



CBI

Capabilities Overview



COMPARATIVE BIOSCIENCES, INC.



Premier Preclinical Contract Research Organization

- Member of GD3 Genesis Drug Discover & Development Services
- **Over 25 years** of experience
- Conveniently **located in the heart of Silicon Valley**
- **State of the art, purpose-built facility**
- Approximately 35 employees
- Highly experienced scientific staff
- **GLP, OECD, FDA, USDA, OLAW**
- **AAALAC Accreditation**



Scientific Overview

We specialize in developing a custom study plan in order to best meet your preclinical research needs and prepare for regulatory submission.

GLP and Non-GLP

Toxicology + Safety

Efficacy + Pharmacology

Pharmacokinetics +
Pharmacodynamics

Ocular and Otic studies

Dermal

Custom + Tailored
Toxicology +
Pharmacology

Model Development +
Validation

In-house Histopathology,
Immunohistochemistry &
TCR

GLP + Non-GLP

in vitro
pharmacology/toxicology

[Visit our website](#)



Our Staff

- **Study Directors**

- PhD level scientists (4)
- Appointed by management for each job
- Serves as single point of control and is responsible and accountable for study conduct and scientific interpretation
- Experienced attentive and communicative
- Rapid study initiation and report preparation

- **Pathology and Histology
(2-acvp pathologist,
immunopathologist, 4 Ras)**

All studies evaluated by ACVP Pathologist
Immunohistochemistry scientist-pathologist

- **Research Associates (~8)**

- Bachelor level scientists
- Extensive and continuous technical training

- **Quality Assurance (2)**

- RQAP-GLP certified QAU
- Rigorous training program for staff

- **Husbandry Staff-4**

- Animal care

- **Experts:**

- ACVO Ophthalmologist, surgeon, veterinarian, cardiologist, statistition

- **Administration-3**

Who is Dr. Carol Meschter?

- **Dr. Carol Meschter**
 - DVM-general practice followed by a move into academia and research
 - PhD – Cornell, Ithaca NY
 - Diplomate in American College of Veterinary Pathology
 - American Health Foundation (cancer research organization)
 - Hoffmann LaRoche, Investigative Toxicology, Nutley NJ
 - Founder of CBI 1996
 - Developed CBI from one scientist and 1 technician to 30+ employees
 - Over 100 peer reviewed publications



More of Dr. Carol Meschter?

Dr. Meschter has been an enthusiastic equestrian since childhood and has been showing ponies and hunters and foxhunted since childhood. As an adult, she has competed and trained in dressage, jumpers and three day events and competes now at the Masters in FEI competitions.

She is a veterinary judge for NATRC competitive trail rides and judges all over the country.

Dr. Carol's Drug Development Expertise

- Toxicology, pharmacology, efficacy
 - Pathology and Immunohistochemistry
 - GLP studies and IND preparation
 - Unique Animal Model Development
-
- **Regulatory Expertise**
 - Multiple INDs and project team experience
 - Training at FDA training courses
 - Experience in establishing IACUC, USDA, AAALAC accreditation and establishing GLP capability and compliance in nonGLP labs



Who is Dr. Chalajour

Dr Fariba Chalajour is a physician-scientist who has strong passion for improving the quality-of-life and making a difference in the world. She takes a positive and motivational attitude towards complex issues and solves difficult problems by fostering effective communication and teambuilding.

- MD with clinical training in cardiovascular surgery
- MBA with focusing on strategic management and leadership
- Physician scientist at University Hospital Humburg, Germany
- Postdoctoral fellow at Stanford University
- Resident physician at University of Southern CA
- Over 20 years experiences in biotech, medical device, biomedical fields
- Over 100 publications, presentations, and awards at national and international meetings

Expertise area:

- GLP and non-GLP pre-clinical and histopathology studies
- Cancer immunology and companion diagnostics
- Preclinical oncology models including xenograft and syngeneic models
- IND enabling preclinical studies for therapeutic antibodies
- Translational and molecular medicine
- Digital pathology and multiplex IHC
- *In vitro* compound testing and molecular imaging

