ALTASCIENCES
CLINICAL SERVICES

Gastrointestinal Disorders

Our Experience

- Over 100 Phase I/II PK or PD studies involving drugs acting locally in the gastrointestinal (GI) tract or systemically:
  - Antacids and mucosal protective agents
  - Gastric antisecretory (anti-H2 and PPIs)
  - GI motility (cisapride and cisapride-like)
  - Dissolution of gallstones
  - Inflammatory bowel disease treatment
- Pharmacokinetic assessments on locally acting drugs despite the low bioavailability of the drug
- Assessment of GI pharmacodynamics response using:
  - Measurement of intra-gastric pH
  - Rectal biopsy
  - Visceral pain model using the barostat method to assess rectal distension and rectal sensory threshold
  - Endoscopy
  - Colonoscopy
- Full clinical pharmacology program for a new prokinetic agent from FIH to DDI; and renal impairment

Case Studies

- A Study to Evaluate the Effect of SYN-004 on the PK of IV Ceftriaxone in Adults With a Functioning Ileostomy
- An interaction study Evaluating the Effect of Esomeprazole on SYN-004 Degradation of Ceftriaxone In Adults With an Ileostomy
- A study to evaluate safety, tolerability and pharmacokinetics of trimebutine 3-Thiocarbamoylbenzenesulfonate (GIC-1001) in a randomized phase I integrated design study: single and multiple ascending doses and effect of food in healthy volunteers
- A Phase 1b Clinical Study on the Analgesic Effect of NCE on Visceral Pain under Rectal Distension and Rectal Sensory Threshold using the Barostat Method in Male and Female Healthy Volunteers
- A study to evaluate the effect of food and formulation on the relative bioavailability of bismuth biskalcitrate, metronidazole and tetracycline given for Helicobacter pylori eradication

Patient Access

- **250+** patients with ileostomy
- **250+** patients with ulcerative colitis
- **250+** patients with Crohn's disease
- **700+** patients with irritable bowel syndrome
- **4000+** patients with gastroesophageal reflux disease (GERD)
- Searchable database to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use and BMI

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Clinical Expertise

- Medical expertise and the support of a gastroenterologist with 20+ years of experience in Phase I/II clinical research
- Administration of different types of formulations (oral, suppository, rectal gel, enema, gastro-retentive capsule, etc.)
- GI condition assessment techniques such as endoscopy, colonoscopy, radiology and X-ray imaging with barium, barostat, microbial and intragastric pH measurement
- Experience with swallowability and palatability assessment

Support Services

Bioanalysis

- Bioanalytical capabilities are supported by over 100 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories
- High throughput bioassays for drug quantitation (operating 24/7), capacity of 60,000 samples per month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

Medical Writing

- Team with over 20 years of experience
- Study design in line with current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- Team with over 20 years of experience
- Electronic Data Capture
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Biostatistics

- All Programming done using SAS®
- Randomization list
- Statistical Analysis Plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data e.g. safety lab
- Creation of CDISC-compliant FDA submission-ready package

Updated August 2019.

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