Seamless Global Execution of Biosimilar Trastuzumab

DiagnoSearch enabled smooth execution of a complex biosimilar program across Phase I (Australia) and Phase III (India), delivering high-quality outcomes through tailored IWRS, fast eligibility verifications, and complete clinical oversight—culminating in expedited product approval.

Situation and Challenge

A global sponsor initiated clinical development of a biosimilar Trastuzumab across two distinct phases:

- Phase I in Australia
- Phase III in India

The program spanned 34 sites and 236 subjects, requiring seamless integration of operations across regions, along with:

- Rapid subject eligibility verification
- Complex IWRS setup for stratified dosing
- High-quality data and documentation aligned with regulatory timelines
- Full-spectrum services across monitoring, data management, and project oversight

Our Solution

DiagnoSearch deployed an integrated, multi-regional team to deliver:

- Comprehensive project management, monitoring, data management, and regulatory coordination
- A custom-built IWRS system tailored to dosing and stratification needs
- Eligibility verifications completed within 2 business days, minimizing site delays
- On-schedule execution of recruitment, site monitoring, and data cleaning
- Real-time collaboration and centralized oversight to keep milestones on track

Results and Impact

- All study milestones met—including recruitment, site activations, and final data submissions
- Regulatory approval achieved within a shortened timeframe
- Seamless coordination across two regions and phases demonstrated DiagnoSearch's ability to:
  - Execute complex, multi-phase studies with precision
  - Adapt technology to protocol-specific needs

- Align trial operations with regulatory strategy
- Deliver results through speed, flexibility, and scientific rigor

Preview Version

Multi-Phase Trastuzumab Trial Across Australia & India

236 Subjects | 34 Sites | Early & Late Phase | Accelerated Approval

DiagnoSearch supported a biosimilar Trastuzumab program from Phase I in Australia to Phase III in India, delivering clinical and operational excellence across continents. With adaptive IWRS, real-time verification, and full-spectrum services, the study met all milestones and achieved swift regulatory clearance.