Regulatory Expertise:

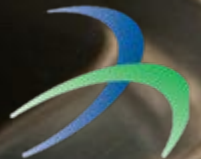
- GLP, GPP, GCP, IRB, and FDA regulations
- IND and medical device regulatory processes
- HIPPA privacy regulation
- USDA ARS Technology Transfer



CBI Animal Facility

OUR ANIMAL FACILITY IS STATE-OF-THE-ART

- Five small animal and four large animal rooms
- Two procedure rooms, two surgery rooms
- Two rooms with ventilation for immuno-compromised animals
- Dual corridor system with pass-thru
- Basil cage washer
- Daily environmental monitoring
- Regular disease, bacterial & water surveillance
- HVAC, light control in each room
- 10-15 air changes per hour with positive air flow and filtered air
- Animal enrichment BSL 2
- 24/7 staff





Species

CBI offers all species except primates

- **Mice and rats:** transgenic, knockout, immuno-compromised, and wild-type strains
- **Guinea Pigs, hamsters, gerbils, chinchillas**
- **Rabbits:** New Zealand White, Dutch Belted
- **Dogs:** Laboratory Beagles
- **Pigs and minipigs:** Gottingen, Yucatan, Duroc, Yorkshires



Test Articles

CBI works with a variety of different and unique types of test articles

- **STING agonists, anticancer viral vaccines, TCR3, CAR T cells**
- **Small and large molecules**
- **Biologics**
 - Peptides and proteins
 - Antibodies
 - Vaccines
 - siRNA & nucleic acids
 - Viral vectors
- **Stem cells & cell therapies**
- **Devices and device drug combinations**
- **Natural products and cannabinoids**



Toxicology Studies

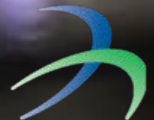
CUTTING EDGE TOXICOLOGY:

STING agonists, anticancer viral vaccines, TCRs, CAR T studies, combination efficacy and toxicity studies

Successful toxicology studies demand the contributions of skilled study directors, toxicologists, pathologists, veterinarians, surgeons, regulatory specialists and support personnel.

Standard Toxicology

- Exploratory, investigative and regulated studies
- Single-dose and multiple-dose studies up to 2 years
- All routes of administration, including unusual routes
- Acute, chronic, carcinogenicity
- Discovery and mechanistic toxicology
- Device, combination, biosimilar studies
- Complete, prompt reports
- Multiple successes with IND submissions for our clients
- Rodents, nonrodents, dogs, pigs





Pharmacology and Efficacy Studies

Animal Disease Models for Multiple Indications

- Ocular + Otic
- Cardiovascular
- Inflammation
- Dermatology
- Arthritis
- Allergic and immune mediated studies
- Wound healing, burns and scarring
- Fibrotic: skin and lung
- Anti-infective studies
- Oncology and xenograft
- Central nervous system
- Regenerative medicine
- Stem cell therapy

CBI offers a wide range of both typical and unique pharmacology and efficacy studies

- Custom and unique model development
- Unusual routes of administration and techniques
- Surgical modeling
- Investigative and specialized studies
- Combination GLP efficacy and toxicology





Histopathology Services

[Visit our website](#)

