



Standard Operating Procedures and Guidelines

Title: Implementation Research: SickleInAfrica Protocol for Newborn
Screening

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Brief Introduction

This comprehensive booklet of SOPs is to facilitate standardization of the research protocol for the Newborn Screening Program of the SPARCO Consortium across seven countries in Sub-Saharan Africa. The overarching aim is to test the performance, acceptability and adoption of a newborn screening intervention using point-of-care testing for early identification of children born with sickle cell disease for enrollment into clinical care. Contained in this document are SOPs for screening of eligible participants, obtaining informed consent, enrollment of participants, transfer of case record forms within study sites, and follow-up of study participants. The document also contains protocols of procedures for the performance of HPLC and point-of-care tests, data storage and management; and protocol for qualitative evaluation of lived experiences of participants.

The SickleInAfrica consortium has adopted the EDGE Research Management System to manage cross-consortium studies. Please access EDGE to obtain more information about the protocol and standard operating procedures (see EDGE SOP for details)

Guideline: Facilities and Resources to Support Newborn Screening in Clinical Networks

Availability of prophylaxis for infection (oral penicillin and EPI administering pneumococcal, meningococcal and Haemophilus influenza type b (Hib) vaccines and folic acid.

Materials and consumables

Filter paper cards, gloves, lancets, spirit swabs, dry gauze squares, Ziplock bags, racks for drying DBS etc.)

Laboratory Investigations

Access to Isoelectric focusing (IEF) or High-performance liquid chromatography (HPLC) for confirmatory testing either in centre within the country or region

Full blood count, urea, creatinine electrolytes, liver function tests, urine analysis and microalbumin

Blood grouping and cross match, antibody screening, pretransfusion VDRL, viral screening Hepatitis B and C, HIV, CMV

Imaging

Chest Xray, TCD ultrasound screening

Education and Counselling Services

Education of healthcare workers, parents and caregivers on how to maintain good health and understand when to seek expert care if there is fever of 38°C or more, dehydration, dactylitis, respiratory illness, enlarged spleen/liver with worsening pallor.

SOP: Workplan

All sites will follow one workplan with minor adjustments to suit their environment.

	project year:	2022				2023			
	project year quarter:	1st	2nd	3rd	4th	1st	2nd	3rd	4th
Setting up the project									
protocol development									
advertise research project									
apply for ethical approval									
recruit research assistants									
recruit study participants									
stakeholder engagement									
purchase consumables & equipment									
train staff to counsel families and caregivers									
Preliminary Phase (validate the performance characteristics and cost of DBS POCT against IEF/HPLC)									
train staff to collect DBS samples									
train staff to perform POCT									
take DBS from each newborn and perform POCT									
send DBSs with positive POCT results for IEF/HPLC confirmation									
store DBS strips for possible future analysis									
analyse the results from the POCT and confirmatory tests									
produce report for preliminary phase (validation results, costs, e.t.c.)									
Phase 1 (quantitative, cross sectional survey)									
design survey instruments									
pilot the surveys									
update the survey instruments									
send out survey to study participants									
collect and analyse survey data									
produce phase 1 report									
Phase 2 (qualitative, focus group discussions)									
identify focus groups from study participant lists									

	All parents of babies with the Sickle Cell Trait are counseled on the implication of being a carrier.	Research nurse
4	Positive babies should be enrolled in the paediatric clinic. The Pharmacy is informed once the patient is identified. The child also commences medication immediately.	Research Nurse Pharmacy Pharmacy
5	Pharmacy maintains record of preventive maintenance treatment	

Ethical, Legal and Social Implications

SickleInAfrica Newborn Screening Parental Consent/Assent forms

Parental Consent Form for Newborn Screening for Sickle Cell Disease

Research Site Identifier []

Participant Identifier []

Who are we?

My name is XXX and I am a research assistant. I am part of the SickleInAfrica consortium which is a group of researchers based in 8 African countries (Ghana, Nigeria, Mali, Tanzania, South Africa, Uganda, Zimbabwe and Zambia). Our central goal is to improve the healthcare services and quality of life for people living with Sickle Cell Disease.

Invitation to be part of a research on Newborn screening for Sickle Cell Disease

We kindly invite you and your child to be part of a SickleInAfrica research on newborn screening for Sickle Cell Disease. In this research, SickleInAfrica researchers want to assess the adoption, barriers and facilitators of using three different methods for the screening of sickle cell disease in new-borns. The results of the research will help us understand how best we can make screening programs for sickle cell disease available to more children in XX Country and across Africa. We are currently carrying out this research in Ghana, Nigeria, Mali, Tanzania, Uganda, South Africa, Zimbabwe and Zambia.

Who are the people that are responsible for this research in Nigeria (Country XX)?

In Nigeria (country XXX), this research is led by Professor Obiageli Nnodu, who is a Medical Doctor and Director of the Centre of Excellence for Sickle Cell Disease Research and Training (CESRTA) at the University of Abuja. Other researchers are based in hospitals across Nigeria and in different African countries.

What will happen if I accept or accept that my child to be part of this research study?

If you accept to be part of this research, you will be asked some questions about yourself, your child and your experiences and knowledge about newborn screening for Sickle Cell Disease and the healthcare system that you use. You might also be asked to attend a focus group discussion.

If you accept for your child to be part of this research, a doctor or a nurse or a researcher will take one or two drops of blood from their foot and use this blood to test if your child has Sickle Cell Disease. If you child tests positive for Sickle Cell Diseases, we will ask you to return for another test to confirm the results. If your child has SCD, the clinic will offer them the necessary care based on the guidelines and we will pay for the first consultation at the sickle cell clinic. Based on the methods we use to test your child, there is a very small chance that our methods might miss a child with SCD. However, if you later notice that your child may have SCD signs and symptoms, please bring the child to the clinic to receive care..

Can I refuse that my child e part of this research?

Yes, you can refuse to be part of this research. The doctors and nurses will continue to take care of your child as they always do when you come to the hospital. You can also stop being part of this research at any time.

How will I benefit from this study?

The most important benefit is that you will have an opportunity to know whether or not your baby has sickle cell disease. If the screening shows that your child has sickle cell disease, health care workers will be able to start medical care early. As the parent, you will receive counselling and education on sickle cell disease. Another benefit is some personal satisfaction in knowing that you are helping researchers to answer important questions that may help improve healthcare for persons living with sickle cell disease

Are there any risks/discomforts of being part of this research?

The collection of a blood spot on special paper from your child and the screening for sickle cell disease has no added medical risks for your child. If the results show that your baby may have sickle cell disease, we will inform a doctor and further testing may be required to confirm this. This process may cause you to worry, even if it turns out that your baby does not have sickle cell disease.

Will I receive any compensation if I take part in this study?

We will compensate you for transport costs.

Confidentiality

Your name and your child's name and any other information that may identify you or your child will not be given to researchers who will be using your child's samples and information.

Can I ask a question?

Yes, please ask the doctor or the nurses or the researcher any question about this project that you do not understand or want to know more.

Contact Information

If you would like more information about this research before/after deciding to participate, please contact Prof XXX on phone XXXXX or email ([XXXXXX](#)). If you think you have not been treated fairly and would like to talk to someone other than the research team, please contact the XXXXX Ethics Committee on telephone number XXXX or write to XXX [email].

What should I do if I want to be part of the research t?

If you decide you want to be part of this research, please answer the questions below and then write your name the date and sign the form.

	Yes	No	N/A
I confirm that I have read and understand this consent form for the above study. I have had the opportunity to consider the information, ask questions and have had these answered fully.			
I understand that my child’s participation is voluntary and I am free to withdraw my child at any time, without giving any reason, without his/her medical care or legal rights being affected.			
I agree to let us telephone call or send SMS reminders about your clinic and study appointments <i>(If you change your mind and would like us to use different methods of contacting you, you can let us know)</i>			
I understand my child’s medical information, and data collected during the study will be stored and used for future research and that our funders may send a committee to check the quality of all the data and how it is being used.			
I would like to be contacted in the future for other research studies on sickle cell disease			

I, (Full Name) _____, agree that my child (name of child)-----
-----, should be part of this research.

(Signature/Thumbprint)

(Write the date)

Administrative use only (To be completed by the research team)

I certify that I have explained the purpose of the research to the parent named above and I have answered the questions that they asked, and that they have given informed consent

Name of Research Staff taking consent

Date and signature

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Consent forms for Participants taking part in the Survey and/or Qualitative study

Introduction

We invite you (or your child) to take part in a sickle cell disease research project on newborn screening for sickle cell disease in Africa. In this research, SickInAfrica researchers want to assess the adoption, barriers and facilitators of using three different technologies for the screening of sickle cell disease in newborns. The research is taking place in Nigeria, Ghana, Mali, Tanzania, South Africa, Uganda, Zambia and Zimbabwe

Who are the researchers in Nigeria (Country XX)

In Nigeria (CountryXX), this project is led by Professor Obiageli Nnodu, who is a medical doctor and Director of the Centre of Excellence for Sickle Cell Disease Research and Training (CESRTA), at the University of Abuja. Other researchers are based in different hospitals across Nigeria and in different African countries.

Who is being invited to be part of the research (Participants)

Participants for this research will be healthcare workers, policy makers, persons living with sickle cell disease, parents of children living with sickle cell disease.

What is required from me if I accept to be part of the research?

If you agree to be part of this research, you will be asked to either complete a questionnaire and/or be part of either a group discussion or one on one research interview, where we will discuss issues around newborn screening for sickle cell disease.

The questionnaire may take about 20 minutes to complete. The group discussions or interviews will last approximately one hour and will be audio recorded. The recordings will be typed out word-for word, after which they will be destroyed. At the end of this project, any information that may potential identify you, such as your name, will be removed from the transcripts and the transcripts may be deposited in a database for use in future research on sickle cell disease.

Confidentiality

We will keep what you say in the discussions or questionnaire confidential. When we write the research reports, any information that will identify you such as your name or where you stay, or work will be removed. The questionnaires, and recordings of the interviews and group discussions will be kept in password-secured computers. We will not publish entire interviews or group discussions, but quotes of what people say may be used to report on this study.

For the group discussions, we will ask everybody in the group to keep the discussion confidential. However, it is important to remember that if you take part in a group discussion, there is possibility that someone who was part of the discussion could talk to other persons about what happened or was discussed during the group sessions

Can I refuse to be part of the study or withdraw at any time even if I had initially accepted?

