

UNIVERSITY OF THE
PACIFIC

Thomas J. Long
School of Pharmacy

Genentech
A Member of the Roche Group

FELLOWSHIP IN INDUSTRY PROGRAM | 2020





Welcome Message from the Associate Dean of Professional Programs

Dear Prospective Fellow,

We are so pleased that you are considering the University of the Pacific's Fellowship in Industry Program (FIP) in partnership with Genentech, Inc. The goal of this program is to increase industry fellowship opportunities offered through partnerships between biopharmaceutical organizations and universities on the West Coast.

At University of the Pacific, the first charter university in California, we value individualized training and focus on leadership development, which are exemplified by our partnership with Genentech. For more than 60 years, the Thomas J. Long School of Pharmacy has been training health care professionals who are problem-solvers, innovators and leaders. Our faculty dives deeper, using research to challenge the status quo of health care and education.

As an FIP fellow, you will be fully immersed in the Clinical Scientist or Clinical Pharmacologist role to support innovative drug development at Genentech. In addition, you will have opportunities to work alongside the faculty and preceptors at the University, Veteran Affairs Palo Alto Health Care System and Travis Air Force Base where you will engage in research collaboration, grant and manuscript development, teaching, student and resident mentoring and other professional development.

I highly encourage you to contact our FIP Director, Dr. Sachin Shah, and the exceptional team of mentors so you can appreciate how deeply committed we are to your future success.

Best Regards,



Allen Shek, PharmD

*Professor of Pharmacy Practice
Associate Dean of Professional Programs
University of the Pacific*

