2019-2020 Visiting Scientist Fellowship (VSF) Positions

Application Category	Number of Positions	Fellowship Role
Regulatory Affairs	3 positions	» Global Operations Labeling Department » US Advertising and Promotion » US and International Policy and Intelligence
Commercial	4 positions	» Global New Product Planning » Global Pricing, Reimbursement, and Access: New Product Planning » Global Public Policy and Public Affairs » US Managed Health Services
Health Outcomes	3 positions	» Internal Outcomes Liaison » Global Patient Outcomes & Real World Evidence Research Scientist (2 positions)
Project Management	4 positions	» Clinical Trial Commercial Product Operations » Clinical Trial Product Management (2 positions) » Pharmaceutical Project Management
Clinical Development and Research	4 positions	» Clinical Design Hub (3 positions) » Clinical Information and Process Automation
Medical	5 positions	» Medical Affairs: Clinical Research Scientist Immunology » Medical Affairs: Clinical Research Scientist Oncology (2 positions) » Global Medical Digital Strategy and Capabilities » Global Medical Information

Regulatory Affairs

US and International Policy and Intelligence

Global Regulatory Affairs (GRA) develops optimal regulatory strategies to deliver innovative medicine approvals for the patients we serve. GRA regulatory policy fosters policy changes that enable the regulatory environment to best accommodate innovative medicines. GRA regulatory policy staff engage with multiple Lilly functions and external regulatory stakeholders (e.g., FDA, EMA, NMPA, PhRMA, EFPIA, and National Health Council) to advocate for constructive regulatory reforms.

The Visiting Scientist Fellow will:

- Assess the potential impact of external global regulatory trends on regulatory strategies and the company's portfolio.
- Develop Lilly positions on key regulatory policy issues and advocate for policy change in the US, Europe, and other countries.
- Cultivate opportunities to engage in external multi-stakeholder coalitions to achieve shared regulatory policy objectives.
- Contribute to briefings and updates for Lilly senior leadership.

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.

Global Labeling Department

The Global Labeling Department (GoLD) leads the development and global implementation of product and device labeling. GoLD efficiently leads the development of accurate and substantiated labeling to enable informed decisions by health care professionals and patients using Lilly products.

The Visiting Scientist Fellow will:

- Provide regulatory leadership to create and update US and Canada labeling components for registration and the product lifecycle.
- Apply competitor knowledge and regulatory precedent to evaluate and set labeling parameters, influence drug development strategy, and propose feasible language for marketed products labeling.
- Work cross-functionally across global affiliates to improve labeling processes.

Commercial

Global New Product Planning

Global New Product Planning (NPP) is the marketing function responsible for providing commercial inputs into drug development. NPP informs what indications to pursue, where a product should be used in the treatment algorithm, who is the target patient, and what benefits will be required in order for a new treatment to be competitive.

The Visiting Scientist Fellow will:

- Be the commercial lead for at least one phase 1 compound, providing input on phase 2 design and commercial requirements for success.
- Participate in market research and advisory boards to understand customers' needs in key markets for specific diseases and pipeline medicines.
- Develop strategic overview documents for critical therapeutic areas that includes: key competitors, clinical development paradigms, and critical efficacy or safety measures necessary to compete.

Global Pricing, Reimbursement and Access: New Product Planning

Pricing, Reimbursement and Access New Product Planning (PRA NPP) is responsible for influencing the 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 ultimate aim 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.

Global Public Policy and Public Affairs

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

The Visiting Scientist Fellow will:

- Develop well-reasoned positions through research, analysis, and collaboration to help Lilly shape public policy to support improved outcomes and incentives for investment in biopharmaceutical innovation
- Apply scientific knowledge and work cross functionally to develop new policy solutions.
- Focus on today's important policy issues such as biologics and biosimilars, healthcare reform, health financing, and benefits design and innovation policy through both a U.S. and global lens.

US Managed Healthcare Services

Managed Healthcare Services (MHS) functions to ensure that the products and solutions offered by Lilly are accessible and affordable to people that need them. MHS manages Lilly USA's business-to business (e.g. wholesalers, PBMs, pharmacies, health systems, and payers) and business-to-patient relationships.

The Visiting Scientist Fellow will:

- Participate in market research and advisory boards to understand payers' needs in key markets from a macroenvironmental level and for specific diseases and pipeline medicines.
- Work with business partners in MHS, US Strategic Pricing, US Medical and Brand Marketing to represent US affiliate requirements to inform the commercial strategy and clinical development program of medicines within the pipeline.
- Lead assessments of US environmental trends and develop PRA strategies based on business and customer needs.

