Syngene

Putting Science to Work

Clinical Development

Innovate | Integrate | Customize | Accelerate

Clinical Development

Capabilities

Human Pharmacology studies to support early phase development of novel drugs, vaccines, biosimilars and generic Drugs

- In-house phase-1 clinic with 190 beds – inspected by EMA and USFDA
- Completed over 750 phase-1 or PK-PD equivalence or Bioequivalence studies
- Over 240+ validated methods available as per USFDA guidelines
- Total Mass Specs: 11 [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 etc.] to support TK< PK, early phase clinical development, BA/BE and TDM studies
- Team of 45 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, Vaccines and Biosimilars

- One of the most experienced Indian CROs in conducting patient-based trials
- Over 100 clinical trials conducted for registering products in US, Europe, India and ROW countries
- Deep experience in Vaccines trials and in Oncology, Diabetes and Auto-immune disorders
- Full service solutions, incl. Clinical Supplies Management, Central Lab and CDM & Biometrics

Central Laboratory

- CAP accredited Central lab offering clinical testing services exclusively for Phase 1-IV clinical trials and BA/BE studies

Regulated Bioanalytical Lab for Large Molecules

- Developed serology, surrogate Nab, Pseudovirion Nab, T-cell for cytokines, T-cell for cell surface marker assays for anti-SARS-COV2 vaccine research
- Developed PK and ADA assays for a COVID-19 Mab therapeutic antibody
- More than 15 years Method Transfer, Development and Validation (FDA/EMA/WHO) experience with LBAs
- Supported key vaccine developing by generating seroconversion and immunogenicity data for qHPV and Malaria
- Scientific capability to develop validate multiplex assays for protein vaccine candidates
- Strong collaborations with CDC, NIH and other international non-profit organizations for vaccine research
- 5 blockbuster MAbs approved by USFDA and EMA, based on the bioanalytical data submitted from this lab
- Experience with 7 Biosimilars, 22+ Monoclonal Antibodies
- 600,000+ samples imported (from various parts of the globe) and analyzed till date, with a track record of Zero compromise on sample shipment
- Existing customers include 5 of the top 10 global Big Pharma/Biotech companies and 1 of the top Animal Health companies
- Influenced favorable 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 – Oracle clinical / Inform
- Paper CRF based data capture - Oracle

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 & Bioanalytical labs are inspected by:
    - US-FDA – 9 audits
    - EMA – 3 audits
    - Thai FDA for GLP – 2 audits
    - ANVISA – Brazil – 2 audits
    - UK-MHRA – 1 audit

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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 more than 5200+ scientists offer both skills and the capacity to deliver great science, robust data management and IP 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 Amgen, Baxter, and Bristol-Myers Squibb, as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK and Merck KGaA.

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

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