




Development and Implementation of an Online Global Pharmacovigilance Certificate Program During the COVID-19 Pandemic

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Abstract

Pharmacovigilance plays a lifesaving role in the practice of medicine. In 2021, during the Coronavirus Infectious Disease 2019 (COVID-19) pandemic, Loyola University Chicago launched a graduate-level Pharmacovigilance Certificate Program (PV-CERT) and a pre-professional non-graduate Pharmacovigilance Certificate Course (EPEC-PV), to provide students a comprehensive and contemporary understanding of the principles and practices of pharmacovigilance. Formal training in pharmacovigilance through this course provided a structured understanding of how safety data are generated through clinical trials and from real-world evidence as well as the regulatory environment in which data are monitored and interpreted. Pharmacovigilance training is of critical importance, especially during the COVID-19 pandemic, during which several drugs were re-purposed for the management of various stages of COVID-19 without conventional safety data. Moreover, the safety of currently-used vaccines is of concern in some populations. Although anticoagulants and antithrombotic medications are crucial in the management of COVID-19, a clear pharmacovigilance program on their use in this indication is not established. As the century progresses, new diseases and infectious agents will require novel therapies for which the evaluation of benefits versus risks will be as essential as it has been for the current COVID-19 pandemic. As such, the Loyola course and accompanying programs on pharmacovigilance will play a key role in educating the next generation of professionals in pursuing careers in the development of therapies that ultimately improve patient outcomes while maintaining rigorous safety standards.

Keywords

pharmacovigilance, COVID-19, pandemic, safety sciences

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Introduction

Modern drug discovery and development are highly complex processes. For example, the progression of a potential drug candidate from discovery to being implemented as a medical treatment requires detailed, multidisciplinary investigations which are generally carried out as a joint effort between national or international public and private institutions and organizations. These processes often require immense resources and are time consuming. The development of any medicinal product usually spans decades from the initial design stages to the final clinical studies. Not only until the conclusion of the research phases are the results then reviewed for potential approval by overseeing governing bodies, such as The Food and Drug Administration (FDA) in the US and The European Medicine Agency (EMA) in Europe. Only if a medication,

treatment, or intervention is approved is it allowed to then be marketed to the public. Subsequently, post-market safety surveillance continues to monitor each new medication after approval and more widespread use for further evaluation.

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Table 1. Generalized Curriculum of Selected Professional Terminal Degrees.

Medical Degree (M.D.)	Doctor of Philosophy (PhD)	Doctor of Pharmacy (Pharm.D.)
Year 1 <ul style="list-style-type: none"> • Molecular and Cellular Biology • Human Anatomy & Physiology • Patient-centered Medicine 	<ul style="list-style-type: none"> • Biochemistry • Molecular & Cellular Biology • Research Methods • Biostatistics • Presentation Skills 	<ul style="list-style-type: none"> • Pharmacy Practice • Chemistry • Biostatistics • Clinical Research Design
Year 2 <ul style="list-style-type: none"> • Mechanisms of Human Disease • Clinical Pharmacology • Patient-centered Medicine • USMLE Step 1 	<ul style="list-style-type: none"> • Biostatistics • Research Methods • Advanced Pharmacology • Physiology • Microbiology • Advanced Electives • Qualifying Examination • Dissertation Research 	<ul style="list-style-type: none"> • Foundations of Medicine • Physiology • Microbiology • Laboratory Medicine • Pharmacology
Year 3 <ul style="list-style-type: none"> • Clinical Clerkships (eg, Internal Medicine, General Surgery, Neurology, etc) 	<ul style="list-style-type: none"> • Dissertation Research 	<ul style="list-style-type: none"> • Therapeutics • Human Disease • Contemporary Topics • Pharmacy Practice
Year 4 <ul style="list-style-type: none"> • Emergency Medicine • Sub-internship and Electives • USMLE Step 2 	<ul style="list-style-type: none"> • Dissertation Research • Dissertation Defense 	<ul style="list-style-type: none"> • Advanced Topics • Pharmacy Practice

USMLE, United States Medical Licensing Examination. Pharmacology courses are bolded.