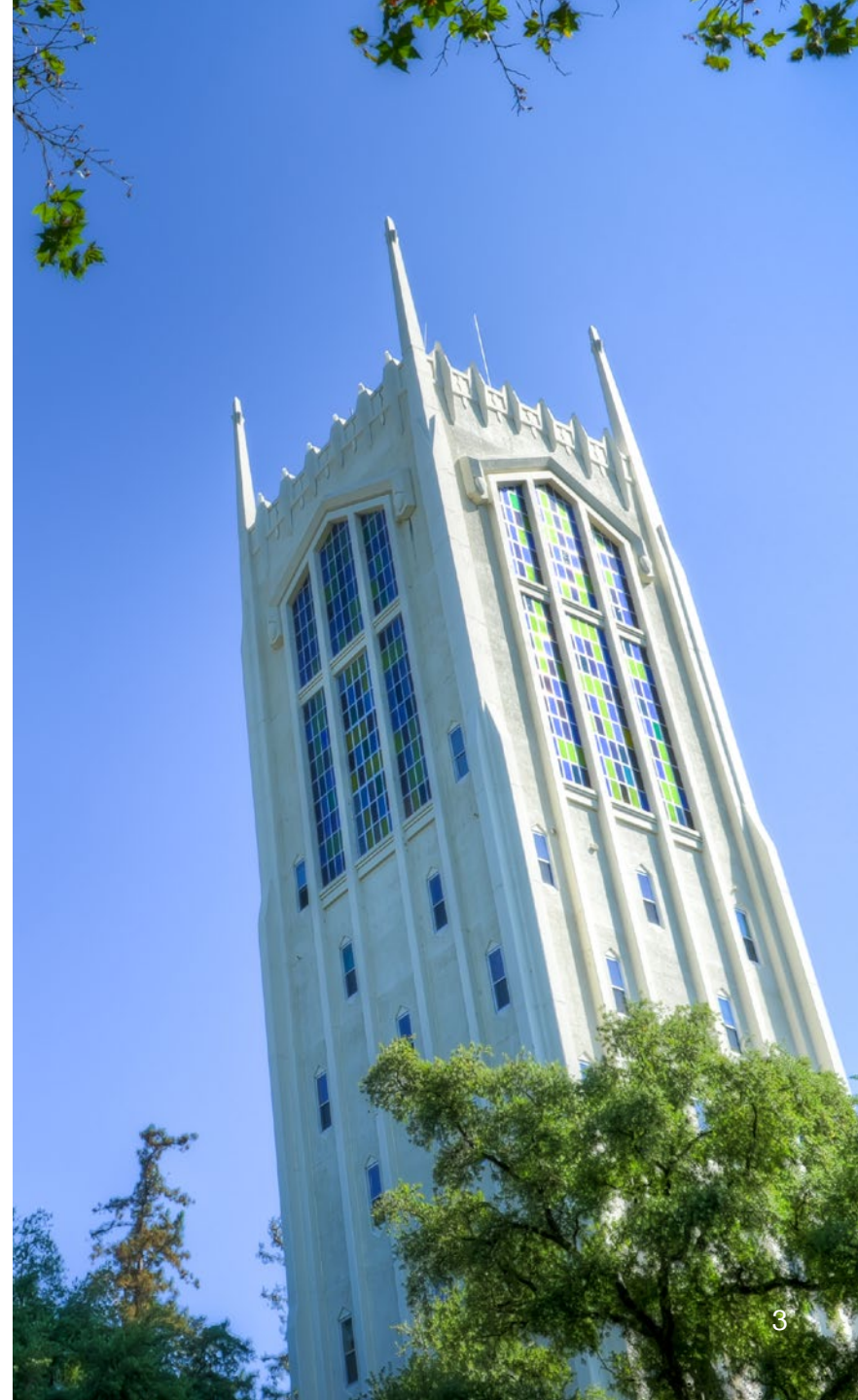
About University of the Pacific

University of the Pacific is a nationally ranked university with a long tradition of dedicated teaching, small class sizes, practical experience and vibrant residential life. The breathtaking main campus in Stockton, California is home to eight schools and colleges, with more than 80 majors and programs of study. The Thomas J. Long School of Pharmacy opened in 1955 and has a long-standing record for producing high-quality pharmacists with the option for dual degree programs (PharmD/PhD or PharmD/MS) and post-doctoral academic fellowships. Over the last nine years, average annual faculty research grants in the School totaled more than one million dollars with extensive participation in NIH and NSF grants and more than 95 percent of faculty publishing. The School touts a unique decentralized Advanced Pharmacy Practice Experience (APPE) model with seventeen regions having faculty members bolstering teaching, scholarship and service.

Learn more at pharmacy.pacific.edu

MISSION

The mission of the Thomas J. Long School of Pharmacy is to prepare students for lifelong success in health careers by providing an excellent, student-centered learning environment. We aspire to develop leadership skills in our students and a strong commitment to their professions, to interprofessional collaboration, and to society. These efforts are assisted by linkages across the University of the Pacific professional and liberal arts programs. We support outstanding professional and graduate teaching, research and other scholarly activity, and services as a means of achieving our mission.



About Genentech

Genentech was founded in 1976, with a goal to develop a new generation of therapeutics created from genetically engineered copies of naturally occurring molecules. Today Genentech continues to use genetic engineering along with other advanced techniques to develop medicines that address major unmet medical needs for patients worldwide.

In March 2009, Genentech became a member of the Roche Group. As part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. Genentech's South San Francisco campus now serves as the headquarters for Roche pharmaceutical operations in the United States.

