Worldwide Clinical Trials | Oncology

Executing Bladder Cancer Trials in a Complex Clinical Landscape

Bladder cancer is the 10th most frequently diagnosed cancer worldwide and the fifth most common in Europe. Men are four times more likely than women to develop the disease, mostly in adults over 55.

In 2022, there were 614,298 new cases globally. Bladder cancer is categorized into **non-muscle invasive bladder cancer, muscle invasive bladder cancer, and metastatic disease**, each requiring tailored clinical and operational strategies.

Robust Pipeline
of bladder cancer trials

Global Footprint

- Programs across North America, Europe, and Asia-Pacific

Study Experience

- 20 Genitourinary oncology trials; 10 bladder cancer trials
- **9 active programs** across Phase II and III
- Real-world data capabilities, including a **2,000-patient Bacillus Calmette–Guérin (BCG) registry study**

Site Experience

- >100 urology and uro-oncology sites

Regulatory Maturity

- Multiple registrational-pathway trials
- One program advanced toward a **Biological License Application** in 2025

We Understand
the nuances of bladder cancer trials

Specialized Site Partnerships

- Community urology practices and Large Urology Group Practice Association groups
- Society of Urologic Oncology networks
- Uro-oncologists at leading academic centers

Operational Challenges We Navigate

- **Intravesical therapy delivery** via catheter, with variability in retention and tolerance
- **BCG shortages** affecting eligibility and timelines
- **Oncolytic virus investigational product** requiring specialized handling
- **Procedure-related adverse events** common to catheter based treatments but generally manageable

Key Endpoints

- **Recurrence-free survival, disease-free survival, event-free survival**
- **Secondary outcomes**: reduced cystoscopy or need for transurethral resection of bladder tumor

Bladder Cancer Trial Expertise

Bladder cancer is a core area for Worldwide Oncology. Our experience spans early-phase proof-of-concept, registrational Phase III, and large observational studies across intravesical therapies, immuno-oncology, targeted agents, and oncolytic virus platforms. Executing these studies requires expertise in catheter based delivery, BCG-related constraints, and recurrence-driven endpoints. Our scientific insight, site relationships, and operational rigor enable high-quality, efficient trials.

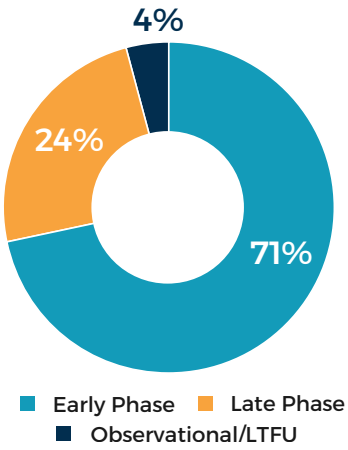
Additional Differentiators

- Flexible solutions & best-in-class technologies
- Data-centric approach with visual analytics & clinical science
- Worldwide Oncology Site Network
- Global Footprint: 4,400+ across U.S., E.U., LATAM & APAC

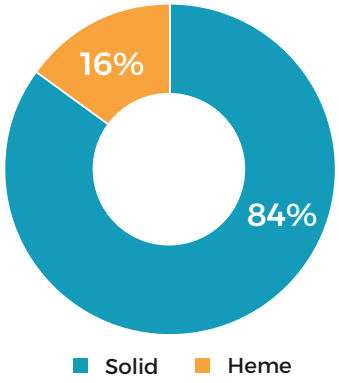
Active Next-Gen Oncology Experience

Working across all phases of clinical development and a range of both solid and hematologic indications, we understand the nuances of complex study designs, novel endpoints, and cutting-edge technologies.

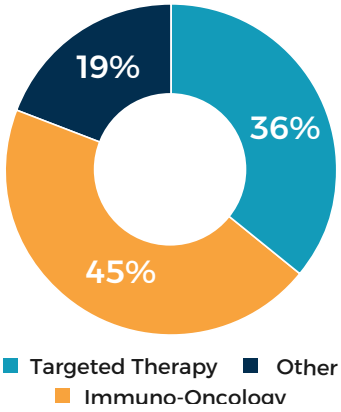
Phase



Indication



Drug Class



Worldwide Clinical Trials

About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a global CRO serving development-driven biopharmaceutical companies, with more than 4,400 professionals operating across more than 60 countries. The company delivers therapeutically dedicated expertise in neuroscience, oncology, rare disease, and internal medicine, with comprehensive support across every development phase – from early-stage and first-in-human studies through Phase III registration trials.

The company's flexible service model – spanning full-service trial management to functional service partnerships through Worldwide Flex – is powered by a people first, partnership driven outsourcing approach that strengthens collaboration, enhances data transparency, and supports more informed decision making. This provides sponsors with tailored, adaptable solutions that keep pace with the evolving demands of clinical research.

Learn more at www.worldwide.com