State of Breast Cancer Clinical Trials (2010–2025)

A Fifteen-Year Review of Momentum, Transparency, and Research Priorities

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Codes and Analysis

Overview and Key Metrics (2010–2025)

Over the past fifteen years, 8,915 breast cancer clinical trials have been registered globally, reflecting sustained investment and growing diversity in study design and sponsorship. Trial activity spans the full clinical development continuum, although a striking majority remain early-phase or exploratory in nature.

More than half of all studies (55.8%) are recorded without a clearly specified phase, highlighting a persistent metadata gap in clinical trial registration. Among trials that do report phase information:

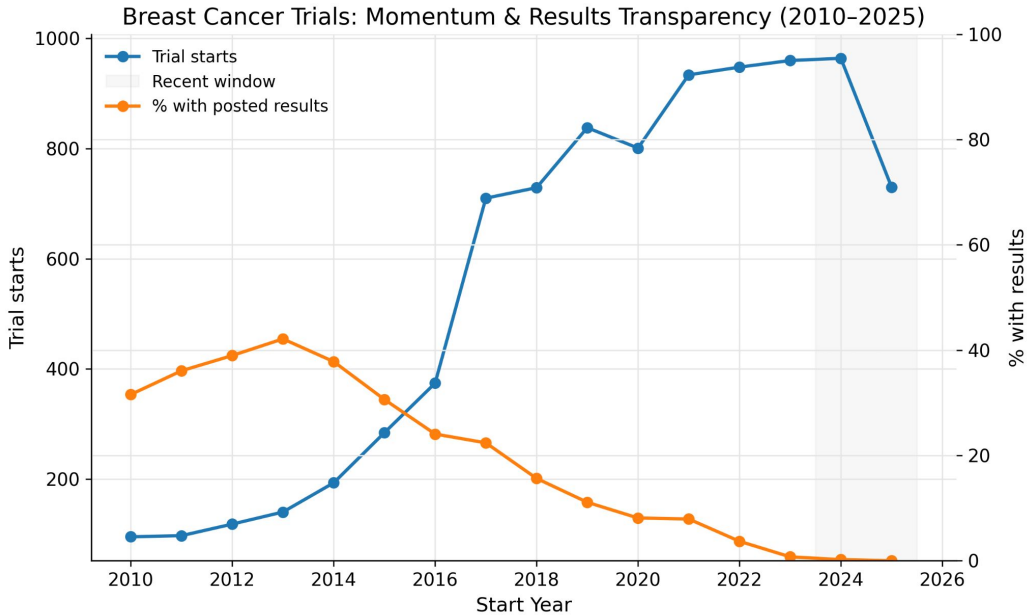
- Phase II studies dominate (17.9%), followed by Phase I (11.6%) and Phase III (6.7%) trials.
- Only 1.7% of trials reach Phase IV, underscoring the limited post-marketing research landscape.

From a sponsorship perspective, breast cancer research remains strongly academically driven:

- Academic sponsors account for 58% of all trials, indicating a robust university and hospital-led research base.
- Industry-sponsored studies represent just 10%, suggesting that while commercial engagement is steady, academia continues to lead innovation in trial initiation.
- The remaining studies are supported by non-traditional or collaborative consortia (32%), and government-backed trials remain rare (<1%).

Trial initiation has remained remarkably consistent across the past five years, averaging nearly 950 new studies annually. This steady momentum demonstrates the continued prioritisation of breast cancer research globally, though the downstream availability of results, as explored in subsequent sections, remains uneven.

Momentum and Transparency



Between 2010 and 2025, the landscape of breast cancer clinical trials has expanded substantially, reaching a total of 8,915 registered studies. The momentum of new trial initiations has accelerated sharply since the mid-2010s, peaking between 2021 and 2024.

However, this growth contrasts starkly with a persistent deficit in results transparency. In the most recent two-year window (2024–2025), 1,694 trials were initiated, yet only 0.1% have posted results, a reflection of reporting lag but also indicative of enduring structural inefficiencies in public data sharing.