Throughout the entirety of these complex processes, the most important consideration of all involved parties is the safety of the medication, treatment, or intervention.

Further complicating these processes are global health crises, such as the Coronavirus Disease 2019 (COVID-19) pandemic which has brought heavy burdens to worldwide health care systems, the global economy, and countless aspects of everyday life for the global population. In addition to the aforementioned devastating impacts the COVID-19 pandemic has inflicted upon society, it has also tested, and brought to light, the strengths and weaknesses of the drug discovery and development processes seeking therapies to find a cure for this public health emergency. For example, several COVID-19 vaccine candidates entered into clinical trials lasting less than 6 months and were subsequently approved for emergency use within 10 months of COVID-19 pandemic onset. As incredible a feat the development of COVID-19 vaccines was in regard to groundbreaking speed in vaccine development history, it would not have been possible had it not been for the pharmacovigilance and long-term safety programs implemented for each of the currently used COVID-19 vaccines in ensuring the long-term safety of our communities.

Thus, pharmacovigilance¹ plays a crucial role in the practice of modern medicine. In response to the COVID-19 pandemic, Loyola University Chicago launched a graduate-level Pharmacovigilance Certificate program (PV-CERT) and a pre-professional Pharmacovigilance Certificate Course (EPEC-PV) designed to provide students with a comprehensive and contemporary understanding of the principles and practices of pharmacovigilance. The Loyola Stritch School of Medicine and the Loyola Business School Executive and Professional Education Center

(EPEC) collaboratively offered the EPEC-PV. The centerpiece of both programs was the PHAR 420 course, entitled Pharmacovigilance: A Practical Approach. This course focused on the evolving regulatory landscape, case studies, and current and future uses of digital technologies in the provision of pharmacovigilance. The topics within the course included the regulatory environment, safety data, real-world evidence, special populations, special topics, and the future of safety science.

Although medical staff (residents, interns, pharmacists, and nurses) and physicians often have introductory training in the processes of drug approval and post-market surveillance, the clinical pharmacology courses typically taught in medical school do not adequately address pharmacovigilance. Similarly, the range of pharmacology courses in the doctoral programs (PhD) only spans from a minimum of an outline lecture on Safety Pharmacology up to a maximum of 4 lectures on Safety and Pharmacovigilance. Although pharmacy school (PharmD) provides more thorough lessons on pharmacovigilance, the content typically covered falls short of providing a comprehensive education in pharmacovigilance sufficient enough to address modern issues. A generalized curriculum of selected professional terminal degrees is presented in Table 1.

As such, the PV-CERT and EPEC-PV programs were designed to fill this educational gap, specifically providing insights into the principles and practices of pharmacovigilance. The students included clinical researchers, healthcare students, and professionals including those holding BS, MS, PhD, MD, DO, NP, and PharmD degrees. Many of the students who were previously medical staff desired to upskill and transition into research positions in academia or the pharmaceutical/biotechnology industry.

Extensive discussion between Loyola faculty and scientific leaders within the pharmaceutical/biotechnological industry supports the notion that leading companies seek educational programs for training staff and new hires in pharmacovigilance. Market analyses performed by Loyola University Chicago found an urgent need of new programs in the field, suggested a paucity of adequate programs, and predicted a marked growth of the pharmacovigilance job market. As this sector grows, the industry will prioritize hiring those educated in pharmacovigilance.

In addition to its role in Industry, Pharmacovigilance is becoming increasingly important for medical education and clinical practice and is an important training requirement for future professionals in health sciences. The COVID-19 pandemic emphasized the growing need for pharmacovigilance in regulatory, research, and other health-related fields. This is particularly true for the long-term pharmacovigilance of currently developed vaccines, which have several rare complications related to the vascular system, and the use of other biotherapies including monoclonal antibodies and genetic manipulation. Interestingly, the anticoagulant drugs, such as heparin-related drugs and direct oral anticoagulants, have been the focus of optimizing the clinical management through various dosing regimens which, despite not currently being addressed, have a significant impact on adverse outcomes and, as a result, are the focus of Pharmacovigilance studies.

