Syngene

Putting Science to Work

Translational and Clinical Research

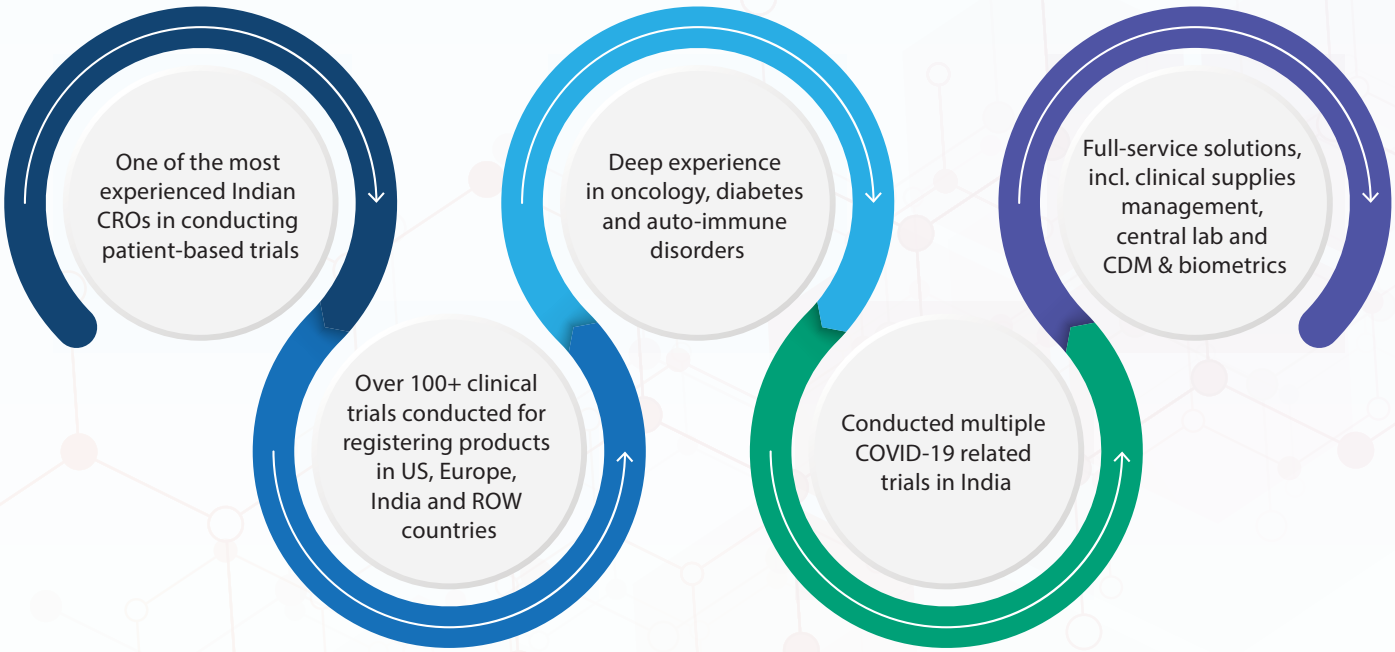
Innovate | Integrate | Customize | Accelerate

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



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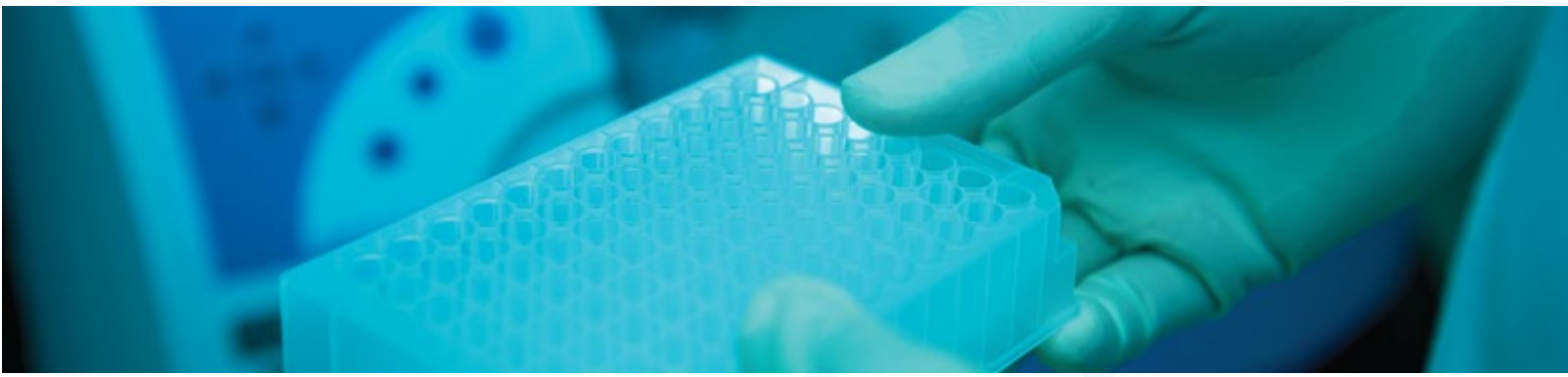
Central laboratory encompassing clinical/ safety lab and bioanalytical services for small molecules & biologics

- CAP accredited central lab offering clinical testing services exclusively for phase 1-IV clinical trials and BA/BE studies.
- FDA-inspected bioanalytical lab offering PK services
- 21CFR-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- Flowcytometry, 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 throughout 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

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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:
  - US-FDA – 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
  - US-FDA – 1 audit
  - PMDA – 1 audit

Notes

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Notes

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About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's 5000+ scientists offer both skills and the capacity to deliver great science, robust data security, and quality manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Baxter, and Bristol-Myers Squibb, as well as 2.2 million sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis, and Merck KGaA.

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

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