Even for the more mature 2023 cohort, only 0.7% of studies have publicly available outcomes. These figures underscore the widening gap between research activity and knowledge dissemination, raising concerns about reproducibility, accountability, and the timely translation of findings into clinical impact.

Planned vs Reported Endpoints

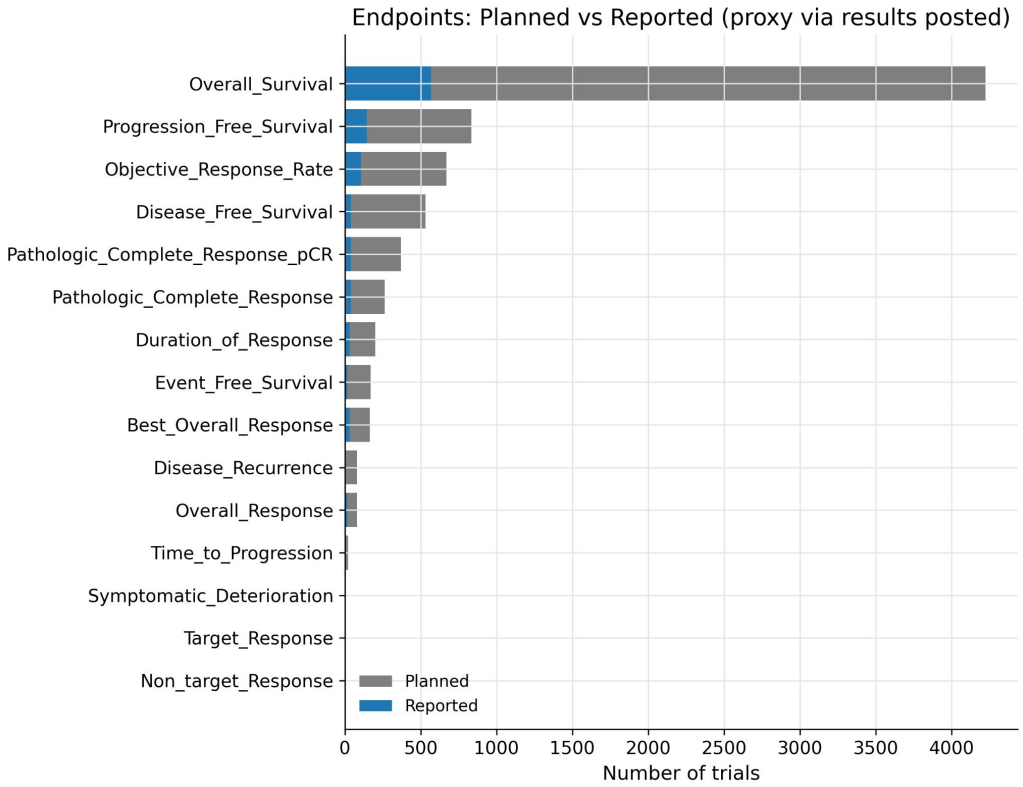
Despite remarkable progress in breast cancer trial registration, transparency in endpoint reporting remains highly uneven.

The majority of studies (over 4,000) include Overall Survival as a planned endpoint, yet only around 13% have publicly posted corresponding results. Similarly, Progression-Free Survival and Objective Response Rate, which are key indicators of therapeutic efficacy, show reporting rates below 20%.