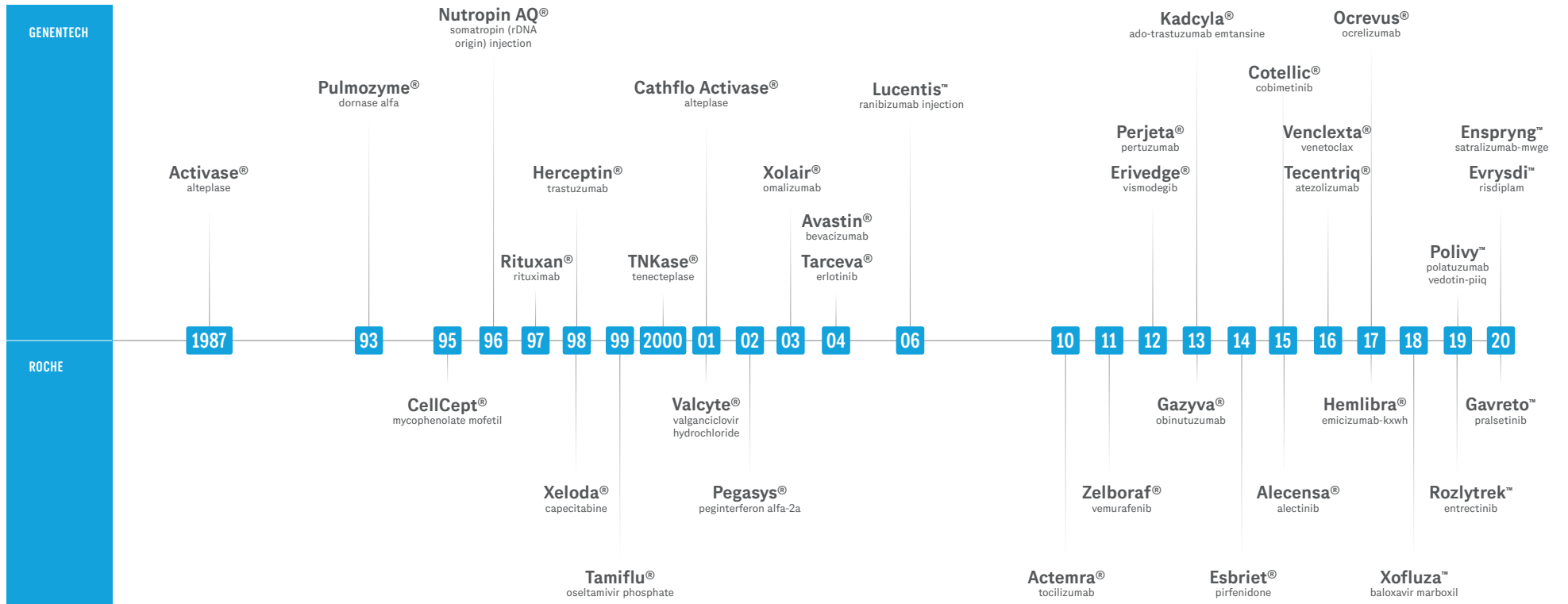
The three Roche values — Integrity, Courage, and Passion — are core to how we want to behave, as individuals and collectively as an organization.

- **Integrity** means we are consistently open, honest, ethical and genuine.
- **Courage** means we are entrepreneurial and thus take risks, reach beyond boundaries and experiment.
- **Passion** means we use our drive and commitment to energize, engage and inspire others.

These values define fundamental attributes for guiding decisions and actions leading to increased innovation and business performance.



FOUR DECADES OF TRANSFORMATIVE MEDICINES





Message from Executive Sponsors of Genentech Fellowship Clinical Science - Oncology Early Clinical Development

Dear Prospective Fellow:

Thank you for your interest in Genentech Early Clinical Development – Oncology in partnership with the University of Pacific Fellowship in Industry Program (FIP). We know that a fellowship is an important commitment in your career development. Our team is excited to offer you the opportunity to extend your knowledge as you contribute to the development of novel cancer therapeutics working alongside experienced clinicians and scientists who are passionate about applying innovative science to clinical research.

Genentech is a leader in developing therapies that shape the care of patients with cancer. Our pipeline reflects our commitment to innovative science and personalized cancer therapies, and includes development programs focused on mutant specific inhibitors, bispecific antibodies, cancer immunotherapy, cellular therapy and personalized cancer vaccines. We believe that our close collaboration with the scientists who have discovered these new drugs and our daily interactions with the oncologists who are conducting clinical trials has been essential to our success.

