INDUSTRY TEAM CASE STUDY

2021 PROJECT REPORTS

Image by: Cricia Rinchon

PRESENTED BY

UNIVERSITY OF TORONTO
FACULTY OF MEDICINE

LSCDS
LIFE SCIENCES CAREER DEVELOPMENT SOCIETY

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ABOUT THE PROGRAM

Over a four month period, 48 outstanding life science trainees, working in teams, conceived of and developed projects to simulate the type of work undertaken in the healthcare industry. Industry advisors guided their efforts. Projects spanned the areas of medical affairs, regulatory affairs, market access and marketing & sales. Overall, project activites included conducting surveys to determine therapeutic needs, gathering insights from key opinion leaders and patient groups, and developing strategies to gain regulatory approval and launch products. Project deliverables took the form of medical education slide decks, financial models, reports and strategic plans. On May 17th, Trainees presented the highlights of their work along with key learnings to their peers in the program and a panel of industry professionals. For the 2021 ITCS Project Report, each team prepared a 1-page overview of their work.

Through the Industry Team Case Study program, trainees take responsibility for their learning, and retain authorship of their projects. In their research, trainees are guided to use publicly available information. The views and opinions expressed herein do not represent those of LSCDS or any other organization. Industry advisors act as volunteer mentors, do not generate project content, and are guided not to disclose proprietary information

ITCS EXECUTIVE TEAM

This program was made possible by the ITCS Executive Team with support from Life Science Career Development Society and the ITCS Industry Advisory Board.

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INDUSTRY SECTORS

ITCS was made possible by Advisors from four sectors; Medical Affairs, Regulatory Affairs, Market Access, and Marketing & Sales. Each Advisor supported a team of 4 trainees who's projects are outlined in this report.

MEDICAL AFFAIRS

This sector serves to bridge the medical community (doctors, researchers, patients) and industry. In addition, it aims to provide scientific support of products to key opinion leaders/providers

Tracy In
Scientific Advisor,
Janssen

Yohan D'Souza
Scientific Affairs VP
LEO Pharma

Alison Foo
Clinical Trial
Leader,**Scimega**

REGULATORY AFFAIRS

Regulatory affairs works to advise companies on legislation and regulations regarding products and contacting government & regulatory agencies to obtain marketing authorization

Patrick Bedford
Principle Consultant
WeCANReg

Leslie Madden
Regulatory Affairs
Director, **Moderna**

Rodrigo Iglesias
Quality & Compliance
Director, **Roche**

MARKET ACCESS

Collect data and analyze how products are used and distributed in the healthcare system. This also involves preparing and launching drugs into market.

Tahir Feroz
Patient Access
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Roche

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Health Economist,
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Patient Access Manager,
EMD Serono

MARKETING & SALES

Marketing and sales is involved with selling products to external stakeholders. This involves communicating product value at conferences, to key opinion leaders and to patient groups

