UC San Diego
Altman Clinical and Translational Research Institute

TRANSLATIONAL SCIENCE
CERTIFICATE
COURSES DESCRIPTION

Total = 10 Units

3 x 2-unit

Foundational Course

CLRE-236
Translational Research Fundamentals

Case Study Course ("See One")

CLRE-238
Applied Translational Research I

Experiential Course ("Do One")

CLRE-239
Applied Translational Research II

4-unit

Capstone Project ("Teach One")

PROJECT
Capstone Project

Summer Quarter
Quarter 1

Fall Quarter
Quarter 2

Winter Quarter
Quarter 3

Student-Specified
Quarter 4

Weekly Time Commitment
(Outside 2-hr Lessons)

Translational Science Certificate
Program Schedule

Title & Course Number	Units	Cost	Summer	Fall	Winter	Spring
Translational Research Fundamentals (CLRE-236)	2.00	$840 USD	Online			
Applied Translational Research I (CLRE-238)	2.00	$840 USD		Online		
Applied Translational Research II (CLRE-239)	2.00	$1,680 USD			Online	
Certificate Capstone Project (CLRE-40004)	4.00	$1,600 USD	Specified by student			

Throughout the Certificate Program

Receive and complete "primers" on the background necessary to understand the subject matters:

- Pharmacology of receptors (Pharmacodynamics)
- Pharmacokinetics
- Intellectual Property
- Regulatory Affairs
- General properties of the major drug chemical modalities

Complete homework assignments meant to:

- Get familiar with typical publication types
- Learn how to extract the essential information reported
- Learn how to prepare “industry-style” PowerPoint presentations

Participate in weekly discussion posts

- Discuss novel concepts around translational science that relate to your area of research and expertise
- Take advantage of the multidisciplinary nature of our program and open your mind to how other areas of biomedical sciences are applying translational science every day

Network with seasoned biomedical industry leaders

- Every course is taught by industry experts from different areas of biomedical sciences
- Expert roundtable events to get closer to our faculty and explore the world of translational science applied today
- Join our exclusive LinkedIn group and stay connected to your classmates and all the faculty that take part in our program
- Personalized educational setting meant for you to create close relationships with our faculty

TRANSLATIONAL RESEARCH FUNDAMENTALS

CLRE-236

Understand the principles and tools of translational medicine and learn about their application in R&D to accelerate and improve the efficiency and effectiveness of the discovery/design and development of different biomedical products

Encompassing everything from drugs/biologics and cell & gene therapy to medical technology

Principles & Tools of Translational Medicine

Lesson 1 Overview of Translational Medicine & Biomarkers

Lesson 2 Omics Tools

Lesson 3 Functional Omics Analysis

Lesson 4 Translational Imaging

Applications to Biomedical Product R&D

Lesson 5 Diagnostics Discovery

Lesson 6 Drug Development

Lesson 7 Non-Clinical Development

Lesson 8 Clinical Development

Lesson 9 Medical Technology

Lesson 10 Cell & Gene Therapy

The Experts

Lesson 1	Regent Laporte, DVM, MSc, PhD - Senior Director, Translational Pharmacology, Peptide Logic Kanthi A. Kollengode, MD, MAS - Clinical Development Lead, Immunology & Fibrosis, Bristol-Myers Squibb M. Paz Rodriguez, DDS, MAS - Dental Surgeon, Santiago, Chile
Lesson 2	Timothy R. Geiger, PhD – Director, Field Application Science, ProteinSimple/Bio-techne
Lesson 3	Elizabeth C. Brunk, PhD - Assistant Professor, Department of Pharmacology, School of Medicine, University of North Carolina
Lesson 4	Patrick McConville, PhD - Vice President, Non-Clinical Research Services, inviCRO; Professor of Practice, Department of Radiology, School of Medicine, University of California, San Diego
Lesson 5	Roberta V. Alexander, PharmD, PhD - Previously Associate Vice President, Clinical Research, Exagen Diagnostics Inc. Kanthi A. Kollengode, MD, MAS - Clinical Development Lead, Immunology & Fibrosis, Bristol-Myers Squibb
Lesson 6	Pierre Riviere, PhD - Founder & Chief Executive Officer, Peptide Logic
Lesson 7	Marina Seme Nelson, PhD - Drug Development Leader, Early Phase Development Solutions, Labcorp Drug Development
Lesson 8	Mark S. Hixon, PhD - Associate Scientific Director, Translational Modeling & Simulation, The Janssen Pharmaceutical Companies of Johnson & Johnsonn
Lesson 9	Andrew Baker, BEng (Hons) – Co-Founder & Chief Executive Officer, Orca Semiconductor, Zepp Health
Lesson 10	Daniel Oliver, MBA - Founder & Chief Executive Officer, Rejuvenate Bio