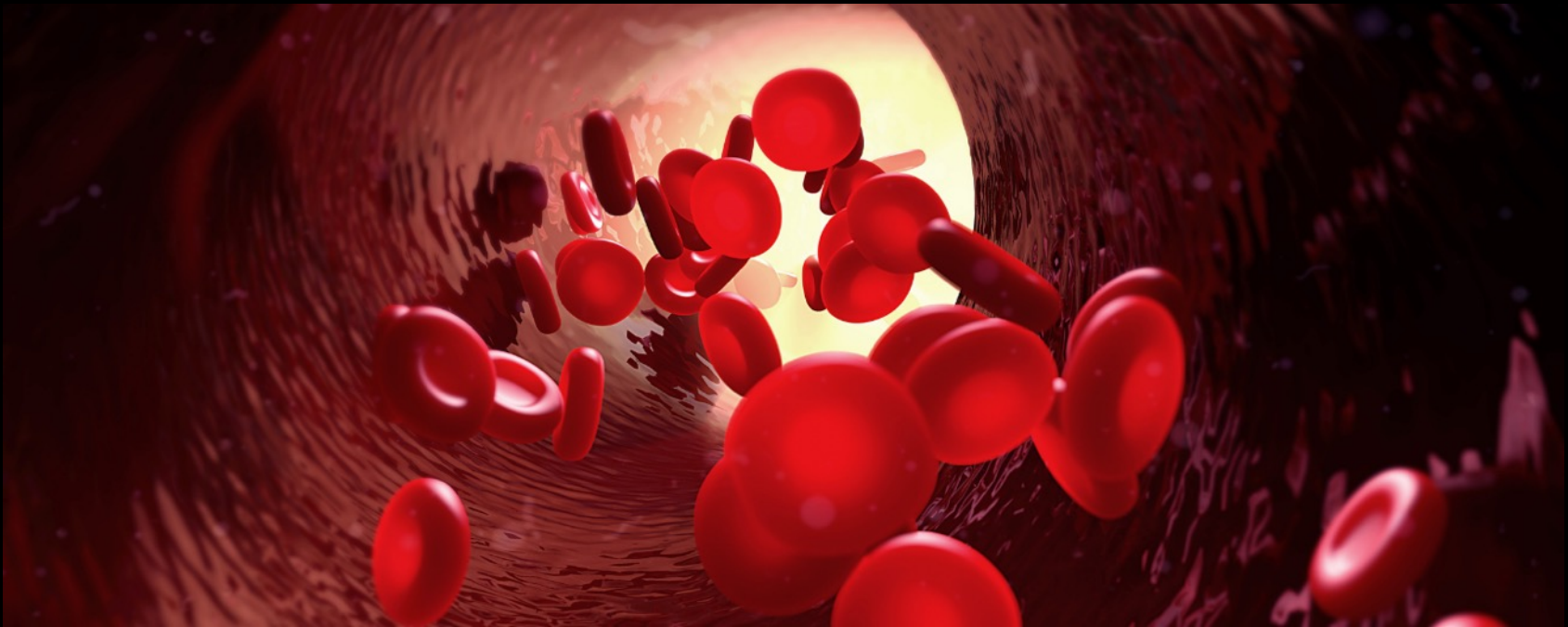
The CBI histology laboratory features
Cutting Edge State of the Art Equipment

- IHC stainer: DAKO/Agilint Link 48
- Standard Stainer: DAKO/Agilent CoverStainer
- Automated Slide labeler: Dako/Agilent slide label printer
- Automated Embedder: Milestone Magnus (High-Throughput Tissue processor and embedder)
- Slide scanner
- Digital imaging: Olympus DDP71 Digital Camera and MicroSuite Five Software
- Digital Imaging -- BF and 3 fluorescent channels capabilities



Additional **Histopathology** **Services**

- **Complete In-House Laboratories**
 - Paraffin, cryotomy, plastic
 - Immunohistochemistry
 - Special Stains
 - Peer Review
- **Sophisticated state of the art equipment.**
- **Digital image analysis and histomorphometry**
- **Highly skilled staff**
- **Validated pathology data acquisition system**
- **Evaluation and reporting by ACVP Board Certified Pathologist**
- **Immunohistochemistry scientist and pathologist**



Pharmacokinetic and Toxicokinetic Studies

[Visit our website](#)

- Exploratory, investigative and regulated studies
- Single-dose or multiple-dose studies
- Standard and nonstandard routes
- Sample analysis from blood, urine, CSF, feces
- Tissue analysis-parts of eye, ear, skin, organs
- Measure Cmax, Tmax, AUC, complete PK reports
- Metabolic and pharmacodynamics studies
- Analytical method development, validation + sample analysis



