NATIONWIDE REGISTRY-BASED COHORT STUDY OF TREATMENT PATTERNS, DISEASE PROGRESSION, AND OUTCOMES IN HORMONE RECEPTOR-POSITIVE, HER2-NEGATIVE BREAST CANCER IN NORWAY (NOR-REAL-BC)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001226

Study ID

1000001226

DARWIN EU® study

No

Study countries

Norway

Study description

NOR-REAL-BC is a retrospective, population-based observational cohort study using secondary data from Norway's nationwide health registries. It characterises the full disease continuum of hormone receptor-positive, HER2-negative (HR+/HER2−) breast cancer, from initial diagnosis through recurrence to metastatic disease.

The study includes adults (≥18 years) with incident, histologically verified HR+/HER2− breast cancer diagnosed between 2012-2025. Patients with another primary malignancy five years before index, excluding non-melanoma skin cancer and benign in situ neoplasms, and autopsy-only diagnoses are excluded. No sampling is applied and the expected study population is approximately 35,000 patients.

The study design uses three parallel entry pathways, each with its own index date: an early breast cancer cohort (stage I–III at diagnosis), a de novo metastatic cohort (stage IV at diagnosis), and a recurrent cohort (early disease with subsequent locoregional and/or distant recurrence). Patients are followed from index until death, emigration or end of study period.

Individual-level data are drawn from the Cancer Registry of Norway including the national breast cancer quality registry, the Norwegian Patient Registry, the Norwegian Prescribed Drug Registry and the Norwegian Primary Care Registry. Data are pseudonymised by the registry holders, linked via a study-specific identifier and analysed within a secure research environment.

The primary objective is to describe clinical characteristics, real-world treatment patterns and outcomes in HR+/HER2− early breast cancer, with

distant recurrence-free survival, locoregional recurrence, overall survival and breast cancer-specific survival as primary endpoints. Secondary objectives address disease progression, de novo metastatic disease, healthcare resource utilisation, endocrine resistance and trial-aligned populations relevant to health technology assessment.

Study status

Ongoing

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

NordicRWE is conducting the study on behalf of Roche Norway AS.

Contact details

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Study timelines

Date when funding contract was signed

Planned: 25/03/2026

Actual: 25/03/2026

Study start date

Planned: 01/01/2012

Actual: 31/12/2025

Data analysis start date

Planned: 01/11/2026

Date of interim report, if expected

Planned: 30/04/2027

Date of final study report

Planned: 30/04/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The study is initiated and funded by Roche Norway AS and is conducted as contract research by NordicRWE AS. The collaboration is governed by a written agreement between the parties, setting out roles, responsibilities, financial terms and publication requirements. NordicRWE AS is the data controller for the processing of health data in the project. Roche is neither data controller nor data processor and has no role in the processing of personal data.

Study protocol

Protocol_-_SL46796_-_GIREDESTRANT_-_v2_-_Norway_(Published)_Redacted.pdf (218.5 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

SL46796

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study topic, other:

HR+/HER2− breast cancer

Study type:

Not applicable

Scope of the study:

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective, nationwide registry-based cohort study of HR+/HER2− breast cancer in Norway (2012–2025), using linked national cancer, hospital, prescription and primary care registries. Three cohorts: early stage (I–III), de novo metastatic, recurrent – followed to death, emigration or study end.

Main study objective:

Retrospective, nationwide registry-based cohort study of HR+/HER2− breast cancer in Norway (2012–2025), using linked national cancer, hospital, prescription and primary care registries. Three cohorts: early stage (I–III), de novo metastatic, recurrent – followed to death, emigration or study end.

Population studied

Short description of the study population

The source population consists of all individuals diagnosed with breast cancer in Norway during the study period (1.1.2012 to 31.12.2025).

The study population will be defined based on the following criteria:

Inclusion criteria:

• Females and males aged ≥18 years at diagnosis

• Incident breast cancer (ICD-10 C50) diagnosed during the study inclusion period

• Hormone receptor-positive (HR+) and HER2-negative breast cancer at diagnosis

• Histologically verified breast cancer

Exclusion criteria:

• Prior history of other primary malignancy within 5 years prior to the breast cancer index date, with the exception of non-melanoma skin cancer and benign in situ neoplasms

• Breast cancer diagnosis identified only at autopsy

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

35.000

Study design details

Setting

Persons. Adults (≥18 years at diagnosis), with incident, histologically verified HR+/HER2− breast cancer (ICD-10 C50).