Your participation in this research is voluntary. Even when you accept to be part of the research, and during or after the study, you decide you no longer want to participate, please let us know and will be destroy any information that has been collected from you or stop using it for new research studies.

Are there any risks/discomforts of being part of this research?

There are no anticipated physical risks of participating in the survey, group discussions or one-on-one interviews. However, you may feel upset or worried when answering some of the questions. To minimize this, you can choose not to answer any question you do not want to.

What are the benefits of participating in the research?

If you decide to participate in this research, you will receive no direct benefit. However, your contribution will inform ongoing discussions on how to improve the care and management of children with SCD in Africa

Will I receive any compensation if I take part in this study?

To compensate you for the cost of transport and that you incurred to be part of this study, at the end of the interview or group discussions, you will be given XXXX

Contact Information

If you would like more information about this research before/after deciding to participate, please contact Prof XXX on phone XXXXX or email ([XXXXXX](#)). If you think you have not been treated fairly or have been hurt by joining this study, please contact the XXXXX Ethics Committee on telephone number XXXX or write to XXX [email].

Please indicate your consent for this interview by responding to the conditions below:

	Yes	No
I understand the purpose of the research and have been provided with sufficient information		
If the questionnaires and transcripts of the interviews or discussions are anonymised, it can be deposited in a public database for use by other researchers		
I agree to take part in this study		

Signature..... Date..... Name.....

Research Team: Investigator’s Statement (To be completed by the researcher)

I confirm that I have carefully explained the proposed study to the participant.

Signature..... Date..... Name.....

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Community Engagement Material

Community Engagement material will include posters, pamphlets and other site appropriate material. This will be distributed via SCD support groups, healthcare facilities and other community-based locations.

Quantitative Data: data/survey instruments

Demographic Data Elements from SickleInAfrica Registry

*Please note a separate SickleInAfrica registry consent form will need to be administered for the inclusion of a child into the SickleInAfrica registry.

*Core demographic data will be collected based on the SickleInAfrica data elements.

Treatment questionnaire for each child

Treatment questionnaires will be developed for site based on the treatment schedule for that specific country. Highlighted below is a vaccination schedule and treatment questionnaire from Nigeria.

Example treatment schedule for Nigeria

AGE	DISEASE	VACCINE/ANTIGEN	SITE
AT BIRTH	Hepatis B Polio Tuberculosis	HBV 1, CPV0 BCG	Upper part of the thigh Oral Upper left arm
6 weeks	Polio DPT, HIB, Hepatitis B Rotavirus Pneumonia & Otis Media	CPV 1 Pentavalent 1 Rotarix 1 Synoflorix 1 or Pevnar 13	Oral Upper part of the thigh (right) Oral Upper part of the thigh (left)
10 weeks	Polio CPT, HIB, Hepatitis B Rotavirus Pneumonia & Otis Media	CPV 2 Pentavalent 2 Rotarix 2 Synoflorix 2 or Pevnar 13	Oral Upper part of the thigh (right) Oral Upper part of the thigh (left)
14 weeks	Polio CPT, HIB, Hepatitis B Pneumonia & Otis Media	CPV 3 Pentavalent 3 Synoflorix 1 or Pevnar 13	Oral Upper part of the thigh (right) Upper part of the thigh (left)
6 months	Vitamin A	Vitamin A	Oral
9 months	Measles, Yellow Fever	Measles, Yellow Fever	Upper part of the thigh (right) Upper part of the thigh (left)

Treatment questionnaire for caregivers

Has your child received the following treatment?

HBV	for Hepatitis B	yes / no / don't know
CPV0	for Polio	yes / no / don't know
BCG	for Tuberculosis	yes / no / don't know
CPV 1	for Polio	yes / no / don't know
Pentavalent 1	for DPT, HIB, Hepatitis B	yes / no / don't know
Rotarix 1	for Rotavirus	yes / no / don't know
Synoflorix 1 or Prevnar 13 (first dose)	for Pneumonia & Otis Media	yes / no / don't know
CPV 2	for Polio	yes / no / don't know
Pentavalent 2	for CPT, HIB, Hepatitis B	yes / no / don't know
Rotarix 2	for Rotavirus	yes / no / don't know
Synoflorix 2 or Prevnar 13 (second dose)	for Pneumonia & Otis Media	yes / no / don't know
CPV 3	for Polio	yes / no / don't know
Pentavalent 3	for CPT, HIB, Hepatitis B	yes / no / don't know
Synoflorix 1 or Prevnar 13 (third dose)	for Pneumonia & Otis Media	yes / no / don't know
Vitamin A	for general health	yes / no / don't know
measles vaccine	for Measles	yes / no / don't know
yellow fever vaccine	for Yellow Fever	yes / no / don't know

Questionnaire for healthcare workers from the selected health facilities

Section one: Socio-demographic information - age/date of birth, sex, marital status, tribe, cadre, year of graduation.

Section two: Total number and types of healthcare workers available in the facility (doctors, nurses, pharmacists, laboratory personnel, midwives, administrators, medical health information officers, community health extension workers, counsellors, nutritionists, physiotherapist), knowledge of SCD, types of services available, availability of space, equipment for screening or diagnosis of SCD and knowledge of point of care screening test for SCD.

Questionnaire for caregivers

Section one: Information on the socio-demographic data of the caregiver- Age/date of birth, sex, tribe, occupation of the mother/guardian, level of education of the mother/guardian and religion, number of children of the mother/guardian, home address (exact location with description of important landmarks, contact telephone, type of phone).

Section two: Information on the knowledge of the mother/guardian about SCD, haemoglobin genotype status, knowledge of newborn screening and acceptability of newborn screening for early diagnosis and intervention for SCD in newborns.

Section three: Information on the outcomes of the point of care screening test (haemoglobin genotype AA, AS, AC, SS, SC and indeterminate)

Qualitative Interviews:

Planning of Focus Groups Discussion and In-depth Interviews

FGD and IDI Guide

- Ensure that the questions are open ended so as that they cannot be answered with a simple “Yes” or “No”
- Keep the questions simple, short and clear. Otherwise, participants will end up discussing the question itself, rather than responding to it.

Logistics for FGD and Interviews

- Determine possible dates and times for the FGD
- Identify and confirm venue for the FGD.
 - Venue should be easy to locate
 - Decide if you will need to provide transport to the venue
- Determine who will be invited, how many persons to invite, and who will do the recruiting.
 - Invite about 10-12 potential participants for each FGD, expect 6-10 to respond and about 5-8 to attend. Keep each FGD to max 8 to allow for max engagement from all participants
 - Give about two weeks from date of invitation to the actual date of FGD
 - Allow at least 3 weeks for the recruitment process. Send reminders (calls, sms, emails etc) to participants a day before the FGD
- If you will be providing snacks/refreshment, ensure that that it is available at the FGD site at least 30 minutes before the end of the FGD
- Print out copies of consent/assent forms (two for each participant)
- Check that recording devices are adequately charged and have sufficient storage
- If providing incentives (reimbursements) have it ready before the start of the FGD

Protocol for FGD Discussion

- Moderator welcomes participants, introduces the Research assistant (note taker) and provides a brief description of the study and group rules (confidentiality, respect)
- Allow time for participants to sign consent form and drop it in a box
- Research Assistant checks that consent forms have been signed
- Switch on the recorder
- Start with questions
- Closing remarks (remind participants of confidentiality rule, and the right to withdraw)
- Keep FGDS to about 60-90 minutes

Telephone or Online IDIs/FGDs

- Confirm (by call or email) interview date and send a calendar invite (if possible)
- For online interviews it is preferable to use a familiar platform like zoom
 - Check that your zoom allows for at least 60 minutes
- Check that you have received the signed consent forms for all participants
- Follow same protocol described above
- Record both on zoom (cloud or computer) and on an external device
- Once zoom session is over, allow for recording to convert and then save

COVID-19 Measures for Face to Face FGDs and Interviews

- Inform participants about covid measures
 - Need to inform moderator if they test positive for COVID-19
 - Moderators will inform participants if any of the attendees test positive for Covid. Confidentiality will be maintained
- Ensure that venue has appropriate ventilation
- Provide sanitisers at the venue

Data Analysis

Transcription of Interviews

- Determine if transcription will be done by the research team or outsourced (transcriptionist). If outsourced?
- Determine how audio recordings will be sent to transcriptionist (email, Drive, WeTransfer)
- Provide a checklist for transcriber
- Number of FGD participants
- Formatting (time stamps; names; speakers)

Post transcription

- Research team checks quality of transcripts against audio and confirm with Transcriptionist

- Anonymise transcripts
- Determine if you will use a software to support analysis or if it will be done manually
- Start thematic analysis

Planning In-depth Interviews

Patient interview guides

Interview Guide for Mothers (Parents)

Healthcare Facility Name: _____

Country: _____

Introduction (sub questions are probes)

1. Can you describe the steps the clinic/healthcare facility asked you to take from when your infant was tested for SCD to when you received the results?
 - a. How old was your child when you did NBS for SCD?
 - b. How long did this process take?
 - c. How did you feel while you were waiting to hear your baby's test results?
 - d. How did you feel about the length of time it took to receive the results?

Experience of NBS for SCD (Intervention Characteristics)

2. Can you please describe the various services you and your infant received at the time of the screening test and afterwards?
 - a. What care did your baby receive before and after testing? (Tests, Checkups, etc)
 - b. What kind of care did you as a mother/parent received (Tests, Checkups, Counseling, etc)
3. What was your experience like when your child was tested for sickle cell disease?
 - a. What were some of the challenges you faced in the process?
 - b. What made you accept the test for SCD for your baby?

Needs, Knowledge and Beliefs about NBS for SCD (Outer setting and characteristic of Individuals)

4. Generally, what is your opinion on testing infants for SCD at birth at facility in your country or setting?
 - a. What do you think are some of the potential benefits of testing for SCD at birth?
 - b. What do you think are some of the potential barriers of testing for

SCD at birth?

- c. What do you think are some of the potential risks of testing for SCD at birth?
- d. What do you think are some of things that could help overcome the potential risks of testing for SCD at birth?
- e. How would you describe your overall experience with SCD at birth (e.g., Positive or Negative, don't know)?

