

# Global Preclinical Services

2024

CONFIDENTIAL

Accelerating Medtech Device Innovation with knowledgeable experts, experience, precision and speed.

We employ more than 140 professionals across our North American and European preclinical facilities including 21 full-time veterinary surgeons, imaging specialists and pathologists, 7 study directors, a dedicated training and education team, quality assurance managers, medical writers, laboratory technicians, and more.

Our global team brings deep preclinical medical device expertise to our clients' projects with state-of-the-art facilities and the ability to complete complex surgical and interventional procedures safely, efficiently, and ethically to deliver the increasing evidence required by key stakeholders including regulatory bodies, investors, IRBs and clinical champions.



### **GLOBAL PRECLINICAL SERVICES**

Atlanta, GA, Worcester, MA, Paris, France

### **Accreditations**

- OECD GLP Certified
- CRF 21 Part 58 GLP Compliant
- FDA registered and inspected
- Fully accredited by the French regulatory authorities

- USDA Registered
- DEA Registered
- OSHA compliant
- PHS Assurance

### **Global Preclinical Services Capabilities**

Our preclinical labs have best in class expertise in comparative anatomy, problem-solving capabilities and scientific excellence, and state-of-the-art equipment in 10 hybrid and conventional OR suites

### **Available Equipment**

- CT Scanner
- MRI
- Cardiopulmonary Bypass
- Echocardiography (TTE, TEE, ICE)
- IVUS/OCT
- 3D Fluoroscopy
- Fiberscopes
- Endoscopy Towers
- Mobile C-arms
- Radiography
- PowerLab/ MAC lab
- Laparoscopic Towers
- Autoclave
- ETOH sterilizer

### **Available Models**

- Small animal models
- Swine, Minipgs, Ovine, Bovine
- Human Cadavers
- Heart failure, peripheral vascular and additional disease models

### **Therapeutic Areas**



- Structural Heart Disease
- Interventional Cardiology
- Vascular Intervention
- Electrophysiology and Cardiac Rhythm Management
- Mechanical Circulatory Assist
- Neurosurgery and Neuromodulation
- Targeted Drug Delivery
- Gastroenterology and Urology
- Orthopaedics
- Would Healing
- Opthalmology
- · Maternal Fetal Health

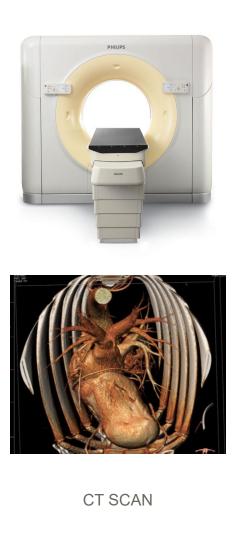
### **Services Offered**

- Proof of Concept
- Acute and Chronic R&D / Feasibility Studies
- GLP-compliant Studies (CRF 21 Part 58 & OECD)
- Surgical, Interventional and BioSkills Training
- Complete In-house Gross & Histopathology Evaluation



## A high-end technical platform











**V-Link** real-time video and data streaming platform

# Broad and Deep Experience





### **Key Figures**

Over **1,000,000** 

Patients treated to date with medical devices validated in our labs

### 3000

Procedures / year

### 800

Implantations / year

### 2500

TAVI to date

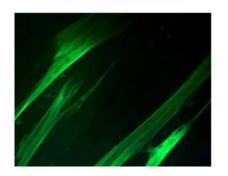
### 1400

TMVR to date

#### 200

TTVR to date



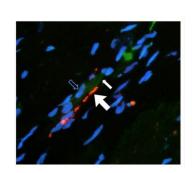
















### Capabilities for each stage of the journey



Veranex has **best-in-class expertise** and is solely dedicated to medical device, diagnostics, drug delivery and digital health innovation.

Product Design & Engineering

Preclinical Solutions

Clinical Research Data Management & Analytics

Regulatory and Quality Systems

Commercial Strategy and Market Access

User needs
 discovery &
 opportunity
 definition

**ACTIVITIES** 

- Human factors & usability testing
- Product definition,design &engineering
- Implementation support

- Early feasibility throughGLP studies
- Conducted in FDA inspected and validated facilities
- BioSkills and investigator training
- Clinical operations, clinical strategy, site support and study design
- Biostatistics
- Medical writing
- Data visualization
- Medical device safety services
- Regulatory, and quality systems consulting for first-of-kind to nextgeneration products
- Global market pricing, reimbursement and market access strategy
- Precision Medicine
- Clinical and economic evidence development and communication
- Market Assessment and Business Strategy

# THANK YOU



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