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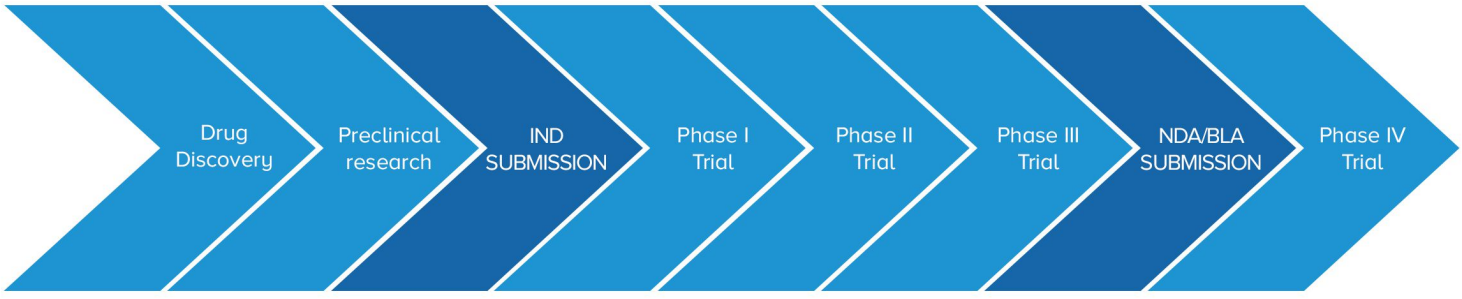
# Olaparib

## An overview of PARP inhibitors in Oncology Clinical Trials

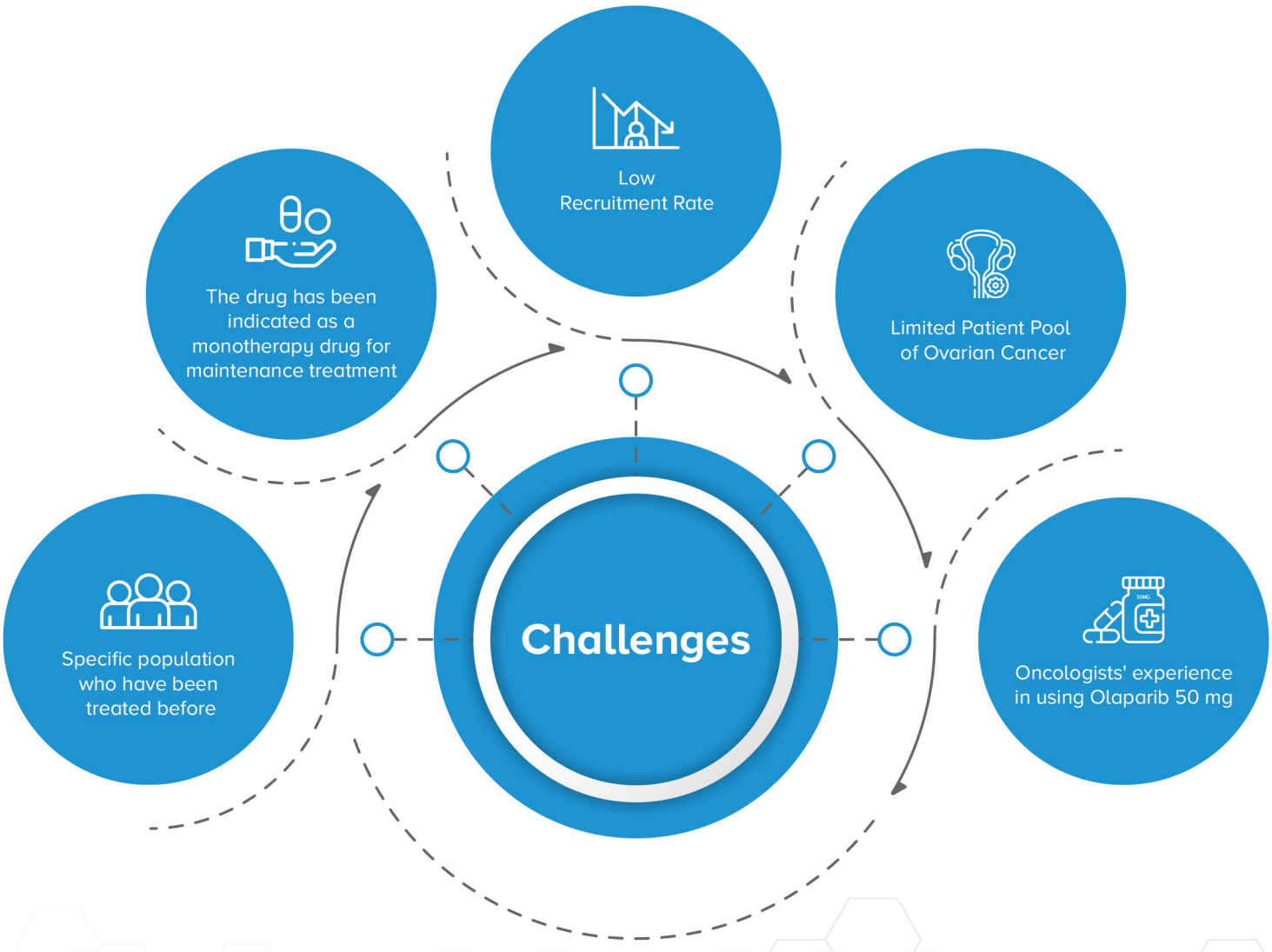
**We are now supporting you through all the stages in a drug development continuum**