peptide logic
Bristol Myers Squibb
bio-techne
R&D SYSTEMS NOVUS BIOLOGICALS
TOCRIS proteinsimple ACD
UNC SCHOOL OF MEDICINE
invicro
Exagen
Patient Focused. Discovery Driven.
labcorp Drug Development
Janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson
ZEPP HEALTH
REJUVENATE BIO

APPLIED TRANSLATIONAL RESEARCH I

CLRE-238

The course is taught through a case study explained step by step by a faculty team of seasoned pharmaceutical industry leaders, including some who were key players in the real-world case being studied.

The case study encompasses the complete arch from the ideation of a new biomedical product to it reaching the market such that it can be used to treat real-life patients.

Using drugs as the archetypal biomedical product, learn how to perform the following tasks:

- Evaluate the science behind a new concept and potential for translatability to humans
- Determine which additional fundamental research may be needed
- Assess whether real-world conditions are favorable for going into proof of concept in patients

Experience and become familiar with the following concepts:

- The importance of the regulatory environment
- Key Investigational New Drug (IND)- enabling pre-clinical activities to reach proof of concept in humans
- Clinical development activities needed to reach proof of concept in patients (the true translational step)
- Clinical development activities needed to obtain drug approval for desired indication(s)
- The importance of early assessment of market penetration and pricing
- The need for post-marketing activities
- Assess life cycle management and competition

Management Team

Claudio D. Schteingart, PhD – Course Co-Director and Lead Faculty
Previously Vice President, Science & Technology Research, Ferring Pharmaceuticals (Retired)

Regent Laporte, DVM, MSc, PhD – Course Director
Senior Director, Translational Pharmacology, Peptide Logic

