

APAP

Acetaminophen-Induced Acute Liver Injury

Comparative Biosciences, Inc.

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COMPARATIVE BIOSCIENCES, INC.

Premier Preclinical Contract Research Organization

- Over 20 years of experience
- Conveniently located in the heart of Silicon Valley, amidst many biotech companies
- State of the art, purpose-built facility
- Approximately 30 employees
- Highly experienced staff
- GLP, OECD, FDA, USDA, OLAW
- AAALAC Accreditation

APAP Model at CBI

- Number of Species have been studied
 - Hampter
 - Mouse
 - Rat
- Mouse is superior model due to similar hepatic liver metabolism
- Single IP induction injection of APAP after fasting at 300mg/kg
- At 24 hrs, terminal blood collection for comprehensive liver function panel including AST & AST
- Optional histology and additional biomarker analysis based upon intervention MOA



APAP Model at CBI

- Additional Endpoint for this model:
 - Necropsy for liver tissue collection
 - IHC
 - Western Blot assay of protein quantification
 - Multiplex assay for Cytokine Activity & other markers
- Option to utilize humanized hepatocyte murine model
 - Novel literature based model
 - CBI could develop at cost to Edison and then provide credit for subsequent model use

CBI's Advantage to Edison

- **Proximity** less than 10 mins away from Edison, we can receive test articles, send over samples, or have scientists participate with our team
- Rapid initiation with our own internal IACUC committee, most study protocols can be approved within 3 days.
 - With this study design, from execution to delivery of clin path data could be as little as 10 business days.
- In house Histopathology with board certified pathologist on site, we can rapidly analyze samples (H&E, IHC, and other special stains)
- Should additional studies be requested from Edison on a reoccurring basis, we are will to extend more prefer pricing and schedule



Service and Quality

- The people at CBI—from the executive team to the study directors to the research associates expect to have to earn your trust and business.
- Our ratio of scientists to non-scientists is one of the highest in the industry. We believe in sound science and every study director is a PhD-level scientist
- 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 with the same SOPs.
- We believe in communication: timely responses to your inquiries and frequent updates on your study are mandatory.
- Rapid initiation and adjustments; with the collective expertise of must larger organizations but the flexibility of a smaller more nimble group.
- You are always welcome at CBI to meet the staff, tour the laboratory and discuss the progress and results of your study.

Our Staff

Study Directors

- PhD level scientists
- 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

Research Associates

- Bachelor Level Scientists
- Extensive technical training

Quality Assurance

- Full time, dedicated
- Rigorous training program

CBI Management

 Experienced senior scientific management-with large and small pharma experience

Summary

- With a focus on quality, CBI provides state of the art:
 - Toxicology
 - Pharmacokinetics
 - Efficacy
 - Pharmacology
 - In house histopathology
- Experienced attentive and communicative study directors
- Rapid study initiation and report preparation
- Established, stable business
- Regulatory compliance
- Favorable pricing structure