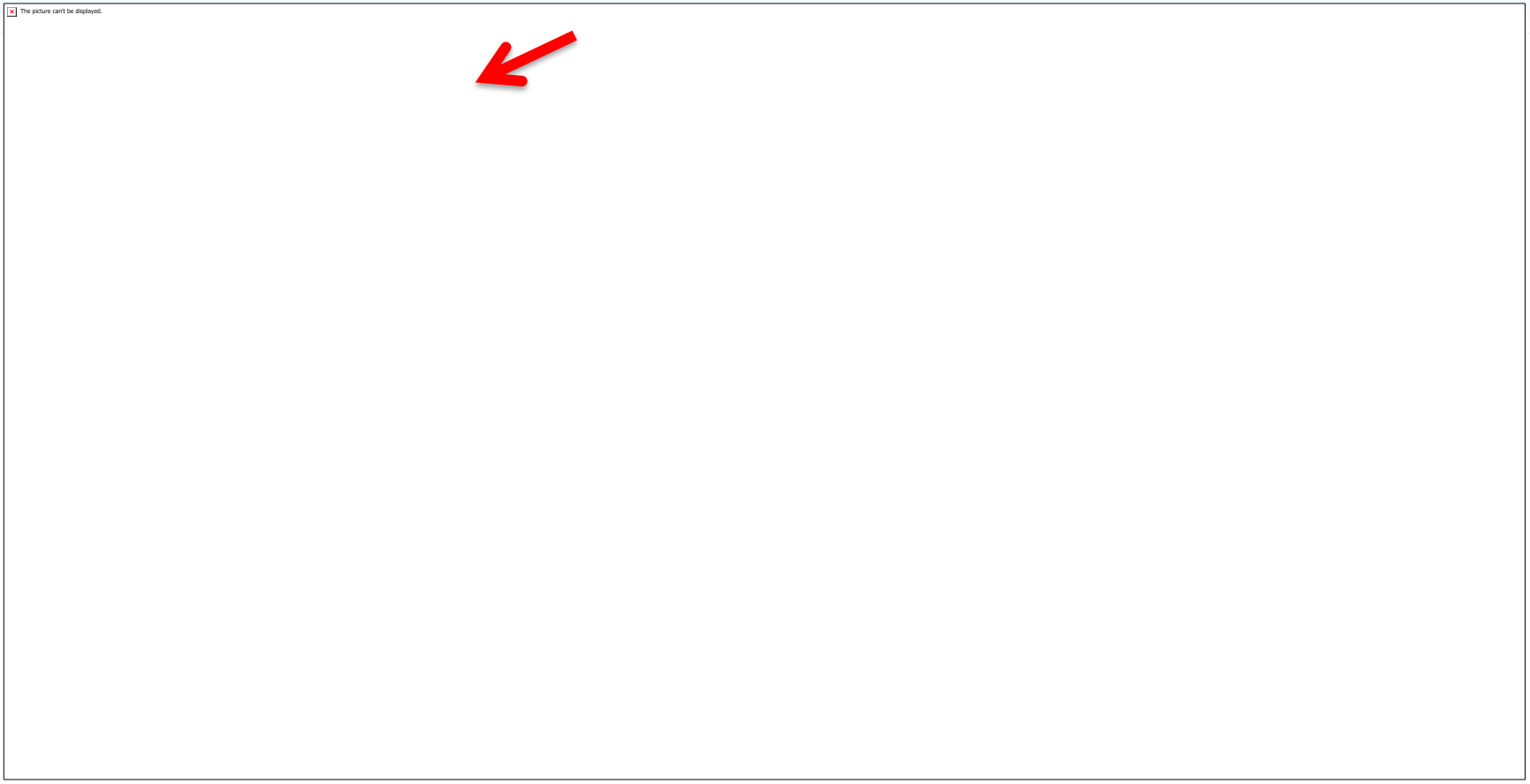
Managing Users: Edit Mobile Workers



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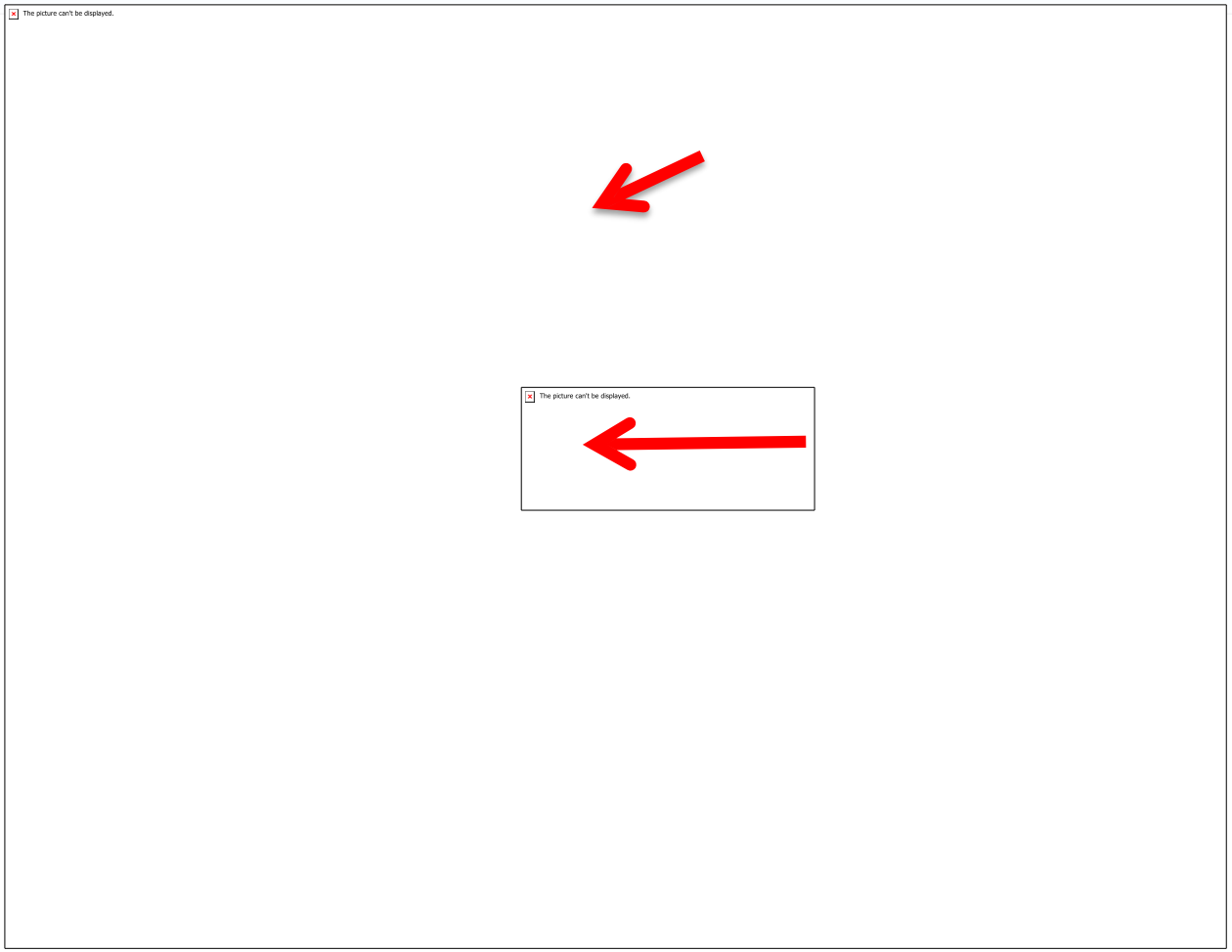
Managing Users: Edit Mobile Workers

Ann & Robert H. Lurie Children's Hospital of Chicago®

Managing Users: Edit Mobile Workers



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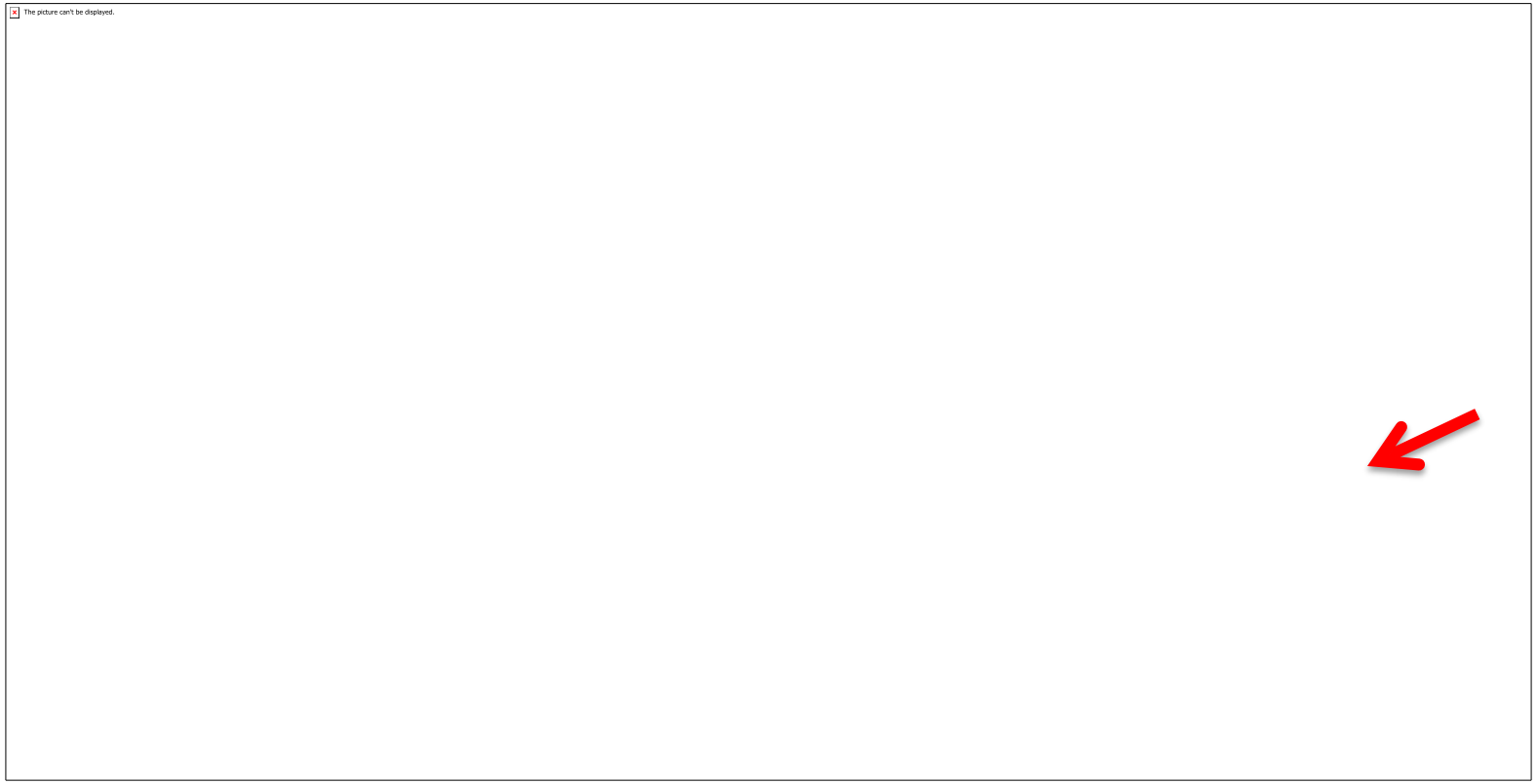
Managing Users: Edit Mobile Workers



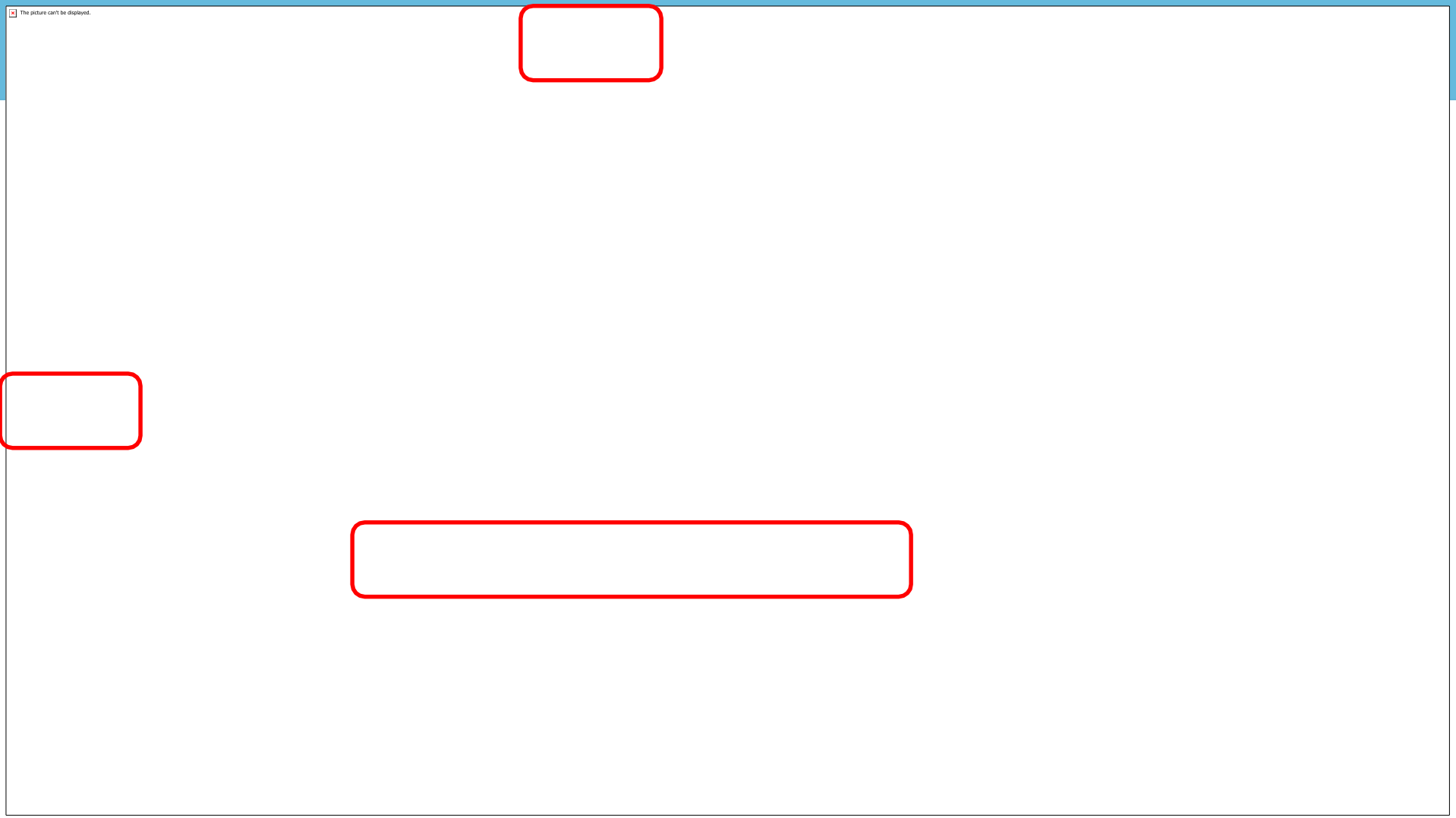
Managing Users: Case Sharing

5. The default in CommCare is that cases can only be accessed by the Mobile Worker who registered them

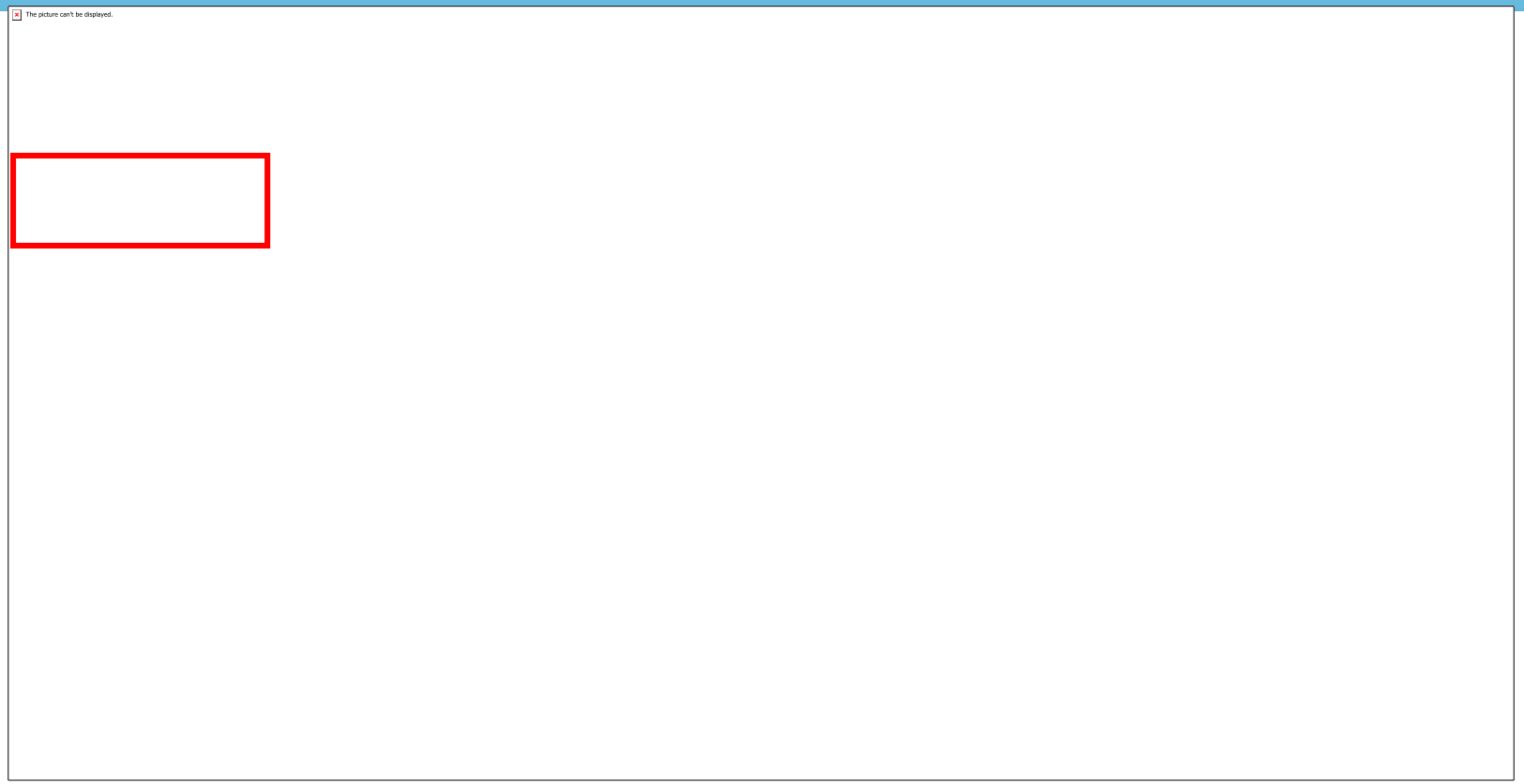
6. In order for all Mobile Workers to access all cases in the system, permission must be granted

7. This is accomplished by putting all mobile workers in an "All Mobile Worker" group and allow that group "case sharing" privileges

