INDIGO COMMUNITY

Summary and Frequently Asked Questions (FAQ)

ABSTRACT

The Indigo Community project is a digital clinical trial that aims to assess the feasibility of mass recruitment to a community cancer survivor study via a large-scale online platform using participant self-enrolment. Our ambition is to develop a firm, pragmatic evidence based on how to collect patient reported data for people living in the community who have previously been treated for cancer.

Indigo Community Trial Management Team

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Summary of study

Aims

- To understand long-term outcomes and service use for patients living with and beyond a cancer diagnosis.
- Utilise a flexible platform for online questionnaires, allowing self-enrolment, consent, and participation.

Design

Observational online questionnaire, with patient self-sign-up and completion. Patients may be invited to take part through (e.g.) digital posters or SMS from GP surgeries, but also through social media and word of mouth.

Trial stages

Two stages:

1. December 2023– April 2024 Pilot phase in NW London CRN
2. June 2024 – June 2025 National phase across England and Wales

Each stage comprises two phases: SMS recruitment via GP practices followed by recruitment via a social media campaign.

Documents

All available in the local information pack available on the official website.

The local information pack contains the protocol, IRAS, Amendment to IRAS, Letters of Approval, RISP, SoECAT, introductory slide deck. SystmOne and EMIS searches are available on the PRIDES platform (link directly on the website above).

Key Details:

Target Recruitment: No limit on practice or participant numbers. Ambition is for >50,000 participants.

The preferred role of the CRN is as below. If this process can be followed, then the trial team does not restrict the number and size of participating practices.

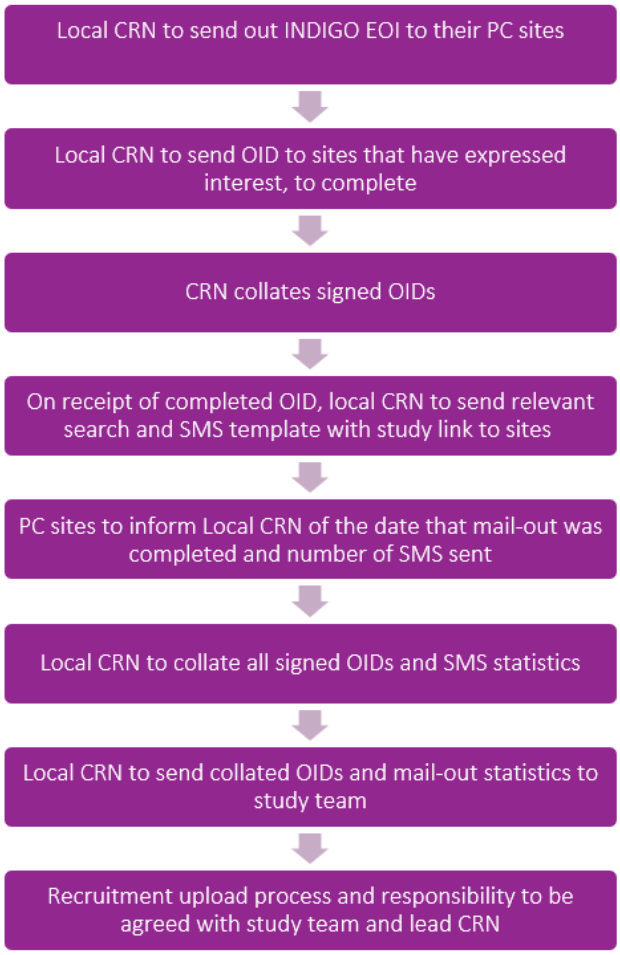

Figure 1: CRN process flowchart

We recognise that not all CRN's can deliver this process. Therefore, where CRNs are unable to support the distribution and collection of OIDs and searches there will be a limit on the size and number of practices. We will only be able to contract with large 'unit' e.g. Federation level, large PCN or large practices, but these will need to be >50,000 patients.