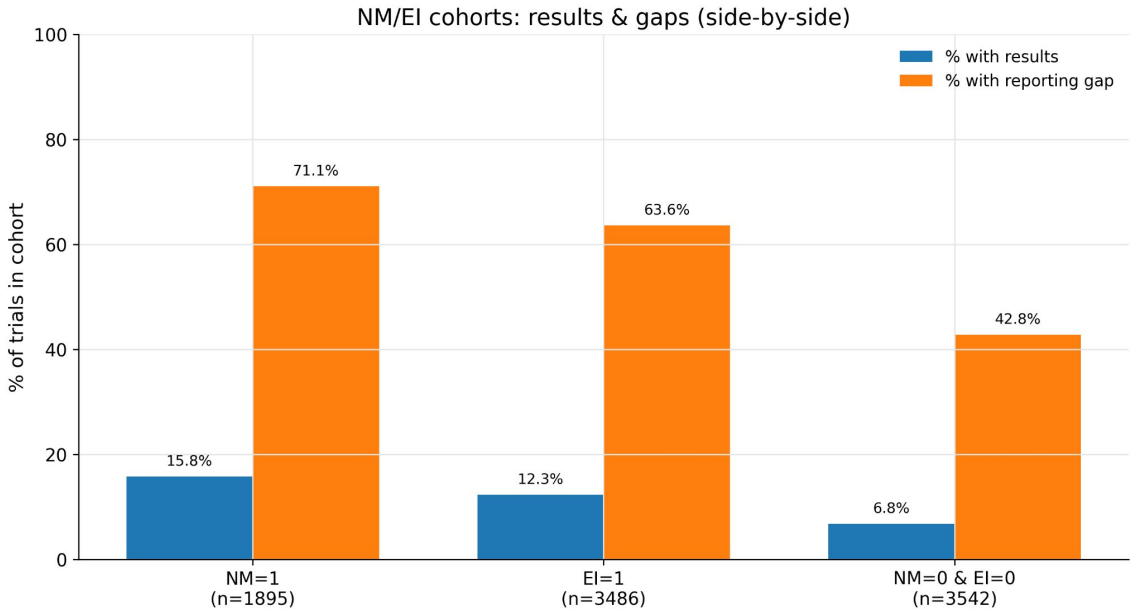
Lower-tier endpoints such as Pathologic Complete Response (pCR), Event-Free Survival, and Disease Recurrence exhibit even weaker transparency, often falling below 10%.

While endpoint definitions are increasingly standardised at the planning stage, dissemination of completed analyses remains sporadic.

This incomplete reporting threatens meta-analytic reliability and delays evidence synthesis across the field.



Transparency Gaps by Trial Type (NM vs EI)



Comparing New Medicine (NM) and Extension of Indication (EI) trials reveals systematic transparency gaps. Only 15.8% of NM trials and 12.3% of EI trials have publicly available results, despite high registration volumes (n=1,895 and n=3,486, respectively).

Moreover, 71% of NM and 63% of EI trials show clear reporting gaps, indicating delayed or missing data publication.

This disparity is more pronounced among exploratory or non-commercial studies (NM=0 & EI=0), where only 6.8% of trials post results. Collectively, the evidence points to a persistent structural lag between trial registration and result dissemination, particularly for early-phase or non-industry studies.

The trend underscores the need for policy reinforcement to ensure accountability and accelerate public data sharing in oncology research.

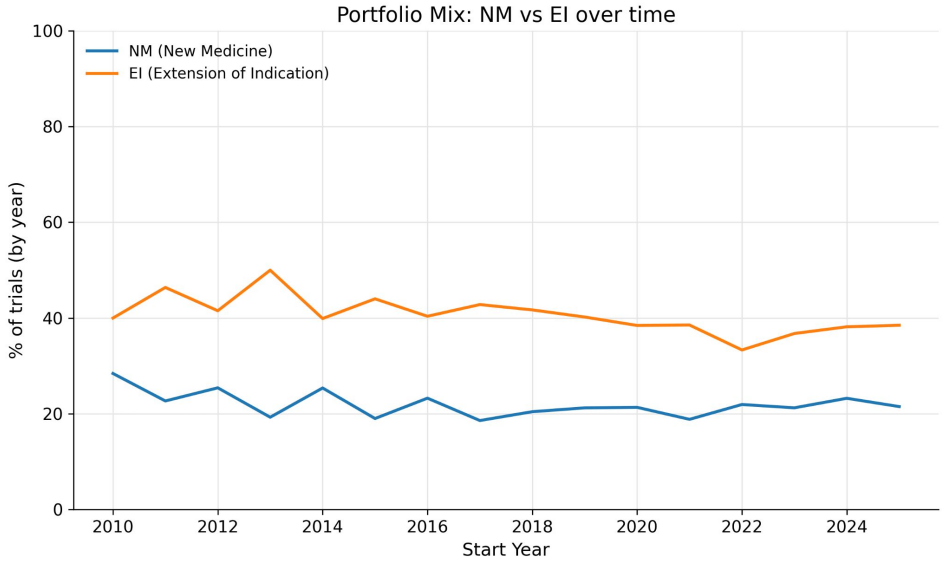
New Medicine vs Extension-of-Indication Trials