Kiran Dharani
Director of Marketing,
Seatle Genetics

Veda Maharajh
Marketing Portfolio
Lead,**Roche**

Medical education strategy to combat misinformation on COVID-19 vaccines

Nicole Revie, Paul Turgeon, Wenfu Bao, Jenna Park

Advisor: Tracy In

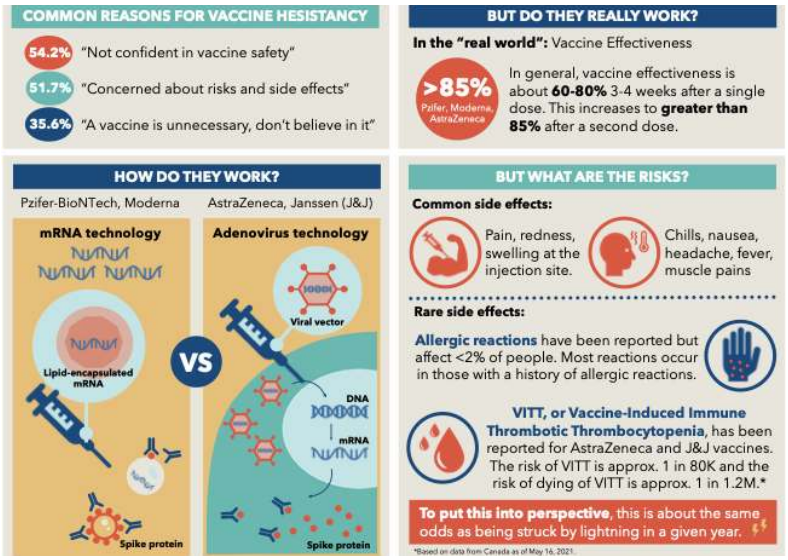
Background: The impact of the COVID-19 pandemic has made vaccination a highly debated topic among the medical community and general population. Since December 2019, COVID-19 has infected 1.33 million Canadians, resulting in approximately 25,000 deaths. While vaccination was once viewed as a light at the end of the tunnel, the expedited nature of these vaccines has resulted in many concerns that have affected public opinion. Vaccine rollout has also been accompanied by a great deal of misinformation circulating online, undermining the public's trust in health services and public or political institutions. To address vaccine hesitancy, vaccine misinformation needs to be addressed clearly and concisely to the public.

Objective: To develop a medical education strategy for the general public on the safety and efficacy of COVID-19 vaccines in Canada. We aim to address common misconceptions surrounding COVID-19 vaccines to improve the public's willingness to get vaccinated.

Deliverables: We approached this problem by developing medical education materials for the general public using lay language to clearly and accurately describe subjects that are commonly misinterpreted. Our research involved diving into the literature on COVID-19 vaccines and side effects and investigating the nuances of vaccine medical affairs. We developed two main deliverables: 1) a COVID-19 vaccine report addressing common questions with scientifically accurate information, and 2) a simplified infographic visually displaying key information on COVID-19 vaccines to appeal to a general audience. Our deliverables include information on the risks of COVID-19 infection, vaccine technology, efficacy and effectiveness, variants of concern, duration of protection, and side effects. We aim to disseminate these deliverables on social media, through patient advocacy groups and science communication channels, to inform the public on COVID-19 vaccines.

Key Challenges: Given the constant updates and new information, developing medical education materials for COVID-19 vaccines was inherently challenging. We focused on the communication of critically reviewed data to provide a clear and scientifically sound review of COVID-19 safety and efficacy. Additionally, the emergency authorization of COVID-19 vaccines has provided a unique perspective into the complexity of vaccine medical affairs.

Conclusion: Overall, our group members gained several insights into vaccine medical affairs and the challenges associated with comparing data across clinical trials. We learned that efficacy is not always the central consideration in choosing a vaccine, especially during a pandemic. Further, we learned that vaccine side effects need to be contextualized by weighing the risks of not being vaccinated.



MSL Case Study: Barriers to Testing RET Biomarker at Diagnosis Among New RET-Targeted Therapies in NSCLC

Katie Mao, Julie Marocha, Ning Yang, Marie-Sara Savard

Advisor: Alison Foo

Introduction: The goal of our team case study was to learn and apply our knowledge of Medical Affairs, with a particular emphasis on learning about the role of a Medical Science Liaison (MSL).

Background: Lung cancer is the number one cause of cancer death in the world, with 85% of cases being non-small cell lung cancer (NSCLC). Around 35% of NSCLC patients harbour a driver alteration. Novel therapies seek to target specific driver alterations to provide tailored treatment. Eli Lilly's RETEVMO (selpercatinib) treats RET-fusion positive NSCLC (2% of patients with a driver alteration) with high objective response rate, long response duration in NSCLC patients, and intracranial activity against brain metastasis. RETEVMO is currently under review by Health Canada and has received expedited approval in the United States.

