Drug Safety and Pharmacovigilance

Final Assessment Report & Implementation Plan
September 2021 (updated July 2022)

Faculty / Affiliated University College	Schulich School of Medicine and Dentistry	
Degrees Offered	Master of Science (MSc)	
Date of Last Review	New program	
Approved Fields	None	
External Reviewers	Susan Abdel-Rahman, Professor University of Missouri	Yaron Finkelstein, Professor University of Toronto
Internal Reviewers	Carol Beynon, Professor Emerita	Tyler Girard, Political Science PhD student
Date of Site Visit	February 19, 26, 2021	
Date Review Report Received	March 11, 2021	
Date Program/Faculty Response Received	Program April 6, 2021 (revised received June 10, 2022) Dean July 21, 2021 (revised received June 10, 2022)	
Evaluation	Approved to Commence	
Approval Dates	SUPR-G: September 12, 2022 ACA: October 26, 2022 Senate:	
Year of Next Review	Year of next cyclical review	

Overview of Western's Cyclical Review Assessment Reporting Process

In accordance with Western's Institutional Quality Assurance Process (IQAP), adopted on May 11, 2011, and revised June 22, 2012, this Final Assessment Report (FAR) provides a summary of the program proposal, report prepared by external reviewers, and internal responses in relation to the proposed **Drug Safety and Pharmacovigilance** Graduate Program to be offered by the Schulich School of Medicine and Dentistry.

This FAR considers the following documents:

- the program's self-study,
- the external reviewers' report,
- the response from the proposers of the Drug Safety and Pharmacovigilance Graduate Program, and
- the response from the Dean, Schulich School of Medicine and Dentistry.

This FAR identifies the strengths of the proposed program and opportunities for program enhancement and improvement, and details the recommendations of the external reviewers, noting those recommendations that require attention.

The Implementation Plan details the recommendations from the FAR that have been selected for implementation, identifies who is responsible for approving and acting on the recommendations, specifies any action or follow-up that is required, and defines the timeline for completion.

The FAR (including Implementation Plan) is sent for approval through SUPR-G, ACA and Senate. Following institutional approval, it is then submitted for approval to the Ontario Universities' Council on Quality Assurance.

The FAR, including the Implementation Plan, is the only document that is made public; all other documents are confidential to Western's Schulich School of Medicine and Dentistry, Drug Safety and Pharmacovigilance Graduate Program, the School of Graduate & Postdoctoral Studies, and SUPR-G.

Executive Summary

The Schulich School of Medicine and Dentistry proposes the development of a one-year interdisciplinary master's program, entitled *Drug Safety and Pharmacovigilance (MDSP),* that will provide effective training and continuous education in the field of drug safety and pharmacovigilance to healthcare professionals and related disciplines to support the protection of patients against potentially disabling or even lethal adverse drug reactions. The program will be taught by experts from the fields of medicine, pharmacology, epidemiology and biostatistics, public health, and law to teach rich and up-to-date curricula covering all aspects of drug safety and pharmacovigilance. The program will be a 3-term, course-based program that includes a clinical practicum, utilizing the many laboratory and service facilities within London and region, and will culminate in a Major Research Project by students related to their practicum. The proposing faculty members note:

> *It is our vision to create safe practices of patient-centered healthcare system, to reduce drug-induced patient harm and death and to empower healthcare professionals to be vigilant for ADRs and their consequences. We believe that through effective training thousands of patients' lives and billions of health care dollars can be saved.*
>
> *Specifically, the graduate from the program will:*
> *1) Have a general understanding of the chemical, pharmacological, toxicological and clinical bases and the pathophysiology of adverse drug reactions.*
> *2) Acquire knowledge of statistical and epidemiological methodologies used to evaluate the incidence and understand the significance of the drug safety problem as a public health issue.*
> *3) Demonstrate a special set of skills to better recognize and assess pharmacovigilance signals in the context of specific cases and therapeutic courses.*
> *4) Be able to better utilize research results and scientific evidence to make appropriate decisions in their professional practice.*
> *5) Critically analyze clinical history and data related to drug safety and synthesize knowledge to promote patient safety and optimize healthcare.*
> *6) Develop leadership skills to drive building effective public health policies that endorse patient safety.*

Learning Outcomes for the new program are clearly outlined and are consistent with those of the University and the Faculty. Specific courses and outlines have been identified focussing on three new courses about adverse events of drug use, pharmacogenomics, and variability in drug response as well as existing graduate level courses in Epidemiology. Human Toxicology, Clinical Pharmacology.