PharmD graduates have the robust clinical and scientific training that is valuable in clinical research. Our training program will provide you the opportunity to learn experientially in a dynamic team setting. The fellow will be matched with a mentor who will offer personalized training on the drug development process and will have access to a wide variety of education programs within the organization. We seek a fellow who shares our passion for applying cutting-edge science to clinical research with the goal to improve the lives of patients with cancer.

On behalf of the Early Clinical Development-Oncology group at Genentech, we wish you the best exploring your fellowship opportunities, and hope that you will consider joining our team. Please contact us if you have any additional questions.

Best Regards,



Stuart Lutzker, MD, PhD
*VP Oncology Exploratory
Clinical Development
Genentech Research and
Early Development
Genentech, A Member of the
Roche Group*



Jennifer Lauchle, MD
*Senior Group Medical Director
Genentech Research and
Early Development
Genentech, A Member of the
Roche Group*

Genentech Fellowship | Clinical Science

This two-year Clinical Science fellowship provides in-depth exposure to Early Clinical Development and understanding the basic principles of clinical research. The fellow will function as a Clinical Scientist and will support Medical Directors/senior-level Clinical Scientists on a diverse set of clinical development activities.

OMNI Early Clinical Development - (Not recruiting this cycle)

gRED's OMNI (Ophthalmology, Metabolism, Neurology, Infectious Disease, Immunology) organization is responsible for developing and executing early development clinical strategies in healthy volunteers and patients to provide data for gRED non-oncology new molecular entities with respect to safety, tolerability, efficacy, pharmacokinetics, pharmacodynamics and the utility of biomarkers.

Oncology Early Clinical Development

Genentech's Oncology Early Clinical Development mission is to provide the clinical leadership and skills to successfully develop novel cancer therapies and the means by which to identify the patients who benefit from them. The organization is responsible for developing strategies for and executing on First-in-Human, Phase 1 and Proof-of-Concept oncology clinical trials. In the role of a Clinical Scientist, the fellow will gain experience in the basic principles of clinical oncology research.

Activities at Genentech

The fellow will function as a clinical scientist and will support medical directors/senior level clinical scientists on the following activities:

- Serve as a clinical science representative on cross-functional sub-teams (i.e. protocol execution, clinical, biomarkers, pharmacokinetics)
- Create, review and present clinical slides for internal (i.e. Genentech/Roche) and external meetings (e.g. Investigator meetings, scientific congresses, advisory boards, site visits, site staff training)
- Develop understanding of Good Clinical Practice (GCP), International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), FDA, EMA, NICE and other relevant guidelines and regulations
- Draft abstracts, posters, manuscripts for scientific meetings
- Author and review of clinical documents (i.e. clinical trial protocols, clarifications and amendments, informed consents, investigator brochures, clinical study reports, investigational new drug submissions)
- Respond to inquiries from health authorities (e.g. FDA, EMA) and study site ethics committees
- Partner with the data management team to assist with the development of case report forms
- Serve as a primary point of contact for study inquiries
- Contribute to ongoing review of the integrity of clinical trial data
- Develop understanding of Phase I-II drug development

OMNI Program Director



Chin Wong, PharmD

*Lead Clinical Scientist
Genentech Research and
Early Development*

OMNI Fellow



Colin Dimond, PharmD

*1st Year Clinical Science Fellow
Genentech Research and
Early Development*

Oncology Program Director



Hatem Dokainish, PhD

*Senior Clinical Scientist
Genentech Research and
Early Development*

Oncology Preceptor



Mengsong Li, PharmD

*Lead Clinical Scientist
Genentech Research and
Early Development*

Oncology Fellow



Essie Liu, PharmD

*2nd Year Clinical Science Fellow
Genentech Research and
Early Development*



Message from Executive Sponsors of Genentech Fellowship Clinical Pharmacology

Dear Prospective Fellow,

Genentech's Clinical Pharmacology department is excited to be a part of the University of the Pacific's fellowship program for Doctor of Pharmacy graduates. The comprehensive training of the Doctor of Pharmacy graduate in clinical therapeutics, applied pharmacokinetics, direct patient care, and translational science provides a unique opportunity to develop and contribute as Clinical Pharmacologists in the drug development industry.