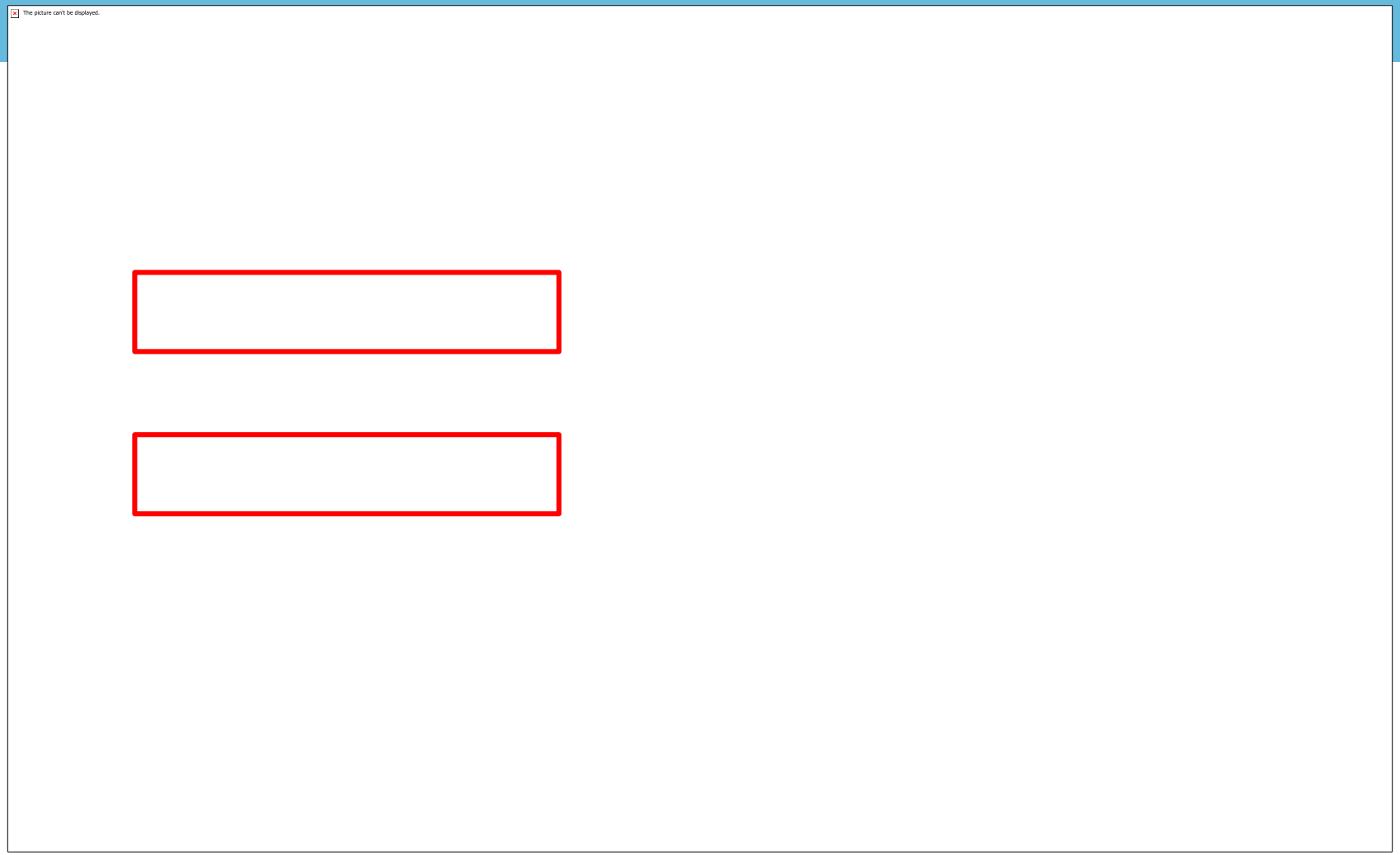
Managing Users: Case Sharing



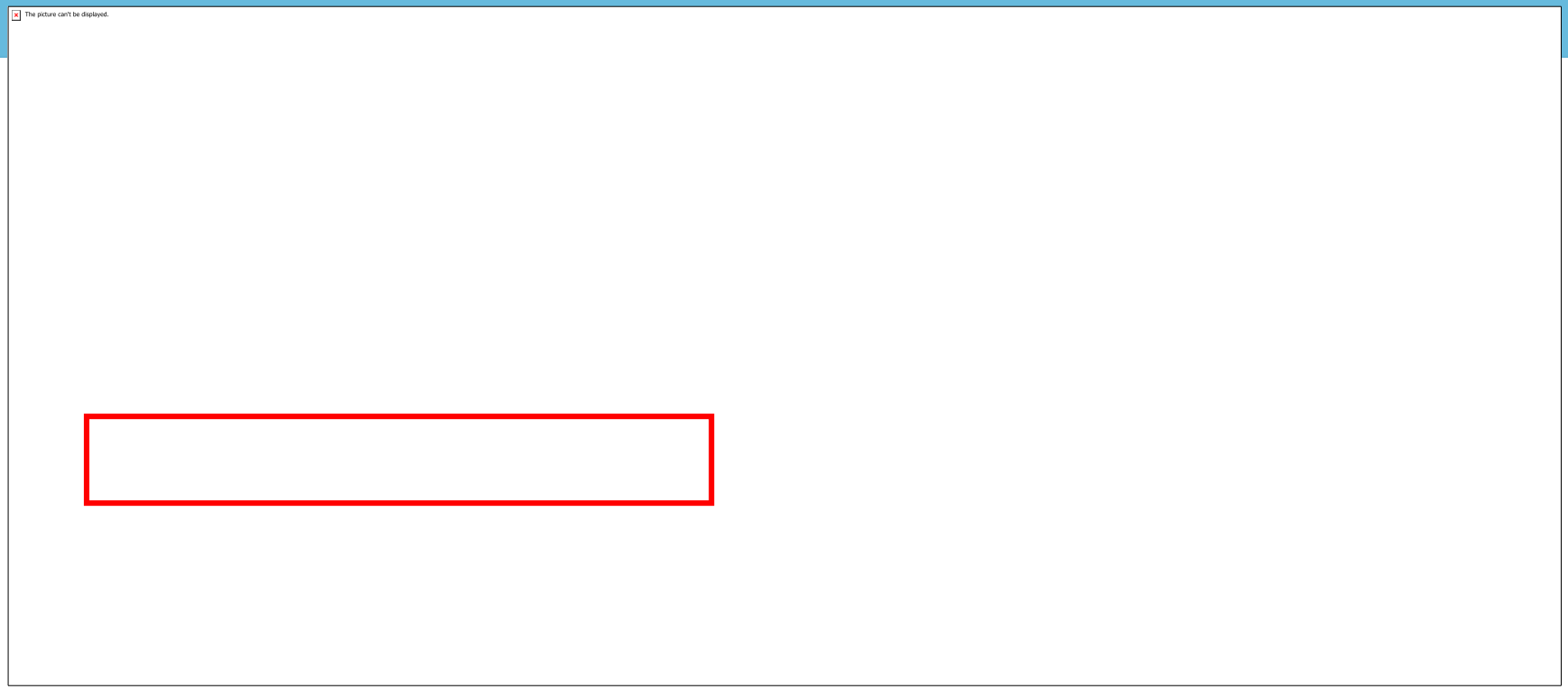
Managing Users: Case Sharing



Managing Users: Case Sharing

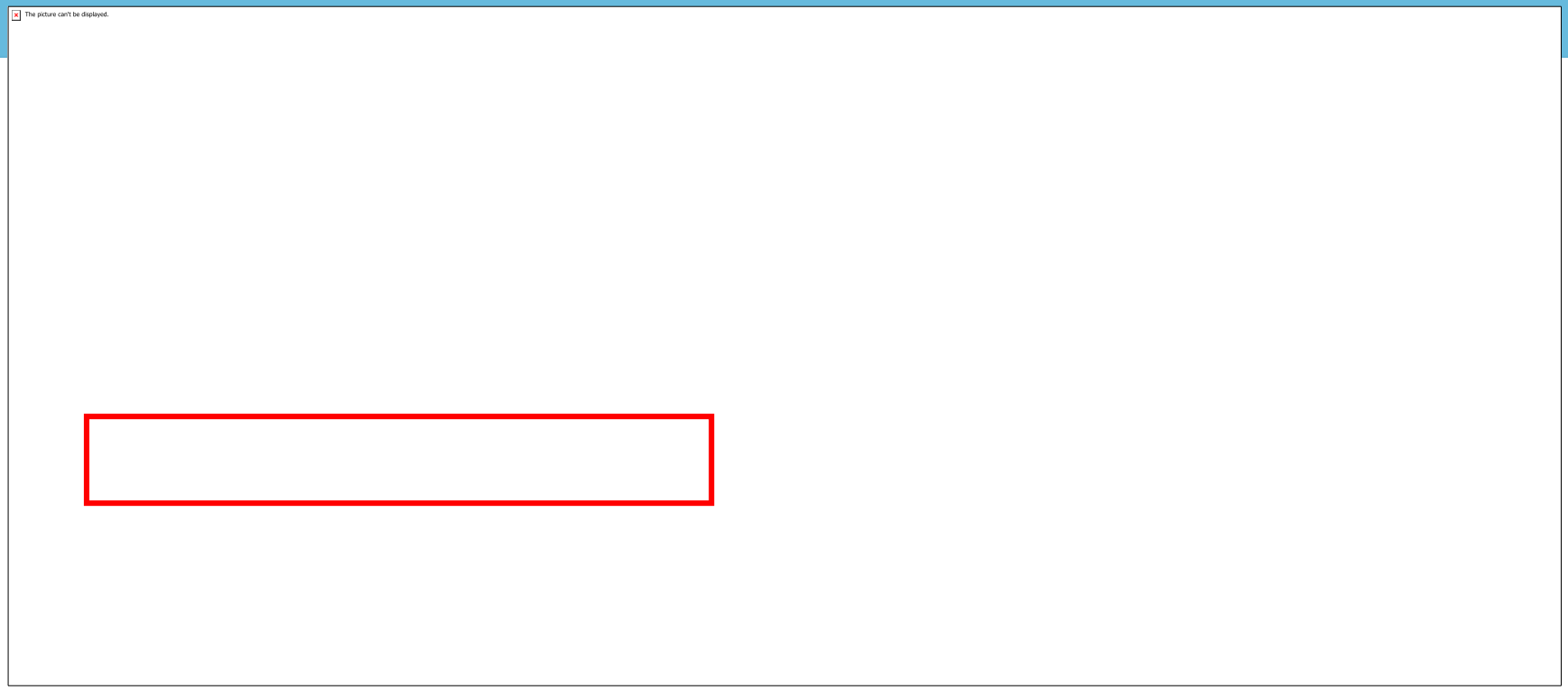


Managing Users: Case Sharing



1. Once the group is set up and case sharing is turned on, you can add the mobile workers you have created.

Managing Users: Case Sharing



2. Once the group is set up and case sharing is turned on, you can add the mobile workers you have created.

3. Whenever you add a new Mobile Worker, you can add them to the case sharing group here or by editing their information directly.

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Understand:

1. After creating a new mobile worker, add them to the All Mobile Workers group

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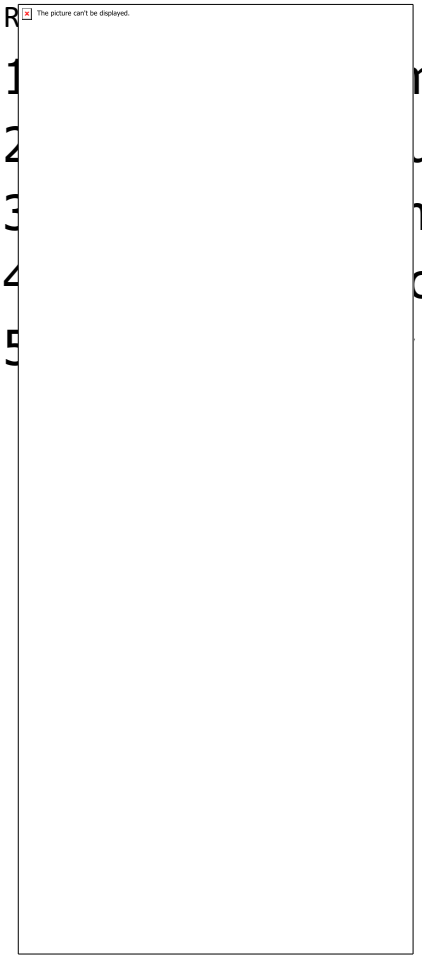
Managing Mobile Worker Performance

1. R



1 n submissions
2 ubmissions
3 nitted
4 case activity
5 times

Time to try!

https://www.commcarehq.org/a/txtxt/dashboard/project/

1. Login to CommCare as a Web User
2. Create a Mobile Worker
3. Add them to the "All Mobile Workers" case sharing group

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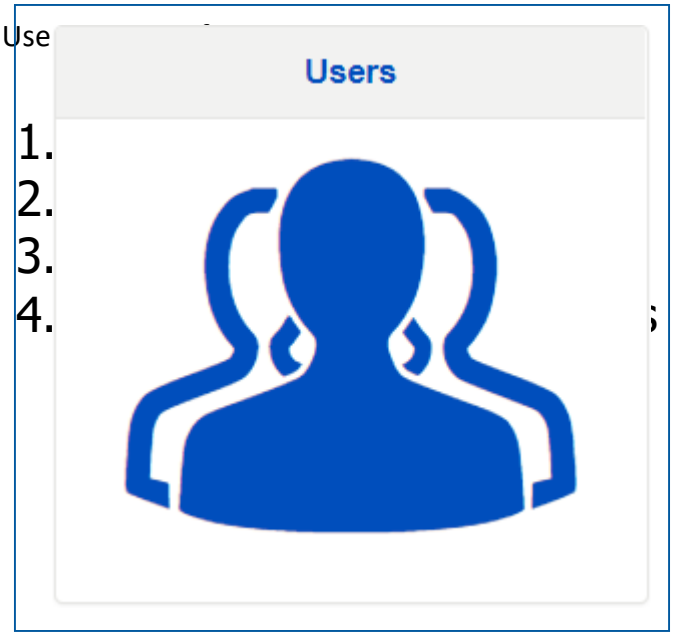
Web User

Creating a Web User

Basics of HQ: Users

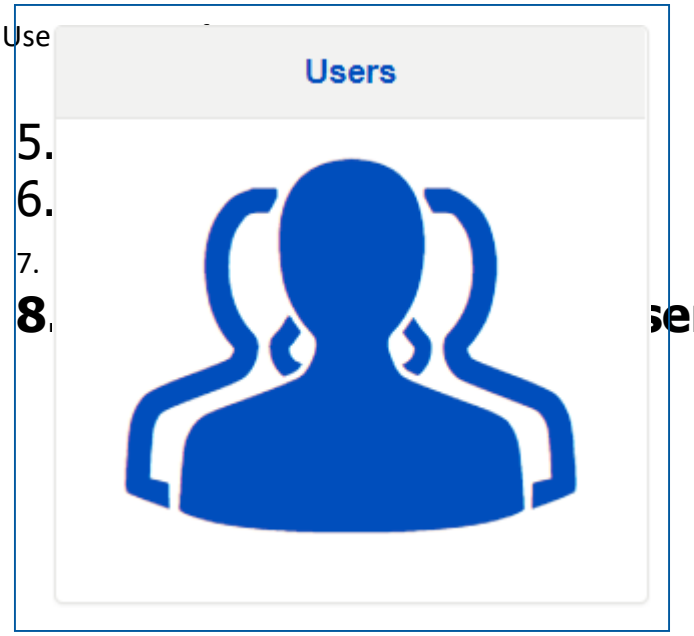
In the Use



1.
2.
3.
4. ; have access to

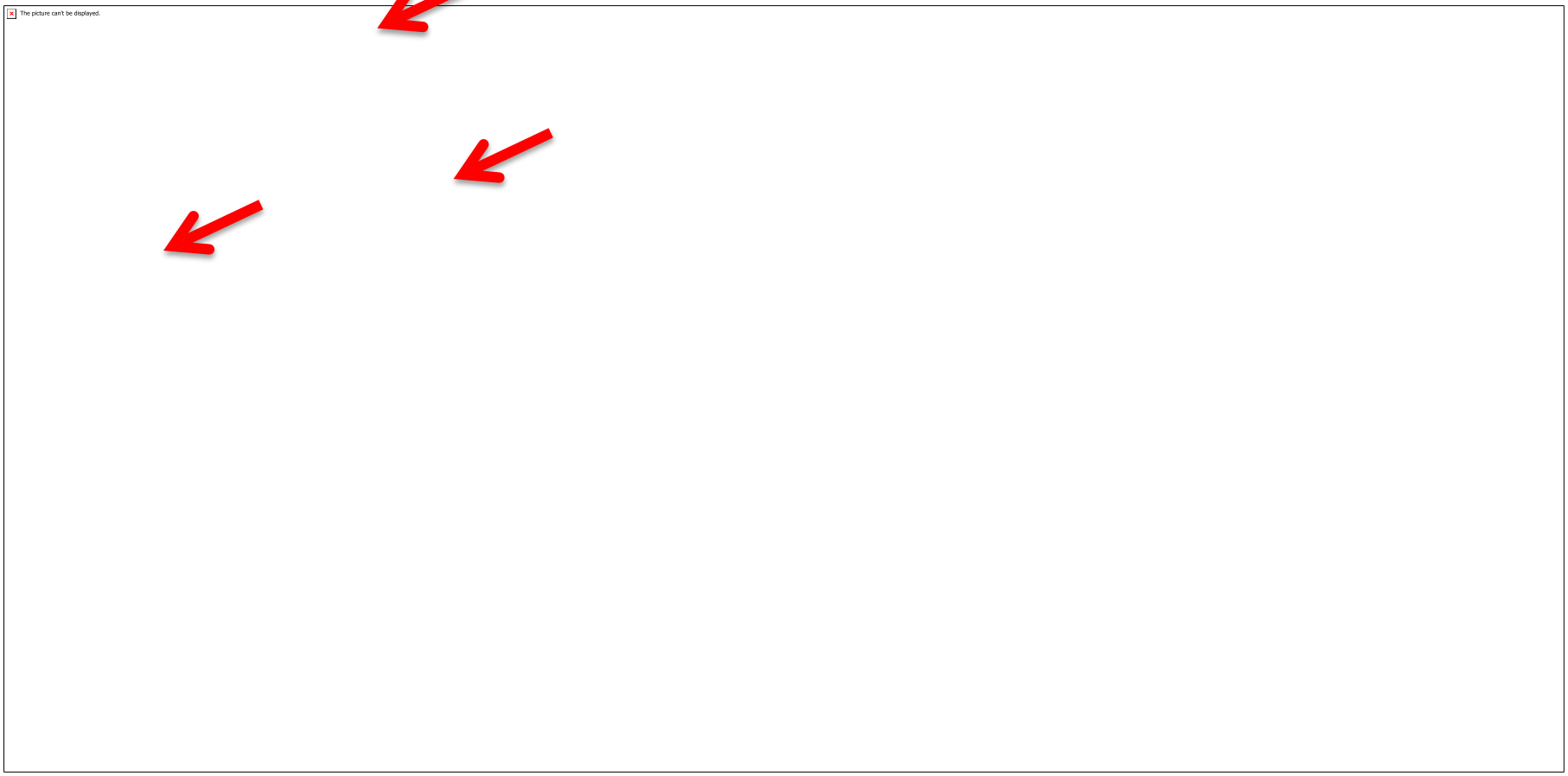
Basics of HQ: Users

In the Use



5.
6.
7.
8. **sers have access to**

Managing Users: Creating a Web User



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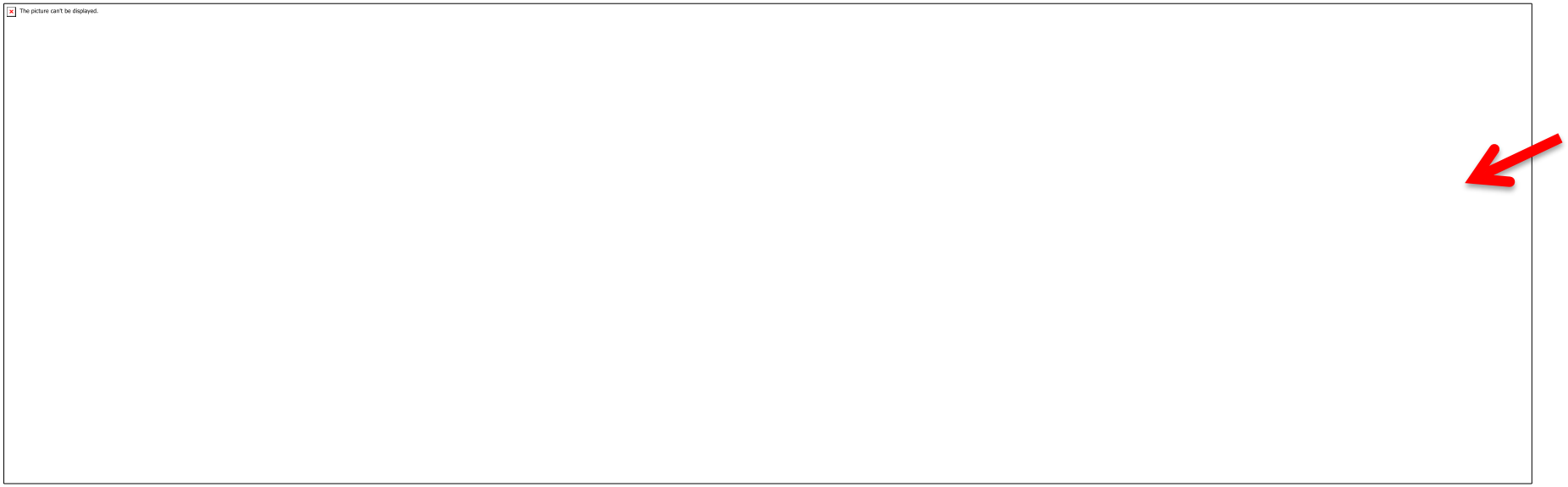
Managing Users: Creating Web User



