INTERACT: Understanding inclusivity in oncology clinical trials: a data-driven approach

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Background

- Appropriate representation in clinical trials is crucial both for ensuring equal access to emerging treatments and for producing results that are generalisable to the patient population.
- There are no comprehensive UK datasets exploring cancer trial participation and under-representation.
- We aim to use a data-driven approach to understand inclusivity of oncology clinical trials:

INTERACT Retrospective
Using NHS datasets to investigate how inclusive existing ICR-CTSU oncology trials were

INTERACT Prospective
Investigating current NHS practice in oncology trial participation and data recording

Building Collaborations
Improving diversity of lived experience and expertise

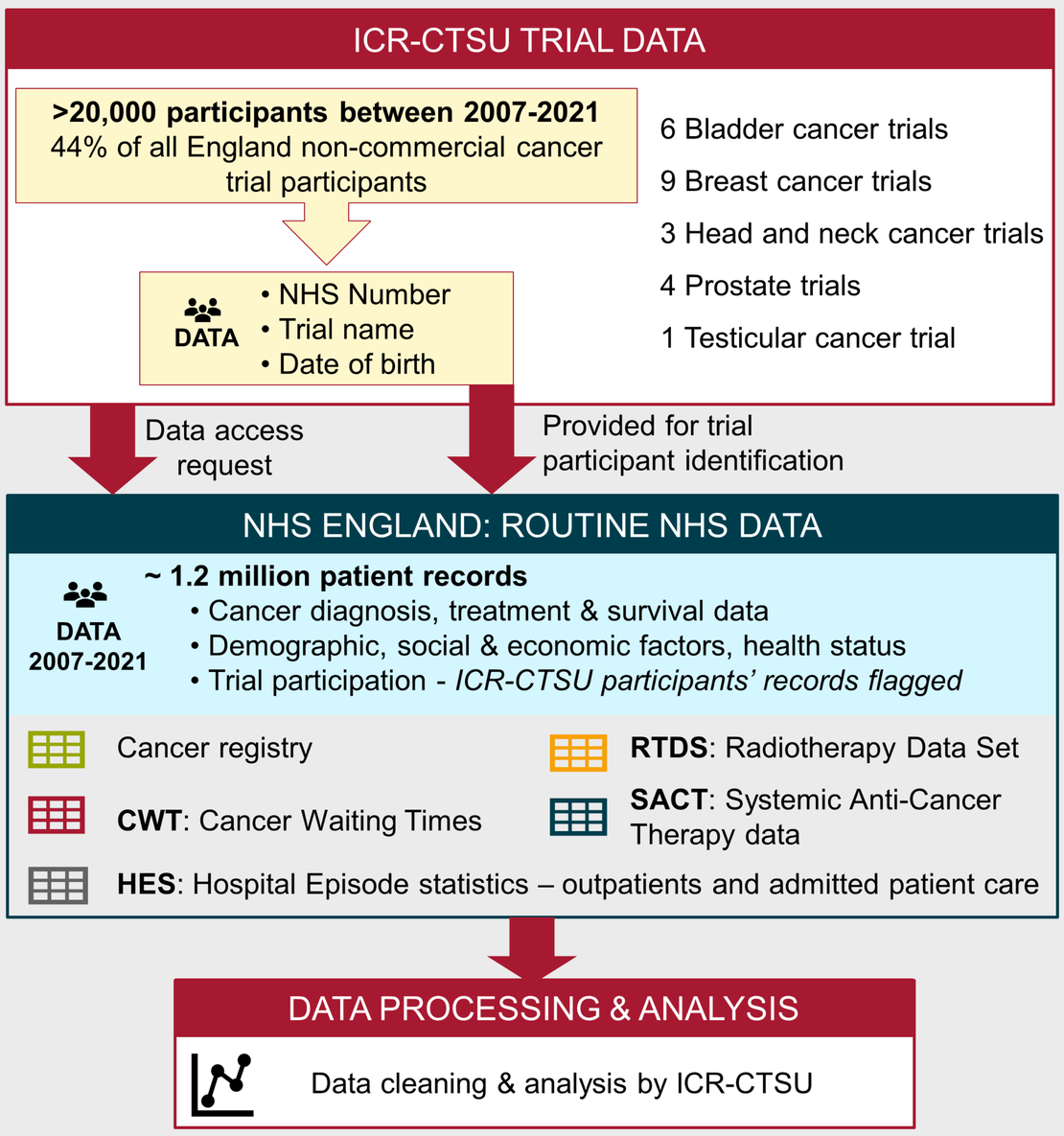
- Findings will inform future work to develop and test evidence-based interventions to improve the inclusivity of clinical trials.