Volume One identifies 6 primary professors and 7 supporting faculty members who will contribute to the program from various departments within the Schulich School of Medicine and Dentistry as well as the Faculty of Law.

Review Process

Due to restrictions of the COVID-19 pandemic, the review occurred over a two-day period via virtual meetings. No site visits were possible.

Over a full 2-day period, the review team met with the:

- Vice-Provost, School of Graduate and Postdoctoral Studies
- Associate Vice-Provost, School of Graduate and Postdoctoral Studies
- Dean, Schulich School of Medicine & Dentistry
- Dean, Faculty of Law
- Vice Dean, Basic Medical Sciences, Schulich School of Medicine & Dentistry
- Graduate Chair, Department of Physiology and Pharmacology
- MDSP Program Committee Chair, Department of Paediatrics
- Adjunct Professor, Department of Physiology and Pharmacology
- Associate Dean, Graduate and Postdoctoral Studies, Schulich School of Medicine & Dentistry
- Chair, Department of Physiology and Pharmacology
- MDSP Faculty members
- Graduate student trainees from the Schulich School of Medicine and Dentistry
- Associate University Librarian

Following the review, the external reviewers submitted a comprehensive report of their findings which was sent to the Graduate Chair and the Dean for review and response.

These formative documents, including Volumes I and II of the Self-Study, the External Report, the program response and the Dean's response, have formed the basis of this summative assessment report of the Drug Safety and Pharmacovigilance Graduate Program. The information has been collated, summarized, and submitted to the SGPS and the Senate Graduate Program Review Committee (SUPR-G) by Dr. Carol Beynon, the Internal Reviewer.

External Reviewers' Report

Summative Assessment

The [proposed] MDSP program… has garnered enthusiasm within the Western University at many levels. ...During the visit, the external reviewers encountered clear interest and commitment for the success of the program at all leadership levels. The MDSP faculty are well established and renowned leaders in the field. Specialized graduate education in drug safety and pharmacovigilance is highly relevant in the healthcare, regulatory, and pharmaceutical industry sectors. There is both an unmet need for a program of this type and the opportunity for professional advancement with the degree that it would confer.

Strengths of the Program

- Addresses a gap that exits in graduate education national and internationally
- Exceptional faculty cohort
- Commitment from Faculty of Law is impressive
- Program outline of courses, practicum and MRP

Areas of Concern Identified / Further Questions

- Need to address how students with various backgrounds will be accommodated to ensure no overlap of previous learnings.
- Need to specifically tie course outlines to Program Learning Outcomes.
- Is there an option for part-time studies?
- Clarify how the practicum will integrate with the MRP
- Ensure full-time faculty leadership for the program.

Summary of the Reviewers' Recommendations and Program/Faculty Responses

The following are the reviewers' recommendations in order as listed by the external reviewers. Recommendations requiring implementation have been marked with an asterisk (*). The process for implementation can be found in the Implementation Plan below.

Reviewers' Recommendations	Program/Faculty Response Summary
1. *Additional detail is required as to how the undergraduate courses currently offered as part of the proposed curriculum will be handled for the graduate students in terms of content (including previous participation in courses), delivery and evaluation. The strategy for evaluating graduate students in the undergraduate courses needs to be clarified and distinguished from the evaluation strategy used for the undergraduate students. The program description would also benefit from greater detail as to how the individual course outcomes align with the overarching MDSP outcomes.*	DEPT RESPONSE: Additional expectations will be required of the graduate students; instructors will develop unique graduate course expectations according to identified Learning Outcomes alongside undergraduate. - This is an important point and planning processes are underway to ensure that this is covered. - We anticipate that this component would be an extra assignment that require critical thinking and literature evaluation skills such as in-depth review germane to key topics in the course. DECANAL RESPONSE: Schulich has a successful history of combining graduate students with undergraduates in some courses in other programs and we anticipate this will be clearly delineated as described by the program response.