Web User will receive an email inviting them to join the project and create a password

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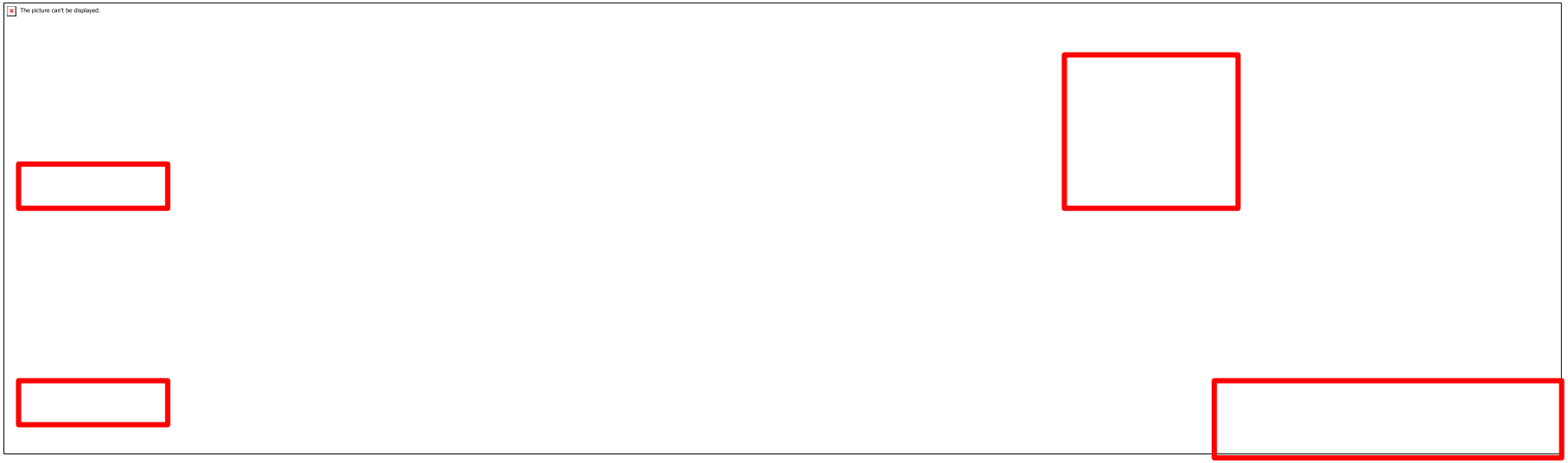
Managing Users: Web User Role

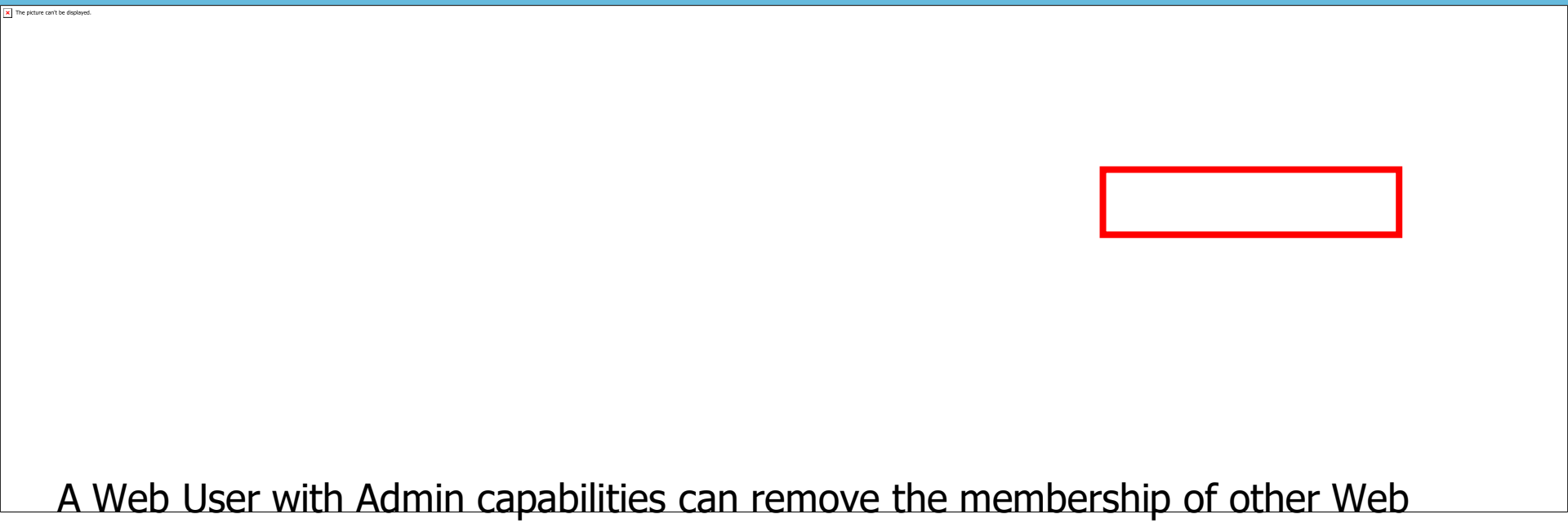


Click to define a role's parameters

Click to choose the levels of access on HQ and the reports that each type of role can access.

To the right of the role, you can also edit the specific access on HQ for each existing role

For example, you could create a unique role that would be constant across organizations



A Web User with Admin capabilities can remove the membership of other Web Users by clicking "Remove Membership" on the Web Users and Roles page.

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Time to try!

https://www.commcarehq.org/a/txtxt/dashboard/project/

1. Login to CommCare as a Web User
2. Create a Web User
3. Make sure their User Rights are accurate

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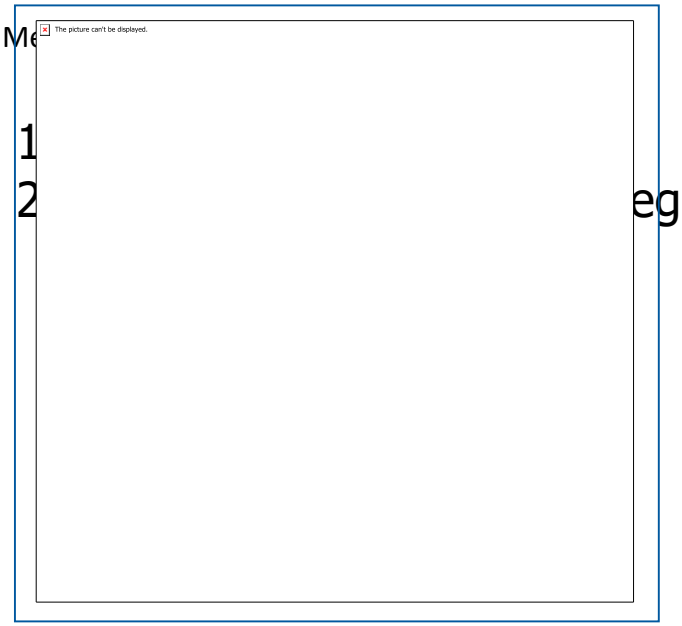
Web User: Other FunctionsSending a Broadcast

Basics of CommCareHQ: Messaging

In the Me



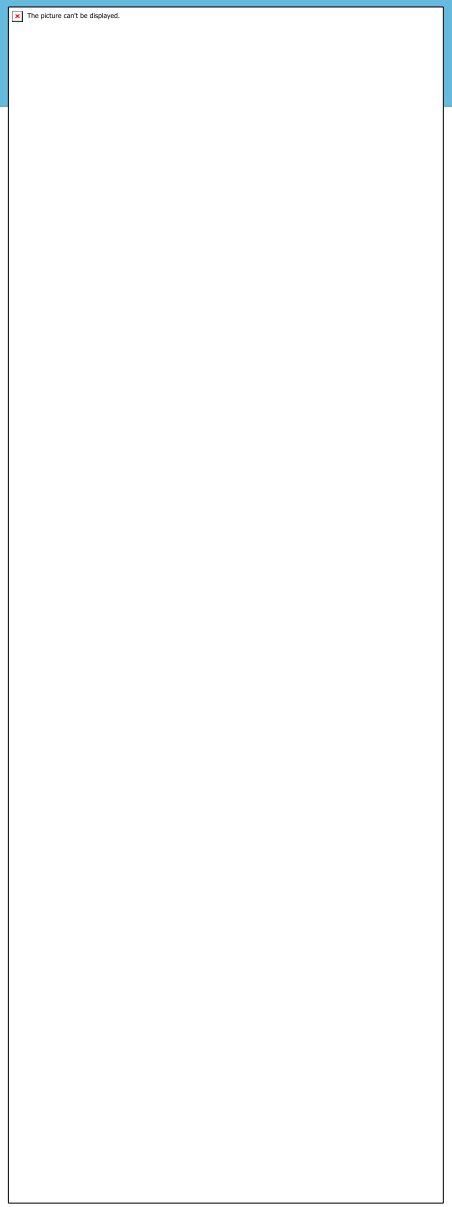
1

2 egistered participants

Finishing Client Registration

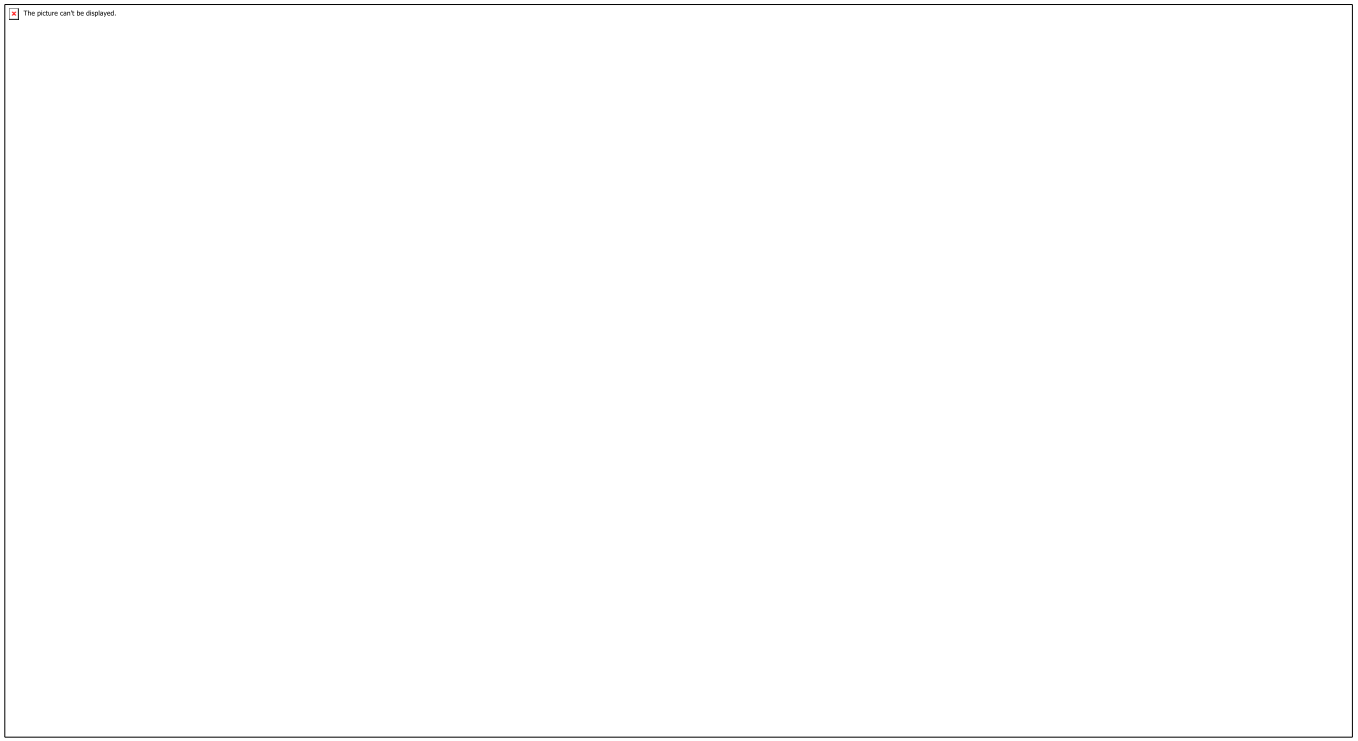
1. Navigate to

   Messaging > Contacts > Case Groups



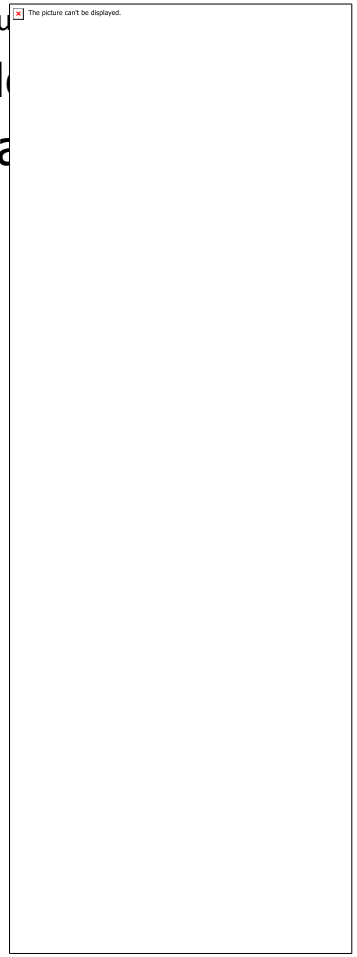
Finishing Client Registration

2. Add every new case to the “All Participants” group using their caseID or phone number

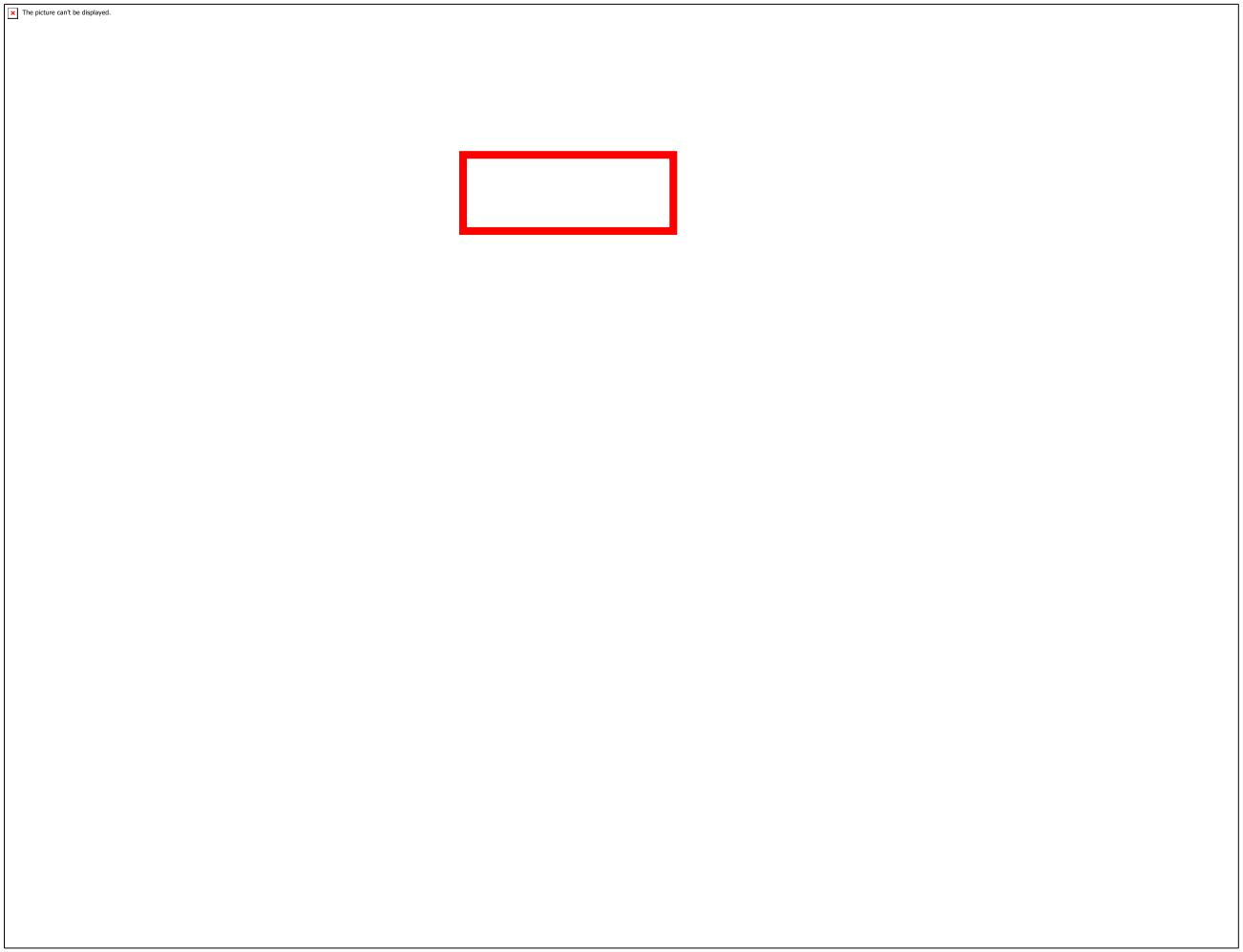


Messaging: Broadcasts

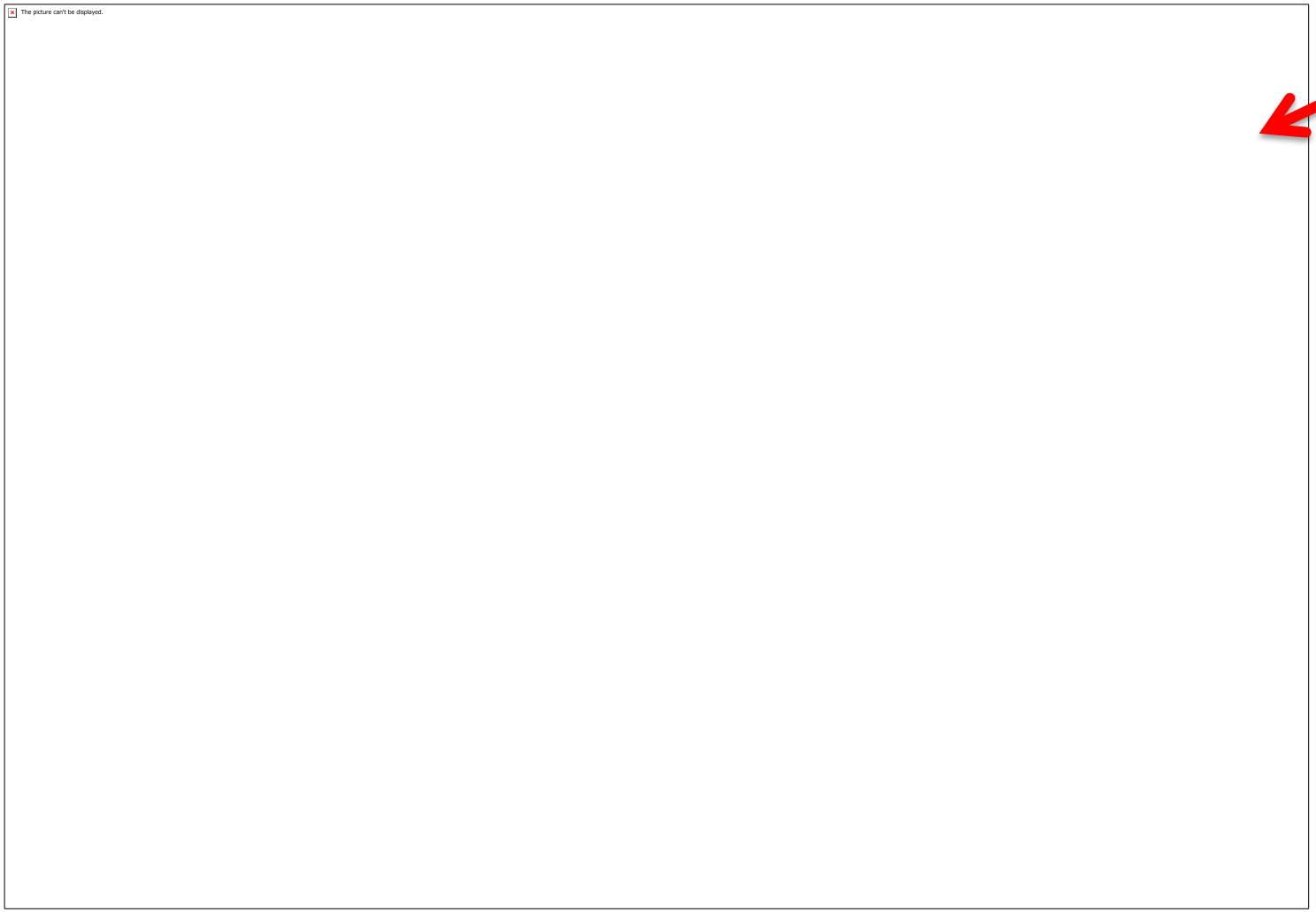
1. Allows you
    1. M you added theirnumber to their profile)
    2. Ca