CBI Capabilities

[Visit our website](#)

CBI PROVIDES STATE-OF-THE-ART:

- Toxicology-standard and specialized
- Pharmacokinetics-standard and specialized
- Efficacy and Pharmacology
- Pharmacology-model conduct as well as development of customized and unique models
- In house histopathology and immunohistopathology
- IND assistance

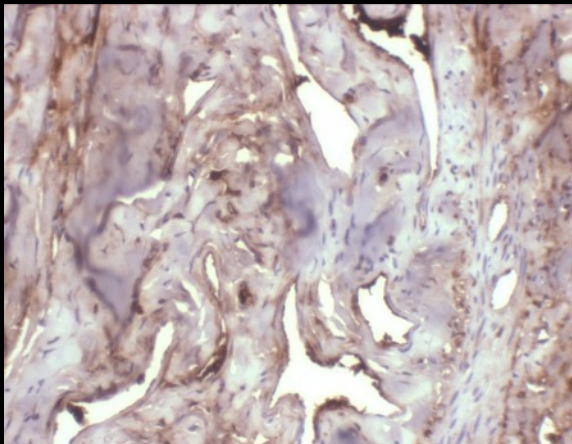
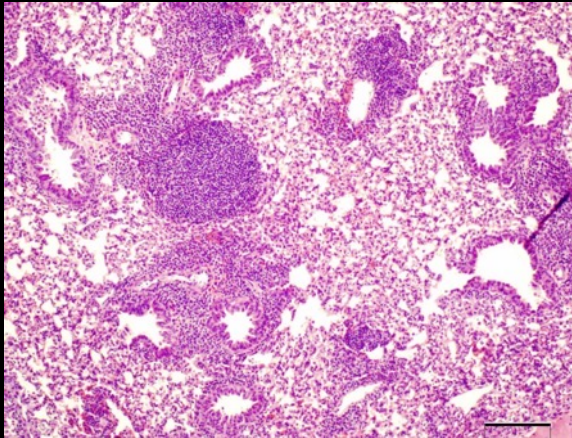
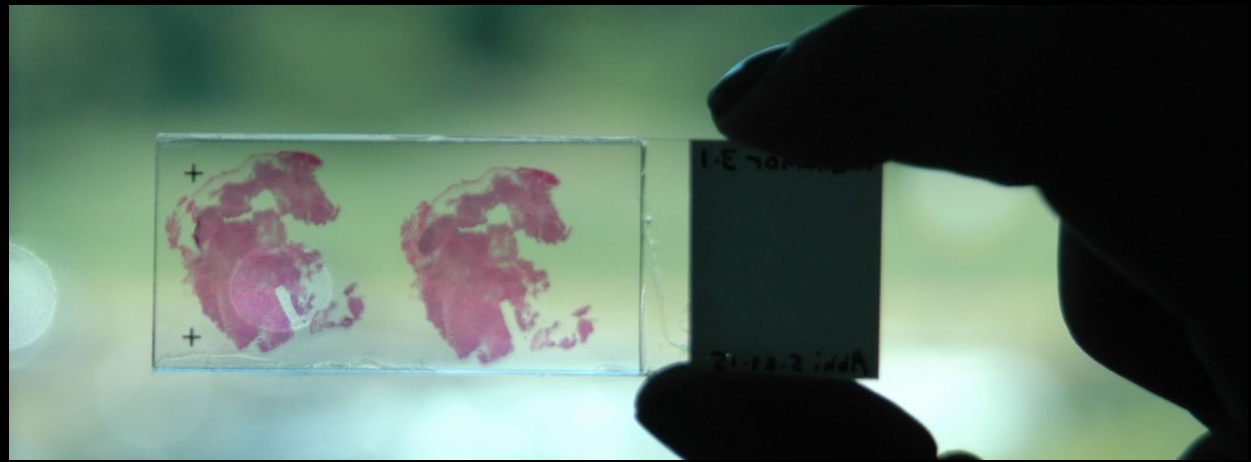
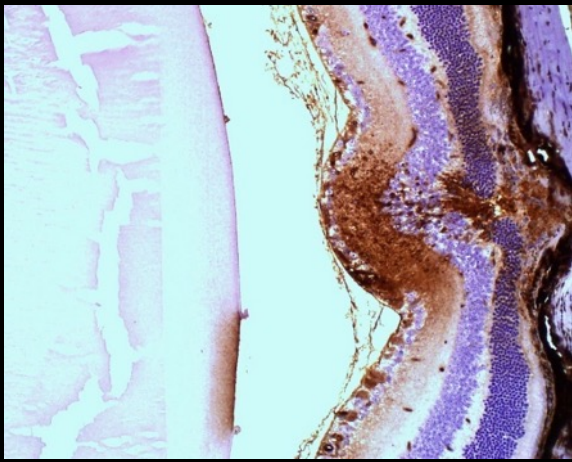