Our UOP-Genentech Clinical Pharmacology fellowship program aims to train graduates who have particular interest in Clinical Pharmacology in the areas of pharmacokinetics, pharmacodynamics, drug metabolism, quantitative pharmacology (including various types of PK/PD data modeling and "what-if" simulation approaches), as well as applying new health/IT technologies and advanced analytic approaches to support drug development. We provide the unique opportunity for trainees to work under the supervision of Senior Clinical Pharmacologists and alongside other cross-functional colleagues across Genentech as they complete this 2-year fellowship.

Our Clinical Pharmacology group based in South San Francisco offers an incredible range of training opportunities in many therapeutic areas including Oncology, Immunology, Neurology, Ophthalmology and Infectious Diseases. Our Clinical Pharmacologists are also well known among their scientific peers for their rigorous, innovative and cutting-edge approaches and we encourage them to publish and present at scientific meetings. We pride ourselves for having a culture that focuses on patients, science and our people.

On behalf of Genentech, thank you for considering this program and I invite you to contact us if you have any questions.

Best Regards,



Amita Joshi, PhD
*Vice President and Global Head of
Clinical Pharmacology Development
Sciences
Genentech Research and Early
Development Genentech,
A Member of the Roche Group*



Luna Musib, PhD
*Associate Director and
Principal Scientist
Genentech Clinical
Pharmacology*

Genentech Fellowship | Clinical Pharmacology

The Genentech Clinical Pharmacology Fellowship program builds on the synergy between the fellow's comprehensive Doctor of Pharmacy training and Genentech's innovation in drug development to prepare the individual for a career in the biotechnology/pharmaceutical industry. The fellow will be part of the gRED Clinical Pharmacology Department, which is responsible for applying the principles of quantitative pharmacology to enable selection of a safe and effective dose, route and regimen for small molecules and biologics. The fellow will gain drug development experience at Genentech by completing research projects in clinical pharmacology and/or modeling and simulation and collaborating with scientists across disciplines within Genentech and Roche. These experiences will potentially lead to publications and presentations at scientific conferences and give the fellow exposure to career opportunities in the biotechnology/pharmaceutical industry.

Activities at Genentech

The Fellow will function as a Clinical Pharmacologist and will support research and development projects, which may include the following activities:

- With guidance from the Genentech and University of the Pacific mentors, design and implement a clinical pharmacology and/or modeling and simulation research project(s).
- Present the results of the research project(s) at Genentech, University of the Pacific, a local and/or national scientific meeting and/or publish them in a peer-reviewed journal.
- Serve as a Clinical Pharmacology lead for a healthy volunteer study for a small and/or large molecule project (e.g., food effect, drug-drug interaction, formulation bridging, bioequivalence)
- Serve as a Clinical Pharmacology lead on cross-functional project sub-teams (including clinicians, pharmacologists, biomarker experts, biostatisticians, regulatory experts), facilitating discussions of clinical pharmacology-related issues
- Develop clinical pharmacology plans for small and/or large molecule projects and obtain buy-in from the project team with support from their mentor
- Author clinical pharmacology sections of documents (e.g., clinical trial protocols, investigator brochures, clinical study reports, health authority pre-meeting packages, NDAs, BLAs)
- Develop hands-on modeling and simulation skills (e.g., noncompartmental, compartmental, PK/PD, and population PK modeling)
- Develop an understanding of ICH, FDA, EMA, PMDA and other relevant Clinical Pharmacology guidances and apply them in their work
- Develop an understanding of Phase I-IV drug development in different therapeutic areas

Clinical Pharmacology Program Director



Katie Maass, PhD

Scientist

Genentech Clinical Pharmacology

Clinical Pharmacology Fellow



Sonoko Kawakatsu, PharmD

2nd year Clinical Pharmacology Fellow

Genentech Clinical Pharmacology



Activities at the Thomas J. Long School of Pharmacy

The fellow will have clinical faculty status at University of the Pacific, Thomas J. Long School of Pharmacy in Stockton, California.

They will be engaged in:

- Conducting research in collaboration with faculty
- Attending professional development meetings
- Developing grant and manuscript writing skills
- Advising Pacific's Industry Pharmacists Organization (IPhO) student chapter
- Mentoring rotational students in professional development and industry opportunities
- Participating in teaching activities (e.g. industry elective, research elective)

Program Mentors



Allen Shek, PharmD

*Professor of Pharmacy Practice
Associate Dean of Professional Programs*



Kate M. O'Dell, PharmD, BCPS, FCSHP

*Professor of Pharmacy Practice
Director of Experiential Programs
Vice Chair of Pharmacy Practice*



**Nancy N. Nguyen, PharmD, BCPS, AAHIVP,
FCSHP**

*Clinical Professor of Pharmacy Practice
Regional Coordinator – Palo Alto*



Sachin A. Shah, PharmD, FACC, FAHA

*Professor of Pharmacy Practice
Regional Coordinator – Travis AFB
Director, Fellowship in Industry Program*

Activities at Travis Air Force Base

The fellow will have volunteer status at Travis Air Force Base, David Grant USAF Medical Center, Department of Pharmacy.

They will be engaged in:

- Guest lecturing
- Clinical trial support
- IRB and IACUC meetings
- Student and resident mentorship
- Projects relevant to United States Air Force

Program Mentors



Tracey J. McGaughey, PharmD, BCPS
*Director of Pharmacy Operations,
Joint Base Andrews, National Capital Region*



Vina E. Howarth, Lt Col, USAF, BSC
*Chief, Pharmacy Operations
David Grant USAF Medical Center, Travis AFB*



Sanaz Ziad, PharmD
*Cardiology Fellow
David Grant USAF Medical Center, Travis AFB*



Kevin Pham, PharmD
*Clinical Research Fellow
Clinical Investigations Facility, Travis AFB*



Brief Overview

Fellowship in Industry Program

University of the Pacific's Fellowship in Industry Program (FIP) was founded in 2017 with the goal of providing exceptional biopharmaceutical industry training for PharmD graduates. We strive to deepen domain specific technical skills while sharpening soft skills for all fellows. The fellows will spend 90 percent of their time at Genentech, Genentech Research and Early Development (gRED). The balance of time will be spent on professional development activities with the University.

University of the Pacific's FIP is unique for several reasons. The program:

1. Integrates pharmaceutical industry training with a blend of academia or hospital practice experiences.
2. Enhances research capabilities via engagement in the Innovative Clinical and Outcomes Research (iCOR) program.
3. Embraces the innovative culture of the San Francisco Bay Area which is home to many health care startup companies.



Sachin A. Shah, PharmD, FACC, FAHA
*Professor of Pharmacy Practice
Regional Coordinator – Travis AFB
Director, Fellowship in Industry Program*



Jeremy Lim, PharmD
*Senior Clinical Scientist
Genentech Research and Early Development
FIP Associate Director and Company Lead*



2019-2020 Fellow Clinical Research

Posters and Publications

- **Liu X, Kawakatsu S**, Tran B, Tran B, Manzeno L, Shih E, Shek A, Lim J, Shah SA. Differences in Glucose Readings Between Right Arm and Left Arm Using a Continuous Glucose Monitor. Poster at American Heart Association-Scientific Sessions, 2020, Virtual Conference. (Abstract #13259)
- **Kawakatsu S**, Zhu R, Zhang W, Tang MT, Lu T, Quartino A, Kågedal M. Longitudinal Placebo Response Modeling in Patients with Ulcerative Colitis. Poster at American Conference on Pharmacometrics 2020.
- **Kawakatsu S**, Bruno R, Kågedal M, Li C, Girish S, Joshi A, Wu B. Confounding Factors in Exposure-Response Analyses and Mitigation Strategies for Monoclonal Antibodies in Oncology. [Under peer-review].
- **Kim N**, Pham K, Shek A, Lim J, Liu X, Shah SA. Differences in Glucose Level Between Left Arm and Right Arm Using Continuous Glucose Monitors. Poster at American Diabetes Association (ADA) 79th Scientific Sessions; San Francisco, CA 2019.
- Kunder R, Yeh F, Chinn L, Dash A, Lewin-Koh N, **Kim N**, Fredrickson J, Yoshida K, Chen S, Wilson M, and Wong C. Multiple Doses of an Anti-FGFR1/KLB Bispecific Antibody (BFKB8488A) are Associated with a Decrease in Hepatic Fat in Patients with NAFLD. Poster at American Association for the Study of Liver Diseases (AASLD) The Liver Meeting 2019; Boston, MA 2019.
- **Kim N**, Pham K, Shek A, Lim J, **Liu X**, Shah SA. Differences in Glucose Level Between Right Arm and Left Arm Using Continuous Glucose Monitors. (Submitted)
- Pham K, **Liu X**, Shah SA, Shek A. Difference in Glucose Levels Between Continuous Glucose Monitor Brands and Application Sites. (Submitted)

On-Going Clinical Research

- Effects of Nelumbo Nucifera Extract on Salivary Cortisol and Anxiolytic Activity in Individuals with Moderate to Severe Anxiety. PI: **Colin Dimond**, PharmD
- Tran B, **Liu X**, **Kim N**, Shah SA. Narrative Review of Digital Biomarkers: A New Landscape for Clinical Research



Perspectives from Fellows

“The UOP-Genentech Fellowship in Industry Program has allowed me to foster skills in both my professional development and personal growth through strong mentorship. I work in an environment that promotes hands-on learning, allowing me to be a contributing member of many multidisciplinary clinical trial teams and external interactions with investigators and site staff as a clinical science representative. My fellowship in oncology research and early clinical development has laid a solid foundation for a fulfilling career as a clinical scientist. Through my faculty role at the University, I teach and mentor students who are also interested in a path to industry. The FIP fellowship program is a testament to Genentech’s commitment in developing future leaders and scientists for the next generation.”

Essie Liu, PharmD

2019-2021 Clinical Science (Oncology) Fellow



“With the diverse set of activities offered across University of the Pacific, VA Palo Alto, Travis Air Force Base and Genentech, this fellowship provides me with ample opportunities to achieve my goal of becoming a well-rounded Clinical Pharmacologist. In this fellowship, I am considered an individual contributor and encouraged to think independently, while receiving effective guidance from caring mentors of diverse expertise. My mentors are a reliable and accessible resource for my training and demonstrate strong support for my professional and personal development. I enjoy that every day is filled with active learning and contributing to projects that I find meaningful.”

Sonoko Kawakatsu, PharmD

2019-2021 Clinical Pharmacology Fellow



Fellowship Eligibility Requirements

A candidate must:

- Be a permanent resident or citizen of the United States
- Have earned a PharmD from an ACPE accredited college of pharmacy before the start of the fellowship term

Application Process

Candidates must submit via email (pharmfip@pacific.edu) all the following application materials by the deadline listed on the University website:

- Letter of intent
- Updated curriculum vitae (CV)
- Three (3) letters of recommendation emailed directly from letter writer to FIP director
- One professional writing sample that demonstrates medical writing ability
- Unofficial pharmacy school transcript emailed to FIP director
- All application materials should be addressed to:
Sachin A. Shah, PharmD, FACC, FAHA
Director, Fellowship in Industry Program
Professor of Pharmacy Practice
Thomas J. Long School of Pharmacy

**See application deadline at
pacific.edu/pharmacy/fellowship/genentech**





UNIVERSITY OF THE
PACIFIC

Thomas J. Long
School of Pharmacy

Genentech
A Member of the Roche Group