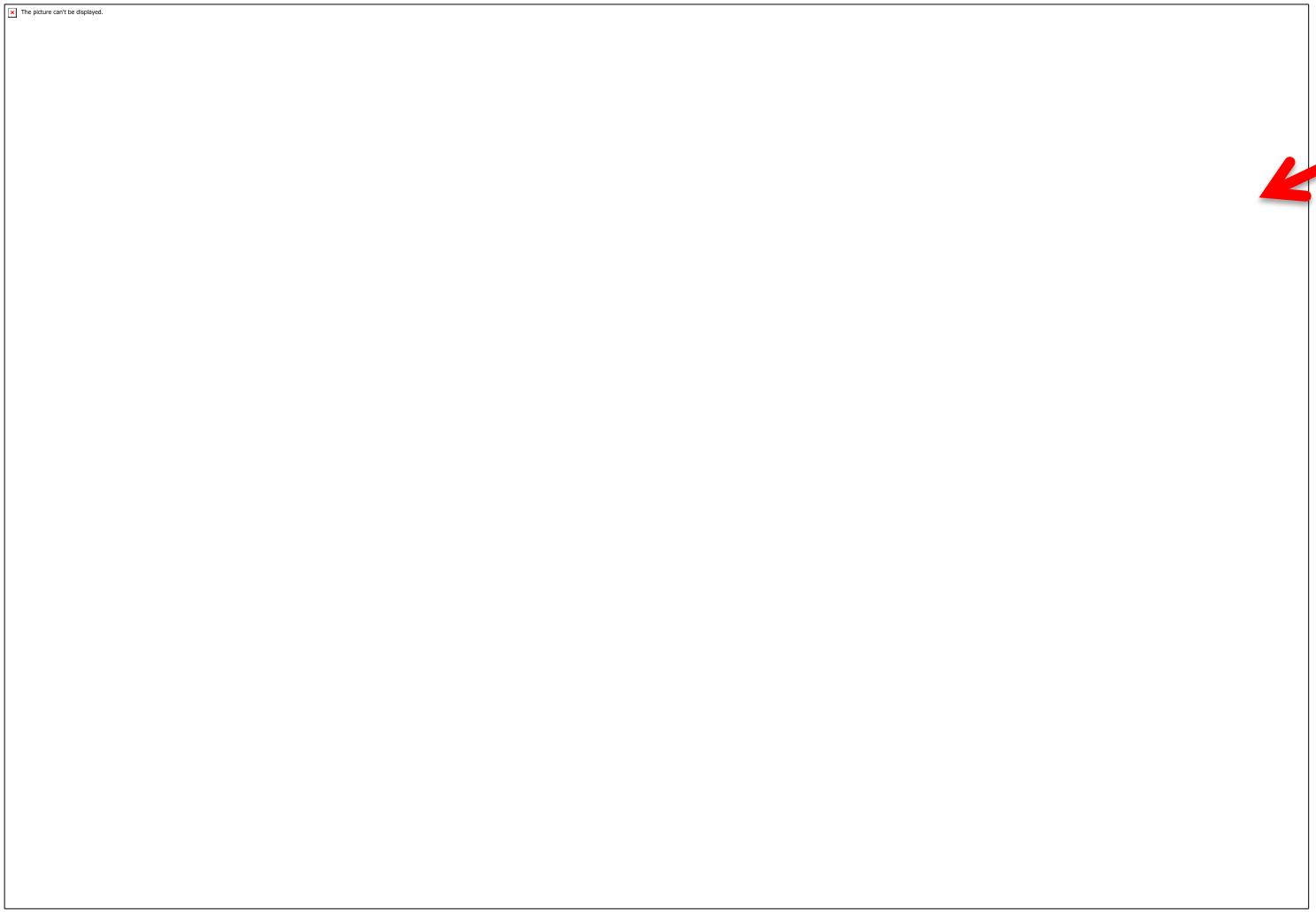
Messaging: Broadcasts



Messaging: Broadcasts

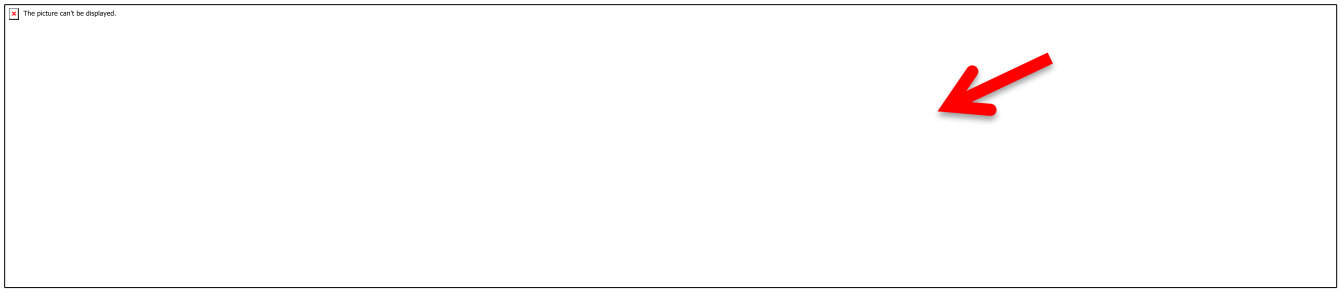


Messaging: Broadcasts

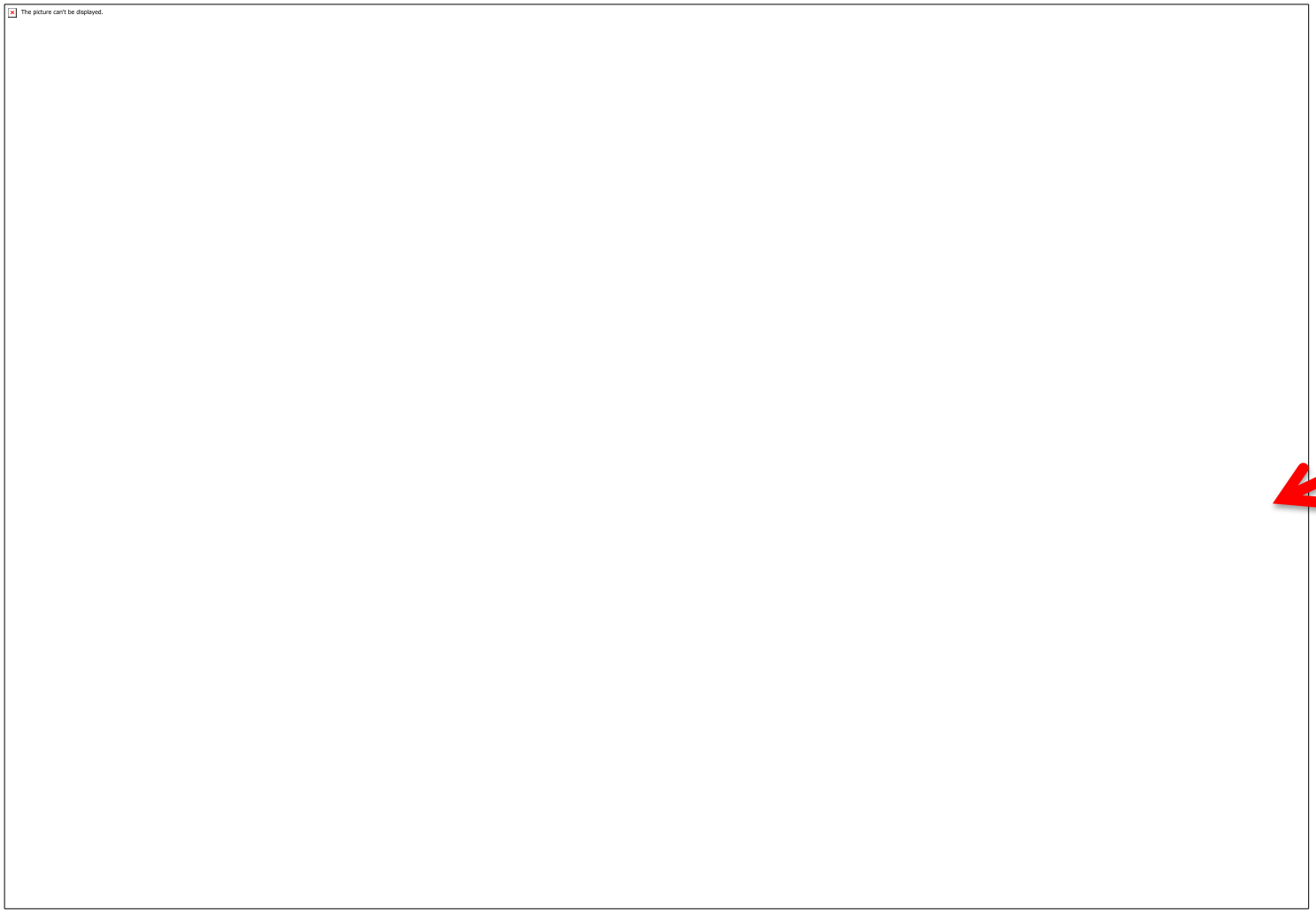


Messaging: Broadcasts

Messaging: Broadcasts



Messaging: Broadcasts



Messaging: Broadcasts

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TechnicalIssues

Most Common Issues

Issues

3. Conflation of Web User/MobileWorker roles

Solutions

4. Only give those that **need**admin access a Web User account

5. (Re)Train staff on different credentials and dashboards

Most Common Issues

Issues

6. Texts are not sending

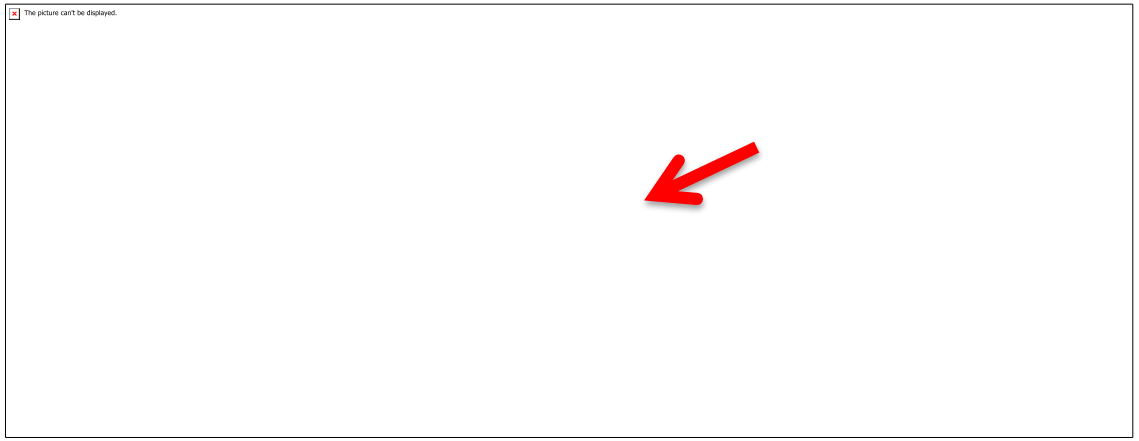
Solutions

7. Confirm the phone number
8. Confirm end date
9. Confirm the ptp has not stopped texts
10. Check Message History, Message Log, ScheduledMessage Events

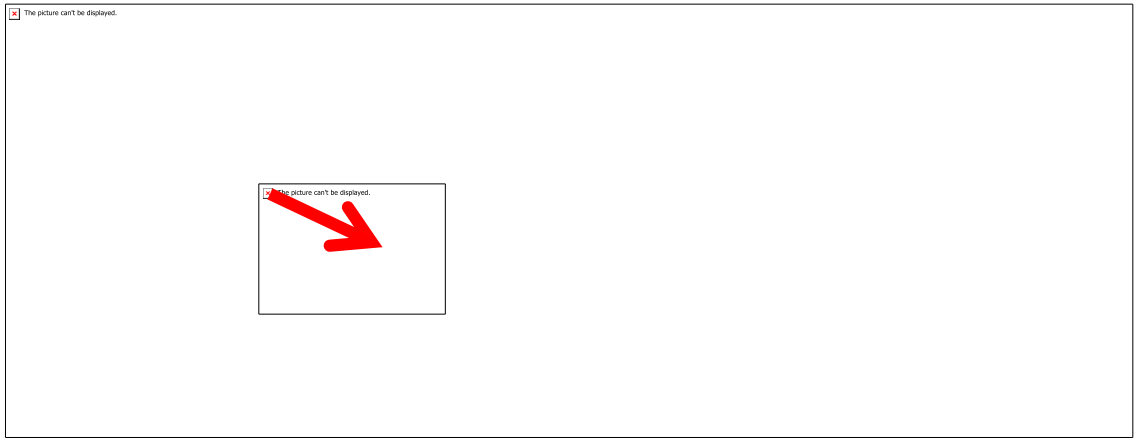
Most Common Issues

11. Remember weekly texts beginsame day, daily do not

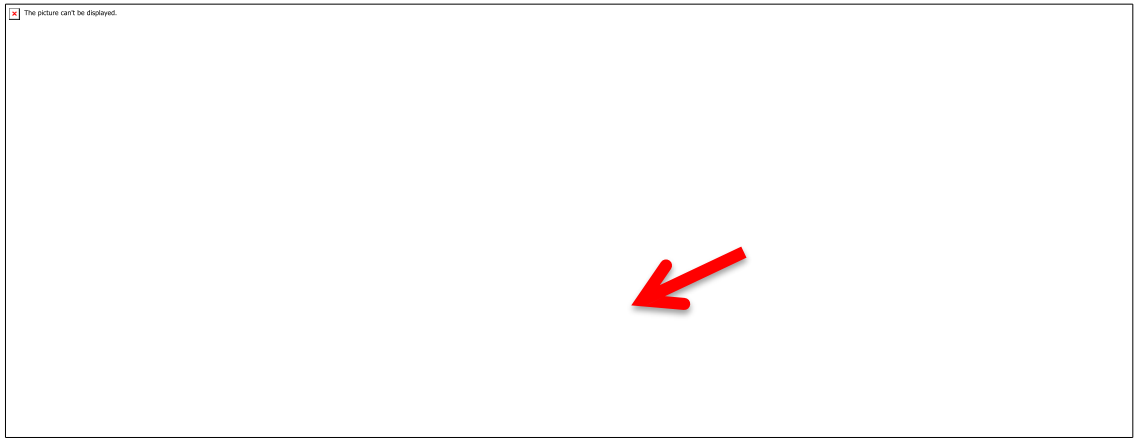
Technical Issues



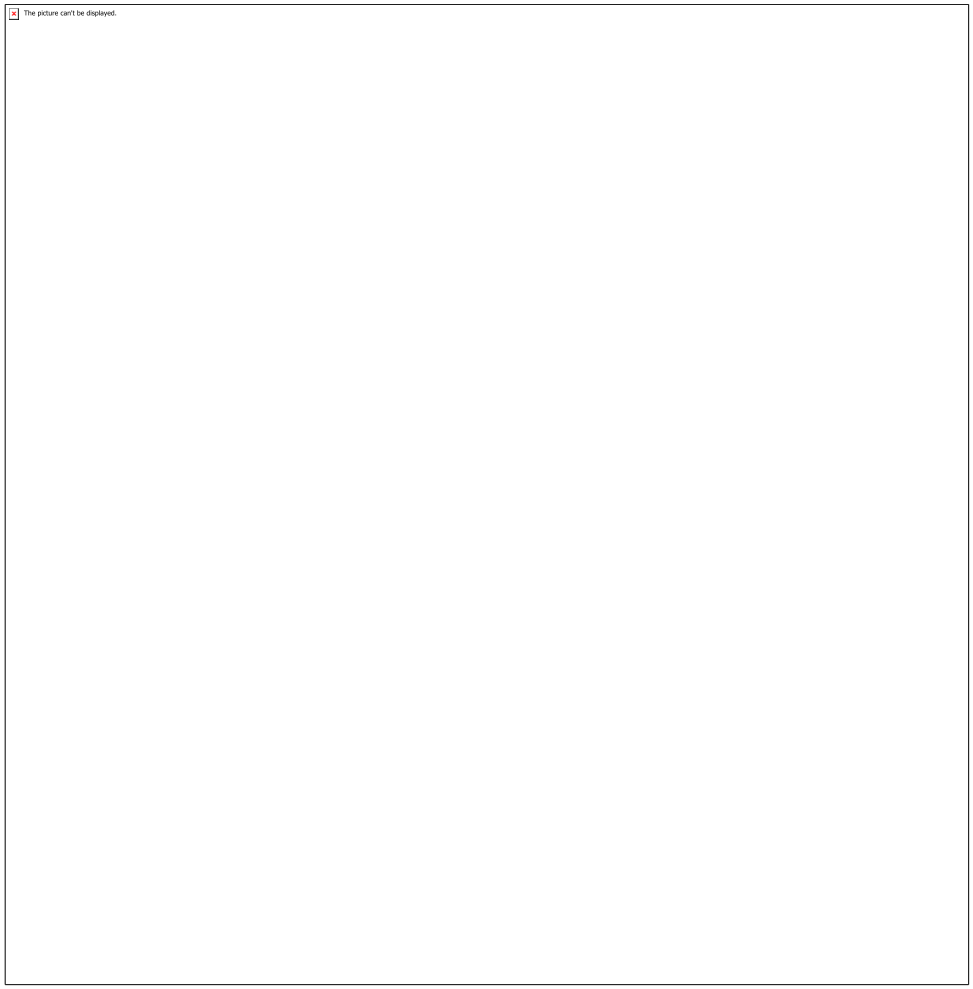
Technical Issues



Technical Issues



Technical Issues: Reporting Issues



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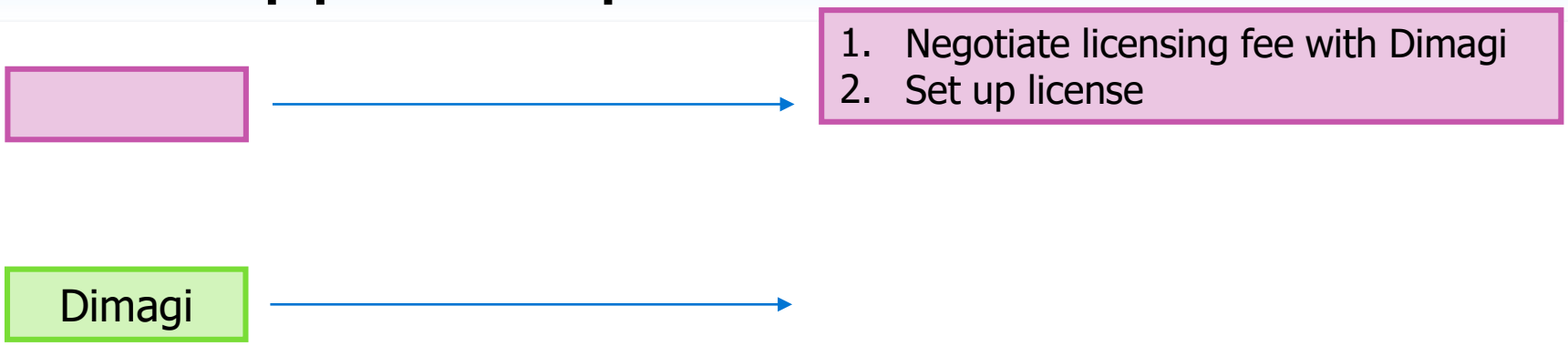
How does BHC requestthe TXTXT App?

