The Specialized and Integrated Preclinical Research Institute

Over the past decade CBSET has partnered with more than 400+ MedTech and BioTech companies, including start-ups and industry-leading corporations, enabling them to initiate clinical studies and gain subsequent US and OUS market approvals for their novel therapeutic, imaging and diagnostic technologies.

- CBSET is a not-for-profit research institute headquartered in Lexington, MA, dedicated to research, education, and the advancement of early-stage biomedical technologies. CBSET’s mission is to help medical device and biotechnology companies develop unique tools and new methods to promote early diagnosis of, 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, wound healing, regenerative medicine, endoscopy/laparoscopy, orthopedics, drug and device safety, drug and device delivery, and diagnostic imaging.
- 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-class regulatory and scientific expertise helps transform early-stage concepts into novel therapies.
- CBSET occupies a 40,000-square-foot, state-of-the-art facility that includes a vari-vium, 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, optical coherence tomography (OCT), endoscopy/laparoscopy, surgical video recording, histology, microradiography, and SEM (Scanning Electron Microscopy).
- CBSET’s professional staff includes PhDs, DVMs and recognized experts in device and drug safety, 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 consulting services, and expert dissemination of information and findings to regulatory and scientific bodies.

CBSET has been the preclinical partner-of-choice for 400+ companies.

CBSET opened the doors to its 35,000-square-foot laboratory in November 2006. CBSET is the preclinical research leader in critically important therapeutic fields such as interventional cardiology, renal disease and dialysis, chronic drug-resistant hypertension, women’s health, minimally invasive surgery, orthopaedics, biological and synthetic tissue repair, drug delivery, bioresorbable devices, combination medical devices and drug-eluting products.

CBSET’s state-of-the-art facilities and equipment are an integral part to achieving regulatory success for a product. Indeed, CBSET — Concord Biomedical Sciences & Emerging Technologies — offers unparalleled GLP-compliant facilities, hospital-grade operating rooms and validated equipment to enable successful research trials of novel therapeutic, imaging and diagnostic technologies.

Our mission is to help sponsors develop unique tools and new methods to promote early diagnosis of, and develop innovative treatments for, complex diseases.
WHAT IF there was a way to seamlessly transform early stage concepts into innovative therapies under one roof?

This is the question the co-founders of CBSET asked themselves in 2005... and then proceeded to answer. “It took $10 million and 6 months to build a brand new facility that enabled us to meet our vision of providing all services needed for medical device development within a single organization,” says Peter Markham, CEO and co-founder. It’s been 7 years since CBSET started its operations in November 2006, growing from 15 to 55 employees and establishing perhaps the finest preclinical science facility in the industry. As is typical of start-up companies, the first year at CBSET required all employees to wear many hats. “Everyone was doing everything once we opened our doors in late 2006. It didn’t matter what your title was,” recalls Dr. Adam Groothuis, who was then COO of CBSET. Since 2006, CBSET has added pathologists, surgical veterinarians, specialized in vivo technicians, auditors, and business development specialists as the organization nearly quadrupled in size. “During the last seven years, we added key individuals, technologies, and new services while maintaining momentum and gaining leadership in new scientific areas,” says Markham. “CBSET has certainly realized its mission to be the premier preclinical development company in life sciences,” adds Dr. Elazer Edelman, Chairman and co-founder.

CBSET has an unrivaled biomedical facility to advance cutting-edge preclinical science.

CBSET’s co-founders have set the MedTech gold standard for preclinical science.

Peter M. Markham: CEO and Co-Founder
President and CEO since 2006, Peter has 25 years of management and regulatory experience in GLP contract research. Prior to CBSET, he was general manager of the Worcester/Southbridge division of Charles River Laboratories, a diverse division of more than 440 employees. Previously, he served as a senior executive at Genzyme Transgenics, Primedia, BioDevelopment Laboratories, and Arthur D. Little. He has broad scientific expertise in both drug and device development. Peter is known for his expertise in GLP regulatory compliance, setting and implementing corporate regulatory strategy and policies, and providing leadership and regulatory strategies for novel technologies. He has authored or co-authored numerous original scientific publications.

