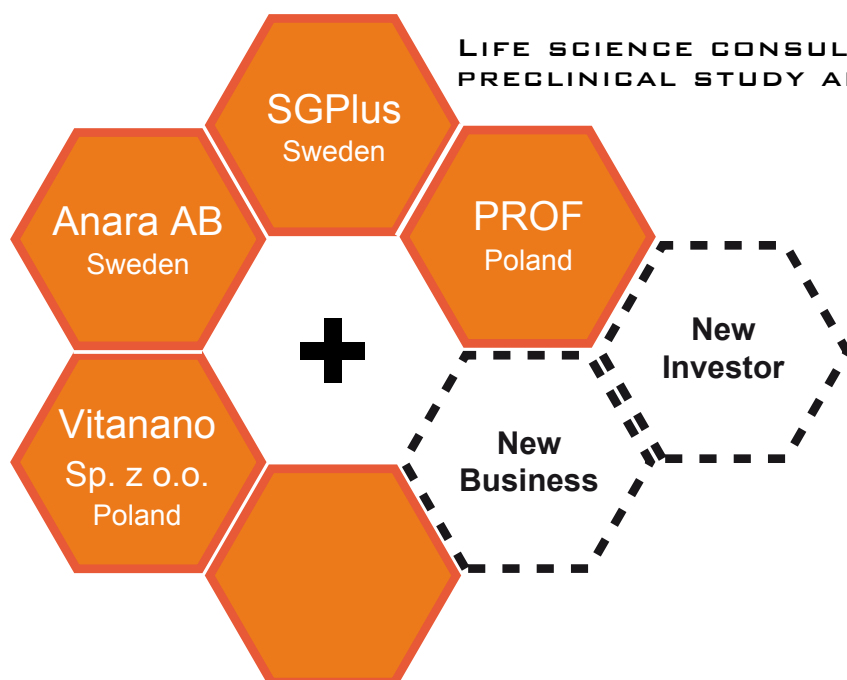


SGP+GROUP

LIFE SCIENCE CONSULTING,
PRECLINICAL STUDY AND RESEARCH



www.sgplus.se

SGP Group offer

01

- Preclinical Unit for 80 large animals (metabolic cages and incubators available)
- Thirty studies conducted between the years 2005 and 2019
- All studies were performed in compliance with relevant laws and guidelines (EMA / FDA)
- Actual time for Ethics Committee approval from protocol receipt 30 days
- Actual time to site ready from protocol receipt 45 days
- Staff involved in the studies are selected from a pool of researchers, worldwide, who are highly experienced with regards to translational studies
- Scientific board composed of Swedish, American, Danish and Polish universities/ research institutions, among others, as well as commercial organization experts to provide guidance with regards to the general operations of the unit and to oversee all sponsor-oriented decisions
- Prepared for Sponsor's audit and Regulatory inspection

Access to

02

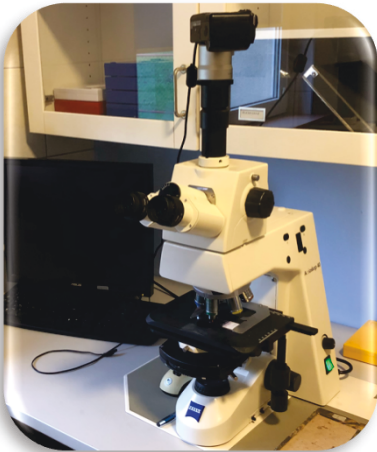
- Diagnostic laboratory
- Surgery room
- CT
- Histopathological laboratory with immunohistochemistry equipment
- Genetic laboratory with next generation sequencing, FISH and other technologies
- Cell growth laboratory
- In vitro laboratory



Main Equipment

03

- Spectrophotometers, HPLC, IEC, PCR
- Medical scales, Centrifuges, Freezers (-20°C, -80°C)
- Light microscope
- Confocal microscope
- Laminar flow
- Chromatograph
- Surgical equipment for small and large lab animals (mice, rats, pigs, dogs, sheep)
- Metabolic cages for rats / mice and pig / dogs / sheep of different sizes, ranging between 5 –100 kg
- Artificial sow system – suckling pigs
- Temperature, humidity and light control system