Breast cancer studies have shown a steady divide between experimental compounds and those adapting prior therapies for broader use.

Extension-of-indication work consistently dominates, typically comprising around 40–50 percent of yearly activity, while new-molecule investigations form a smaller but stable share near 20–25 percent. This profile highlights a research environment oriented towards refining and expanding existing treatments rather than introducing unfamiliar agents.

The persistence of this pattern reflects both clinical pragmatism and regulatory inertia. Repurposed interventions allow faster translation and reduced development risk, yet they also limit therapeutic novelty.

Conversely, trials of untested drugs face heavier operational demands and delayed disclosure of findings. Together, these dynamics portray a field advancing through accumulation and optimisation rather than radical transformation.

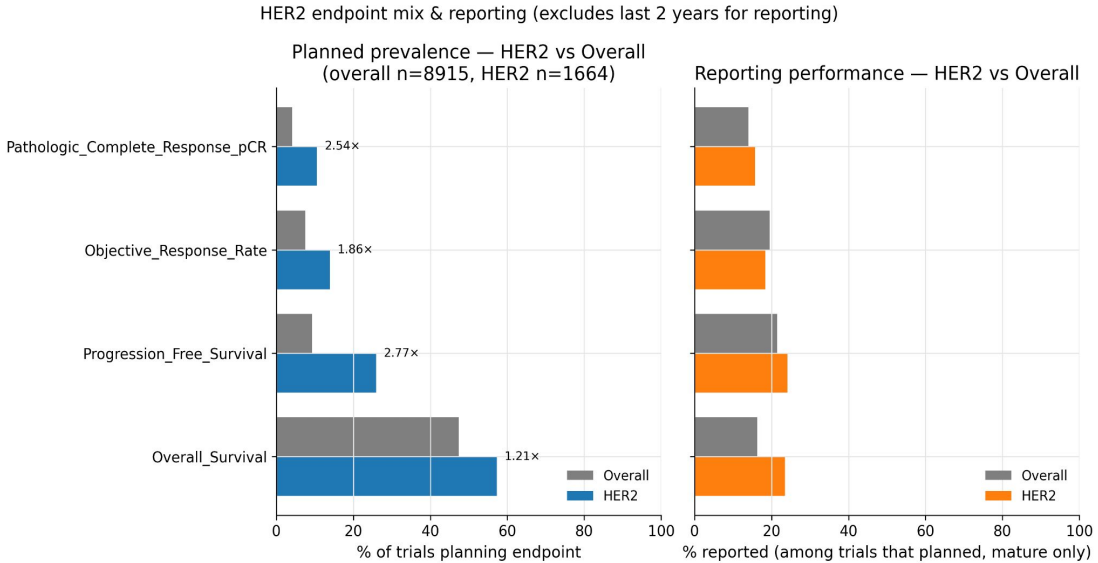


HER2-Positive Breast Cancer Trials

HER2-positive breast cancer remains a major focus of clinical investigation, accounting for around one in five breast cancer trials since 2010. This subgroup exhibits both a stronger alignment with survival-based endpoints and higher reporting compliance compared with the broader research landscape.