Academic Focus

The focus of the course is to train students to understand and develop basic competence in pharmacovigilance, which is defined as the science and activities related to the detection, assessment, understanding, and minimizing of adverse events or any other drug-related problems.¹ The course is based upon the textbook *Pharmacovigilance: A Practical Approach* (Elsevier).

The course is designed for medical, clinical, and scientific professionals, including:

- Professionals in industries connected to the development and marketing of pharmaceuticals and medical devices, especially those who wish to upskill to advance or switch careers.
- Graduate, medical, and post-baccalaureate students seeking employment in this growing sector.
- Individuals who currently work in epidemiology, biotech, life science, or pharmaceutical industries who wish to refresh their knowledge or move into the pharmacovigilance field.
- Medical and hospital staff (physicians, residents, interns, nurses, pharmacists, or administrators) who are generally involved in reporting and require an understanding of how efficacy and safety data are gathered from both clinical trials and real-world evidence, and how this information is evaluated to inform early detection and reporting of adverse events.

By the time participants completed the course, they were able to:

- Describe the regulatory environment and apply regulatory guidance to drug safety
- Evaluate and assess data and real-world evidence.
- Identify and evaluate signal management and causality assessment information
- Evaluate benefit-risk, signal management, product safety monitoring, and vaccine safety monitoring data.
- Appraise opportunities and challenges for special populations, including pediatric, elderly, and in pregnancy.
- Interpret evidence obtained in pharmacovigilance, including behavioral science, patient perspectives, and risk communication, as it applies to the evaluation of drug safety.
- Understand medical device vigilance and post market surveillance.

Flexibility was the key to providing useful educational opportunities to students during the COVID-19 pandemic. From the beginning of the program launch, the entire curriculum was delivered online to reduce contact and follow Centers for Disease Control and Prevention (CDC), state, and University requirements during the worst days of the pandemic. Though a challenge, this was an opportunity to accommodate international and nontraditional students through the course's online format. The increased flexibility enabled many of the instructors to participate to a higher degree as well. The key features of our approach to course design and operations were a focus on student- and outcomes-oriented teaching and assessment. Additionally, we were highly interactive, communicative, flexible, up-to-date, and inclusive of current events, especially safety and pharmacovigilance issues and actions related to the pandemic.

Program Outcome and Impact

A total of 25 students enrolled and completed the Phar 420 course from January 2021 to May 2021 (8 in PV-CERT and 17 in EPEC-PV). By the Spring 2022 term, the PV-CERT program had grown to 23 students, and the EPEC program had accepted another 17 students. Three PV-CERT students completed the program in May, 2022 as did 17 EPEC-PV students. All students had bachelor's degrees, and many had additional degrees including PharmD, PhD, or M.D. Most (56/57) students had either clinical or scientific training. Several comments from a random variety of students who completed the course are summarized below:

- "Before the class, I was a newcomer to pharmacovigilance. As a seasoned academic pediatric hematologist oncologist, I have treated many children with cancer, had experience in clinical research and had provided numerous contributions to the international efforts to cure cancer over the years. In fact, the most common question I was asked was, why did you go into safety? There are multiple answers. There are projects on my bucket

list which I could not complete anywhere else. For example: with which mathematical framework might we predict the frequency of adverse events when drugs are combined? I am fascinated by the opportunity to quantify medical experience, aggregate data, and use artificial intelligence to improve patient care; and does not the word “vigilance” have an exciting ring to it? – What if you could combine all this from a highly impactful position, and make it count for cancer patient survival and quality of life!”