2. *Particular attention may be placed regarding potential program candidates and their varied backgrounds and needs. In those regards, the program is presented as a full-year commitment, which can impact the applicant pool. Discussion has been made about potential part-time/virtual/asynchronous options, either at the program launch or in later years.*	DEPT RESPONSE: At this point, applicants will be required to have a background in medical sciences as outlined in the brief. The course part of the program can be offered on-line and on a part-time basis. We are currently putting together an application for a CIHR funding opportunity for a training program in drug safety, which will be designed around the MDSP program in collaboration the Drug Safety and Effectiveness Cross-Disciplinary Training (DSECT) Program. Based on this, remote delivery of the entire program is very possible and could be implemented early after the program launch. DECANAL RESPONSE: Supports for the development of online resources for this program will be made available through Digital Intern positions.
3. *University and faculty leadership should ensure the adequateness of financial, space and human resources, both teaching and administrative faculty, for this program.*	DEPT RESPONSE: Agreed; Dean has committed support. DECANAL RESPONSE: Budgetary approval has been received for a new tenure-track appointment in the Dept. of Physiology and Pharmacology and it is anticipated that the position will be able to directly support the Pharmacovigilance program. A current Faculty member has agreed to serve as the director of the program. In consultation with the Department of Physiology & Pharmacology, the Faculty will develop a succession plan for the director position in the next year. Schulich will also provide necessary administrative support to enable the program to run effectively.
4. *The reviewers suggest that appropriate resources include a larger pool of committed faculty with graduate level teaching background and dedicated/ protected time for this task that will allow a more balanced workload in both the development and delivery phases and to ensure program sustainability.*	DEPT RESPONSE: There is no doubt that the program requires resources and dedicated faculties able to teach the new courses and take the duty of supervising MRPs. The primary and supporting faculties listed in the brief have committed to supporting the program.
5. **We recommend special attention is made to the practicum aspect of the program. The program will need to provide proper and varied types of placements, and the university should have resources in place to support students while at practicum off-campus, with adequate mentorship,*	DEPT RESPONSE: Careful planning for adequate high-quality practicum sites will done once the program is launched. The program has already identified several practicum sites, which are adequate for the small enrollment rate during the first few years of the program. DECANAL RESPONSE: The program will utilize the services of the Schulich Experiential Learning Coordinator

oversight, and individualized performance evaluation.	and with the help of the core faculty, practicum placements will be carefully created and monitored.
6. *It should be clarified whether financial assistance will be available for students.*	DEPT RESPONSE: Students will be entitled to the normal avenues of financial assistance at Western.
7. *…there is a disproportionate burden of responsibility placed on adjunct faculty and more peripheral members, for both the development of graduate-level courses and delivery of teaching. Better resourcing and balancing would benefit the program and ensure its success and sustainability.*	DEPT RESPONSE: Agreed that a dedicated full-time faculty member is required for both content and leadership. This has been committed to by the Dean's Office. DECANAL RESPONSE: See #3 above.

Implementation Plan

The Implementation Plan provides a summary of the recommendations that require action and/or follow-up. In each case, the Graduate Program Chair and/or the Department Chair/Director, in consultation with the SGPS and the Dean of the Faculty/School is responsible for enacting and monitoring the actions noted in Implementation Plan. The number of recommendations prioritized for implementation has been reduced as many are already being actioned, as described in the program and faculty responses above. As a result, the recommendations not appearing in the implementation table are recommendations #1, #2, #3, #4, #6, and #7.

Recommendation	Proposed Action and Follow-up	Responsibility	Timeline
Recommendation #5: *The program will need to provide proper and varied types of placements, and the university should have resources in place to support students while at practicum off-campus, with adequate mentorship, oversight, and individualized performance evaluation.*	• A detailed practicum outline (Handbook) to be created that outlines roles and responsibilities of all participants as well as assessment and evaluation criteria. • The link between the practicum and the culminating MRP should be described. • A list of potential practicum placements should be created prior to the first implementation of the program with more placements than number of students to ensure compatibility matches for each student. • A faculty member should be assigned to provide oversight, to support students while on practicum, and to provide supervision.	Program chair Faculty planning team	By December 2022