Across studies, 16.5% of HER2 trials have publicly posted results, compared with 10.9% overall, suggesting somewhat greater transparency and maturity of evidence. On average, HER2 trials achieve a CONSORT results score of 1.63, again exceeding the overall mean of 1.41.

Endpoint-level analysis highlights the consistency of outcome planning. HER2 trials are notably more likely to measure progression-free survival (26%), overall survival (57%), and pathologic complete response (11%), each occurring roughly 1.2–2.8 times more often than in the full dataset. While reporting rates remain modest, HER2 trials demonstrate marginally stronger disclosure for key endpoints such as overall survival (24% vs 16%) and pathologic response (16% vs 14%), reflecting an evidence base that, although not complete, is comparatively more open and harmonised with regulatory expectations.

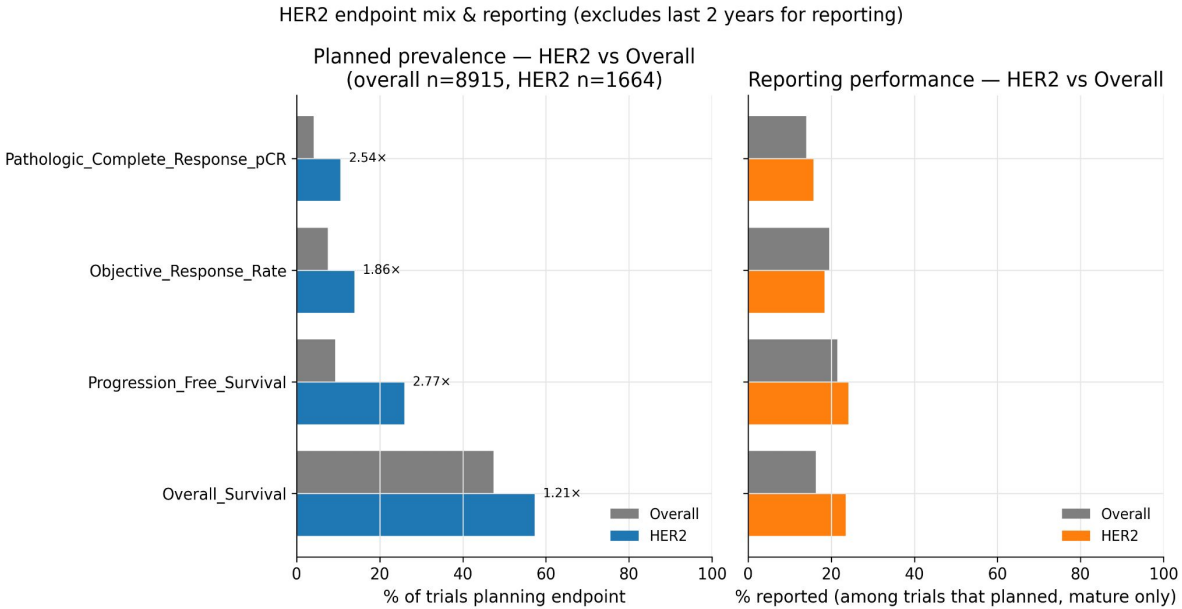


BRCA-Mutated Breast Cancer Trials

Trials targeting BRCA-mutated breast cancer constitute a small but strategically important subset, only 71 studies identified to date, but show distinct characteristics. Reporting practices within this group are markedly better than the field average: 24% of trials have publicly posted results, over twice the overall rate. Similarly, their average CONSORT score of 1.92 suggests greater attention to transparent reporting and adherence to publication standards