Service and Quality

[Visit our website](#)

Thoroughness in planning and execution is key to a successful study.

- All protocols are vetted and approved by multiple personnel. Our QAU has a rigorous training program. All non-GLP studies are conducted in the spirit of GLP.
- ***We believe in sound science.*** Our ratio of scientists to non-scientists is one of the highest in the industry. Every study director is a PhD-level scientist.
- ***We believe in communication.*** Timely responses to your inquiries and frequent updates on your study are mandatory.
- ***We welcome visitors.*** You are always welcome at CBI to meet the staff, tour the laboratory and discuss the progress and results of your study.



Examples of Histology

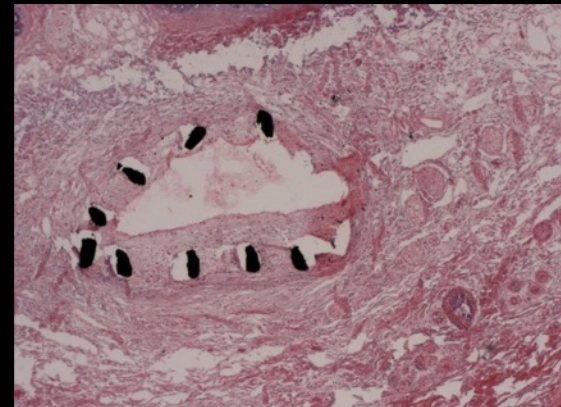
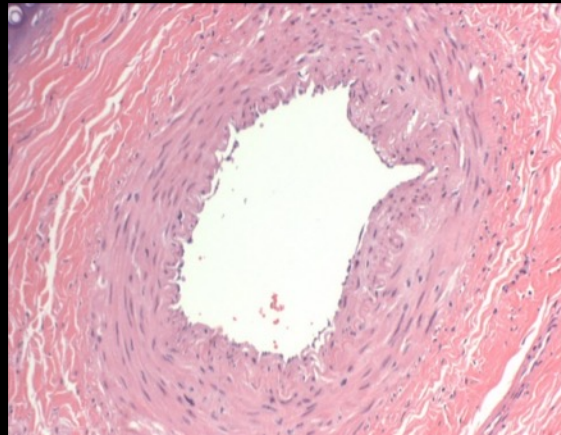
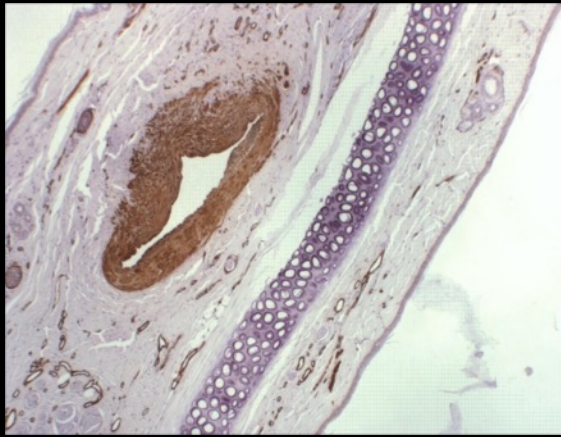
Acute CNV rat model, Day 3

