

# Patient benefits of a digital data platform for sickle cell disease

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<b>Registration date</b> 09/09/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/09/2024	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Sickle cell disease (SCD) is a group of inherited health conditions that affect the red blood cells. The symptoms include painful episodes called sickle cell crises, which can be very severe and last up to a week. The current understanding of SCD's full natural history and the available treatment options for patients fall far behind that of many other diseases with a similar prevalence. Patient care is impacted by limitations around the data available to their clinicians outside of infrequent contacts with treatment centres, meaning the standard of care and speed at which it can be delivered is frequently lacking.

This study aims to find out whether a unified SCD digital data platform and wearable device improves patient experiences and outcomes through better monitoring of key metrics around pain crises and severe complications of the disease. These will be tracked through a combination of hospital and GP medical records, genetic information, as well as real-time data collected from the wearable devices.

By combining these into a complete digital patient profile, the aim is to provide patients and clinicians with better insight into the disease's natural history, which interventions have worked well to improve future treatment, and inform when a patient may be at risk of crises or severe end-organ pathologies. The work will study vital parameters collected over a long duration within a group of patients with SCD to determine how these relate to acute and chronic illnesses, as well as healthcare utilisation.

### Who can participate?

1. Children with sickle cell disease aged 5-15, with consent from and attendance/guidance by parent or legal guardian
2. Adults with sickle cell disease aged 16 and over

### What does the study involve?

No interventions or changes to medical treatment will be involved in the study, and all participants will follow the same study protocol.

The study will be conducted remotely, with patients participating in initial pre-study focus groups virtually over video call, in addition to a post-study focus group at the end of the study. The study of the technology will be ongoing, and participants will wear either their own or a study-provided smartwatch during their day-to-day lives, to track their vital parameters on a

constant and automated basis. These will include metrics such as heart rate and activity levels. The study will also involve the collation of each participant's hospital and medical GP records alongside this live wearables collected data, within the digital platform. The participant will need only provide informed consent for this, and the study team will manage the data requests and integration.

What are the possible benefits and risks of participating?

There are no direct benefits in terms of changes to treatment or other aspects of participants' care. The results will add to the current knowledge about SCD, potential triggers of pain crises or complications, and individual treatment options. It will provide participants with a greater understanding of their daily health and medical history, including information that they may choose to share with their clinical team to help manage their disease.

No interventions or changes to medical treatment are involved in the study, and the only potential risk will be data security. This has been securely addressed by the study team to ensure strong cybersecurity measures, encryption and two-factor authentication needed to access the digital platform.

Where is the study run from?

London North West University Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?

July 2020 to December 2025

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Kim Summers, kim@saniushealth.com

## Contact information

### Type(s)

Public, Scientific

### Contact name

Dr Kim Summers

### ORCID ID

<https://orcid.org/0000-0002-1351-3732>

### Contact details

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

288780

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

IRAS 288780

## **Study information**

### **Scientific Title**

Digital sickle cell – evaluating live evidence for vaso-occlusive crisis and end-organ damage intervention & prevention: benefits of implementing a unified digital sickle cell disease data platform, including real-time wearable device data, in disease management, patient experience, and clinical outcomes

### **Acronym**

DiSC-ELEVEN

### **Study objectives**

To determine the benefits of incorporating a unified digital data platform, in-depth digital patient profile and wearable device into standard care for sickle cell disease - collating historical patient data, a full genetic background, and live patient data - to real-world patient experiences and clinical outcomes.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Submission pending

### **Study design**

Multicentre observational pilot/feasibility study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Sickle cell disease

### **Interventions**

The study will be an observational trial, revolving around the use of a mobile app by participants in order to provide initial consent to participate and share their medical records with the study, key details, and link a wearable smartwatch.

The trial of the technology will be ongoing for 12 months, and participants will wear either their own or a study-provided smartwatch during their day-to-day lives, in order to track their vital parameters on a constant and automated basis. These will include metrics such as heart rate and activity levels.

The study will also involve the collation of each participant's hospital and medical GP records alongside this live wearables collected data, within the digital platform. The participant will need only provide informed consent for this, and the study team will manage the data requests and integration.

The digital data platform will unify information from multiple sources in order to provide a full patient profile that can be accessed by both patients and their clinicians. No further interventions will be involved, patients only required to wear their smartwatch on a daily basis in order for the device to collect key health metrics on an automated basis. The study will be conducted remotely, patients participating in initial pre-study focus groups virtually, over video call, in addition to a post-study focus group at the end of the trial.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Mobile app and wearable smartwatch

### **Primary outcome(s)**

1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 3 months
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of the follow-up period at 13 months

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

01/12/2025

## **Eligibility**

### **Key inclusion criteria**

1. Children with sickle cell disease of any phenotype aged 5-15 years of age, with consent from and attendance/guidance by parent or legal guardian
2. Adults with sickle cell disease of any phenotype aged 16 years and over
3. Able and willing to sign written informed consent
4. Interest in participating in the study
5. Known history/diagnosis of sickle cell disease

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

5 years

**Sex**

All

**Key exclusion criteria**

1. Incapacity to provide informed written consent
2. Known allergic reaction to any materials in wearable device

**Date of first enrolment**

01/12/2024

**Date of final enrolment**

01/12/2024

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**London North West University Healthcare NHS Trust**

Haematology and Sickle Cell Centre

Central Middlesex Hospital

Acton Lane

London

United Kingdom

NW10 7NS

**Study participating centre**

**Barts Health NHS Trust**

Pathology and Pharmacy Building

80 Newark Street

London

United Kingdom  
E1 2ES

## Sponsor information

**Organisation**  
Eleven

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The researchers do not plan to share patient-level/raw data, as they anticipate some participants may wish to continue using the digital platform post-trial as part of their disease management. De-identified, cohort-level data will be made available upon request by clinicians, researchers who provide a methodologically sound proposal, or those developing novel therapeutic options who may require the real-world evidence base generated by the study. These proposals should be directed to Dr Kim Summers, kim@saniushealth.com, and will include a data access agreement. Links to the data will be provided upon request.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version V1	03/09/2020	08/10/2020	No	No