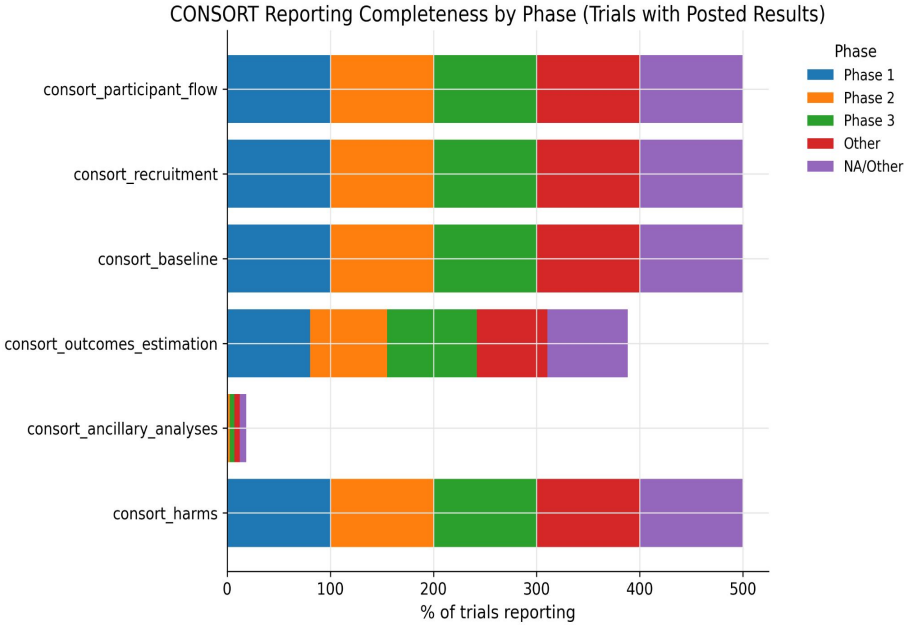
Endpoint patterns indicate a concentration on response-based and survival outcomes, with objective response rate and progression-free survival appearing 1.3–1.8 times more frequently than in the broader trial set. Strikingly, the reporting success within these trials is considerably stronger; over half of studies that planned these endpoints have disclosed corresponding results.

This likely reflects the clinical maturity and translational urgency of BRCA research, where genomic targeting strategies have progressed rapidly into confirmatory and post-approval contexts.



CONSORT Reporting Practices Across Phases

Across all completed and result-posting breast cancer trials, compliance with CONSORT reporting standards is high for structural elements but inconsistent for analytical transparency. Participant flow, recruitment, baseline data, and harms are almost universally reported across every phase, each approaching 100% adherence. This consistency indicates that most investigators meet the core regulatory and ethical expectations for describing who was included, how participants were managed, and what adverse outcomes were observed.



However, statistical and interpretative completeness remains uneven. The item “outcomes estimation”, reflecting whether trials quantify effect sizes and precision, is reported in only 70–85% of cases, depending on phase. The sharpest decline is seen in exploratory and early-stage studies (Phase II), where only three in four trials quantify outcomes transparently.

The most striking weakness is in “ancillary analyses” and “numbers analysed”, where reporting falls near zero. This omission persists across all phases, including Phase III, underscoring a structural gap in how secondary and sensitivity analyses are shared publicly.