- “The Loyola University Pharmacovigilance class provided a comprehensive, in-depth overview of the entire, rapidly developing field, including medicine and physiology, regulations, safety operation principles, and international components of drug and device development. Numerous educators shared insights in how the various minds of professionals experienced in drug development function. Peer students and interactive classes showed the diversity of cultures and educational backgrounds coming together in the field and provided invaluable experience on the way to becoming a teacher myself.”
- “I opted to participate in the pharmacovigilance (PV) course at Loyola as my role within AbbVie, unlike previous roles I held within the field, required me to have better appreciation of safety science and be able to engage with colleagues cross-functionally to exchange scientific safety information.”
- “The course at Loyola exceeded my expectations in terms of both the extensive nature of the coursework that spanned a diversity of pharmacovigilance topics and the world-class faculty who delivered the material. The balance between learning the theory and applying this through case studies makes the course highly beneficial to many PV professionals - not only those that are new to PV, but also those wanting to develop a greater appreciation of the breadth of the discipline.”
- “The sheer volume of safety data that is available from a variety of sources coupled with the rapid emergence of AI and machine learning technology provide a fertile ground for PV to pivot more into real-time safety monitoring. While this is no small feat, revolutionizing PV in this way would see enhanced protection of patients and the emergence of faster innovations to market for patients and families who need them. It is an exciting time to be working in this space and I recommend this course to anyone willing to further explore the possibilities that PV has to offer.”
- “Prior to my participation in the pharmacovigilance course at Loyola University, I had limited exposure to drug safety science. The topic was less emphasized in medical school compared to embryology or biochemistry, and much of the clinical didactics I received during internal medicine and gastroenterology training focused on treatment algorithms and drug efficacy. As a practicing gastroenterologist, I regularly witnessed complications related to NSAID and anticoagulant use as well as a variety of drug induced liver injuries. However, understanding drug safety through clinical experience alone is like attempting to understand automotive engineering simply by driving a car.”
- “Formal training in pharmacovigilance through the Loyola course provided a structured understanding of how safety data is generated through clinical trials and from real-world evidence, the regulatory environment in which data are monitored and interpreted, and how external forces changing healthcare delivery facilitate early signal detection and adverse event prevention. The development of an intellectual framework to understand pharmacovigilance is critical to the work of a pharmaceutical physician. However, more broadly, there is a significant need for healthcare prescribers to receive more rigorous training in pharmacovigilance to enable accurate adverse event reporting, facilitate individualized risk-benefit discussions, and enhance patient safety through appropriate prescribing practices.”
- “Drug-related hospitalizations account for 7% of hospitalizations globally and greater than 50% are considered preventable.² Formal pharmacovigilance and drug safety education within national medical education curriculums has the potential to reduce preventable errors and impact global public health. The industry-academia collaboration between AbbVie and Loyola University represents a landmark step forward in the progression of pharmacovigilance as an academic discipline. Expert-designed drug safety education is key to building a safer future for medicines.”
- “Prior to participating in the Loyola/AbbVie Pharmacovigilance: A Practical Approach course, I considered my task as a drug safety review physician to be responsible for understanding my study drug and its protocols, reviewing individual adverse event reports to determine if my study drug was responsible for an adverse drug reaction, and making sure I helped my company meet regulatory requirements. Coming from a clinical Emergency Medicine practice background, I was accustomed to rapidly identifying a problem, taking action, and seeing a result. My role in drug safety review, while an interesting and novel utilization of my medical knowledge, often caused me to wonder if and how the discrete data points I was generating will help a future prescriber or a future patient make the decision to start, continue, or stop taking the drug. Another curious and unfamiliar territory I often found myself in was in various safety meetings where I would struggle to understand the role of the various attendees, how and why we all fit together. As a newcomer to the pharmaceutical industry, I couldn’t help but feel that big picture clarity was elusive because I didn’t know enough to ask the right questions.”
- “The Loyola/AbbVie Pharmacovigilance: A Practical Approach course singlehandedly raised the curtain on drug safety and pharmacovigilance for me. From defining and explaining the history and foundation of drug safety,

the course articulated the evolution toward and practice of modern pharmacovigilance. Shifting away from the traditional drug safety reactive model, pharmacovigilance proactively surveils the drug safety environment by looking for signals and trends. Real-world insight into how our drug performs in large populations and across disease states allows us to provide better information to patients and healthcare providers. The course has provided firm ground upon which I have been able to cultivate a deeper understanding of my work, grow my engagement and influence with cross-functional colleagues, and has ultimately given me the confidence to be a team member who leans in.”