INTERACT Retrospective (INTERACT-R)

Use routine data from NHS England to:

- Compare characteristics of ICR-CTSU trial participants to those who did not join a trial overall and within each trial's key eligibility criteria.
- Identify any groups under-represented within trials, taking an intersectional perspective.

Figure 1: Summary of INTERACT Retrospective data flow



- NHS REC and Confidentially Advisory Group (CAG) approvals required.

INTERACT Prospective (INTERACT-P)

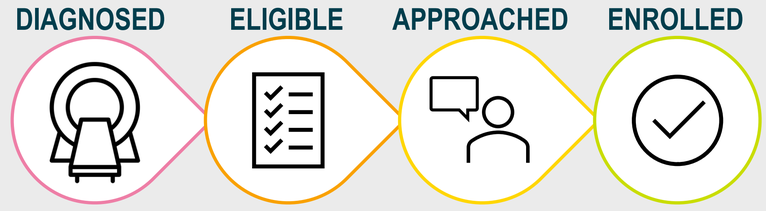


Figure 2: Clinical trial enrolment

SURVEY

- Over 150 UK NHS Trusts surveyed about current demographic and trial participation data collection and auditing processes.
- Understanding availability and completeness of demographic data within site systems.

AUDIT

- Review of all new solid cancer diagnoses in 2024 at 3 pilot NHS sites.
- Data access, cleaning and collation led by clinical leads at each site.
- Demographic and clinical characteristics compared with patients invited to and enrolled in oncology trials to identify disparities in trial access.

Service evaluations - no sharing of individual patient data to ICR, therefore ethics approval is not required.

Building Collaborations

- Collaborating with patient advocates, NHS partners, researchers and community organisations working with minority groups to support ongoing and future work.
- Plain-language information leaflets developed to support outreach.

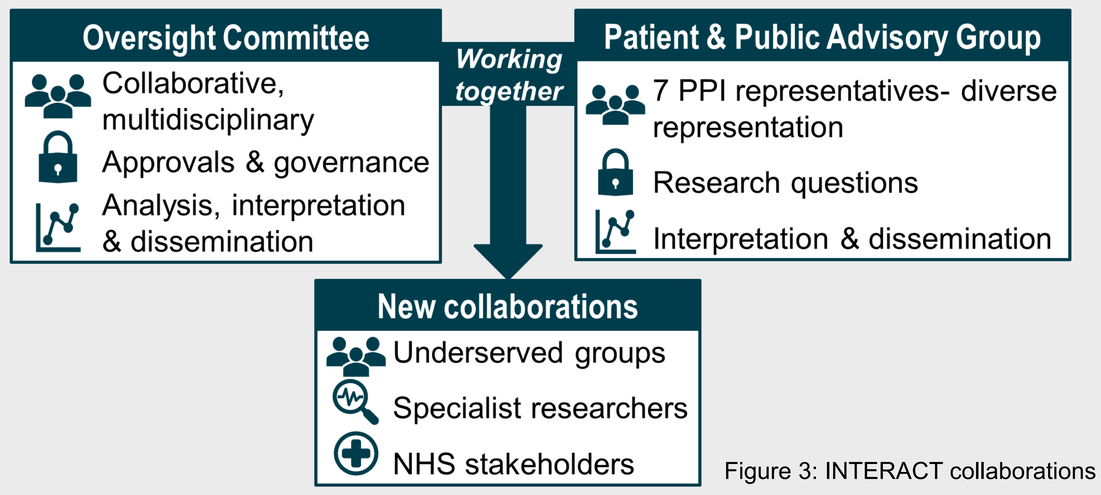


Figure 3: INTERACT collaborations

Challenges

- **Consent:** Lack of explicit consent from trial cohort for INTERACT-R, necessitating Confidentiality Advisory Group (CAG) approval.
- **Data quality:** Incomplete and inconsistent routine NHS datasets, with several demographic and clinical fields either unavailable or inaccessible and across multiple databases.
- **Site variation:** Substantial variation across NHS sites in INTERACT- P, with demographic and trial-related information stored in different formats, and systems, complicating standardised data capture.
- **Data recording:** Differences in how key characteristics are recorded, including variation in use of sex versus gender fields and variable completeness of data such as ethnicity, potentially impacting comparability across sites.
- **NHS Capacity:** Limited capacity for INTERACT-P survey responses, slowing data return and affecting the representativeness of responses.

Contact

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