# Exploring the potentialities of Olaparib drug in treating Cancer

Olaparib is the first functional PARP inhibitor drug to be licensed for clinical use and a 150 mg tablet is indicated for the treatment of Advanced Ovarian Cancer, Metastatic Breast Cancer, Pancreatic & Prostate Cancer. The discovery of this drug conveys the promise of synthetic lethality in cancer treatment. The drug is a PARP (Poly - (ADP ribose) polymerase) disrupting drug used as a maintenance treatment drug for Cancers induced by BRCA-1 and BRCA-2 mutations.

## Challenges in conducting Olaparib Clinical Trials



# Key Strategies for Effective Olaparib Trials

## Effective Site & Investigator Selection

Our extensive investigator database includes highly trained and experienced personnel with a proven track record in diverse Oncology studies. We carefully evaluate each investigator's expertise, experience in Ovarian Cancer research, and site capabilities to ensure the highest quality of data collection and patient care

## Robust Study Design

Our clinical team invests significant effort in establishing clear primary and secondary endpoints that align with the study's objectives. We meticulously determine treatment duration and patient follow-up plans to track the drug's long-term effects

## Adverse Event Monitoring and Management

Participant safety is paramount in any clinical trial. Our dedicated Pharmacovigilance team works closely with investigators to develop a comprehensive plan for monitoring and managing adverse events (AEs). By employing advanced safety reporting systems and continuous monitoring, we promptly address any AEs, ensuring participant safety

## Collaborative Data-centric Approach

At Veeda, collaboration and data-centricity are central to success. Our clinical data management team plays a crucial role in ensuring data accuracy, completeness, and adherence to regulatory standards. By using advanced data analytics and statistical methodologies, we generate reliable results and facilitate data-driven decision-making

## Regulatory Compliance and Quality Assurance

Our CRO adheres to all applicable regulations and guidelines to ensure data integrity and patient safety. Rigorous quality assurance processes are in place to monitor study conduct, data collection, and reporting, mitigating risks and maintaining the credibility of trial findings

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**300+** Ovarian Cancer Patients Enrolled

