

Syngene

Putting Science to Work

Translational and Clinical Research

Science
For People
**ADVANCING
INNOVATION**

Integrated Capabilities
Connecting Translational
Insights to Clinical Outcomes

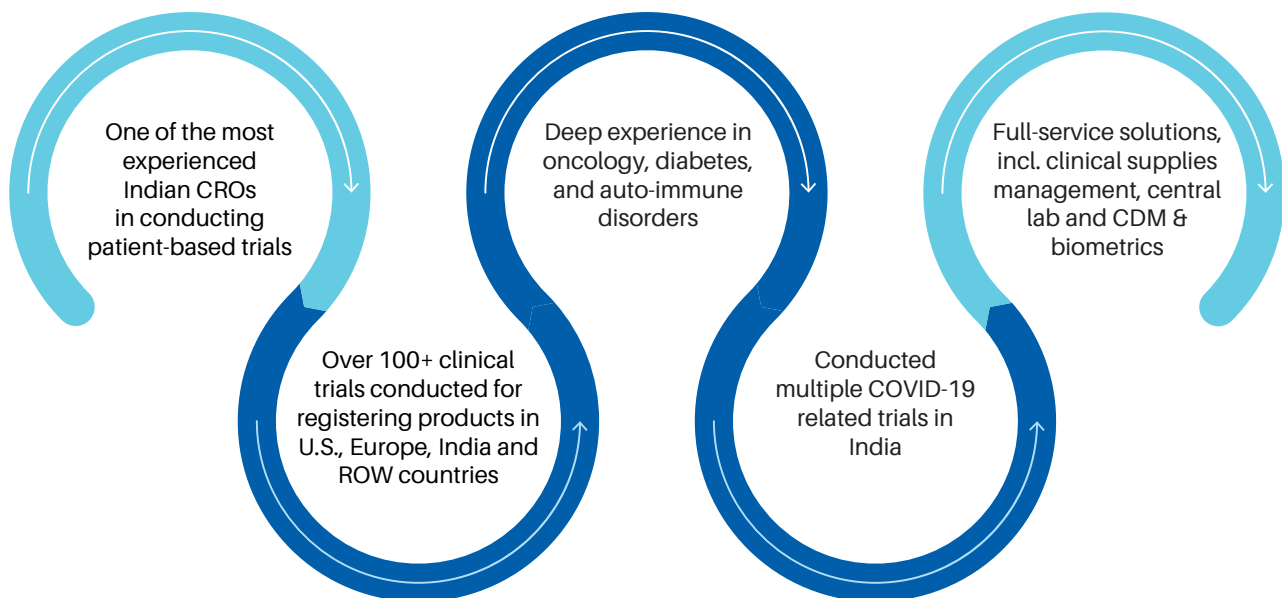


Capabilities

BA / BE and Phase Studies to Support Development of Generic Drugs

- Conducted over 800 BA / BE or PK / PD or phase-1 trials ((SAD & MAD), DDI studies, food effect studies)
- Clinic with 190 ward care beds and 12 ICU beds
- Over 260+ validated methods available as per USFDA guidelines
- Total mass specs: 10 [API 4000s and API 6500s]
- State-of-the-art instrumentation [with qualification]
- Analysis of drug(s) and / or metabolite(s) in biological specimen [e.g. blood, plasma, serum, human aqueous humor etc. to support TK<PK, early phase clinical, BA / BE and TDM studies]
- Team of 30 qualified and experienced researchers with experience in method development, validation and regulated bioanalysis for a wide range of chemically diverse drug molecules

Clinical Trial Management (Phase I-III Trials) of Novel Drugs and Biosimilars



Central Laboratory Encompassing Clinical / Safety Lab and Bioanalytical Services for Small Molecules and Biologics

- CAP accredited central lab offering clinical testing services exclusively for phase I-IV clinical trials and BA / BE studies
- FDA inspected bioanalytical lab offering PK services
- 21 CFR Part 11 compliant laboratory information management system with customizable project management and reporting capabilities
- NABL (ISO15189)
- Supported over 100 NDAs / BLAs
- Fit for purpose – Specialty biomarkers
- Technology platforms – Flow cytometry, ELISA, PCR etc
- Assay capabilities – Cell based assays, PCR and molecular diagnostics, ELISA, ELISPOT
- PD and exploratory analysis



Regulated Bioanalytical Lab for Large Molecules

- 15 biologic molecules approved by USFDA and EMA, based on the bioanalytical data submitted from this lab
- Experience with 7 biosimilars, 50+ monoclonal antibodies and few vaccines
- 700,000+ samples imported (from various parts of the globe) and analysed till date, with a track record of zero compromise on sample shipment
- Existing customers include 5 of the top 10 big global pharma/biotech companies and 1 of the top animal health companies
- 18+ years of rich and diverse experience
- Adept at method transfer, development and validation based on FDA / EMA / WHO guidance
- Influenced favourable change in Indian govt's policy on import of biological samples for testing – no wait period for license, ~4 - 6 days sample travel time from US / EU, no wait period for clearance from customs, expedited reporting can be handled, especially for dose escalation studies requiring 1 week TAT



Clinical Data Management and Biometrics

- Stand alone or integrated data management for phase I - IV studies
- Statistics and SAS programming for clinical and non-clinical development programs
- Data acquisition: Web based through in-house eCRF, Paper CRF based data capture

Translational Science



High throughput drug screening assays on organoids / PDX platform



Biomarker discovery and validation studies in clinical samples



Access to well annotated bio-samples (tumor tissue, blood, plasma, FFPE) with ethical and regulatory compliance



Strong partnership with hospitals, clinics and third-party organizations



Integration of wet lab data to bioinformatics analysis using AI-ML integration



Companion diagnostic development using our comprehensive translational platform

Regulatory Track Record

- Audited by major life sciences Co's & regulatory agencies from North America and Europe
- Certifications / accreditations: ISO 9001:2008, 14001, OHSAS 18001, AAALAC, GLP
- HPU & small molecule bioanalytical labs are inspected by

USFDA - 11 audits

EMA - 4 audits

Thai FDA for GLP - 2 audits

ANVISA - Brazil - 4 audits

UK-MHRA - 1 audit

- Regulatory track record for regulated bioanalytical lab for large molecules

USFDA - 1 audit

PMDA - 1 audit



Notes

Notes

About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated CRDMO (Contract Research, Development and Manufacturing Organization), serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's ~6000 scientists bring the skills and capacity to deliver great science, strong data security, and quality manufacturing, at speed, helping improve time-to-market and lower the cost of innovation. This is backed by ring-fenced dedicated centers, as well as ~3 Mn sq. ft. of specialist discovery, development, and manufacturing facilities.

For more details, visit www.syngeneintl.com or write to us at bdc@syngeneintl.com