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#RESEARCHNEVERSTOPS

CLINICAL SERVICES PLATFORM

- Fully integrated drug development services supporting preclinical and clinical needs, up to regulatory approval and commercial phases
- Integrated API development and manufacture
- Integrated formulation support, with a broad range of oral dosage forms using conventional and bioavailability enhancing approaches
- Clinical supply suitable from First in Human to Phase III, fully GMP-compliant and with capacity to handle active ingredients classified up to OEB5 (OEL>0.5 $\mu g/m^3$)
- Sample management and bioanalysis supporting both chemical and biological analytes
- Pharmacokinetic (NCA, PBPK, population PK) and statistical analysis
- Metabolism to identify and select human metabolites for future monitoring
- Quality unit to support GxP regulations

AREAS OF EXPERTISE

API	FORMULATION DEVELOPMENT	CLINICAL SUPPLY	SAMPLE MANAGEMENT – BA	PK & STATISTICAL ANALYSES	METABOLISM

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Drug Substance
Development of synthetic route and processes suitable for clinical supply from Phase I to Phase III and commercial manufacture.

Drug Product
- Development and GMP manufacturing of a broad range of dosage forms suitable for oral and inhaled administration.
- Expertise on oral availability challenges.

Sample Management
Timely checking of clinical samples, generation of Laboratory Manual, support for clinical centres with shipment of clinical PK and/or PD kits for sample collection/storage and an offer for long term storage of biological samples at -20/-80°C.

Bioanalysis
Providing precise and timely data using state-of-the-art facilities and instrumentation, performing method development, validation and sample analysis to measure drug and metabolite concentrations in matrices, including plasma, serum, cerebrospinal fluid (CFS), urine, broncoalveolar lavage, sputum and a wide range of tissue homogenates. Our comprehensive services can be performed on small or large molecules including: monoclonal antibodies, oligonucleotides, peptides and proteins.

PK and Statistical Analysis
- NCA, PBPK, population PK, PK/PD and statistical analysis designed to meet the specified clinical study objectives, with input provided at protocol drafting stage where required. Fully validated software and processes allow delivery of robust and reproducible data analysis, fully audited and reported for regulatory submission, whilst dose escalation studies can be supported with fast turn-around options for pre-defined parameters. Data driven iterative modelling can be untertaken, as well as predictions for special populations or to address DDI concerns/study requirements.
- Standardisation of pharmacokinetic concentrations and pharmacokinetic parameters data to the CDISC format in accordance with CDISC SDTM requirements (PC and PP domains).

Metabolism
Structural identification of human metabolities in both plasma and urine clinical samples.

Clinical Trial support
Evotec can assist up to PoC with clinical study design, project management, selection of Phase I clinical units and clinical CROs for data management and monitoring.