

FREEDOM OF INFORMATION ACT 2000**ROYAL CORNWALL HOSPITALS NHS TRUST****RESEARCH AND DEVELOPMENT**

Date request received	03/06/2025	FOI Ref	29069
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Details of FOI Request

Q3	Does your trust participate in any clinical trials for breast cancer? If so, please provide the name of each trial, and the number of patients taking part.
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RESPONSE

Study Short Title	Study Full Title	Active Participants
ASTEFLANIA	T-DM1 + Atezolizumab in high-risk HER2+ patients with residual disease after neoadjuvant taxane-based and HER2-targeted therapy	1 On Follow Up
ATNEC	ATNEC–Axillary management in T1-3N1M0 breast cancer patients with FNA or core biopsy proven nodal metastases at presentation who convert to node negative after NEOadjuvant Chemotherapy	13 Recruited Randomised
AURORA	AURORA: Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer	2 On Follow Up
Breast Cancer Her 2	A Randomized, Double-Blind, Phase III Study of Pembrolizumab versus Placebo in Combination with Neoadjuvant Chemotherapy and Adjuvant Endocrine Therapy for the Treatment of High-Risk Early-Stage Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative (HR+/HER2-) Breast Cancer (KEYNOTE-756)	5 On Follow Up
CLEE011O12301C (TRIO033) - NATALEE	A phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant treatment in patients with hormone receptor-positive, HER2-negative, early breast cancer -NATALEE.	3 On Treatment 1 On Follow Up
c-TRAK TN	c-TRAK TN: A randomised trial utilising ctDNA mutation tracking to detect minimal residual disease and trigger intervention in patients with moderate and high risk early stage triple negative breast cancer	3 On Follow Up
FAIM	Randomised Open-label Phase II study of induction standard of care Fulvestrant	2 On Follow Up

Study Short Title	Study Full Title	Active Participants
	and CDK4/6 inhibition with the Addition of Ipatasertib in Metastatic ER+/HER2-breast cancer patients without ctDNA suppression	
FAST-Forward	FAST FORWARD - To Identify A 5-Fraction Schedule Of Curative Radiotherapy Delivered In 1 Week That Is At Least As Effective And Safe As The Current UK Standard 15-Fraction Regimen Delivered Over 3 Weeks Following Primary Surgery For Early Breast Cancer	23 On Follow Up
HER2-RADiCAL	The HER2-RADiCAL study (Response ADaptive CAre pLan) – Tailoring treatment for HER2 positive early breast cancer	5 On Follow Up
IMPORT HIGH	Randomised trial testing dose escalated intensity modulated radiotherapy in women with higher than average local tumour recurrence risk after breast conservation surgery and appropriate systemic therapy for early breast cancer	5 On Follow Up
KORTUC phase II	Randomised phase II trial testing efficacy of intra-tumoural hydrogen peroxide as a radiation sensitizer in patients with locally advanced/recurrent breast cancer.	3 On Follow Up
LORIS	A Phase III Trial of Surgery versus Active Monitoring for Low Risk Ductal Carcinoma in Situ (DCIS)	5 On Follow Up
MK2870-010	An Open-label, Randomized Phase 3 Study of MK-2870 as a Single Agent and in Combination with Pembrolizumab Versus Treatment of Physician's Choice in Participants with HR+/HER2-Unresectable Locally Advanced or Metastatic Breast Cancer	1 On Treatment
MK-3475 + Chemotherapy as Neoadjuvant and Adjuvant therapy for TNBC	A Phase III, Randomized, Double-blind Study to Evaluate Pembrolizumab plus Chemotherapy vs Placebo plus Chemotherapy as Neoadjuvant Therapy and Pembrolizumab vs Placebo as Adjuvant Therapy for Triple Negative Breast Cancer (TNBC)	7 On Follow Up
MonarchE: Phase 3 Study of Abemaciclib in Breast Cancer (JPCF)	MonarchE: Protocol I3Y-MC-JPCF A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer	2 On Follow Up

Study Short Title	Study Full Title	Active Participants
OPTIMA	Optimal Personalised Treatment of early breast cancer using Multiparameter Analysis	13 On Follow Up
PALbociclib CoLLaborative Adjuvant Study	A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)- negative early breast cancer	10 On Follow Up
persevERA Breast Cancer	A phase iii randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of gdc-9545 combined with palbociclib compared with letrozole combined with palbociclib in patients with estrogen receptor-positive, her2-negative locally advanced or metastatic breast cancer	2 On Treatment
PHERGain	Chemotherapy-free trastuzumab and pertuzumab in HER2-positive breast cancer: FDG-PET response-adapted strategy. The PHERGain study	3 On Follow Up
POSNOC.	POSNOC - POSitive Sentinel NOde: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatment in women with early stage breast cancer who have metastases in one or two sentinel nodes.	7 On Follow Up
PRIMETIME	Post-operative avoidance of radiotherapy: biomarker selection of women categorised to be in a very low risk group by IHC4+C	74 On Follow Up
SMALL Trial	SMALL: A Phase III, randomised, multi-centre trial addressing overtreatment of small screen-detected breast cancer by comparing standard surgery versus minimally invasive vacuum-assisted excision	5 On Follow Up
TRAK-ER	A randomised trial of early detection of molecular relapse with circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard endocrine therapy in patients with ER positive HER2 negative breast cancer	11 Recruited Randomised 2 On Treatment
UNIRAD	UNIRAD: Randomized, double-blind, multicentre phase III trial evaluating the safety and benefit of adding everolimus to adjuvant hormone therapy in women with poor prognosis, ER+ and HER2-primary breast cancer who remain free of disease after at least 1 year of adjuvant hormone therapy.	14 On Follow Up