- “True to its proactive core, the future of pharmacovigilance will invariably look to technologic innovation and shift toward a patient-centric approach to drug safety. Ultimately, the goal is to achieve predictive signaling. Implementation of digitalization, cognitive case processing and machine learning technology will allow for more efficient and accurate case processing and better handling of the ever-growing body of safety data while freeing up human capital to perform essential safety assessment. Increasingly moving toward a patient-centric approach, PV will better understand a product’s real-world use and develop a drug’s true benefit-risk profile. The importance of cognitive and behavioral sciences in PV speaks to the vital role of the patient experience and perspective in drug development and safety. PV will move to adapt, adopt, and think big to continually strive for the safety and health of our patients.”
- “When the pandemic started in 2020, there were a lot of questions and concerns about our future as a family and as professionals. My wife was a primary care physician, and I was working as a part-time practice manager at a dermatology office. When schools began to shut down, one of us had to stay home. We were unsure of what the future would hold, but we knew that through science, humanity would find a way to make it through the pandemic. As the months trudged along, I was approached by a family member to investigate a pharmacovigilance (PV) course given by Loyola University Chicago and AbbVie. I agreed, initially, out of curiosity as I was unsure what PV meant outside of looking at the “side-effects of pharmaceuticals.” I had never been introduced to the term “pharmacovigilance” in my university. In my ignorance, I just assumed that by using a set of algorithms, one could determine whether or not a pharmaceutical would be approved for the market. Once I began the course, I soon realized just how wrong I was. I finished the course in Spring 2021. I realized that the PV environment was more than “just an algorithm for drugs.” Instead, it was an artform where specialists from many fields worked together to create an environment that keeps patients safe while also advancing humanity’s future via healthcare.”
- “Throughout the course, we had many discussions with lecturers and students, but one evening in particular stood out to me. We had a theoretical Alzheimer’s therapeutic with \times side effects and \times benefits. Prior to taking the course, one would believe that a therapeutic with less side effects would be the best. Unfortunately, that is not the case with many therapeutics. Multiple therapies had the same number of side effects and so, the theoretical PV team had to discuss which medications should be pushed from trial to release. At this point, the art of PV came to form; each member of the PV team had insight on which aspect might be more important compared to the adverse events. Some members even shared personal stories that might affect one’s decision on therapies. It was at that moment that I realized that no algorithm would ever be able to supersede the decision-making of a PV team - because patients are human. The interactions of multidisciplinary professionals are necessary to form a functional and effective PV team, and no computer will be able to replicate the humanity needed to make these decisions.”
- “The course could not have come at a better time than Spring 2021, as multiple COVID-19 vaccinations were starting to be released by the FDA’s EUA. It was a real-time, real-life example of how PV was being utilized and also highlighted how PV impacts humanity”
- “I enrolled in the Pharmacovigilance Certificate Program with a BS in Biology and 5 years of experience as a clinical trial coordinator. While managing Phase II-IV investigational drug trials, I was looking for professional development opportunities to supplement my knowledge on drug discovery and development. The pharmacovigilance courses provided me with the opportunity to learn how investigational products enter clinical trials, how they are assessed for safety and efficacy, and how experts are continuously monitoring safety pharmacology in the real world. The course not only gave context to my previous experiences in research, but the information I learned is especially valuable today as we navigate new therapies for COVID-19.”
- “Through the use of technology, I received a high-quality education without interrupting my work schedule. Instructors from all around the world provided a rich and interactive learning experience. Graduating with the Pharmacovigilance Certificate taught me the extraordinary value of translational pharmacology research. It inspired me to continue my education in drug discovery and development. I am now a PhD student at Loyola University Chicago’s Department of Molecular Pharmacology and Therapeutics, and I look forward to contributing to the evolution of scientific knowledge and its impact on the future of healthcare.”
- “As Registered Nurse with over a decade of experience in clinical safety monitoring, I joined the Loyola class to expand my knowledge in the global regulations that drive our industry as well as to gain a better understanding of pharmaceutical product development.”
- “This class delivered on these expectations and much more. In addition to receiving a comprehensive overview

of pharmacovigilance past and present and the drug development process, industry experts and educators provided comprehensive training on epidemiology, benefit-risk management, and post-market surveillance. Each lecturer enhanced our understanding by providing personal experiences and case studies, allowing the students to apply what we learned to real-world practice.”