- MAC IHC staining
- Demonstrating marked up regulation of MAC Expression at laser site

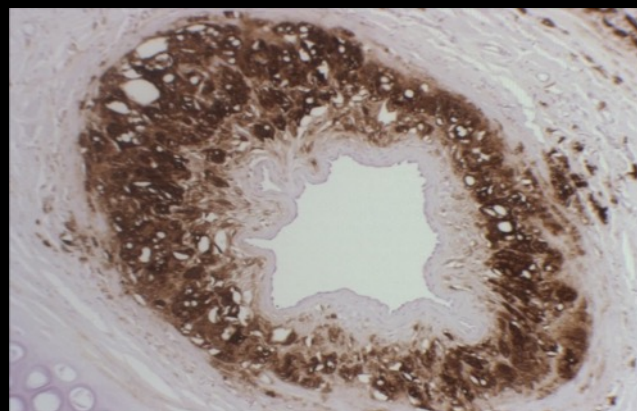
Plant tissue classification

- . Dermal tissue.
- . Vascular tissue.
- . Ground tissue.
- . Meristematic tissue.



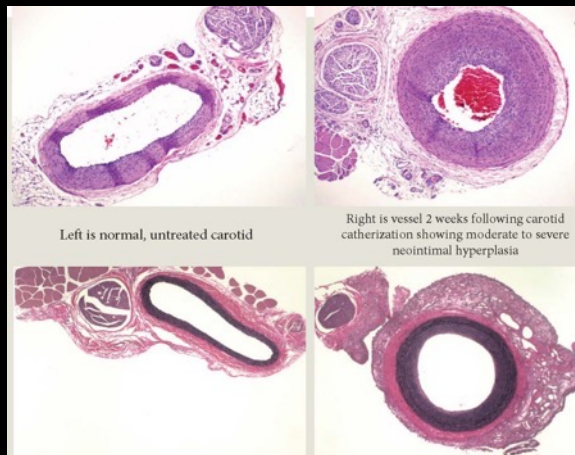
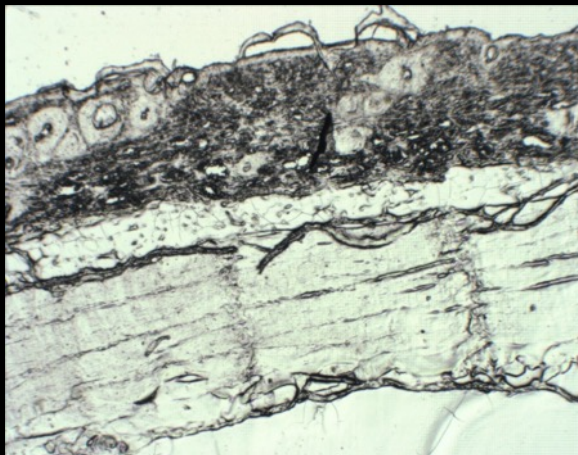
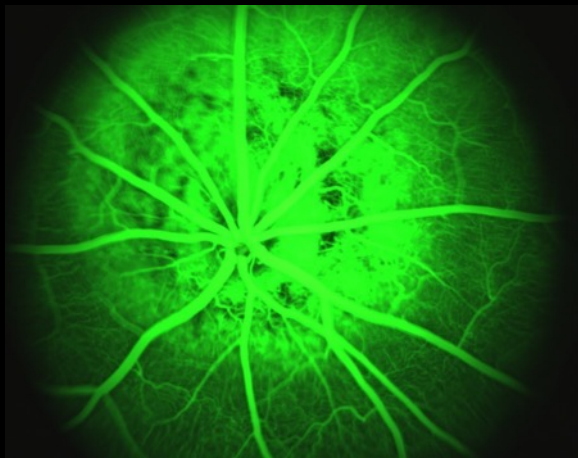
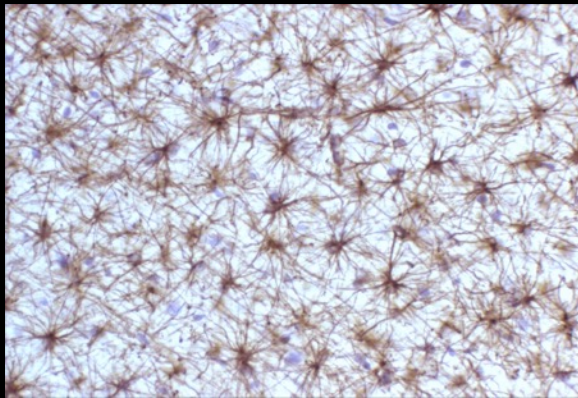