Preferences for NBS for SCD (Implementation Process)

7. Thinking about the services mothers receive during delivery and afterwards at what point during the process do you think the babies should be tested for SCD?
8. If an infant is to be tested for SCD at birth, what information would be helpful for mothers or parents to know beforehand?
 - a. How can providers prepare mothers for SCD testing for their babies?
 - b. What type of information would make mothers more likely to accept SCD testing for their babies?

Questions about implementation of NBS (Inner setting)

9. Would you want to know your baby's SCD status before leaving the hospital? Why or why not?
 - a. What are some reasons that mothers would want their infant's test results on the same day?
 - b. What are some reasons that mothers would not want their infant's test results on the same day?
10. How can providers prepare mothers for SCD testing and any results that they might receive?
11. Are there any other concerns or questions you have about NBS for SCD?

Interview Guide: HCW and Policy Makers

Introductory/Overview Questions

1. Please tell us a bit about your roles and responsibilities here at the hospital/ministry of Health?
 - a. How are you involved in care for newborn or management of SCD?
 - b. What are some of the challenges that you have experienced in providing these services?

2. What are the services that a mother and her newborn will receive, from the time the mother delivers to when they are discharged? (for HCW) Registration, lab tests, checkups, etc?

Perception of NBS for SCD in Country X (Intervention Characteristics)

3. From your perspective, what is the benefit of providing NBS for SCD in Country X?
4. What are some barriers you anticipate for NBS for SCD in Country X?
 - a. Do you foresee specific barriers for the health care facility or local government/District? (Workload, time, etc.)
 - b. How can these barriers be overcome?

Questions about implementation of NBS (Inner setting)

5. How do you think NBS for SCD can be incorporated into the health system in Country X?
 - a. Where should babies be tested (Maternity, vaccination centers, etc)?
 - b. Given the services provided to newborns at hospitals, when in your opinion would be the best time to do NBS for SCD?
 - c. Based on your experience what resources or support would be needed to implement a NBS for SCD in Country X?
 - d. What resources or support would be needed to implement NBS for SCD in Country X?
 - e. What implications would incorporating NBS for SCD into the current hospital routine have on hospital staff? And mothers?
6. Who should be responsible for performing NBS for SCD tests?
 - a. How would performing these tests impact this person's ability to complete their other responsibilities?
 - b. How would this impact care of mother and baby?
 - c. How confident would providers feel initiating ART based on positive point of care testing results?

Knowledge and Beliefs about NBS for SCD (Outer setting and characteristic of Individuals)

7. What do you think are some benefits of NBS for SCD?
8. What are some concerns mothers might have about NBS for SCD?
9. What are some concerns and challenges HCW and policy makers might have about NBS for SCD? (Acceptance, workload training, etc.)
10. How could these provider challenges and concerns be minimized?
11. Do you have any concerns regarding NBS for SCD in Country X?

Data Collection Tool: Focus Group Questions for Measuring Adoption, Implementation cost, and Maintenance/Sustainability

Note: We will conduct FGD (N= 3-6/per site) with key stakeholders (policy makers, midwives, physicians, nurses, councilors and parents of children with SCD) to explore preferences for NBS for SCD and the barriers and facilitators of the use of the 3 NBS technologies at the different SIA Sites. FGD guides will be guided by CFIR. The CFIR domains most relevant for clinical perspective are the individuals involved in implementation (knowledge and beliefs about the technology, self-efficacy to use the technology), inner and outer settings (implementation climate, structural characteristics, external policies, culture, networks, and communications).

Please complete the below questions for your site

Country Name:

Site ID:

- 1) How many health care workers trained in the 3 technologies this month?
_____ health care workers
- 2) How many babies were screened for SCD this month?
_____ patients
- 3) How many patients were referred for further management _____ patients

4) Other comments:

.....
.....
.....
.....

Adoption

1. How receptive do you think patients will be to the use of the 3 technologies?
 - a. *Probe: What will determine whether patients are receptive to the technologies?*
2. How receptive do you think the participating sites will be to regular use of the technologies?
 - a. *Probe: What factors do you think will determine whether sites are receptive to the technologies?*
3. In your opinion, do the technologies align with the sites mission for new born screening? Why or why not?

Implementation and cost

4. What are the cost implications (ie. Monetary, time, etc.) for patients using the 3 technologies?
5. What items or resources do you feel would benefit patients most as an incentive to use the 3 technologies?
6. What training will staff need to successfully implement the 3 technologies?

Maintenance / Sustainability

7. What are some factors that may help to successfully maintain regular use of the technologies at your site in the long -term?
8. What are some barriers that may impede the regular use of the technologies at your site in the future and going forward?
9. In your opinion, what factors may influence whether the technologies will become part of routine practice at your site?

**Data Collection Tool
Practice Capacity Survey**

Please complete the below questions for your site

Country Name:

Site ID:

Demographics

1. Country:
2. Name of Health Facility/ Affiliation: _____ Peds
Adult
3. Type of facility (check all that apply):
Public Private Government Non-Government Teaching
4. Your Age: _____
5. Sex: Male Female
6. Highest level of education completed:
Primary Secondary Technical training Bachelors Masters Doctorate
7. Training:
Physician Medical Officer Specialized Physician
(specialty) _____
Matron Nu Nurse/Midwife Other (specify) _____

8. How many years have you been providing Sickle cell disease care ? _____ Not Applicable

The following questions assess the management and control of sickle cell in your healthcare facility at the organizational, provider, and patient level.

Organizational

9. How many patients with sickle cell are seen in a month at your facility? _____

10. Among the patients, how many are adults? _____ How many are children? _____

11. Which of the following investigative approach is used for the assessment of sickle cell disease at your facility?

	Yes	No	Do not know
HPLc			
Electrophoresis			
Sickling Test _____			
Other (please specify) _____			

12a. Please list any technologies that you use for new born screening for SCD?

12b. Provide any challenges that you encounter while using each of the technologies?

13. What medications or treatment options are available for the patients at your facility for sickle cell management?

	Yes	No	Do not know
Hydroxyurea			

Antibiotics			
Pain relieving medications			
Vaccinations			
Blood transfusion			
Bone marrow transplant			

14. How often are medications for sickle cell management readily available at your facility or at the nearby pharmacy?

Very often Quite often Occasionally Rarely Never

15. Are the medications for sickle cell management provided to patients covered by NHIS?

Yes No Do not know

16. If no to question #15, how much do the patients pay out of pocket for the medications (in dollars)? _____

17. How do most patients with sickle cell at your facility cover the cost of medication treatment or consultation?

Fully out of pocket Partial payment Private Insurance NHIS
Other (specify) _____

Healthcare Provider

18. What is the first-line of sickle cell medication for patients based on the available medication at your facility? _____

19. Who is responsible for **identifying** sickle cell patients in your facility? (check all that apply)

Physician Medical Officer Specialized Physician
(specialty) _____
Nu Other / lab (specify) _____
Matron Nurse/Midwife

20. Who is responsible for **the treatment** of sickle cell patients in your facility? (check all that apply)

Pain management			
Healthy diet, Importance of being hydrated			
Infection prevention			
Physical activity			
Other (specify) _____			

26. What are the sources of knowledge of the beneficial effects of sickle cell management options (i.e. medication adherence -hydroxyurea) among patients?

Doctor
Pharmacist

Non-physician health-care provider (i.e. Nurses)

Television or media

Family members

Lay acquaintance

Other (Specify) _____

Data Collection Tool: Program Sustainability Assessment Tool v2

Please complete the below questions for your site

Country Name:

Site ID:

In the following questions, you will rate your program across a range of specific factors that affect sustainability. Please respond to as many items as possible. If you truly feel you are not able to answer an item, you may select “NA.”

For each statement, circle the number that best indicates the extent to which your program has or does the following things.

Environmental Support: Having a supportive internal and external climate for your program

	To little or no extent					To a very great extent		
	1	2	3	4	5	6	7	NA
1. Champions exist who strongly support the program.	1	2	3	4	5	6	7	NA
2. The program has strong champions with the ability to garner resources.	1	2	3	4	5	6	7	NA
3. The program has leadership support from within the larger organization.	1	2	3	4	5	6	7	NA
4. The program has leadership support from outside of the organization.	1	2	3	4	5	6	7	NA
5. The program has strong public support.	1	2	3	4	5	6	7	NA

Funding Stability: Establishing a consistent financial base for your program

	To little or no extent					To a very great extent		
	1	2	3	4	5	6	7	NA
1. The program exists in a supportive state economic climate.	1	2	3	4	5	6	7	NA
2. The program implements policies to help ensure sustained funding.	1	2	3	4	5	6	7	NA

3. The program is funded through a variety of sources.	1	2	3	4	5	6	7	NA
4. The program has a combination of stable and flexible funding.	1	2	3	4	5	6	7	NA
5. The program has sustained funding.	1	2	3	4	5	6	7	NA

Partnerships: Cultivating connections between your program and its stakeholders

	To little or no extent					To a very great extent		
1. Diverse community organizations are invested in the success of the program.	1	2	3	4	5	6	7	NA
2. The program communicates with community leaders.	1	2	3	4	5	6	7	NA
3. Community leaders are involved with the program.	1	2	3	4	5	6	7	NA
4. Community members are passionately committed to the program.	1	2	3	4	5	6	7	NA
5. The community is engaged in the development of program goals.	1	2	3	4	5	6	7	NA

Organizational Capacity: Having the internal support and resources needed to effectively manage your program and its activities

	To little or no extent					To a very great extent		
1. The program is well integrated into the operations of the organization.	1	2	3	4	5	6	7	NA
2. Organizational systems are in place to support the various program needs.	1	2	3	4	5	6	7	NA
3. Leadership effectively articulates the vision of the program to external partners.	1	2	3	4	5	6	7	NA
4. Leadership efficiently manages staff and other resources.	1	2	3	4	5	6	7	NA
5. The program has adequate staff to complete the program's goals.	1	2	3	4	5	6	7	NA

Program Evaluation: Assessing your program to inform planning and document results

	To little or no extent					To a very great extent		
1. The program has the capacity for quality program evaluation.	1	2	3	4	5	6	7	NA
2. The program reports short term and intermediate outcomes.	1	2	3	4	5	6	7	NA
3. Evaluation results inform program planning and implementation.	1	2	3	4	5	6	7	NA
4. Program evaluation results are used to demonstrate successes to funders and other key stakeholders.	1	2	3	4	5	6	7	NA
5. The program provides strong evidence to the public that the program works.	1	2	3	4	5	6	7	NA