- “The future of safety science continues to evolve with advances in technology and new approaches to data collection and analytics. Courses such as this will ensure biopharmaceutical professionals have the tools and knowledge to proactively ensure the safety of our patients and compliance with pharmacovigilance regulations.”

During the COVID-19 pandemic, Loyola University Chicago launched the global Pharmacovigilance professional programs to provide comprehensive and up-to-date information on the principles and practices of pharmacovigilance. The course experience validated the students’ belief that there are significant professional opportunities in the field, and they plan to obtain additional education and training. According to the students who completed the course, the Loyola University pharmacovigilance class had uniquely strong industry participation, professional structure, and academic reputation. The course at Loyola exceeded their expectations in terms of both the extensive nature of the coursework that spanned a diversity of up-to-date pharmacovigilance topics as well as the world-class faculty who delivered the material. Formal training in pharmacovigilance through the Loyola course provided a structured understanding of how safety data is generated through clinical trials and from real-world evidence, the regulatory environment in which data are monitored and interpreted, and how external forces changing healthcare delivery facilitate early signal detection and adverse event prevention. The Loyola/AbbVie Pharmacovigilance: A Practical Approach course singlehandedly raised the curtain on drug safety and pharmacovigilance to a new group of students in its inaugural year.

From the comments provided by several of the participants above, it is clear that a diverse group of professionals with responsible positions in the pharmaceutical industry and academia have provided their objective assessment of this course and the collective opinion underscores not only the importance of the course, but also the timely nature of this course and the extraordinary effort academia and industry have put forth to create this platform for education. Moreover, the need for pharmacovigilance and drug safety science-related subject matter for the inclusion in biomedical curricula at both pre- and post-graduate levels is identified. These comments are very encouraging and useful and reinforce the global impact of educational programs to address drug safety issues.

Focus Group Results

In addition to the comments from several students, a focus group of seven students shared personal perspectives of the course’s value from the standpoint of both the academic content and access to a network of pharmacovigilance

leaders. These students had either clinical or scientific training, and up to 30 years of experience in the life sciences industry. Their rationale for taking the course included:

- The desire to work in the pharmacovigilance field without prior formal training or experience.
- Advancing their existing knowledge of the pharmacovigilance field, including understanding the complexities and inter-related elements of pharmacoepidemiology, benefit-risk management, safety data science, and others.
- Expanding their understanding of the different professional roles available in pharmacovigilance.

The course experience validated the students’ belief that there are significant professional opportunities in the field, and they plan to obtain additional education and training:

- One student is going to pursue a full certificate in pharmacovigilance from Loyola University Chicago.
- Another student who currently works in pharmacovigilance was inspired to take on additional project work to apply the new knowledge they learned in the course, with the goal of professional advancement.
- A student was encouraged to join the PhD program at Loyola University in order to pursue pharmacology research.
- Three (of eight) PV-CERT students obtained new jobs in the pharmaceutical industry or pharmacovigilance field as of this writing (within three months of the program).

All students shared a common interest in reframing their academic and professional experiences to apply their knowledge and skills in new ways to support public health and patient safety.

Discussion on Career Opportunities in Pharmaceutical Industry

The pharmaceutical industry attracts diverse science, technology, engineering, and mathematics professionals due to the complexity of drug development, the myriad opportunities available, and their potential to positively impact patients’ lives. Research scientists, physicians, pharmacists, nurses, epidemiologists, and statisticians, among other professionals, can find rewarding roles in research & development or commercial domains where they can apply both their academic training and real-world experience to solve complex scientific and business problems, all while working for the benefit of patients.