Additional Examples of Histology



Histology is the study of organs, histology, the study of tissues, and cytology, the study of cells, modern usage places all of these topics under the field of histology.





Interesting **Histology** **Microscope** **Slides**



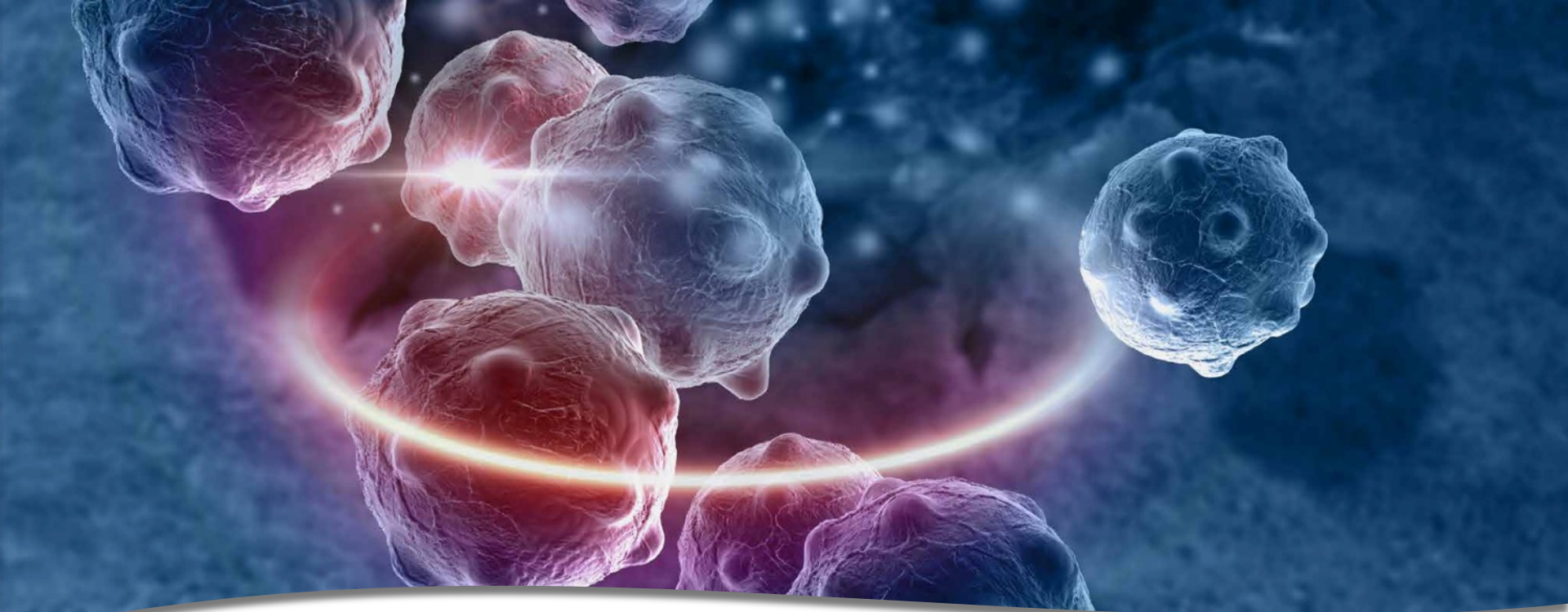
A close-up photograph of a dog's eye, specifically a black Labrador Retriever. The eye is looking towards the camera. A black, crescent-shaped contact lens is fitted on the lower part of the eye. The background is a soft, out-of-focus grey.

