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
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

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