The COVID-19 pandemic has driven demand for products and services across the healthcare system, particularly in the pharmaceutical industry. Thus, despite the popularity of the pharmaceutical industry as a desired career path, talent has become scarce since 2021. In fact, research conducted by an executive talent firm revealed that 68% of global pharmaceutical and biotechnology leaders report finding and attracting quality hires as their top challenge.³ Pandemic-related demand for workers, coupled with the need for specialized scientific and health care capabilities and knowledge, have created a gap in our industry.

The pharmacovigilance field is experiencing the effect of this gap as companies, hospitals, and governments continue to invest in patient safety. Pharmacovigilance requires a unique combination of knowledge, skills, and experience because it bridges public health with research and development. Professionals with scientific or clinical experience who are willing to upskill in the pharmacovigilance discipline will be able to find many satisfying career opportunities. Kugener et al noted that traditional medical, public health, and pharmacy schools do not include drug safety and pharmacovigilance courses.⁴ This gap impacts the understanding of regulatory reporting responsibilities and restricts the potential talent pipeline. As discussed by Kugener et al, fixing the talent shortage will rely on programs' abilities and participation in training new students in all the cutting-edge scientific technologies and methods, such as pharmacovigilance.⁴ As a flexible, adaptable, and diverse educational resource, the Phar 420 course can also be utilized as a foundational guide for the development and broadening of medical education by implementing it in medical curricula in order to not only deepen students' understanding and appreciation of pharmacovigilance, but also to establish a groundwork early on that will only be further solidified as students progress throughout their professional careers. Indeed, while the diminishing talent pipeline continues to dwindle, it is more crucial now than ever to implement educational policies and changes that will not only allow us to respond to inevitable future pandemics, but also to prepare for them so that we may reduce their burden to society on a global scale.

While this course is currently focused on drug safety sciences and their potential application to the COVID-19 pandemic locally, it has already included participants on a national scale with global implementation planned. Indeed, through collaboration with other international academic institutions, this course will have a profound impact on global pharmacovigilance and pave the way for future courses to be developed, implemented, and advanced. Additionally, there have been discussions to collaborate with international academic institutions, peer organizations, regulatory parties, and professional associations to enhance the impact of this course. Furthermore, machine-learning, artificial intelligence, and other advanced media approaches will be considered to continue the improvement and delivery of, not only this course, but also other educational modalities aimed at progressing other areas of drug safety sciences.

The pharmaceutical industry is highly regulated to protect both patients taking medicines and the industries making them. All live in a fast-moving world of technology and innovative science where agility is key to developing groundbreaking new medicines for patients. Medicinal products are developed to provide therapeutic benefits for patients while limiting adverse events. The key to detecting, assessing, and addressing adverse events is the core of Pharmacovigilance. This field needs to be agile and evolve with modern medicine. The academic/industry collaborative effort was the perfect modality for achieving this. The regulators and pharmaceutical industry are responsible for ensuring that the benefit-risk balance of a product is positive for the intended population. The ongoing educational efforts are key to fulfilling this

responsibility. Assessing evidence that impacts the benefit-risk profile of a product as it is developed and delivered into the population ultimately improves patient outcomes.

As of June 2022, over 1,000,000 Americans have died from COVID-19 since the beginning of the pandemic. Furthermore, despite the availability of vaccines since December 2020, only 64.5% of adults in the U.S. are fully vaccinated.⁵ The pharmaceutical industries, CDC, and FDA continuously assess the risks and benefits of COVID-19 treatments and vaccinations. Pharmacovigilance training is of critical importance in assessing the benefit to risk profile of new treatments and vaccines during rapidly evolving pandemics, such as the COVID-19 pandemic. As a result of its mutational abilities which have rendered the virus resistant to certain medications and current vaccines, COVID-19 has posed challenges today that did not exist just one year ago. For example, long-COVID syndrome, which requires long-term management with currently available vaccines and therapeutics, not only poses significant, additional pharmacovigilance challenges, but also brings to question the potential for future, more devastating sequelae of COVID-19 infection. COVID-19 has evolved at an extraordinary pace and, in order to combat it, we need to do the same through therapeutic development and pharmacovigilance. Thus, despite the efficacy of currently defined curricular objectives, advancing this course through the inclusion of translational topics, renewed guidelines, and refined information will be absolutely crucial in dealing with future global pandemics, both those posed by COVID-19 and those that will come after it.