Program Adaptation: Taking actions that adapt your program to ensure its ongoing effectiveness

	To little or no extent					To a very great extent		
	1	2	3	4	5	6	7	NA
1. The program periodically reviews the evidence base.	1	2	3	4	5	6	7	NA
2. The program adapts strategies as needed.	1	2	3	4	5	6	7	NA
3. The program adapts to new science.	1	2	3	4	5	6	7	NA
4. The program proactively adapts to changes in the environment.	1	2	3	4	5	6	7	NA
5. The program makes decisions about which components are ineffective and should not continue.	1	2	3	4	5	6	7	NA

Communications: Strategic communication with stakeholders and the public about your program

	To little or no extent					To a very great extent		
	1	2	3	4	5	6	7	NA
1. The program has communication strategies to secure and maintain public support.	1	2	3	4	5	6	7	NA
2. Program staff communicate the need for the program to the public.	1	2	3	4	5	6	7	NA
3. The program is marketed in a way that generates interest.	1	2	3	4	5	6	7	NA

4. The program increases community awareness of the issue.	1	2	3	4	5	6	7	NA
5. The program demonstrates its value to the public.	1	2	3	4	5	6	7	NA

Strategic Planning: Using processes that guide your program’s direction, goals, and strategies

	To little or no extent						To a very great extent		
1. The program plans for future resource needs.	1	2	3	4	5	6	7	NA	
2. The program has a long-term financial plan.	1	2	3	4	5	6	7	NA	
3. The program has a sustainability plan.	1	2	3	4	5	6	7	NA	
4. The program’s goals are understood by all stakeholders.	1	2	3	4	5	6	7	NA	
5. The program clearly outlines roles and responsibilities for all stakeholders.	1	2	3	4	5	6	7	NA	

Governance

SOP: Research Study Roles and Responsibilities - SickInAfrica

Purpose:

This Standard Operating Procedure (SOP) describes the methods for Essential documentation, Authority and Delegation of Responsibilities. This document also outlines the responsibilities of individual study personnel working in the SickInAfrica consortium. This procedure is intended to meet GCP guidelines (Good Clinical Practice) state regulations.

Responsibilities

- The PI may delegate certain responsibilities to another qualified member of the research team. The delegation of responsibility should be clearly documented. The PI retains full responsibility for the procedures described in this standard operating procedure.
 - The Principal Investigator (PI) shall maintain all required documentation for clinical research studies conducted at the study site
 - The Principal Investigator shall obtain and store all required regulatory documents for each study.
 - The Principal Investigator shall maintain records of study administrative activities and data from each study subject

 - The Principal Investigator/Study Co-coordinator and all the study staff are responsible in for making recommendations for alterations and site organization.
- A. Local Lead Principal Investigator:**
- These roles are in addition to those outlined in the AE-SAE reporting SOP
 - Delegation of authority and responsibilities as recorded on the Delegation of Responsibilities Log
 - First port of call for reporting of serious adverse events (SAE)/suspected unexpected serious adverse reaction (SUSAR)
 - Overall medical oversight of study patients in conjunction with study doctor/nurse
 - Oversight of whole site study team
 - Oversight of local study budget
 - Communication of study related activities to Regulatory and Ethics Review Bodies
 - Oversight of laboratory specimen collection, storage and sample shipping as required
 - Facilitation of monitoring visits
 - Guarantor of secure storage and sufficient supplies of study drugs and consumables in conjunction with study doctor/nurse/laboratory technician/pharmacist
- B. Research Assistants/Data Capturer**
- Outpatient and In-patients
 - Obtaining informed patient consent from patient or next-of-kin
 - Filing of consent forms
 - Translation
 - Establishing and maintaining a positive relationship with study patients
 - Documentation of relevant clinical information in patient records

- Organising follow-up care on patients
- Ensure adequate study (clinic) supplies. Study coordinator if replacements required.
- Tracing non-attenders through note entries, phone calls ,text messages or visiting them in the community
- Book next out-patient follow-up appointment
- Ensuring study forms are completed in real time, kept accurate and up to date
- Responding to data queries
- Other study related activities
- Ordering I equipment
- Positive relationship building with all hospital staff.
- Ensuring adequate supplies in conjunction with pharmacist and study manager and coordinators.

C. Study Co-ordinator/Research Fellow

- Overall management of the study
- Report to Principal Investigator
- Ensure Investigator Site File is kept up to date and stored securely. Ensure orders are placed and received as required for study consumables/equipment
- Ensure site is ready for monitoring/audit visits

Manuscript/authorship agreements

To be included

Data Management & Analyses

Qualitative Data Management

Three types of qualitative data will be generated: The field notes, audio recordings and associated transcripts. Another information relevant for data management is informed consent.

Three different elements of identification will be used for this Source ID, data labels, and file names:

Source ID: unique reference number assigned to each interviewee or FGD participant. This will be done in sequential order (P1, P2, P3) as they participate in the study. As a group, FGDs will be labelled in sequential order as F01, F02.... Their stakeholder group Mother (M); healthcare worker (HCW); Policy maker (PM)

Data Labels: This refers to data type that is collected- e.g. consent forms (IC); audio recording (AR) researchers notes (RN); Transcripts (VT); In-depth Interviews (IDI) and Focus group

discussions (FGD); Sites- Ghana (GH), Mali (ML), Nigeria (NG) Tanzania (TZ) Uganda (UG), Zambia (Zam); Zimbabwe (Zim)

File Names: Files will be labeled such that they can be linked to the source ID. We will start with the participant/group number-the type of data-Specifics for data-Country-Stakeholder Group-Date of collection.

For example, P1-IC; P3-AR-IDI; P4-VT-IDI-UG; F5-VT-FGD-Zam. All file names will end with the date (YYYY-MM-DD). For example, F7-AR-FGD-ML-HCW-2022-09-17

Data Storage

Transcripts for each SPARCo site will be uploaded to NVivo 12. Two NVivo files will be created, a Master file and a copy. The Master file will be saved and the copy will be used for analysis.

Data Security ad Sharing: Please refer to the SickInAfrica Data Sharing Policy

Laboratory Tests

HemoTypeSC procedure for standard method

Blood collection procedure

1. The lateral heel of each infant will be cleaned with alcohol, punctured to obtain blood drops to be captured on Guthrie cards following well-established procedures (Clinical and Laboratory Standards Institute Approved Standard NBS01-A6 (Clinical and Laboratory Standard Institute 2013).
2. Tests will be run on each participate in this project using these methods:
 - a. A reference method, which is Iso electric focusing (IEF/HPLC)
 - b. POCT (HemoTypeSC) method using DBS
3. DBS will be made on filter paper cards following the HemoTypeSC instruction manual.
4. DBS will be allowed to dry for a minimum of 3h at 18°C–25°C. Afterwards the blood sample will be eluted and HemoTypeSC normal procedure followed to determine the test result.

HemoTypeSC POCT Test Procedure

Instructions For Use HemoTypeSC™ is a rapid test kit intended to determine the presence of hemoglobin A, S and C in whole blood. The kit is intended for in vitro diagnostic use by health professionals. This test is a competitive lateral flow immunoassay incorporating monoclonal antibodies for determination of the presence of hemoglobins A, S, and C. HemoTypeSC™ provides rapid detection of hemoglobin phenotypes HbAA, HbSS, HbSC, HbCC, HbAS, and

HbAC. HemoTypeSC™ results are not affected by fetal hemoglobin. Phenotype HbS/β0-thalassemia will produce the same HemoTypeSC™ result as HbSS. Other hemoglobin variants (e.g., HbD and HbE) will produce the same HemoTypeSC™ result as Hb. (See Figure 1 for an illustration of the test procedure).

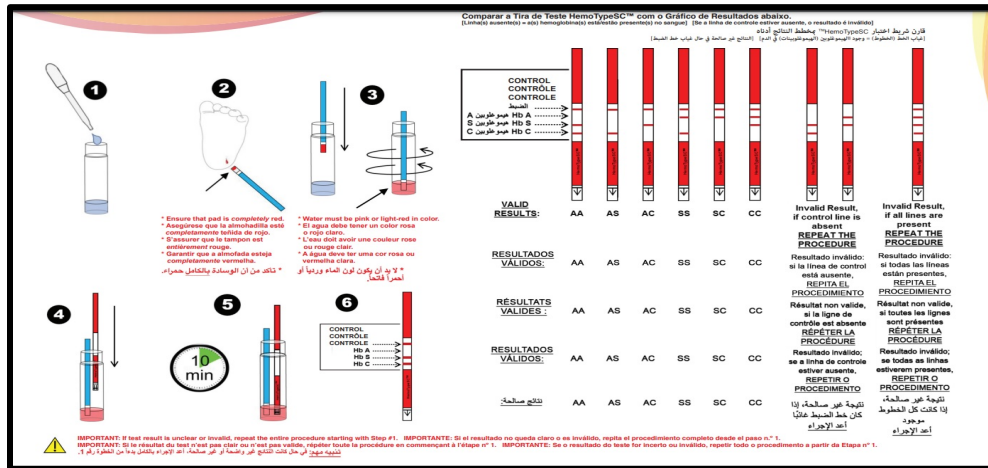


Figure 1: Procedure for HemoTypeSC testing.

1. Using a Dropper Pipette, add six (6) drops of water to the Test Vial. Place the Test Vial in a compatible rack.
2. Open Vial of Blood Sampling Devices, remove one Blood Sampling Device, and reclose Vial. Obtain a blood sample – a small drop is sufficient (1 to 2 microliters). Touch the white pad of the Blood Sampling Device to the blood sample, until the white pad absorbs the blood droplet. Ensure that the entire white pad has turned red.
3. Insert Blood Sampling Device into Test Vial water and swirl to mix. a) Sufficient swirling is essential for blood to be properly transferred into Test Vial. b) Check visually to ensure that water has become pink or light-red in colour. See Figure 2

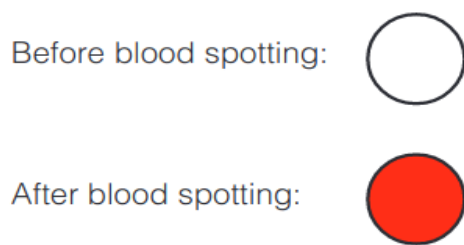


Figure 2: dried blood spot procedure

4. c) Leave Blood Sampling Device in the Test Vial after swirling.
5. Open Vial of Test Strips, remove one Test Strip, and reclose Vial. Insert HemoTypeSC™ Test Strip into Test Vial with arrows pointing DOWN.
6. Wait 10 minutes.
7. Take HemoTypeSC™ Test Strip out of the Test Vial and read the results.



