ORS Preclinical Models Section Workshop*
Bench to Bedside: How Appropriate Preclinical Models Are Imperative to Translation
Friday, February 4, 2022
1:00 PM – 4:00 PM Workshop
4:00 PM – 5:00 PM Networking Event
Tampa Convention Center, Rooms 15-17

Choosing the appropriate preclinical model when taking an idea from bench to bedside means the difference between success and failure of bringing an idea to market in research. Utilizing the correct animal model is not easy and many of us fall into similar traps in that we use the model that we are familiar with, or that is financially viable but not entirely applicable. Often, we learn best from experiences of others that have had wonderful successes and even more impactful, epic failures.

Three teams of investigators (each a basic scientist and a clinician) have brought an idea from bench (in vitro) to bedside (in vivo) successfully using preclinical models. These teams will highlight the lessons learned along the way including:

- How the appropriate animal models were chosen
- FDA implications
- How proper numbers of animals were decided upon and their valuable insights if they “had to do it all over again”.

Attendees will have the opportunity submit questions and be part of the interactive conversation. Ample discussion time is planned for each segment of the workshop.

Agenda

<table>
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<tr>
<th>Time</th>
<th>Event Description</th>
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<tr>
<td>1:00 PM – 1:05 PM</td>
<td>Welcome and Introduction to Workshop</td>
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<td></td>
<td>Laurie Goodrich, DVM, PhD, Diplomate ACVS, Colorado State University, ORS Preclinical Models Section Past Chair</td>
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<td>1:05 PM – 2:00 PM</td>
<td>Session 1: Progression of BEAR Technique: concept to commercialization: the preclinical model is pivotal in the journey</td>
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<td>ACL injuries are currently treated by replacing the torn ACL with a graft of tendon, typically taken from elsewhere in the leg. We have developed a new technique, bridge-enhanced ACL restoration, which places a novel implant loaded with the patient's blood, in between the torn ligament ends, and provides an environment conducive to ligament healing. We will talk about the journey from concept to commercialization for this implant, including the preclinical trials, clinical trials, and FDA marketing approval process.</td>
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<td>Speakers: Braden Fleming, PhD, Rhode Island Hospital/Warren Alpert Medical School of Brown University</td>
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<td>Martha Murray, MD, Children's Hospital Boston</td>
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*Pre-registration for this program is required.
2:00 PM – 3:00 PM  
**Session 2: Modeling Post-Traumatic Osteoarthritis: Lessons from Tissue-Level Investigation to Preclinical Animal Models to the First In-Human Trial of Adjuvant Therapy**

This team is embarking on the first in-human trial of an adjuvant therapy to mitigate or prevent posttraumatic osteoarthritis in patients sustaining pilon fractures using Amobarbital, a reversible inhibitor of mitochondrial membrane complex I. This therapy was developed through sequential investigations from initial molecular-level and tissue-level experiments through preclinical small and large animal modeling. We will summarize experimental progression detailing key pathomechanistic disease structure findings, therapeutic interventional effects and detailed preclinical modeling that has led to obtaining an IND to begin in-human testing.

**Speakers:**
Todd McKinley, MD, IU Health Methodist  
**Uma Sankar, PhD,** Indiana University School of Medicine

3:00 PM – 4:00 PM  
**Session 3: Pathway to Development: A study in moving a bone regeneration technology from the bench-top to the bedside**

Three specialists will discuss their collaborative efforts throughout the past few years. Topics for this session will focus on the regulatory pre-submission process, designing and carrying-out numerous translational preclinical studies utilizing the three R's, and putting the pieces of the puzzle together to present an accurate, concise, and thorough data package to a regulatory agency for review.

**Speakers:**
Jeremiah Easley, DVM, Preclinical Surgical Research Laboratory, Colorado State University  
Brian Margulies, MS, PhD, Zetagen Therapeutics, Inc  
Kirk McGilvray, PhD, Colorado State University

4:00 PM – 5:00 PM  
**Networking Event**

*Names in bold are ORS Preclinical Models Research Section members.*

Interested in learning more about the ORS Preclinical Models Research Section?  
Stop by the ORS Lounge in the poster/exhibit hall or visit [https://www.ors.org/preclinical-models-section](https://www.ors.org/preclinical-models-section).