Recruitment can be uploaded by local CRN or NWL CRN (but this may be less accurate at practice level). Approach will be confirmed with each CRN prior to opening trial.

Contracting

Standard OID used for mapping recruitment back to practices; helps allocate accruals to individual sites.

Costs

As described on SoECAT. The trial does not provide any per-participant funding for recruitment. However, the study is NCRN badged, and thus participating practices and CRNs should receive money for trial recruitment.

Frequently Asked Questions (FAQs)

Why is an OID being used to cover PIC activity?

All CRN Primary Care Networks have been added via an amendment as PIC sites to the study, and a standard OID will be used between Sponsor and site to allow us to map recruitment back to practices, where possible.

Furthermore, an OID is being used in this study as the Sponsor, Imperial College London (ICL) is only able to sign off PIC agreements when sites feed into Imperial as a research site. As ICL is not a research site for INDIGO Community (participants self-consent online), an OID must be used which can be signed between the Sponsor and site.

Are accruals mapped back to practices?

Accruals are mapped back to individual practices where possible. Where participants provide their postcode then accrual is mapped back to the closest participating GP practice. Where the participant does not share their postcode then the accruals are averaged over the number of recruiting practices in a geography.

Do participants indicate their GP practice in the questionnaire?

No, participants are not asked for details of their GP practice. This decision was made to remove a barrier to participation as not all people have details of their GP easily available.

Trust is key to participation in trials and therefore we allow participants to control how much data they share with the trial team. If they provide their post code recruitment will map back to their local GP practice. Where they do not provide postcode then these participants will be grouped and then allocated as an average to each participating practice.

As it is possible to complete the questionnaire anonymously, is there a risk of duplicate responses?

Yes, that risk does exist however the impact of that risk is extremely low as recruitment will be measured in 1000's of participants.

Are GPs required to check the patient list before SMS contact?

No, it is a local decision based on database accuracy confidence, not a stipulation from the study.

Can practice groups submit EOIs instead of individual practices?

Yes, specifying EOIs from practice groups is acceptable and is our preferred approach. As a key aspect of the trial is exploring the costs of recruitment to a digital only trial, we do not have a large infrastructure. Therefore, from a practical level OIDs covering practice groups, PCRNs, federations are preferred.

Can we advertise the trial in our Practice, hospital, or community setting?

Yes, you will be able to. We need to submit an amendment to allow this (so you cannot do this currently) but in our next amendment we will be adding that physical posters in practices/on screens in practices or clinics can be used to support recruitment,

What is the text in the SMS?

This was developed with NW London CRN and approved in our ethics application.

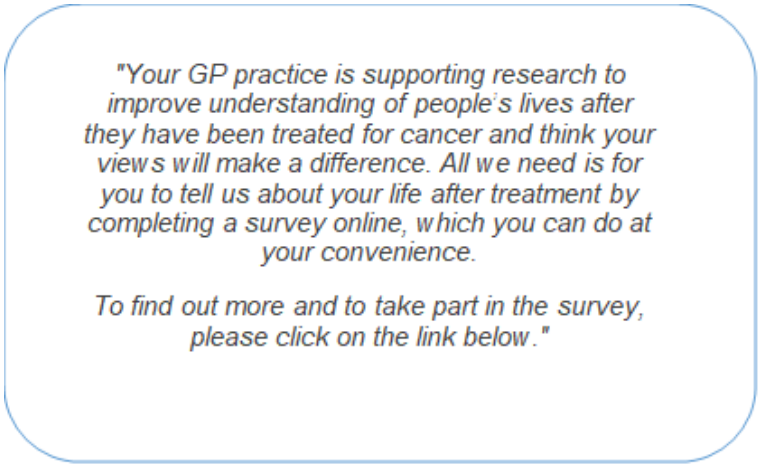

Figure 2: Text message sent to eligible cancer patients

My question has not been answered, what is the best email address to contact you?
You can reach out and ask us anything on imperial.admin.indigo.trial@nhs.net.