



- Audited by USFDA, EMA, MHRA, ANVISA, Thai FDA
- **800+ Studies:** Including standard BA/BE and a diverse portfolio of Phase I studies (Biosimilar, Vaccines SAD, and MAD)



- Small and large molecules
GLP certified and USFDA audited
- 700K+ large molecules
analyzed
- 260+ validated methods for
small molecules



- Full-service solution provider from Phase I to Phase IV
- 100+ patient-based studies



- Safety and esoteric investigations
- 1st CAP accredited lab in India
- Validation and development for biomarkers
- 63+ clinical trial projects supported



- Biobanking
- Clinical biomarker validation
- Novel biomaker identification using multi-omics approach
- Organoids / NAM models
- AI / ML integration

© Syngene International Limited, All Rights Reserved



15+ Countries with Strategic CRO Partnerships

Across North America, Europe, and Asia

Comprehensive Clinical Trial Services



Protocol Development



Regulatory Submissions



Early and Late Phase Trial Management & Monitoring



Central Lab Data Management & Biometrics



Clinical Study Reports

Proven Expertise in Delivering Global Clinical Trials

- **35+ Successful Global Regulatory Inspections**
USFDA, EMA, ANVISA, MHRA
- **Therapeutic Breadth**
Across oncology, cardiology, dermatology, rheumatology, nephrology, and more
- **Experience with Diverse Molecule Types**
Small molecules, mAbs, bispecifics, CAR-Ts



200+
Sites

950+
PIs

35+
KOLs

Global Clinical Trials Executed with Precision

End-to-End, Digitally Enabled Delivery Across Regions and Phases



Multi-Region Trial Delivery

Execution of global clinical trials with seamless coordination across India, Sri Lanka, U.S., and EU



Advanced and Complex Studies

CAR-T cell therapy trials, NBE Phase 1 trials, Biosimilar trials, Phase 3 trials across U.S., and India



Digitally Enabled Full Phase Coverage

Supporting a Phase I patient study and a Phase III global trial through a united digital ecosystem integrating EDC, CTMS, ePRO, and centralized ECG, and imaging services