M. Paz Rodriguez, DDS, MAS – Course Manager
Dental Surgeon, Santiago, Chile

The Experts

Mark Fineman, MAS, MS, PhD
Chief Development Officer, Glyscend

David G. Parkes, PhD
Chief Scientific Officer, Abvance Therapeutics

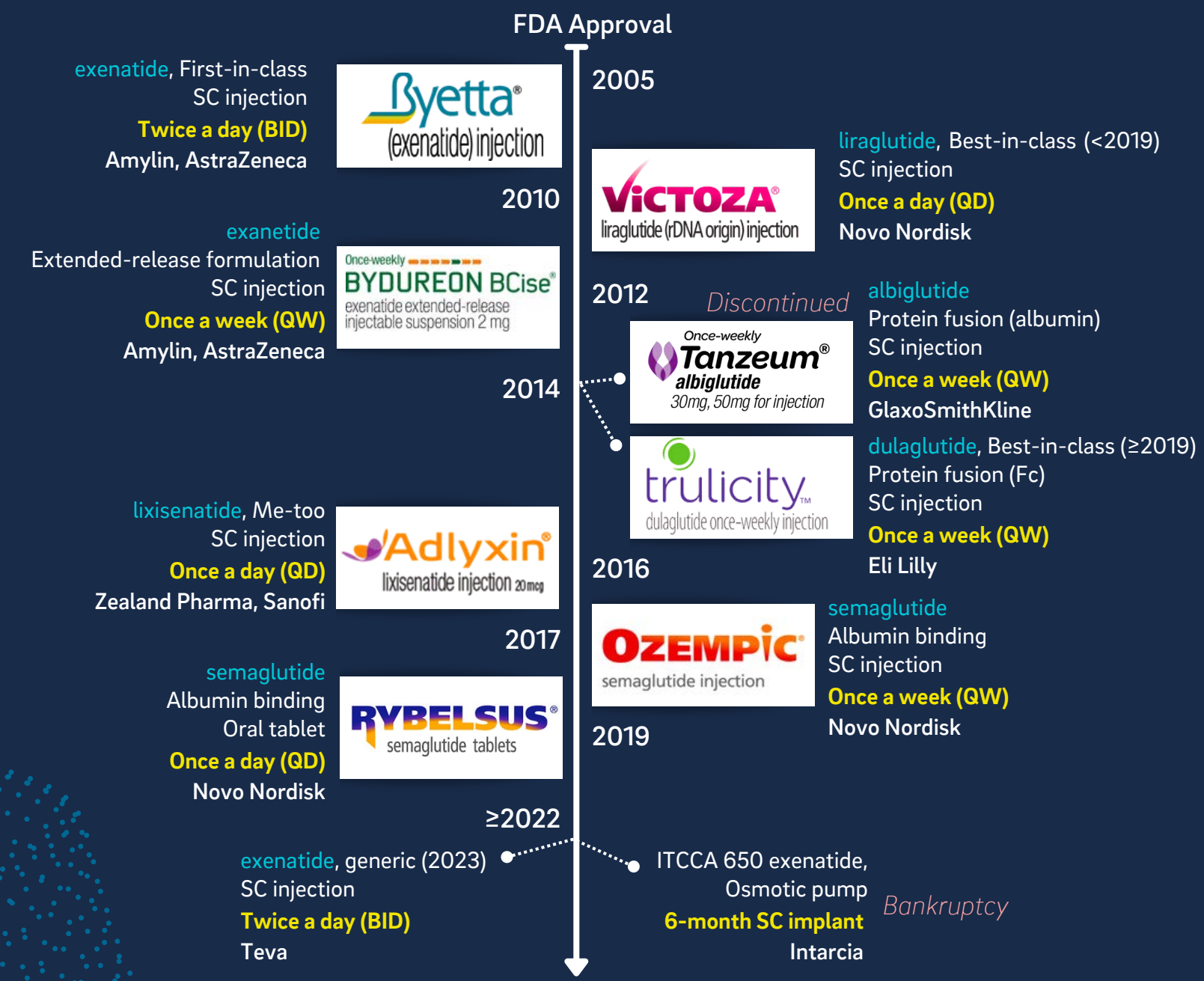
Steven L. Bender, PhD
Founder & Principal Consultant, NexTx Insights;
Entrepreneur in Residence, Boxer Capital

Wolfgang Glaesner, PhD
Chief Scientific Officer, Biotechnology R&D,
Lilly Biotechnology Center, Eli Lilly & Co.

Thomas A. Bicsak, PhD
Principal Consultant, Opus Regulatory

Michael K. Dunn, PhD, MBA
Senior Director, Scientific Information & Intelligence,
Ferring Pharmaceuticals

