EVALUATION OF DRUG-DEVICE COMBINATION PRODUCTS

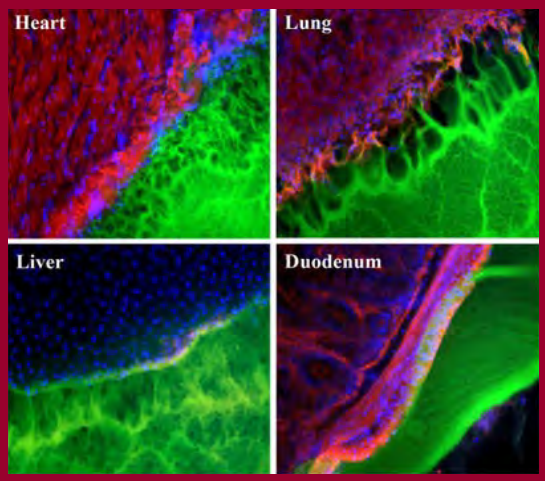
The combination of drugs and devices is an evolving, dynamic approach to increasing safety and efficacy beyond what either the drug or device alone can offer. Addition of a drug to a device can augment device performance by altering the local biological microenvironment to, for example, change cell populations that interact with the device or prevent microbial infiltration. Devices can be utilized to deliver drugs directly, thereby increasing local concentrations and decreasing systemic exposure. Beyond this, the advent of biologics has necessitated delivery methods that bypass the digestive system, and often require prolonged or continuous drug delivery. Novel drug delivery devices, including catheter-based systems, pumps and injection technologies, have begun to uniquely address these challenges, with significant innovation occurring constantly.

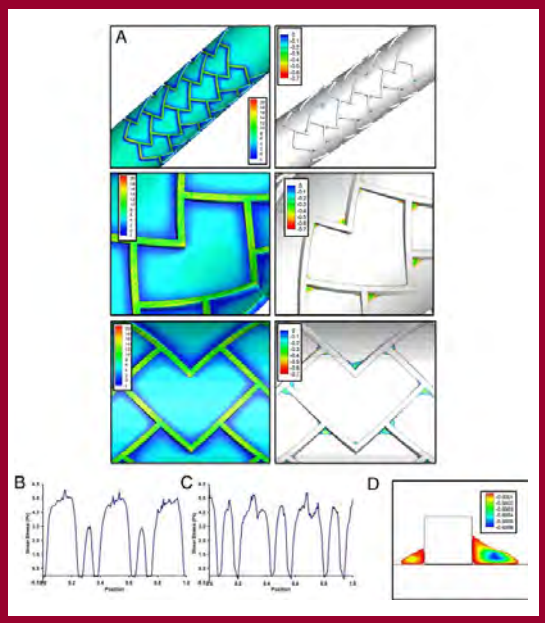
Preclinical evaluation of drug-device products requires intimate understanding of the primary mode of action of the combination product as well as the regulatory requirements governing the approval process for both drugs and devices. In addition, special tools may be needed to evaluate local tissue response, biocompatibility and target organ efficacy in response to drug-device combination products.

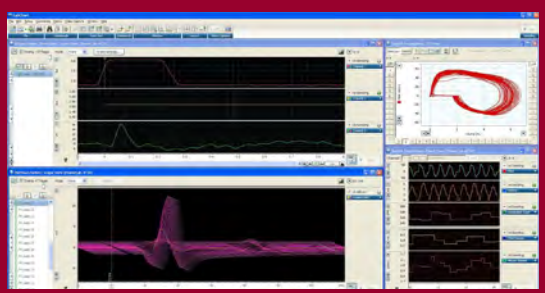
CBSET is a leader in the pre-clinical *in vivo* evaluation and development of novel diagnostic and therapeutic technologies, and can provide support for all phases of biomedical discovery and development research. Our world-renowned expertise in non-GLP and GLP evaluation of small molecule and biologic drugs, as well as medical devices, makes CBSET the ideal partner in the evaluation of your drug-device combination product. CBSET offers expert scientific and regulatory services in various areas including:

- Local and systemic pharmacokinetics
- Pharmacodynamic response in target organs or tissues
- Evaluation of biomarkers of safety and/or efficacy
- Assessment of *in vivo* biocompatibility
- Target or distant organ toxicity
- Evaluation of PK / PD relationships
- Computational modeling of local drug concentration and receptor binding

Beyond this, CBSET's experienced team of professionals will guide you through the necessary preclinical evaluations leading up to clinical testing of your novel drug-device combination product.







ABOUT CBSET

CBSET is an AAALAC accredited, not-for-profit, pre-clinical research organization dedicated to research, education, and the advancement of early-stage biomedical technologies. Our mission is to assist in methodologies uniquely suited for novel and innovative treatments for complex diseases. We offer a full range of GLP and non-GLP services, ranging from early product evaluation through lead optimization and pre-clinical safety, to physician assessment and training courses. We specialize in the development and application of techniques in the fields of cardiology, electrophysiology, orthopedics, wound healing, regenerative medicine, endoscopy/laparoscopy, drug and device delivery and safety, cellular therapy, and diagnostic imaging. Our world-renowned regulatory and scientific expertise helps transform early-stage concepts into novel therapies.

CBSET EXPERTISE

Our professionally trained staff and consultants provide expertise for all phases of biomedical discovery and development research including regulatory consulting, veterinary medicine, surgery and minimally invasive surgery, imaging, pharmacokinetics and drug metabolism, drug and device safety, pharmacology, lead optimization, and specialized histopathology and pathology. 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. Our expertise includes:

- Stents/balloons
- Novel catheters/wires
- Robotic-assisted surgery
- Vessel sealing/closure devices
- Heart valve replacement/repair
- Cardiopulmonary bypass
- Beating heart technology
- Electrophysiology devices
- Tissue ablation devices
- Endovascular/NOTES surgery
- Laparoscopic surgery
- Orthopedic devices
- Novel surgical instruments
- Wound healing devices
- GLP training and regulatory consulting

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CBSET FACILITIES

CBSET offers an unparalleled, GLP-compliant, 30,000 square foot state-of-the-art facility within minutes of Cambridge, Boston, and Logan International Airport. Our facility includes vivariums, catheterization/imaging labs, and full surgical suites containing the latest equipment for fluoroscopy, echocardiography (TEE/TTE), electrophysiology, IVUS, optical coherence tomography (OCT), endoscopy/laparoscopy, orthopedic surgery, and surgical video recording. CBSET offers dedicated labs for GLP-compliant SEM, specialty histopathology/pathology, metabolism and pharmacokinetics

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