Study Short Title	Study Full Title	Active Participants
DUALITYBIO	A Phase 3, Randomized, Multi-center, Open-label Study of DB-1303 Versus Investigator's Choice Chemotherapy in Human Epidermal Growth Factor Receptor 2 (HER2)-low, Hormone Receptor Positive (HR+) Metastatic Breast Cancer Patients whose Disease has Progressed on Endocrine Therapy (ET) (DYNASTY-Breast02)	Open – No Active Participants
ELEGANT	Elacestrant versus Standard Endocrine Therapy in Women and Men with Node-positive, Estrogen Receptor-positive, HER2-negative, Early Breast Cancer with High Risk of Recurrence - A Global, Multicenter, Randomized, Open-label Phase 3 Study (ELEGANT)	Open – No Active Participants
MK2870-012	A Phase 3, Randomized, Open-label, Study to Compare the Efficacy and Safety of Adjuvant MK-2870 in Combination with Pembrolizumab (MK-3475) Versus Treatment of Physician's Choice in Participants With Triple Negative Breast Cancer (TNBC) Who Received Neoadjuvant Therapy and Did Not Achieve a Pathological Complete Response (pCR) At Surgery	Open – No Active Participants
MK6482-029	A Phase 2, Randomized, Active-controlled, Open-label, Multicenter Study of Belzutifan Plus Fulvestrant in Participants With Estrogen Receptor Positive, HER2 Negative Unresectable Locally Advanced or Metastatic Breast Cancer After Progression on Endocrine Therapy	Open – No Active Participants
SAFE-DE	Safe De-escalation of Chemotherapy for Stage 1 Breast Cancer	Open – No Active Participants
BARBICAN	BARBICAN: A randomised, open-label Phase II study to determine the contribution of ipatasertib to neoadjuvant chemotherapy plus atezolizumab in women with triple-negative breast cancer	Closed to recruitment – No Active Participants
BC-CDK4-Ph3	AN INTERVENTIONAL, DOUBLE-BLIND RANDOMIZED, MULTICENTER PHASE 3 STUDY OF PF-07220060 PLUS FULVESTRANT COMPARED TO FULVESTRANT IN PARTICIPANTS OVER 18 YEARS OF AGE WITH HORMONE RECEPTOR (HR)-POSITIVE, HER2-NEGATIVE ADVANCED/METASTATIC BREAST CANCER WHOSE DISEASE PROGRESSED AFTER PRIOR CDK 4/6 INHIBITOR BASED THERAPY	Closed to recruitment – No Active Participants
DESTINY-06	Phase III Study of Trastuzumab Deruxtecan versus Investigator's Choice Chemotherapy in HER2-Low, Hormone Receptor Positive,	Closed to recruitment – No Active Participants

Study Short Title	Study Full Title	Active Participants
	Breast Cancer Patients whose Disease has Progressed On Endocrine Therapy in the Metastatic Setting (D9670C00001)	
POETIC	POETIC - Trial of Perioperative Endocrine Therapy - Individualising Care	Closed to recruitment – No Active Participants
ROSCO	Response to Optimal Selection of neo-adjuvant Chemotherapy in Operable breast cancer: A randomised phase III, stratified biomarker trial of neo-adjuvant 5-Fluorouracil, Epirubicin and Cyclophosphamide vs Docetaxel and Cyclophosphamide chemotherapy	Closed to recruitment – No Active Participants
NCRN250 APHINITY - Traz + Pertuzumab in HER2+ as adjuvant therapy in HER2+ Br Ca	A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer	Closed to recruitment – No Active Participants
POETIC-A	PreOperative Endocrine Therapy for Individualised Care with Abemaciclib	Closed to recruitment – No Active Participants

Additional Commentary

Request received by R&D 03/06/2025.

With reference to the clinical trial question (Q3), the data included relates to any clinical trials for breast cancer which are currently recruiting participants or have participants under treatment or in follow-up.

The number of active participants relates to those participants currently undergoing treatment or in follow-up.

We have also listed active clinical trials at RCHT that do not have any active participants.

Thankyou.

Date Response Sent

13/06/2025