**25** Proven and successful Regulatory Audit record (FDA & AGES)

**180+** Metastatic Breast Cancer Enrolled

**>300** Experienced investigators in conducting Oncology Clinical Trials

**>55** Investigator Sites for Oncology BE Studies

## Medical Monitoring in Oncology Trials

- Medical Management Plan (MMP)
- Medical Data Review Plan (MDRP)
- Site Interaction
- 24-Hour Medical Coverage
- Review of Laboratory Parameters
- Review of Patient Listings
- Medical Teleconferences
- Medical Review

## Recruitment & Regulatory Plan for Success

Choose study specific sites according to study design

Site staff training prior recruitment

Educating patients about study methods with hightransparency

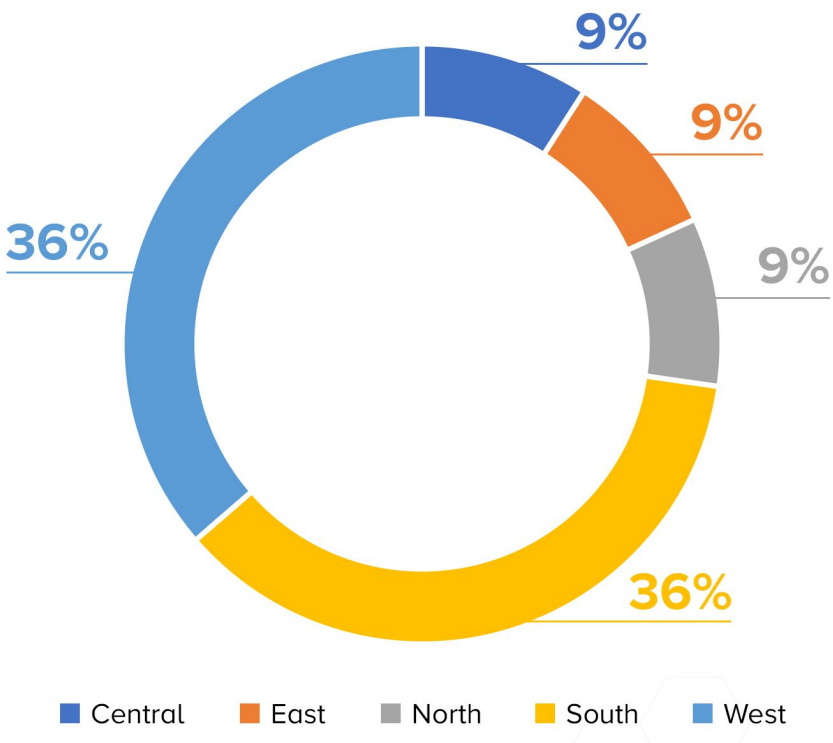
Effective and transparent client communication

Construct detailed protocols with great attention to practicality and feasibility

# Our Recruitment Approach

- Our past patient track record shows average recruitment rate for BE studies in Ovarian Cancer (1 Patient/Month) & Metastatic Breast Cancer (0.75 Patient/Month)
- Training of investigators and study teams during site initiation visit
- Continuous follow up with sites for ongoing stabilization of patients and planning randomization of patients
- Working closely with site teams for pre-identified patient database & pre-setting recruitment targets for sites
- Engaging sites & PIs for regular recruitment discussions
- Routine monitoring visit in a frequency of once in a month at each site
- Preparation of monitoring visit reports on CTMS platform

# Veeda's Investigator Site Network



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# Key Differentiators

## Flexible

Tailored solutions for adaptable study design and execution

Agile approach for seamless adaptation to changing circumstances

## Quality & Compliance

Robust systems ensuring data integrity & regularity compliance

Regular audits for adherence to ethical & regulatory standards

## Efficiency

Meticulous planning for streamlined study operations and execution

Advance technologies optimizing processes for efficient study completion

# Streamline your Clinical Trials

CTMS enables Veeda to maintain a centralized, relevant, and up-to-date study and operational database; thus providing users with real-time operational visibility.

- Monitor Site Recruitment
- Automated Alerts
- Robust Reporting Capability
- Site Monitoring
- CRA Visit Colander
- Study Contacts Database

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