TXTXT App Set-Up

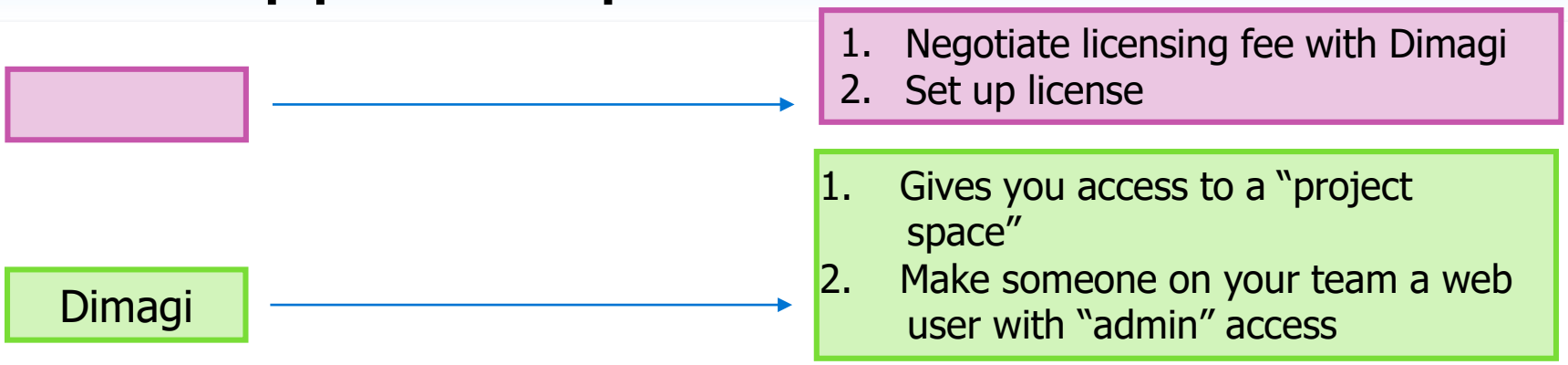
Your Clinic →

TXTXT App Set-Up

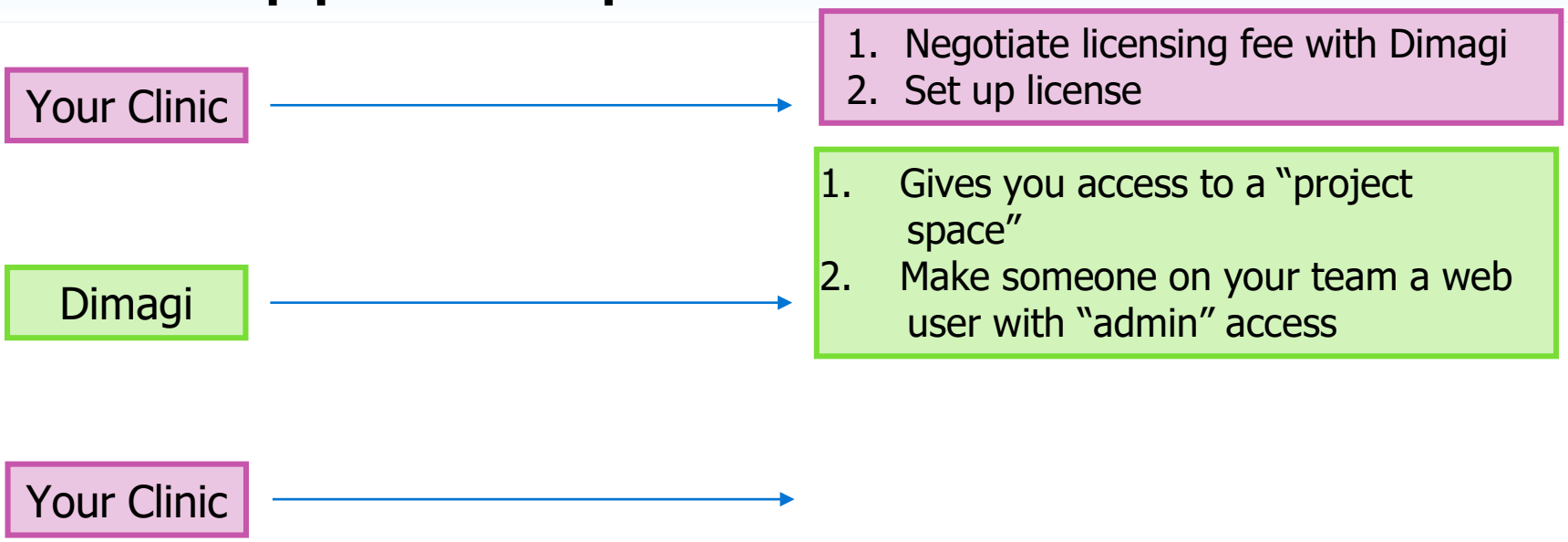
TXTXT App Set-Up



TXTXT App Set-Up



TXTXT App Set-Up



TXTXT App Set-Up

Your Clinic →

1. Negotiate licensing fee with Dimagi
2. Set up license

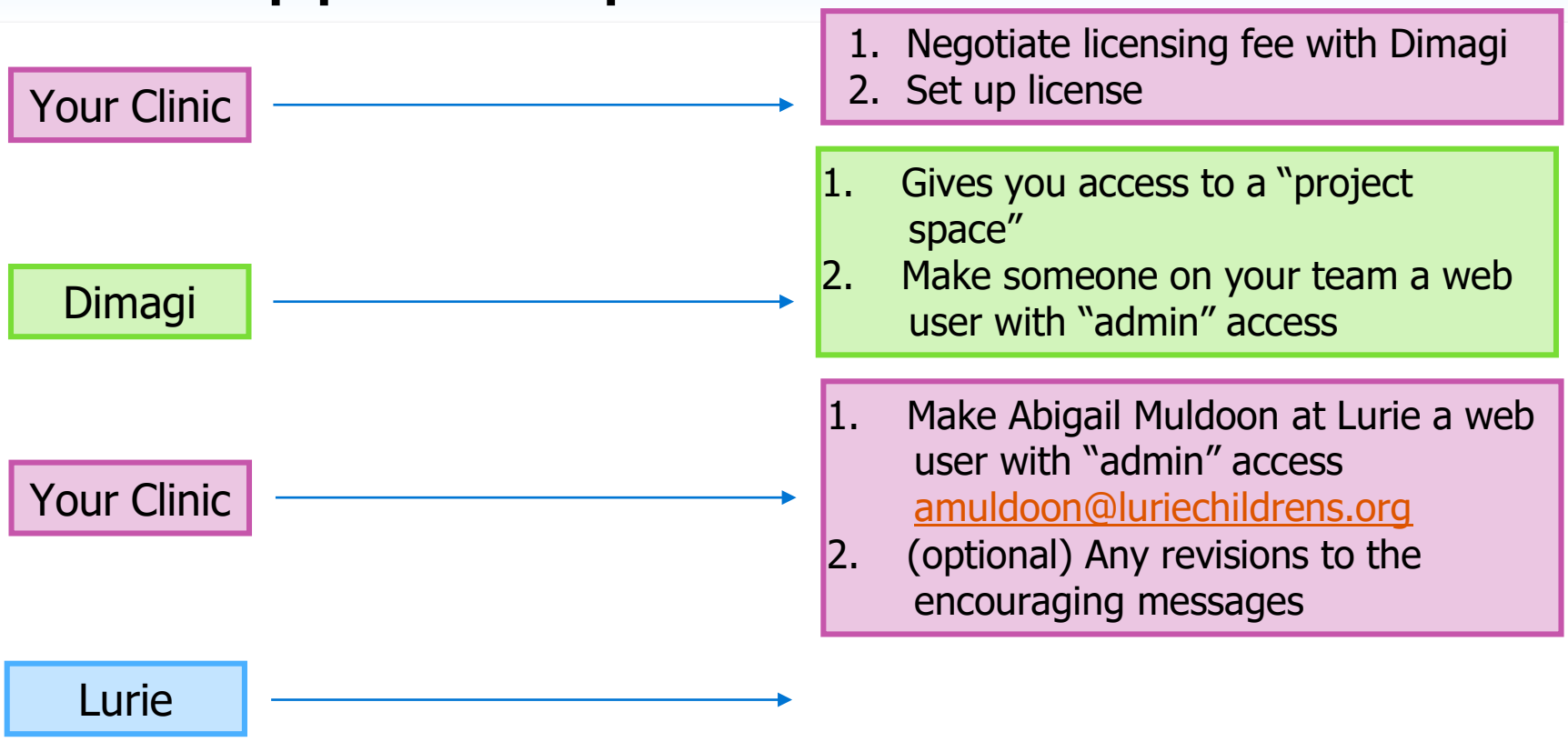
Dimagi →

1. Gives you access to a "project space"
2. Make someone on your team a web user with "admin" access

Your Clinic →

1. Make Abigail Muldoon at Lurie a web user with "admin" access. amuldoon@luriechildrens.org
2. (optional) Any revisions to the encouraging messages

TXTXT App Set-Up



TXTXT App Set-Up

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2. Set up license

Dimagi →
1. Gives you access to a "project space"
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Your Clinic →
1. Make Abigail Muldoon at Lurie a web user with "admin" access amuldoon@luriechildrens.org
2. (optional) Any revisions to the encouraging messages

Lurie →
1. Build/test your project space
2. Change your clinic's web user access to "admin_noapps"

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TXTXT App Set-Up

Your Clinic →

1. Negotiate licensing fee with Dimagi
2. Set up license

Dimagi →

1. Gives you access to a "project space"
2. Make someone on your team a web user with "admin" access

Your Clinic →

1. Make Abigail Muldoon at Lurie a web user with "admin" access amuldoon@luriechildrens.org
2. (optional) Any revisions to the encouraging messages

Lurie →

1. Build/test your project space
2. Change your clinic's web user access to "admin_noapps"

Your Clinic →

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TXTXT App Set-Up

Your Clinic	1. Negotiate licensing fee with Dimagi 2. Set up license
Dimagi	1. Gives you access to a "project space" 2. Make someone on your team a web user with "admin" access
Your Clinic	1. Make Abigail Muldoon at Lurie a web user with "admin" access amuldoon@luriechildrens.org 2. (optional) Any revisions to the encouraging messages
Lurie	1. Build/test your project space 2. Change your clinic's web user access to "admin_noapps"
Your Clinic	1. Add staff as mobile workers/web users 2. Start registering users

TXTXT App Set-Up

You did it!

Go you!

2. Start registering users

APPENDIX C Eligibility Screener (Aim 1)

ELIGIBILITY SCREENING INTERVIEW

SCREENING DATE: |____|____|--|___|____|--|____|____|____|____|
Month Day Year

STAFF INITIALS: |__|____| **SCREENING PHASE:** In Person | Phone
(Circle one)

Hi, My name is *(name)* **and I'm one of the staff members working on the Midwest Treatment Text (TXTXT) project, which is being conducted in partnership with Midwest AIDS Education and Training Center (MATEC) and Lurie Children's Hospital of Chicago. This project will explore whether daily text message reminders can help adolescents and young adults living with HIV do a better job of taking their medications and staying in HIV care. Are you interested in hearing more about it?**

Response: If yes, continue. If no, thank them for their time and discontinue screening.

Thanks for your interest in our project. As I just said, the purpose of the study is to explore whether daily text message reminders can help adolescents and young adults living with HIV do a better job of taking their medications.

If you are eligible and decide to enroll you will be asked to provide your cell phone number and to create a text message reminder for yourself. This personalized reminder will be sent to you daily, at a time that you decide. You will be asked to text back when you take your medications. You will also continue to meet with your medical provider. Additionally, we'll ask you to complete a computer-based questionnaire at your first visit. We'll also ask you to fill out the questionnaire again at 3 months and 6 months. You will be able to complete the survey online if you prefer you can also come into the clinic site to fill out the computer survey.

If you are eligible and decide to participate, we will keep all information we collect from you strictly confidential. We will need to ask you for contact information so that we can invite you back for various stages of the intervention.

To find out if you're eligible to participate in this project, I'll need to take less than 5 minutes to ask you some questions. Your answers to these questions will be kept confidential. That is, at this point, I will not be asking you any identifying information: I won't ask for your name, address, phone number or birthday. One of the reasons we stress confidentiality is that we <u>do</u> ask some very personal questions, and it is very important that you be as honest and as accurate as you can be with your answers.It is only if you are eligible and interested in participating that I will ask for your name and date of birth.

Are you willing to answer some questions to determine if you are eligible for the study?

Response: If yes, continue with Screening Questions. If no, ask for reasons why:

☐ No interest 01
☐ Worried about anonymity 02
☐ Study takes too long 03
☐ Afraid of research/guinea-pig 04
☐ Rather not say 05
☐ Other 06

If other, specify _____

Thank the participant for their time.

INSTRUCTIONS: This screening interview may be conducted in person or by phone. If eligibility is determined by phone, participants must make an appointment to reconfirm their answers to the screening questions in person before signing consent. Participant ID numbers will only be assigned (a) after the screening questions determine the volunteer to be eligible for this study and (b) after the participant signs the assent/consent form. Regardless of whether or not the participant is eligible, record the participant's responses to all questions.

RECRUITER INITIALS: |__|___| **SCREENING DATE**: |__|___|--|___|___|--|___|___|___|___|
Month Day Year

---

1. First, how old are you?

   |___|___| years ***(If participant is not 16-35 yrs., check ineligible and continue)*** ☐ Ineligible

2. What was sex assigned at birth?

   ☐ Male
   ☐ Femal
   ☐ e
   Interse
   x

3. How do you self-identify in terms of

   ☐ gender?Male
   ☐ Female
   ☐ Transgender woman
   ☐ Transgender man
   ☐ Other, Specify _____

4. Are you of Hispanic (Spanish) or Latino

   ☐ origin?Yes
   ☐ No

5. How do you describe your race or ethnic

   ☐ background?Asian/Pacific Islander
   ☐ Black/African American
   ☐ Native American/Alaskan
   ☐ NativeWhite
   ☐ Latino/Hispanic
   ☐ Multi-racial 5a) If "Multi-racial," specify _____
   ☐ Other 5b) If "Other," specify _____

6. What is your preferred language?

   ☐ English
   ☐ Spanis
   ☐ h
   Other language, if "other", specify _____***(Check <u>ineligible</u> and continue)***

7. Do you have a cell phone that can send and receive text messages?

☐ Yes
☐ No ***(Check ineligible and continue)*** ☐ Ineligible

8. How often would you say you use your cell phone for sending or receiving text messages?

☐ Never ***(Check ineligible and continue)*** ☐ Ineligibl
☐ e1-2 times per week
☐ 3-5 times per weekAlmost every day Every day
☐ Several times a day

9. Have you ever been told by a doctor or other health care provider that you have HIV infection orhave AIDS?

☐ Yes
☐ No ***(Check ineligible and go to ineligible script)*** ☐ Ineligible

10. Have you ever taken antiretroviral medications or HIV medications?Yes
☐ No ***(Check ineligible and go to ineligible script))*** ☐ Ineligible

11. Can you tell me when you started taking antiretroviral medications or HIV medications?

☐ ≤ 1 month ago ***(Check ineligible and continue)*** ☐ Ineligibl e
1. ☐ 1 but ≤ 6 months ago
2. 6 but ≤ 24 months ago
3. 24 months ago

12. Are you currently participating in any other research studies or programs about HIV treatment or medication adherence (support for taking your HIV medications)?
☐ Yes ***(Check ineligible and go to ineligible script))***
☐ No ☐ Ineligible

13. I need to know how you are doing with taking your HIV medications. Remember that this is a studyfor people who are having trouble taking their meds. Please answer as honestly as you can.

1. How many medication doses would you say you missed in the past 7 days? ☐ doses

2. How many medication doses would you say you missed last month? ☐

If a) is 1 or less AND b) is less than 3, check ineligible ☐Ineligible

Questions 14-18 are for the interviewer only.
DO NOT ASK THESE QUESTIONS OF THE PARTICIPANT.

RECRUITER INITIALS: |__|___| **SCREENING DATE**: |__|___|--|___|___|--|___|___|___|___|
Month Day Year

---

3. Does the volunteer appear to speak and understand English or Spanish?
   - ☐ Yes
   - ☐ No ***(Check ineligible and continue)*** ☐ Ineligible

4. Does the volunteer appear cognitively functioning and able to understand the assent/consentprocess?
   - ☐ Yes
   - ☐ No ***(Check ineligible and continue)*** ☐ Ineligible

5. Does the volunteer appear visibly distraught or emotionally unstable (i.e. suicidal, manic, exhibitingviolent behavior)?
   - ☐ Yes ***(Check ineligible and continue)*** ☐ Ineligibl
   - ☐ eNo

6. Does the volunteer appear intoxicated or under the influence of psychoactive agents?
   - ☐ Yes ***(Check ineligible)*** ☐ Ineligible
   - ☐ No

7. Aside from eligibility criteria, does the volunteer appear to be a good fit for the project?
   - ☐ Yes
   - ☐ No ***(Check ineligible and briefly explain below)*** ☐ Ineligible

   _____
   _____
   _____

INSTRUCTIONS: If any of the above ineligible boxes are checked, read the INELIGIBLE script. If none of theineligible boxes are checked, read the ELIGIBLE script below.

SCRIPT FOR INELIGIBLE VOLUNTEERS:

Participants for this project are selected based on the questions you were just asked. Based on your answers, it turns out you're not eligible to participate. Thank you for taking the time to talk with me about our project.

SCRIPT FOR ELIGIBLE VOLUNTEERS:

Thank you very much for the information you provided. Based on your answers to these questions,you are eligible to participate in this project. That means that if you want to participate in the text message project, you may. Do you think you might be interested in taking part in this project?

Response: If "NO", thank them for their time. If "YES":

Before we go any further, I need to get your name and birthdate, then schedule an appointment with you.