Health Outcomes

Internal Outcomes Liaison

The Outcomes Liaison (OL) team is responsible for delivering clinical and real world evidence to US value-based customers. Outcomes Liaisons directly interact with value-based customers (e.g. payers) to communicate and translate the health outcomes research generated into meaningful and actionable evidence for decision-makers.

The Visiting Scientist Fellow will:

- Serve as a liaison between field-based OLs and internal business partners to ensure the necessary resources and insights are flowing both directions.
- Interact with HO Scientists to understand and support the research plans and projects for specific brands and learn HO research concepts.
- Leverage an understanding of the clinical and health outcomes data to support external value-based customer responses and interactions.

Real World Evidence Research Scientist

Lilly's Global Patient Outcomes & Real World Evidence (GPORWE) function generates and communicates evidence that helps differentiate Lilly's medicines from other treatments so that payers, patients and doctors understand when and how to use the medicines and the expected patient benefits.

The Visiting Scientist Fellow will:

- Provide scientific methodological and conceptual expertise to assist in the development and/or commercialization of a product and ensure successful fulfillment of health outcomes research plans to help enable access for patients.
- Focus on diseases and/or treatments that Lilly is developing within oncology/biomedicines (migraine, pain and autoimmune disorders) and may span the entire lifecycle of product development and commercialization.
- Be responsible for the conduct, quality and integrity of real world evidence studies and scientific disclosures resulting from this research.

Project Management

Clinical Trial Commercial Product Operations

The Clinical Trial Commercial Product Team advances clinical development by establishing & executing sourcing strategies for all Phase I-III clinical trials – ensuring that medicinal products are supplied in a manner that maximizes time and cost effectiveness of study conduct while assuring regulatory compliance.

The Visiting Scientist Fellow will:

- Lead transformational initiatives across the Molecule Innovation Hub to enhance the timely delivery of products to clinical trial patients, while aligning with the global clinical strategies.
- Provide high quality and timely regulatory insights related to clinical trial materials, to drive solutions that meet needs of Lilly affiliates and the business.
- Utilize excellent self-management, leadership, communication and organizational skills to effectively manage upward and cross-functionally.

Clinical Trial Product Management

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.).
- Have the opportunity to 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 Management

The Pharmaceutical Project Manager (PPM) provides proactive cross-functional leadership for drug development, translating and executing 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/projects in Lilly's portfolio.

Clinical Development and Research

Clinical 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 study development process by working in partnership with asset teams and the Design Hub's Therapeutic Area Sleeves 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.
- Have the opportunity to connect asset teams with new and innovative capabilities that can enhance trial feasibility, patient and site experience, and overall business processes.

Clinical Information and Process Automation

The Clinical Information and Process Automation (CIPA) organization creates efficiencies through consolidation, modernization and automation of Clinical processes and technologies. In partnership with IT and other clinical functional leadership, CIPA manages, oversees and develops strategies for core resources, financials, vendors and assets.

The Visiting Scientist will:

- Learn about and ensure technology processes are optimized across clinical design, delivery, and analytics.
- Help influence new technology and processes that will enhance clinical development and execution.
- Define, measure, and achieve proficiency with new tools/technology and processes applicable to focus areas.

Medical

Global Medical Digital Strategy and Capabilities

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

Med Affairs Clinical Research Scientist (CRS) – Oncology

The Oncology Medical Affairs and Development Clinical Research Scientist role is cross-functional role. Opportunities for a fellow may include development and approval of medical resources, promotional materials, publications, and disease state education among other items.

The Visiting Scientist Fellow will:

- Efficiently deliver accurate, balanced, substantiated scientific information through our internal and customer facing channels of scientific information.
- Work cross-functionally and globally to lead the execution of the integrated launch project plan supporting the launch roadmap; including, but not limited to lifecycle planning, phase 3b/4 planning, brand planning, training, scientific data disclosure strategy development and its tactics.
- Drive external engagement planning and execution at congresses and medical society engagements.

Med Affairs Clinical Research Scientist (CRS) – Immunology

The fellow in this role will work with our global immunology brand development teams to help translate cross-functional needs for medical affairs support (affiliates, regulatory, marketing etc.) into feasible integrated global medical affairs plans.

The Visiting Scientist Fellow will:

- Work to develop customer support materials, disease state educational materials, advisory board content and preparation, scientific conference materials and other medical knowledge management tools in support of our future and current marketed products.
- Focus on supporting the execution of a brand's global medical thought leader plan, particularly the tactics linked to the global medical objectives.
- Complete work cross-functionally and globally in the development and execution of the medical programs and tools to meet customer needs, driving for consistency and continuity in all medical channels.

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:

- Complete work cross-functionally and globally in the development and execution of medical information responses (medical letters, FAQs, slide kits, literature searches, publications, webpages, etc.) according to appropriate procedures
- 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

"Take what you find here and make it **better and better**"

-Col. Eli Lilly