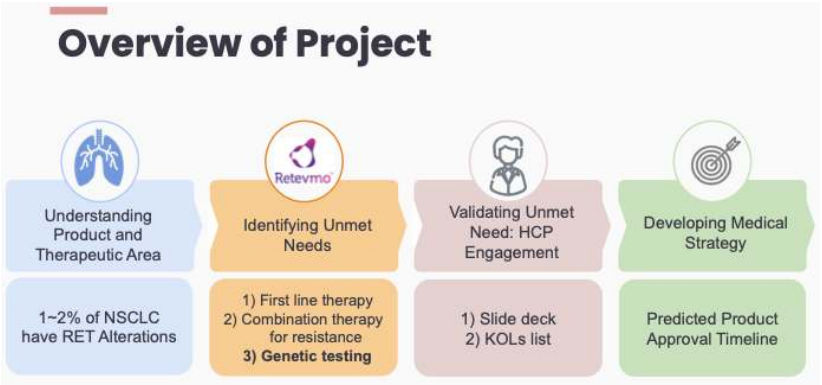
Methods: Our process included: 1) understanding the therapeutic landscape and product; 2) identifying a clinical unmet need; 3) interacting with healthcare providers (HCPs) to validate and gain further insights into the unmet need; and, 4) developing a medical strategy to address the unmet need.

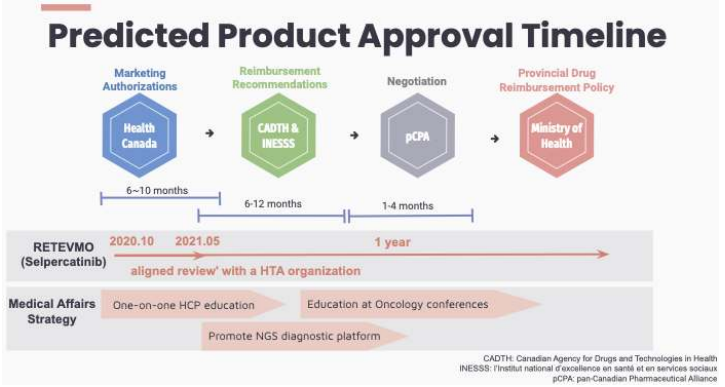
Results: We identified 3 major unmet needs and further explored #3: Potential for RETEVMO to succeed as first line therapy; Investigation of RETEVMO in combination therapy with osimertinib to address EGFR treatment resistance, and with crizotinib to address MET-dependent resistance to RET inhibition by RETEVMO; A lack of wide RET biomarker testing at diagnosis.

Through our interaction with an HCP, we learned that RETEVMO's clinical trial data is strong, and that the major hurdles to RET diagnosis are: 1) a lack of approval for RET-targeted therapies, such as RETEVMO; 2) a slow transition to NGS panel testing which is currently in progress; and, 3) a lack of MSL-HCP interactions for RET-targeted therapies.

Conclusion: Our medical strategy to address a lack of RET biomarker testing is to continue one-on-one interactions with HCPs, promoting the use of NGS panels and increasing data dissemination of RET-targeted therapies at Oncology conferences.

Acknowledgements: Special thank you to Alison Foo, our extraordinary mentor who guided us throughout the project. Thank you to Yohan D'Souza and Tracy In for their time and feedback on our deliverables. Also, thank you to Dr. Paul Wheatley-Price for his insights on the barriers to RET testing and feedback on our mock MSL interaction.





Gap Analysis & Patient Engagement for the Clinical Landscape of Alopecia Areata Treatment