8. Compare Test Strip to Results Chart

HemoTypeSC Procedure for Dried Blood Spot (DBS) method

HemoTypeSC™ can be adapted for use with dried blood spots (DBS) if stored at 10-25°C and away from moisture for up to 5 months or at -20-0°C and away from moisture for up to 2 years. The DBS should be cut to be a 3/16" (4.76 mm) diameter circle and must be completely red with blood.

Blood collection procedure

1. The lateral heel of each infant will be cleaned with alcohol, punctured to obtain blood drops to be captured on Guthrie cards following well-established procedures (Clinical and Laboratory Standards Institute Approved Standard NBS01-A6 (Clinical and Laboratory Standard Institute 2013).
2. Tests will be run on each participant in this project using these methods:
 - a. A reference method, which is Iso electric focusing (IEF/HPLC)
 - b. POCT (HemoTypeSC) method using DBS
3. DBS will be made on filter paper cards following the HemoTypeSC instruction manual.
4. DBS will be allowed to dry for a minimum of 3 h at 18°C–25°C. Afterwards the blood sample will be eluted and HemoTypeSC normal procedure followed to determine the test result.

HemoTypeSC POCT Test Procedure

1. Using a Dropper Pipette, add six (6) drops of water to the Test Vial. Place the Test Vial in a compatible rack.
2. Cut out DBS to be the same size as the above circles and completely submerge under the water inside the Test Vial.
3. Wait 10 minutes.
4. Open Vial of Test Strips, remove one Test Strip, and reclose Vial. Insert HemoTypeSC™ Test Strip into Test Vial with arrows pointing DOWN.
5. Wait 10 minutes.
6. Take HemoTypeSC™ Test Strip out of the Test Vial and read the results. Compare Test Strip to Results Chart below for reference.

Further information on HemoTypeSC™ test

See the following link for a youtube video that describes the HemoTypeSC™ test procedure:

https://www.youtube.com/watch?v=Lvx_Xi9bwdM

Notes for the reading of test results

- Red lines may appear at each of three hemoglobin variant- specific locations (HbA, HbS, & HbC), and a control location.
- The PRESENCE of a line indicates the ABSENCE of the hemoglobin variant.
- The ABSENCE of a line indicates the PRESENCE the hemoglobin variant.

Contents of the HemoTypeSC™ Test Kit

The test kit includes:

1. Foil Pouch containing the following: a. Vial of 50 single-use Test Strips b. Vial of 50 single-use Blood Sampling Devices – vial may contain extra c. Three reusable Dropper Pipettes
2. Instructions for Use Materials Not Provided: 1. Water – use drinking water, NOT saline solutions 2. Timer
3. *Lancing Device and Lancets
4. *Test Vials (1.5 - 5 mL tubes or vials may be used)
5. *Rack for holding Test Vials

* Available as part of the HemoTypeSC™ Accessory

Caution

Observe applicable biohazard safety procedures when handling Test Strips and human blood. Do not reuse any test strips or blood sampling devices. Some immobilized Test Strip reagents are derived from human sources - refer to local and national guidelines for biohazard safety handling procedures

Storage

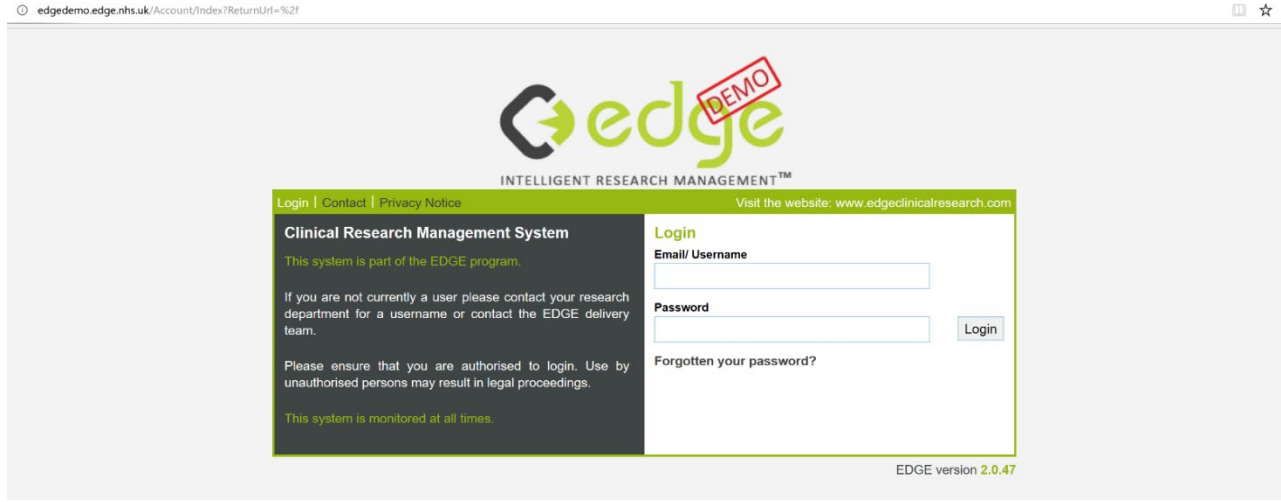
Store at 15-40°C and away from moisture. Test Strip Vial, Blood Sampling Device Vial, and Dropper Pipettes are provided in a sealed Foil Pouch, reject if seal is broken upon receipt. The Expiration Date of the unopened pouch is printed on the pouch. Do not use any components after the expiration date. IMPORTANT: Use or discard all Test Strips, Blood Sampling Devices, and Dropper Pipettes within 30 days of opening the Foil Pouch

EDGE System

Accessing EDGE

Open your Internet browser (Internet Explorer, Firefox, Google Chrome or Safari) and in the URL / Address box type <https://sa.edge-clinical.org>. You will be directed to the EDGE log on page.

Enter your username and password (provided separately) and then click **LOGIN** where you will be directed to the **EDGE Home Screen**.



Your EDGE Profile

Updating your Details

HOME > MY PROFILE > MY DETAILS

To update your contact information, click **EDIT** in the top right corner and amend the details. When you have finished click **SAVE** to apply the changes. If your details change at any time, please ensure you update this as soon as possible.

The screenshot displays the 'My details' form for a user named 'EDGE, Mr User'. The form includes the following fields:

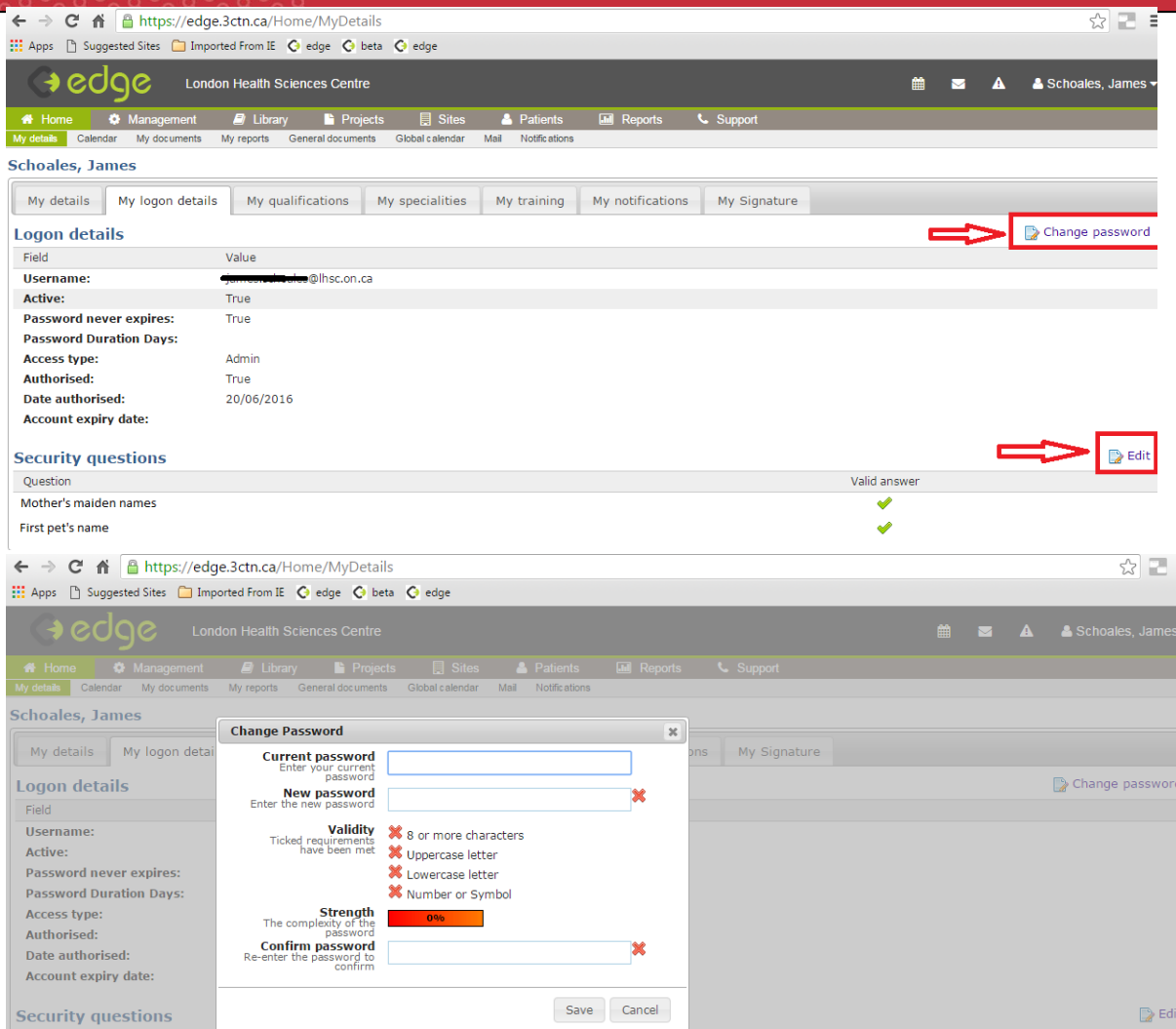
- Title:** Mr
- Forename:** User
- Surname:** EDGE
- Gender:** Male
- Date of Birth:** 29/05/1991
- Address:** Clinical Informatics, Southampton University Hospital Trust, Tremona Road, Southampton
- Postcode:** (empty)
- Email:** edge@edgeclinicalresearch.com
- Phone:** 02380 794615
- Mobile:** 07845 306958
- Fax:** 02380 798790
- Pager:** 07770 589478
- Personal URL:** (empty)
- Professional Registration Number:** (empty)
- Organisation:** International EDGE Program Team

The background interface shows the user's profile summary with a 'Change Image' and 'Delete Image' button, and an 'Edit' button in the top right corner.