Human resources

04



- Administrative manager
- Project manager
- Laboratory coordinator
- Data manager
- Investigational Medical Product coordinator
- Medical writer
- Veterinarian
- Surgeons
- Anesthesiologist
- Qualified and trained trial-specific team from different European Universities
- Staff on site that are well trained with regards to PoLLASA, IATA, SW and FELASA research principles relating to animal research

- Internal SOPs (administration, monitoring & auditing, AE reporting, data management, carrying out the research studies, animal surgery, animal care etc. – work in progress)

Quality
05

Preclinical trial experience

06

- Non-clinical efficacy evaluation
- General toxicology (non-GLP)
- Safety pharmacology
- Pharmacokinetics and pharmacodynamics
- ADME study
- Experimental surgery
- Innovative – explorative studies

Our animal models

07

- Pancreas as a single organ: relationship between the endocrine and exocrine pancreatic function in sheep, cattle, pigs and rats
- Short reflexes: Cholecystokinin (CCK) stimulation of the exocrine pancreas via short peptidergic reflexes originating in the duodenum
- Animal growth: relation to development of the pancreas and gut function
- Local gut inflammation model
- Induction of precocious gut maturation
- Absorption of macromolecules from the gut and lungs
- Lymph visceral and thoracic duct flow in pigs, sheep and rats
- Jugular, portal, hepatic and mesenteric vein, as well as abdominal arteries catheterization in rats and pigs
- Pancreatic and bile secretion model in pigs and rats
- Visceral and extra-corporal circulation in pigs, sheep and goats
- Skin circulation / perfusion in goats
- H. pylori model in mice
- Nephrectomy (9/10)/ ovariectomy and gastrectomy in rats and pigs
- Exocrine pancreatic insufficiency (EPI) pig model
- Diabetes type I and type II / Metabolic syndrome – pig model
- Global and focal cerebral ischemia / Infant hypoxia model in rodents
- Preterm pig model
- Anodontia model in neonatal pigs
- Medical materials testing (implantology/stomatology/oral surgery) in rats, rabbits and pigs
- Myoelectrical activity of the gut and uterus – pig model

Industry cooperation

08

- Gramineer Int SE: osteoporosis – alpha keto glutarate (AKG)
- Solvay Pharm GE: EPI – exocrine pancreas insufficiency (EPI) – pancreatic enzymes (Creon)
- Arexis AB SE: lipid digestion / absorption, retardation of brain development, milk formula supplementation of neonates – bile salt stimulate lipase (BSSL)
- Alnara Pharm Ltd USA: cystic fibrosis (CF) – microbial pancreatic like enzymes (Liprotamase) formulation (amylase, lipase, protease)
- Biovitrum AB SE: lipid digestion / absorption, retardation of brain development – milk formula supplementation for neonates – bile salt stimulate lipase (BSSL)
- Addisseo SAS FR: amino acids feed supplementation – methionine
- Essentys AB SE: osteoporosis – alpha ketoglutarate (AKG)
- Grespo AB SE: age-related degenerative brain changes / Alzheimer – microbial pancreatic like enzymes / AKG
- Alcresta Ltd USA: necrotizing enterocolitis (NEC), food liquid formula fat pre-digestion – devise RELIZORB
- Allena Param USA: hyperuricemia (gout) / hyperoxalemia (kidney stones) – microbial uricase / oxalodecarboxylase
- Polpharma Ltd PL: schizophrenia – aripiprazole
- Synspira USA: CF – microbial pancreatic like enzymes (New Creon)
- JHJ Ltd PL: intrauterine growth retardation (IUGR) in pigs – AKG
- Biolek Ltd PL: weaning diarrhoea – phytohemagglutinin (Suilectin)
- Foundation for Mother's Milk Bank PL: human milk for experiments on preterm pigs

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