The COVID-19 pandemic has posed certain challenges for the pharmaceutical industry necessitating the rapid development of safer vaccines, anti-viral drugs, and other therapies. The FDA has fast tracked the approval of these vaccines and medications. Therefore, the safety profile of these agents is not fully explored, necessitating additional pharmacovigilance study to demonstrate their safety in valid trials. This course has offered a timely platform to focus pharmacovigilance approaches in dealing with complex issues related to COVID-19 patient management which include optimal use of anticoagulants such as heparin, anticoagulant management of long COVID syndrome, understanding of the thrombotic complications related to vaccines and more importantly drug interactions and their impact on outcome. Thrombotic and vascular complications are hallmarks of COVID-19 pathogenesis requiring different targets to develop optimized drugs and vaccines. The information provided in this course will help in training individuals to develop programs for the safer approaches and improved vaccine and other medication for COVID-19. Attendees of this course will continue to be able to teach other groups and further disseminate the important information related to pharmacovigilance and its impact on drug development.

Conclusion

Pharmacovigilance plays a crucial role in the practice of medicine. In 2021, during the COVID-19 pandemic, Loyola University Chicago initiated the certificate Pharmacovigilance professional programs, providing comprehensive and up-to-date information on the principles and practice of pharmacovigilance based on a

published print and digital textbook, *Pharmacovigilance: A Practical Approach* (Elsevier). Formal training in pharmacovigilance through the Loyola courses provided a structured understanding of how safety data are generated through clinical trials and from real-world evidence as well as the regulatory environment in which data are monitored and interpreted. Pharmacovigilance training is of critical importance, especially during the COVID-19 pandemic. The COVID-19 Pandemic represents a multi-factorial and complex syndrome resulting in vascular and thrombotic complications. The vaccines, repurposed drugs, and new anti-viral agents, along with biomarker profiling, are a focus of pharmacovigilance investigations for their optimized implementation in this syndrome. As the century progresses, new diseases and infectious agents will require novel therapies for which the evaluation of benefits versus risks is essential. The Loyola course and programs on Pharmacovigilance play a key role in educating the next generation of professionals in pursuing careers in the development of therapies that ultimately improve patient outcomes. Although, we now have better options to fight against COVID-19, we still need new drug discovery and development programs in many disease states such as cancer, neurodegenerative diseases, and infectious diseases without established safe and effective treatment options.

Programs

The Loyola Pharmacovigilance-Certificate (PV-CERT-graduate level multi-course certificate) <https://ssom.luc.edu/pharmacology/programs/pharmacovigilancecertificate/>

The Loyola Executive and Professional Education Center - Pharmacovigilance (EPEC-PV-professional single course on pharmacovigilance) <https://www.luc.edu/executiveeducation/takeacourse/pharmacovigilanceapacticalapproach/>

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Author Contributions

All authors contributed to, edited, and approved the final manuscript.

Conflict of Interest

- Thao Doan, Fabio Lievano, Linda Scarazzini, and Kate Liebelt are full-time employees at AbbVie, and have no conflict of interest related to the matters discussed in this manuscript.

- Mark Jaradeh is a medical student at the Stritch School of Medicine, Loyola University Chicago, and has no conflict of interest related to the matters discussed in this manuscript.
- Jawed Fareed is a Professor of Pathology and Pharmacology at Loyola University Chicago, Health Sciences Division, and has no conflict of interest related to the matters discussed in this manuscript
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Not applicable.

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Note

1. According to the World Health Organization, "pharmacovigilance" is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

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