Worldwide Clinical Trials

Glioblastoma Multiforme

Glioblastoma multiforme (GBM) is a devastating brain cancer with an extremely poor prognosis for patients. With an incidence of about 3.21 per 100,000 people, GBM is the most-common type of CNS tumor. **Its survival rate is approximately 40% within the first year of diagnosis and 17% in the second year.**

Little advancement has been made in GBM treatment in the past two decades. The standard of care is surgery followed by radiation and chemotherapy. However, complete removal of the tumor is difficult. For most patients, the best hope is for a prolonged life with the condition or some improvement in the quality of their remaining life.

A disease with many facets

While almost all GBM tumors recur after first-line therapy, a standard approach to treating recurrent GBM effectively has thus far proven elusive. While recent advancements in the understanding of GBM have revealed potential targets for treatment, there remains ample space for therapeutic developers to explore ways to improve treatment of this aggressive disease.

What we know for sure

We know glioblastoma multiforme does not respond to a one-size-fits-all therapy. With both intra- and inter-tumor heterogeneity, GBM is highly resistant to treatment and is subject to frequent tumor recurrence.

We've learned more. Now we can do more.

The increasing knowledge about GBM complexity creates new opportunities for treatment exploration. Recent research has addressed subtypes of GBM, each with unique mechanisms driving tumor development. With diverse mechanisms of action, we can now explore more nuanced treatment applications.

Our Expertise

225+ Peer-reviewed Journals

400+ Global Oncology Experts

300+ Enrolled Patients

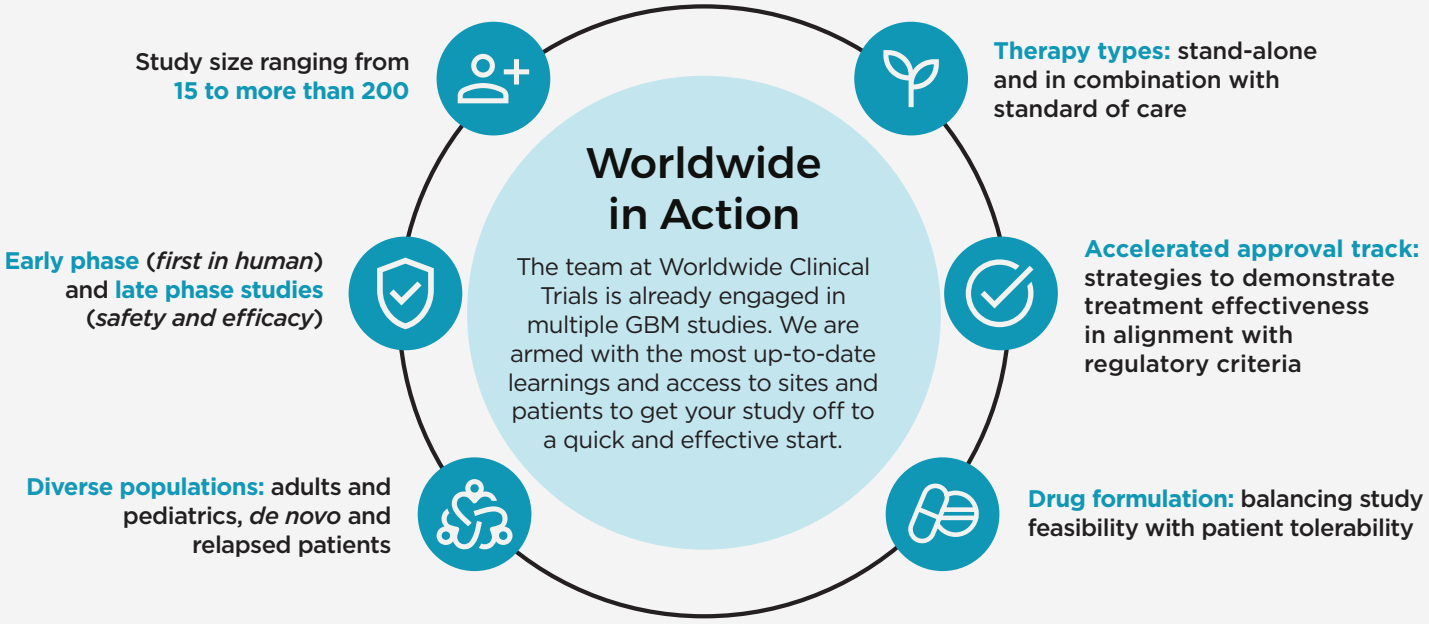
ISR reports

Rated Overall Top Performer

Budget Factors | Delivery Factors
Staff Characteristics | Accessibility
Services | Customer Loyalty

From diverse mechanisms of action to novel treatment combinations and modes of administration, exciting new therapeutic possibilities abound for GBM.