Amin Kamaleddin, Michelle Dubinsky, Pimyupa Manaswiyoungkul

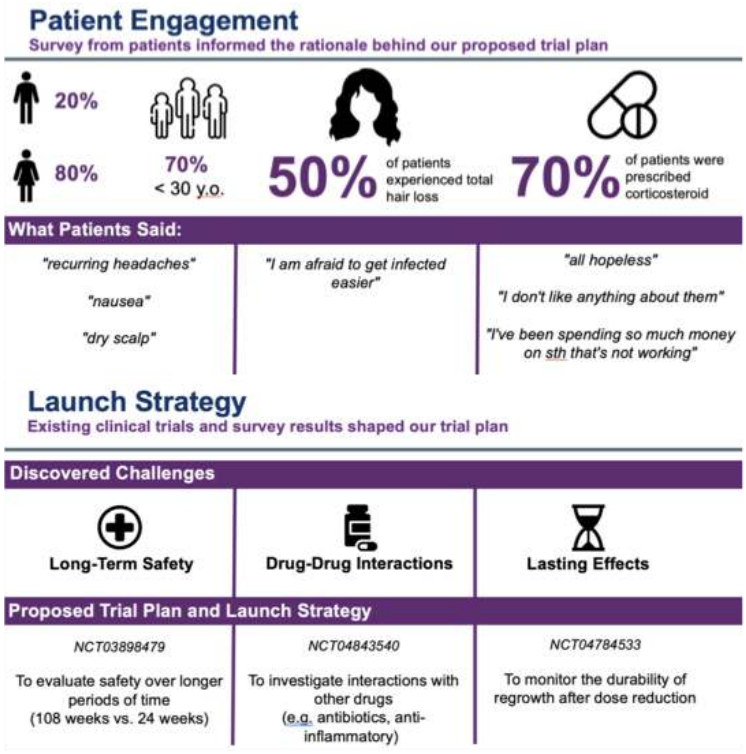
Advisor: Yohan D'Souza

Alopecia Areata (AA) is the most common form of a rare autoimmune disease that results in patchy hair loss in patients due to the hostile immune attack of the hair follicles. Approximately seven million individuals are affected by this disease in the US alone; however, there are no dedicated treatments for AA. Despite hair loss, the hair follicles are rarely destroyed, providing an opportunity for regrowth. Physicians often resort to the use of corticosteroids requiring a significant amount of time before regrowth is observed. Additionally, limited efficacy is observed as the hair may still fall out after the treatment is stopped due to undesired side effects associated with long-term use of corticosteroids. The clinical landscape presents a clear unmet medical need for the treatment of AA, calling for the development of a more effective and safer therapeutic strategy.

Thus, we aimed to search for a potential drug to promote as first-line therapy for AA through evaluation of compounds currently undergoing phase I/II clinical trials. From our research, we came across CTP-543, a selective oral JAK inhibitor that was recently granted a breakthrough therapy designation for the treatment of AA. CTP-543 is a deuterated analog of Ruxolitinib, better known by its brand name Jakavi (Novartis). With a desirable half-life (t1/2 >3h) and promising safety and efficacy profiles, we simulated the medical educator's role to inform physicians and key opinion leaders regarding the advantages of CTP-543 over existing treatment options. Herein, we established an engagement tactic identifying therapeutic gaps to aid in late-stage clinical trial design, address key questions, and gauge interest from a marketing perspective. Upon discussions with patients living with AA, the majority were concerned about potential side effects after long-term use of the prescribed drugs. Additionally, due to the immunosuppressive effects of JAK inhibitors, the JAK-antibiotics interactions were also explored in the literature. Lastly, most patients felt unsatisfied with the lasting effects of their prescribed drugs.

Given the findings from our comprehensive literature review, strategic gap analysis, and survey results, we proposed our launch strategy based on A) long-term effects, B) drug-drug interactions, and C) lasting effects. In conclusion, we believe that CTP-543 presents as a promising therapeutic compound for first-in-line treatment for the treatment of AA due to its enhanced efficacy, improved pharmacokinetic profile, and well-tolerated safety profile.

Phase II clinical trial results using CTP-543 for the treatment of Alopecia



Strategy to guide Quralis preclinical activities for ALS drug candidate QRA-244 toward first-in-human trials

Ali Momin, Alisa Ugodnikov, Arushi Jaiswal, Edward Ellazar

Advisor: Patrick Bedford

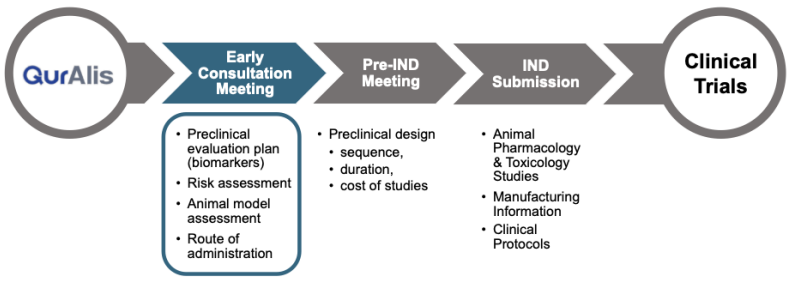
Background: Amyotrophic Lateral Sclerosis (ALS) is a progressive neurodegenerative disease with a 5-year survival rate of 20%. ALS is characterized by degeneration of upper and lower motor neurons that gradually results in loss of muscle control and paralysis. Individuals diagnosed with ALS lose the ability to walk, talk, eat, swallow, and eventually breathe. ALS cases are stratified into either Sporadic ALS (SALS), which encompasses 90% of ALS cases, or Familial ALS (FALS), which is primarily driven by mutations in the SOD1, C9ORF72, TARDBP (TDP-43) and FUS/TLS genes.