CBI Premiere Projects

CBI Current Projects

In addition to our usual projects we are conducting:

- Pharmacokinetics-specialized-intravesicular and IV in dogs
- Ocular blue light study to assess retina damage
- Complex bladder toxicology studies with intravascular tumor implantation and assessing efficacy and toxicity of intravesicular and IV test articles
- In house histopathology and immunohistopathology-TCR study and human tumor cell binding assessment with therapeutic monoclonal antibodies.
- Cataract surgery-phacoemulsion and implantation of new IOL into rabbits
- Carotid-neointimal hyperplasia
- STZ-induced retinopathy
- Laser induced macular degeneration



NEW

TCR2 Studies

[Visit our website](#)

At CBI, we are expanding the possibilities for cancer patients by fully engaging the T-cell receptor (TCR) complex which identifies tumor cells and directs the immune system to fight them.

- **TCR Services**
- Preliminary studies
- Extensive controls
- Slide evaluation & interpretation
- Internal peer review
- *In vitro* cross-reactivity
- *In vivo* binding of test articles
- *In vivo* binding of test articles
- *In vivo* binding of test articles
- Analysis of potential treatment-related effects
- Potential immune complex deposition in kidneys
- Immunophenotyping
- Monoclonal preclinical safety
- Clinical trial support
- Final Report

Safety and Efficacy
in Preclinical Animal
Research.



NEW

Biocompatibility And Devices

[Visit our website](#)

CBI's Biocompatibility Testing Services For Medical Devices

We take pride in the technical depth, experience and breadth of services we offer, while maintaining our focus on putting our clients' needs first.

CBI has conducted numerous studies related to dural, amnionic, pericardial and other patches, coated films, sutures, matrices, osteoinduction materials, cartilage regeneration, morselized bone, spinal fusion, bone regeneration and tendon repair. These studies are often customized or unique experiments.



NEW

In Vitro Pharmacology And Toxicology

OUR IN VITRO PHARMACOLOGY STUDIES

- Safety Pharmacology
- Dog Cardiovascular
- Rat respiratory
- Rat Central Nervous System
- Irwin Battery
- Others as requested

OUR IN VITRO ASSAYS

- Colorimetrix Assays: MTT/Elisa
- Genotoxicity (Bacterial Mutagenicity/ In Vitro Mouse Lymphoma Assay
- Cell-based assay: Cell viability; Hepatocyte metabolism assay; Cytotoxicity tumor/normal cell line)
- Bovine Cornea



NEW

Subcutaneous Implants

[WATCH OUR VIDEO!](#)

There are three main areas of activity in a surgical procedure: Preparation, Surgery and Recovery.

A **subcutaneous implant**, or **subcutaneous pellet**, is an [implant](#) that is delivered under the [skin](#) into the [subcutaneous tissue](#) by surgery or injection and is used to deliver a drug for a long period of time.

Prior to the surgical event, the medical staff are briefed, prepared, and work together seamlessly as a team for a successful operation. There is generally written SOPs or methods and for complex procedures, the veterinarian is consulted.

Summary

- **CBI provides state of the art:**
 - Toxicology
 - Pharmacokinetics
 - Efficacy and Pharmacology
 - Pharmacology
 - In house histopathology
- **Experienced attentive and communicative study directors**
- **AVCP pathologist and Immunohistochemistry pathologist**
- **Rapid study initiation and report preparation**
- **Established, stable business**
- **Regulatory compliance**
- **Favorable pricing structure**
- **Multiple successes with FDA and IND submissions**