Changing your Password

HOME > MY PROFILE > MY LOGON DETAILS

Click on your name in the top right corner of your **HOME** page (or any page) in EDGE. Click on **MY PROFILE** and click **MY LOGON DETAILS**. Click **CHANGE PASSWORD** to change password or **EDIT** to change your security questions



Your password must be validated by meeting the following criteria:

- At least eight characters long
- Use of an uppercase character (A-Z)
- Use of a lowercase character (a-z)
- Use of numbers or symbols (1 -9)

If your password does not comply with the 4 parameters it will not be accepted. An “X” symbol will appear next to the unfulfilled criteria. You will need to enter your password twice in order to confirm it and click **SAVE** to complete.

Resetting your Password

If you do forget your password, click **FORGOTTEN YOUR PASSWORD** on the **LOGON** screen and follow the on-screen prompts to email a new password to you nominated email address. You must know your username (usually your email address) in order to complete this process. If you are unable to log on using the **FORGOTTEN YOUR PASSWORD** link please contact your Local Administrator.



Updating your Profile

HOME > MY PROFILE >

My Qualifications – To include qualifications click **ADD** on the right hand side and select the qualification from the drop down list

My Specialities – To include specialities click **ADD** on the right hand side and select the relevant speciality area from the drop down list

My Responsibilities – The responsibilities relate to the use of the site delegation log See ‘**Delegation Log**’

My Training – To include training click **ADD** on the right hand side and select the relevant training course and date

My Notifications – Choose which notifications you would like to receive from EDGE as in application notifications or emails.

My Signature – Upload an image of your signature and initials.

My Attributes - See ‘**Creating Attributes**’

Projects

Finding a Project

HOME > PROJECTS > GLOBAL PROJECTS

All information regarding a project is stored under the **PROJECTS** tab within **EDGE**. This section is separated into three sub-sections:

Assigned Projects– These are projects which you as an individual user are currently involved in. These could be at an administrative level, project management level or read only user level.

Organisation Project– This tab denotes the project which your organisation is currently involved in, either as a site or sponsor for the study.

Global Projects– The last tab is a global list of all studies being managed within the EDGE

application both inside and outside your organisation.

Project Local Reference	NIHR Portfolio Study ID	Short Title	Full Title	Owner	Status	Sites
UoA14457	17692	(18F-FAABULOUS)	18F- Fluoride Assessment of Aortic Bioprostheses Durability and Outcome	The Princess Alexandra Hospital NHS Trust	Project in Setup	Auckland District Hospital (Open)
UoA14788	15784	(AGENSYS) AGS-16C3F-15-3	A Study of AGS-16C3F vs. Avitinib in Metastatic Renal Cell Carcinoma	University Hospital Southampton NHS Foundation Trust	Open to recruitment	Auckland District Hospital (Open)
ACH58745	17069	(AMBER) Abdominal Massage for neurogenic bowel dysfunction in people with MS	Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis (AMBER Abdominal Massage for Bowel Dysfunction Effectiveness Research)	The Princess Alexandra Hospital NHS Trust	Open	Auckland District Hospital (Open) Starship Children's Hospital (Open)
UoA12569	98562	(CCTG) CRC.6	A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients With Resected Stage III Colon Cancer	New Zealand Demo / Test	Open to recruitment	Aesot Hospital (Open) Auckland District Hospital (Open) Hickmores Hospital (Open) Rangurly Hospital (Completed)
UoA15866	55748	100,000 Genomes Project - Cancer ATS Study	100,000 Genomes Project - Cancer Auckland Training Study	University Hospital Southampton NHS Foundation Trust New Zealand Demo / Test	Open	Auckland District Hospital (Open) Starship Children's Hospital (Open) Auckland District Hospital (Open) Hickmores Hospital (Open)
		New Zealand KISS Study: Kinase Inhibition with Sprycel Start-up	A phase II study of dasatinib followed by imatinib in newly diagnosed, previously untreated patients with chronic phase CML in New Zealand	New Zealand Demo / Test	Open to recruitment	Auckland District Hospital (Open)

Adding Users or Teams to a Project Site:

**HOME > PROJECTS > (Select Applicable Project) > SITES > (Select Applicable Site)
STAFF**

After assigning the sites to your projects in EDGE you will need to assign the relevant staff to those sites.

At a site level select the **STAFF** tab. If you have staff set up as a team click **ADD TEAM** in the top right corner. Alternatively, you can add staff members individually by clicking **ADD USER**. Each member of staff will need to have their permission for the project site assigned.

- **Manage Access:** A user given 'Manage' permission at a project site level will have read / write access to this project site. This user will be able to edit any of the data within the Project site on behalf of their organisation and files, attributes and workflows to the site.
- **Clinical:** All staff members at site level who will be actively recruiting patients to a project will need to have clinical access. This can include data managers or coordinators who are entering recruitment details on behalf of their clinical teams

Users can have a combination of both Manager and / or Clinical access, or alternatively a user can have neither. A user with neither Manager or Clinical access will allow them a **READ ONLY** access to the project site information.

The screenshot shows the EDGE User Test Project interface. The main content area displays a table of project site staff. An 'Add Staff' modal window is open, allowing the user to add a new staff member. The modal includes fields for 'User' (name), 'Role' (currently 'EDGE Knowledge & Delivery Officer'), and checkboxes for 'Manager' and 'Clinical' access. Below the modal, there is a list of existing staff members with 'remove' links.

Staff	Role	Organisation	Active	Logon	Manage	Clinical	
Admin, Mr edge	EDGE Portfolio Administrator	EDGE Canada Coordinating Centre	✓	✓	✓		
Carleton-Prangnell, Mr Tobias		International EDGE Program Team	✓	✓	✓		Edit Delete
Osler, Mr David	EDGE Knowledge & Delivery Officer	International EDGE Program Team	✓	✓	✓		Edit Delete
TEST-ADMIN, Mr EDGE		International EDGE Program Team	✓	✓	✓		Edit Delete
Whelan, Mr Patrick		International EDGE Program Team	✓	✓	✓		Edit Delete
Wolsley, Mr Clive		International EDGE Program Team	✓	✓	✓		Edit Delete
admin, Mr edge	EDGE Knowledge &		✓	✓	✓		
Wolsley, Mr Clive			✓	✓	✓		

Recruiting Patients

Adding a Patient

HOME > ADD A PATIENT

or

HOME > PROJECTS > ASSIGNED PROJECTS > (Select Applicable Project) > SITES > (Select Site) > PATIENTS

Any user of EDGE (Admin, Manager or User) with **Clinical Access** to a Project Site can recruit a patient to that project site.

To start patient recruitment select either the **PATIENTS** tab at Project Site level or use the **ADD A PATIENT** icon on the Home screen.



Add a new patient

Add a new patient to one of the projects that you have clinical access to

The screenshot shows the EDGE system interface. At the top, there is a navigation bar with 'Home', 'Projects', 'Patients', and 'Support' tabs. The user is logged in as 'USER, MR TEST (USER) INTERNATIONAL EDGE PROGRAM TEAM'. The main content area is titled '*EDGE Knowledge Team Test Project*' and 'EDGE Testing Site 1'. Below this, there are tabs for 'Details', 'Attributes', 'Workflows', 'Staff', 'Notes', 'Statistics', 'Finances', and 'Patients'. A search bar is present with the text '[Filter by Patient Status]'. Below the search bar, there is a table titled 'Project site patients' with columns for Name, DoB, ID Number, Hospital Number, Current status, and Status date. The table contains five rows of data, all with '(anonymous)' as the name. The current status values are 'Recruited / Randomised', 'Off Study', 'Recruited / Randomised', 'Recruited / Randomised', and 'Screened'. The status date for all rows is '01/01/2012'. There are 'Delete' links for each row. At the bottom of the table, it says 'Page 1 of 1' and '(5 records returned)'. There are also links for 'Download Excel', 'Download PDF', and 'Add a patient'.

Name	DoB	ID Number	Hospital Number	Current status	Status date
(anonymous)		Local Number :		Recruited / Randomised	01/01/2012
(anonymous)		Local Number :		Off Study	01/01/2012
(anonymous)		Local Number :		Recruited / Randomised	01/01/2012
(anonymous)		Local Number :		Recruited / Randomised	01/01/2012
(anonymous)		Local Number :		Screened	01/01/2012

Clinical Informatics Research Unit, EDGE Program
Somers Cancer Research Building, HP824, Southampton General Hospital, Southampton
SO14 6YD, United Kingdom

Clicking either of these functions will open the patient recruitment screen.

When clicking the **ADD A NEW PATIENT** function from the **HOME SCREEN**, the first patient recruitment screen will ask you to select which Project and site the patient recruitment is taking place at. Select the Project and Site from the drop down boxes. Once complete click **NEXT**.

Project and Project Site
Select a project and project site that you want to recruit a patient to

Project
EDGE Knowledge Team Test Project

Project site
EDGE Testing Site 1

Cancel Next

Note:

If you are unable to find your project or project recruitment site please ensure you are assigned to the project site and that you have been given clinical permissions.

After clicking **NEXT** you will be asked to enter the patient identifier details. This will be one of the following as defined when setting up the project site:

Patient Identifier
Enter the unique number used to identify your patient

Local Number

When you completed the applicable Patient Identifier click **NEXT**. The **PATIENT DETAILS** screen will then prompt you to enter the patient demographic details.

Patient Details
Verify or enter your patients details

Title	Mr
Forename	Test
Surname	Patient
Dob	13/12/1983
Gender	Male
Ethnicity	White - British
Language	English
Address	1 Lodge Road Othertown
Postcode	ED12 6GE
Email	testpatient@edgeclinicalresearch.com
Phone	01962 867188
Mobile	07845 306958

Cancel Prev Next

When the patient details have been completed click **NEXT**.

