Clinical Development Partner
Linical

THE HERO PROJECT

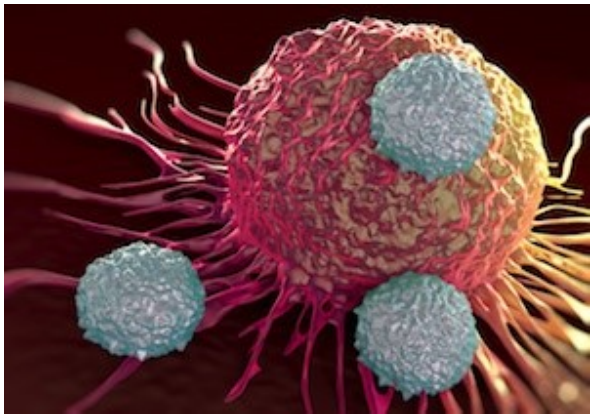
Driving Early Phase Cancer Research Forward

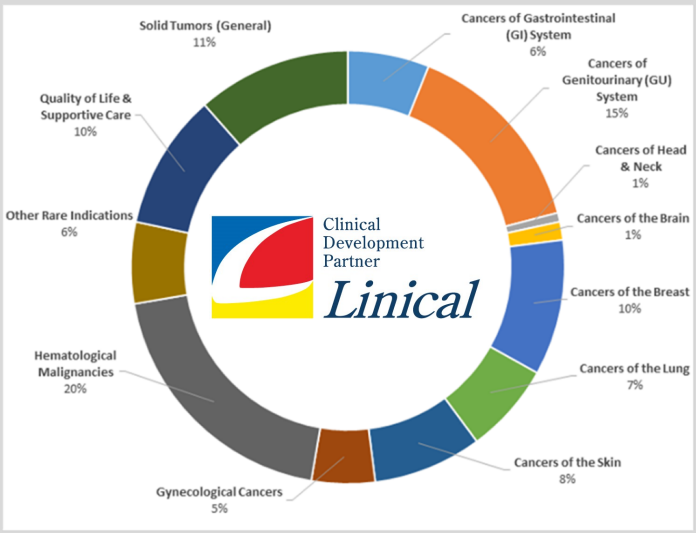
Overview:

HERO (Helping Early Research in Oncology) is the solution to your oncology and hematology research needs. Linical Accelovance determined that Sponsors needing phase I/II oncology assistance have not been well served by the CRO sector. The larger CROs are not attentive to smaller studies, while small niche CROs can lack the advantages and global reach available at Linical Accelovance. It was from this unmet need that we developed the HERO Project. HERO provides:

- Phase I and II Solutions
- Dedicated Oncology-Focused Teams
- Rapid Start-Up
- Pre-Negotiated Site Agreements
- CFR Part 11 Compliant Systems

HELPING
EARLY
RESEARCH in
ONCOLOGY





Types of Oncology Work / Therapies:

Linical Accelovance has experience in supporting sponsor development of many types of cancer therapies and programs of varying complexity, including:

- Immune Checkpoint Modulators
- Cellular Immunotherapies
- Oncolytic Viruses
- Peptide Vaccines
- Bispecific T-Cell Engagers
- Adoptive Cell-Based Research
- Adaptive Study Methodologies Including Basket Study Design

People:

Linical Accelovance's solution consists of project teams that are trained in conducting traditional oncology studies, as well as immuno-oncology and who focus solely on phase I/II studies. Our project teams are built from this pool of oncology specialists and in most cases the teams tend to rotate together providing an experienced, cohesive team.

Linical Accelovance provides executive oversight on each project, and our oncology and hematology experts add value to your program with deep strategic and regulatory expertise. Linical Accelovance will also employ governance boards to facilitate all aspects of development programs.

Systems:

Our HERO systems are an art of integration, specially built for early phase oncology studies to allow for rapid deployment and real-time study data for go/no-go decisions.

- EDC systems live in 4-6 weeks on avg.
- Validated oncology specific CRFs
- Pre-designed patient profile reports
- CFR Part 11 compliant eTMF and CTMS
- Real-time data portal

Sites:

With HERO, you have access to a strong network of oncology focused sites that can be ready within 45 days. HERO is structured to streamline start-up and get your program up and running through:

- Quick-start HERO member sites
- KOL-based sites
- High-enrolling, indication-focused sites
- Pre-negotiated site MSAs
- Expedited budgets and contracts

FULL SERVICE CRO

- Protocol Development
- Project Management
- Vendor Management
- Feasibility & Site Management
- Clinical Trial Monitoring
- Biostatistics
- Data Management
- Pharmacovigilance and Drug Safety
- Medical Monitoring
- Medical Writing
- Patient Engagement Solutions
- Regulatory Affairs, IND Services & FDA Meetings
- Clinical Pharmacology Strategy and Design

Patient Engagement:

We have learned that if you are not marketing your study, it likely is not enrolling. In our experience, marketing your study = positive enrollment. We encourage the production of both patient and site facing marketing plans. Our dedicated Patient Engagement Solutions Group, or PES, is available to provide these services to improve recruitment and retention. The patient facing solutions use novel techniques such as:

- Patient pre-pooling
- Office-based patient engagement
- Social media
- Local outreach
- Digital communication
- Call center initiated reminders
- Study concierge services
- Patient-facing tools
- Memory aids for protocol criteria
- Scheduling reminders

Global Reach:

Linical Accelovance's bandwidth spans across the globe, giving you the global reach you need for your program.

Americas:

- Stuart, FL
- Boston, MA
- New York, NY
- San Diego, CA
- Canada

Asia:

- Japan
- China
- South Korea
- Taiwan
- Singapore

Europe:

- Germany
- United Kingdom
- Netherlands
- Czech Republic
- Spain
- France
- Italy
- Hungary
- Poland
- Romania
- Slovakia
- Portugal
- Austria
- Belgium
- Switzerland

THE HERO PROJECT

Accelerate. Advance. Achieve.
Proven success in your Oncology clinical trial.

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