Immuno-oncology | Novel chemotherapies | Anti-angiogenic therapies | Device-based treatments



What you need to know

You have the science, and now you're ready to work with patients. Before embarking on your GBM clinical trial, be sure you've got your bases covered.

- Do you intend to combine your novel treatment with standard of care? Modes of administration must be compatible with other ongoing treatments.
- Does your study strike the necessary balance between compelling endpoints and patient tolerability? Your successful trial needs your patients to be willing to enroll and to be able to sustain their participation.
- Do you have the input of professionals with in-depth experience with GBM in the clinical setting? Ongoing expert guidance can help you avoid unnecessary pitfalls through the course of your study.
- Is your protocol compatible with regulatory considerations? Your study endpoints should be established strategically to answer the specific questions regulators want answered.

GBM Capability

- Worldwide is working with sponsors to drive new mechanisms of action, with the goal of attacking GBM at the subtype level.
- Our unique approach to GBM draws on a holistic and comprehensive set of services, empowering sponsors to make informed decisions faster.
- With capabilities and facilities to support early phase oncology work, we can get your novel therapy from first-in-human through post-market.
- We have neuro-oncologists available on consult to support protocol design with their up-to-the minute knowledge of the patient's experience in the clinical setting.
- Our in-house experts are experienced in oncology, and in GBM specifically, and can adapt to results in real time to take quick, decisive action to keep your study on the right track.

Meet Your Glioblastoma Multiforme Team

As we grow our oncology team at Worldwide Clinical Trials, we are attracting top talent across all indications, and particularly professionals with experience in GBM. Our in-house experts are driven by scientific curiosity and a personal commitment to helping this underserved patient population.

Gary E. Fishbein, M.D., MPH

Executive Medical Director, Oncology Therapeutic Area Lead, Medical Affairs

Gary Fishbein is Executive Medical Director and Oncology Therapeutic Area Lead at Worldwide Clinical Trials. A fellowship-trained medical oncologist, he worked in hospital practice and with a biotech company before moving into leadership in the CRO context. He has more than 15 years of experience as a CRO medical director and has monitored oncology trials across all phases of development. In addition to his clinical work, he is highly engaged in training and mentoring the next generation of clinical researchers.

Aleksandra Stańczak, PhD

Senior Director, Project Management

Dr. Stanczak brings almost 20 years in global preclinical and Phase 1 clinical research in laboratory and project management roles for CROs and pharma. Co-authoring almost 10 publications, she has experience with cancer biomarkers and targeted therapies for solid tumors and bladder, gastric, and non-small cell lung cancers.

Jim Eamma

Senior Director, Project Management

Jim's work in therapeutic development spans more than two decades and includes work in academic, clinical, and CRO settings. With first-hand experience in large, global, multi-site oncology clinical trials, he knows intimately the many moving parts that keep a study on track. An accomplished oncology investigator and project manager, he brings a pragmatic and effective approach to project management, ensuring our sponsor partners receive high-quality service and effective study execution.

Jana Knezevic

Associate Director, Project Management

Jana has more than 12 years of experience in oncology and a personal commitment to improving treatments for cancer patients. She has honed her expertise in clinical leadership and trial management in CRO, sponsor, and academic contexts. In her current role, she provides oversight and leadership to the project team while engaging at all levels to ensure our sponsors received top service within targeted timeline and budget.

Bioanalytical Lab Services

- 2,500 LC-MS/MS assays developed, including marketed oncology drugs
- Deep expertise in molecularly targeted anti-cancer agents (e.g. kinase inhibitors)
- PK/PD relationships in animal anti-tumor efficacy studies
- Regulated bioanalysis in GLP-Toxicology studies of both large and small animal studies
- Experience in pharmacokinetics data analysis
- Quantitation of cytotoxic payloads of antibody-drug conjugates (ADCs)
- Assays for relevant biomarkers in oncology (e.g., CEA, CA-125, PSA, p-MEK, p-ERK)
- Multi-analyte assays, including metabolites
- Radiolabeled AME (absorption, metabolism, and excretion) oncology studies
- Biomarkers for both patient stratification and pharmacodynamics, including peptides, proteins, and phospho-proteins
- Bioanalysis (tumor, tissues, CSF, synovial fluid) for site-of-penetration and target organ studies
- Novel platforms available for therapeutic antibodies (SISCAPA and nSMOL)
- Microsampling, including plasma microcapillaries and dried blood spot analysis
- Chiral separation and quantitation of enantiomers

Reference

https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme

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Whatever the size or complexity of your GBM study, the team at Worldwide Clinical Trials stands at the ready to provide service and advice that's customized to your unique needs

For more information on how we can partner with you to support your clinical trial, please contact us.