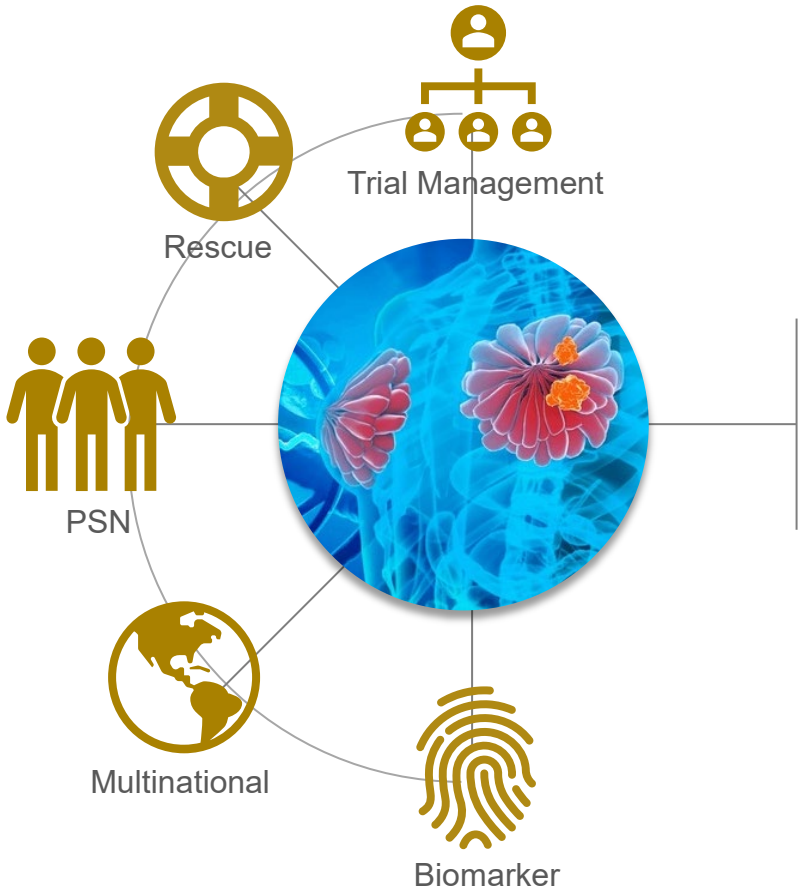
# RESCUE, REGISTRATIONAL Case Study: Phase 3 Randomized, Parallel, Multi-Center Study of Patients with Locally Advanced or Metastatic Breast Cancer




**Situation:**

This Phase 3, randomized, double-blind, multi-center trial evaluates the efficacy and safety of an investigational agent compared to physician's choice of treatment in patients with germline BRCA-mutated, locally advanced or metastatic breast cancer. All participants had previously received chemotherapy for metastatic disease. The study aims to determine whether the investigational therapy offers a clinical advantage in a genetically defined, treatment-experienced population.

**Precision Services:**

- Full-Service Trial Management

**>430**
Patients

**>140**
Sites

**FDA**
Approval from P3

# Registrational Phase 3, PARPi Breast Cancer Case Study: Randomized, Parallel, Multi-Center, Rescue

Project included Phase 2 moving into Phase 3 trial

- Rescue trials with Precision managing three CROs
- Precision had involvement in CSR process
- Key success factor was to ensure sites understanding of the unique mechanism of action (i.e. locking PARP enzyme activity and trapping PARP at site of DNA damage)
- FDA approved of PARPi for mBC for genetic mutation based on Phase 3 trial
- EU Marketing authorization granted soon after FDA approval

## DEMOGRAPHICS

- Patients with Locally Advanced or Metastatic Breast Cancer
- Phase 2: France, Germany, Spain, UK and USA
- Phase 3: France, Germany, Spain, UK, USA, Australia, Belgium, Brazil, Ireland, Israel, Italy, Poland, Russia, South Korea, Taiwan, Ukraine, 140+ sites
- 430+ enrolled

## SERVICES PROVIDED

- Full Service Trial Management

# Lessons Learned in Biomarker-Driven Phase 3 Metastatic/Locally Advanced Breast Cancer

- **Precision/ Sponsor Experience:** Key Opinion Leaders (KOLs) and access to the patient population played a critical role in getting the trial on track after rescue
  - Relationships open critical doors in testing new drugs, especially in an IP vs SOC situation
- **Precision Site Network:** Established relationships and predictable start-up processes enabled us to move quickly
  - We leveraged our site relationships to activate sites very soon after rescue
- **Pharmaintelligence Databases:** For this trial, site-level competitive landscape/experience was just as important as trial staff.
  - Thanks to our site relationships, we could up and running quickly but we also had easy access to information regarding the competitive landscape for our target population
- **Health Informatics Data Networks:** This was a biomarker driven trial with targeted therapies. We needed to match the patient based on genomic sequencing data
  - Ready accesses to databases with genomic sequencing data was a vital time saver in identifying patients

## TAKEAWAYS

- For niche populations, access to KOLs can help access the target patient population.
- Having an established site network made it easy to identify where the opportunity was greatest
- Trial success doesn't happen in a bubble. While trial staff makes a real difference, site-level experience and competition have a measurable impact on enrollment.
- For biomarker-driven studies, leveraging established health informatics data networks can streamline the biomarker identification/patient identification process