Participant Name*:_____ Date of Birth*: |___|___|--|___|___|--|___|___|___|___|

Month Day Year

CONFIRM AGE GIVEN WITH DOB

*With the completion of this box, this document now contains confidential identifying information and should be securely filed with other confidential identifying records for this participant (e.g., Contact Information Sheet, Consent/Assent Form).

RECRUITER INITIALS: |__|___| **SCREENING DATE**: |__|___|--|___|___|--|___|___|___|___|
Month Day Year

What's a good time for you to come in? |_|___|--|___|___|**at**_____:_____AM/PM

And if we miss you at that time, what's a good way to contact you to follow up?Phone:

☐ Ok to leave a voicemail message?

What's your cell phone provider? _____

Just as a reminder, we need you to bring your cell phone with you to the visit because if you arerandomly chosen to receive texts, we will test the text message system with your phone.

Email:

☐ Ok to email?

Investigator/Designe

_____ _____ _____
Signature Print Name Date

☐ Entered into screening database Screening ID: _____

APPENDIX D Text message tailoring form (Aim 1)

Personalization Tool
TXTXT Intervention

[INSERT DIMAGI web address here]

1. What is the name of your cell phone provider?

1. AT&T
2. Boost Mobile
3. Cricket
4. MetroPCS
5. Sprint
6. Tello
7. T-mobile
8. TracFone
9 - US Cellular 10 – US Mobile11 – Verizon
12- Virgin
97 – Other

1a.If Other, specify: _____

2. What is your cell phone number? ----------_____

[NOTE: Counsel Participant to text “STOP” if they want to stop receiving texts, “START” toreceive them again]

3. What language do you want to receive text messages in? 1- English 2- Spanish

For first medication dose:

4. What time would you like to receive the text message reminder to take your medication?
___:___AM/PM

4a. What do you want the text message reminder to say? (Limit 160 characters)

_____

_____

Note to interviewer: Does chosen text message disclose status? If so, discuss with participantand suggest alternate options.

4b. Fifteen minutes after you receive the first text, we will send you another text that will ask youto respond (via text) once you have taken your medication. What do you want this text message to say?

_____

_____

+ respond "1:Yes" if you took your medication, "2: No" if you did not

If a second medication dose:

Note to interviewer: If only one medication dose, skip to END

5. Time_:_____AM/PM

If a third medication dose:

Note to interviewer: If only two medication doses, skip to END

6. Time_:_____AM/PM

APPENDIX E Encouraging messages (Aim 1)

Encouraging Messages

The following is a list of encouraging messages to be programmed for automated reply.

Replies for "Yes" Taken Meds

1. Great job!
2. Way to go!
3. Keep it up!
4. Good work!
5. You rock!
6. Nice!
7. That's great!
8. Sweet!
9. Woo who!
10. YEAH!!
11. Good work!
12. I'm so glad to hear that!
13. Yay!
14. That's wonderful!
15. That's amazing!
16. You're awesome!
17. That is excellent
18. You should be proud!
19. Fabulouso!
20. That's fantastic!
21. Super duper
22. You're a rock star
23. high five!
24. thumbs up!
25. Hurray!
26. Woot! Woot!
27. Spectacular!
28. Splendid
29. You are so magical
30. Tremendous!
31. Marvelous
32. You're extraordinary
33. YAS!
34. Awesome!
35. Killing it!
36. You got this!

Replies for "No" Taken Meds

1. You can do it!
2. Go for it, you still have time!
3. Ooops! Now!
4. Uh oh, but you still have time.
5. Come on! You got this!
6. Oh no! You got this, don't quit!
7. Shoot! Better a little late than never.
8. Shucks, you still have time.
9. You've got it, you still have time!
10. Try, try again
11. Just do it!
12. Dang! Now!
13. Drat, you still got this!
14. Bummer! Don't quit!
15. Fooey, do it now!
16. Blast. Do it now!
17. Aw crud. Better late, than never.
18. Darn! You still have time!
19. Dangit!
20. It is what it is. You got this!

Appointment Reminder messages

1. You have a visit coming up on [DATE/time]
2. Don't forget your visit on [DATE/time]
3. See you on [DATE/time] for your visit
4. See ya soon! [DATE/time]
5. Your scheduled visit is

[DATE/time]Medication Refill

reminder

1. Pick up your vitamins [DATE]
2. Thumbs up for pick-up [DATE]
3. Just a reminder to get your things [DATE]
4. You have a pick up [DATE]
5. Package for you [DATE]

APPENDIX F Measures via CASI (Aim 1)

BARRIERS AND FACILITATORS OF ADHERENCE

People may miss taking their HIV medications for various reasons. Here is a list of possible reasons why you may have missed taking any HIV medication in the past month.

In the past month, how often have you missed taking your medications because you:

Please circle only one response for each question

		Never	Rarely	Sometimes	Often
1	Were away from home?	0	1	2	3
2	Were busy with other things?	0	1	2	3
3	Simply forgot?	0	1	2	3
4	Had too many pills to take?	0	1	2	3
5	Wanted to avoid the side effects?	0	1	2	3
6	Did not want others to notice you taking medication?	0	1	2	3
7	Had a change in daily routine?	0	1	2	3
8	Felt like the drug was toxic/harmful?	0	1	2	3
9	Fell asleep/slept through dose time?	0	1	2	3
10	Felt sick or ill?	0	1	2	3
11	Felt depressed/ overwhelmed?	0	1	2	3
12	Had problem taking pills at specified times (with meals, on empty stomach, etc.)?	0	1	2	3
13	Ran out of pills?	0	1	2	3
14	Felt good?	0	1	2	3

15 Do you use a pillbox to help you remember to take your medications? □ 1 Yes □ 0 No

1. Are there circumstances in your life that make taking your medications on a regular basis more difficult?

1. 1 Yes □ 0 No (SKIP to Q18)

1. What are the circumstances in your life that make taking your medications

_____

2. difficult?(Describe in brief)

2. Are there circumstances in your life that make taking your medications on a regular basiseasier?

1. 1 Yes □ 0 No (SKIP to next measure)

1. What are the circumstances in your life that make taking your medications easier?

.....

DEMOGRAPHIC QUESTIONNAIRE

DEM1. What is your date of birth?__/___/_____[mm/dd/yyyy]

DEM2. Which of the following best represents how you think of yourself?

1-Gay (lesbian or gay)
2 -Straight, this is not gay (or lesbian or gay)3 –Bisexual
97 -Something else

DEM2a. If =97, specify__

DEM3. What is your sex assigned at birth/biological sex?

1. – Male
2. – Female

97 – Something else

.DEM3a. If =97, specify:_____

DEM4. How do you describe your gender identity?

1. Male
2. Female
3. Transgender woman
4. 4- Transgender man

1. Non binary
2. Gender queer/Gender expansive

97-Something else

DEM4a. If =97, specify:_____

DEM5. Are you Hispanic or Latino/a?

1- Yes

0- No

DEM5a. (If =1), Are you: Mexican, Mexican American, or Chicano/a; Puerto Rican; Cuban; or another category ofSpanish/Hispanic/Latino/a that we have not mentioned?

1. - Yes, Mexican, Mexican American, Chicano/a

2. -Yes, Puerto Rican, Puerto Rican

American3 - Yes, Cuban, Cuban American

97 – Yes, Other Spanish/Hispanic/Latina

DEM5b. If =97, specify:_____

DEM6. What do you consider to be your primary race or ethnic background (check all that apply)?

1. – White

2. – Black/African

American3 – Asian

1. – American Indian/Alaskan Native
2. – Native Hawaiian or Other Pacific Islander

DEM7. What is your highest level of education?

1 - Less than 8th grade

2 - Completed 8th grade, no high school

1. - Some high school (completed some grades 9^{th}-12^{th}, but no diploma or GED)

2. - High school diploma or GED

3. -Trade School Certificate

1. - Some college

2. - Undergraduate degree

3. -Some graduate school

4. -Graduate degree

DEM8. Are you currently a student?

1-Yes

0-No

DEM9. What was your household income over the past 12 months from all sources before taxes? Household incomerefers to the total amount of money from all people living in the household.

1 - Less than $10,0002 -$10,000 - $19,999

3 - $20,000 – $29,999

4 - $30,000 - $39,999

5 - $40,000 - $49,999

6 - $50,000 - $59,999

7 - $60,000 - $69,999

8 - $70,000 - $79,999

9 - $80,000 or more

77- Don't know

DEM10. Including yourself, how many people depend on this income?_

DEM11. Do your sources of income or support include any of the following? Your sources of income mayinclude public assistance and non-traditional jobs. Check all that apply:

1- Traditional job (retail, office, restaurant; paid in regular intervals)2- Day labor (paid by the day, no promise of additional work)

3- Selling or dealing drugs

1. Sex work, survival sex or prostitution

2. Street income (panhandling, boosting or stealing)5- Unemployment benefits

6- SSI or disability7- Food stamps

1. Income provided by a partner

2. Income provided by other family members10- Income provided by a "sugar daddy"

1. No income

2. Student stipend 13 None of the Above

14 Under-the-table ("off the books," not reported to the government by the employer)97- Something else

DEM11a. If =97, specify:

DEM12. In your lifetime, have you ever been homeless at all? That is, you slept in a shelter for homeless people, on the streets, at a friend or relative's house for a few nights or weeks, or another place not intended for sleeping.

1 – Yes

0 – No (skip to DEM26)

DEM12a. Approximately how many total nights have you not had a regular place to stay during your lifetime?

____years and_____nights

DEM12b. In the past 3 months, were you homeless at any time?

1 – Yes
0 – No

DEM13. What is your zip code where you currently live?___

DEM14. Which of the following best describes your current living situation? By current living situation we mean whereyou have been staying during the past seven days.

1. Your own place, a room, apartment, or house that is your home
2. Temporarily doubled up with others, in someone else's house, apartment, or room
3. A temporary or transitional housing program
4. An SRO, that is a "single room occupancy" hotel or motel
5. In a shelter for homeless people
6. In jail, prison, or a halfway house
7. In drug treatment, a detox unit, or drug program housing
8. In a hospital, nursing home, or hospice
9. In an abandoned building, a public place like a bus station, a store or another place notintended for sleeping

10. On the street or anywhere outside such as a park, under a bridge, or in a campground97- Something else

DEM14a. If =97, specify:_____

DEM15. How long have you lived at your current place (in # of years and # of months)? _____

DEM16. Are you currently involved in a committed relationship with someone who you consider your boyfriend/girlfriend, spouse, or domestic partner?

1. - Yes
0- No (skip to END of DEM)

DEM16a. How long have you been in this relationship? (If you are currently involved in more than one relationship, selectthe most significant one).

1. - Less than a month
2. - One month to six months
3. - More than six months to a year

4. - More than a year to three years5 - More than three years

HIV Medication Taking Self-efficacy Scale

Indicate on the following scale how confident you are in the following:

1. That you can keep a clinic appointment

Not Confident									**Totally Confident**
1	2	3	4	5	6	7	8	9	10

2. That you can follow your overall treatment regimen

Not Confident									**Totally Confident**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

3. That you can follow a plan for taking HIV medication

Not Confident									**Totally Confident**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

4. That you can take HIV medication with correct intervals

Not Confident									**Totally Confident**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

5. That you can take the correct dose

Not Confident									**Totally Confident**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

6. That you can take HIV medication at work

Not Confident									**Totally Confident**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

7. That you can take HIV medication on a weekday

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

8. That you can take HIV medication on a weekend

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

9. That you can take HIV medication at social outing

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

10. That you can take HIV medication at a party

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

11. That you can take HIV medication at a planned event

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

12. That you can take HIV medication at an unplanned event

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

13.That you can take HIV medication at travel

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

1. That you can take HIV medication when you feel well

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

2. That you can take HIV medication when you feel ill

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

3. That you can take HIV medication when you are having medication sideeffects

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

4. That you can take HIV medication when you are having in a crisis

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

<u>Outcome expectancy (OE)</u>

5. That taking HIV medication will improve your health

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

19.That taking HIV medication will improve quality of life

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

1. That taking HIV medication will improve function ability

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

2. That taking HIV medication will allow for a long life

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

3. That taking HIV medication will allow you to lead a near normal life

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

4. That taking HIV medication will decrease HIV related symptoms

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

5. That taking HIV medication will decrease viral load

Not Confident									Totally Confident
1	2	3	4	5	6	7	8	9	10

6. That taking HIV medication will increase T-cell count

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

7. That taking HIV medication will prevent hospitalization

Not Confident									Totally Confident
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

HIV Medication Adherence

This questionnaire asks you how often you take your HIV medication. Some people get busy and forget to take their HIV medications or forget to carry their medications with them. Other times peoplefind it hard to take their medications like their doctor told them to, such as “with food” or “on an empty stomach.” Other people decide to skip medications to avoid side effects (like feeling sick to your stomach) or to just not take their medications that day. It’s important for us to understand what people with HIV are really doing with their medications. For these questions, please report what you are actually doing. Don’t worry about it if you don’t take all of your medicine. We want to know what is really happening, not what you think we “want to hear.”

1. Do any of your HIV medications have special instructions, such as “take with food” or “on anempty stomach” or “with plenty of fluids?”

☐ 1 Yes ☐ 2 No (If NO, skip to question #2)

1. IF YES, how often did you follow those special instructions over the last four days?

Never	Some of the time	About half of the time	Most of the time	All of the time
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

2. Some people find that they forget to take their pills on the weekend days. Did you miss any ofyour HIV medications last weekend—last Friday, Saturday or Sunday?

☐ 1 Yes ☐ 2 No

3. During the past 4 days, on how many days have you missed taking all doses of your HIV medications?

1. none
2. one day
3. two days
4. three days
5. four days

Now I'm going to ask you about the last 30 days. For all of your current HIV medications, what percent time (%) from 0 to 100 did you take your medication as prescribed in the last 30 days?

0% time would mean, "NONE of the time," 50% time would mean HALF of the time and 100% would mean ALL of the time. Numbers in-between would mean amounts between NONE and ALL of the time.

6. Please put an "X" on the line below at the point showing your best guess about how much youhave taken these drugs in the **last 30 days**. [display VAS SCALE GRAPHIC].

NONE **ALL**

Treatment acceptability measure

Adapted from: https://link.springer.com/content/pdf/10.1007/bf00960091.pdf

How effective do you think this program (TXTXT) is ~~mightbe~~?	1= very ineffective 2 3 4 5 6 7= very effective
How acceptable do you find the program (TXTXT) to be?	1= very unacceptable 2 3 4 5 6 7= very acceptable
How likely do you think it is that this program (TXTXT)will have negative impact?	1= very unlikely 2 3 4 5 6 7= very likely

TXTXT Acceptability Survey

1. Did you receive text message reminders on the days and times yourequested them?

   1- Yes 2- No

2. How often did you read the text messages?

   4- Always 3- Often 2- Sometimes 1- Never

3. How often did you find the text messages intrusive or bothersome?

   4- Always 3- Often 2- Sometimes 1- Never

4. Did anyone find out you were HIV+ because you received the textmessages?

   1- Yes 2- No

5. How often did you respond “yes” to the text indicating you took your medication, when you really didn’t take them?

   4- Always 3- Often 2- Sometimes 1- Never

The goal of the TXTXT intervention is to support daily medication adherence and ultimately improve viral suppression.

6. Thinking about your experience with the TXTXT intervention, whatworked best? What would you like to see changed?

   _____

7. Do you have any other suggestions for improving the TXTXT intervention?

   _____

Client Satisfaction Questionnaire (CSQ-8)

Please help us improve the text messaging intervention by answering some questions aboutyour experiences. We are interested in your honest opinion, whether they are positive or negative. Please answer all of the questions.

1. How would you rate the quality of your experience with the text message reminders?

4	3	2	1
Excellent	Good	Fair	Poor

2. Did you get the kind of text message reminder experience that you wanted?

4	3	2	1
No, definitely not	No, not really	Yes, generally	Yes, definitely

3. To what extent have the text messaging reminders met your needs?

4	3	2	1
Almost all of my needshave been met	Most of my needs havebeen met	Only a few of my needshave been met	None of my needs havebeen met

4. If a friend were in need of similar help taking their medication, would you recommendthe text reminder intervention to him or her?

4	3	2	1
No, definitely not	No, not really	Yes, generally	Yes, definitely

5. How satisfied are you with the amount of help you have received with the reminders?

4	3	2	1
Quite dissatisfied	Indifferent or mildly dissatisfied	Mostly satisfied	Very satisfied

6. Have the text messaging reminders helped you to take your medication?

4	3	2	1

Yes, they helped a greatdeal	Yes, they helped somewhat	No, they really didn't help	No, they seemed to makethings worse

7. In an overall, general sense, how satisfied are you with the text message reminderintervention?

4	3	2	1
Very satisfied	Mostly satisfied	Indifferent or mildly dissatisfied	Quite dissatisfied

8. If you were to seek help again, would you want to receive the text messagereminders?

4	3	2	1
No, definitely not	No, not really	Yes, generally	Yes, definitely

1. likert scale: Not at all, slightly, somewhat, mostly, very

Intervention Utility Questionnaire; modified from:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2954428/#!po=76.6667

1. To what extent did you find the TXTXT intervention easy to use?
2. To what extent did you find the TXTXT intervention convenient to use?
3. To what extent did you find the TXTXT intervention understandable?
4. To what extent did you find the TXTXT intervention useful?
5. To what extent did you find the TXTXT intervention enjoyable?
6. To what extent did you find the TXTXT intervention consistent with other adherence strategies?
7. To what extent did you find the TXTXT intervention suitable for helping you remember to takeyour medication?
8. To what extent did you find the TXTXT intervention generally effective?
9. To what extent did you find the TXTXT intervention effective as a long term support foradherence?

FIDELITY CHECKLIST

PARTICIPANT NAME:_____ INTERVIEWER INITIALS: |____|___|

VISIT DATE: |__|___|--|___|___|--|___|___|___|___| **VISIT TYPE (CIRCLE):** Initial | 3M | 6M

Month Day Year

1. Completed study assessment? □ Yes □ No
1. Completed adherence counseling (initial visit only)? □ Yes □ No □ N/A
1. Completed personalization form (or updated at FU)? □ Yes □ No
1. Next appointment scheduled (initial, 3M only)? □ Yes □ No □ N/A
    - Date___/___/_____Time___:___am/pm
1. Updated contact information? □ Yes □ No □ N/A

Comments:

_____

_____

_____

APPENDIX H Recruitment script: Aim 2 TXTXT participants ages 16-35 years (Aim 2)

Hi, My name is *(name)* and I'm one of the staff members working on the Midwest Treatment Text (TXTXT) project, which is being conducted in partnership with MATEC and Lurie Children's Hospital of Chicago. Thank you so much for your participation in this important project. I'm reaching out today to see if you are interested in taking part in a short interview to tell me more about your experiences with the TXTXT program. The interview will take about 30 minutes and you will receive a $40 incentive for your participation. Are you interested in hearing more about it?

Response: If yes, continue. If no, thank them for their time and discontinue.

Thanks for your interest in our project. As I just said, the purpose of this interview is to hear more about your experience with daily text message reminders. I will ask you a series of questions, and I'll want to hear about both the good things about the program and things that you might suggest we do differently. Your feedback will help us improve the program for the future. Do you have any questions?

APPENDIX I Recruitment script: Aim 2 TXTXT clinic staff ages 18+ (Aim 2)

Hi, My name is *(name)* and I'm one of the staff members working on the Midwest Treatment Text (TXTXT) project, which is being conducted in partnership with MATEC and Lurie Children's Hospital of Chicago. Thank you so much for your participation in this important project. I'm reaching out today to see if you are interested in taking part in a short interview to tell me more about your experiences with the TXTXT program. The interview will take about 60 minutes. Are you interested in hearing more about it?

Response: If yes, continue. If no, thank them for their time and discontinue.

Thanks for your interest in our project. As I just said, the purpose of this interview is to hear more about your experience with the TXTXT intervention. I will ask you a series of questions, and I'll want to hear about both the good things about the program and things that you might suggest we do differently. Your feedback will help us improve the program for the future. Do you have any questions?

