Revalia Bio

Liver Drug Delivery & Distribution Study Package

Where does the drug go?

QUESTIONS THIS STUDY ANSWERS

- How much of the drug is retained in the liver, and where does it concentrate?
- How fast is drug cleared, and what does it metabolize into?
- Which route and delivery parameters give the best exposure?
- Which dose and delivery method will be the best translation to first-in-human?

WHAT THIS STUDY LETS YOU DECIDE (EXAMPLES)

- Carry a lead forward using functional human organs
- Optimize the delivery route and dose
- Optimize candidates to reach the target tissue

Core Study

Organ Viability & QC

- Comprehensive donor EMR screening
- Baseline functional perfusion assessment (lactate clearance, bile production*, hemodynamic stability)
- Baseline histopathology

Functional Assessments

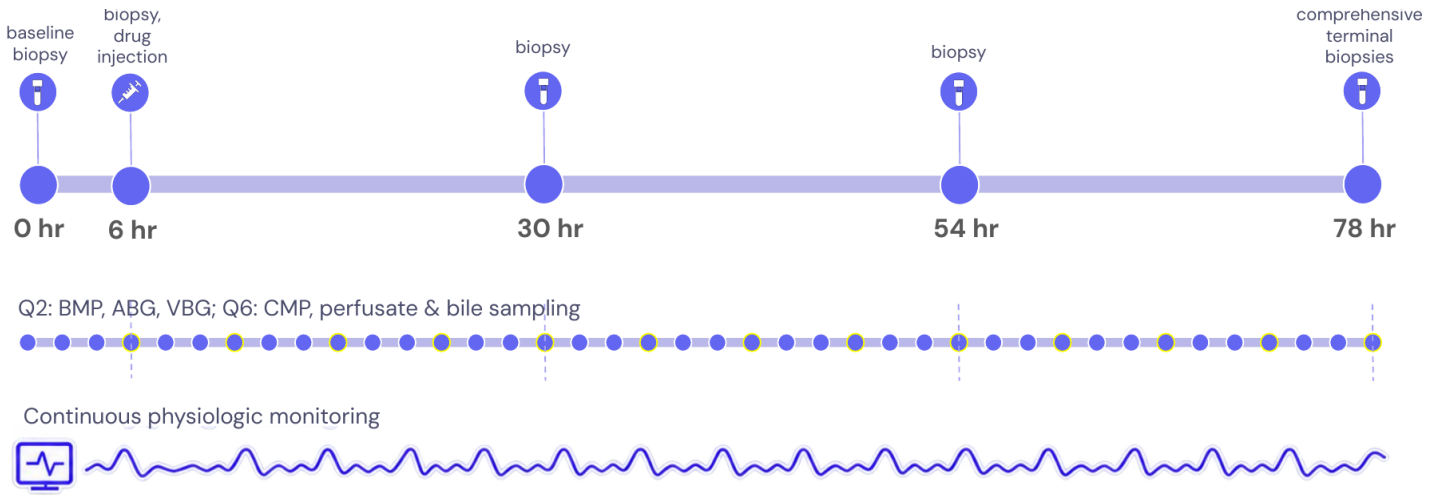
- Continuous hemodynamics
- Basic Metabolic Panel (BMP)
- Arterial/Venous/Portal Blood Gas
- Comprehensive Metabolic Panel (CMP)
- Histology assessments

Delivery & Distribution

- Standard intravenous, intra-arterial, or portal delivery procedures
- Dynamic drug measurements in perfusate, bile*, and tissue (mapped by region)
- PK analysis and readout

bile may not be produced in all cases

Protocol snapshot



0-6 hr QC validation window.

Go beyond our standard offerings for a study design tailored precisely to your needs, with Enrollment, Protocol and Delivery upgrades plus custom assays.

Bring us the question. We'll deliver the data.
Book a first study design session at **revaliabio.com**

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Liver Drug Delivery & Distribution, Assessments & Expansions

Core study assessments

Baseline functional perfusion assessment	Lactate clearance, bile production*, hemodynamic stability, VO2
Continuous hemodynamics	Hepatic artery and portal vein* flow and pressure
Basic Metabolic Panel	Glucose, calcium, sodium, potassium, chloride, bicarbonate, BUN, creatinine
Arterial Blood Gas / Venous Blood Gas	pH, pO2, pCO2, SaO2, SvO2
Comprehensive Metabolic Panel	ALP, ALT, AST, total protein, total bilirubin

Dynamic drug measurements (dependent on modality)

Small molecule or peptide	Arterial, venous, portal, and bile* drug concentration–time profiles by LC-MS/MS, Drug measurements in tissue, by region by LC-MS/MS, PK analysis and readout
Oligonucleotide	Arterial, venous and bile drug concentration–time profiles by LC-MS/MS, Drug measurements in tissue, by region by LC-MS/MS, PK analysis and readout
Viral vector or lipid nanoparticle	Perfusate vector genome concentration–time by qPCR, Vector genome copy number by organ region by qPCR, Transgene mRNA by RT-qPCR

Study expansions

Enrollment Upgrades	• Priority Enrollment Status • Targeted Donor Enrollment with Disease Specific Cohorts**
Protocol Upgrades	• Custom Assay upgrades • Custom Sampling Protocols (outside of standard protocol) • Custom Perfusate Additions (e.g. addition of complement) • Total Perfusate Exchange • Extended Perfusion
Delivery Specific Upgrades	• Custom Device Training & Integration • Real-Time Fluoroscopy-Based Delivery Assessment • Additional Sensors Installed (e.g. Delivery Specific Pressure Measurements) • Delivery Optimization

**bile may not be produced in all cases*

***Disease-specific cohorts may extend time to donor enrollment*

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