Note:

If your organisation or site has chosen to make some or all of these fields mandatory you will not be able to continue with the patient recruitment until those fields are completed.

After clicking **NEXT** you will be directed to the **PROJECT DATA** screen to complete the patient's Randomisation Number, Hospital, the Project Arm (If Applicable), Consultant Name and Referring Site (if Applicable).

The Consultant and Referring sites will automatically populate with the closest matches as you type. Once you have completed this information click **NEXT**.

Project Data

Enter project specific data about your patient

Randomization no.	<input type="text" value="79681622"/>
Hospital no.	<input type="text" value="22618697"/>
Project arm	<input type="text" value="Arm 2 - Drug 2"/>
Consultant	<input type="text" value="Batchelor, Mr James (EDGE Administration)"/>
Referring site	<input type="text" value="Clatterbridge Cancer Centre Liverpool"/>

Cancel

Prev

Next

Note:

If you are unable to find the Consultant name or Referring Site details please contact your Local Administrator

After clicking **NEXT** you will be required to complete or partially complete the patient's workflow status. Enter a date against the relevant fields. Your name will automatically populate the column next to the date to record that you have commenced recruitment. If you are not the member of staff who has recruited the patient (e.g. a colleague or Data Manager), please select the correct member of staff from the drop down box.

When you have started or completed the workflow to the patients current status click **NEXT**.

Patient Status
Enter all the dates up to the current status of your patient

Pre-Screened	01/01/2012	by	User, Mr Test
Approached	01/02/2012	by	User, Mr Test
Consented	01/03/2012	by	User, Mr Test
Screened	01/04/2012	by	User, Mr Test
Recruited / Randomised	01/05/2012	by	User, Mr Test
On treatment	01/06/2012	by	User, Mr Test
On follow-up		by	User, Mr Test
Completed		by	User, Mr Test

Patient is off study

Before completing the patient’s recruitment, the following page will provide you with a space to enter any comment regarding the patient. Clicking next on patient comments will display a summary page of the information you have entered after. To correct or edit this information click the **PREV** tab, if all the details are correct click **FINISH**. To abandon the patient recruitment and remove all the data click **CANCEL**.

Patient Summary
Verify the recruitment details and finish the process

Project:	*EDGE Knowledge Team Test Project*
Project site:	EDGE Testing Site 1
Local Number:	N/A

Title:	Mr
Forename:	Test
Surname:	Patient
Dob:	13/12/1983
Gender:	Male
Address:	1 Lodge Road Othertown
Postcode:	ED12 6GE
Email:	testpatient@edgeclinicalresearch.com
Phone:	01962 553433
Mobile:	07845 334355

After clicking **FINISH**, a notification will appear in the top right corner of the screen to inform you that the patient has been added to the Project Site.

Note:

If you experience problems recruiting a patient, please contact your Study Manager or Local Administrator.

[Finding a Patient Record](#)

HOME > PATIENTS

Users of EDGE with clinical access will be able to view patient information at project sites which they have been granted clinical permission for. Users, Administrators, or Study Managers will NOT be able to access patient information for Projects or Sites outside their organisation or Sites within their organisation for which they do not have clinical access assigned.

To begin searching for a patient record, navigate to the **PATIENT** tab in EDGE. If searching by name alone has returned multiple entries, you can click the **ADVANCED SEARCH** function to refine your search criteria further by date of birth and patient identifying number.

Advanced search

Title:	<input style="width: 80%; height: 20px;" type="text"/>
Forename:	<input style="width: 90%; height: 20px;" type="text"/>
Surname:	<input style="width: 90%; height: 20px;" type="text"/>
Date of Birth:	<input style="width: 80%; height: 20px;" type="text"/>
ID Number:	<input style="width: 80%; height: 20px;" type="text"/>
Randomisation No:	<input style="width: 80%; height: 20px;" type="text"/>
Hospital Number:	<input style="width: 80%; height: 20px;" type="text"/>
Consultant:	<input style="width: 80%; height: 20px;" type="text"/>

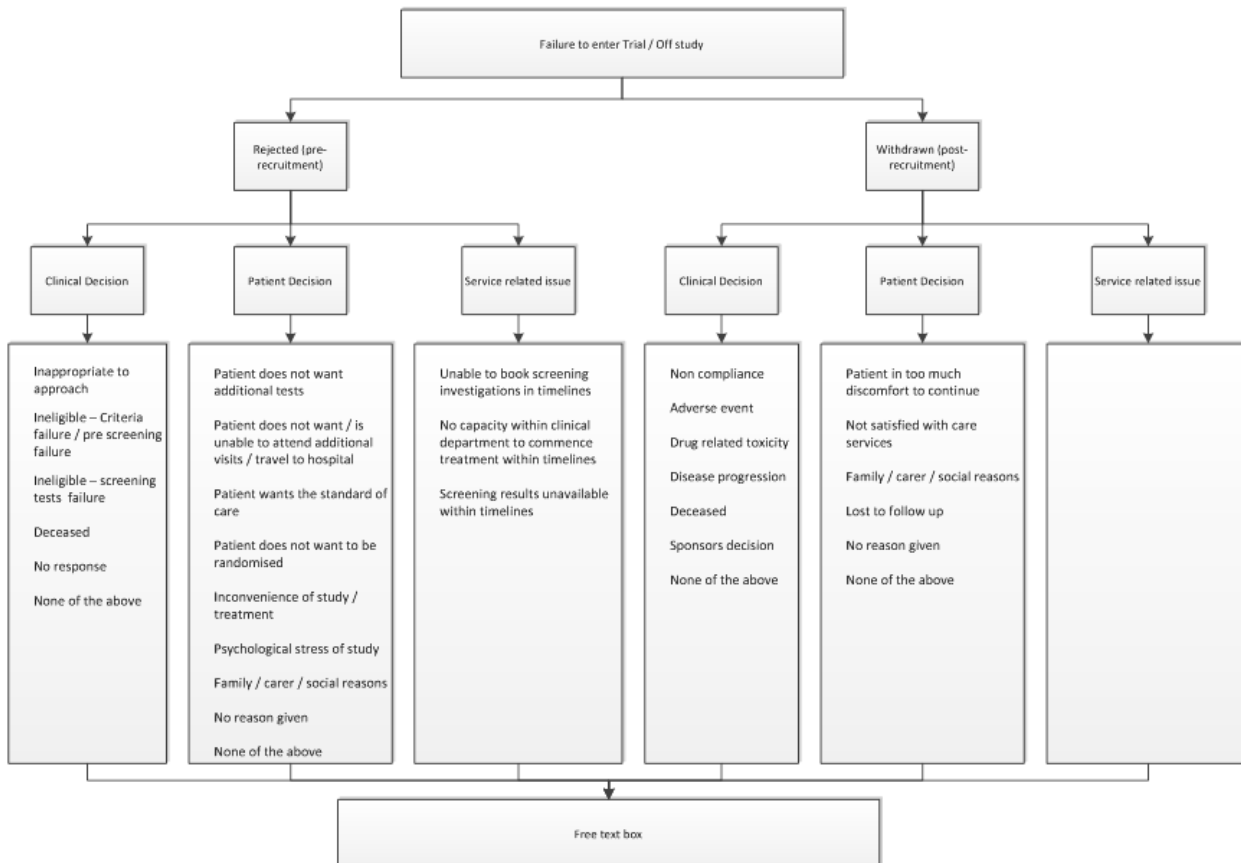
[Recording Patients as off Study](#)

HOME > PROJECTS > ASSIGNED PROJECT (Select Applicable Project) > SITES > (Select Site) > PATIENTS > (Select Applicable Patient)

If a patient has been added into EDGE and for any reason does not enter the project or comes off the project after recruitment they must be marked as "Off Study".

This list will provide options to select as to why the patient has come off the project. Both of the Rejected and Withdrawn reasons are split down into 3 decision tree categories;

- Patient – A list of options that identify the decision was made by the patient
- Clinical - A list of options that identify the decision was made by a clinical member of staff
- Service – A list of options that identify the decision was neither made by the patient or by someone clinical, but instead is due to an issue related to service provision within the organisation.



To mark the patient as "Off Study" click **TAKE PATIENT OFF STUDY** within the patient status box in the specific patient record.

Once you have selected a decision category (Patient, Clinical, Service) you are then able to select a specific reason. These reasons are standard across all organisations and not changeable within any organisation.

Once you have selected all of the relevant information through the drop down menu's you are then able to record free text comments in case more detail is needed beyond that already

captured. Once you have completed the details click **SAVE**.

The screenshot shows the 'Update Off Study Details' dialog box in the EDGE User Test Project interface. The dialog is titled 'Update Off Study Details' and contains the following fields:

- Patient is off study
- Off study date**: 19/05/2014 (The date the patient was taken off study)
- Off study user**: Osler, Mr David (Who took the patient off study)
- Reason**: Rejected (The off study reason)
- Decision**: Patient (The off study decision)
- Description**: No reason given (The off study description)
- Comments**: No reason was given by the patient (Any comments regarding this patient being taken off study)

Buttons for 'Save' and 'Cancel' are visible at the bottom of the dialog.

