

CELL-BASED THERAPIES

In Vivo Assessment for Cell-Based Therapeutics

Cell-based medicines are being developed for every therapeutic area, each a novel regulatory challenge. CBSET is a non-profit, 501(c)(3) research institute that specializes in the advancement of novel therapies.

Common test articles include:

- Stem cells
- Engineered cell lines
- Autologous strategies
- Engineered tissues and tissue products
- Combination products (implanted, transcutaneous)

CBSET's Multi-Disciplinary Approach

Develop testing paradigms with experts in regenerative medicine

CBSET has a long history of success in supporting regenerative medicine. Our institute assimilates in-life procedures in animal models, *ex vivo* analyses and *in silico* models in a cohesive collaboration.

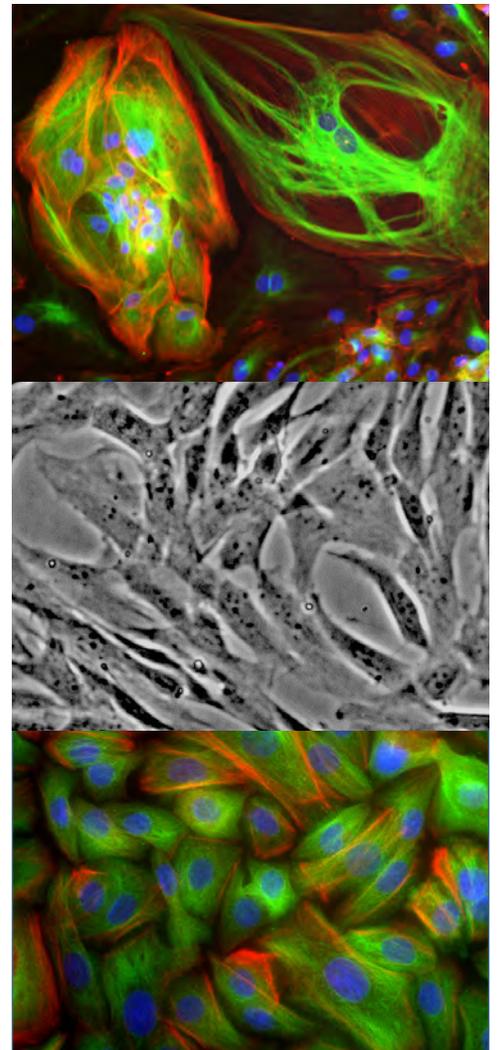
Key applications include:

- Efficacy
- Safety and tumorigenicity
- Cell persistence
- Delivery paradigms
- Translatability/model development
- Complex pathologies

Integrate lab animal sciences with physical modeling and pathology

CBSET's multi-disciplinary approach can pair the complexities of anatomic and surgical methods with a deep understanding tissue effects for a variety of endpoints:

- Bio-distribution
- Computational and 3D modeling
- Surgical methods - on-site operating suites and multiple imaging modalities
- IHC, morphology, and quantitative imaging methods
- Comprehensive, GLP-compliant histopathology capabilities



ABOUT CBSET

CBSET is a state-of-the-art biomedical research institute located in Lexington MA.

Our mission is to advance biomedical research, through innovative, high-quality services. We combine top-tier research with operational expertise. Since our inception, CBSET has continued to develop technical and scientific acumen through collaborative projects in the medical device, pharmaceutical and academic communities. Our 40,000 square foot, GLP-compliant, AAALAC-accredited facility includes vivaria, procedure rooms, catheterization / imaging labs, surgical and necropsy suites, histopathology, SEM, and a range of other technologies.

Why CBSET?

- **Credibility.** We are recognized as unbiased experts, bringing independent credibility to your regulatory filings.
- **Culture.** Our culture is science rather than commerce; we welcome unprecedented models and creative collaboration.
- **Mission.** As a 501(C3), non-profit corporation, our motivation is to enable your success; your product is our mission.
- **Integrated resource.** Our multidisciplinary team includes board-certified veterinary, quality, biological and quantitative sciences expertise, as well as board-certified pathologists – all in one facility.

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Approach the pre-IND with a credible partner

With the novel paradigms presented by cell-based medicines, the FDA is open to new scientific arguments. CBSET is an ideal partner in preparing, presenting, and defending your GLP studies for regulatory review. Our open paradigm of collaboration is an ideal framework to develop an efficient regulatory strategy. Our status as a non-profit, 501(c)(3) institute and long track record of safety assessments gives collaborations impeccable credibility.

- Audited GLP-compliant large animal facilities (USDA, FDA)
- Operational compliance and animal welfare accreditation - GLP, OLAW, AAALAC
- Animal sciences – 2 full-time ACLAM-certified DVM
- Experts in safety assessment – 2 full-time boarded DACVPs

A Multi-Disciplinary Paradigm for Cell-Based Therapy Assessments

