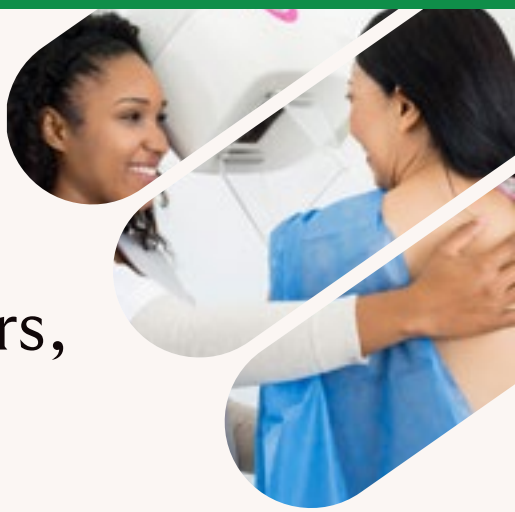
Info sheet – Breast Cancer

Proven in Large Global Breast Cancer Programs



Your breast cancer trials deserve a provider who delivers, even in the most dynamic global landscapes.

Early Phase I/II | Large-Scale Phase III & Registrational | HR+ / HER2+ / TNBC / Metastatic | High Performing Site Network (EPON) | Biomarker & Precision Medicine Expertise Experience

CORE CAPABILITIES

Translational and Biomarker

End-to-end biomarker-driven strategy, from protocol design through execution. Our experience spans inclusion of patients with broad biomarker profiles from hormone receptor-positive (HR+)/ HER2-negative disease, triple-negative breast cancer (TNBC), HER2-positive and HER2-low populations, and studies involving genomic biomarker selection such as PIK3CA, AKT1, and PTEN alterations, as well as PD-L1 and TROP2-driven. Selection of centers that perform these analyses routinely and willing to invest the time and resources to find that one rare patient defines FORTREAs EPON network in early phase to the global community of sites in later phase.

Biomarker-driven design | Molecularly selected cohorts | CDx integration | Precision oncology execution

Site Network and Enrollment

Pre-qualified oncology site network with strong KOL relationships and active breast cancer pipelines across US, EU and APAC, reducing activation lag significantly.

EPON collaboration network | 70+ high-performing oncology sites | Early-phase experience | Strong referral pipelines

5-YEAR OVERVIEW

Proven delivery at the scale of the largest global breast cancer trials

117 Breast cancer studies in last five years

34K+ Patients enrolled globally

500+ Sites

5 Registrational-Intent Breast Cancer Studies

*2021-2025 Fortrea internal metrics.

Patient-Centricity, Diversity and PRE Excellence

Patient Recruitment and Engagement (PRE) strategies designed for breast cancer trials, integrating patient advocacy collaborations , culturally tailored outreach, diversity-focused recruitment, and biomarker testing support to optimize recruitment performance into the trial, as well as retention on the trial.

Diversity plans (design–execution–reporting) | Real-time monitoring | Global patient access | Inclusive recruitment

Fortrea

Integrating actionable Data Insights, Medical Experience + Operational Excellence

Backed by a global team of 50+ medical Oncology specialists, with deep involvement from design through execution with strategy and operational planning.

Integrated medical-operational delivery | Protocol optimization | Scientific + operational alignment

Trusted, Predictable Delivery

Integrated delivery excellence powered by actionable data insights guiding operational delivery strategy, to dedicated biostatistics, regulatory, and market access specialists supporting high-quality execution, patient enrollment continuity, and robust data generation in complex and rapidly evolving clinical environments.

Adaptive delivery model | Protocol flexibility | Resilient enrollment | Complex trial execution

Integrated Vendor and CDx Ecosystem

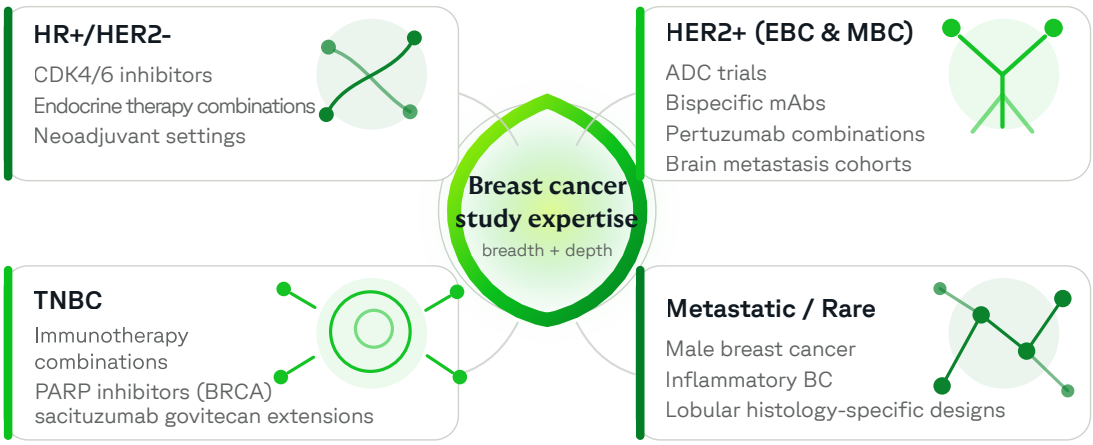
Experienced management of complex multi-vendor environments — integrating, imaging, companion diagnostics, radiopharmaceutical supply chains, and specialised manufacturing logistics with end-to-end oversight and data transparency.

CDx + lab integration | Multi-vendor coordination | End-to-end oversight | Data transparency Radiopharmaceutical supply & handling | Manufacturing logistics coordination

OUR PROCESS — FROM STRATEGY TO SUBMISSION

01	02	03	04	05
Protocol & Feasibility	Site Selection & Activation	Enrollment & Monitoring	Data Lock & Analysis	Regulatory Submission

Indication depth



Fortrea

Why sponsors choose us

- Trusted, predictable delivery in complex breast cancer trials
- Scalable global execution with strong monitoring and control
- Faster start-up and assured enrollment timelines
- Real-time visibility and proactive risk management
- **EMA, FDA, NMDA, PMDA experience** – single CRO for global submissions
- Flexible FSP or full-service engagement models allows you to decide the best delivery model

FORTREA – COMBINING SCIENTIFIC LEADERSHIP WITH DELIVERY EXCELLENCE

50+ Oncology Peer Reviewed Publications* (2020–2026)

12+ Breast Cancer-Specific Studies

8+ High-Impact Oncology Journals

*Our scientific and clinical teams co-author in journals such as JCO, Lancet Oncology, and Breast Cancer Research — reflecting hands-on therapeutic depth, not just operational delivery.

Global Regulatory Experience

- 65 oncology agency interactions across FDA, EMA, PMDA and NMPA (2020–2025)
- FDA Fast Track Designation support for HER2-positive breast cancer
- Experience supporting accelerated development pathways
- Rolling NDA and global submission support

Case study
Story of largest global breast cancer mega trial

Article
Combining multiple therapies for metastatic breast cancer

Publication
Peer reviewed journal article by Fortrea oncologists

Let's accelerate your breast cancer program.

Request a feasibility assessment or therapeutic area overview deck, or talk to our team.

DISCOVER MORE

Together Exceptional is possible...

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