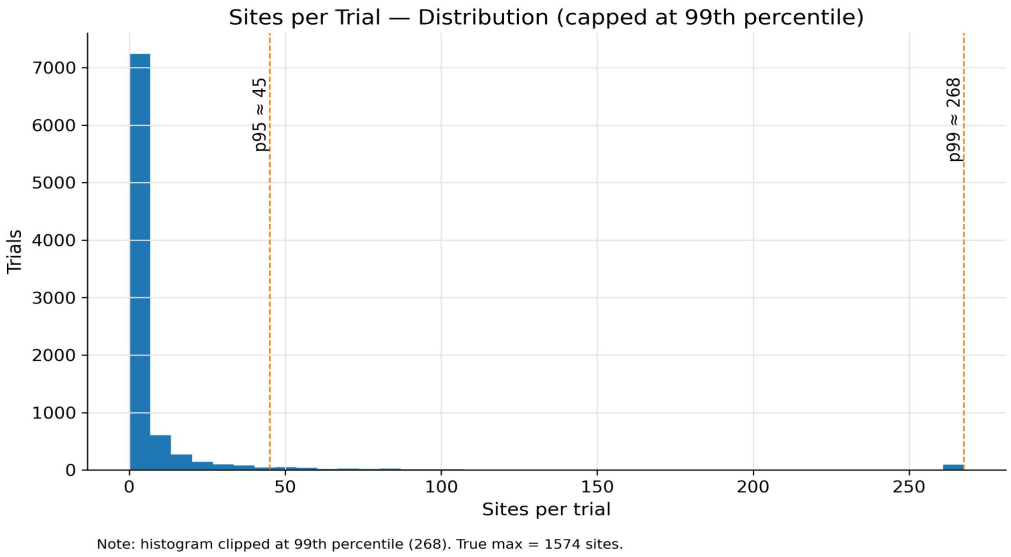
Together, these results suggest that while operational transparency is strong, analytic transparency remains partial, particularly in earlier phases. The consistency of reporting harms but not numerical analysis reveals a cautious but incomplete culture of disclosure, one that prioritises procedural accountability over interpretive clarity.

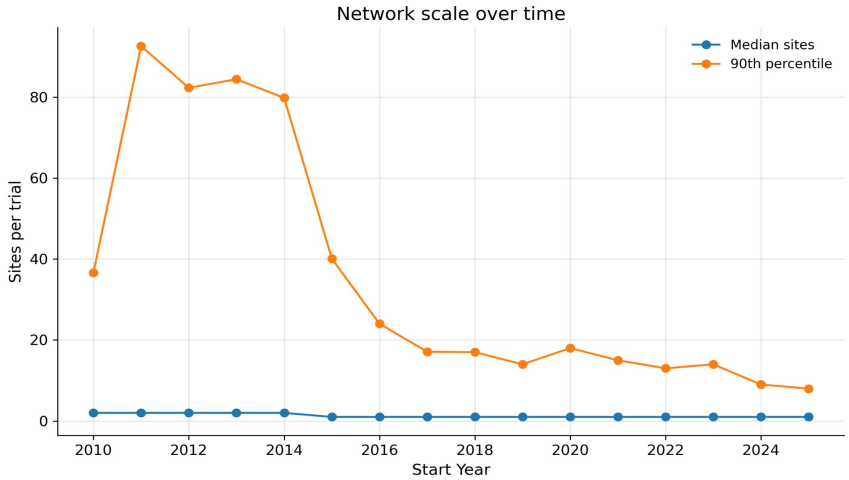
Geographical Access and Trial Footprint

The majority of breast cancer trials operate within narrow geographic boundaries, typically involving a single site or a very small cluster. The median number of sites per trial is just one, indicating limited spatial reach and localised enrolment practices.

