A PROPOSAL FOR A PHARMD/MASTER OF SCIENCE (MS) IN CLINICAL AND EPIDEMIOLOGICAL RESEARCH DUAL DEGREE PROGRAM AT UCSF

This proposal was developed by a group of faculty and staff from the School of Pharmacy in the Departments of Clinical Pharmacy, Bioengineering and Therapeutic Sciences as well as Department of Epidemiology & Biostatistics. Input was obtained from UCSF faculty and staff and the Graduate Division.

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Section 1. Introduction

This proposal outlines the creation of a PharmD/Master of Science (MS) Dual Degree Program in the rapidly evolving field of Clinical and Epidemiological Research. The proposed new dual degree program will train the next generation of scientists on building core knowledge in science and therapeutics as well as in essential patient care skills, experiencing pharmacy practice in various clinical settings, exploring new ideas and innovations in science and practice, as well as train them in advanced epidemiologic and biostatistical methods and specialized topics such as outcomes research, implementation science, data science, clinical informatics, pharmacoepidemiology, and decision and cost-effectiveness analysis. The establishment of this program will lead to transformational changes occurring in the field of pharmacoepidemiology as well as clinical research and clinical trials. This program will give students the competitive edge for the most desirable careers in government, leaders in drug discovery and development in the pharmaceutical industry, or other health settings where they will engage in academic instruction, clinical care, and research. In addition, students in the PharmD-MS program will meet all requirements for licensure as a pharmacist in the State of California.

The proposed PharmD/MS in Clinical and Epidemiological Research Dual Degree Program supports UCSF's Academic Mission statement: "...to attract and educate the nation's most promising students to future careers in the health sciences and healthcare professions..."; "to encourage and support research and scholarly activities to improve our basic understanding of the mechanisms of disease...and "to serve the community at large through educational and service programs that take advantage of the knowledge and skills of UCSF faculty, staff and students".

1.1 Aims and objectives

The UCSF School of Pharmacy has been number one in research funding from the National Institutes of Health (NIH) every year for over four decades. Our research encompasses the entire spectrum from understanding molecules to ensuring patients receive the right medications. With three departments focused on bioengineering and drug development sciences, pharmaceutical chemistry, and clinical pharmacy, along with a world-class faculty, our school is uniquely poised to educate the next generation of scientists focused on basic and clinical research and translating the research results to clinical practice. In addition, the Department of Epidemiology and Biostatistics is the largest department of epidemiology in the University of California (UC) system in terms of full-time primary faculty and affiliated faculty, and dedicated researchers, many of whom are leaders in their fields. Research interests range from aging and global health to biostatistics, cancer and cardiovascular disease.

Within UCSF, both PharmD and MS in Clinical and Epidemiological Research are mature degree programs, with faculty who are leaders in academia and have a track record of successful graduates. We will be utilizing two world-class educational programs to provide a streamlined (4-year) program, culminating in a PharmD/MS dual degree. The proposed PharmD/MS is dedicated to developing the next generation of clinical researchers by integrating rigorous pharmacy education with advanced training in clinical and epidemiological research methods. We propose to matriculate the first students into the PharmD/MS dual degree program in Summer 2027.

Graduates of this dual degree program will be qualified professionals with patient care skills combined with research skills and experience in both industry and regulatory (government) jobs. The PharmD portion will consist of core didactic courses, clinical skills courses, as well as Introductory Pharmacy Practice Experiences (IPPEs) and six Advanced Pharmacy Practice Experiences (APPEs). Two APPEs are to be completed immediately following the completion of the didactic curriculum, followed by a longitudinal clinical practice experience in the third year, and three APPEs in the fourth year. The MS portion over the third and fourth year of the PharmD/MS dual degree program will consist of didactic courses (38 units of epidemiology, biostatistics, and electives), mentored research resulting in products of research (review, abstract, manuscript), and teaching experience.

The curriculum is designed around core courses that are mainly focused on principles of pharmaceutical sciences, patient care skills, epidemiology, clinical research, and biostatistics. Students achieve core competencies through immersion in these core courses. Core competencies are listed in Section 2.3.2 and curriculum in Section 5. Lectures will be supplemented with hands-on workshops that allow students to develop and strengthen their acquired skill set.

1.2 Historical development of the field

The History of Dual PharmD-MS Degree Programs

The field of pharmacy continues to evolve and expand each year. Changes to pharmacy education and training have allowed pharmacists to assume increasingly diverse roles beyond medication dispensing and management of therapy to providing healthcare and conducting research in academia and industry. The rapid advancements in pharmaceutical sciences, including pharmacoepidemiology, clinical trials, big data, and informatics, highlighted a critical gap: the need for experts who could bridge clinical practice and research.

The history of dual PharmD and Master's degree programs emerged in the latter half of the 20th century with an MBA (Master of Business Administration) as a way to equip pharmacists with business acumen for leadership roles in the pharmacy industry. Many colleges of pharmacy such as University of Maryland School of Pharmacy started offering these PharmD/MBA dual degree programs to address the growing need for administrative responsibilities within pharmacy profession. However, only a few schools of pharmacy in the United States offer a combination of PharmD with Master's degree (other than MBA), mainly Master's degree in Public Health (MPH). A more detailed description of these PharmD/MS dual degree programs, comparing these programs to our proposed PharmD/MS is provided in section 3.1.

The Pressing Need for Clinician-Scientists

The growing demand for professionals with both strong patient care skills and research expertise, along with experience in both industry and regulatory (government) roles, is primarily driven by the need to bridge the gap between clinical practice and scientific advancements. This ensures the development of new safe and effective treatments while adhering to strict regulatory standards. With the growing complexity of clinical trials and drug development regulations, professionals with deep understanding of clinical research are crucial for navigating compliance issues.

The field has also seen large advances in clinical trials with new techniques such as adaptive clinical trials, real-world data (RWD), real-world evidence (RWE), and equitable trial design to traditional healthcare. One method that has gained traction post-COVID pandemic is the decentralized clinical trials, bringing trials to patients, rather than patients to trial sites. In these trials, incorporating telemedicine and decentralization increases trial access to larger and more diverse applicant pools. Additionally, it decreases the workload for trial investigators, with novel electronic tools. Data science in clinical research is also an emerging discipline in response to the explosion of available and complex data in biomedicine and related streams. Examples of complex data include those from the laboratory (e.g., genomics and other "-omics"), biomedical imaging, electronic medical records, and other "found" data (e.g., social media). Not only are the preclinical and clinical portions of drug development rapidly transforming, but post-clinical strategies for commercialization, marketing, and post-marketing surveillance and vigilance are also evolving.

Additionally, the administration of the most effective and safest medications to patients based on evidence-based decision making requires professionals who can critically evaluate research data and translate it into practical patient care applications. Implementation science (IS) aims to improve the adoption of evidence-based practices and policies in clinical care and public health, and the development of best evidence through community engagement. There is an increasing global concern that the tremendous advances achieved in developing effective tests, treatments, and preventive measures are not being fully translated into improved population health. This again highlights the pressing need for clinician-scientists who have both clinical and research skills to help adopt evidence-based clinical practices.

Given the wide range of disciplines and techniques that are required for effectively treating patients with complex needs and for generating evidence about cutting-edge advances in drug therapy, it is clear that a multi-disciplinary approach involving collaboration and integration of clinical and epidemiological research along with clinical training is essential. Training a new generation of clinician-scientists in pharmaceutical sciences and clinical and epidemiological research will lead to the next stages of innovation and advances for the future of clinical practice as well as drug discovery and development. The proposed dual degree program will provide education and training in clinical research and epidemiology in the MS portion along with building the student's core knowledge in essential patient care skills and practicing pharmacy in the PharmD portion. The graduates of the proposed dual degree program will be clinician-scientists who are not only capable of translating research results into clinical practices, but will be preparing, leading, and regulating clinical research. This program will prepare graduates for careers in government, leaders in drug discovery and development in the pharmaceutical industry, or other health settings where they will engage in academic instruction, clinical care, and research.

1.3 Strengths at UCSF

UCSF is the leading university exclusively focused on health and is a world-renowned biomedical research institution. It consistently ranks in the top group of higher learning institutions in total federal funding for research and training. The culture of innovation and multidisciplinary collaboration has resulted in faculty winning nearly every leading prize in the health sciences and countless discoveries in the treatment and prevention of disease. Among faculty members are 7 Nobel laureates, 53 National Academy of Sciences members, 100 National Academy of Medicine members, 18 Howard Hughes

Medical Institute investigators, 65 American Academy of Arts and Sciences members, and 68 fellows of the American Association for the Advancement of Science members.

UCSF School of Pharmacy has been a national and international leader in research, clinical practice, and education for decades. In 2023, and for the 44th consecutive year, the UCSF School of Pharmacy received more research funding from the National Institutes of Health than any other pharmacy school nationwide. UCSF School of Pharmacy created the profession of Clinical Pharmacist, the profession without which the modern hospital and ambulatory care cannot be imagined. In 2018, the School of Pharmacy launched an innovative, integrated, competency-based three-years curriculum that is producing pharmacy graduates ready for the challenges of the 21st century health care.

The UCSF Department of Epidemiology & Biostatistics is considered the largest department of epidemiology in the UC system in terms of full-time primary faculty, affiliated faculty, and dedicated researchers. This department house multiple data sets, which are used in teaching and in producing highquality scholarship. One of these datasets is the Greater Bay Area Cancer Registry (GBACR) (an NCI-Surveillance, Epidemiology and End Results (SEER) registry), which maintains some of the highest quality control measures among cancer registries. GBACR data, collected from nine Bay Area and Central Coast counties, are recognized not only for their high quality, but also for the rich racial and ethnic diversity of the population that the registry represents. Also, the San Francisco Coordinating Center is a collaborative enterprise among researchers from the Department of Epidemiology and CPMC Research Institute. It has over 20 years of experience in conducting multicenter studies and clinical trials. The Coordinating Center has a large repository of data, biospecimens, radiographic images and genotype data from long-term studies on important health outcomes such as aging/longevity, breast cancer prevention, cardiovascular disease, cognitive function/dementia, endocrine disorders, insomnia/sleep disorders, genetics, neonatology, osteoarthritis, osteoporosis, and research methods in biostatistics and study design. In addition to its collaborative role in research, the department of Epidemiology & Biostatistics provides specific services in biostatistical and bioinformatics consultations through the Clinical and Translation Science Institute as well as support for complex, large-scale, high-volume research through its Data Systems Services group.

It is evident that UCSF exceeds the intellectual capital and programmatic resources needed to initiate a PharmD/MS dual degree program in clinical and epidemiological research, along with the stature to attract the most competitive students at UCSF, in the UC system, and internationally.

The proposed PharmD/MS in clinical and epidemiological research dual degree program will draw on faculty resources, programs, institutes, centers, and research areas uniquely available at UCSF. A review of UCSF programs and resources are outlined below, starting with the three departments in the School of Pharmacy.

1.3.1 Department of Clinical Pharmacy

The Department of Clinical Pharmacy is involved in educating Doctor of Pharmacy (PharmD) students and other health professional students at UCSF. It is also involved in the training of the postdoctoral PharmD residents to ensure they develop the skills needed for clinical practice through the pharmacy residency program. The department also provides fellowship opportunities for PharmD, PhD, and MD graduates with specialized training ranging from the lab to the clinic, company, and government agencies.

These fellowship programs include the UCSF-Genetech Clinical Development Fellowship Program, Program for Outcomes, Pharmaceutical Economics, and Policy Studies (PrOPEPS) Pharmacoeconomic Fellowship, and the UCSF Center for Translational and Policy Research on Precision Medicine (TRANSPERS). Overall, the department provides innovative, interprofessional experiences to students and pharmacists, and educates them to apply evidence-based approaches to practice. It also optimizes health outcomes through partnerships with patients, caregivers, healthcare professionals, policymakers, and health plans. Moreover, the Department of Clinical Pharmacy shares its expertise nationally and internationally through courses, offered to professionals in industry, regulatory agencies, academia, and healthcare. An example of these courses is (Rx for Change: Clinician-assisted Tobacco Cessation), a comprehensive tobacco cessation training program that equips health professional students and practicing clinicians, of all disciplines, with evidence-based knowledge and skills for assisting patients with quitting. As for research, the department generates and disseminates knowledge to advance patient care, medication safety, disease prevention and treatment, health care cost-effectiveness and quality, and pharmacy education. The department supports scholars whose work is critical to the research mission of UCSF. Research in the Department of Clinical Pharmacy focuses on the precise, personalized relationship between patients and their medications. It also examines broader relationships between patients and the

pharmacy education. The department supports scholars whose work is critical to the research mission of UCSF. Research in the Department of Clinical Pharmacy focuses on the precise, personalized relationship between patients and their medications. It also examines broader relationships between patients and the health care and public policy environments that influence factors, such as medication cost and access, health disparities, and pharmacy practice models. The fundamental goal of the department's research is to ensure the safest, most effective use of affordable, accessible medications for all patients. This goal might be accomplished via a clinical study on the genetic response of a patient group to a drug, or through a practice study that looks at a new way to ensure patients are taking their medications as prescribed and reporting any medical problems or lifestyle challenges with their regimens. The department's research areas mainly focus on clinical research, education research, and health services and policy research. Within the clinical research area, the department researchers seek to determine the safest, most effective use of medications for a given patient or population with a specific disease, focusing on medication outcomes and comparative effectiveness, pharmacoepidemiology, pharmacogenomics, as well as pharmacodynamics and pharmacokinetics. Within the education research area, the department researchers determine, develop, and implement the most effective means of teaching how to deliver pharmacy care by creating and evaluating training programs and curricula. Within the health services and policy research area, the department researchers study broad medication-related factors that affect the health of patients and populations, focusing on global health, health disparities, health policy analyses, health delivery education, pharmacoeconomics, personalized medicine, and pharmacy practice research.

Faculty in the Department of Clinical Pharmacy rank among the elite pharmacy educators and practitioners, and their research explores the safest, most effective use of medicines as well as non-clinical factors that affect the health of patients and populations, such as health policies and the cost-effectiveness of medication therapies. They prepare PharmD students to become leaders of the profession, train pharmacy residents as therapeutics specialists, teach healthcare professionals about safe and effective medication use, share their expertise beyond UCSF, and continually educate themselves about new developments in their field. Many faculty pharmacists practice in acute and ambulatory care settings at UCSF Health as well as in hospitals, clinics, community pharmacies, and physician group practices throughout California. Additionally, faculty pharmacists regularly apply medication therapy management (MTM), working with patients, families, and physicians toward a safe, effective, and cost-conscious medication therapy plan. In MTM, the pharmacist reviews the patient's medication history, creates a personal medication record, creates a medication-related action plan, intervenes to address medication-related problems, and documents and tracks MTM services. The Department of Clinical Pharmacy and

the UCSF Health Pharmacy Enterprise have worked together since the 1960s to improve the pharmacy care of patients. The vision of the Department of Clinical Pharmacy is to change the face of pharmacy through innovation to improve health.

1.3.2 Department of Bioengineering and Therapeutic Sciences (BTS)

The UCSF Department of Bioengineering and Therapeutic Sciences (BTS) trains students to study the complex processes of biology and apply their knowledge to the development and rational use of therapeutics to improve health. BTS research ranges from how an individual's genetic profile affects drug response to how nanotechnology can be used to build devices and drive the development of new medicines, medical devices, and diagnostic tests. The BTS faculty are experts in fields of microelectromechanical systems to drug metabolism and transport, and from computational biology to personalized medicine. The scientist-educators who advance research in the BTS department are closely involved with 5 PhD programs administered by the School of Pharmacy: PhD in Bioengineering, PhD in Biological and Medical Informatics, PhD in Biophysics, PhD in Chemistry and Chemical Biology, and PhD in Pharmaceutical Sciences and Pharmacogenomics.

The BTS faculty are also engaged in other programs such as teaching students in the UCSF Doctor of Pharmacy (PharmD) program how and why medications act in patients. They work jointly with the Department of Bioengineering at UC Berkeley and administer the Master of Translational Medicine (MTM) program which imparts students with the knowledge and skills necessary to bring medical innovation from the engineer's bench to the patient's bedside. BTS houses the UCSF-UC Berkeley Joint Graduate Group in Bioengineering, offering a joint PhD program for students who are interested in pursuing academic or research-focused careers along with a Master of Engineering (MEng), a professional degree program with a strong emphasis on engineering and entrepreneurship, that is designed for students planning to move directly into industry after completing the program. The BTS also offers the Master of Science in Artificial Intelligence and Computational Drug Discovery and Development (AICD3), which trains students to apply computer science, data science, statistical analysis, machine learning, and other data-driven methods to redefine the discovery and development of new drugs and therapies.

The BTS department's vision is to have discovery and development of astute therapeutics flow freely from continuous innovations in research in computational biology, precision medicine, and therapeutic bioengineering and in graduate-level science and health professions education.

1.3.3 Department of Pharmaceutical Chemistry

The Department of Pharmaceutical Chemistry research areas include chemical biology and medicinal chemistry, computational chemistry and biology, physical biology and protein and cellular engineering. Its research explores fundamental biological mechanisms and molecules of therapeutic relevance for better health, empowered by novel technologies at the interface of chemistry, physics, and computational sciences. Pharmaceutical Chemistry research into new molecular treatment targets, new and more precise ways to therapeutically alter target activity, and new biomarkers to track disease and treatment efficacy helps elucidate the biological principles of small molecules, proteins, and cellular design and allows the application of these principles to positively impact the therapeutic outcome of patients. The Pharmaceutical Chemistry faculty help train students in many PhD programs at UCSF. The department is involved with 5 PhD programs administered by the School of Pharmacy, together call the Quantitative Biosciences Consortium (QBC): PhD in Bioengineering, PhD in Biological and Medical Informatics,

PhD in Biophysics, PhD in Chemistry and Chemical Biology, and PhD in Pharmaceutical Sciences and Pharmacogenomics. It is also engaged in teaching students in the Doctor of Pharmacy (PharmD) and professional degree programs in other UCSF schools.

1.3.4 Quantitative Biosciences Institute (QBI)

Quantitative Biosciences Institute (QBI) is an organized research unit within UCSF's School of Pharmacy focused on quantitative biology and collaborations around it. At the heart of their collaborative efforts is technology and the data derived from it. QBI scientists are experts in developing experimental and computational tools that can be applied to many biological or biomedical problems. These tools play a key role in bridging discovery research and clinical worlds resulting in novel therapies for disease. Its technologies include cryo-electron microscopy (CryoEM), microfluidics, docking, mass spectrometry, x-ray crystallography, and modeling protein structure.

In addition to the UCSF School of Pharmacy departments and resources, the PharmD/PhD Dual Degree Program in Pharmaceutical Sciences and Pharmacogenomics will draw from the strengths of the School of Medicine and other related UCSF-affiliated programs. These groups are outlined below.

1.3.5 UCSF School of Medicine Department of Epidemiology and Biostatistics (DEB)

The Department of Epidemiology and Biostatistics (DEB) and its faculty provide a broad range of expertise in research areas ranging from aging and global health to biostatistics, cancer and cardiovascular disease, methods and analysis. The program offers courses in 17 areas of concentration including bioinformatics, biostatistics, data science, machine learning, and precision public health and computational epidemiology. The department also provides specific services in biostatistical and bioinformatics consultations through the Clinical and Translational Science Institute as well as support for complex, large-scale, high-volume research through its Data Systems Services group. Additional services through the Center for Bioinformatics & Molecular Biostatics include providing data, analytic and statistical support including training for UCSF students and faculty.

1.3.6 The UCSF Institute for Human Genetics (IHG)

The Institute for Human Genetics (IHG) is an Organized Research Unit within the School of Medicine, serving as the hub for all activities related to human genetics at UCSF. It is composed of over 80 faculty members from all four schools, Medicine, Pharmacy, Nursing, and Dentistry, all who share a passion for human genetics. Led by director Nadav Ahituv, the Institute provides a focal point for genetics and genomics research, industry partnerships, technologies, training, and education. IHG's Genomics Core Facility also provides state-of-the-art technology to the UCSF campus, including DNA extraction, genotyping, sequencing, and data analysis.

The IHG focuses on several research areas, including bioethics, cancer and cardiovascular genetics, functional genomics, genetic epidemiology, immunogenetics, metabolic genetics, neurogenetics, pharmacogenetics, population genetics, reproductive genetics, and statistical genetics. Members of IHG actively participate in several PhD training programs through teaching and mentoring. These programs are PSPG, Biomedical Informatics (BMI), Biomedical Sciences Graduate Program (BMS), Developmental & Stem Cell Biology Graduate Program (DSCB), Epidemiology and Translational Sciences (ETS), Graduate Program in Bioengineering (BioE), Herbert W. Boyer Program in Biological Sciences (PIBS), Integrative Program in Quantitative Biology (iPQB), Neuroscience Program, Oral and

Craniofacial Sciences Graduate Program (OCS), and Tetrad Program. The BMS track in genomics and genetics was converted specifically to human genetics, and the PSPG and BMI graduate programs were infused with a large number of new faculty in the areas of pharmacogenetics and computational genomics, greatly strengthening offerings for graduate students. The IHG also provides several professional schools and training programs within the School of Medicine, Nursing, and Pharmacy, as well as the genetic counseling. It provides bioinformatics workshops, including DNA variant analysis and RNA-seq analysis. The IHG additionally offers the Genomics & Precision Medicine Online Course, which aims to provide participants with baseline knowledge of genomics, an overview of the clinical applications of genomic medicine, the clinical validity and utility of new tests, and the ethical and social issues inherent in this field. The IHG provides the UCSF community with key services for genetic and genomic research, including research Illumina sequencing, whole genome sequencing, SNP genotyping, and DNA extraction. It also provides High Performance Computing & Data Storage services.

1.3.7 Clinical and Translational Science Institute (CTSI)

Established in 2006, the Clinical and Translational Science Institute at UCSF was one of the first 12 academic institutions selected to be part of the NIH's national Clinical & Translational Science Consortium. UCSF's CTSI has a charter to transform clinical and translational research to ensure that the best health solutions get to patients as quickly as possible. CTSI is a cross-campus institute, with scientist leaders at its helm. The CTSI is a tremendously important part of the training environment at UCSF. The CTSI Clinical Research Centers provide an array of adult and pediatric services and translate promising clinical research ideas into successful clinical protocols. UCSF's CTSI is involved in national committees and activities in all major areas identified as necessary to support clinical and translational research.

1.3.8 The Chan Zuckerberg Biohub Network (CZ Biohub Network)

The Chan Zuckerberg Biohub Network is a group of non-profit research institutes that bring together scientists, engineers, physicians and other translational scientists, and technologists with the goal of pursuing grand scientific challenges on 10- to 15-year time horizons. Established in 2016 in collaboration with Stanford University, UCSF, and the University of California, Berkeley (UCB) to promote fundamental research that elucidates the mechanisms underlying disease and to develop new technologies that will lead to actionable diagnostics and effective therapies. To achieve these goals, CZ Biohub Network has established an in-house research program focused on infectious disease, cell biology, and technology platform development in areas including genomics, genome engineering, advanced optical microscopy, data science, and bioengineering. One of CZ Biohub Network's goals is to enhance collaboration between researchers and clinicians at Stanford, UCSF, and UCB. The extramural award program will draw on the strengths of all three institutions to carry out innovative, high-risk research that is likely to have high impact and would otherwise not be funded by conventional sources. San Franciscobased research efforts are currently focused on understanding dynamic cell systems, mapping changes in cell behavior in response to disease and infection to define underlying mechanisms and to identify potential targets for therapeutic intervention and diagnostic tools.

CZ Biohub Network welcomes applications from faculty teams representing diverse disciplines such as engineering, computer science, informatics, the physical sciences, the clinical sciences, and the biomedical sciences. The scope of proposals is open to all areas of biology, biomedical research, and technology development, including areas that are well outside the current CZ Biohub Network's Human Cell Atlas, Infectious Diseases Initiative, and Neurodegeneration Challenge Network. CZ Biohub

Network wants teams to pursue ideas that excite them most and to address the questions or opportunities that team members consider to be fundamentally important based on their shared insights, expertise, and vision.

1.3.9 The UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (UCSF-Stanford CERSI)

Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. The UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI) – the first regulatory science center on the West Coast – supports FDA's mission of protecting public health and advancing regulatory science through collaborative research projects, education/training, and outreach. Launched in 2014, UCSF-Stanford CERSI brings together a world-class team of scientists from two outstanding academic institutions to focus on innovative regulatory science research and training in collaboration with FDA scientists—generating new knowledge, tools and standards that help FDA in its regulatory decision-making. The center promotes interaction and collaboration between FDA scientists and the UCSF/Stanford community through an FDA Visiting Scientist Program as well as co-sponsored workshops and scientific meetings. In addition, UCSF-Stanford CERSI organizes courses and events on various aspects of regulatory science for UCSF and Stanford graduate students, postdoctoral fellows, industry scientists and FDA staff. CERSI research projects often result in scientific publications and contribute to FDA guidance documents. Several UCSF-Stanford CERSI research projects are with FDA Office of Clinical Pharmacology scientists.

The center aims to meet scientific challenges in issues of critical importance in the development and evaluation of FDA-regulated products and at a time of rapid technological progress by: 1) advancing regulatory science through the development and application of quantitative and systems-level methodologies, 2) creating a West Coast presence of the FDA to enhance its interactions with academia and the pharmaceutical, biotechnology, and high-tech industries around regulatory science, and 3) recruiting trainees into industry-partnered fellowships with local pharmaceutical companies, Genentech and Gilead. The UCSF-Stanford CERSI builds on the enormous strengths of UCSF and Stanford University in the quantitative sciences and pharmacology to provide novel education, exchange, and collaborative research programs that focus on three key FDA priority areas as described in the FDA Strategic Plan for Regulatory Sciences: 1) improving preclinical safety and efficacy tests, 2) improving clinical trials and evaluation, and 3) harnessing diverse data sets through information sciences to accelerate and improve new drug development.

1.3.10 Pharmacogenomics Research Network (PGRN)

For over 25 years, NIH has supported the Pharmacogenomics Research Network, now including over 450 members worldwide. The PGRN is the premier pharmacogenomics network in the world and has a major goal of supporting research and implementation of pharmacogenomic discovery and clinical testing. Kathleen Giacomini, current Dean of the UCSF SOP and Professor in the Department of Bioengineering and Therapeutic Sciences, is the Co-PI of the NIH-PGRN Hub, which is the central coordinating body of the PGRN. Faculty members in PSPG program Drs. Bani Tamraz, Pharm.D., Ph.D., Janel-Long-Boyle, Pharm.D., Ph.D., Kathy Giacomini, Ph.D., Ron Krauss, M.D., and Akin Oni-Orisan, PharmD., Ph.D., are actively involved in the PGRN to enhance scientific exchange and to expand the boundaries of understanding drug response within the context of precision medicine – within the PGRN and between

the PGRN and the scientific community at large. The PGRN-Hub organizes and sponsors semi-annual scientific meetings, often associated with annual meetings of major scientific societies such as the American Society for Clinical Pharmacology and Therapeutics (ASCPT), and monthly research in progress seminars. The PGRN-Hub and its activities play a major role in this proposed dual degree program and stimulating research in pharmacogenomics.

1.3.11 The UCSF Bakar Computational Health Sciences Institute (BCHSI)

The UCSF Bakar Computational Health Sciences Institute (BCHSI) headed by Atul Butte, MD, PhD, serves as a cornerstone of UCSF's efforts to harness the power of innovative computational technologies and "big data" to impact human health. BCHSI in collaboration with the UCSF Library, the Gladstone Institute, and the UC Berkeley D-Lab works to provide computational tools and other educational resources for UCSF students, faculty and staff. Additionally, BCHSI has built an infrastructure that provides UCSF scientists with the tools and training to advance the knowledge and application of machine learning and graphical network-based analytics across the spectrum of scientific research including basic science, clinical, translational and population health. BCHSI assets and resources include Wynton HPC, which is a large, shared high-performance compute (HPC) cluster; other data and tools, including Natural Language Processing (NLP), radiological images, and meta-data extracted from DICOM (Digital Imaging and Communications in Medicine) headers; and the Scalable Precision Medicine Open Knowledge Engine (SPOKE). The SPOKE is a database containing multiple types of biological data, which allows the identification of new connections, with implications for biomedical applications like personalized medicine.

1.3.12 The UCSF Helen Diller Family Comprehensive Cancer Center

As a National Cancer Institute (NCI)-designated "comprehensive cancer center," the highest status given, The Cancer Center aims to shepherd new approaches to cancer prevention, detection, and treatment into clinical and population settings. The Center combines basic science, clinical research, epidemiology and cancer control, and patient care. From scientific research into molecular and genetic causes of cancer to clinical research into the safety and efficacy of innovations in cancer diagnosis and prognosis, the Cancer Center is also home to three of the five prestigious Specialized Programs of Research Excellence (SPORE) grants, sponsored by the National Cancer Institute.

Research themes include cancer disparities, hereditary cancers, precision medicine, population health, and immunotherapy, with key initiatives materializing through the Center for BRCA (BReast CAncer) Research, Global Cancer Program, Molecular Oncology Initiative, Precision Cancer Medicine Building, San Francisco Cancer Initiative, UC Cancer Consortium, and UCSF Cancer Research Strategic Plan. The Center is affiliated with numerous hospitals and clinics as part of UCSF Health (Section 1.3.9) with the goal of increasing accessibility to clinical research trials and express referrals to cancer specialists in the Northern California region. The Cancer Center also collaborates closely with the Lawrence Berkeley National Laboratory, the oldest U.S. Department of Energy National Laboratory.

1.3.13 UCSF Health

Ranking among the best hospitals in the nation by U.S. News & World Report, UCSF Health/Medical Center provides convenient, award-winning, highly-specialized care with over 100 locations throughout Northern California. Services range from primary care to organ and bone marrow transplants to intensive newborn care.

UCSF Health brings together a vast range of specialists to drive breakthroughs and advancements in medical technologies and treatments with 750,000 patient visits annually. Not only does UCSF Health provide world-class care to patients, it has also earned a perfect score on the LGBT Healthcare Equality Index for eight consecutive years, Magnet designation from the American Nurses Credentialing Center (<7% designation rate), and six quality and patient safety awards from Health Grades. As a leading health sciences university, UCSF is actively involved in more than 1,700 clinical trials. All trials are conducted in coordination with UCSF Medical Center.

1.3.14 The Center for Data-driven Insights and Innovation (CDI2)

The Center for Data-driven Insights and Innovation (CDI2) oversees the University of California Health Data Warehouse (UCHDW), a unique data asset created by electronic health records (EHR) as well as claims data from UC's six health centers, its self-funded health plans, and other external sources. UCHDW currently holds modern data from over six million patients seen at a UC facility since 2012. These patients received care from nearly 150,000 health care providers in over 200 million encounters, with over 600 million diagnosis records, with over 400 million procedures, more than 600 million medication records, and with over two billion vital signs measurements and test results. Over 650,000 of these patients are primary care patients.

Current activities include, but are not limited to, Pharmacy Initiatives, enabling a system-wide pharmacy work group to identify areas of opportunity in the self-funded plan drug spend. Analyses included comparator lists of brand and generic drugs, system-wide trends for drugs prescribed as "dispense as written," and data for UC Care patients' diabetes treatment pathways. In 2018, this initial work started with four specific drugs in the areas of diabetes, cardiovascular disease, and psychiatry.

As detailed above, UCSF possesses superior scholarship and its faculty, research, and graduate programs are world-renowned. Building on the strengths of UCSF, the proposed PharmD/MS Program will provide students the opportunity to train and become leaders in the field of clinical research and epidemiology while providing them with clinical practice training.

1.4 Timetable for development of the program

We have developed a new overall curriculum for the PharmD/MS Dual Degree Program in Clinical and Epidemiological Research. Our target matriculation time is Summer of 2027. The program anticipates an initial enrollment of five students for the first year. Up to twenty students will be admitted per cohort per academic year after the first year of implementation of the program.

The proposed timeline is for developing the dual degree program is shown in Table 1.

Table 1. Proposed Timeline for PharmD/MS Dual Degree Program Development.

Date Action	Proposal review step	Status
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03/03/2025	Proposal to be submitted to the PharmD Curriculum & Educational Policy Committee (CEPC)	CEPC	CEPC review and approval by 03/10/2025
03/03/2025	Proposal to be submitted to Epidemiology and Biostatistics Educational Leadership Committee (ELG)	Epidemiology and Biostatistics ELG	Epidemiology and Biostatistics ELG review and approval on the 03/11/2025 meeting
03/06/2025	Proposal to be submitted to Graduate Council	Graduate Council	Graduate Council informal review by 03/20/2025
03/17/2025	Proposal to be submitted to the Epidemiology and Biostatistics Executive Committee	Epidemiology and Biostatistics Executive Committee	Epidemiology and Biostatistics Executive Committee review and approval on the 04/02/2025 meeting
03/26/2025	Proposal to be submitted to Budget & Resource Management (BRM)	BRM	Anticipated BRM review and approval by 04/25/2025
05/01/2025	Proposal to be sent to the SOP Faculty Council (SOP FC)	SOP FC	Anticipated SOP FC review and approval at the 05/08/2025 meeting
05/08/2025	Proposal to be sent to the SOP Full Faculty	SOP Full Faculty	SOP-full faculty vote (two weeks to be allowed for voting – anticipated approval by 05/22/2025)
05/12/2025	Proposal to be submitted to Graduate Division	Graduate Division	Anticipated Graduate Division review and approval by 06/18/2025
05/2025	Submit notification of changes to APPEs to the Accreditation Council for Pharmacy Education (ACPE)	ACPE	Review at the June 2025 ACPE Board Meeting
05/26/2025	Proposal to be submitted to Grad Council & Academic Planning and Budget (APB)	Grad Council	Grad Council & APB concurrent review

06/19/2025	Proposed program to be presented at the Grad Council meeting	Grad Council	Anticipated Grad Council approval
06/20/2025	Proposal to be submitted to the Executive Council (UCSF-specific committee)	Executive Council	Anticipated Academic Senate Executive Council review
07/23/2025	Proposed program to be presented to the Executive Council (UCSF-specific committee)	Executive Council	Anticipated Academic Senate Executive Council approval
07/24/2025	Proposal to be submitted to Executive Vice Chancellor & Provost (EVCP) & Chancellor	EVCP & Chancellor	Anticipated EVCP & Chancellor approval by 08/25/2025
08/26/2025	Proposal to be submitted to the Coordinating Committee on Graduate Affairs (CCGA)	CCGA	Anticipated CCGA review and approval (4- 6 months) on 01/26/2026
01/26/2026		CCGA & UCEP	Anticipated CCGA & UCEP approval
12/01/2026		Application deadline	
02/15/2027		Accepting first cohort	
07/2027		First cohort of students matriculates	

1.5 Relationship of the proposed program to existing programs at UCSF

The proposed four-year PharmD/MS Dual Degree Program in Clinical and Epidemiological Research is a unique joint effort between the UCSF School of Pharmacy's PharmD program and the Master of Science in Clinical and Epidemiological Research program from the UCSF Graduate Division. The proposed program will include three-year PharmD program and six academic quarters of the MS program. Below we describe the overlap in course content between the proposed program and the existing PharmD and MS programs.

<u>PharmD program at UCSF:</u> this program prepares students academically for a wide-open future in pharmacy practice while supporting their professional growth. This three-year, year-round PharmD

curriculum is science-based, tightly integrated, and experiential. Scientific thinking underlies all coursework. Students actively engage in their learning as they build core knowledge, experience pharmacy practice firsthand from the first day of class and explore new ideas and innovations in science and practice. The proposed dual degree program curriculum will draw from the PharmD program and will additionally include an MS portion in clinical research and epidemiology. This will include integration of the PharmD curriculum and IPPEs in the first two years of the proposed dual degree program, two APPEs in the second year, one longitudinal APPE over 30 consecutive weeks in the third year, followed by three APPEs as well as studying for the North American Pharmacist Licensure Examination (NAPLEX) in the last (fourth) year of the proposed dual degree program. In this dual degree program, the MS research project will count towards the PharmD discovery project (the PharmD discovery project will be waived), one APPE will be substituted by clinical practice during the third year (MS studies) of the program that is composed of one clinic day weekly.

MS Program in Clinical and Epidemiological Research: The overall goal of the MS Program is to increase the number and quality of clinical researchers defined (using the broad NIH definition) as those participating in patient-oriented, translational, epidemiologic, comparative effectiveness, behavioral, outcomes or health services research. The graduates of this program will be able to independently design, implement, and interpret creative and rigorous research. A main focus of the program is to develop principal investigators (i.e., individuals who will lead research teams), either for persons already coming to the program with a doctoral-level degree or for those who go on to obtain a doctoral degree. The training, however, is also useful as a stand-alone terminal degree for persons who will play critical supportive roles on research teams, such as clinical research coordinators. Our goal is to balance the needs of these different types of students, which sometimes differ in terms of their goals, expectations, and stage of training. It is expected that graduates will work in a variety of environments, including academic centers, foundations, government agencies, and industry. In their work, graduates will be prepared to participate across the spectrum of research including translating the advances of basic science to human populations, determining causes and interventions to prevent and treat disease, and promoting the use of evidence-based practices in clinical medicine and public health.

The standard MS in Clinical and Epidemiological Research includes 38 units of coursework to be completed over 7 quarters. Students also participate in mentored research and complete products of research including a comprehensive literature critique, presentation of an original research abstract at a national or international meeting, and submission of a first-author research manuscript to a peer-reviewed journal. Students also have a one quarter educational apprenticeship to gain teaching experience.

Students in the proposed dual degree program will only be required to complete 6 quarters of MS-focused studies due to overlap with the PharmD Epidemiology, Biostatistics, and Population Sciences curriculum and Discovery Project. The dual degree program curriculum will draw from both PharmD and MS programs and complement existing curriculum with development of additional courses in response to the program's unique competencies.

Coursework details for the PharmD/MS Dual Degree Program in Clinical and Epidemiological Research can be found in Section 5.

PharmD/MS in Clinical and Epidemiological Research Sequential Degree

Historically, if students wished to achieve both a PharmD and MS in Clinical and Epidemiological Research, students could enroll in the two separate programs sequentially, spending three years for PharmD studies and 2 years (7 quarters) for MS studies, requiring 5 years total. In contrast, students in the proposed dual degree program will be able to complete their studies in 4 years due to the integration of the two programs.

1.5.1 Alignment with Campus Academic Plan and Priorities

The proposed PharmD/MS Dual Degree Program in Clinical & Epidemiological Research is also well aligned with UCSF's current academic plan and priorities. First, we see resonance with the School of Medicine's 2025 Strategic Plan to Advance and Harness Technology of "pushing the boundaries of technology, its human interface, and data-driven applications in all areas of education, research, and healthcare." With a specific emphasis on biostatistics, big data, and clinical informatics, the PharmD/MS Dual Degree Program aims to help expand this technological frontier. Second, the proposed program is well aligned with the School's of Medicine's 2025 Strategic Plan to Lead Innovation and Discovery of "continuing to promote curiosity-driven research to further our understanding of fundamental science; support excellence and innovation in education to meet the needs of society; and join with our community to use discovery to improve health locally and globally". With a specific emphasis on the use of machine learning/artificial intelligence in biomedical sciences, real-world data, translating evidence into policy along with the clinical experience gained from the PharmD portion, the PharmD/MS Dual Degree Program in Clinical and Epidemiological Research aims to help expand this pillar.

The PharmD/MS Dual Degree Program in Clinical and Epidemiological Research also satisfies multiple points in the School of Pharmacy's 2022-2027 Strategic Plan for Education. Integrating the PharmD and MS programs aligns with goal 2.3.1 "Promoting and supporting in-depth training in basic and clinical science and practice through sustainable expansion and enhancement of degree, fellowship, and residency programs"

The program is also consonant with the broader UCSF Health's Vision 2025 strategic plan, following one of its top priorities to "discover, develop, and embrace digital technology to deliver value to patients and referring physicians, and redesign our institution on a robust digital foundation." Keeping patient-centered care at the forefront of focus and aligning with the School of Pharmacy's recent appointment of Ryan Hernandez as a co-vice dean of diversity, equity, and inclusion (DEI), the PharmD/MS Dual Degree Program in Clinical and Epidemiological Research will embrace UCSF's core commitment to improving DEI.

1.6 Relationship of the proposed program to other UC programs

PharmD/MS in Clinical and Epidemiological Research Dual Degree Program is unique and will be the only program offering this dual degree in the University of California system.

UCSD has both a PharmD and MS in Clinical Research but does not offer a formal dual degree program and does not advertise informal sequential degree pathways.

UC Irvine has both a PharmD and a MS in Epidemiology but does not offer a formal dual degree program and dose not advertise informal sequential degree pathways.

1.7 Contributions to diversity

UCSF is committed to diversity and strives to build a broadly diverse and inclusive community. The UCSF School of Pharmacy excels thanks to the contributions of people of all backgrounds, and is aligned with UCSF's PRIDE (Professionalism, Respect, Integrity, Diversity and Excellence) values and strives to embody these values in everything the School does. UCSF School of Pharmacy Admissions Committee has been using holistic recruitment and admissions process for a number of years already and the Committee representatives have been invited to national conferences to share the practices that have led to the success in recruitment and academic success of a diverse student body. The same strategies, criteria, and experiences will be applied to identify and matriculate the students for the PharmD/MS Program. Moreover, one of the main themes of the School of Pharmacy's current strategic plan is Diversity, Equity, and Inclusion (DEI), which aims to cultivate a culture of DEI among trainees, faculty, and staff; establish the infrastructure, programs, and events to support DEI efforts; and increase recruitment and retention of diverse trainees, faculty, and staff. The PharmD/MS Dual Degree Program will adhere to and continue to advance diversity, equity, inclusion, belonging, and justice in all its forms at all levels of operation. In addition, we will establish a Diversity Committee that will have the role in the program governance to ensure not only that the program does not discriminate against applicants, staff, and faculty based on any of the mentioned characteristics but it ensures that the program reflects UCSF's PRIDE values and reflects our community and state.

Additionally, the MS in Clinical and Epidemiological Research program has a strong commitment to diversity. All faculty are required to complete UCSF Diversity, Equity, and Inclusion Champion training. All course directors can receive extra funding every three years to revise their course materials, including for revisions to promote inclusivity. A course entitled "Social Determinants of Health: What Every Researcher Should Know" is a required course for the program.

Commitment to diversity outreach and equity

We will follow the guidance and best practices of the UCSF Office of Diversity and Outreach to identify, recruit, and retain diverse students, faculty, and staff.

- 1. Student Recruitment: Considerable attention will be paid to recruiting underrepresented students including underrepresented ethnic minority students. We plan to actively recruit for a diverse and highly qualified pool of applicants via these guidelines:
 - Members of the Admissions Committee will be composed of at least 50% women and underrepresented minorities to ensure that women and underrepresented minorities have an equal opportunity to serve on the Admissions Committee.
 - Members of the Admissions Committee will review and use UCSF institutional guidelines and best practices on unconscious bias, and will employ a holistic approach to evaluation of applicants.
 - The program application will not allow submission of GRE scores.
 - A DEI officer (or "Equity Advisor") will serve in addition to the faculty representatives on the Admissions Committee.

- Advertisements for the program will include the following language: "UCSF seeks candidates whose experience, teaching, research, or community service has prepared them to contribute to our commitment to diversity and excellence."
- Recruitment and advertising events will target programs promoting diversity in pharmaceutical and biological sciences. These events will also focus on programs and institutions that serve underrepresented groups and women.
- Direct Pipeline Programs: Three programs housed in UCSF School of Pharmacy include Pharmacy Post-Baccalaureate Program, Pharm Tech to PharmD Pathway, and UC Merced – UCSF BS to PharmD Program.
- Annual ongoing presence at CSU campuses, many of which are designated as Hispanic Serving Institutions (i.e. CSU Dominguez Hills, CSU Long Beach, CSU Pomona).
- Heavy Presence in the Central Valley, a designated healthcare desert with a large population of underrepresented students (CSU Fresno, CSU Bakersfield, UC Merced, etc.)
- Active participation by faculty in the Summer Undergraduate Research Program sponsored by the Graduate Division.
- UCSF faculty visits to minority institutions and institutions with significant minority student populations.
- Advertisements and special mailings to minority institutions and institutions with significant minority student populations
- Participation in the MARC program.
- The program will engage and participate in outreach programs aimed at underrepresented groups, including the AI4ALL summer program at UCSF. The AI4ALL program provides high school students from underrepresented groups access to educational, research, mentorship and grant funding opportunities in computer science disciplines including Artificial Intelligence and Machine Learning.
- To extend our reach for potential candidates outside of UCSF, we will expand our recruitment activities. These activities will include scheduling direct outreach activities at the American Society for Clinical Pharmacology and Therapeutics annual meeting; and a partnership with Historically Black Colleagues/Universities (HBCUs) with our presence at Atlanta University Center Consortium's (AUCC) annual recruitment event. AUCC members include Clark Atlanta University, Spelman College, and Morehouse College.
- 2. Faculty Recruitment: faculty from the PharmD and MS in Clinical Research programs will engage in this proposed dual degree program. Additionally, the program will actively work to identify and recruit diverse and highly qualified faculty via these guidelines:
 - Search committee members will be of diverse background and experiences and have demonstrated commitment to advancing Diversity, Equity, Inclusion, and Belonging.
 - The search committee will include a DEI officer (or "Equity Advisor")

 Recruitment and advertising will emphasize promotion of diversity in the mathematical, computer, health, and biological sciences, and that target professional organizations for underrepresented groups.

1.8 Administration of the program

The School of Pharmacy at UCSF will house and administer the dual degree program admissions and all academic aspects of the PharmD training within the dual degree program. The School of Pharmacy will provide administrative space and support for program faculty, and access to workspaces for students, as well as access to conference and meeting rooms for seminars at the UCSF Mission Bay and Parnassus campuses. The School of Pharmacy will also provide the students with the clinical practice experience for the PharmD program in community pharmacies, health systems, medical centers and hospitals, ambulatory care clinics, managed care, and industry within San Francisco Bay Area and locations throughout California. The PharmD faculty are affiliated with the three main departments of School of Pharmacy: Bioengineering and Therapeutics Sciences, Clinical Pharmacy, and Pharmaceutical Chemistry. They develop and deliver the PharmD degree program, which is administered by the Dean's Office. Faculty members outside the School of Pharmacy (like those affiliated with Department of Cellular and Molecular Pharmacology, Cardiovascular Research Institute, and Department of Physiology) also teach in the PharmD program.

The MS in Clinical and Epidemiological Research is a self-supporting program housed within the UCSF Graduate Division with faculty drawn from the School of Medicine (mostly from the Department of Epidemiology and Biostatistics) and School of Pharmacy. Elaine Ku, MD, MAS, is the Program Director, and Alexis Beatty, MD, MAS serves as the Faculty Lead for the program as well as the Director for dualdegree programs including the sequential MD-MS and the proposed dual-degree PharmD-MS. Drs. Ku and Beatty were selected to lead the program after an open recruitment and review process by a search committee in 2021 and both are alumni of the Masters' program, have taken the core coursework, and are familiar with the mechanics of the program. Ms. Clair Dunne, MPA is the Program Coordinator, responsible for course management, student progress, website and database administration. She is assisted by additional staff in course scheduling, classroom technical support, syllabus management, application processing, and financial management. All education programs in the Department of Epidemiology and Biostatistics (including the MS in Clinical and Epidemiological Research) are overseen by June Chan, ScD who is Vice Chair of Education in the Department of Epidemiology and Biostatistics, and Inez Bailey, who is Senior Director of Academic Development and Strategy in the Department of Epidemiology and Biostatistics. The program has an Advisory Committee that meets twice yearly and established Bylaws that guide the administration of the program. Faculty that comprise the Masters committee for each student will include 1) Committee Chair: Faculty appointed in the Department of Epidemiology and Biostatistics (primary or secondary), 2) Biostatistician appointed in the Department of Epidemiology and Biostatistics, and 3) Subject Matter Expert (Faculty appointed within the School of Pharmacy, except in special circumstances where the Committee Chair is also dual-appointed within the School of Pharmacy, when another UCSF faculty may be appointed to the committee).

The PharmD portion of the proposed dual degree program is granted by the School of Pharmacy and the MS portion in Clinical Research and Epidemiology is granted by the Graduate Division. The budget will be overseen jointly by the School of Pharmacy and Graduate Division.

1.9 Governance of the program

The PharmD/MS Dual Degree Program in Clinical Research and Epidemiology will be governed by four committees and associated faculty and members. The four committees are the 1) Steering Committee, 2) Curriculum Committee, 3) Admissions Committee, and 4) Diversity Committee.

- 1) Steering Committee is the governing body of the PharmD/MS Dual Degree Program in Clinical Research and Epidemiology, which will represent and provide overall leadership for the program and be responsible for its implementation. The Steering Committee members are Igor Mitrovich, MD, Dr. Alexis Beatty, MD MAS, Dr. Valerie Clinard PharmD, Dr. Jennifer Cocohoba, PharmD MAS. The Steering Committee will be responsible for the recruitment, assessment, and final selection of the PharmD/MS students. The Steering Committee will also define the skills, attributes, and knowledge of the program graduates. It will be also responsible for the ongoing review of the program effectiveness, including regular feedback from the students and program faculty. Other responsibilities of the Steering Committee include establishing relationships and maintaining liaison with other departments, organizations, programs, and students within and outside UCSF; ensuring timely and accurate communication with instructional faculty; and overseeing funding and resources of the program.
- Curriculum Committee will be composed of members from both the PharmD Curriculum Committee and the MS (Clinical Research and Epidemiology) Curriculum Committee. The PharmD Curriculum Committee includes Michael Grabe (Chair), PhD, Xiaokun Shu, PhD, Joanne Chun, PharmD/PhD, Katherine Gruenberg, PharmD, Conan MacDougall, PharmD, Valerie Clinard, PharmD, Jaekyu Shin, PharmD, Tram Cat, PharmD. The MS Curriculum Committee includes June Chan, ScD, Inez Bailey, MS, Elaine Ku, MD, MAS, Catie Oldenburg, ScD, MPH, John Kornak, PhD, Lydia Zablotska, MD, PhD, MPA, Rebecca Graff, ScD, Alka Kanaya, MD, Maria Garcia, MD, MPH, MAS, Pryia Shete, MD, MPH. Each committee shall meet yearly and as needed. Once the program is established, members of both Curriculum Committees will be responsible for reviewing and evaluating the existing curriculum and any proposed changes. Curriculum effectiveness will be assessed through student course evaluations and faculty assessment. Both Curriculum Committees will propose guidelines for student support including advising and mentoring. Additionally, the Curriculum Committee will identify and evaluate new instructional faculty.
- 3) The Admissions Committees. The program will utilize the two existing Admissions Committees (one in the PharmD Program and the other in the MS Program). The Steering Committee will work with the two admissions committees to plan recruitment strategies that will successfully recruit a high-quality, diverse student population. The respective admissions committees will use a holistic admission strategy and be responsible for the review, evaluation, and selection of applicants for interviews. The committees will interview selected applicants and then rank and admit students to each program independently. The Steering Committee will work with the respective admissions committees to address any discrepancies and to finalize the list of the applicants selected for the PharmD/MS Program.
- 4) The Diversity Committee will be composed of members from both the PharmD Program and the MS program in Clinical Research and Epidemiology. The Committee will be chaired by Meghan Morris,

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PhD who leads the Department of Epidemiology and Biostatistics Committee on Diversity, Equity, Inclusion and Access (MS Program). The rest of the Committee will be comprised by one additional member from the Department of Epidemiology and Biostatistics and two members from the School of Pharmacy. The committee shall meet yearly and as needed. They are responsible for 1) reviewing integration of training on health equity, systemic racism, ethics, and health disparities in the curriculum, 2) soliciting feedback from matriculated students and from faculty, in particular those identifying with groups and communities underrepresented in the STEM fields, using both online anonymous surveys and focus groups, 3) conducting Town Hall meetings, at which the results of both surveys and focus groups will be presented and discussed and feedback on means to improvement will be actively solicited, and 4) reviewing recruitment practices, admissions outcomes, and climate survey and focus group feedback, and presenting a formal evaluation with concrete recommended next steps to the faculty and student body. Formal benchmarks will include absolute numbers and proportions of student applicants, accepted students, and matriculated students, who identify as members of marginalized or underrepresented groups.

1.10 Program Evaluation

The PharmD/MS Dual Degree Program Steering Committee will establish a review process to ensure continuous, timely and thorough outcomes assessment of the program in its initial phase and as it develops and grows. The process includes meetings of the Steering, Curriculum, and Admissions Committees. In the first two years of student enrollment, the committees will meet every 6 months. The Steering Committee will meet to review assessments and proposals from the Curriculum and Admissions Committee and discuss topics including but not limited to:

- Curriculum content
- Student number, diversity, and quality
- Student performance (evaluations)
- Student support
- Student feedback through experience surveys
- Faculty feedback through experience surveys

After the first 2 years of student enrollment, the Steering, Curriculum, and Admissions Committees will meet annually.

The program will employ the following outcome measures as part of the evaluation process:

- Course evaluations: After each quarter of instruction, students will provide feedback for each
 course through standardized course evaluations. The Curriculum Committee and faculty for the
 respective course will review the evaluations and submit findings and propose actions/changes to
 the Steering Committee.
- Faculty evaluations: After each quarter of instruction, students will provide feedback and evaluate
 the performance of the instructional faculty. This evaluation will include an assessment of
 teaching methods and effectiveness in teaching course materials. Any concerns will be noted and
 addressed by the Curriculum and Steering Committees. The Curriculum and Steering Committees
 will meet with the instructional faculty to discuss outcomes of the faculty evaluations and address

- any areas that necessitate change or improvement. These changes will be documented and maintained in the Program records.
- Exit interview: At completion of the program, students will participate in a 1-on-1, 30-minute exit interview conducted by a member of the Curriculum Committee. Students will be asked to provide feedback on their education along with ideas on how to improve the student experience. This will allow students to reassess curriculum and their research experiences following the completion of the program. It will also allow students to provide feedback on topics not captured in the above evaluations. To supplement exit interviews, an exit survey will also be distributed by the Curriculum Committee to graduating students to provide a platform for those who feel more comfortable sharing their experiences anonymously.
- Career Outcomes evaluations: Graduates of the PharmD/MS Program will be asked to complete a survey two- and five-years post-graduation that assesses the impact of the program on their skills and expertise, career path, ability to get a job in their desired area (current position), and career satisfaction. The key metrics will include: 1) transition to academic positions, research positions, and healthcare settings; 2) number of publications; 3) grant funding; 4) awards, and other forms of recognition.

In addition to program review, a peer evaluation system is in place at UCSF as well as regular performance reviews of deans, departmental chairs, and faculty for purposes of promotion and advancement.

The Program Leads will be responsible for keeping records of the above outlined evaluations and data that will establish the basis for annual reports of program performance. The evaluations and data will be reviewed by the Coordinating Program committee annually. This information will also be used for the Academic Program Review conducted by the UCSF Graduate Council and Graduate Division.

1.10.1 Student Performance Evaluation

Student performance will be evaluated by homework, class participation, written tests, laboratory tests, oral and written presentations, and committee evaluation of MS products of research (comprehensive literature critique, abstract presentation at a national or international meeting, and first-author manuscript submitted to a journal for peer review). After each quarter of instruction, students will be asked to give feedback and evaluate each course in terms of content as well as faculty teaching effectiveness. At the completion of the program, students will also be asked to self-evaluate as well as evaluate the overall program.

For the MS committee, students will be expected to have committee reviews at three points in their participation in the MS degree: winter quarter of their first year of MS (third year of the PharmD/MS program), within 9 months of graduation, and within 3 months of graduation. The MS committee will review the student's progress and expected products of research (comprehensive literature critique, abstract, and manuscript).

SECTION 2. PROGRAM

The difficulty in attracting talented and qualified potential students into our proposed dual degree PharmD/MS program is generally acknowledged. This is attributed to the challenges of balancing and adapting to both pharmacy practice coursework and MS coursework with the transition from PharmD into MS, and an expected completion time of about 4 years (intensive full-time). Based on that, we will take a highly aggressive recruitment strategy through direct and indirect recruitment:

Direct Recruitment:

A. We will use our internal <u>listserv</u> to advertise the program to the entire School of Pharmacy student body.

B. <u>Print advertisement</u>: We will design posters to advertise our proposed PharmD/MS Dual Degree Program, which will be displayed in the School of Pharmacy and School of Medicine bulletin boards close to student affairs as well as residents' lounges. In these posters, we will highlight the main advantages of obtaining a PharmD/MS degree in Clinical and Epidemiological Research and how integration of both clinical and research skills can make the graduates of this program more competitive in academia and/or industry.

Indirect Recruitment:

- A. Web based recruitment: We will create a webpage for the UCSF PharmD/MS in Clinical and Epidemiological Research Dual Degree Program, which will serve as a valuable resource for attracting candidates.
- B. Active recruitment at scientific meetings at both a regional and national level: Regionally, the program will be promoted at events such as the UC Berkeley Graduate School Fair, UC Davis Graduate School Fair, UC Irvine Graduate School Fair, and Stanford Graduate Fair. Nationally, the PharmD/MS in Clinical and Epidemiological Research Dual Degree Program will be promoted at annual organizational meetings such as the American Society for Clinical Pharmacology and Therapeutics (ASCPT), American College of Clinical Pharmacology (ACCP), American Association of Pharmaceutical Scientists (AAPS), and American College of Clinical Pharmacy (ACCP), Society for Advancement of Chicanos/Hispanics & Native Americans in Science (SACNAS), Annual Biomedical Research Conference for Minoritized Scientists (ABRCMS), Out in Science, Technology, Engineering, and Mathematics (oSTEM), and Women in Science, Technology, Engineering, and Mathematics (WiSTEM) meetings.
- C. <u>Google advertisement</u>: To reach more potential students nationally and internationally, we will create Google advertisements that can target specific keywords, and interests (e.g PharmD/MS, Epidemiology, Clinical Research).
- D. <u>Outreach to pharmaceutical companies</u>: The PharmD/MS program graduates are expected to be highly qualified professionals with clinical and research skills (qualified for industry positions). Based on that, we will create an outreach plan to pharmaceutical companies to further promote our PharmD/MS dual

degree program, highlighting the mutual benefits of creating a pipeline of highly qualified professionals needed for industry jobs (potential for future workforce needs).

2.1 Applicant qualifications

Students must be admitted into both PharmD and MS programs. For the PharmD/MS Dual Degree program eligibility:

- Students must satisfy all PharmD prerequisites with course work approved by the Office of Student Affairs (all prerequisites must be completed prior to July 1 of the year of entry into the program). It is the responsibility of the applicants to verify if their course work is approved to meet the UCSF PharmD prerequisites. Applicants are also expected to have adequate preparation in the biological and physical sciences. In most cases, adequate background preparation includes courses such as analytical geometry and calculus, physics, physical chemistry (physical pharmacy), organic chemistry, biochemistry, molecular biology, pharmacology, and biological sciences.
- Students who have completed an undergraduate degree from an accredited institution with a minimum grade point average of 3.0 on a 4.0 scale (equal to a letter grade of B).
- If offered admission, students must be able to secure and maintain a valid intern pharmacist license with the California Board of Pharmacy.
- All students offered provisional admission will be required to complete a criminal background check prior to final admissions decisions.
- For scholars who are primarily based in other training programs at UCSF, supervisor's assurance that at least 70% of time will be available August through May to divide between the activities of this program and the conduct of the trainee's clinical research projects.
- Three to four letters of recommendations are required for both PharmD and MS programs. Applicants will be asked for referees on the graduate division application. Referees will be asked to complete an evaluation form and submit their letter online.
- Preference will be given to applicants who have demonstrated knowledge or experience in some aspect of a health-related field (e.g., clinical practice, public health, health promotion), being currently enrolled in a program or having relevant work experience. Although not required, this prior knowledge or experience is preferred because program scholars will be required to perform original research in an area of their choosing to fulfill graduation requirements. Prior substantive knowledge or experience in a health-related field can be very helpful in identifying a research area of interest and in maintaining motivation for the work.
- Applicants whose native language is not English will be eligible for admission under the same conditions but need to demonstrate proficiency in English by taking the Test of English as a Foreign Language (TOEFL, http://www.toefl.org), or the International English Language Testing System (IELTS, https://www.ielts.org/en-us/) exam, or have demonstrated proficiency in English by completing one year of full-time study with a minimum GPA of 3.2 in an accredited University in the United States. Minimum

acceptable scores for the TOEFL exam will be 550 (paper version) and 213 (computer version). Minimum acceptable scores for the IELTS exam will be 7.

- Graduate Record Examination (GRE) scores will not be accepted, reflecting evolving best practices around standardized testing. In seeking to increase the diversity of students, the program will employ a holistic review approach, evaluating a range of applicant's attributes, experiences, and academic metrics. Prospective students will be from diverse cultural, economic, and social backgrounds.

Students who are already matriculated to the PharmD program may apply to PharmD-MS dual degree program in their first or second year in the PharmD program.

2.2 Diversity

UCSF celebrates diversity and is committed to building a broadly diverse and inclusive community. The PharmD/MS Dual Degree Program in Clinical and Epidemiological Research also places a high value on diversity and has a deep appreciation for the perspectives and rich experiences that a varied student body and faculty can bring to the educational process. Strategies to uphold these values throughout the recruitment and admissions process can be found in Section 1.7.

The UCSF Office of Diversity and Outreach leads the campus effort to foster a culture of equity and inclusion by serving as the central resource for internal and external community members. It fosters a collaborative culture by leading outreach efforts to increase the number of underrepresented students at all levels of the educational pipeline and to increase the diversity of the pool for faculty, staff and leadership positions. Additionally, it is the home of a wealth of resources such as the Multicultural Resource Center, Diversity Hub, LGBT Resource Center, free on-demand training and many other programs to support a welcoming climate.

In an effort to reach underrepresented applicants, the UCSF Office of Diversity and Inclusion will be featured prominently on the homepage of the Program's website. As the website will be an integral marketing tool, featuring this resource will highlight UCSF's and the Program's commitment to foster an environment inclusive to everyone. Promotion of the Program will also occur at university campuses, which possess diverse student bodies.

The following scholarship opportunities related to DEI will be also available:

- -Justice, Equity, Diversity, and Inclusion (JEDI) Scholarship, which supports students who have demonstrated their commitment to diversity and addressing healthcare disparities.
- -Champion of Diversity Scholarship, which recognizes students who have made a significant impact on addressing DEI initiatives.

2.3 Program of study

The MS portion of the PharmD/MS Program will conform to the Requirements for the Masters' of Science Plan II as outlined by the UCSF Graduate Council Regulations and Procedures. This plan requires 38 units of coursework and comprehensive examination (or capstone project, 6 units). The

minimum University of California requirement for a master's degree is three quarters in residence and completion of 36 units of study.

2.3.1 Unit Requirements

This intensive, full-time, 4 years PharmD/MS Dual Degree Program in Clinical and Epidemiological Research is a unique joint effort between the UCSF School of Pharmacy's PharmD program and the Clinical and Epidemiological Research MS program from the Graduate Division. Through careful structuring of the UCSF PharmD-MS Dual Degree Program, it is possible for students to complete the requirements for both the PharmD and MS degrees in a shorter time (4 years) than would be expected in a sequential PharmD/MS program or if the two degrees were obtained separately (5-5.5 years). Unlike the PharmD program, which has a set, three-year curriculum, the MS is a research degree, and, as a result, the duration of the path is not fixed. Traditional MS students typically require a minimum of 2 years (7 quarters) to complete their degree, but efficiencies built into the PharmD-MS Dual Degree Program will allow the completion of the MS portion in 6 quarters. It is estimated that UCSF PharmD-MS students will be able to complete both degrees within 4 years. The PharmD-MS degree will only be awarded after completion of the required coursework (full unit requirements) including the PharmD curriculum, clinical experience for the PharmD curriculum, coursework for the MS degree (38 units over 6 quarters), and committee acceptance of the products of research. This very rigorous program requires a full-time commitment and is not suited for students with concurrent employment or work. This curriculum will present students the skills to conduct rigorous clinical and epidemiological research related to pharmaceutical sciences and clinical applications.

2.3.2 Required Courses

The curriculum has been carefully designed to ensure mastery in pharmacy practice, patient care, pharmaceutical sciences, and clinical and epidemiological research, that will pave the way to perform basic and clinical research and to translate basic science research into clinical application. The course of study will prepare graduates for careers in academia, as faculty members in schools and colleges of pharmacy, government, leaders in clinical research in the pharmaceutical industry, or other health settings where they will engage in academic instruction, clinical care, and research.

All courses in the curriculum are required. Special exceptions may be made for students demonstrating prior mastery in course subjects. Students should submit a petition to the Curriculum Committee and the relevant course instructor(s) to test out of said course. No more than two courses can be waived. Decisions will be made at the discretion of the Curriculum Committee in collaboration with course instructors. For the MS portion, students will choose the electives they will take based on which track they will be enrolled in (Clinical Informatics, Health Data Science, or Implementation Science).

Table 2 outlines these specific skill-based goals for the program along with expected competencies and outcomes, learning methods, and means of assessment to gauge those outcomes. Each didactic course is designed to map to these competencies and skills. All courses are described in greater detail in Section 5.

Table 2.

Competencies and Outcomes	Learning Methods	Assessment
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PharmD Curriculum: Baseline knowledge and fundamental concepts in pharmacy profession	Coursework of Foundations I: Area 1 (Therapeutic sciences), Area 2 (Inquiry), Area 3 (Social and Administrative Sciences) Coursework of Foundations II	Objective written exams, homework assignments, class participation
PharmD Curriculum: In-depth exploration of science and therapeutics, and inquiry, through the lens of eight organ systems and disease categories	Integrated Themes Year 1 themes: Cardiovascular Science & Therapeutics; Respiratory Science & Therapeutics; Renal Science & Therapeutics; Gastrointestinal Science & Therapeutics Year 2 themes: Endocrine Science & Therapeutics; Neuroscience & Therapeutics; Oncology Science & Therapeutics; Infectious Disease Science & Therapeutics	Objective written exams, homework assignments, patient cases, and class participation
PharmD Curriculum: Hands-on pharmacy practice and communications skills	Coursework: Applied Patient Care Skills (APCS) course	Objective written exams, homework assignments, class participation
PharmD Curriculum: Clinical experiences that reflect the situations and challenges student will face as a practicing pharmacist	Practice rotations: Introductory Pharmacy Practice Experiences (IPPEs) in community pharmacies, health systems, medical centers and hospitals, ambulatory care clinics, managed care, and industry; and Advanced Pharmacy Practice Experiences (APPEs) at a medical center, hospital, or clinic setting that provides real-world pharmacy experience	
MS Curriculum: Learning about research study design, data analysis and management, sample size calculations, power calculations	EPI 202 – Designing Clinical Research	Reading assignments and problems sets, and a final submission of a completed protocol

MS Curriculum: Comprehend the basic of the Relational Database Model and learning how to develop simple and useful data collection systems	EPI 218 – Data Collection and Management for Clinical Research	Six weekly assignments, an online quiz, and a final project (which has two parts: generation of research study data collection and management system that the student has built; and creation of a brief data collection and management plan)
MS Curriculum: Demonstrating the use of STATA for importing, cleaning, managing, describing and analyzing clinical research data	BIOSTAT 212 – Introduction to Statistical Computing in Clinical Research	Computer lab assignments, and a final project
MS Curriculum: Understanding of federal, state, and UCSF policies and resources available to further support the student's research endeavors	EPI 201 – Responsible Conduct of Research	In-person lectures, discussion groups, and participation in an online ethics forum
MS Curriculum: Understanding the contribution of epidemiology to identifying and addressing public health issues, strengths and limitations of common study designs, and understanding the major biases and knowing how to address them	EPI 203 – Epidemiologic Methods	Homework assignments, and a final exam
MS Curriculum: Understanding how to apply epidemiological methods to clinical decisions (e.g diagnostic tests)	EPI 204 – Clinical Epidemiology	Problem sets, a problem-writing assignment, and a final exam
MS Curriculum: Understanding the basic biostatistics terms and notation, and acquiring the skills to manage and summarize data and conduct basic statistical using STATA or R	BIOSTAT 200 – Biostatistical Methods for Clinical Research I	Homework assignment, Midterm assignment, and a final exam
MS Curriculum: Practicing applying concepts taught in TICR Program courses, and obtaining assistance with each student's research project	EPI 220/230 - TICR Program Seminar for First-Year Master's and Certificate Program Scholars	Attendance and participation

MS Curriculum: Identifying the meaning and implications of race/ethnicity, socioeconomic status, and other core concepts, and recognizing how these constructs are shaped by systems of power and oppression.	EPI 222 – Social Determinants of Health and Health Disparities	Homework assignments
MS Curriculum: Describing the roles of descriptive versus inferential statistic, identifying characteristics of the research question, and understanding how to handle a single outcome variable and multiple predictor variables	BIOSTAT 208 – Biostatistical Methods for Clinical Research II	Homework assignments, and a final exam
MS Curriculum: Be able to develop a research question using PI(E)CO framework, designing a brief systematic review protocol, understanding the basic methods of meta-analysis and its related concepts, and developing analytical skills using a practice dataset	EPI 212 – Publishing and Presenting Clinical Research	Take home assignments, class participation, and a presentation
MS Curriculum: Understanding the basics of survival analysis and repeated measures data, and applying Cox regression and multiple predictor regression in the repeated measures settings	BIOSTAT 209 – Biostatistical Methods for Clinical Research III	Homework assignments, quizzes, and a data analysis project
MS Curriculum:	Students will choose the electives on general topics or in specialized tracks (Clinical Informatics, Health Data Science, or Implementation Science). Section 5 describes in a greater detail all of the electives available	

YEAR 1

SUMMER (17 units)	FALL (15 units)	WINTER (15.5-18 units)	SPRING (17.5-20 units)
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Coursework of	Cardiovascular Science &	Inquiry Immersion	Renal Science &
Foundations I (PHARMIS	Therapeutics Inquiry	(PHARMIS 122) (2.5	Therapeutics Inquiry
110): Area 1 (Therapeutic	(PHARMIS 111) (11.5	units)	(PHARMIS 113) (6 units)
sciences), Area 2	units)		
(Inquiry), Area 3 (Social		Respiratory Science &	Gastrointestinal Science &
and Administrative	APCS II (CL PHARM	Therapeutics Inquiry	Therapeutics Inquiry
Sciences) (14.5 units)	171) (1 unit)	(PHARMIS 112) (9.5	(PHARMIS 114) (8 units)
		units)	
APCS I (CL PHARM	IPPE – Community A (2.5		APCS IV (CL PHARM
170) (2.5 units)	units)	APCS III (CL PHARM	173) (1 unit)
		172) (1 unit)	
			IPPE – Community B
		IPPE – Community B	(2.5-5 units)
		(2.5-5 units)	

YEAR 2

SUMMER (13.5 units)	FALL (17-19 units)	WINTER (16-18 units)	SPRING (15.5-17.5 units)
Coursework of	Neuroscience &	Oncology Science &	
Foundations II	Therapeutics Inquiry	Therapeutics Inquiry	IPPE – Health Systems
(PHARMIS 115): spans	(PHARMIS 117) (14.5	(PHARMIS 118) (5.5	(1.5-3.5 units)
all levels of pharmacy	units)	units)	
practice including special			Two APPEs (each is 7
populations, therapeutic	APCS VI (CL PHARM	Infectious Disease Science	units)
sciences, health care	175) (1 unit)	& Therapeutics Inquiry	·
policy, and evidence-		(PHARMIS 119) (8 units)	
based health care (3 units)	IPPE – Health Systems		
	(1.5-3.5 units)	APCS VII (CL PHARM	
Endocrine Science &		176) (1 unit)	
Therapeutics Inquiry			
(PHARMIS 116) (9.5		IPPE – Health Systems	
units)		(1.5-3.5 units)	
APCS V (CL PHARM			
174) (1 unit)			

YEAR 3

SUMMER (4+electives	FALL (11.5+electives	WINTER (5+electives	SPRING (5+electives
units)	units)	units)	units)
Designing Clinical	Responsible Conduct of	Social Determinants of	Publishing and Presenting
Research (EPI 202) (2	Research (EPI 201) (0.5	Health and Health	Clinical Research (EPI
units)	units)	Disparities: What Every	212) (1 unit)
		Researcher Should Know	
Data Collection and	Epidemiologic Methods	(EPI 222) (1 unit)	
Management for Clinical	(EPI 203) (4 units)		

Research (EPI 218) (1		Biostatistical Methods for	Biostatistical Methods for
unit)	Clinical Epidemiology	Clinical Research II	Clinical Research III
	(EPI 204) (3 units)*	(BIOSTAT 208) (3 units)	(BIOSTAT 209) (3 units)
Introduction to Statistical			
Computing in Clinical	Biostatistical Methods for	TICR Program Seminar	TICR Program Seminar
Research (BIOSTAT 212)	Clinical Research I	for First-Year Master's and	for First-Year Master's and
(1 unit)	(BIOSTAT 200) (3 units)	Certificate Program	Certificate Program
		Scholars (EPI 220/230) (1	Scholars (EPI 220/230) (1
Electives**	TICR Program Seminar	unit)	unit)
	for First-Year Master's and		
Clinical practice	Certificate Program	Electives**	Electives**
experience (one clinic day	Scholars (EPI 220/230) (1		
weekly)***	unit)	Clinical practice	Clinical practice
		experience (one clinic day	experience (one clinic day
	Electives**	weekly)***	weekly)***
	Clinical practice		
	experience (one clinic day		
	weekly)***		

YEAR 4

SUMMER (14 units)	FALL (6+electives units)	WINTER (3+electives units)	SPRING (7 units)
Two APPEs (each is 7 units)	Clinical Epidemiology (EPI 204) (3 units)*	Master's Seminar II (EPI 221) (1 unit)	One APPE
	Master's Seminar II (EPI 221) (1 unit) Educational Practice (EPI 300) (2 units)**** (Summer or Fall)	Educational Practice (EPI 300) (2 units)**** (Summer or Fall) Electives**	
	Electives**		

^{*}Students can opt to take EPI 204 in MS year 1 (year 3 of PharmD/MS) or MS Year 2 (year 4 of PharmD/MS)

2.3.3 Student Assessment and Grading

^{**}More details are provided for the electives in Section 5. Students must take at least 38 MS units for graduation, including required and elective courses. There are no requirements or limits for units per quarter.

^{***}Clinical practice experience in year 3 counts towards one longitudinal APPE (7 units) over 30 consecutive weeks.

^{****} Educational Practice assignments will be made in May of MS year 1 (year 3 of PharmD/MS). Students may complete assignments during one quarter of the 2nd MS year (year 4 of PharmD/MS).

The following PharmD courses will be graded P/NP (Pass/Not Pass) or S/U (Satisfactory/Unsatisfactory): PHARMIS 110 Foundations I, PHARMIS 115 Foundations II, PHARMIS 111 Cardiovascular Science & Therapeutics Inquiry, PHARMIS 112 Respiratory Science & Therapeutics Inquiry, PHARMIS 113 Renal Science and Therapeutics Inquiry, PHARMIS 114 Gastrointestinal Science and Therapeutics Inquiry, PHARMIS 116 Endocrine Science and Therapeutics Inquiry, PHARMIS 117 Neuroscience and Therapeutics Inquiry, PHARMIS 118 Oncology Science and Therapeutics Inquiry, PHARMIS 119 Infectious Disease Science and Therapeutics Inquiry, APCSs (CL PHARM 170-176), IPPEs, APPEs, and PHARMIS 122 Inquiry Immersion.

The following MS courses will be graded P/NP or S/U: EPI 220/230 (First Year MS Seminar), EPI 222 (Masters Seminar II), EPI 201 Responsible Conduct of Research, EPI 212 Publishing and Presenting Research, and the electives (EPI 248 Community-engaged Research and BIOSTAT 211 Mathematical Foundations of Biostatistics). Students will be given a letter grade for the following MS courses: EPI 202 Designing Clinical Research, EPI 218 Data Collection and Management for Clinical Research, EPI 203 Epidemiologic Methods, EPI 204 Clinical Epidemiology, BIOSTAT 200 Biostatistical Methods for Clinical Research II, BIOSTAT 208 Biostatistical Methods for Clinical Research II, BIOSTAT 209 Biostatistical Methods for Clinical Research III, BIOSTAT 212 Introduction to Statistical Computing, and all the electives (except the ones mentioned above which are graded P/NP or S/U). Grades will be determined from assessment of competencies via methods outlined in Table 2.

Following UCSF Policy on Student Progress guidelines:

(https://graduate.ucsf.edu/policy-student-progress)

Unsatisfactory progress indicators for the program will include:

- Failing grades in any course
- Falling below a 3.0 GPA
- Failure to find a research mentor
- Unsatisfactory work with research mentor
- Unprofessional conduct in the lab/research environment (rotation or thesis, as reported by the PI)
- Failure to complete products of research in a timely fashion (by completion of program)
- Issues in academic misconduct and professionalism infractions

It is the policy of the Training in Clinical Research (TICR) Program that one "C" grade or less (or one "U" grade) will trigger a discussion between the program director and the student about the expected level of performance in the program. Two or more grades of "C" or less (or two or more "U" grades) will trigger a formal review by the program and the chair of the scholars' master's committee. This formal review will develop an individualized remediation plan to address the deficiencies. A memorandum of understanding will be generated that clearly outlines specific steps and associated timeline that the scholar must fulfill in order to return to satisfactory performance. The memorandum will be signed by the following parties: the scholar, the master's committee chair, and the program director. Should a scholar be unable to fulfill the expectations according to the timeline outlined in the memorandum, the student will be subject to dismissal from the program.

Note: Disciplinary problems and other infractions that fall within the scope of UCSF's Policy on Student Conduct and Discipline will be referred for consideration by UCSF's Director of Student Rights and Responsibilities.

Process by which failing students will be notified and remediated:

Students whose progress is unsatisfactory (according to one or more of the criteria listed above) will be notified and will meet with the advisor and the program director to develop an individualized remediation plan to address the deficiencies. The meeting results in a memorandum of understanding that clearly outlines specific steps and associated deadlines that the student must fulfill in order to receive a satisfactory report. The report is then signed by the following parties: the student, the primary advisor, and the program director. At this point, the report is filed in the student's academic file within the program, and a copy is sent to the assistant dean for diversity and learner success.

Should the student be unable to fulfill the expectations according to the timeline outlined in the letter, the student will be subject to dismissal from the program. Depending on the student's standing in the program, students may be allowed to leave with either degree (PharmD or MS degree) if they meet the requirements for either degree, but don't meet the requirements for both degrees.

The process for in-depth review of a student's eligibility for dismissal will follow the UCSF Divisional Procedure for Student Grievance in Academic Affairs, section 4.0, and will be conducted by the program's in-depth committee. The in-depth review committee shall consist of three faculty members on the curriculum committee.

Additionally, all students in the proposed PharmD/MS dual degree program must acquire teaching experience as part of their graduate studies. Through EPI 300 Clinical Research Educational Practice (Educational Apprenticeship), students in their fourth year (any quarter) of the PharmD/MS dual degree will have opportunities to serve as small group discussion leaders (i.e., Teaching Assistants), holding office hours for students and grading homework assignments and projects. Teaching performance is monitored by the course directors and the graduate advisors. The teaching requirement is one quarter.

2.3.4 MS Committee and Products of Research

Students will be expected to have established their MS committee by the Winter quarter of their first year of MS studies (third year of the PharmD/MS program). The MS committee will be responsible for reviewing and determining the appropriateness of products of research for achievement of the MS degree. The requirements for products of research are as follows:

Comprehensive literature critique: Each master's student composes a systematic review and critique of the literature pertinent to a specific research question (or set of related questions) in his or her research field, culminating in a five to 10-page report that demonstrates a mastery of the field's literature. The fundamental objective of this requirement is for the scholar to demonstrate that he or she can evaluate a number of papers/reports regarding a particular substantive question (or set of related questions), provide high-level critique of the threats to validity in the individual papers and then come to a conclusion about the question(s) in hand. The critique must have a methods section detailing the process for identifying and analyzing the articles.

First-authored oral or poster presentation at a national or international meeting: Students are required to submit a first-authored abstract to a nationally or internationally recognized scientific meeting/conference within the scholar's academic field and have that abstract accepted for either poster or oral presentation. It may be acceptable in selected cases, with pre-approval by the scholar's master's

committee, to present work that was started prior to enrollment in the program. It is expected that the work represents a substantive contribution to the scholar's research field.

Submission as first author of a peer-reviewed manuscript: Using data analyzed (but not necessarily collected) during residence in the master's program, students must prepare and submit a first-authored manuscript for publication in a peer-reviewed journal that is approved by the master's committee. The manuscript may be a comprehensive extension of the work submitted in abstract form to a national meeting. It is expected that the work represents a substantive contribution to the scholar's research field.

2.3.5 Licensure Exam

As outlined in section 2.3.2, the students in the proposed dual degree program will finish their PharmD curriculum (including Foundations I and II, Integrated Themes, Patient Care Skills/APCSs, IPPE Practice Rotations) in the first two years of the program. They will also be also engaged into two APPEs in the second year, clinical practice experience (composed of one clinic day weekly) throughout their MS studies (year 3 of the program), followed by three APPEs in their last (fourth) year of the program. At the end of the Spring quarter of this year, the students will be able to apply for the pharmacy board examination that they can take after graduation to become licensed pharmacists. To support the students' preparation for this exam, the Synthesis Weeks provide time to further integrate concepts learned in each Integrated Theme. To take the North American Pharmacist Licensure Examination (NAPLEX), the examinee must be a graduate of a pharmacy school accredited by the Accreditation Council for Pharmacy Education (ACPE), and he/she must also meet the eligibility requirements of the state or jurisdiction where he/she wants to practice as a pharmacist. To be licensed as a Pharmacist in California, the person must pass the NAPLEX and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). To be made eligible to sit for the NAPLEX and/or CPJE, the California State Board of Pharmacy (Board) must determine that the examinee have met all the requirements for examination.

SECTION 3. PROJECTED NEED

3.1 Enrollment

An estimate of 5 students is to be matriculated at implementation of the program in Summer 2027. Based on student interest, we expect growth to up to 20 students per cohort after year 2 of enrollment. Soaring advances in pharmaceutical sciences (such as the use of RWD) have led to a dramatic change in the way science is conducted across industry and academia. This has resulted in an enormous demand for scientists with interdisciplinary skill sets in clinical practice, clinical research, and epidemiology. UCSF is one of the world's preeminent institutions in these fields. Our stature and location attract the top innovators and talent in science, education, and care.

There are several PharmD/MS Dual Degree Programs currently offered by the U.S universities including University of Arizona, University of Michigan, Mercer University, University of Southern California (USC), Rutgers University, Virginia Commonwealth University, University of Maryland, Western New England University, and Long Island University. However, most of these programs are either PharmD/MPH or PharmD/MBA. A few universities offer PharmD/MS programs in other fields. For example, PharmD/MS in Regulatory Science program is offered by USC, University of Maryland, and Long Island University. Also, PharmD/MS in Pharmaceutical Sciences program is offered by Mercer

University and Western New England University. Additional programs include PharmD/MS in Pharmacoeconomics and Health Outcomes offered by Mercer University; PharmD/MS in Biopharmaceutical Marketing, PharmD/MS in Gerontology, PharmD/MS in Global Medicine, and PharmD/MS in Healthcare Decision Analysis offered by USC; PharmD/MS in Health Outcomes, Policy and Economics (HOPE) offered by Rutgers University; and PharmD/MS in Artificial Intelligence, PharmD/MS in Pharmaceutics-Cosmetics Sciences, and PharmD/MS in Pharmaceutics-Industrial Pharmacy offered by Long Island University. Our proposed PharmD/MS is the first to be offered in Clinical Research and Epidemiology in the U.S.

3.2 Volume and quality of student demand for the program

Student demand for programs that combine both clinical skills as well as clinical research and epidemiological skills continues to grow, reflecting the community awareness of the rapid advances in these fields. Also, the pressing need of applying evidence-based medicine underscores the need for clinician-scientists. As described in section 3.1, our proposed PharmD/MS Dual Degree Program is unique since it is the first one among the existing U.S.-based PharmD/MS programs to be offered in Clinical Research and Epidemiology. According to the Bureau of Labor Statistics (BLS), employment of medical scientists, including clinical pharmacologists, is projected to grow 11% over the next 10 years. The BLS also projects that employment of epidemiologists is expected to grow 27% between 2022 and 2032, which is much faster than the average growth rate for all occupations.

Clinical Research and Epidemiology Programs:

Due to the rising number of clinical trials, their increased complexity, and the increased number of decentralized and patient-centric trials, the global clinical research organizations market size was estimated at USD 90.4 billion in 2023. The global market is also poised to depict a growth rate of 12.2% from 2024 to 2030 (https://www.grandviewresearch.com/pipeline/clinical-research-organizationsprocurement-intelligence-report). Additionally, due to the rise in EHR and RWD use, the global deidentified health data market size was estimated at USD 8.09 billion in 2024 and is expected to grow at a rate of 9.07% from 2025 to 2030. The market growth is driven by the increased integration of data analytics in healthcare, which supports large-scale studies (https://www.grandviewresearch.com/industryanalysis/de-identified-health-data-market-report). Concurrently, the number of degree programs in clinical research and epidemiology conferred in the US has significantly increased in recent years, reflecting the rapid growing demand for skilled professionals in this field due to increasing complexity in clinical trials and the need for evidence-based medicine. However, the is no program in the U.S which integrates the PharmD degree which provides the students with clinical practice skills with a degree program in clinical research and epidemiology. The proposed program fills in this gap, by offering students both clinical and research skills. The graduates of the proposed program will be capable to work in various career sectors including government and industry. In a survey conducted by the UCSF School of Pharmacy on May 2024 on potential dual degree programs, the PharmD students expressed their high interest in an additional graduate degree (like MS) for someone with PharmD (82.2% of the surveyed students said that this additional degree will be extremely/very/moderately useful and 70% of them said they will be pursuing an additional degree if one was offered by the school). Overall, there is a significant interest among our PharmD students and pharmacy school applicants for a path to industry career, which can be made possible through our proposed program.

As an interdisciplinary program and UCSF leading the fields of health in intellectual energy and reputation, we anticipate significant interest from students with a variety of backgrounds. Overall, the acceptance rate for a PharmD/MS program often falls within the range of only 20-50%, demonstrating competitive demand.

3.3 Opportunities for placement of graduates

The course of study will prepare graduates for careers in academia, as faculty members in schools and colleges of pharmacy, government, leaders in clinical research in the pharmaceutical industry, or other health settings where they will engage in academic instruction, clinical care and research.

Biotechnology companies continue to increase hiring demand, fueled by sizable rounds of venture capital financing, new contracts with Big Pharma partners, and initial public stock offerings. Almost 50% of all pharmaceutical companies are currently hiring for at least one position, and at a faster rate than all other industries. Job posting sites including Indeed and LinkedIn list over 1700 postings for PharmD/MS graduates/holders. Most of these postings are roles in pharmaceutical industry, spanning around various roles. These roles include Translational Science Leads/ Translational Medicine Scientists, Clinical Research Scientists, Clinical Research Associates, Clinical Informaticists, Clinical Genomics Scientists, Biomedical Data Managers, Associate Directors in Clinical Pharmacology, Biostatisticians, Medical Writing Science Managers, Clinical Outcomes Scientists, Medical Science Liaisons, and Computational Scientists.

The proposed PharmD/MS program not only provides participants with the foundational knowledge necessary to secure employment, but also prepares them to become the next leaders in drug discovery and development, clinical research, and epidemiology.

The abundant number of professional opportunities for graduates of PharmD/MS are also evidenced by numerous conferences dedicated to clinical pharmacology, clinical pharmacy, clinical research, epidemiology, healthcare informatics, and more:

- American College of Clinical Pharmacology (ACCP) https://www.accp1.org/
- American College of Clinical Pharmacy (ACCP) https://www.accp.com/meetings/am25/index.aspx
- American Society for Clinical Pharmacology & Therapeutics (ASCPT) https://www.ascpt.org/meetings/annual-meeting
- Association of Clinical Research Professionals (ACRP) https://2025.acrpnet.org/
- American College of Epidemiology (ACE) https://www.acepidemiology.org/
- International Society for Environmental Epidemiology (ISEE) https://www.iseepi.org/
- Interdisciplinary Association for Population Health Science (IAPHS) https://iaphs.org/
- American Society of Tropical Medicine and Hygiene (ASTMH) https://www.astmh.org/
- American Society of Human Genetics (ASHG)

- https://www.ashg.org/
- International Genetic Epidemiology Society https://www.geneticepi.org/
- American Public Health Association (APHA) https://www.apha.org/
- Population Association of America (PAA) https://www.populationassociation.org/home
- Society for Clinical Trials (SCT) https://www.sctweb.org/
- Society for Pediatric and Perinatal Epidemiologic Research (SPER) https://sper.org/
- Society for Epidemiology Research (SER) https://epiresearch.org/
- Other conferences advised by the student's MS committee based on his/her research subject matter

3.4 Importance to the discipline

With a plethora of new technologies and their applications, the drug discovery and development environment is rapidly changing. The adoption of RWD and decentralized clinical trials are accelerating drug discovery and development, which drives demand for clinical trial expertise. Understanding the new technologies applied in drug discovery and development and staying on the cutting edge of innovation, especially among professionals with patient care skills, is essential to raising the next generation of pharmaceutical leaders and scientists.

In a workshop held at the 18th Annual Conference of the Pharmaceutical Contract Management Group in September 2022, there was a consensus that clinical trial designs are expected to become more complex in the future with an increasing role of new technologies. Since it is expected that more complex clinical trials would require the collection of much higher volumes of data from variety of sources, there will be a greater need for data scientists (PMID: 37313038). There are also currently unmet medical needs, since a growing number of diseases (especially rare diseases) have limited treatment options, which pushes the need for new drug candidates. Based on Company and McKinsey, the demand for clinical research professionals exceeds supply and the trend is projected to continue for years, which means that there will continue to be a shortage of qualified clinical research staff for the foreseeable future (https://www.mckinsey.com/industries/life-sciences/our-insights/accelerating-clinical-trials-to-improve-biopharma-r-and-d-productivity).

UCSF is the leading university exclusively focused on health and its graduate programs should reflect this. Its standing as a world-renowned, leading research institution and the Schools of Pharmacy's and Medicine's excellence makes it the ideal environment for implementing this program. As explained in sections 3.1 and 3.2, our proposed PharmD/MS Dual Degree Program is the first to be offered in Clinical Research and Epidemiology among the currently existing U.S.-based PharmD/MS programs. Graduates will be prepared for careers in academia, as faculty members in schools and colleges of pharmacy, government, leaders in drug discovery and development in the pharmaceutical industry, and will be able to translate basic science research into clinical application (evidence-based medicine), which is a current

pressing need. Specifically, graduates will be able to address challenges related to complex clinical trials, pharmacoepidemiology, clinical research, biostatistical methods for clinical research, health disparities, clinical epidemiology, clinical informatics, genetic epidemiology, and use of RWD for evidence generation.

3.5 Ways in which the program will meet the needs of society

The National Institutes of Health (NIH) spends \$45B on medical research annually, pouring over 84% of its budget into extramural research through grants to universities, medical schools, and other research institutions including UCSF. Over the past 20 years, spending on research and development in the pharmaceutical industry has increased by 118% to about \$83B, with the average cost of developing a single therapy ranging anywhere from a few hundred million to \$4B. Much of this cost accumulates due to time-intensive processes during initial drug discovery and research; utilizing decentralized clinical trials, RWD, artificial intelligence/machine learning and other technologies can and will greatly reduce the resources needed in these processes, allowing new medications to reach the market at record speeds and lower costs. Additionally, decentralized clinical trials allow for faster recruitment and timelines, enhance trial participant access and engagement, improve participant's retention, and allow for real-time data collection and analysis. Also, the use of RWD can significantly reduce time-intensive processes in early drug discovery and development by providing insights into the targeted patient population, disease progression, treatment patterns, biomarker discovery, adherence analysis, feasibility assessment, and early safety signal detection. All these factors increase the accessibility to medicine for all, especially people with rare disease diagnoses, disabilities, racial and ethnic minority groups, rural areas, and lower-income socio-economic groups with historically lower access and higher barriers to medicine.

The interdisciplinary nature of our proposed PharmD/MS program in Clinical Research and Epidemiology will also contribute to developing much-needed scientific investigators, equipped with clinical and research skills, with deep connections to application areas of research, healthcare, biotechnology, and pharmaceuticals. Graduates will become thought leaders in their fields with hybrid skill sets to think both analytically and innovatively, driving pivotal advances for drug discovery and development as well as translating basic research science into clinical practice.

Beyond the United States, there remains deep disparities in medicine from structural and historical roots, made even more apparent by the COVID-19 pandemic. The PharmD/MS program will emphasize the values of diversity, equity, inclusion, belonging, and justice to develop the next generation of clinician-scientists with both the training and experiences to create lasting, transformative change. Graduates of the PharmD/MS program can use clinical research and epidemiological methodologies to develop new knowledge that delivers critical scientific discoveries with broad influence locally and globally. These discoveries drive advancements in health for patients, families, and communities around the world.

3.6 Relationship of the program to research and professional interests of the faculty

A list of supporting faculty from the Department of Epidemiology and Biostatistics involved in the MS portion of the PharmD/MS in Clinical Research and Epidemiology Program is provided in Section 4.1. These faculty are engaged in a broad variety of clinical research, epidemiological studies and methodologic activities across several areas of concentration. These include bioinformatics, biostatistics, cancer epidemiology, clinical epidemiology, environmental and occupational epidemiology, epidemiology of aging, epidemiology of cardiovascular and neurological disorders, genetic epidemiology, global health,

implementation science, infectious disease epidemiology, life course epidemiology, machine learning, precision public health and computational epidemiology, reproductive, perinatal, and neonatal epidemiology, research methods in epidemiology, and social epidemiology. In addition to the many projects that are led by departmental faculty, a unique feature of the department of Epidemiology and Biostatistics is the emphasis given to interdisciplinary collaboration, carrying the expertise in research methods and analysis to other departments and institutions.

In Appendix 1 and 2, are Letters of Support from the Dean of the School of Pharmacy as well as the Department Chair, expressing their support for the program.

3.7 Program differentiation

There is an increased demand for qualified professionals with patient care skills combined with research skills and experience. This combination of skills allows for the clinical focus that can inform important research questions. In academia, there is a recognized shortage of pharmacy faculty, which underscores the need for graduates who can contribute to both teaching and research. Other career paths that require clinician-scientists include pharmaceutical industry and government (FDA and NIH). Additionally, there is a significant interest among our current students and pharmacy school applicants for a path to careers in industry and clinical translational science.

The advantages of our proposed PharmD/MS in Clinical Research and Epidemiology dual degree program include increasing visibility of PharmD program in the light of declining applicant numbers, attracting students interested in combining both clinical and research degrees, facilitating training in academia, industry, and regulatory agencies, expanding career opportunities for PharmD graduates, and earning both degrees in 4 years instead of 5-5.5 years for the sequential degree or for studying the two degrees separately.

As emphasized in section 3.1, our proposed PharmD/MS program is the first to be offered in Clinical Research and Epidemiology among the currently existing U.S.-based PharmD/MS programs. Also, as explained in Section 1.5, the existing sequential PharmD/MS program in Clinical and Epidemiological Research requires 5 years for completion of both degrees sequentially. As outlined in Section 1.6, although UCSD has both a PharmD and MS in Clinical Research and UC Irvine has both a PharmD and MS in Epidemiology, both do not offer a formal dual degree program and do not advertise informal sequential degree pathways. This makes our proposed PharmD/MS in Clinical Research and Epidemiology program unique, being the only program offering this dual degree in the University of California System.

On a broader scale, UCSF has excellent and unique resources to support the PharmD/MS program, staff, faculty, and students in general. UCSF is a world-renowned institution where students will be trained and mentored by the nation's leading experts in their field. Additionally, the SF/Bay Area is centered among various technology, biotechnology and biopharmaceutical companies, all of which have a huge demand for clinician-scientists. With the increasing application of innovative technologies as well as clinical research and epidemiological methodologies to all aspects of drug discovery and development, the range, options, and opportunities for employment for graduates of the PharmD/MS in Clinical Research and Epidemiology Program are immense.

SECTION 4. FACULTY

The students in the PharmD/MS dual degree program in Clinical Research and Epidemiology will be supported by existing UCSF faculty from the departments of Bioengineering and Therapeutic Sciences (BTS), Pharmaceutical Chemistry, Clinical Pharmacy, and Epidemiology and Biostatistics, among others.

4.1 Participating faculty

The faculty comprising the proposed PharmD/MS Dual Degree Program are listed below. Letters of support from the UCSF Faculty is included in Appendix 2.

Affiliation
PharmD Program
Department of Bioengineering and Therapeutic Sciences
Department of Bioengineering and Therapeutic Sciences
Office of the Executive Vice Chancellor & Provost
Department of Pharmaceutical Chemistry
Department of Clinical Pharmacy
Department of Pharmaceutical Chemistry
Department of Clinical Pharmacy*
Department of Clinical Pharmacy*
Department of Bioengineering and Therapeutic Sciences
Department of Bioengineering and Therapeutic Sciences
Department of Pharmaceutical Chemistry
Department of Clinical Pharmacy*
Department of Bioengineering and Therapeutic Sciences
Department of Clinical Pharmacy*
Pharmacy Management Group
Department of Bioengineering and Therapeutic Sciences
Department of Clinical Pharmacy*
Department of Clinical Pharmacy*
Department of Clinical Pharmacy
Department of Bioengineering and Therapeutic Sciences
Department of Pharmaceutical Chemistry
Department of Clinical Pharmacy
Department of Pharmaceutical Chemistry
Department of Clinical Pharmacy
Department of Clinical Pharmacy*
Department of Bioengineering and Therapeutic Sciences
Department of Bioengineering and Therapeutic Sciences
Department of Bioengineering and Therapeutic Sciences
Department of Pharmaceutical Chemistry

James Fraser, PhD	Department of Bioengineering and Therapeutic Sciences
Danica Galonić Fujimori, PhD	Department of Cellular and Molecular Pharmacology
Zev Gartner, PhD	Department of Pharmaceutical Chemistry
Jason Gestwicki, PhD	Department of Pharmaceutical Chemistry
Kathy Giacomini, PhD, BSPharm	Department of Bioengineering and Therapeutic Sciences
Yessica Gomez, PhD	Department of Pharmaceutical Chemistry*
Michael Grabe, PhD	Cardiovascular Research Institute
John Gross, PhD	Department of Pharmaceutical Chemistry
Katherine Gruenberg, PharmD, MA	Department of Clinical Pharmacy*
Su Guo, PhD	Department of Bioengineering and Therapeutic Sciences
Chad Hatfield, PharmD, MHA	UC Davis Health
Stuart Heard, PharmD	Department of Clinical Pharmacy
Yvette Hellier, PharmD	Department of Clinical Pharmacy*
Ryan Hernandez, PhD	Department of Bioengineering and Therapeutic Sciences
Bo Huang, PhD	Department of Pharmaceutical Chemistry
C. Anthony Hunt, PhD	Department of Bioengineering and Therapeutic Sciences
Jeroen Jansen, PhD	Department of Clinical Pharmacy
Shannan Takhar, PharmD	Department of Clinical Pharmacy*
Robyn Kaake, PhD	Department of Bioengineering and Therapeutic Sciences
Tanja Kortemme, PhD	Department of Bioengineering and Therapeutic Sciences
Desi Kotis, PharmD	Office of COO
Nevan Krogan, PhD	Department of Bioengineering and Therapeutic Sciences
Lisa Kroon, PharmD	Department of Clinical Pharmacy
Janel Long-Boyle, PharmD, PhD	Department of Clinical Pharmacy*
Shalini Lynch, PharmD	Department of Clinical Pharmacy
Conan MacDougall, PharmD, MAS	Department of Clinical Pharmacy*
Aashish Manglik, MD, PhD	Department of Pharmaceutical Chemistry
James R. McNulty, PharmD	Department of Clinical Pharmacy
Igor Mitrovic, MD	Department of Physiology*
Emily Mrig, PhD	Department of Clinical Pharmacy
Jeffrey Neitz, PhD	Department of Pharmaceutical Chemistry
Akinyemi Oni Orisan, PharmD, PhD	Department of Clinical Pharmacy
Kathryn Phillips, PhD	Department of Clinical Pharmacy
Tiffany Pon, PharmD	Department of Clinical Pharmacy*
Adam Renslo, PhD	Department of Pharmaceutical Chemistry
Rosa Rodriguez-Monguio, PhD, MS	Department of Clinical Pharmacy
Shuvo Roy, PhD	Department of Bioengineering and Therapeutic Sciences
Andrej Sali, PhD	Department of Bioengineering and Therapeutic Sciences
Nancy Sambol, PharmD	
, - : ,	Department of Bioengineering and Therapeutic Sciences
Daniel Santi, MD, PhD	

Jason Sello, PhD	Department of Pharmaceutical Chemistry
Rita Shane, PharmD	Department of Clinical Pharmacy
Jaekyu Shin, PharmD, MS	Department of Clinical Pharmacy*
Seth Shipman, PhD	Department of Bioengineering and Therapeutic Sciences
Brian Shoichet, PhD	Department of Pharmaceutical Chemistry
Xiaokun Shu, PhD	Department of Pharmaceutical Chemistry
Tristan Storm, PharmD	Department of Bioengineering and Therapeutic
	Sciences*
David Smith, PharmD	Department of Clinical Pharmacy
Danielle Swaney, PhD	Department of Bioengineering and Therapeutic Sciences
Francis Szoka, PhD	Department of Bioengineering and Therapeutic Sciences
Bani Tamraz, PharmD, PhD	Department of Clinical Pharmacy*
Trang Trinh, PharmD, MPH	Department of Clinical Pharmacy*
Candy Tsourounis, PharmD	Department of Clinical Pharmacy*
Rupa Tuan, PhD	Department of Cellular and Molecular Pharmacology*
Marieke Kruidering, PhD	Department of Cellular and Molecular Pharmacology
Gregory Kincheloe	Department of Anatomy
Samantha Valle-Oseguera, PharmD	Department of Clinical Pharmacy*
Lei Wang, PhD	Department of Pharmaceutical Chemistry
Michelle Wang, PharmD, PhD	Department of Bioengineering and Therapeutic Sciences
Jonathan Watanabe, PharmD, MS, PhD	Department of Clinical Pharmacy
Jim Wells, PhD	Department of Pharmaceutical Chemistry
Catera Wilder, PhD	Department of Bioengineering and Therapeutic Sciences
Leslie Wilson, PhD	Department of Clinical Pharmacy
Beth Apsel Winger, MD, PhD	Department of Clinical Pharmacy
Lani Wu, PhD	Department of Pharmaceutical Chemistry
Katherine Yang, PharmD, MPH	Department of Clinical Pharmacy*
Sharon L. Youmans, PharmD, MPH	Department of Clinical Pharmacy*
Balyn Zaro, PhD	Department of Pharmaceutical Chemistry
Liang Zhao, PhD, MAS, MBA	Department of Bioengineering and Therapeutic Sciences
Crystal Zhou, PharmD	Department of Clinical Pharmacy*
	MS Program
Ku, Elaine, MD, MAS	Program Director, Clinical & Epidemiological Research
	(DEB) & Medicine (Nephrology)**
Beatty, Alexis, MD, MAS	Faculty Liaison & MD/MS Program Director,
	Epidemiology & Biostatistics**
Pletcher, Mark, MD, MPH	Chair, Epidemiology & Biostatistics**
Chan, June, DSc	Vice Chair of Education, Epidemiology & Biostatistics
	& Urology**
Sarah Ackerman, PhD, MPH	Social Behavioral Sciences (Nursing)**
Patience Afulani, PhD, MD, MPH	Ob/Gyn, Reproductive Sciences**
Joelle Brown, MPH, PhD	Epidemiology & Biostatistics/OBGYN**

William Brown III, PhD, DrPh, MA	Medicine (Informatics)**
Susan Buchbinder, MD	Medicine (ZSFGH)
Adithya Cattamanchi, MD	Medicine (Infectious Diseases)**
Christine Dehlendorf, MD, MAS	Family & Community Medicine**
Nadia Diamond-Smith, PhD, MS	Epidemiology & Biostatistics**
Alison El Ayadi, ScD, MPH	Ob/Gyn, Reproductive Sciences**
Jean Feng, PhD, MS	Epidemiology & Biostatistics**
Meghana Gadgil, MD, MPH	Medicine (General Internal Medicine)**
Stathis Gennatas, PhD	Epidemiology & Biostatistics**
David Glidden, PhD, MS	Epidemiology & Biostatistics**
Rebecca Graff, ScD	Epidemiology & Biostatistics**
Beth Griffiths, MD, MPH	Medicine (General Internal Medicine)**
Thomas Hoffman, PhD, MA	Epidemiology & Biostatistics**
Alison Huang, MD, MPhil, MAS	Medicine (General Internal Medicine)**
Chiung-Yu Huang, PhD, MS	Epidemiology & Biostatistics**
Fei Jiang, PhD, MS	Epidemiology & Biostatistics**
Andrew Kerkhoff, MD, PhD, MS	Medicine (Infectious Diseases)**
Raman Khanna, MD, MAS	Medicine (Hospital Medicine)**
Rachel King, PhD, MPH	Epidemiology & Biostatistics**
Mi-Ok Kim, PhD, MS, MA	Epidemiology & Biostatistics**
Kim Koester, PhD, MA	Medicine (Infectious Diseases)**
Michael Kohn, MD, MPP	Epidemiology & Biostatistics**
Kerstin Kolodzie, MD, PhD, MAS	Anesthesia
John Kornak, PhD	Epidemiology & Biostatistics**
Tracy Lin, PhD	Institute for Health & Aging**
Leo Liu, MD	Medicine (Hospital Medicine)**
Jeffrey Martin, MD, MPH	Epidemiology & Biostatistics**
Mohsen Malekinejad, MD, MPH, DrPh	Epidemiology & Biostatistics/Global Health
Ali Mirzazadeh, PhD, MD, MPH	Epidemiology & Biostatistics**
Meghan Morris, PhD, MPH	Epidemiology & Biostatistics**
Thomas Newman, MD, MPH	Epidemiology & Biostatistics**
Anobel Odisho, MD, MPH	Urology**
Catie Oldenburg, ScD, MPH	Proctor Foundation**
Patrick Phillips, PhD, MS, MA	Medicine (Pulmonary/ZSFGH)**
Travis Porco, PhD, MPH	Proctor Foundation**
Vinay Prasad, MD, MPH	Epidemiology & Biostatistics**
Aaron Scheffler, PhD, MS	Epidemiology & Biostatistics**
Laura Schmidt, PhD, MSW, MPH	Institute for Health Policy Studies**
Christopher Seaman, MA	Epidemiology & Biostatistics**
Starley Shade, PhD, MPH	Epidemiology & Biostatistics**

Priya Shete, MD, MPH	Medicine (Pulmonary & Critical Care)/ Epidemiology &
	Biostatistics**
Josh Senyak	Epidemiology & Biostatistics**
Matt Spinelli, MD, MAS	Medicine (Infectious Diseases)**
Jacqueline Torres, PhD, MA, MPH	Epidemiology & Biostatistics**
Gilmer Valdes, PhD	Radiation Oncology**
Erin Van Blarigan, ScD	Epidemiology & Biostatistics**
Aida Venado Estrada, MD, MAS	Medicine (Pulmonary & Critical Care)**
Peter Washington, PhD	DoC-IT & Medicine**
Jan Yeager, MDes	Clinical Innovation Center
Lydia Zablotska, MD, PhD, MPA	Epidemiology & Biostatistics**

^{*}Individual faculty members identified by an asterisk are core teaching faculty in the PharmD program (including Integrated Theme Directors, Applied Patient Care Skills Directors, Inquiry Director, Experiential Education Directors, as well as Associate Dean of Student Affairs in charge of professional development).

SECTION 5. COURSES

The PharmD/MS Dual Degree Program curriculum will consist of core and elective courses. Core and elective courses for the Program will be drawn from the PharmD and the MS in Clinical Research and Epidemiology existing courses.

The main proposed curricular changes to PharmD curriculum are:

- 1. Waiving of the PharmD discovery project. In the proposed PharmD/MS Dual Degree Program, the MS research project will count towards the PharmD discovery project. The MS products of research will be also counted as two non-clinical APPEs (CL PHARM 190A and 190B).
- 2. The proposed dual degree program will also include clinical practice experience throughout MS year 1 (year 3 of the proposed PharmD/MS program) (one clinic day every week over 30 consecutive weeks), which will count towards one elective APPE in direct patient care setting.
- 3. The proposed dual degree program will include two APPEs in the second year of PharmD/MS, and three APPEs in the MS year 2 (year 4 of the proposed PharmD/MS program). Of these total five APPEs, four will be core rotations (General Medicine, Community, Hospital, and Ambulatory Care), and one will be elective (not in the direct patient care setting).

Regarding the PharmD curricular changes #2 and 3, the PharmD/MS students will complete a total of 6 APPEs, which will add up to 1440 hours of APPEs and that satisfies the Accreditation Standards. The order in which the APPEs are taken will be scheduled based on the student's wishes and the rotation availability.

The only proposed curricular change to MS curriculum is:

- Requirement for 6 quarters of instruction vs. 7 quarters

5.1 Existing courses

^{**}MS core faculty.

The following list contains existing courses available to PharmD/MS Program students from the PharmD program:

Required core courses for PharmD:

PHARMIS 110 Foundations I (Summer, 14.5 units)

Summer of YEAR 1 PharmD/MS

Instructor(s): Joanne Chun, Katherine Yang

Foundations I is an integrated course that provides foundational concepts which will serve as the basis for content that will be taught in all subsequent preclinical courses. The content of this course spans all levels of pharmacy practice including the therapeutic sciences, health care policy and management, and evidence-based health care. A key emphasis of this course is to lay the foundation for the development of compassionate critical thinkers and transformative leaders in healthcare.

CL PHARM 170 Applied Patient Care Skills I (Summer, 2.5 Units)

Summer of YEAR 1 PharmD/MS

Instructor(s): Leslie Floren, Crystal Zhou

The APCS course trains students to care for patients by advancing skills in three areas: hands-on (e.g., immunizations), communication, and critical thinking skills. Activities incorporate self-reflection and are designed to uphold principles of DEI. This course introduces students to history taking, patient interviewing, chart documentation, immunizations, and aseptic technique. Students are evaluated through direct observation in skills sessions and an OSCE.

PHARMIS 111 Cardiovascular Science & Therapeutics (Fall, 11.5 Units)

Fall of YEAR 1 PharmD/MS

Instructor(s): Jaekyu Shin

This Cardiovascular Integrated Theme course focuses on the medical treatment of 4 cardiovascular diseases (ischemic heart disease, dyslipidemia, heart failure, and arrhythmias) by integrating related basic and clinical sciences as well as behavioral/social/administrative sciences. It also explores knowledge gap in inquiry classes. The course concludes with a Synthesis week for reflection, exploration of careeroptions, and integration with the Foundations I course content.

CL PHARM 171 Applied Patient Care Skills II (Fall, 1 Units)

Fall of YEAR 1 PharmD/MS

Instructor(s): Crystal Zhou

The APCS course complements the core, inquiry, and experiential education elements of the curriculum. The purpose of the APCS course is to help students further build upon their knowledge to care for patients as a whole and enhance communication skills with patients and other healthcare providers both orally and in writing. The APCS course is fully case-based and will focus on advancing 3 domains: hands-on skills, communication skills, and critical thinking skills.

<u>CL PHARM 181 Introductory Pharmacy Practice Experience- Community A (Fall, 2.5 Units)</u> Fall of YEAR 1 PharmD/MS

Instructor(s): Valerie Clinard

Through IPPEs, student pharmacists are expected to master foundational competencies in multiple domains including patient care, population health, interprofessional practice, practice management, professional development and medical information. Each student will complete a longitudinal experience in a community pharmacy setting. The student pharmacists will become a member of the healthcare team.

PHARMIS 112 Respiratory Science & Therapeutics (Winter, 9.5 Units) Winter of YEAR 1 PharmD/MS

Instructor(s): Yessica Gomez

This is an integrated course focused on pharmacologic/non-pharmacologic approaches to tobacco cessation, medical treatment of 5 common diseases, and conditions involving the respiratory system. This is done by integrating related basic, clinical, and behavioral/social/administrative sciences. It also explores knowledge gaps in inquiry classes. The course concludes with a Synthesis week for reflection, exploration of career-options, and integration with previous course content.

PHARMIS 122 Inquiry Immersion 1 (Winter, 2.5 Units)

Winter of YEAR 1 PharmD/MS

Instructor(s): Joanne Chun

This Inquiry Immersion course within the Bridges Curriculum is a two-week block that includes foundational didactics, a selective mini-course, and scholarship skill-building.

CL PHARM 172 Applied Patient Care Skills III (Winter, 1 Units)

Winter of YEAR 1 PharmD/MS

Instructor(s): Jennifer Cocohoba

The APCS course trains students to care for patients by advancing skills in three areas: hands-on (e.g., immunizations), communication, and critical thinking skills. Activities incorporate self-reflection and are designed to uphold principles of DEI. This course trains students to conduct a respiratory physical exam, demonstrate pulmonary device use, and provide counseling on respiratory conditions. Students are evaluated through direct observation in skills sessions and an OSCE.

PHARMIS 113 Renal Science and Therapeutics (Spring, 6 Units)

Spring of YEAR 1 PharmD/MS

Instructor(s): Igor Mitrovic, Tristan Storm

This integrated theme course focuses on the pharmaceutical interventions available in the medical treatment of hypertension and chronic kidney disease by integrating related basic and clinical sciences as well as behavioral/social/administrative sciences. It also explores knowledge gaps through inquiry sessions. The course predominantly focuses on the practice of drug dosing adjustments needed in renal dysfunction and renal replacement therapy.

PHARMIS 114 Gastrointestinal Science and Therapeutics (Spring, 8 Units)

Spring of YEAR 1 PharmD/MS

Instructor(s): Cathi Dennehy

This integrated theme course focuses on the pharmaceutical interventions available in the medical treatments of inflammatory bowel disease, irritable bowel syndrome, liver disease, and gastrointestinal

reflux and peptic ulcer disease. Pharmaceutical self-care as well as the basics of nutrition are also introduced in this course. It also explores knowledge gaps through inquiry sessions.

<u>CL PHARM 173 Applied Patient Care Skills IV (Spring, 1 Units)</u> Spring of YEAR 1 PharmD/MS

Instructor(s): Crystal Zhou

The APCS course trains students to care for patients by advancing skills in three areas: hands-on (e.g., immunizations), communication, and critical thinking skills. Activities incorporate self-reflection and are designed to uphold principles of DEI. CP173 trains students to assess blood pressure, conduct motivational interviewing, and participate in case-based exercises on renal and gastrointestinal conditions. Students are evaluated through direct observation in skills sessions and an OSCE.

<u>CL PHARM 182 Introductory Pharmacy Practice Experience - Community B (Winter, Spring, 2.5-5 Units)</u>

Winter and Spring of YEAR 1 PharmD/MS

Instructor(s): Valerie Clinard

Through IPPEs, student pharmacists are expected to master foundational competencies in multiple domains including patient care, population health, interprofessional practice, practice management, professional development and medical information. Each student will complete a longitudinal experience in a community pharmacy setting. The student pharmacists will become a member of the healthcare team.

PHARMIS 115 Foundations II (Summer, 3 Units) Summer of YEAR 2 PharmD/MS

Instructor(s): Sharon Youmans

Foundations II is an integrated course that provides foundational concepts which will serve as the basis for content that will be taught in all subsequent preclinical courses for the second year of the PharmD curriculum. The content of this course spans all levels of pharmacy practice including the therapeutic sciences, health care policy and management, and evidence-based health care.

PHARMIS 116 Endocrine Science and Therapeutics (Summer, 9.5 Units) Summer of YEAR 2 PharmD/MS

Instructor(s): Candy Tsourounis

This integrated theme course focuses on the pharmaceutical interventions available in the medical treatments of diabetes, thyroid and adrenal disorders. Pharmaceutical self-care are also introduced in this course. It also explores knowledge gaps through inquiry sessions.

<u>CL PHARM 174 Applied Patient Care Skills V (Summer, 1 Units)</u> <u>Summer of YEAR 2 PharmD/MS</u>

Instructor(s): Bani Tamraz

The APCS course trains students to care for patients by advancing skills in three areas: hands-on (e.g., immunizations), communication, and critical thinking skills. Activities incorporate self-reflection and are designed to uphold principles of DEI. This course trains students on their ability to demonstrate blood glucose monitoring and insulin injection and counsel on endocrine-related conditions. Students are evaluated through direct observation in skills sessions and an OSCE.

PHARMIS 117 Neuroscience and Therapeutics (Fall, 14.5 Units)

Fall of YEAR 2 PharmD/MS

Instructor(s): Stephanie Hsia, Rupa Tuan

This integrated theme course focuses on the pharmaceutical interventions available in the medical treatments of stroke, epilepsy, pain insomnia, anxiety disorders, major depressive disorder, schizophrenia, Alzheimers' disease, Parkinsons disease, and alcohol/opioid/substance use disorders. It also explores knowledge gaps through inquiry sessions.

CL PHARM 175 Applied Patient Care Skills VI (Fall, 1 Units)

Fall of YEAR 2 PharmD/MS

Instructor(s): Trang Trinh

The APCS course trains students to care for patients by advancing skills in three areas: hands-on (e.g., immunizations), communication, and critical thinking skills. Activities incorporate self-reflection and are designed to uphold principles of DEI. This course trains students to counsel patients on neurological and psychiatric conditions, conduct telehealth visits, and present patients to a preceptor. Students are evaluated through direct observation in skills sessions and an OSCE.

PHARMIS 118 Oncology Science and Therapeutics (Winter, 5.5 Units)

Winter of YEAR 2 PharmD/MS

Instructor(s): Janel Long-Boyle

This integrated theme course focuses on the role of the clinical pharmacist in the treatment of a patient requiring chemotherapy or immunotherapy as treatment (malignant and non-malignant disease). It also explores knowledge gaps through inquiry sessions.

PHARMIS 119 Infectious Disease Science and Therapeutics (Winter, 8 Units)

Winter of YEAR 2 PharmD/MS

Instructor(s): Conan MacDougall

This integrated theme course focuses on antimicrobial regimen selection, antimicrobial stewardship, and the pharmaceutical interventions available in the treatment of respiratory tract infections, urinary tract Infections, skin and soft tissue infections, fungal infections, CNS infections, GI infections, sepsis and septic shock, HIV infection, viral hepatitis, viral infections, and tuberculosis. It also explores knowledge gaps through inquiry sessions.

CL PHARM 176 Applied Patient Care Skills VII (Winter, 1 Units)

Winter of YEAR 2 PharmD/MS

Instructor(s): Katherine Gruenberg

The APCS course trains students to care for patients by advancing skills in three areas: hands-on (e.g., immunizations), communication, and critical thinking skills. Activities incorporate self-reflection and are designed to uphold principles of DEI. This course trains students to conduct calculations, counsel patients, communicate with providers, and critically evaluate infectious diseases and oncology conditions. Students are evaluated through direct observation in skills sessions and an OSCE.

<u>CL PHARM 183 Introductory Pharmacy Practice Experience - Health Systems (Fall, Winter, Spring, Summer, 1.5-3.5 Units)</u>

Fall, Winter, and Spring of YEAR 2 PharmD/MS

Instructor(s): Valerie Clinard

Through IPPEs, student pharmacists are expected to master foundational competencies in multiple domains including patient care, population health, interprofessional practice, practice management, professional development and medical information. Each student will complete a concentrated and a longitudinal experience in a health system pharmacy setting. The student pharmacists will become a member of the healthcare team.

<u>CL PHARM 191A Direct Patient Care APPE Elective (Fall, Winter, Spring, Summer; 7 Units)</u> Instructor(s): Staff

A core required rotation, this course is a supervised pharmacy experience where students develop & explore their roles on an interprofessional healthcare team, sharing responsibilities with patients, caregivers, & other health professionals for drug therapy outcomes in a patient care setting. Students are expected to master competencies in multiple domains including patient care, population health, interprofessional practice, practice management, professional development & medical information.

<u>CL PHARM 191B Direct Patient Care APPE Elective (Fall, Winter, Spring, Summer; 7 Units)</u> Instructor(s): Staff

A core required rotation, this course is a supervised pharmacy experience where students develop & explore their roles on an interprofessional healthcare team, sharing responsibilities with patients, caregivers, & other health professionals for drug therapy outcomes in a patient care setting. Students are expected to master competencies in multiple domains including patient care, population health, interprofessional practice, practice management, professional development & medical information.

<u>CL PHARM 192 Hospital Pharmacy Systems & Practice APPE (Fall, Winter, Spring, Summer; 7 Units)</u>

Instructor(s): Staff

A core required rotation, this course is a supervised pharmacy experience where students develop & explore their roles on an interprofessional healthcare team, sharing responsibilities with patients, caregivers, & other health professionals for drug therapy outcomes in a health system setting. Students are expected to master competencies in multiple domains including patient care, population health, interprofessional practice, practice management, professional development & medical information.

CL PHARM 193 Community Pharmacy Systems & Practice APPE (Fall, Winter, Spring, Summer; 7 Units)

Instructor(s): Staff

A core required rotation, this course is a supervised pharmacy experience where students develop & explore their roles on an interprofessional (IP) healthcare team, sharing responsibilities with patients, caregivers, & other health professionals for drug therapy outcomes in a community pharmacy setting. Students are expected to master competencies in multiple domains including patient care, population health, IP practice, practice management, professional development & medical information.

CL PHARM 194 Acute Patient Care APPE (Fall, Winter, Spring, Summer; 7 Units)

Instructor(s): Staff

A core required rotation, this course is a supervised pharmacy experience where students develop & explore their roles on an interprofessional (IP) healthcare team, sharing responsibilities with patients, caregivers, & other health professionals for drug therapy outcomes in an acute patient care setting. Students are expected to master competencies in multiple domains including patient care, population health, IP practice, practice management, professional development & medical information.

CL PHARM 195 Ambulatory Patient Care APPE (Fall, Winter, Spring, Summer; 7 Units)

Instructor(s): Staff

A core required rotation, this course is a supervised pharmacy experience where students develop & explore their roles on an interprofessional (IP) healthcare team, sharing responsibilities with patients, caregivers, & other health professionals for drug therapy outcomes in an ambulatory care setting. Students are expected to master competencies in multiple domains including patient care, population health, IP practice, practice management, professional development & medical information.

The following list contains existing courses available to PharmD/MS Program students from the MS Program in Clinical and Epidemiological Research:

Required core courses for MS:

EPI 202 Designing Clinical Research (Summer, 2 units)

Summer of YEAR 3 PharmD/MS

Instructor(s): Mark Pletcher

A workshop for students to design their own protocol for carrying out a clinical research project. Specific topics are: the research question, study designs, study subjects, measurements, sample size, ethical considerations, presets, data management, quality control, and proposal writing.

EPI 218 Data Collection and Management for Clinical Research (Summer, 1 Unit) Summer of YEAR 3 PharmD/MS

Instructor(s): Michael Kohn, Josh Senyak

Instruction in data collection and management for clinical research, including the relational database model, data collection forms, reports, and exports to statistical packages. Specific applications include REDCap and Microsoft Access with the option of exporting to Stata or R. Build SQL statements using the Access query design tool.

BIOSTAT 212 Introduction to Statistical Computing in Clinical Research (Summer, 1 Unit) Summer of YEAR 3 PharmD/MS

Instructor(s): Aida Venado Estrada

This course will introduce clinical researchers to the use of computer software for managing and analyzing clinical research data. Currently available statistical packages will be described and the roles of spreadsheet and relational database programs discussed. Use of STATA for managing, cleaning, describing, and analyzing data will be taught in lecture and laboratory sessions.

EPI 201 Responsible Conduct of Clinical Research (Fall, 0.5 Units)

Fall of YEAR 3 PharmD/MS

Instructor(s): Sara Ackerman

Instruction in identifying and resolving common ethical dilemmas that arise in clinical research, how research is regulated, and misconduct in research. This course meets the NIH requirement for training in research ethics.

EPI 203 Epidemiologic Methods (Fall, 4 Units)

Fall of YEAR 3 PharmD/MS

Instructor(s): Catie Oldenburg, Jennifer Smith, Erin Van Blarigan

An introductory course to the theory and methods of epidemiology, including an overview of the measures of disease occurrence in populations, measures of association between exposures and outcomes, major study designs used in epidemiology, and major sources of bias in epidemiologic studies. It aims to develop participants skills in the critical evaluation of epidemiologic studies, and will provide the foundation for more advanced methods in study design, causal inference, and biostatistics.

EPI 204 Clinical Epidemiology (Fall, 3 Units)

Fall of YEAR 3 or 4 PharmD/MS

Instructor(s): Michael Kohn, Tom Newman

This is primarily a course about diagnosis and prediction. In public health and clinical practice, diagnostic tests estimate the probability of a prevalent disease, and risk prediction models evaluate the likelihood of an incident outcome. The course will cover: performance measures used for diagnostic tests and risk prediction models; design and critical appraisal of research studies to evaluate tests and risk models; and using the results of tests and risk models. The students can opt to take EPI 204 in either year 3 or year 4 of the PharmD/MS dual degree program.

BIOSTAT 200 Biostatistical Methods for Clinical Research I (Fall, 3 Units) Fall of YEAR 3 PharmD/MS

Instructor(s): Ali Mirzazadeh

This course is an introduction to the study of biostatistics. Course addresses types of data, their summarization, exploration and explanation, as well as concepts of probability and their role in explaining uncertainty. Course concludes with coverage of inference applied to means, proportions, regression coefficients and contingency tables. Throughout the course, the software program STATA will be used.

EPI 220/230 TICR Program Seminar for First-Year Master's and Certificate Program Scholars (Fall, Winter, and Spring, 1 Units)

Fall, Winter, and Spring of YEAR 3 PharmD/MS

Instructor(s): Lydia Zablotska

The TICR Program First-Year Seminar provides scholars the opportunity to have their research intensively critiqued by a group of interested peers and helps bring together in practical situations the theoretical topics covered in other parts of the TICR Program. It also gives scholars experience critiquing others' work, which will be a regular task in their professional activities. We start in Fall Quarter by reviewing protocols created in the Summer Designing Clinical Research course and then move in Winter and Spring to discussing the implementation of research, including questionnaires, procedures, abstracts, manuscripts, or new protocols.

EPI 222 Social Determinants of Health and Health Disparities: What Every Researcher Should Know (Winter, 1 Unit)

Winter of YEAR 3 PharmD/MS

Instructor(s): Christine Dehlendorf, Meghan Morris

An introduction to the knowledge and skills needed to conduct high-quality research in diverse human populations with an emphasis on understanding the measurement and influence of race/ethnicity and socioeconomic status on health.

BIOSTAT 208 Biostatistical Methods for Clinical Research II (Winter, 3 Units)

Winter of YEAR 3 PharmD/MS

Instructor(s): Aaron Scheffler

Instruction in multiple predictor analyses as a tool for control of confounding and for constructing predictive models. Topics will include exploratory data analyses, linear regression, and logistic regression. The STATA statistical package will be used.

EPI 212 Publishing and Presenting Clinical Research (Spring, 1 Unit) Spring of YEAR 3 PharmD/MS

Spring of TEXES That in Div.

Instructor(s): Vinay Prasad

This course will provide instruction in preparing manuscripts for publication in the medical literature including how to prepare title and abstract; introduction and methods; results and discussion.

BIOSTAT 209 Biostatistical Methods for Clinical Research III (Spring, 3 Units)

Spring of YEAR 3 PharmD/MS

Instructor(s): Chiung-Yu Huang

Advanced instruction in multiple predictor analyses. Topics will include survival analysis and regression for repeated measures. In the final weeks of the course, participants will receive individualized instruction for the analysis of their own data.

EPI 221 Master's Seminar II (Fall, Winter, and Spring, 1 Unit)

Fall and Winter of YEAR 4 PharmD/MS

Instructor(s): Jeffrey Martin

These seminars provide a forum for presenting scholars' own work to peers, instructing peers in methodologic topics, and critiquing the work of others are skills that clinical researchers will use throughout their careers. Accordingly, the Master's Seminar II will be dedicated to scholars presenting the current status of their research projects to their peers as well as instructing their peers in methodologic topics germane to all clinical researchers.

EPI 300 Educational Practice (Fall, Winter, Spring, and Summer, 2 Units)

Fall or Winter of YEAR 4 PharmD/MS

Instructor(s): Elaine Ku, Alexis Beatty, Catie Oldenburg, Dave Glidden

This experience may involve leading a weekly small-group discussion section (10-12 students), holding office hours for students and grading homework assignments and projects. Satisfactory completion of this requirement is required for advancement to degree completion. These Educational Practice assignments

will be made in May of year 3 of the PharmD/MS program. Students may complete assignments during one quarter of the fourth year of the PharmD/MS.

Elective courses (students will select of the following electives to be taken in any quarter of YEAR 3 or 4 PharmD/MS):

- Highly recommended electives are EPI 205 and BIOSTAT 210.
- Students may take electives in any quarter.
- Students must take electives to achieve a total of 38 units required for graduation.
- Students may take additional electives beyond the required 38 units if desired.
- The MS portion of the PharmD/MS program currently has three optional tracks of specialized instruction in which scholars can elect to enroll: Clinical Informatics, Health Data Science, and Implementation Science. Scholars in these tracks will be required to take the core set of courses in epidemiological and biostatistical methods that underlie clinical research and will use their elective courses for focused instruction in their track's specific objectives.
- <u>Clinical Informatics Track</u>: In addition to taking core courses on fundamentals of epidemiology and biostatistics, learners in the Clinical Informatics Track will take a series of multidisciplinary elective courses to deepen expertise in clinical informatics. Students are required to take Introduction to Clinical Informatics (EPI 232) and other electives related to clinical informatics totaling at least 8 units. Other electives eligible for Clinical Informatics Track credit include Use of Electronic Health Record Data for Research (EPI 231), and Clinical Informatics Artificial Intelligence (EPI 233).
- <u>Data Science Track</u>: In addition to taking core courses on fundamentals of epidemiology and biostatistics, learners in the Data Science Track have the following electives: BIOSTAT 202: Introduction to the Science of "Big Data", DATASCI 223: Applied Data Science with Python, DATASCI 224: Understanding Machine Learning: From Theory to Applications, and DATASCI 225: Machine Learning in R for the Biomedical Sciences II: Methods for Prediction, Pattern Recognition, and Data Reduction.
- <u>Implementation Science (ImS) Track</u>: Students in this track are exempt from taking EPI 218, and they are required to take EPI 245 with two additional ImS electives. Students may not take more than three ImS within the MS portion of the PharmD/MS program. These ImS electives include EPI/IMS 241, 242, 243, 246, 247, 248, 249, and 250.

Summer quarter courses:

- EPI 232 Introduction to Clinical Informatics, William Brown, Raman Khanna (2 Units)
- BIOSTAT 202 Opportunities and Challenges of Complex Biomedical Data: Introduction to the Science of "Big Data", Karla Lindquist (3 Units)
- BIOSTAT 213 Programming for Health Data Science in R, Stathis Gennatas (2 Units)

Fall quarter courses:

- EPI 210 Epidemiology of Aging, Jacqueline Torres (2 Units)
- EPI 263 Demographic Methods for Health, Nadia Diamond-Smith (1.5 Units)
- IMS 243 Human Centered Design, Meghana Gadgil (2 Units)
- IMS 245) Introduction to Implementation Science: Theory and Design, Adithya Cattamanchi, Andrew Kerkhoff (2 Units)
- IMS 248 Community-Engaged Research, Sara Ackerman (2 Units)
- BIOSTAT 210 Biostatistical Methods for Clinical Research IV, David Glidden (2 Units)

- BIOSTAT 214 Programming for Health Data Science in R II, Stathis Gennatas (2-3 Units)
- DATASCI 217 Introduction to Python and Data Science Tools, Christopher Seaman (1-2 Units)
- DATASCI 226 Bayesian Methods and Gaussian Processes, John Kornak (2-3 Units)

Winter quarter course:

- EPI 205 Clinical Trials, Alison Huang, Patrick Phillips (2 Units)
- EPI 207 Epidemiologic Methods II, Jason Chan, Rebecca Graff (3 Units)
- EPI 213 Cost-Effectiveness Analysis in Medicine and Public Health, Tracy Lin (2 Units)
- EPI 217 Molecular and Genetic Epidemiology, Thomas Hoffmann (2 Units)
- EPI 226 Informatics Tools for Health Disparities Research, William Brown (2 Units)
- EPI 231 Use of Electronic Health Record Data for Research, Anobel Y. Odisho (3 Units)
- IMS 242 Program Evaluation to Enhance Implementation and Adaptation, Priya B. Shete (2 Units)
- IMS 246 Designing Individual-Level Implementation Strategies, Emilia De Marchis, Matthew Spinelli, Sara Ackerman, Adithya Cattamanchi, Margaret Handley, Courtney Lyles, Justin White (2 Units)
- EPI 258 A NIH F & K Grant Writing Workshop, Erin Van Blarigan, Amy Conroy (3 Units)
- IMS 267 Quantitative Methods, Sara Ackerman, Kim Koester (2 Units)
- EPI 269 Equity Issues in Reproductive Health, Patience Afulani, Nadia Diamond-Smith (2 Units)
- BIOSTAT 211 Mathematical Foundations of Biostatistics, Fei Jiang (2 Units)
- BIOSTAT 216 Machine Learning in R for the Biomedical Sciences: Methods for Prediction, Pattern Recognition, and Data Recognition, Adam Olshen (3 Units)

Spring quarter courses:

- EPI 233 Artificial Intelligence in Clinical Informatics
- IMS 241 Study Designs for Intervention Research in Real-World Settings, Starley B. Shade, Joelle Brown (2 Units)
- IMS 247 Designing Interventions to Change Organizational Behavior, Laura Schmidt
- IMS 249 Translating Evidence into Policy, Beth Griffiths (2 Units)
- IMS 250 Mixed Methods Research, Patience Afulani, Alison El Ayadi
- EPI 262 Pharmacoepidemiology, Michael Kelsh (2 Units)
- EPI 265 Advanced Epidemiologic Methods: Application & Interpretation, Catie Oldenberg (3 Units)
- EPI 266 Mathematical Modeling of Infectious Diseases, Travis Porco (1.5 Units)
- EPI 268 Econometric Methods for Causal Inference, Justin White (2-3 Units)
- BIOSTAT 215 Advanced Approaches to the Analysis of Observational Data, Tom Newman (3 Units)
- DATASCI 223 Applied Data Science with Python, Christopher Seaman (2 Units)
- DATASCI 224 Understanding Machine Learning: From Theory to Application, Jean Feng (3 Units)
- DATASCI 225 Advanced Machine Learning for the Biomedical Sciences II, Gilmer Valdes (3 Units)

5.2 Proposed courses

All courses of the proposed PharmD/MS program are existing PharmD and MS (Clinical Research and Epidemiology) courses. No new courses will be proposed for this program.

5.3 Staffing of courses

Existing courses that will be part of the PharmD/MS curriculum are already staffed by their respective Departments. The arrangement for the amount of time and resources allocated to support PharmD/MS Program students enrolled in the classes will be reviewed yearly and will be adjusted as needed.

5.4 Admission Process

Prospective students will apply to both PharmD and MS programs by completing both PharmD and MS applications. Current UCSF PharmD students can apply to the MS program directly by completing the MS application. To be eligible to apply, students must have completed a bachelor's degree or recognized equivalent degree from an accredited institution with a minimum GPA of 3.0 on a 4.0 scale. Students must satisfy all PharmD and MS prerequisites with course work approved by the Office of Student Affairs (all prerequisites must be completed prior to July 1 of the year of entry into the program). Overall, qualified applicants will have diverse backgrounds with an undergraduate degree in the biological sciences, genetics, chemistry, bioinformatics, pharmacology, engineering, or pharmacy. Applicants whose native language is not English need to demonstrate proficiency in English by taking TOEFL or IELTS or have demonstrated proficiency in English by completing one year of full-time study with a minimum GPA of 3.2 in an accredited University in the United States. A detailed description of the applicant qualifications is provided in section 2.1.

Applications for the PharmD portion will be submitted through Pharmacy College Application Service (PharmCAS) and will include official transcripts and three to four letters of recommendations. Shortlisted candidates will undergo an interview process with two members of the community (such as a faculty member and a current student) to assess their commitment, communication skills, critical thinking, empathy, and future plans. On the day of the interview, the candidates will have an essay exercise, which can help the admission committee assess their writing skills, problem solving, and critical thinking abilities. interpersonal skills, and alignment with program goals.

Applications for the MS portion will be submitted through the UCSF Graduate Division portal and will include official transcripts, current CV, three letters of recommendations (these can be the same letters as applied toward the PharmD application), and Personal Statement. The MS admissions committee will evaluate and rank candidates during the application review process based on potential for a career in research, academic preparation, and likelihood of success in the MS program.

For a prospective student applying for both programs, they have to state his/her intention to apply to the PharmD/MS Dual Degree Program in the PharmD application. In the MS application, they also have to indicate that they submitted the recommendation letters, course history, and information related to honors, awards, and fellowships in their PharmD application.

The Steering Committee will work with the respective admissions committees to address any discrepancies and to finalize the list of the applicants selected for the PharmD/MS Program.

SECTION 6. RESOURCE REQUIREMENTS

6.1 Faculty and Staff Support

The PharmD/MS program will not need any faculty and it will utilize existing faculty in the PharmD and MS programs. To implement the program, there will be two Program Leads (0.25 FTE) and a Program Administrator/TBD (To Be Determined) (0.5 FTE).

Student charges will fund all faculty, staff and operational costs for the program. There is no anticipated net negative fiscal impact on teaching capacity or operations of other programs on the campus.

6.1.1 Program Leads

There will be two Program Leads. The first Program Lead (Dr. Alexis Beatty, MD, MAS) is a full-time UCSF employee with 1.0 FTE. She an Associate Professor in the Department of Epidemiology and Biostatistics, School of Medicine and she is also appointed in the Department of Medicine, Division of Cardiology and sees general cardiology patients. Dr. Beatty is the Director of the UCSF MD/MS Program and Faculty Lead of the UCSF Training in Clinical Research (TICR) Program. Since 2024, Dr. Beatty serves as the Co-Director of the UCSF Cardiac Rehabilitation and Wellness Center. Dr. Beatty's research focuses on developing, testing, and implementing innovative delivery models for cardiac rehabilitation to improve outcomes and reduce disparities. Her interests also include innovative delivery models for cardiovascular prevention and treatment and digital clinical study methods. Dr. Beatty received several awards, including Elizabeth Barrett-Connor Research Award in Epidemiology and Prevention for Investigators in Training from the American Heart Association in 2012 and Ruth L. Kirschstein National Research Service Award from the National Heart, Lung, and Blood Institute in 2011.

The second Program Lead (Dr. Igor Mitrovic) is a full-time UCSF employee with 1.0 FTE. He is a Professor of Physiology and Clinical Pharmacy and the Vice Dean for the UCSF PharmD Education. Dr. Mitrovic is responsible for the physiology curriculum across the professional schools at UCSF (Medicine, Pharmacy, and Dentistry). Dr Mitrovic has served on numerous committees (including 18 years on Admissions Committee at the UCSF School of Medicine). Dr. Mitrovic has also done international work in curricular and faculty development. Over the years, he has received numerous teaching awards as a teacher in the School of Pharmacy, School of Medicine and School of Dentistry including Long Awards in the School of Pharmacy, Excellence of Teaching Awards in the School of Dentistry, Kaiser Teaching Awards in the School of Medicine as well as Distinction in Teaching Award from the UCSF Academic Senate. Also Dr. Mitrovic has received an honorary Doctorate from University of Kragujevac Republic of Serbia. Dr. Mitrovic is a designer of a completely new, competency-based curriculum in UCSF School of Pharmacy which is based on the cutting edge educational and neuroscience of learning research. He has also participated in creating UC Merced/UCSF BS/MD SJV PRIME+ program and is a creator of UC Merced/UCSF BS/PharmD 3+3 hybrid program. Dr. Mitrovic has mentored many high school, undergraduate as well as UCSF underrepresented students. He has also mentored numerous postdoctoral fellows, residents and junior faculty to help them excel as educators.

Both Program Leads will provide leadership to the PharmD/MS Program while also providing oversight of the program budget, funding, and resources to ensure fiscal stability, managing marketing and recruitment activities, and helping to facilitate Faculty development. They will engage with the PharmD and MS Curriculum Committees and oversee curriculum and competencies development and evaluations as outlined in Section 2.3.2. Both Program Leads will be continually involved in strategic growth and vision of the Program and serve as the primary liaison within UCSF and other programs, institutions, industry partners, and professional societies. They also supervise the Assistant Program Director or Program Administrator.

Duties and responsibilities:

• Program Growth and Vision

- Program Liaison
- Budget development and management
- Marketing
- Recruitment
- Faculty hiring
- Faculty development
- Competencies (Curriculum)
- Student progression and wellbeing
- Teaching
- Oversee faculty support

6.1.2 Program Administrator

The PharmD/MS Program Leads will coordinate with the Program Administration that already exists for the PharmD and MS programs. The PharmD Program Administrator/TBD (0.5 FTE) will have expertise in program administration and will provide support to all dual degree programs in the School of Pharmacy (including PharmD/MS Program).

The MS in Clinical and Epidemiological Research Program Administrator is Ms. Clair Dunne, MPA, who is a full-time UCSF employee with 1.0 FTE. Ms. Dunne has over 10 years of experience administering the Masters' program.

The Program Administrators are responsible for supporting the Program Leads and assist with developing procedures to ensure effective operation of the Program.

Duties and responsibilities:

- Management of admissions process
- Management and coordination of course and class scheduling
- Oversee student advising and support
- Coordination of committees
- Correspondence and communications
- Monitoring student progress
- Student financial support
- Student Curricular Materials
- Tracking course and instructor evaluations
- Website development and maintenance
- Supporting students with transition from PharmD to MS

6.1.3 Program Finance Assistant

The PharmD and MS programs will utilize staff with financial expertise in the respective programs to support the Program Leads and play an important role in ensuring the financial health and sustainability of the PharmD/MS Program. Key responsibilities include:

- Budget management: Assist in development and management of the program's budget
- Identify funding sources and allocate resources

- Maintain financial records (track expenses, generate invoices, and prepare financial statements)
- Financial analysis and strategy recommendations
- Assist students navigating the financial aspects of the program (student charges, financial aid, and scholarships)

6.1.4 Program Faculty

The faculty of the PharmD/MS Dual Degree Program are existing faculty members of both the PharmD program and the MS program in Clinical and Epidemiological Research. As outlined in Section 4.1, the faculty of the PharmD/MS are faculty member from a number of UCSF departments, including the Departments of Clinical Pharmacy, Bioengineering and Therapeutic Sciences, Pharmaceutical Chemistry, Epidemiology and Biostatistics, Cellular and Molecular Pharmacology, Physiology, Informatics, Infectious Diseases, Reproductive Sciences, General Internal Medicine, Hospital Medicine, and Pulmonary & Critical Care. A wide range of faculty members at UCSF have indicated their enthusiasm for the program and their willingness to serve on PharmD/MS committees as well as serve as faculty or research advisors and mentors.

Core Program Faculty

The Core Program Faculty of the PharmD/MS Program will teach and coordinate courses of the PharmD and MS in Clinical and Epidemiological Research Programs listed in Section 2.3.2. See table 4.1 for a listing of Program Faculty, including core PharmD and MS faculty. The Core Program Faculty will play a critical role in maintaining the quality and relevance of the program and will serve as:

- 1. Course Directors: Course directors will be responsible for planning and designing courses and delivering instruction to students.
- 2. Mentoring and advising students: As described in Sections 1.10.1 and 2.3.4, each student is expected to have established their MS Committee by the end of the Winter quarter of their first year of MS studies (third year of the PharmD/MS) and will meet on a regular basis throughout the MS years.

In addition, the PharmD/MS Program will have a steering committee of 3-5 members, including:

Igor Mitrovic, MD Alexis Beatty, MD, MAS Valerie Clinard, PharmD Jennifer Cocohoba, PharmD, MAS

6.1.5 MS Committee

Each scholar will form a master's committee, which will consist of three faculty members:

-A representative from the scholar's academic field of interest (e.g., cardiology). This individual should be conducting primary research in the scholar's chosen field and will typically be a faculty member at UCSF. Upon approval from the MS program directors, individuals from outside of UCSF (e.g., UC, Berkeley, Stanford University, or the biotechnology or pharmaceutical industry) may serve in this capacity. -An epidemiologist/clinical researcher faculty member (primary or secondary/affiliated appointment) from the UCSF Department of Epidemiology and Biostatistics. If possible, a faculty member with working knowledge of the scholar's substantive interests should be chosen.

-A biostatistician faculty member (primary or secondary/affiliated appointment) from the UCSF Department of Epidemiology and Biostatistics. This committee member will be assigned by the department according to the scholar's substantive interests and methodologic needs.

The purpose of this committee is both to provide mentorship and to evaluate the achievement of the requirements for graduation. With the exception of the biostatistician (who will be assigned by the program), scholars should select and submit committee members to the Master's Program Director by the end of the Winter Quarter in the first year of their MS studies (third year of the PharmD/MS program), and to meet with their committee at least quarterly, thereafter, to review progress and set future objectives.

One committee member should be selected as the Chairperson, whose role is to arbitrate when there is significant disagreement among committee members or to advocate for the scholar if he/she is experiencing difficulties gaining access to other committee members or scheduling meetings of the committee. The Chairperson must hold either a primary or secondary/affiliated faculty appointment in the Department of Epidemiology and Biostatistics. It is expected that scholars will meet with their committees at least quarterly to review progress and set future objectives.

By March 1 of the first year of their MS studies (third year of the PharmD/MS program), scholars will be required to complete the first meeting form indicating: 1) that they have had at least one meeting with all 3 members of their Master's Committee present and, 2) that the committee members and scholar agree that the scholar is making satisfactory progress toward meeting the program requirements (i.e., the comprehensive literature review, first-authored presentation and manuscript). The completed form should be sent by March 1 of the first year in the MS portion of the PharmD/MS program. Scholars must complete this form in order to be eligible to register for subsequent quarters.

Nine months prior to when scholars anticipate completing the last of their original research products (i.e., the comprehensive literature review, first-authored presentation and manuscript), scholars are required to complete the second committee meeting form indicating that they have had at least one meeting with all 3 members of their Master's Committee present where the content and timeline were agreed upon regarding the completion of the three research products. The purpose of this second committee meeting is to ensure that the Committee is well aware of the exact projects the scholars have chosen to fulfill their requirements.

At no less than 3 months prior to the date that scholars anticipate completing the last of their original research products (i.e., the comprehensive literature review, first-authored presentation and manuscript), scholars are also required to complete the third committee meeting form indicating that they have had at least one meeting with all 3 members of their Master's Committee present where a final plan and timeline were agreed upon regarding the content and completion of the three research products. The purpose of this third/final meeting is to ensure that the Committee is well aware of and agrees with the final plans the scholar has made to fulfill the program's research product requirements. The objective is to avoid last minute submissions to Committee members, which defeat the purpose of obtaining the members' well-reasoned advice. It is, however, anticipated that the scholar will continue to meet with Committee members, either together or individually, after this third meeting for further mentoring and review of the scholar's work. When planning for final approval of products by Master's Committee members, scholars

should expect that Committee members may require as long as three weeks to return comments to the scholar. Therefore, Committee members should be presented with drafts of the required products well before the scholars' anticipated graduation.

6.2 Library acquisitions

UCSF provides internet access to a large and comprehensive set of scientific journals so that faculty and students have easy access to the published literature. UCSF has two libraries, one on the Parnassus Heights Campus and another at Mission Bay. The Library conducts classes and consultation for research projects and literature review. The Library also runs a Data Science Initiative which provides training in finding, sharing, and managing data; bioinformatics and statistics; programming; and data visualization. The Parnassus Heights Library also holds a collection of books, primary research documents, and archival journals.

All researchers and students have internet-based access to digital holdings from anywhere on campus and remotely via VPN, as well as access to the extensive holdings of the nine other campuses in the UC system. The Parnassus Library has a Teaching and Learning Center (TLC) with state-of-the-art computer and conferencing equipment that enhances the educational experience across curricula and training programs. The TLC supports curricular activities that use simulation, technology-enhanced small group learning, and computing labs or that require presentation practice.

There are no anticipated additional costs for library acquisitions as the books and journals necessary for the PharmD/MS program are currently used by other graduate programs.

6.3 Computing requirements

All faculty labs and offices are equipped with computers available for image processing, word processing, and data analysis. The UCSF Information Technology Services (ITS) provides a campus-wide high-speed network infrastructure, which allows investigators to access a wide variety of computing technologies. Because the UCSF campus is geographically diverse, ITS uses a high-speed SONNET Ring backbone infrastructure to allow virtually instantaneous access to campus computing resources from any campus location, including a number of clinical facilities affiliated with UCSF. The computing capabilities of the campus are constantly growing and expanding. Computing resources are conveniently located throughout the campus. Students are provided with UCSF e-mail accounts and cloud-based server storage. Computer (IT) support is provided by the Departments of faculty mentors. Free access to standard and high-end computer workstations is provided to the program and its fellows by the UCSF Library.

In addition, computational resources are available through the Institute for Human Genetics (IHG). The available computational resources are among the world's best. Hardware platforms include high-performance workstations from Digital Equipment, Hewlett Packard, IBM, Silicon Graphics, Dell, Apple, and Sun Microsystems. The computers and workstations on campus are connected to a campus-wide local area network, which in turn is connected via a high-speed microwave link to the Internet. Access to remote computer facilities, such as the NSF-sponsored supercomputer centers, is also available via this Internet link. Access to extensive literature databases is available through systems such as MEDLINE and the University's MELVYL system. An online journal system, RED SAGE, provides desktop access to full text and graphic images for a growing number of journals. A central aspect of the computer resources is a computational cluster housed in the IHG. The IHG cluster for computationally demanding projects is a

Linux Cluster. This is an HPC cluster consisting of 10 compute nodes housed in a Dell 1855 chassis. Each node provides 2 EM64T Xeon processors running at 3.6 MHz, 800 MHz front-side bus along with an L2 1 MB cache. Memory is provided by 2-2GB DDR 3200 sticks of RAM. The Master node is a Dell PE2850 with 4 EM64T Xeon processors running at 3.2 MHz, 800 MHz front-side bus along with an L2 1 MB cache. Memory is provided by 2-2GB DDR 3200 sticks of RAM. Main storage for the cluster is provided via 110GB RAID1 disk array with a 250GB RAID5 disk array for short-term data staging. Larger and long-term data storage is provided by a multi-terabyte EMC Storage Area Network adjacent to the cluster. Platform Rocks version 3.3.0 is used for cluster head and compute node management and provisioning. Sun Gridengine 5.3 provides distributed resource management and is integrated with Platform LAVA for batch job queuing, processing, and management. Software maintained on the cluster includes current licenses for SAS and SAS/Genetics (version 9.1.2), STATA (version 7.0), Maple (version 7), Matlab (version 6.1), and S-PLUS (version 6). Maintained public domain software includes the R statistical programming language (version 2.1.1), TeX/LaTeX, Perl, Python, and recent versions of the Free Software Foundation (GNU) programming utilities. The current complement of genetics software includes but is not limited to Aspex, FBAT, Fisher, GeneHunter, Mendel, PHASE, S.A.G.E., SOLAR, and STRUCTURE.

No additional computing costs, outside of personal computers for staff, are needed. On-campus internet is already available to matriculated students. Students will provide their own desktop or laptop computers for class activities and homework. Matriculated students will receive the standard computing support available from the UCSF Library's Learning Tech Support Center. The UCSF Library has a full suite of technology for problem-based learning (e.g., the Collaborative Learning Environment). All UCSF faculty can use UCSF Library educational technology without cost. Video conference and teleconference technology will be available in the dedicated program space in the Mission Bay campus.

6.4 Equipment

No equipment needs are anticipated.

6.5 Space and other capital facilities

Program faculty have offices and laboratories, which include desk space for trainees, provided by UCSF at various campus locations. The majority of program faculty are located at the Mission Bay Campus, where there is desk space for trainees and classrooms for didactic training.

The PharmD/MS Program will occupy space on the Mission Bay campus. Program faculty and staff will have a dedicated workspace provided by the School of Pharmacy. Classrooms and conference rooms on the Mission Bay campus will be available to the Program and are booked through a standard process through UCSF's Educational Technology Services.

During the second year of the MS studies, students will have access to focus/conference/kitchen/lactation rooms on the second floor at Mission Hall at Mission Bay. They will also have access to the Graduate Division Study rooms on the first floor of Mission Hall. This location also includes exercise equipment (bike/thread mill) and the Graduate Division food pantry. Mission Hall is situated near multiple UCSF housing locations, the UCSF community center, library and the Graduate Division offices.

6.6 Other operating costs

6.6.1 Software License fees

STATA is available for free through the library, but students are encouraged to purchase STATA as it offers additional flexibility: <u>Software for Statistics</u>, <u>Analysis</u>, <u>and Visualization - UCSF Library</u> No new software license needs are anticipated.

6.6.2 Guest lecturers

Guest lecturers are anticipated as part of the MS Pharmacoepidemiology course (EPI 262), which will enrich the teaching program.

6.6.3 Incidental expenses

Brochures and advertising, teaching materials, software, and other educational support costs will be covered by program charges.

SECTION 7. PROGRAM BUDGET AND CHARGES

The Master's degree program will follow a self-supporting model and receive no state support. It will be funded entirely by revenues generated by the program (student charges) and other non-state revenues, including corporate partnerships and sponsorships. The estimated student program charge for the MS at the launch of the program, pending Presidential approval, will be \$93,429.

The informational data sheets below are the result of a multitude of meetings and collaborations with respective parties from SOP, SOM-MS, Grad Division/PhD, Student Services, and BRM who provided input and vetting. The data provided are only estimates at the time provided. The **assumptions** of these programs are to start in FY27-28 with each of their respective cohorts accepting 2 students per cohort per fiscal year although it is possible that the actual demand may indicate a need for a larger student enrollment.

The expense assumptions per program are minimal; from providing stipends to program leads, to marketing, and other administrative shared costs.

This data will be reviewed again during the overall PharmD program proposal in Fall 2025

Information Provided:

- Estimated Enrollment Cohort Map by Fiscal Year per Quarter; showing when a student is enrolled in which program (assume 2 students per cohort per program per fiscal year)
- Estimated Enrollment Map showing PDST tuition per student
- Estimated Expenses of each of these programs on the Pharm D side
- Estimates of Program By FY/QTR Revenue, Expenses, and Net
- Estimated PDST tables for future fiscal years

Pharm D-MS Enrollment Cohort Map

These estimates are based on 2 students entering the cohort per quarter per academic year.

			FY27-28	FY28-29	FY29-30	FY30-31	FY31-32	FY32-33	FY33-34	FY34-35
YEAR	QUARTE R	PharmD/M S Cohorts	PharmD/M S Cohort 1	PharmD/M S Cohort 2	PharmD/M S Cohort 3	PharmD/M S Cohort 4	PharmD/M S Cohort 5	PharmD/M S Cohort 6	PharmD/M S Cohort 7	PharmD/M S Cohort 8
FY27- 28	Q1 Summer	2	2							
FY27- 28	Q2 Fall	2	2							
FY27- 28	Q3 Winter	2	2							
FY27- 28	Q4 Spring	2	2							
FY28- 29	Q1 Summer	4	2	2						
FY28- 29	Q2 Fall	4	2	2						
FY28- 29	Q3 Winter	4	2	2						
FY28- 29	Q4 Spring	4	2	2						
FY29- 30	Q1 Summer	4	to MS	2	2					
FY29- 30	Q2 Fall	4	to MS	2	2					
FY29- 30	Q3 Winter	4	to MS	2	2					
FY29- 30	Q4 Spring	4	to MS	2	2					
FY30- 31	Q1 Summer	6	2	to MS	2	2				
FY30- 31	Q2 Fall	4	to MS	to MS	2	2				
FY30- 31	Q3 Winter	4	to MS	to MS	2	2				
FY30- 31	Q4 Spring	6	2	to MS	2	2				
FY31- 32	Q1 Summer	6		2	to MS	2	2			
FY31- 32	Q2 Fall	4		to MS	to MS	2	2			
FY31- 32	Q3 Winter	4		to MS	to MS	2	2			
FY31- 32	Q4 Spring	6		2	to MS	2	2			
FY32- 33	Q1 Summer	6			2	to MS	2	2		
FY32- 33	Q2 Fall	4			to MS	to MS	2	2		
FY32- 33	Q3 Winter	4			to MS	to MS	2	2		
FY32- 33	Q4 Spring	6			2	to MS	2	2		
FY33- 34	Q1 Summer	6				2	to MS	2	2	
FY33- 34	Q2 Fall	4				to MS	to MS	2	2	
FY33- 34	Q3 Winter	4				to MS	to MS	2	2	
FY33- 34	Q4 Spring	6				2	to MS	2	2	
FY34- 35	Q1 Summer	6					2	to MS	2	2
FY34- 35	Q2 Fall	4					to MS	to MS	2	2
FY34- 35	Q3 Winter	4					to MS	to MS	2	2
FY34- 35	Q4 Spring	6					2	to MS	2	2

PharmD-MS estimated PDST per Student and Estimated Tuition

The map shows when a student is enrolled in which program. This map is used for student services as well as the running of the curriculum.

						PDST Tuition Cost
PharmD/MS Estimated PDST per Student						PDST Only
	Fiscal Year	Q1 Summer	Q2 Fall	Q3 Winter	Q4 Spring	(PharmD)
Year 1 (Summer of 2027)	FY27-28	Pharm D	Pharm D	Pharm D	Pharm D	\$36,240
Year 2	FY28-29	Pharm D	Pharm D	Pharm D	Pharm D	\$37,328
Year 3	FY29-30	SOM-MS	SOM-MS	SOM-MS	SOM-MS	
Year 4	FY30-31	Pharm D	SOM-MS	SOM-MS	Pharm D	\$19,800
					TOTALS	\$93,368

Total Tuition Costs		
In State	Outstate	In or Out of State
Tuition - Pharm D	Tuition - Pharm D	(MS)
\$66,219	\$78,464	
\$68,202	\$80,447	
		\$50,506
\$35,510	\$39,591	\$42,923
\$169,931	\$198,502	\$93,429

MS Epi program is a self-supporting program (Ref: Chan Nguyen/Alexis email March 2025)

Pharm D-MS Estimated Expenses on Pharm D side

The expense assumptions per program are minimal, including providing stipends to program leads, marketing, and other administrative shared costs.

Pharm D - MS	Program Effort	FY28	FY29	FY30	FY31	FY32	FY33	FY34	FY35
Program Leads/Steering Committee	Stipends	\$9,500	\$9,500	\$9,500	\$9,500	\$9,500	\$9,500	\$9,500	\$9,500
(Guest, Marketing, etc)	100.0%	\$10,927	\$11,255	\$11,593	\$11,941	\$12,299	\$12,668	\$13,048	\$13,439
Shared Cost of Assistant/Admin	25.0%	\$6,789	\$13,984	\$14,404	\$14,836	\$15,281	\$15,740	\$16,212	\$16,698
Estimated Service Costs (Kanbar, Occupancy, Skills)	Estimates	\$3,460	\$3,564	\$3,671	\$3,781	\$3,895	\$4,011	\$4,132	\$4,256
	Estimated Expenses PharmD-MS	\$30,676	\$38,304	\$39,168	\$40,058	\$40,975	\$41,919	\$42,891	\$43,893

PharmD-MS By FY/QTR Revenue, Expenses, and Net Estimates

YEAR	QUARTER	PharmD/MS Cohorts	PDST Tuition	PDST Gross (Enrollment*Tuition)	SFA (33%)	Net To School (66%)	Estimated Expenses	PharmD/MS (Net)
FY27-28	Q1 Summer	2	\$ 9,060	\$18,120	\$6,040	\$12,080	\$7,669	\$4,411
FY27-28	Q2 Fall	2	\$ 9,060	\$18,120	\$6,040	\$12,080	\$7,669	\$4,411
FY27-28	Q3 Winter	2	\$ 9,060	\$18,120	\$6,040	\$12,080	\$7,669	\$4,411
FY27-28	Q4 Spring	2	\$ 9,060	\$18,120	\$6,040	\$12,080	\$7,669	\$4,411
FY28-29	Q1 Summer	4	\$ 9,332	\$37,328	\$12,443	\$24,885	\$9,576	\$15,309
FY28-29	Q2 Fall	4	\$ 9,332	\$37,328	\$12,443	\$24,885	\$9,576	\$15,309
FY28-29	Q3 Winter	4	\$ 9,332	\$37,328	\$12,443	\$24,885	\$9,576	\$15,309
FY28-29	Q4 Spring	4	\$ 9,332	\$37,328	\$12,443	\$24,885	\$9,576	\$15,309
FY29-30	Q1 Summer	4	\$ 9,612	\$38,448	\$12,816	\$25,632	\$9,792	\$15,840
FY29-30	Q2 Fall	4	\$ 9,612	\$38,448	\$12,816	\$25,632	\$9,792	\$15,840
FY29-30	Q3 Winter	4	\$ 9,612	\$38,448	\$12,816	\$25,632	\$9,792	\$15,840
FY29-30	Q4 Spring	4	\$ 9,612	\$38,448	\$12,816	\$25,632	\$9,792	\$15,840
FY30-31	Q1 Summer	6	\$ 9,900	\$59,400	\$19,800	\$39,600	\$10,014	\$29,586
FY30-31	Q2 Fall	4	\$ 9,900	\$39,600	\$13,200	\$26,400	\$10,014	\$16,386
FY30-31	Q3 Winter	4	\$ 9,900	\$39,600	\$13,200	\$26,400	\$10,014	\$16,386
FY30-31	Q4 Spring	6	\$ 9,900	\$59,400	\$19,800	\$39,600	\$10,014	\$29,586
FY31-32	Q1 Summer	6	\$ 10,197	\$61,182	\$20,394	\$40,788	\$10,244	\$30,544
FY31-32	Q2 Fall	4	\$ 10,197	\$40,788	\$13,596	\$27,192	\$10,244	\$16,948
FY31-32	Q3 Winter	4	\$ 10,197	\$40,788	\$13,596	\$27,192	\$10,244	\$16,948
FY31-32	Q4 Spring	6	\$ 10,197	\$61,182	\$20,394	\$40,788	\$10,244	\$30,544
FY32-33	Q1 Summer	6	\$ 10,503	\$63,018	\$21,006	\$42,012	\$10,480	\$31,532
FY32-33	Q2 Fall	4	\$ 10,503	\$42,012	\$14,004	\$28,008	\$10,480	\$17,528
FY32-33	Q3 Winter	4	\$ 10,503	\$42,012	\$14,004	\$28,008	\$10,480	\$17,528
FY32-33	Q4 Spring	6	\$ 10,503	\$63,018	\$21,006	\$42,012	\$10,480	\$31,532
FY33-34	Q1 Summer	6	\$ 10,818	\$64,908	\$21,636	\$43,272	\$10,723	\$32,549
FY33-34	Q2 Fall	4	\$ 10,818	\$43,272	\$14,424	\$28,848	\$10,723	\$18,125
FY33-34	Q3 Winter	4	\$ 10,818	\$43,272	\$14,424	\$28,848	\$10,723	\$18,125
FY33-34	Q4 Spring	6	\$ 10,818	\$64,908	\$21,636	\$43,272	\$10,723	\$32,549
FY34-35	Q1 Summer	6	\$ 11,143	\$66,858	\$22,286	\$44,572	\$10,973	\$33,599
FY34-35	Q2 Fall	4	\$ 11,143	\$44,572	\$14,857	\$29,715	\$10,973	\$18,742
FY34-35	Q3 Winter	4	\$ 11,143	\$44,572	\$14,857	\$29,715	\$10,973	\$18,742
FY34-35	Q4 Spring	6	\$ 11,143	\$66,858	\$22,286	\$44,572	\$10,973	\$33,599

7.1.1 Student Support

Students enrolled in the PharmD/MS dual degree program in Clinical Research and Epidemiology will be eligible for federal student loans and all other loans and scholarships administered through UCSF. Other funding will be provided by external partnerships (e.g. Genentech). The PharmD/MS Program is dedicated to supporting students from underrepresented groups and will pursue support from various sources including industry and foundations to assist with student funding.

The PharmD/MS dual degree program in Clinical Research and Epidemiology is an intensive four-years program requiring full-time commitment. Students will not have the opportunity to take on other work responsibilities.

7.1.2 Health and Other Benefits

All graduate students will be provided with a comprehensive health plan and other benefits in accordance with UCSF Graduate Division policies.

SECTION 8. GOVERNANCE

8.1 Program leadership

The PharmD/MS Program Steering Committee will govern the proposed program.

8.2 Faculty and staff

As described in Section 6.1.3, Program Faculty are current faculty members from both PharmD program and the MS program in Clinical Research and Epidemiology. The MS Faculty focus on several research areas, including bioinformatics, clinical epidemiology, genetic epidemiology, global health, implementation science, and machine learning.

Key positions within the program's staff include the Program Director described in Section 6.1.1, the Program Administrator described in Section 6.1.2, and the Program Finance Assistant described in Section 6.1.3.

SECTION 9. CHANGES IN SENATE REGULATIONS

This program does not require any changes in Senate Regulations.

APPENDIX 1. Letter of support from UCSF School of Pharmacy Dean

Kathy Giacomini, PhD, BSPharm

Dean, School of Pharmacy



Kathleen M. Giacomini, PhD, BSPharm

Dean

Troy C. Daniels Distinguished Professor of Pharmaceutical Sciences

Associate Vice Chancellor, Pharmacy Affairs

School of Pharmacy

UCSF Medical Sciences Box 0403 513 Parnassus Ave Rm S126 San Francisco CA 94143

415-476-8010 kathy.giacomini@ucsf.edu pharmacy.ucsf.edu www.ucsf.edu February 20, 2025

Alexis Beatty, PharmD, PhD, MAEd Igor Mitrovic, MD Program Leads, PharmD/MS Dual Degree Program

Re: Institutional Letter of Support for the PharmD/MS in Clinical and Epidemiological Research Dual Degree Program

Dear Drs. Mitrovic and Beatty,

I enthusiastically support the PharmD/MS in Clinical and Epidemiological Research Dual Degree Program. With the significant expansion of biotech and pharmaceutical research and development (the number of clinical trials has quadrupled in the last decade), the need for licensed clinicians with expertise in designing and conducting clinical research is everincreasing. Moreover, the need for educators training the next generation of pharmacists and clinical researchers in academia follows a similar growth curve. This program will provide the participants with foundational knowledge in clinical research, population science, therapeutics, and essential patient care skills. Students will be studying how to design and evaluate studies that assess the effectiveness of medications in patient populations while, at the same time, learning the mechanisms of disease and the science behind the medications' ability to alter disease course coupled with mastering the art of clinical practice. This Program will transform precision medicine and individualized patient care academically and in the private sector.

The UCSF School of Pharmacy leads the Nation in pharmacy education and has a long history of educational innovation. At a rate that is unmatched in the country, over 80 percent of our PharmD graduates regularly secure postgraduate training. Our school is where clinical pharmacy was born, and we have continued this innovative spirit with the design and launch of our innovative integrated three-year curriculum. As Dean of the School, my goals are to capitalize on the resources of our school and University and support training programs such as this one to enhance the preparation of our PharmD students for the challenges and opportunities of the 21st century's job markets and ensure that we continue to be leaders in pharmacy education for years to come.

In summary, I trust that UCSF's accelerated (4 years) PharmD/MS in Clinical and Epidemiological Research Dual Degree Program provides an outstanding opportunity for attracting and training students from diverse backgrounds and preparing them for clinical practice, government, academia, and industry jobs. This program offers a unique advantage of awarding both a PharmD and an MS degree upon completion, while fully



adhering to all PharmD accreditation standards. We are exceptionally well prepared to achieve these goals thanks to our extensive state-of-the-art facilities; our well-funded, productive, and highly engaged faculty, our comprehensive array of student support services; our central resources dedicated to the responsible conduct of research, the promotion of diversity and inclusion, and the evaluation of outcomes for training programs; and our commitment to the success of this and other training programs.

I wish you the best of luck with this proposal.

Sincerely,

Kathleen M. Giacomini, PhD, BSPharm

Kathlen M. Giacomini

Dean of the School of Pharmacy

Co-PI, UCSF-Stanford Center of Excellence in Regulatory Science and Innovation

Troy C. Daniels Distinguished Professor of Pharmaceutical Sciences

Associate Vice Chancellor, Pharmacy Affairs School of Pharmacy

APPENDIX 2. Letter of support from Department Chair

Mark J. Pletcher, M.D., M.P.H.

Department of Epidemiology and Biostatistics



Mark J. Pletcher, MD, MPH Professor and Chair Department of Epidemiology & Biostatistics

Mission Hall Global Health & Clinical Sciences Building UCSF Box 0560 550 16th Street, Second Floor San Francisco, CA 94158

tel: 415.514.8008 mark.pletcher@ucsf.edu

www.ucsf.edu epibiostat.ucsf.edu February 12, 2025

Leslie Floren, PharmD, PhD, MAEd Brian Shoichet, PhD Program Leads, PharmD/PhD Dual Degree Program

Dear Drs. Floren and Shoichet,

I am writing to provide my strong support for the PharmD/MS in Clinical & Epidemiological Research dual degree program in collaboration with the School of Pharmacy. This collaboration aligns with our mission of advancing health worldwide through developing, teaching, and applying the methods of epidemiology and biostatistics. As Chair of the Department of Epidemiology & Biostatistics, I believe this program would offer a remarkable opportunity to learners interested in pursuing either academic research positions or private biomedical/pharmaceutical industry research. This dual-degree program is designed to fill that gap, preparing graduates uniquely equipped to contribute to patient care and the critical areas of clinical trials, data analysis, and evidence-based treatment protocols. The dual training will enable graduates to take on roles as clinical researchers, regulatory affairs specialists, and leaders in developing new therapeutics.

Additionally, this relationship is beneficial for our learners. The program has the potential to foster strong interdisciplinary collaboration between the School of Pharmacy and Epidemiology & Biostatistics. Traditionally, our learners have come from within UCSF with career goals in academic medicine or academic research. In recent years, there has been a significant change in our student body. More of our learners are interested in working in private industry, and coincidentally, we have seen an increase in applicants with international pharmacy degrees. We are in the process of expanding our learning opportunities in pharmacoepidemiology and career support. Traditionally, we have not had a strong relationship with the private sector, but we hope this relationship will provide this cohort with mentorship and career or research opportunities. We are well situated to work with the School of Pharmacy on this program as we currently have an MD/MS program in collaboration with the School of Medicine. Our faculty and staff have experience supporting learners who are pursuing multiple educational goals simultaneously. We are confident that this program will attract highly motivated students who seek to expand their professional skill sets and make meaningful contributions to pharmacological and clinical research.

In conclusion, the PharmD/MS in Clinical and Epidemiological Research dual degree program will position the UCSF Department of Epidemiology and Biostatistics and School of Pharmacy as pioneers in advancing pharmaceutical and clinical research.

I wholeheartedly endorse this program and look forward to its successful implementation.

Sincerely,



Mark J. Pletcher, M.D., M.P.H.

Professor and Chair

Department of Epidemiology and Biostatistics

University of California, San Francisco