

COLLABORATIVE WORKING EXECUTIVE SUMMARY

Project Title: Increasing representation and improving the experience of ethnic minority patients in breast cancer clinical trials.

Project description

Roche Products Limited (**Roche**), Macmillan Cancer Support & Macmillan Cancer Support Trading Limited, (**Macmillan**) and NHS Race and Health Observatory (**NHSRHO**) propose to work together under a Collaborative Working Agreement. This project proposes to explore ethnic inequalities in breast cancer clinical trials and to design and implement interventions. This is with the aim of increasing the representation, improving patient retention and the experience of black and ethnic minority patients in breast cancer clinical trials and, generating evidence that will enable scaling up to more cancer types, areas of the UK and potentially other minority groups.

Organisations involved

Roche Products Limited; Macmillan Cancer Support, Macmillan Cancer Support Trading Limited, NHS Race and Health Observatory, Barts Health NHS Trust and The Christie NHS Foundation Trust.

Project Rationale

Black African, Asian and Caribbean heritage people are significantly underrepresented in clinical research in the UK and globally¹. For breast cancer, these same groups, particularly young black women, are reported to have more aggressive tumour profiles², present with later stages of disease and higher mortality rates and experience poorer cancer care³.

Research by the UK's National Institute for Health Research (NIHR) found that barriers to successful inclusion of under-served groups could be clustered under several headings: communication between research teams and participant groups; how trials are designed and delivered; and distrust in the research process. A rapid review of inclusion in clinical trials also

¹[https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435#Groups_by_Demographic_Factors_\(Age,_Sex,_Ethnicity,_Education\)](https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435#Groups_by_Demographic_Factors_(Age,_Sex,_Ethnicity,_Education))

² E. Copson, B. Eccles, T. Maishman, S. Gerty, L. Stanton, R.I. Cutress, et al.

Prospective observational study of breast cancer treatment outcomes for UK women aged 18-40 years at diagnosis: the POSH study J Natl Cancer Inst (Bethesda), 105 (13) (2013), pp. 978-988

³ Cancer and black and minority ethnic communities. Race Equality Foundation

<https://raceequalityfoundation.org.uk/health-care/cancer-and-black-and-minority-ethnic-communities/> (2018)

⁴ Bodicoat, D.H., Routen, A.C., Willis, A. et al. Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. Trials 22, 880 (2021). <https://doi.org/10.1186/s13063-021-05849-7>

identified access to trials, eligibility criteria, attitudes and beliefs, lack of knowledge around clinical trials, and logistical and practical issues⁴ .

Roche is deeply committed to addressing these barriers to clinical trial participation and advancing inclusive research globally. The NHS Race and Health Observatory is a new, independent organisation, set up to explore ethnic inequalities in access to healthcare, experiences of healthcare, health outcomes, and inequalities experienced by black and minority ethnic members of the health and care workforce. Macmillan Cancer Support is a charity providing specialist physical, financial and emotional support to people living with cancer across the UK. A partnership between these organisations with a strong commitment to advancing inclusion will ultimately lead to improved representation of ethnic minority patient recruitment into breast cancer clinical trials.

Project Objective

Given the rationale above, there is an urgent need to take bold and intentional steps to improve ethnic minority recruitment into breast cancer clinical trials in the UK. Breast cancer remains one of the largest investments for Roche R&D in the short and long term. Therefore, this project is seeking to pursue several objectives;

- To improve representation of black and ethnic minority patient recruitment into breast cancer clinical trials.
- To improve patient retention and the experience of black and ethnic minority patients in breast cancer clinical trials.
- To generate evidence that will support adoption of the recommended interventions in future research.

Project Approach

The parties will collaborate to design and implement multiple interventions and evaluate their effectiveness. The interventions include four main elements:

1. Creating new accessible and engaging materials to ensure patients are empowered to understand breast cancer and clinical trials, supported to address concerns and barriers, and know how to access support. This will be informed by user involvement supported by local community health organisations.
2. These materials will be shared with all breast cancer patients at two identified NHS trusts- one at Barts Health NHS Trust and one at The Christie NHS Foundation Trust - by two newly hired clinical posts supported by this project. These sites were chosen as they are two of the busiest and most ethnically diverse clinics in the UK. The supported clinical post-holders' primary focus will be to work closely with patients diagnosed with breast cancer, to support them with informed decision-making and ensure they have the best possible experience should they decide that trial participation is right for them.
3. Engagement in the wider community to ensure that patients are supported beyond clinical settings.

4. Independent evaluation of the effectiveness of the project and evidence-based recommendations for improving representation and experience within clinical trials in the future.

Benefits for Patients

- Improved access to and experience of clinical trials for patients from minority ethnic groups which will often lead to better outcomes for those patients.
- Greater access to representation in research and the opportunity to take part in research, which has been reported as leading to both personal satisfaction from the opportunity to receive innovative treatment and social satisfaction from the opportunity to make things better for others.

Benefits to NHS

- An enhanced population of clinical trial participants will better represent the different groups that form the population the NHS serves which will help to make evidence-based medicine applicable to all communities.
- Increased racial and ethnic diversity in clinical trials and research recruits will improve the validity, equality, and scientific rigour of research carried out by or for the NHS.
- Access to and participation in research by individuals from minority ethnic groups will improve patient treatment and outcomes.
- Faster recruitment & better retention of patients within clinical trials.
- Building trust with and within communities and healthcare providers by demonstrating inclusive research which could lead to a 'halo effect' which may help generate more inclusive healthcare outside of a direct research space.

Benefits to Roche

- Inform Roche's future research design and improve access to clinical trials.
- Roche hopes to build broader advocacy in inclusion to trials by sharing best practice with other relevant stakeholders.

This document has been produced by Roche Products Ltd, Macmillan Cancer Support and NHS Race and Health Observatory.

Date of Preparation: April 2023

PromoMats Number: M-GB-00009946

This document was produced by Roche Products Ltd