Case Study: GLP-1 Receptor Agonists for Type 2 Diabetes



Lesson	Topic	Faculty (Lead Faculty in Bold)
1	• Introduction • Pharmacodynamic primer/review	**Claudio D. Schteingart,** Regent Laporte
2	• Pharmacokinetic primer/review • Drug chemical modalities review: Peptides, biologics	**Claudio D. Schteingart, Wolfgang Glaesner**
3	• Regulatory affairs primer • Intellectual property primer	**Thomas A. Bicsak Michael K. Dunn**
4	• First-in-class (FIC): Ideation of glucagon-like protein 1 (GLP-1) receptor agonists for type 2 diabetes • Example of solved homework	**Claudio D. Schteingart,** David G. Parkes, Mark Fineman, Thomas A. Bicsak
5	• From first-in-class to 2nd generation: From BYETTA to BYDUREON	**David G. Parkes, Mark Fineman**
6	• Follow-on GLP-1 receptor agonists • Semaglutide oral (RYBELSUS)	**Claudio D. Schteingart,** David G. Parkes, Mark Fineman, Thomas A. Bicsak
7	• Drug chemical modalities review: Small molecules • The other drug classes: Dipeptidyl peptidase-4 (DPP-4) inhibitors & sodium/glucose cotransporter 2 (SGLT-2) inhibitors	**Steven L. Bender Claudio D. Schteingart**
8	• Combination products, obesity products, coagonists • Market performance, wrap up, critical analysis	**Claudio D. Schteingart, David G. Parkes, Mark Fineman,** Thomas A. Bicsak
9	• Oncology drug discovery & development	**Steven L. Bender**
10	• The Amylin Pharmaceuticals adventure	**Mark Fineman, David G. Parkes,** Thomas A. Bicsak

APPLIED TRANSLATIONAL RESEARCH II

CLRE-239

Following CLRE-238, this course applies the translational knowledge acquired through the past courses, and develops week by week a case for a biomedical product.

Student teams perform (desk) research on a drug class for a specific indication and prepare a comprehensive presentation. Each team will be guided/mentored by a pharmaceutical industry veteran through key papers, pharmacology, drug development concepts and market research for them to understand all that goes behind the scenes in translational science.

At the end of the course, each student team presents their case study to a jury panel of R&D leaders playing the role of the upper management of a pharmaceutical company that needs to decide whether to in-license a drug candidate to complete its development.

Learn to perform a thorough critical evaluation of a new approach to treat a disease—here, a new drug class addressing a specific molecular target.

Become familiar with the most important steps in the discovery/design and development of a biomedical product using drugs as example

Understand what elements go into making an educated decision on whether and how to advance a new idea, molecular target, drug, etc. into a translational program.

Topics Covered

The Basic Science & Rationale

- Brief description of the disease(s)
- Standard of care
- Unmet medical need (& market size)
- Brief description of molecular target and its regulation and function
- Evidence for involvement of molecular target in disease pathophysiology, including human translational data
- Key in vitro and ex vivo models and studies (including all omics)
- Key in vivo animal models and studies
- Postulated mechanisms of action
- Gaps about the basic science
- Confidence of translatability of the treatment approach to patients (Go/NoGo) based on available data

Learn about the most important steps necessary to evaluate whether transition to the next phase is warranted

Preclinical Work & Early-Stage Clinical Development

- Type of molecules put into clinical development
- Pre-clinical toxicology
- Phase 1 and phase 2 trials and their influence in drug translational science

Phase 3 Trials, Regulatory Issues, Market Issues

- Phase 3 trials
- FDA labels and approvals
- Market size, penetration and competition

Role-play the function(s) that you might assume at a large pharmaceutical company, biotechnology startup company or at an early academic translational effort

Case A: KRAS inhibitors for solid tumors

KRAS is the most frequently mutated oncogenic driver in human cancer, which has long made it a "Holy Grail" for cancer drug discovery.

Several different KRAS mutations occur in human cancer, and all have the general result of stabilizing the GTP-bound "on state" of KRAS that results in the activation of multiple downstream pathways driving cellular proliferation.

One of the more frequent mutations is G12C, especially in non small cell lung cancer.

Following a groundbreaking publication from the Shokat lab in 2013, several companies have developed potent and selective covalent inhibitors of KRAS G12C. The most advanced of these, sotorasib, received FDA accelerated approval for the treatment of KRAS G12C-mutated non-small cell lung cancer on May 28, 2021.