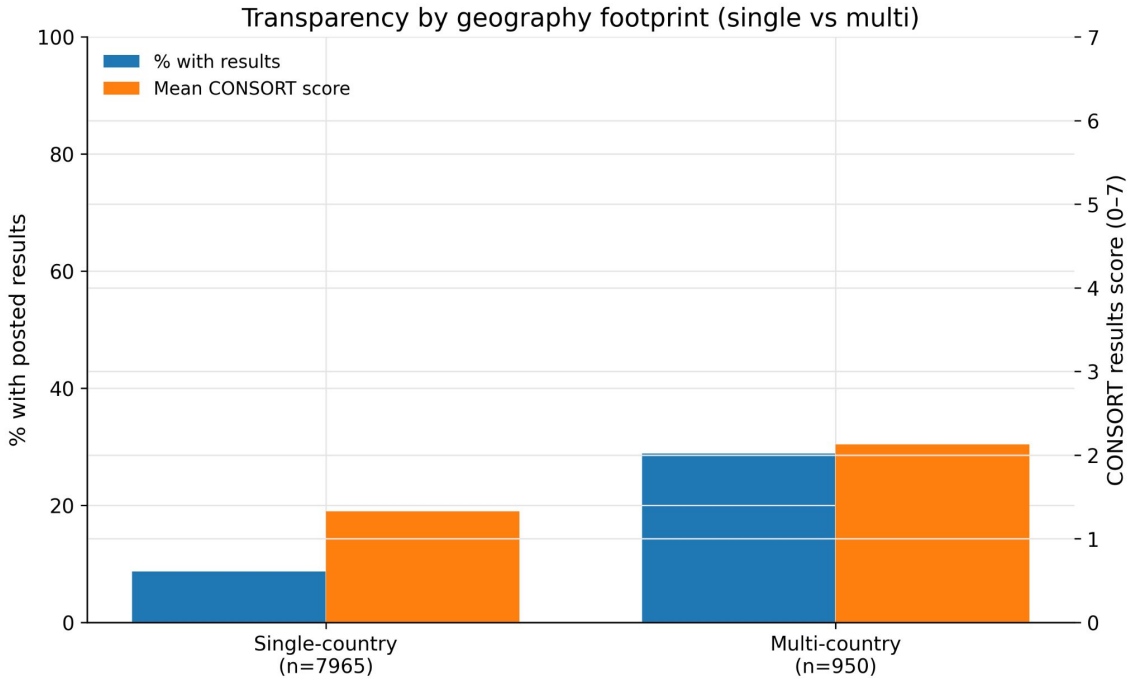
However, a small proportion of studies demonstrate substantial geographic expansion, with the 95th percentile reaching approximately 45 sites and rare outliers exceeding 1,500. This uneven distribution suggests that large-scale international networks remain the exception rather than the norm.

Over time, network size has contracted. In the early 2010s, the upper decile of trials operated across 80–90 sites, but by 2025, the equivalent figure had fallen below 10. This shift likely reflects a transition towards precision-targeted therapies, smaller molecularly defined populations, and an increasing use of decentralised or adaptive designs that reduce dependence on large physical networks.





Transparency and Collaboration Footprint



International collaboration emerges as a key driver of transparency and data completeness. Among 8,915 total breast cancer trials, only 950 involve multiple countries, yet these studies perform significantly better in reporting and disclosure.

Roughly 29% of multi-country trials have posted results compared with just 9% for single-nation studies. They also achieve higher quality of reporting, with a mean CONSORT score of 2.13 versus 1.33.

This pattern suggests that broader geographic engagement is associated with stronger regulatory oversight, enhanced accountability, and greater scientific transparency.
Multi-country trials not only expand patient diversity but also set higher reporting standards, bridging the gap between global collaboration and public trust in trial outcomes.

Conclusion and Reflections

Over fifteen years of breast cancer clinical trial data reveal a research landscape that has expanded in ambition but remains uneven in transparency and accessibility. While the total number of trials has grown sharply, gaps persist in result disclosure, endpoint reporting, and multi-country collaboration.

Our analysis leveraged Large Language Models (LLMs) to automatically extract, harmonise, and interpret complex trial data. This approach allowed for standardisation of free-text fields, identification of hidden reporting trends, and automated scoring of CONSORT quality indicators, insights that would otherwise require months of manual review. By integrating natural language reasoning, the analysis captures both quantitative precision and contextual nuance, making evidence more interpretable for clinical, academic, and policy audiences.

Beyond analytics, this project serves as part of a wider commitment to Breast Cancer Awareness. Each visualisation underscores the collective responsibility to improve research transparency, equitable access, and data integrity, so that every trial, regardless of location or sponsor, contributes meaningfully to patient outcomes.

As the field evolves toward more personalised and global research, combining data science with human-centred ethics will be essential to closing the gap between innovation and accountability.