Revalia Bio

Liver Early Efficacy Study Package

Does the drug do what you intend?

QUESTIONS THIS STUDY ANSWERS

- Does your drug engage the target you designed for?
- Does engagement change how the organ functions?
- Does the effect translate in the disease state your patients have?
- What dose range elicits the response you intend?

WHAT THIS STUDY LETS YOU DECIDE (EXAMPLES)

- Confirm target effect in human tissue before a clinical biopsy is possible
- Relate exposure to response and choose a dose range
- Judge whether the mechanism produces a functional organ response

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

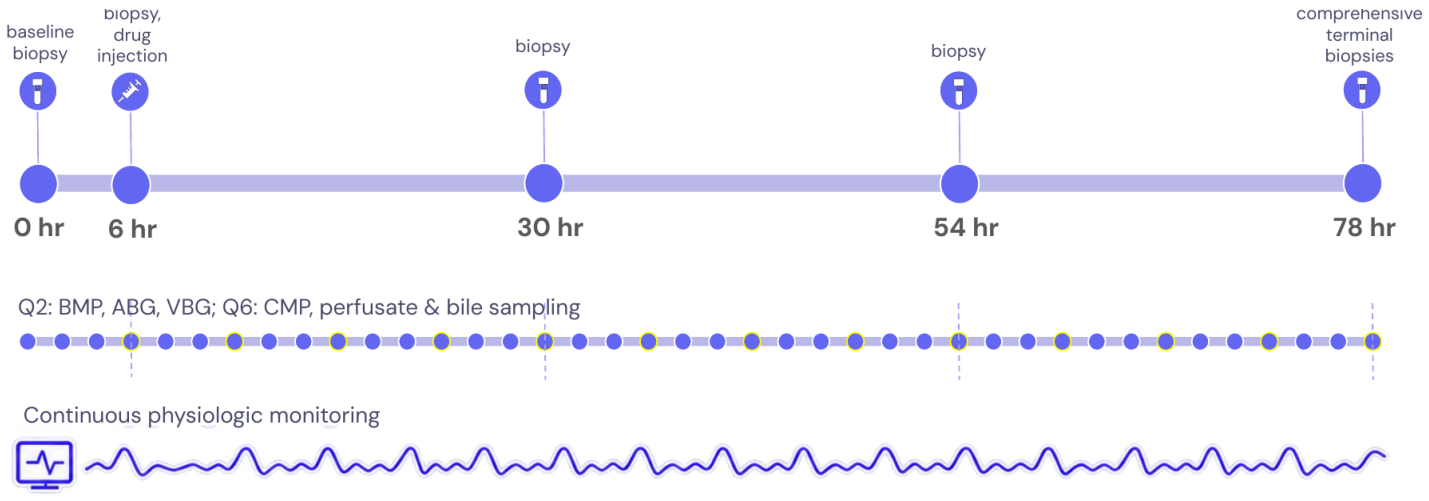
- Standard intravenous, intra-arterial, or portal delivery procedures
- Dynamic drug measurements in perfusate, bile*, and tissue (mapped by region)
- PK analysis and readout

Target Effect

- A single qualified, target-specific assay developed with your team
- Transcriptomic or proteomic profiling

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.

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Liver Early Efficacy Package, Assessments & Expansions

Core study assessments

Baseline functional perfusion assessment	Lactate clearance, bile production*, hemodynamic stability, VO2
Continuous hemodynamics and function	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
Target-specific Assay	(choose one) ELISA, qPCR, IHC, Immunofluorescence, Fluorescent *in situ* hybridization for DNA, RNA, or both (RNAscope platform)
Transcriptomic (or other mono-omic) profiling	(choose one) Bulk RNA-seq or other mono-omics (lipidomics, metabolomics, proteomics)

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 parent and metabolites, Clearance and metabolite formation profiles, 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 parent and metabolites, Parent compound clearance and metabolite formation profiles, 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 • Custom Substrate or Tracer Challenges • Dose Escalation Study Design
Delivery Upgrades	• Custom Device Training & Integration • Real-Time Fluoroscopy-Based Delivery Assessment • Additional Sensors Installed for 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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Custom assay upgrades

Cell Specific Transcriptomic Profiling	• sc/sn RNA-seq • 10x spatial transcriptomics
Drug Metabolite Profiling	• LC-MS/MS
Targeted Inflammatory Profiling	• IL-1B, IL-6, IL-18, IL-12p70, IL-23, TNFa, MCP-1, MIP-1a, IP-10
Targeted Oxidative Stress Profiling	• Immunofluorescence (3-Nitrotyrosine; 4-Hydroxynonenal)
Kidney-Specific Injury	• KIM-1, Clusterin, Calbindin, VEGF-A, Osteoactivin, TFF3 • Singleplex ELISA (e.g., NGAL in perfusate and urine)
Target-Specific Assays	• qPCR • Immunohistochemistry (H&E, alcian blue, picrosirus red) • Immunofluorescence (CD31, TUNEL, Annexin V, ECAD, Megalin , ASGPR1 , LDLR) • Western Blot • Fluorescent *in situ* hybridization for DNA, RNA, or both (RNAscope platform) • Bulk RNA-seq • Proteomics • Metabolomics • Lipidomics
Urinalysis	• Specific Gravity • Total Protein • Urine chemistry: Sodium (Na), Potassium (K), Chloride (Cl), TCO2, Anion Gap, Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), Creatinine (Crea), Lactate, pH, HCO3-, Base Excess
Bile Acid Profiling	• Bile chemistry: Sodium (Na), Potassium (K), Chloride (Cl), TCO2, Anion Gap, Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), Creatinine (Crea), Lactate, pH, HCO3-, Base Excess • Proteomics • Targeted LC-MS/MS

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