APPENDIX J Semi-structured Interview Guide (Aim 2)

MIDWEST TXTXT

Semi-structured Interview Guide for Clinic staff

Interview Date: / /_____

Start Time: : AM/PM

Site:_____

Interviewer Initials: _____

INTRODUCTION AND PURPOSE OF THE INTERVIEW

Thank you for your participation in this interview. This interview is being audio recorded only (not video recorded). The interview is confidential so I'm not going to ask your name and I ask that you not identifyanyone else by name, if you can avoid it. If you do identify individuals, do not worry, when this interviewis transcribed, we will remove all references to individuals.

I'm going to go through a set of questions that asks you about the Midwest TXTXT program, including your experiences with the way the program was set-up and how it worked, as well of the internal andexternal factors that may have influenced implementation at your clinic location. Any questions so far?

OK, let's begin…

Section A: General Questions

Before we begin our conversation, I have a few quick questions about you.

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☐ Front The pic... – The pi... The picture can't be displayed. The picture can't be displayed.

☐ Provider The picture can't be displayed.

☐ Middle The picture can't be displayed.

☐ Executive

☐ Other (specify) _____

The picture can't be displayed. The picture can't be displayed.

☐ Direct Service ☐ Indirect Service

A2c. How would you describe your primary race? (check all that apply)

☐ Black or African American ☐ White

☐ Asian

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The pic... The picture can't be displayed. Other: ethnicity?

The picture can't be displayed. The picture can't be displayed.

The pic... The picture can't be displayed. The picture can't be displayed.

☐ The picture can't be displayed. years ☐ The picture can't be displayed. years ☐ The picture can't be displayed. years ☐ The pic... years

Section B: Questions about the TXTXT Program:

Intervention Characteristics

B1. [Evidence and Strength] What was your impression of how effective TXTXT would be before it was implemented?

Probe: What were your feelings or impressions about the promise of the intervention topromote adherence?

Probe. What do influential stakeholders think of the intervention?

influential stakeholders may include well-respected/senior clinicians, administrative leaders, etc.

B2. [Relative Advantage] How does TXTXT compare to other ART adherence interventions in yoursetting?

B3. [Relative Advantage] Is there another intervention that you would rather implement? If so, what intervention? Talk me through why you would rather implement this intervention opposed to TXTXT.

B4. [Adaptability] Did you make any adaptations in how you implemented the TXTXT in comparison tohow you were trained to implement it?

Probe: If you made adaptations, how successful were they?

Probe: Were there adaptations that you wanted to make but couldn't?

B5. How complicated is the intervention to implement?

Probe: Duration (length), scope, radicalness/differentness, centrality to mission, intricacy andnumber of steps required to implement, special knowledge?

B6. What is your impression of the training materials and supporting materials?

Probe: Did you consult the training materials when you had a question? Why or

why not?Probe: Did you need other resources that you didn't have?

B7. What were the costs associated with implementing the intervention?

Probe: What are your impressions of the costs? Reasonable, not reasonable?

Outer Setting

B8. [Patient Needs, Resources]: How well do you think the intervention meets the needs of the program participants?

Probe: How important is medication adherence support in comparison to other needs theyhave?

B9. [Patient Needs, Resources]: What barriers did the participants have to receipt of the intervention, ifany?

B10. [Patient Needs, Resources]: Have you heard stories from individuals about their experiences withthe intervention? If so, what did they say?

B11. [Cosmopolitanism]: What kind of information exchange do you have with others outside of yourclinic related to the intervention?

Probe: What type of information is exchanged?

Probe: Does the organization encourage you to network with others?

B12. [Peer Pressure]: Can you tell me what you know about other organizations that have implementedsimilar programs?

Probe: Does implementing this intervention provide an advantage to your organization overothers?

B13. [External Policies & Incentives]: What kind of local, state or national guidelines or expectations influenced your decision to implement this intervention?

Inner Setting

B14. [Structural Characteristics]: How did the infrastructure of your organization impact the implementation (social architecture, size, # years serving the community, physical layout]?

Probe: Are changes needed to better accommodate the intervention?

B15. [Networks & Communications]: Were meetings about the intervention implementation heldregularly? If so, with what frequency. If not, why not?

B16. [Networks & Communications]: When new information like staff departures occur, how do you findout?

B17. [Networks & Communications]: When you need to solve a problem, who are the go-to people?

B18. [Culture]: How would you describe the culture of your organization?

Probe: Do you think the organization's culture impacted the implementation of theintervention?

B19. [Culture]: To what extent are new ideas embraced to make improvements at your organization?

B20. [Implementation Climate]: What was the general receptivity in your organization to implementingthe intervention?

Probe: Was there a strong need for the intervention? How essential is

it?Probe: How well does it fit?

Probe: Was it well integrated?

Probe: Did it complement current programs?

B21. [Implementation Climate]: Was the intervention implementation a priority for the organization?

Probe: How did you juggle competing priorities in your work on this project?

B22. [Implementation Climate]: Were there any incentives to implement this intervention (will your rolebe recognized)?

B23. [Implementation Climate]: Were there goals set for implementation of this initiative?

Probe: Were the goals monitored for progress?

B24. [Implementation Climate]: If you saw a problem with implementation what did you do?

Probe: What was the reaction to this problem?

B25. How supportive was leadership of this initiative?

Probe: What support did you receive to make it

successful? B26. Were there sufficient resources to implement

the intervention?

Probe: Technical assistance?

B27. Was the level of training adequate?

Probe: When you had questions about implementation, who did you ask?

Probe: What was the relationship with MATEC like? Describe the level of training, support, communication you received from MATEC.

Characteristics of Individuals

B28. [Knowledge and Beliefs] Do you think the intervention was effective?

B29. [Confidence] How confident are you that you successfully implemented the intervention?

B30. [Stage of Change]: How well prepared were you to implement the intervention?

B31. [Individual Identification with the Organization]: How much do you identify with the mission of the organization?

Probe: Does that impact your commitment to the organization and/or this initiative?

B32. [Other Personal Attributes]: Are there any personal traits that you have that helped withimplementation of this initiative? For you or others?

Probe: Are there skills that were needed on the team but you didn't have?

Process

B33. [Planning]: Was there a clear plan articulated to you to implement this initiative?

B34.[Engaging]: Was there a formal project manager or coordinator appointed to run the intervention?

B35. [Engaging]: Were there people outside the agency that were supposed to help to implement it? Didthat work as planned?

B36. [Engaging] How did you communicate to individuals that might be eligible for the intervention? Didthat work as planned?

B37. [Executing]: Was the intervention implemented as planned? Why or Why not?

Section E: Closing

Is there anything else you think is important for me to know to understand how the Midwest TXTXT program is working for young people living with HIV?

Thank you for your time.

Turn off recorder.

END TIME: :__AM/PM

MIDWEST TXTXT

Semi-structured Interview Guide-TXTXT PARTICIPANT

Interview Date: __/__/____ Semi-structured Interview Guide (**Aim 2**)
Start Time:__:__AM/PM
Site:_____
Interviewer Initials: _____

_____

INTRODUCTION AND PURPOSE OF THE INTERVIEW

Thank you for your participation in this interview. This interview is being audio recorded only (not video recorded). The interview is confidential so I'm not going to ask your name and I ask that you not identify anyone else by name, if you canavoid it. If you do identify individuals, do not worry, when this interview is transcribed, we will remove all references to individuals.

I'm going to go through a set of questions that asks you about the Midwest TXTXT program, including your experiences withthe way the program was set-up and how it worked. Any questions so far?

OK, let's begin…

Questions about the TXTXT Program:

Intervention Characteristics

1. [Evidence and Strength] What was your impression of how effective TXTXT would be when you first heard about it?Probe: What were your feelings or impressions about the promise of the intervention to promote adherence?
2. [Relative Advantage] In your opinion, should [clinic name] continue to make offering TXTXT a priority?
3. [complexity] What did you find most complex in participating in the TXTXT intervention?Outer Setting
4. [Patient Needs, Resources]: Tell me about your experiences with TXTXT.
5. [Patient Needs, Resources]: What barriers did you face in participating in TXTXT, if any?Inner Setting
    1. [Structural Characteristics]: What types of changes should we make to how we conduct TXTXT?Characteristics of Individuals
2. [Knowledge and Beliefs] Do you think the intervention was effective?
3. [Stage of Change]: Have you recommended TXTXT to others? Why or why not?
    4. [Knowledge and Beliefs] What value or benefit did you receive from participating in the TXTXT?Process
5. [adaptability] In what settings might TXTXT work best? How should we offer TXTXT to patients? Who should offer it?

Closing

Is there anything else you think is important for me to know to understand how the Midwest TXTXT program is working foryoung people living with HIV?

Thank you for your time.

Turn off recorder.

END TIME:___:___AM/PM

APPENDIX K (Aim 2): Standard of care questionnaire

Standard of care questionnaire

Clinic name:
Date:

This set of questions is designed to document the current standard of HIV care and adherence supports for youth and young adults living with HIV at your site. We are interested in learning more about your clinic's HIV care services, the staff involved, programmatic supports, challenges and facilitators for retention in care.

1. Describe the clinic's standard of care for HIV care (**probe***: define, staff involved, barriers/facilitators, changes implemented, how this compares with other clinics in the area*)

2. Describe linkage to HIV care for youth and young adults. (**probe***: define, staff involved, barriers/facilitators, changes implemented, how this compares with other clinics in the area*)

3. Describe retention in HIV care for youth and young adults. (**probe***: define, staff involved, barriers/facilitators, changes implemented, how this compares with other clinics in the area*)

4. Describe current adherence supports for youth and young adults living with HIV. (**probe***: define, staff involved, barriers/facilitators, changes implemented, how this compares with other clinics in the area*)

5. Describe the demographics of the youth and young adults who receive HIV care services at your agency. Are there any trends in retention in care or adherence among subgroups of youth and young adults? (if yes, probe more details)

6. Does the clinic offer any of the following as a part of HIV care (or to support retention in care):
    1. Transportation assistance
    2. Childcare
    3. Food assistance
    4. Housing assistance
    5. Legal assistance
    6. Benefits navigation
    7. Stipend or monetary incentive
    8. Any other supports not mentioned? List other:

APPENDIX L Informed Consent Forms

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Adult Consent to Take Part in a Research Study

Aim 1: Participants aged 18-35 years

Study Name: Midwest TXTXT
Sponsored by: U.S Centers for Disease Control and Prevention U01PS005214
Name of Study Doctor/Researcher: Amy K Johnson, PhD

This consent form describes a research study for which you might qualify being conducted by a researcher at Ann &Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's"), the Midwest AIDS Training and Education Center (MATEC), and [local clinic name].

In this study we are interested in learning about how receiving daily text message reminders to take HIV medication might impact viral suppression and retention in HIV care.

Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your regular care.

What are the purpose and goals of this study?
The main purpose of this research study is to determine how well text messaging (Short Message Service - SMS) works to improve of the rate of HIV in the blood (viral load) of young persons receiving HIV treatment at [Insert sitename]. The study will also evaluate whether the text messaging works to improve how well young persons take their HIV medications (called adherence) and remain under the care of their medical providers (calledretention in care), and whether young persons accept and are satisfied with the program being tested.

We are asking you to be in this research study because we want to learn more about ways to support young people adhering to HIV medications and remaining in HIV care.

If I agree to take part in this study, what would I need to do?

There will be a total of up to 600 participants in this study at different sites throughout the United States. Up to 50 participants will be included at [Insert Site Name]. You will be in this study for 12 months and complete 3 computer assisted surveys during this time.

At each time point (baseline, 3 months, 6 months), we will collect information from you in a computer questionnaire format on your HIV treatment knowledge, adherence to medication, and satisfaction the text

messaging program. This questionnaire will take about 15 minutes to complete. You will be able to complete the surveys at 3 months and 6 months online from home or you could come in to the [local clinic name] to complete the survey on a computer.

During the study, we will also look at your medical records to collect information about the dates when you pick-up your HIVmedication from the pharmacy, the dates of your clinic visits, and the results of viral load and other monitoring tests that the clinic has performed on you. This will help us to see how the study worked over time. We will keep your name and other identifying information confidential.

In addition to these things, your site will be randomly assigned to begin the study intervention. The timing for when this happens is chosen at random, like the flip of a coin. When this happens, you may receive the intervention right away for at least 6 months or will start about 3 months from now and receive the intervention for at least 3 months. Once you begin the intervention, you will receive daily- automated text messages at the usual time you take your medication to remind you to use them. You will be involved in the development of the messages that you will receiveto remind you to take your medication, and these messages will be personal to you and based on the choices you make. The content of the reminders will be such that people around will not understand the message you have received. Only you will understand. This is to protect your privacy. You will be expected to acknowledge receiving the message and indicate whether you have taken your medication with a YES or NO. In response to this acknowledgment, you will receive an encouraging follow-up message.

What are the risks, side effects, or discomforts related to the study?
You may find some of the survey questions difficult to answer or you may not want to answer them. You may skip any question that you do not want to answer. During this study, you will be informed about anything that may affect your continued participationor your health.

What are the benefits from this study?
The information learned may help researchers learn more about designing programs and support for young people living withHIV to support medication adherence. You may or may not benefit from receiving the text messages to support HIV medication adherence. This information learned from thisstudy may help others in the future.

What other options do I have?
You do not have to be in this study if you don't want to. Your doctors at [Insert Site Name] will not be upset with you. If youjoin the study and then change your mind, it is okay for you to leave this study at any time.

What if the researcher or I do not think I should stay in the study?
You can stop taking part in this study at any time. Your decision will not affect your regular care.

Returning Study Results:
The study team will not return study results to you. You can ask the study team any questions you have about study results.

Important New Information:
We will tell you if we learn new information that may make you change your mind about being in this study.

Will my information be used in future research studies?

The study team may share your information for future research. They will remove identifiers such as your name and other information that can be linked to you before this is done. The study team and other researchers may use this for other studieswithout getting consent from you.

Costs Related to this Study:

The study requires use of an existing cell phone with text messaging capabilities, you will not incur any costs beyond yourexisting cell phone plan. The study sponsor will not pay for your cell phone or cell phone plan.

Payment for Taking Part in this Study:

You will not be paid for taking part in this study.

Your Rights When Taking Part in this Study:

If you agree to take part in this study, you are not giving up any of your legal rights. You can stop participating in this study atany time. Your choice will not affect your regular care.

Additional Information:

Who can answer my questions about this study?

You can ask Amy K Johnson (akjohnson@luriechildrens.org; 312 227 7733) or the clinic staff at [Insert Site Name] anything about the study or if you feel you have been harmed. If you are not happy with this study and want to talk with someone else or want to talk about your rights as a participant, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110 or by email at IRB@luriechildrens.org.

You will be given a copy of this consent form.

Certificate of Confidentiality

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. There are some important things that youneed to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. Forexample, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs.

The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate alsoDOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate

of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Planned Sharing of Your Information:

For this study, the [local clinic name] will share information from your medical records, including your most recent viral load, CD-4 count, and date of HIV services with the study team at Lurie Children's Hospital. Federal and state laws do not allow sharing of sensitive health records without your permission.

If you agree to take part in this study, you also give permission for the use and sharing of your ~~de-identified~~ information from which we removed any information that may identify you like your name and birthdate ("deidentified") with persons outside of this study. This permission lasts until the study is completed.

The study staff, employees, and Medical Staff of Lurie Children's, the Midwest AIDS Training and Education Center(MATEC), and [local clinic name] may use your information for this study and share it, as required for auditing purposes, with:

1. The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children whotake part in research studies).
2. The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.

These are the only people to which we will give your information. We cannot guarantee that those listed above will not share itwith others without your permission.

Your name will not be included in any written or verbal reports of study results.

What if I decide not to give permission to use and give out my information?
If you decide not to allow the release your information, you will not be able to take part in this study. If you give permission to the use of your information, you can withdraw it at any time. Your request should be submitted directly to the researcher using either the email or phone number (akjohnson@luriechildrens.org; 312 227 7733). The study team can still use any information collected before you tell them to stop.

Can I review or copy my information?
You cannot see your study records while the study is ongoing. You still have a right to request a copy of yourmedical record and tests related to regular medical care that is given during the same time as the study.

Signatures:
Participant/LAR Signature:

By signing this form, I affirm:
1. I have read this form.
2. The research has been explained to me.
3. All of my questions have been answered. I consent to take part in this research study.

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Signature of Participant or Legally Authorized Representative (LAR):	Date:
Printed Full Name:	

Signature of Authorized Person Obtaining Consent/Witness*:

I certify that I have explained the above to the participant/LAR and the signature was obtainedvoluntarily.	
Signature:	Date:
Printed Full Name:	

**If the study includes the use of records related to mental health or developmental disabilities, the person obtaining consentalso serves as the witness to consent for use of relevant records.*

Signature of Interpreter/Witness*:

☐ Not applicable, no interpreter used.
I attest that the study information has been presented to the participant/LAR in their native language.
Signature of Interpreter/Witness:
Printed Full Name or Unique Phone ID/Company Name:

Note to Investigators: When obtaining consent from a non-English speaking participant/ LAR

When a study-specific translated consent document is not available, a translated "short form" (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

1. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*
2. *The participant/LAR should sign the short form (in the language they understand).*
3. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*
4. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form mustbe given to the participant/LAR.*

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Adolescent Agreement to Take Part in a Research Study

Aim 1: Adolescent assent for aged 16-17 years

Study Name: Midwest TXTXT
Sponsored by: U.S Centers for Disease Control and Prevention U01PS005214
Name of Study Doctor/Researcher: Amy K Johnson, PhD

We want to tell you about a research study at Lurie Children's, the Midwest AIDS Training and Education Center (MATEC), and [local clinic name].

In this study we are interested in learning about how receiving daily text message reminders to take HIV medication might impact viral suppression and retention in HIV care.

Research studies help us find better ways to take care of and treat children and young adults. Taking part in a research study is voluntary. Itis your choice to take part in this research study.

Why is this study being done?
The main purpose of this study is to determine how well text messaging (Short Message Service - SMS) works to improve of the rate of HIV in the blood (viral load) of young persons receiving HIV treatment at [Insert site name]. The study will also evaluate whether the text messaging works to improve how well young persons take their HIV medications (called adherence) and remain under the care of their medical providers (called retention in care), and whether young persons accept and are satisfied with the program being tested.

We are asking you to be in this research study because we want to learn more about ways to support young people adhering to HIV medications and remaining in HIV care.

What will happen in this study?
There will be a total of up to 600 participants in this study at different sites throughout the United States. Up to 50 participants will be included at [Insert Site Name]. You will be in this study for 12 months and complete 3 computer assisted surveys during this time.

At each time point (baseline, 3 months, 6 months), we will collect information from you in a questionnaire format on your HIV treatment knowledge, adherence to medication, andsatisfaction the text messaging program. This questionnaire will take about 15 minutes to complete.

During the study, we will also look at your medical records to collect information about the dates when you pick-up your HIV medication from the pharmacy, the dates of your clinic visits, and the results of viral load and other monitoring tests that the clinic has performed on you. This will help us to see how the study worked over time. We will keep your name and other identifying information confidential.

In addition to these things, your site will be randomly assigned to begin the study intervention. The timing for when this happens is chosen at random, like the flip of a coin. When this happens, you will receive the intervention for at least 3 months and up to 6 months. Once you begin the intervention, you will receive daily automated text messages at the usual time you take your medication to remind you to use them. You will be involved in the development of the messages that you will receive to remind you to take your medication, and these messages will be personal to you and based on the choices you make. The content of the reminders will be such that people around will not understand the message you have received. Only you will understand. This is to protect your privacy. You will be expected to acknowledge receiving the message and indicate whether you have taken your medication with a YES or NO. In response to this acknowledgment, you will receive an encouraging follow-up message. If your clinic site is randomized to the observation, that is randomly assigned to start the intervention at the 3-month timepoint, you will not receive text messages but will receive the standard of care at the clinic you are enrolled at. At the 3-month time point, you will be enrolled into the text messaging reminder intervention.

