Revalia Bio

Kidney Drug Delivery & Distribution Study Package

Where does the drug go?

QUESTIONS THIS STUDY ANSWERS

- How much of the drug is retained in the kidney, 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 (hemodynamic stability, urine production*)
- Baseline histopathology

Functional Assessments

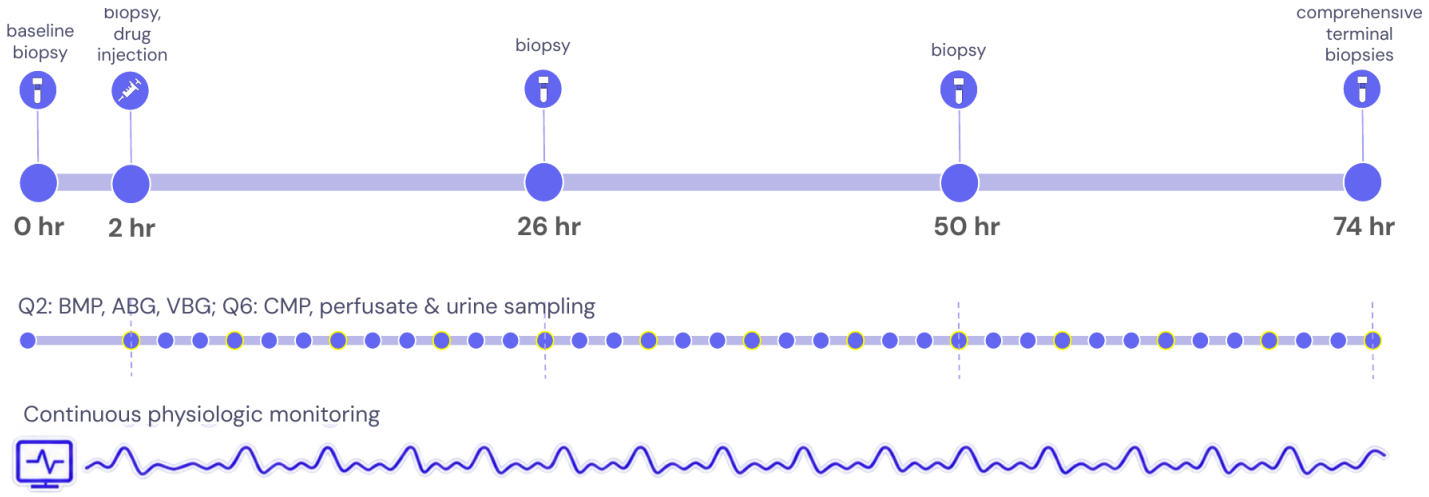
- Continuous hemodynamics
- Basic Metabolic Panel (BMP)
- Arterial/Venous Blood Gas
- Comprehensive Metabolic Panel (CMP)
- Histology assessments

Delivery & Distribution

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

urine may not be produced in all cases

Protocol snapshot



0 - 2 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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Kidney Drug Delivery & Distribution, Assessments & Expansions

Core study assessments

Baseline functional perfusion assessment	Hemodynamic stability, urine production*, VO2
Continuous hemodynamics	Arterial flow and pressure, renal resistance
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	Creatinine, BUN, electrolytes, total protein

Dynamic drug measurements (dependent on modality)

Small molecule or peptide	Arterial, venous and urine* 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 urine* 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** • Paired Kidney Study Design
Protocol Upgrades	• Custom Assay upgrades • Custom Sampling Protocols (outside of standard protocol) • Custom Perfusate Additions (e.g. addition of complement) • Total Perfusate Exchange
Delivery Specific Upgrades	• Custom Device Training & Integration • Real-Time Fluoroscopy-Based Delivery Assessment • Retro-Ureteral Delivery • Additional Sensors Installed (e.g. Delivery Specific Pressure Measurements) • Delivery Optimization

**urine may not be produced in all cases*

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

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