The screenshot shows the 'Patient Status' table and a summary box for the off-study details. The status is 'Pre-Screened' as of 11/04/2014. The summary box lists:

- Taken off study by: Osler, Mr David
- Date: 19/05/2014
- Reason: Rejected
- Decision: Patient
- Description: No reason given
- Comments: No reason was given by the patient

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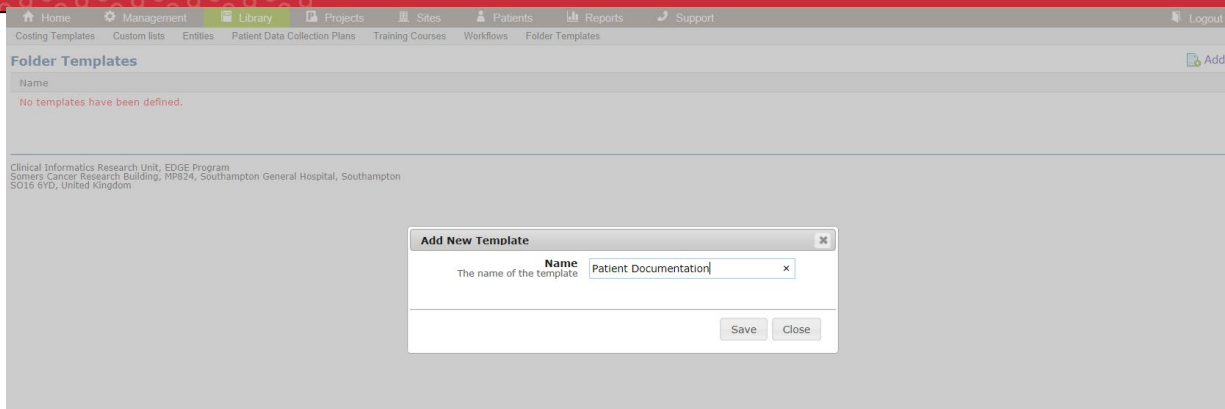
Files & Folders in EDGE

Creating Folder Templates

HOME > LIBRARY > TEMPLATES

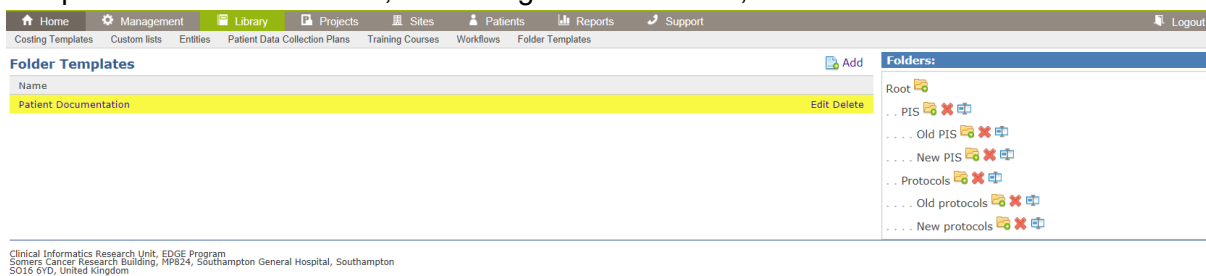
Creating folder templates allows users to assign templates to project and project site file sections. This ensures quick, easy and standardised folder templates across multiple projects.

To create a folder template, click **ADD** in the top right of the screen and enter a name for the folder template. Once you have entered the name clicked **SAVE**, the folder template name will appear in blue on the screen. Click on the folder template name and the options to add further folders should appear on the right hand side of the screen.



To add folders to the template folder, click the picture of the folder with the + sign on it. This will create a sub folder. You now have 3 options, indicated by images next to the New Folder. These allow you to either add a new folder within that sub folder, delete that sub folder or rename that sub folder.

Once you have completed your folder template, it may look similar to the below image which is comprised of one main folder, containing two sub folders, each of which contain two sub folders.

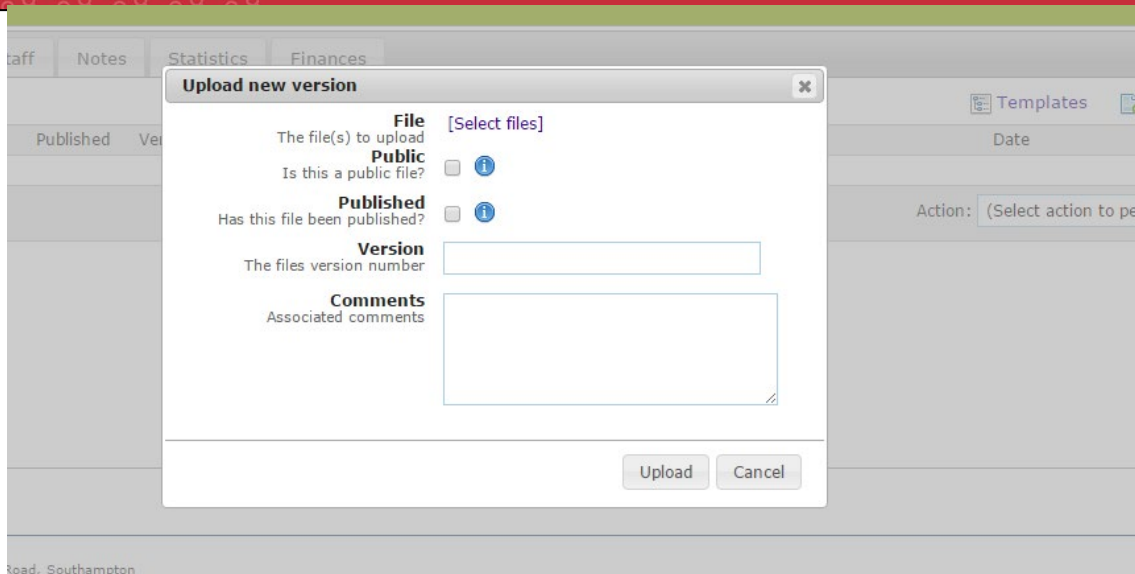


Project and Project Site Files

HOME > PROJECTS > ASSIGNED PROJECTS > (Select Project Name) > FILES

The project and project site files section allows you to store the high level project related documents in EDGE. To upload a file click, **ADD FILE** in the top right corner and select **CHOOSE FILE** to upload a file.

Only staff with Manage permissions can upload Project files. Users without manage permissions can download and view files.



File Visibility

- Public – users from your organisation and any organisation which you are collaborating with can see this document
- Private – Only users in your organisation with appropriate permission can see this document

Version Controlling Files:

To upload a new version of a file in EDGE click the **UPLOAD NEW VERSION** icon to the right of the file name. A dialogue box will open to select the new file, a version number and comments can be uploaded to this file. To complete click **UPLOAD**.

To view all versions of a single document click the clock next to the **EDIT / DELETE** icon for the file, this will open a dialogue box with the document history.



Workflows

Completing a Workflow at a Project or Project Site

HOME > PROJECTS > (Select applicable Project) > WORKFLOWS
HOME > PROJECTS > (Select applicable Project) > (Select applicable Project Site) > WORKFLOWS

In order to apply a workflow you **will need to have manage permission on that study**.

Click the **WORKFLOWS** tab at the project or project site level. To add a workflow to the project click **ADD** in the right hand corner and select the relevant workflow from the drop down box. Only workflows with the correct type can be set at the specific level.

Once you have selected your required workflow you can add comments to the front page (e.g. who is assigned to this workflow) as well as selecting to make the workflow "Public" or "Private".

Public Workflow	Private Workflow
By marking a workflow as public within the Project record the workflow will be visible and editable to organisations which you have chosen to collaborate with. If you have not set any collaboration the workflow will not be visible to any other organisation.	Workflows which do not have the public box checked will remain private. No organisations will be able to view this workflow even if collaborations have been set.

To complete click **SAVE** to apply it to the Project or Project Site.

Multiple workflows can be applied and completed at one time and multiple users can complete multiple workflows. The progress of each workflow is shown by the coloured flag on the left side of the screen.

- **Red:** Applied to the project but no stages of the workflow have been started
- **Orange:** The workflow is in progress and stages have been started
- **Green:** Completed

Public	State	Workflow	Added	Comments	Target (days)	Days Elapsed	Days Elapsed (including delays)	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1.0 Initial Assessment - EXAMPLE <small>Show comments</small> Next task: Key Details	24/05/2019 <small>By Gibbons, Mr Tim (New Zealand Demo / Test)</small>					Edit Delete

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The workflow's title is shown with the next step due to be completed, the date it was added and by which team member, as well as the target days it will take to complete alongside the actual number of days it has taken. To edit a workflow click the highlighted workflow title or the **EDIT** function.

Within the workflow each step will be numbered.

	Complete	Days delay	Days spent	Comments
1. Key Details <small>Insert local study name, IRAS No, workflow name/number Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
2. Electronic folder <small>Create a new electronic folder if not already done under "Prechosen", and copy over the standard template study folders. Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
3. Email sponsor <small>Email sponsor with the RSV email template. Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
4. Study Set Up Attribute <small>Have you added on the "Study Set Up Attribute" Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
5. Trial Summary Sheet <small>Commence the Trial Summary Sheet (TSS) if not started already Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
6. Principle Investigator <small>Who is the Principle Investigator for the study? Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
7. Study Team <small>Who is the lead nurse / practitioner for this study? Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
8. Confirmation Required? <small>Does this study require formal Confirmation of Capacity and Capability? Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
9. Proposed target / Participant Population <small>What is the proposed target for this study? Do we expect to have the participant population available to achieve this</small>	<input checked="" type="checkbox"/>	0	0	
10. Support Departments <small>Which support departments are likely to be required for this study? Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
11. Forecast Issues <small>Are there any initial red flags on this study from the information you have at present? Show procedure</small>	<input checked="" type="checkbox"/>	0	0	
12. Initial Assessment Outcome <small>Do you anticipate you will be able to set up and run this Study once a full review has been undertaken? Show procedure</small>	<input checked="" type="checkbox"/>	0	0	

Edit Workflow Item

Key Details

Completed
Date completed:

Delay
Delay in days (if applicable):

Comments

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When each step is completed, select the applicable step of the workflow and check the **COMPLETED** box alongside the completion date, the number of days delay and any comments associated with this step. Then click **SAVE**.

The rest of the workflow can now continue to be completed, the days delay and comments will accumulate and be displayed on the front page of the workflow.

The screenshot shows the EDGE software interface. At the top, there is a navigation bar with the 'edge' logo and user information: 'TEST-ADMIN, MR EDGE (ADMIN) INTERNATIONAL EDGE PROGRAM TEAM'. Below this is a menu with options: Home, Management, Library, Projects, Patients, Reports, Support, and Logout. The main content area is titled '*EDGE User Test Project*' and 'EDGE Testing Site 2'. It features a tabbed interface with 'Workflows' selected. The 'Project site governance workflows' section contains a table with the following data:

Workflow	Added	Target (days)	Elapsed (days)	
R&D Approval 2 Workflow complete	03/09/2012 by TEST-ADMIN, Mr EDGE	30	-6	Edit Delete
Site Radiology Next task: Cost implications	03/09/2012 by TEST-ADMIN, Mr EDGE	8	25	Edit Delete
RSCH: Oncology Set-Up Next task: Trial Coordinator to receive SSI from Sponsor	03/09/2012 by TEST-ADMIN, Mr EDGE	42		Edit Delete

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