What are the bad or harmful things that could happen in this study?
You may find some of the questions difficult to answer or you may not want to answer them. You may skip any question that you do not want to answer. During this study, you will be informed about anything that may affect your continued participation or your health.

What are the good things that could happen in this study?
You may or may not have any benefit from being in the study. It is possible that you will get better, stay the same, or get worse. If the study helps you, we do not know how long this will last. We hope to learn something that could help other children in the future. During your participation in this study, you may enjoy receiving text message reminders for medication and clinic appointment adherence.

What other options are there?
You do not have to be in this study if you don't want to. Your doctors at [Insert Site Name] will not be upset with you. If you join the study and then change your mind, it is okay for you to leave this study at any time.

Who will see your information?
We will do everything we can to make sure that your medical records are kept confidential.

For this study, the [local clinic name] will share information from your medical records, including your most recent viral load, CD-4 count, and date of HIV services with the study team at Lurie Children's Hospital.

Federal and state laws do not allow sharing of sensitive health records without your permission.

If you agree to take part in this study, you also give permission for the use and sharing of your ~~de-identified~~ information from which we removed any information that might identify you like your name and birthdate ("deidentified") with persons outside of this study. This permission lasts until the study is completed.

The study staff, employees, and Medical Staff of Lurie Children's and [Insert Site Name] may use your information for this study and share it with:

1. The Institutional Review Board (the committee that is in charge of protecting the rights ofall adults and children who take part in research studies).
2. The Office of Human Research Protections (OHRP), the Food and Drug Administration(FDA), or other government offices.
3. Other Researchers who request access to the de-identified data for research purposes.

These are the only people to which we will give your information. We cannot guarantee that those listed above will not share it with others without your permission.

Your name will not be included in any written or verbal reports of study results.

To protect the information that you will give us, we will assign you a unique participant identification number (PID) at study enrolment. Your PID will be used by you throughout the period of your participation in this study. We will ensure the privacy of your information by keeping it in a secured place and by protecting them with the password.

In order to send you text messages, your phone number (but not your name or other information) willbe entered into a website owned by Dimagi, Inc. This company has policies in place to protect your privacy and will not to give your phone number out to anyone else.

Certificate of Confidentiality

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give thempermission to release information to insurers, your doctors, or any other person not

connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Will there be payment or gifts for being in this study?
You will not be paid for taking part in this study.

What if I decide not to give permission to use and give out my information?
If you decide not to allow the release your information, you will not be able to take part in this study. If you give permission to the use of your information, you can withdraw it at any time. Your request should be submitted directly to the researcher using either the email or phone number (akjohnson@luriechildrens.org; 312 227 7733). The study team can still use any information collected before you tell them to stop.

Who can answer questions about this study?

You can ask Amy K Johnson (akjohnson@luriechildrens.org; 312 227 7733) or the clinic staff at [Insert Site Name] anything about the study or tell her if you think you have been harmed. If you are not happy with this study and want to talk with someone else, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110 or by email at IRB@luriechildrens.org.

We will tell you if we learn new information that may make you change your mind about being in this study.

If you do not want to be in this study, that is okay.

Signatures Participant
Signature:

<table>
<tr><td colspan="2">By signing this form, I affirm:
1. I have read this form.
2. The research has been explained to me.
3. All of my questions have been answered.
4. I give my assent to take part in this research study.</td></tr>
<tr><td>Signature of Adolescent:</td><td>Date:</td></tr>
<tr><td colspan="2">Printed Name:</td></tr>
</table>

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Signature of Authorized Person Obtaining Assent/Witness:

I certify that I have explained the above to the participant/LAR and the signature was obtained voluntarily.	
Signature:	Date:
Printed Name:	

**If the study includes the use of records related to mental health or developmental disabilities, the person obtaining consent also serves as the witness to consent for use of relevant records.*

When it is not possible to obtain written assent:
To be completed by the Person Obtaining Assent.

Initials	This adolescent is unable to given written assent, but has given verbal assent toparticipate in the study.

Initials	This adolescent is unable to give written or verbal assent. The study PI (or delegate) has obtained a waiver of assent from the IRB Chair. Note: To request a waiver, e-mail IRB@LurieChildrens.org.

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

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Adolescent Agreement to Take Part in a Research Study

Aim 2: For participants aged 16-17 years

Study Name: Midwest TXTXT
Sponsored by: U.S Centers for Disease Control and Prevention U01PS005214
Name of Study Doctor/Researcher: Amy K Johnson, PhD

We want to tell you about a research study at Lurie Children's, the Midwest AIDS Training and Education Center (MATEC), and [local clinic name].

We are asking you to be in this research study because you have participated in the text messaging study and we are interested in learning more about your experiences and your thoughts on receiving the text messages.

Research studies help us find better ways to take care of and treat children and young adults. Taking part in a research study is voluntary. Itis your choice to take part in this research study.

Why is this study being done?
The main purpose of this study is to determine how well text messaging (Short Message Service - SMS) works to improve the amount of HIV in the blood (viral load) of young persons receiving HIV treatment at [Insert site name]. The study will also evaluate whether the text messaging works to improve how well young persons take their HIV medications (called adherence) and remain under the care of their medical providers (called retention in care), and whether young persons accept and are satisfied with the program being tested.

We are asking you to be in this research study because you have participated in the text messaging study and we are interested in learning more about your experiences.

What will happen in this study?
There will be a total of up to 60 participants in this study at different sites throughout the midwestern United States. About 4-5 participants will be included at [Insert Site Name]. This study visit is only one time and you will be asked to complete an interview which will take about 30 minutes to complete, the interview will be conducted either in person, by phone, or by secure video call

What are the bad or harmful things that could happen in this study?

You may find some of the questions difficult to answer or you may not want to answer them. You may skip any question that you do not want to answer. During this study, you will be informed about anything that may affect your continued participation or your health.

What are the good things that could happen in this study?
There are no direct benefits to you for participating in this survey. The information learned may help researchers learn more about designing programs and support for young people living with HIV to support medication adherence.

What other options are there?
You do not have to be in this study if you don't want to. Your doctors at [Insert Site Name] will not be upset with you. If you join the study and then change your mind, it is okay for you to leave this study at any time.

Who will see your information?

There will be no sensitive health information about you collected or shared.

If you agree to take part in this study, you also give permission for the use and sharing of your de-identified information from which we removed any information that might identify you like your name and birthdate ("deidentified") with persons outside of this study. This permission lasts until the study is completed.

The study staff, employees, and Medical Staff of Lurie Children's, , the Midwest AIDS Training and Education Center (MATEC), and [local clinic name] may use your information for this study and share it with:

1. The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
2. The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.
3. Other Researchers who request access to the de-identified data for research purposes.

These are the only people to which we will give your information. We cannot guarantee that those listed above will not share it with others without your permission.

Your name will not be included in any written or verbal reports of study results.

Certificate of Confidentiality

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from

federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOTBE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used forother research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your owninformation. It also does not stop you from getting copies of your own information.

Will there be payment or gifts for being in this study?

You will receive $40 (cash or gift card) as a token of appreciation after completing the survey.

Who can answer questions about this study?

You can ask Amy K Johnson (akjohnson@luriechildrens.org; 312 227 7733) or the clinic staff at [Insert Site Name] anything about the study or tell her if you think you have been harmed. If you are not happy with this study and want to talk with someone else, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110 or by email at IRB@luriechildrens.org.

We will tell you if we learn new information that may make you change your mind about being in this study.

If you do not want to be in this study, that is okay.

Signatures

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Participant Signature:

By signing this form, I affirm: 1. I have read this form. 2. The research has been explained to me. 3. All of my questions have been answered. 4. I give my assent to take part in this research study.	
Signature of Adolescent:	Date:
Printed Name:	

Signature of Authorized Person Obtaining Assent/Witness:

I certify that I have explained the above to the participant/LAR and the signature was obtained voluntarily.	
Signature:	Date:
Printed Name:	

**If the study includes the use of records related to mental health or developmental disabilities, the person obtaining consent also serves as the witness to consent for use of relevant records.*

When it is not possible to obtain written assent:
To be completed by the Person Obtaining Assent.

Initials	This adolescent is unable to given written assent, but has given verbal assent toparticipate in the study.

Initials	This adolescent is unable to give written or verbal assent. The study PI (or delegate) has obtained a waiver of assent from the IRB Chair. Note: To request a waiver, e-mail IRB@LurieChildrens.org.

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Adult Consent to Take Part in a Research Study

Aim 2: Consent for participants ages 18-35 years

Study Name: Midwest TXTXT
Sponsored by: U.S Centers for Disease Control and Prevention U01PS005214
Name of Study Doctor/Researcher: Amy K Johnson, PhD

This consent form describes a research study for which you might qualify being conducted by a researcher at Ann &Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") the Midwest AIDS Training and Education Center (MATEC), and [local clinic name].

We are asking you to be in this research study because you have participated in the textmessaging study and we are interested in learning more about your experiences and your thoughts on receiving the text messages.

Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as yourfamily or healthcare providers before you decide to take part in this study. The study staff will also explain the studyto you and answer any questions that you may have. Your decision will not affect your regular care.

What are the purpose and goals of this study?
The main purpose of this study is to determine how well text messaging (Short Message Service - SMS) worksto improve suppression of HIV in the blood of young persons receiving HIV treatment at [Insert site name]. The study will also evaluate how well the intervention fits into the current clinic environment.

We are asking you to be in this research study because you work at [Insert site name] and we believe you will havevaluable insight into how the intervention fits at your agency.

If I agree to take part in this study, what would I need to do?

There will be a total of about 24 participants in this study at different sites throughout the midwestern United States. Up to 2 participants will be included at [Insert Site Name]. The study consists of a one time individual interview that will last up to one hour. Interviews will be conducted either in person, via phone, or secure video call.

What are the risks, side effects, or discomforts related to the study?
You may find some of the questions difficult to answer or you may not want to answer them. You may skip anyquestion that you do not want to answer.

What are the benefits from this study?
The information learned may help researchers learn more about designing programs and support for young peopleliving with HIV to support medication adherence. You will not benefit from taking part in this study. This information learned from this study may help others in the future.

What other options do I have?
You do not have to be in this study if you don't want to. Your doctors at [Insert Site Name] will not be upset withyou. If you join the study and then change your mind, it is okay for you to leave this study at any time.

What if the researcher or I do not think I should stay in the study?
You can stop taking part in this study at any time. Your decision will not affect your regular care.

Returning Study Results:
The study team will not return study results to you. You can ask the study team any questions you have about studyresults.

Important New Information:
We will tell you if we learn new information that may make you change your mind about being in this study.

Will my information be used in future research studies?
The study team may share your information for future research. They will remove identifiers such as your name and other information that can be linked to you before this is done. The study team and other researchers may use this forother studies without getting consent from you.

Costs Related to this Study:

There are no costs associated with taking part in this study.

Payment for Taking Part in this Study:

You will not be paid for taking part in this study.

Your Rights When Taking Part in this Study:

If you agree to take part in this study, you are not giving up any of your legal rights. You can stop participating inthis study at any time. Your choice will not affect your regular care.

Additional Information:
Who can answer my questions about this study?

You can ask Amy K Johnson (akjohnson@luriechildrens.org; 312 227 7733) or the clinic staff at[Insert Site Name] anything about the study or report to her if you think you have been harmed. If you are not happy with this study and want to talk with someone else, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110or by email at IRB@luriechildrens.org.

You will be given a copy of this consent form.

Certificate of Confidentiality

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative,legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES
NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOTstop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate ofConfidentiality does not stop you from releasing your own information. It also does not stop you from getting copiesof your own information.

Planned Sharing of Your Information:

~~The information that may be collected and shared will include your:~~

5. ~~Personal information~~
6. ~~Records from study visits and phone calls~~

There will be no sensitive health information about you collected or shared

. If you agree to take part in this study, you also give permission for the use and sharing of your information from which we removed any information that may identify you like your name and birthdate ("deidentified") with persons outside of this study This permission lasts until the study is completed.

The study staff, employees, and Medical Staff of Lurie Children's, the Midwest AIDS Training and EducationCenter (MATEC), and [local clinic name] may use your deidentified information for this study and share it with:

7. The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
8. The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.
9. Other Researchers who request access to the de-identified data for research purposes.
10.

These are the only people to which we will give your information. We cannot guarantee that those listed above will not share it with others without your permission.

Your name will not be included in any written or verbal reports of study results.

What if I decide not to give permission to use and give out my information?
If you decide not to allow the release your information, you will not be able to take part in this study. If you give permission to the use of your information, you can withdraw it at any time. Your request should be in writing andsent to the researcher. The study team can still use any information collected before you tell them to stop.

Can I review or copy my information?
You cannot see your study records while the study is ongoing. You still have a right to request a copy of yourmedical record and tests related to regular medical care that is given during the same time as the study.

<u>Signatures:</u>
Participant/LAR
Signature:

By signing this form, I affirm: 1. I have read this form. 2. The research has been explained to me. 3. All of my questions have been answered. I consent to take part in this research study.	
Signature of Participant or Legally Authorized Representative (LAR):	Date:
Printed Full Name:	

Signature of Authorized Person Obtaining Consent/Witness*:

I certify that I have explained the above to the participant/LAR and the signature was obtained voluntarily.	
Signature:	Date:
Printed Full Name:	

**If the study includes the use of records related to mental health or developmental disabilities, the person obtaining consent also serves as the witness to consent for use of relevant records.*

Signature of Interpreter/Witness*:

☐ Not applicable, no interpreter used.
I attest that the study information has been presented to the participant/LAR in their nativelanguage.
Signature of Interpreter/Witness:
Printed Full Name or Unique Phone ID/Company Name:

Note to Investigators: When obtaining consent from a non-English speaking participant/ LAR

When a study-specific translated consent document is not available, a translated "short form" (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

4. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*

5. *The participant/LAR should sign the short form (in the language they understand).*

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

6. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*

7. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the shortform must be given to the participant/LAR.*

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Adult Consent to Take Part in a Research Study

Aim 2: Consent for staff ages 18+

Study Name: Midwest TXTXT
Sponsored by: U.S Centers for Disease Control and Prevention U01PS005214
Name of Study Doctor/Researcher: Amy K Johnson, PhD

This consent form describes a research study for which you might qualify being conducted by a researcher at Ann &Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") the Midwest AIDS Training and Education Center (MATEC), and [local clinic name].

We are asking you to be in this research study because you were employed at[local clinic name] during the implementation of the text messaging study. We are interested in learning more about your experiences and your thoughts on implementing the study in your local clinic.

Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as yourfamily or healthcare providers before you decide to take part in this study. The study staff will also explain the studyto you and answer any questions that you may have. Your decision will not affect your regular care.

What are the purpose and goals of this study?

The main purpose of this study is to determine how well text messaging (Short Message Service - SMS) works to improve suppression of HIV in the blood of young persons receiving HIV treatment at [Insert site name]. The study will also evaluate how well the intervention fits into the current clinic environment.

We are asking you to be in this research study because you work at [Insert site name] and we believe you will have valuable insight into how the intervention does or does not fit at your agency.

If I agree to take part in this study, what would I need to do?

There will be a total of about 24 participants in this study at different sites throughout the midwestern United States. Up to 2 participants will be included at [Insert Site Name]. The study consists of a one time individual interview that will last up to one hour. Interviews will be conducted either in person, via phone, or secure video call.

What are the risks, side effects, or discomforts related to the study?

You may find some of the questions difficult to answer or you may not want to answer them. You may skip anyquestion that you do not want to answer.

What are the benefits from this study?

The information learned may help researchers learn more about designing programs and support for young peopleliving with HIV to support medication adherence. You will not benefit from taking part in this study. This information learned from this study may help others in the future.

What other options do I have?
You do not have to be in this study if you don't want to. Your doctors at [Insert Site Name] will not be upset with you. If you join the study and then change your mind, it is okay for you to leave this study at any time.

What if the researcher or I do not think I should stay in the study?
You can stop taking part in this study at any time. Your decision will not affect your regular care.

Returning Study Results:
The study team will not return study results to you. You can ask the study team any questions you have about studyresults.

Important New Information:
We will tell you if we learn new information that may make you change your mind about being in this study.

Will my information be used in future research studies?
The study team may share your information for future research. They will remove identifiers such as your name and other information that can be linked to you before this is done. The study team and other researchers may use this forother studies without getting consent from you.

Costs Related to this Study:

There are no costs associated with taking part in this study.

Payment for Taking Part in this Study:

You will not be paid for taking part in this study.

Your Rights When Taking Part in this Study:

If you agree to take part in this study, you are not giving up any of your legal rights. You can stop participating in this study at any time. Your choice will not affect your regular care.

Additional Information:
Who can answer my questions about this study?
You can ask Amy K Johnson (akjohnson@luriechildrens.org; 312 227 7733) or the clinic staff at[Insert Site Name] anything about the study or if you think you have been harmed. If you are not happy with this study and want to talk with someone else, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110or by email at IRB@luriechildrens.org.

You will be given a copy of this consent form.

Ann & Robert H. Lurie Children's Hospital of Chicago

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MRN:

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NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate ofConfidentiality does not stop you from releasing your own information. It also does not stop you from getting copiesof your own information.

Planned Sharing of Your Information:

There will be no sensitive health information about you collected or shared.

If you agree to take part in this study, you also give permission for the use and sharing of your information from which we removed any information that may identify you like your name and birthdate ("deidentified") with persons outside of this study. This permission lasts until the study is completed.

The study staff, employees, and Medical Staff of Lurie Children's, , the Midwest AIDS Training and Education Center (MATEC), and [local clinic name] may use your information for this study and share it with:

8. The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
9. The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.
10. Other Researchers who request access to the de-identified data for research purposes.

These are the only people to which we will give your deidentified information. We cannot guarantee that those listed above willnot share it with others without your permission.

Your name will not be included in any written or verbal reports of study results.

What if I decide not to give permission to use and give out my information?

If you decide not to allow the release your information, you will not be able to take part in this study. If you give permission to the use of your information, you can withdraw it at any time. Your request should be via phone or email sent to the researcher (akjohnson@luriechildrens.org; 312 227 7733). The study team can still use any information collected before you tell them to stop.

Can I review or copy my information?

You cannot see your study records while the study is ongoing. You still have a right to request a copy of your medical record and tests related to regular medical care that is given during the same time as the study.

Signatures: Participant/LAR
Signature:

By signing this form, I affirm: 11. I have read this form. 12. The research has been explained to me. 13. All of my questions have been answered. I consent to take part in this research study.	
Signature of Participant or Legally Authorized Representative (LAR):	Date:
Printed Full Name:	

Signature of Authorized Person Obtaining Consent/Witness*:

I certify that I have explained the above to the participant/LAR and the signature was obtained voluntarily.	
Signature:	Date:
Printed Full Name:	

**If the study includes the use of records related to mental health or developmental disabilities, the person obtaining consent also serves as the witness to consent for use of relevant records.*

Signature of Interpreter/Witness*:

☐ Not applicable, no interpreter used.
I attest that the study information has been presented to the participant/LAR in their nativelanguage.
Signature of Interpreter/Witness:
Printed Full Name or Unique Phone ID/Company Name:

Note to Investigators: When obtaining consent from a non-English speaking participant/ LAR

When a study-specific translated consent document is not available, a translated "short form" (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

14. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*

15. *The participant/LAR should sign the short form (in the language they understand).*

Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

16. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*

17. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the shortform must be given to the participant/LAR.*

APPENDIX M: Cost Analysis Variables (Aim 1)

Staffing
Number of staff
Per each staff:
Role of staff person
Monthly salary
Total hours worked per month
Total hours worked per month on TXTXT project

Activities
Report on hours per month, by activity, per staff:
Training/review SOPs
Preparing materials
Screening participants
Enrolling participants
Conducting follow-up with participants
Attending team meetings
Data management
Administrative tasks
Other <specify>

Non Labor
Computer/phone usage
Software
Rent for space
Other <specify>