Elazer Edelman, MD, PhD: Chairman, Co-Founder
Dr. Edelman is the Thomas D. and Virginia W. Cabot Professor of Health Sciences and Technology, and is an attending cardiologist at the Brigham and Women's Hospital. He directs the Harvard-MIT Biomedical Engineering Center (BMEC), dedicated to applying the rigors of the physical sciences to elucidate fundamental biologic processes and mechanisms of disease. BMEC programs span a wide range of disciplines, with its resources made available to investigators from MIT and Harvard. Dr. Edelman has authored or co-authored 226 original scientific publications.

Adam Groothuis, PhD: CBSET Co-Founder
Dr. Groothuis, a director of CBSET, is considered an authority in preclinical science and has advised many medical device companies. Prior to joining Mitralign, he was COO at CBSET, where he was responsible for research in cardiovascular devices and daily operational oversight. Previously, he was Associate Director of the Experimental Cardiovascular Interventional Laboratories at Brigham and Women’s Hospital. He has authored or co-authored 13 original scientific publications and is frequently invited as faculty to national and international congresses.
Butch Stanley, MS, DVM, DACVP
Director, Pathology, CBSET

“Our pathologists employed novel histopathology methods to evaluate the time-course tissue response and pathophysiology of the renal arteries, renal nerves, and kidneys following numerous denervation procedures.”

Peter Markham, CEO, CBSET

“We are proud to have had Vessix Vascular as a Sponsor, providing support for all phases of its biomedical discovery and development research.”

Raymond W. Cohen, Former CEO
Vessix Vascular, Acquired by Boston Scientific, November 2012

“CBSET was our preclinical development partner in the best sense of the word, an integral part of our product’s success.”

James “Butch” Stanley, DVM, DACVP, Director of Pathology for CBSET.

“We were challenged to complete all preclinical development in just eight months, and we did.”

Bullet-proof study design, 140 animals evaluated, exhaustive histopathology, data analysis and reporting... in 32 weeks.

Although the anti-hypertensive drug market is big business ($18 billion annually), about half of hypertensive patients who are on drug therapy do not achieve adequate control of their blood pressure. The door is wide open for more effective hypertension therapies.

“Vessix Vascular came to us with a prototype design looking for our help with animal studies,” says James “Butch” Stanley, DVM, DACVP, Director of Pathology for CBSET. “We were challenged to complete all preclinical development in just eight months, and we did.”

Uncontrolled hypertension is a huge, underserved clinical market in the U.S., where 1 in 3 adults has hypertension, which translates to about 78 million cases.

SPONSOR: Vessix Vascular was the venture capital-backed developer of a novel medical device, the V2 Renal Denervation System™, for the nonsurgical treatment of patients with drug-resistant hypertension.

RENAL DENERVATION: An increase in renal sympathetic nerve activity has been shown to be a significant contributing factor in developing chronic hypertension. Renal “denervation” seeks to interrupt the nerve signals between the kidneys and the brain that control the blood pressure response to certain stimuli. But, how best to “shut down” these nerve fibers located in the renal artery without surgery, and how can we know that the treatment is effective, safe and durable?

CHALLENGE: Reduction of kidney norepinephrine (NEPI) is a critical biomarker for determining the efficacy of renal denervation. But, the analytical hurdles present in quantifying NEPI in the sub-endogenous range are daunting. Physiological levels of NEPI are puny — and NEPI is inherently unstable, subject to rapid metabolic and non-metabolic oxidative degradation. Nevertheless, accurate measurement of a decrease in NEPI after neural ablation is essential to reliably compare novel technologies.

SOLUTION: Addressing complex analytical issues, CBSET had to develop a novel HPLC-MS/MS assay that accurately quantifies NEPI concentrations in porcine kidney tissue. The innovative assay is specific, sensitive, stable, robust, and linear over 3 orders of magnitude; indeed, it has significantly upgraded assay performance and data reliability in the sub-endogenous range, allowing assessment of efficacy and aiding in the differentiation and selection of the best treatment.

What the experts are saying:

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In a news release on November 8, 2012, Boston Scientific announced its intent to acquire Vessix Vascular. Below is an excerpt from the release.

Vessix Vascular was the venture capital-backed developer of a novel medical device, the V2 Renal Denervation System™, for the nonsurgical treatment of patients with drug-resistant hypertension.

In my experience, the system offers ease of use, faster treatment times with decreased patient discomfort and an intuitive approach to renal denervation that leverages the expertise of the interventionalist with balloon catheter technology.