CBSET:
A LEADER IN THE EVALUATION OF NOVEL DIAGNOSTIC, THERAPEUTIC AND IMAGING TECHNOLOGIES
CBSET

CBSET, Inc. is an AAALAC accredited, not-for-profit, pre-clinical research organization dedicated to research, education, and the advancement of early-stage biomedical technologies. CBSET’s mission is to help our sponsors develop unique tools and new methods to promote early diagnosis and develop innovative treatments for complex diseases. CBSET specializes in the development and application of novel, minimally invasive and surgical techniques in the fields of cardiology, electrophysiology, orthopedics, wound healing, regenerative medicine, endoscopy/laparoscopy, drug and device safety, drug and device delivery, cellular therapy, and diagnostic imaging.

PRE-CLINICAL RESEARCH SERVICES

CBSET provides GLP (Good Laboratory Practice) and non-GLP research services ranging from early product evaluation, through lead optimization and pre-clinical safety, to physician assessment and training. CBSET’s world-renowned regulatory and scientific expertise helps transform early-stage concepts into novel therapies.

STATE-OF-ART BIOMEDICAL FACILITIES

CBSET’s more than 40,000 square foot state-of-the-art facility includes vivariums, catheterization/imaging labs, surgical suites, dedicated labs for SEM, histopathology/pathology, and drug metabolism and pharmacokinetics. CBSET offers the latest equipment for fluoroscopy, echocardiography (TEE/TTE), electrophysiology, IVUS, CT, 3D rotational angiography, optical coherence tomography (OCT), endoscopy/laparoscopy, orthopedic surgery, surgical video recording, histology, faxitron and SEM.
FROM NOVEL CONCEPTS TO MEDICAL REALITIES

CBSET provides research support for all phases of biomedical discovery and development research. CBSET’s specialities include expert preclinical cardiovascular research services and medical device testing.

CBSET’s professionally trained staff of more than 55 FTEs includes PhDs, DVMs and recognized experts in drug and device safety, surgical and minimally invasive surgery, imaging, specialized histopathology and pathology, veterinary medicine, pharmacology, lead optimization, pharmacokinetics and drug metabolism, and regulatory consulting. These individuals provide the basis for successful scientific collaborations, rapid concept advancements, unparalleled consultation services, and expert dissemination of information and findings to regulatory and scientific bodies.
CBSET offers a full range of GLP and non-GLP services, from early product evaluation through lead optimization and pre-clinical safety, to physician assessment and training courses. CBSET offers specialized expertise in cardiovascular device development, endoscopic/laparoscopic procedures, electrophysiology, orthopedic surgery, wound healing, surgery and disease models, metabolism and pharmacokinetics, and histopathology/pathology.

CBSET Expertise

- Stents/balloons
- Catheters/wires
- Heart valve replacement/repair
- Vessel sealing/closure devices
- Electrophysiology devices
- Tissue ablation devices
- Endoscopic/NOTES procedures
- Laparoscopic surgery
- Hernia repair devices
- Wound healing devices
- Cardiopulmonary bypass
- Beating heart technology
- Cosmetic surgery
- Orthopedic devices
- Novel surgical instruments
- GLP training and regulatory consulting

Proof of Concept Studies

CBSET’s experienced team of professionals will help you develop and execute early device and therapy evaluations in the appropriate animal model by providing:

- Expertise developing novel surgical models
- Veterinary oversight for complicated procedures
- Association/affiliation with veterinary surgeons and consultants
- Flexibility in terms of your development needs
- Lab space with minimal technical support, or full study oversight and technical support

GLP Safety and Efficacy Studies

The CBSET facility is AAALAC-accredited and fully compliant with the Good Laboratory Practice Regulations (GLPs) of the Department of Health and Human Services, Food and Drug Administration (Code of Federal Regulations Title 21, Part 58). Staff and senior management are committed to provide the highest quality reports and services to each client.

Expert Consulting

CBSET offers consulting services on all study-related components such as product design and iteration, proof of principal testing, animal model development, animal model selection, surgical and interventional approaches, safety and efficacy testing, novel histology and pathology analyses, key veterinary practices, and overall regulatory strategies. CBSET offers consulting services on all study-related components such as:

- Product design and iteration
- Proof of principal testing
- Animal model development and selection
- Surgical and interventional approaches
- Safety and efficacy testing
- Novel histology and pathology analyses
- Key veterinary practices
- Overall regulatory strategies

Physician Training and Assessment

CBSET provides physician training and assessments in a clinical-grade, state-of-art biomedical research facility. CBSET offers training in:

- Clinical trial investigator training
- Sponsor-run product-specific instructional cases
- Surgeon-to-surgeon training
- Product evaluations

Interventional/Surgical Expertise

CBSET provides expertise in minimally invasive (percutaneous) endovascular access for all types of cardiovascular and peripheral procedures, endoscopic and laparoscopic procedures, and novel procedure development, including:

- State-of-the-art equipment, including GE Innova 2100 Fixed Flat-Panel Fluoro unit with true multi-modality 3D guidance & 3D rotational angiography
- Fully-equipped, configurable surgical suites
- Scientific staff featuring thought leaders with extensive industry experience
Pharmacokinetics/Computer Modeling
Novel drug eluting device designs pose new challenges in their development and regulatory approval. CBSET embraces the full complexity of combination devices, leveraging its expertise in experimental and modeling techniques to study the mechanisms underlying device implantation, elution kinetics, efficacy and safety. Modeling services include:

- Specialized ex-vivo and benchtop models of elution and drug transport
- GLP pharmacokinetics/toxicokinetics
- PK data analysis and reporting
- In-vitro and in-vivo kinetic models for combination products
- Consulting services on the use of mechanistic modeling for educating clinicians and streamlining the regulatory process

Histology/Pathology
The goal of CBSET’s histopathology team is to work together with sponsors and interventionalists to produce the highest quality study results. With your specific project in mind CBSET’s team of experts will assist you in determining options for specimen sampling, preparation and evaluation. CBSET provides a GLP-compliant facility staffed by an experienced team of ACVP board-certified veterinary pathologists and HTL and HT certified technicians. Laboratory capabilities include:

- Small and large animal necropsy
- High-resolution faxitron radiographic imaging
- Tissue trimming and macroscopic imaging
- Paraffin and plastic resin processing, embedding, sectioning and staining
- Microtomy and EXAKT micro-grinding
- Histochemical staining: routine Hematoxylin and Eosin (H&E) as well as special stains (e.g., Verhoeff Elastin Stain)
- Novel histologic method development
- Immunohistochemical staining
- Immunofluorescence staining and imaging
- Scanning electron microscopy (SEM)
- Digital macro and micro image capture

Expert Data Analysis and Reporting
- GLP and non-GLP reporting
- Secure Web-based data and slide review
- Qualitative and quantitative pathology scoring/analysis
- Morphometric analysis
- Interpretation of complex results
- Statistical evaluation
- FDA-compliant reporting
- High-resolution image appendices
FACILITIES TO DRIVE SUCCESSFUL INNOVATIONS

CBSET’s state-of-the-art facilities and equipment are an integral part to achieving regulatory success for your product. CBSET offers unparalleled GLP-compliant facilities, hospital-grade operating rooms and validated equipment to enable successful research trials of your product.

Conference Rooms
CBSET’s conference rooms offer wireless internet, audio and visual transmission directly from the operating room, teleconference capabilities, observation window, private gowning area and lockers, bathroom, and direct access to the surgical suites.

Surgical Suites
CBSET provides state-of-the-art and fully equipped surgical suites equipped with anesthesia machines, ventilators, hemodynamic and airway gas monitoring systems, surgery tables, and hospital grade fluoroscopy systems. Each suite has a dedicated prep and recovery room.

Necropsy Suites
CBSET hosts two dedicated necropsy suites for full tissue harvest and fixation. The suites include downdraft tables, fume hoods for directed ventilation, and direct pass-through windows to the histology laboratory to ensure direct chain of custody for all materials.

Histopathology Labs
CBSET provides dedicated histopathology laboratories, staffed with certified and experienced technologists, and offering a wide range of light microscopy endpoints, including: paraffin and plastic processing, microgrinding and polishing of large devices, routine and special stains and immunohistochemistry.

Housing
The CBSET facility includes 20,000 square feet of housing and has been completely designed to meet all GLP specifications, including, but not limited to environmental lighting systems, temperature and humidity control, controlled water systems, and stainless steel modular housing units. CBSET sets the precedent in multispecies facilities, with accommodations for swine, sheep, calves, rabbits and rodents (mice and rats). CBSET’s facility has received full AAALAC accreditation.

Amenities
Additional amenities available to CBSET sponsors include: benchtop workspace, ADME/metabolism and pharmacokinetics labs, dedicated test article control and retention space, monitored dedicated sample storage, compliant and controlled on-site data storage unit, break rooms and animal welfare amenities.

Equipment
CBSET offers the latest equipment for echocardiography, fluoroscopy, IVUS, CT, 3D rotational angiography, endoscopy, surgical video recording, TEE/TTE, faxitron and SEM, including: fluoroscopy systems, ultrasound systems, Artery Blood Flow Simulation Unit (Flow Loop System), Optical Coherence Tomography (OCT), Olympus endoscopic system, GE Healthcare Centricity CA1000 workstations, GE CardioLab/ComboLab, MicroPace Cardiac Stimulator, Hitachi SEM, Leica automated resin processor, Thermo Shandon paraffin processor, precision sawing, microgrinder, microtome, automated stainers, Olympus stereoscope, microscopes (single and double headed) and digital cameras, and Olympus digital image processing and analysis.