Some general concepts that this case will introduce include:

- Oncogenic drivers and precision medicine
- Small molecule covalent inhibitors
- Cancer drug discovery and associated preclinical data packages
- Distinctive aspects of clinical development in Oncology
- Differentiation and competitive positioning

Case B: CGRP pathway blockers for migrane

Migraine is a severe throbbing headache, often accompanied by nausea, vomiting, and extreme sensitivity to light and sound.

Attacks typically occur from a few times to >15 times a month and are very debilitating. The prevalence of migraine in the US population is surprisingly high. The exact cause of migraine is unknown. Treatments are unsatisfactory and have side effects.

Evidence that blocking the calcitonin gene-related peptide (CGRP) pathway might be useful to treat migraine accumulated over several decades.

Drugs to treat migraine by addressing the CGRP pathway have been recently approved:

- Monoclonal antibodies (mAbs) against the CGRP receptor or CGRP itself
- Small molecule antagonists at the CGRP receptor

These offer for the first time a preventive treatment against migraine.

The Mentors

KRAS Team

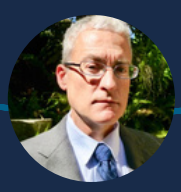
Steven L. Bender, PhD
Founder & Principal Consultant, NexTx Insights;
Entrepreneur in Residence, Boxer Capital

CGRP Team

Claudio D. Schteingart, PhD
Previously Vice President, Science & Technology Research, Ferring Pharmaceuticals (Retired)

The Jury Panel for Final Presentations

Mark Fineman, MAS, MS, PhD
Chief Development Officer, Glyscend



Mark S. Hixon, PhD
Associate Scientific Director,
Translational Modeling & Simulation
The Janssen Pharmaceutical
Companies of Johnson & Johnsonn

Kanthi A. Kollengode, MD, MAS
Clinical Development Lead,
Immunology & Fibrosis, Bristol-Myers Squibb

Management Team

Regent Laporte, DVM, MSc, PhD – Course Director
Senior Director, Translational Pharmacology, Peptide Logic

M. Paz Rodriguez, DDS, MAS – Course Manager
Dental Surgeon, Santiago, Chile

CAPSTONE PROJECT
CLRE-40004

Focus on addressing the needs that biomedical companies have in the translational science and/or business development areas.

Industry Track:

Opportunities for Students in Established Companies

Such efforts could include:

- New asset due diligence assessment
- Positioning research
- Therapeutic indication selection
- Investigational New Drug (IND) application development
- Investigator's Brochure (IB) creation
- Clinical trial protocol writing

Mentored by:

Thomas A. Bicsak, PhD
Principal Consultant, Opus Regulatory

Entrepreneurship Track:

Opportunities for Students to work with Startup Companies

- Develop a fundamental understanding of business risk considerations related to the initial start up of a Phase 1, Phase 2, or Phase 3 clinical trial on a case-by-case basis
- Identify and develop company gaps to help guide strategic critical business decisions
- Frame problems, make data-based arguments, successfully communicate logical arguments
- Students learn to bring together key opinion leaders and interview and/or present them to their client teams
- Build international relationships with biomedical companies looking to enter the US market – new perspectives on cultural differences and challenges

Mentored by:

John M. York, PharmD, MBA
Founder, Principal, & Chief Executive Officer, Akita Biomedical; Adjunct Professor, Ernest Mario School of Pharmacy, Rutgers University; Lecturer, Rady School of Management & Jacobs School of Engineering, University of California, San Diego

At the end of the capstone project, students present the final deliverable to course faculty and client company management for evaluation

Course Management:

M. Paz Rodriguez, DDS, MAS – Course Co-Director
Dental Surgeon, Santiago, Chile

FOR MORE INFORMATION:

Dr. M. Paz Rodriguez, DDS, MAS

Communication Director

mpr002@health.ucsd.edu

Scholarship Opportunity

Aimed at passionate individuals:

- Postdoctoral scholars without a fellowship to support the certificate course fees
- Biomedical industry professionals from small companies not offering educational programs

Enroll Today