Place. Norway, nationwide and population-based. Universal healthcare with mandatory registry reporting gives complete national coverage across primary and specialist care. Data are drawn from linked national cancer, hospital, prescription and primary care registries, pseudonymised by the registry holders and analysed in a secure research environment.

Time period. Inclusion period 1.1.2012–31.12.2025. Index date = date of breast cancer diagnosis; for the recurrent cohort, date of first registry-based evidence of recurrence. Covariates are assessed from 2008 (2007 for prior primary cancers); primary care data from 2016. Follow-up runs from index until death, emigration or end of study period.

Selection criteria. Included: age ≥18 at diagnosis; incident C50 diagnosed within the inclusion period; HR+/HER2− status at diagnosis; histological verification. Excluded: other primary malignancy within 5 years before index (except non-melanoma skin cancer and benign in situ neoplasms); autopsy-only diagnosis. No sampling is applied – the full eligible national population is included (~35,000 expected HR+/HER2−).

Groups. No treatment arms or formal comparators; the design is descriptive with three parallel entry pathways: eBC (stage I–III at diagnosis), de novo mBC (stage IV at diagnosis), and recurrent BC (early disease with subsequent locoregional and/or distant recurrence). Analyses are further stratified by e.g. tumour characteristics, adjuvant risk group, nodal status, drug class, calendar period and menopausal status.

Comparators

Not applicable — descriptive study, no formal comparator.

Outcomes

Primary outcomes

Distant recurrence-free survival (DRFS) — eBC cohort only. Time from diagnosis to the earliest of death from any cause, distant metastasis, initiation of systemic therapy indicative of metastatic disease, or radiotherapy indicating advanced disease. Censoring at emigration or end of study.

Locoregional recurrence (LRR) — first recurrence confined to the ipsilateral breast, chest wall or regional nodes after primary treatment, in the absence of prior or simultaneous distant disease. Identified from procedure codes, radiotherapy records and diagnosis codes. Systemic therapy may serve as supporting, not standalone, evidence.

Overall survival (OS) — time from index date to death from any cause; applicable to all three cohorts. Breast cancer-specific survival (BCSS) — time to breast cancer death from national mortality data, with other-cause death treated as a competing event.

Secondary and exploratory outcomes

Endocrine resistance, via a registry-based composite algorithm combining endocrine therapy exposure with subsequent progression or treatment escalation; classified as primary (event within ~24 months of adjuvant endocrine therapy initiation) or secondary (thereafter, or within ~12 months of discontinuation).

Treatment patterns, including time to treatment initiation, persistence, lines of therapy and sequences (neoadjuvant, adjuvant, 1L–3L+ metastatic), and switching within and across drug classes.

Healthcare resource utilisation, covering admissions and length of stay, outpatient and primary care contacts, procedures, diagnostics and dispensed drugs.

Full operational definitions are specified in the SAP.

Data analysis plan

Approach. Analyses follow a predefined SAP and are primarily descriptive, aligned with RWE best practice. No formal causal inference framework is applied; estimates are presented with confidence intervals rather than as tests of hypotheses. Analyses will be performed in validated software (R).

Descriptive analyses. Continuous variables summarised as mean, SD, median, IQR, minimum and maximum; categorical variables as counts and percentages. Where group comparisons are made, chi-square or Fisher's exact test is used for categorical variables and parametric or non-parametric tests for continuous variables. All tests are two-sided at the 0.05 level, interpreted cautiously and without adjustment for multiplicity.

Time-to-event analyses. DRFS, OS, BCSS and time to treatment discontinuation are estimated by Kaplan–Meier methods, reported as survival curves, and median survival where estimable. For BCSS, non-breast-cancer death is treated as a competing event, with cumulative incidence functions estimated where appropriate. Parametric models are selected by comparison by AIC/BIC, visual comparison with Kaplan–Meier curves and landmark estimates.

Measures of occurrence. Incidence rates (e.g. recurrence, endocrine resistance) are estimated as events divided by person-time at risk, with confidence intervals.

Validity. Internal validity is supported by predefined, clinically informed algorithms for cohorts, treatment lines and endpoints; transparent reporting of missingness (no imputation in primary analyses); and sensitivity analyses varying recurrence definitions, exposure and persistence assumptions, line-of-therapy rules and time windows. External validity rests on complete nationwide coverage without sampling.

Summary results

Not yet available.

Data management

Data sources

Data source(s), other

1) Cancer Registry of Norway, incl. the national breast cancer quality registry
2) Norwegian Patient Registry
3) Norwegian Prescribed Drug Registry
4) Norwegian Primary Care Registry

Data sources (types)

Disease registry

Drug registry

Population registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes