

Eli Lilly & Company

Visiting Scientist Fellowship 2022-2023



The Visiting Scientist Fellowship is a highly respected pharmaceutical industry-based program, which has developed competitive and marketable industry professionals since 1994. A deeply involved, influential, and passionate network of more than 175 alumni across the pharmaceutical industry are contributing to the development of the next generation of medicines to improve patient lives.

Designed to train professionals for a career in the pharmaceutical industry, the fellowship offers a wide array of dynamic and challenging positions, while creating an environment that fosters personal and professional development. This one-year post graduate program presents PharmD, MD and relevant PhD or Master's degree graduates with cross-functional exposure to clinical development, commercial, medical, project management and regulatory aspects of drug development. Fellows directly impact the business at Eli Lilly and Company to speed innovation while developing valuable and lifelong career skills.

Visiting Scientist Fellowship 2022-2023 Position Descriptions

Table of Contents

Commercial	2
Global Public Policy (GPP).....	2
Global Pricing, Reimbursement, and Access - New Product Planning.....	2
Lilly Value and Access US Strategy and Capabilities.....	3
Novel Tech Modalities/Ventures.....	3
Clinical Development and Project Management	4
Clinical Development Design Hub.....	4
Clinical Trial Project Management (CTPM).....	4
Pharmaceutical Project Manager (PPM).....	5
Clinical Services, Supplies and Capabilities.....	5
Global Scientific Communications.....	6
Health Outcomes	7
GPORWE Center of Expertise.....	7
Outcomes Liaison.....	7
Medical Affairs	8
Global Medical Information.....	8
Global Medical Digital and Medical Affairs Education.....	8
Clinical Research Scientist: US Oncology.....	9
Clinical Research Scientist: US Immunology.....	9
Regulatory Affairs	10
Global Labeling Department.....	10
Regulatory Strategy: North America.....	10
US Advertising and Promotion.....	11

Commercial

Global Public Policy (GPP)

Global Public Policy provides strategic analysis, expert insights, and practical recommendations on healthcare policy issues affecting Lilly and key stakeholders. GPP focuses on domestic and global policies affecting healthcare coverage, access, reimbursement, affordability, and advancement.

The Visiting Scientist Fellow will

- Develop well-reasoned issue assessments, policy landscape evaluation, and position development through research, analysis, and collaboration to help Lilly shape the public policy environment and support improved outcomes and incentives for investment in biopharmaceutical innovation.
- Apply scientific knowledge and work cross functionally to develop and support policy recommendations, which could be used to advance Lilly priorities with policy makers.
- Focus on today's important policy issues such as drug pricing, healthcare reform, biologics and biosimilars, health financing, benefits design and innovation policy through both a U.S. and global lens.

Global Pricing, Reimbursement, and Access - New Product Planning

Global Pricing, Reimbursement, and Access - New Product Planning (PRA NPP) is responsible for influencing the development of pipeline and business development medicines to reflect critical payer needs identified through payer feedback. They also provide price and access recommendations for forecasts to support key business decisions with the goal of ensuring patients can access Lilly medicines and deliver strong business results. The focus is on the USA, Japan, and major European markets.

The Visiting Scientist Fellow will

- Work across therapeutic areas in the pipeline to apply scientific expertise in a commercial role.
- Work with the Global Public Policy fellow to deliver an environmental review of key markets and identify key opportunities/threats pertaining to pricing and market access.
- Participate in market research and advisory boards to understand payers' needs and develop reports that outline key takeaways and implications.
- Work on strategic projects based on business need and support the team in the development of price and access recommendations.

Lilly Value and Access US Strategy and Capabilities

Lilly Value and Access US Strategy and Capabilities is responsible for value-based pricing, market access, value-based arrangements, and strategy work to support launches for products in the US. In particular, the fellow will be part of the team that oversees value-based strategies to support launch excellence in the US market. Through this experience, the fellow will gain a deep understanding of the evolving US payer environment and the work Lilly must do to develop strong value propositions for our medicines.

The Visiting Scientist Fellow will

- Support and lead strategy development for anticipated US value assessments (ICER reviews) of Lilly assets or therapeutic areas.
- Review value-based arrangement outcomes and provide recommendations for value-based strategies to enhance the brand value proposition using these outcomes.
- Develop a deep dive assessment of channel strategies to support a specific asset in the US.
- Support development of relevant new capabilities based on an evolving US environment.
- Work cross-functionally with partners in value excellence, strategy and innovation, global patient outcomes and real-world evidence, and global pricing, reimbursement, and access on strategic projects to support the business.

Novel Tech Modalities/Ventures

The Visiting Scientist Fellow will work with a range of novel modalities to inform the next wave of preclinical external innovation. The fellow will gain insight on external innovation approaches and preclinical experiments to evaluate new modalities.

The Visiting Scientist will

- Be responsible for tracking all executed proof-of-concept external collaborations.
- Develop strategic recommendation to optimize engagement and decision making for proof-of-concept external collaborations.
- Develop enduring resource for all executed proof of concept external collaborations.
- Participate in select external innovation engagement activities.

Clinical Development and Project Management

Clinical Development Design Hub

The Design Hub drives collaboration and the planning of clinical programs/trials through use of data sources, targeted innovation, and expertise in functional trial delivery.

The Visiting Scientist Fellow will

- Gain exposure to Lilly's therapeutic areas and the clinical development process by working in partnership with asset teams and the Design Hub's Therapeutic Area Groups to improve and optimize study design and feasibility.
- Provide input into key strategic decisions for a clinical program/trial, which may include country and site allocation, financial modeling, patient recruitment and retention, study training and targeted innovation.
- Connect asset teams with new and innovative, data-driven capabilities that can enhance trial feasibility, patient and site experience, and overall business processes.

Clinical Trial Project Management (CTPM)

The Clinical Trial Project Manager (CTPM) leads the cross-functional study team in the development and execution of clinical trials and is accountable globally to deliver trial(s) on time with high quality and within scope and budget. The CTPM leverages project management, clinical trial process, and scientific expertise to drive actions and coordinate efforts to achieve trial deliverables.

The Visiting Scientist Fellow will

- Understand the roles and responsibilities of functions peripheral to the CTPM position in clinical development (data management, medical writing, supply planning, regulatory, etc.)
- Collaborate with the study team to develop study-related documentation and gain hands on experience in clinical trial execution activities.
- Create and manage trial timelines and budgets.

Pharmaceutical Project Manager (PPM)

The Pharmaceutical Project Manager (PPM) provides proactive cross-functional leadership for drug development to translate and execute the strategy for delivering a medicine to patients.

The Visiting Scientist Fellow will

- Serve as the central hub and integration point of the drug development core team, working closely with individuals from Clinical, Chemistry, Manufacturing & Control (CMC), Toxicology, ADME, Regulatory, Health Outcomes, Legal, Discovery, and Marketing.
- Impact the drug development strategy and execution through the project timeline, scope, budget, and risk to enable decision making for senior leadership.
- Develop and utilize necessary project management skills to facilitate delivery of team timelines throughout drug development on budget and within scope for a project(s) in Lilly's portfolio.

Clinical Services, Supplies, and Capabilities

The Clinical Services, Supplies, and Capabilities organization is focused on bringing clinical research to people around the world. We are responsible for strategically providing clinical trial support services, planning, and supplying materials, and creating and delivering innovative capabilities to support the execution of clinical trials globally for all business units across all phases of development. We aim to make clinical research possible for all participants regardless of their proximity to research sites and locations.

This group is within the Clinical Capabilities organization and partners across functions within the Clinical Design, Delivery and Analytics (CDDA) and Product Research and Development (PRD) to provide operational solutions that enable asset strategies across the portfolio including solutions that optimize trial designs for participants.

The Visiting Scientist Fellow will

- Learn about, experience and influence capability development within the organization to enhance clinical design and delivery.
- Lead transformational initiatives across the Molecule Innovation Hub to enhance the timely delivery of products to trial participants while aligning with global clinical strategies.
- Participate in one or more key projects or trial-level delivery programs centered on bringing the trial/trial assessments to the participants.

Global Scientific Communications

Global Scientific Communications (GSC) plays a critical role in executing end-to-end content strategy through the creation of clear, innovative, and engaging research-based, medical communications for external audiences. Our writing teams lead the authoring of content for purposeful, label-driven regulatory submission packages and support the scientific disclosure strategy through peer-reviewed publications. We support these workstreams from start to finish, supplying our molecule teams with best practices and areas to optimize. For instance, we cohesively and consistently capture external analytics for our publications and leverage new technologies to create dynamic data visualizations for optimal audience amplification and impact.

The Visiting Scientist Fellow will

- Lead the development of scientific disclosure and clinical submission strategies to enable effective dissemination of scientific information and the timely approval of Lilly medicines.
- Leverage innovative data visualization techniques to communicate data in a clear, concise, and compelling manner.
- Create meaningful, cohesive, engaging, and sustainable content that is used by cross-functional, multidisciplinary partners.

Health Outcomes

GPORWE Center of Expertise

Lilly's Patient-Focused Outcomes Center of Expertise (PFO COE), provides scientific expertise to ensure that patients' perspectives are incorporated into drug development, including in evaluation of treatment benefit and when assessing benefits and risks of treatments. The PFO COE collaborates cross-functionally as experts in Clinical Outcome Assessments (COAs), developing effective COA measurement strategies across therapeutic areas.

The Visiting Scientist Fellow will

- In collaboration with cross-functional teams, including general health outcomes scientists, develop meaningful and innovative patient-focused measurement strategies.
- Focus on diseases and/or treatments that Lilly is developing within the assigned therapeutic area.
- Be responsible for the design and execution of measurement-related (including instrument development/adaptation/measurement properties assessment, development of evidence packages) studies as needed to support research across the portfolio and spanning the lifecycle of development.

Outcomes Liaison

The Outcomes Liaison (OL) team is responsible for delivering clinical, economic, observational, and value-based evidence to formulary decision-makers. Outcomes Liaisons serve the medical needs of our value-based decision maker customers (e.g., payers) across the US and across all therapeutic areas and products.

The Visiting Scientist Fellow will

- Serve as a liaison between field-based OLs and internal business partners to ensure the necessary evidence/resources/insights are flowing both directions.
- Interact with colleagues across GPORWE, medical affairs, and commercial to optimize the research generated and the solutions delivered to address customer needs.
- Leverage an understanding of the clinical and health outcomes data and evidence to support customer responses and interactions.

Medical Affairs

Global Medical Information

Global Medical Information (GMI) plays an integral role in driving medical launch strategy through creation of answers to unsolicited requests from customers (consumers, health care professionals, and payers) and through collection and analysis of customer insights.

The Visiting Scientist Fellow will

- Assist in the development and execution of medical information responses (medical letters, FAQs, slide kits, literature searches, etc.) in support of a product launch, according to appropriate procedures.
- Establish and maintain relationships within compound and cross-functional teams, across regions and geographies, to ensure quality responses designed to improve the customer experience. Contribute to a multi-channel content strategy that delivers medical information to customers within their preferred channel.
- Research and respond to unsolicited medical information inquiries from HCPs and consumers in a prompt, accurate, and compliant manner. Serve as the medical information expert in ongoing comprehensive product/disease area training to affiliate and call center partners.
- Work collaboratively with Global Medical Digital and Medical Affairs Education fellow to monitor our medical social media channels.

Global Medical Digital and Medical Affairs Education

The Global Medical Digital Strategy and Capabilities team partners cross functionally with departments such as global medical information, global medical education, global scientific communications, and field based medical professionals to enhance the Lilly customer experience for healthcare providers and to provide best in class digital services to customers.

The Visiting Scientist Fellow will

- Be exposed to a variety of emerging medical digital technologies.
- Gain insight into customer channel preferences and the medical digital landscape. Innovate delivery of medical information across digital channels through proof of concept and pilot projects.
- Support the Medical Affairs Portfolio team in conducting assessments for the key digital solutions delivered by Medical Education, the process related to them, and lead the creation of a self-serve model for Tier 2 & 3 priority assets.
- Implement the process and create a roadmap for continuous improvement and adaptation based on business partner feedback.

Clinical Research Scientist: US Oncology

The Oncology Medical Affairs Clinical Research Scientist role is a cross-functional role supporting new product launch and our legacy portfolio. Opportunities for a fellow may include development and delivery of medical resources, promotional materials, publications, and disease state education among other items.

The Visiting Scientist Fellow will

- Efficiently deliver accurate, balanced, and substantiated scientific information through our internal and customer facing channels.
- Work cross-functionally and globally to support the execution of the integrated launch project plan supporting the launch roadmap; including, but not limited to lifecycle planning, brand planning, scientific training, and scientific data disclosure strategy development.
- Drive external engagement planning and execution at congresses and medical society engagements.

Clinical Research Scientist: US Immunology

The US Immunology Medical Affairs fellow will have responsibilities aligned with the role of a Clinical Research Scientist (CRS) and will work with cross-functional business partners, global and field medical colleagues (i.e., Medical Science and Outcomes Liaisons), and the marketing team(s), acting as a bridge between the US healthcare environment and Lilly to support our shared goal of making life better. The fellow will be integrated as a fully contributing member of an internal medical affairs team to prepare and support launch execution and/or support lifecycle management.

The Visiting Scientist Fellow will

- Develop customer support materials, disease state educational materials, advisory board content to support interactions with external thought leaders, scientific conference materials to educate HCPs, and other medical communication tools (e.g., scientific disclosures) in support of our future and currently marketed products.
- Routinely interface with internal partners to understand scientific (data disclosure plans, clinical development plans, etc.) and brand strategies.
- Provide deep medical expertise on disease state and product, and continuously monitor the evolving external environment, to inform evolution and support execution of scientific and brand strategies.
- Develop as a professional through mentorship, attendance at medical congresses, leadership opportunities, and experience as an accountable individual (while a member of a team) in delivering tactics to achieve the medical affairs strategy.

Regulatory Affairs

Global Labeling Department

The Global Labeling Department (GoLD) within Global Regulatory Affairs leads the development of labeling for drug and combination device products. GoLD is responsible for developing labeling that is used by Lilly affiliates around the world in addition to specific US and Canada labeling deliverables.

The Visiting Scientist Fellow will

- Serve as the labeling associate responsible for managing product labeling within a specific therapeutic area.
- Lead updates to the product's core labeling including the Company Core Data Sheet (CCDS), which is an internal reference document that includes relevant safety and efficacy information for healthcare provider and patient labeling worldwide.
- Lead updates to the product's carton and container labels and instructions for use that are marketed in the US and Canada.
- Work with a wide variety of functions within corporate center (e.g., medical, safety, marketing, etc.) and with Lilly affiliates around the world.

Regulatory Strategy: North America

The Regulatory Strategy scientist in Global Regulatory Affairs develops regulatory strategies, leads regulatory risk assessments, and influences drug development teams on the non-clinical and clinical requirements to achieve approval of marketing applications in the US and Canada. The scientist also leads interactions with the US Food & Drug Administration (FDA) and Health Canada (HC) to inform on drug development strategies to support strategic and compliance submissions.

The Visiting Scientist Fellow will

- Understand FDA and HC laws, regulations and guidance related to the drug development process and requirements to obtain product approval.
- Assist in the development of regulatory strategies, communicate submission and approval requirements and regulator expectations, and consult on regulatory issues and regulatory risks.
- Collaborate with other regulatory colleagues and internal partners such as research & development and drug development teams.
- Monitor upcoming and recent approvals of competitive development programs.

US Advertising and Promotion

US Advertising and Promotion is responsible for advising US Marketing, Business Communications, and Medical Affairs on developing accurate, balanced, substantiated product, and disease information to enable informed decision making by our patient, provider, and payer customers. The US Advertising and Promotion team interprets and applies US advertising regulations and communicates the expectations of FDA's Office of Prescription Drug Promotion to cross-functional teams.

The Visiting Scientist Fellow will

- Understand FDA regulations and guidance, industry codes, and Federal and State laws on prescription drug advertising and promotion.
- Work directly with internal business partners such as marketing, legal, medical affairs and other commercial and corporate representatives to ensure that promotional materials comply with regulations and company policies.
- Monitor the environment for advertising and promotion changes that could affect the pharmaceutical industry.