



**ALTASCIENCES**  
CLINICAL SERVICES

# Infectious Diseases

Altasciences is a leading full-service clinical pharmacology CRO with an expertise in the management and conduct of infectious disease early drug development programs. We have completed over 140 studies on treatments for infectious diseases in patients or healthy participants. The studies have covered a multitude of therapeutic indications, such as hepatitis B and C, influenza, HIV, pneumonia, septicemia and fungal infections.

ANTIVIRALS	ANTIBACTERIALS	ANTIFUNGALS	VACCINES	PARASITES
<ul style="list-style-type: none"><li>• Hepatitis B</li><li>• HIV</li><li>• Hepatitis C</li><li>• Influenza</li></ul>	<ul style="list-style-type: none"><li>• Pneumonia</li><li>• Traveler's Diarrhea</li></ul>	<ul style="list-style-type: none"><li>• Onychomycosis</li><li>• Tinea</li><li>• Candida</li></ul>	<ul style="list-style-type: none"><li>• Influenza</li><li>• Rabies</li><li>• Cholera</li><li>• Clostridium difficile</li></ul>	<ul style="list-style-type: none"><li>• Ringworm</li><li>• Tapeworm</li></ul>

## Clinical Expertise

- Experience with adaptive, umbrella first-in-human designs involving healthy participants and patient arms
- Design and conduct of proof-of-concept studies
- Support services including customized protocol design, data management, bioanalysis, biostatistics and reporting
- Ability to administer medication via multiple routes – including intravenous (bolus or infusion), intranasal, intramuscular, subcutaneous and ophthalmic

## Patient/Participant Access

- **500+** patients with Hepatitis B Virus (HBV) infection
- **5,500+** patients with Hepatitis C Virus (HCV) infection, genotypes 1, 2 and others
- Access to hospital-based research facilities and their experienced staff, set up for viral or parasite challenges in healthy participants
- Searchable database to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use, and BMI
- Access to vendors for viral load, viral genotype, bacterial identification and microbiome analysis
- Access to industry experts: virologists, gastroenterologists and infectious disease regulatory specialists
- Purpose-built clinical pharmacology units to accommodate long-term stays

[contact@altasciences.com](mailto:contact@altasciences.com)  
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## Studies and Experience

- A Phase Ib study evaluating GS-7340 in Treatment-Naive Adults with Chronic Hepatitis B (CHB) Infection
- A Phase Ib study evaluating GS-9620 in virologically suppressed subjects with Chronic Hepatitis B Virus Infection
- A Double-Blind, Randomized, Placebo-Controlled, Single and Multiple-Dose Ranging, Adaptive Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Antiviral Activity of GS-9620 in Treatment-Naive Subjects with Chronic Hepatitis B Virus Infection
- A Single and Multiple Dose Study of MK-3682 (IDX21437) in Healthy and Hepatitis C Virus (HCV)-Infected participants (MK-3682-001)

# 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