Current ALS treatments target neuronal hyperexcitability and oxidative stress pathways to reduce neurotoxicity and slow disease progression. However, these treatments are unable to reverse disease progression and are mainly symptom-managing. Based on expert opinion, an ideal therapy for ALS would favorably impact both survival and function and confer a greater benefit than existing treatments. To address this unmet need, QurAlis, a prominent biotechnology firm, developed the small molecule compound QRA-244. QRA-244 is a selective Kv 7.2/7.3 potassium channel opener that targets motor neuron hyperexcitability-induced disease progression, which occurs in 50% of ALS patients. In comparison to similar drugs in clinical trials, the improved channel specificity of QRA-244 is expected to translate into a better clinical safety profile with comparable or better efficacy. As a result, patients treated with QRA-244 can expect a higher quality of life while receiving disease-modifying treatment.

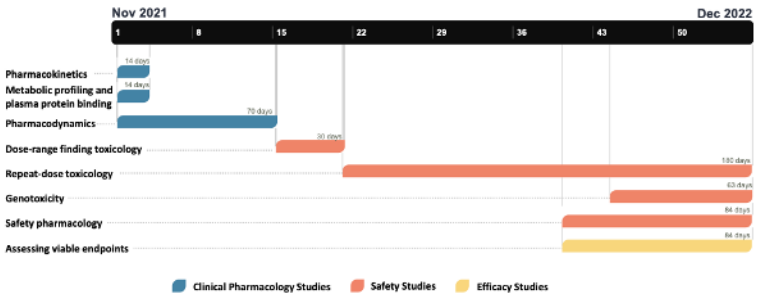
Objective: Guide QurAlis's preclinical activities for QRA-244, through the regulatory pipeline to achieve first-in-human trials. The focus of the engagement was to perform preliminary regulatory risk assessment, develop QurAlis's preclinical study design, and provide a recommendation to prepare QurAlis for a successful early consultation meeting with the FDA.

Outcome: We identified key issues and mitigations for QurAlis to present to FDA regulators, assembled appropriate background material and key discussion points for a successful early consultation meeting. Our strategy was built on assessments of route of administration, animal models, preclinical pharmacology, toxicology, efficacy biomarkers, FDA guidelines for ALS drug development and clinical trials. We additionally considered priority key stakeholders, including FDA regulators, patients and key opinion leaders in the field.

Deliverables: A preliminary Target Product Profile, Preclinical evaluation plan, Decision matrices for selecting route of administration & animal models, Clinical trial enabling strategy, Dates of key milestones in moving to clinical trials



Focus: Strategy for planning preclinical studies in preparation for meeting with FDA



A Theoretical Canadian Regulatory Strategy for a New Drug Submission of eli-cel

Rebecca Wu, Zheng Song, Ryan Smith, Ronald Ireland

Advisor: Leslie Madden

Cerebral adrenoleukodystrophy (CALD) is a devastating X-linked genetic disorder caused by a mutation in the ABCD1 gene that affects approximately 1 in 21,000 male newborns. Due to the progression of symptom onset, individuals with CALD experience mortality within 2-4 years. Currently, the only effective therapy for CALD is a hematopoietic stem cell (HSC) transplant, which carries significant risk of graft failure.

bluebird bio has developed a novel gene therapy, elivaldogene autotemcel (eli-cel) to introduce a functional copy of the ABCD1 gene to HSCs isolated from patients with CALD. After promising results from its phase 2-3 study, eli-cel was accepted into the Priorities Medicines scheme (PRIME) and was granted an accelerated assessment by the EMA in Europe. Furthermore, the FDA granted eli-cel Orphan Drug status, Rare Pediatric Disease designation, and Breakthrough Therapy designation. eli-cel has yet to be approved by any regulatory body.

Our team simulated the role of Regulatory Affairs consultants for bluebird bio who is currently seeking regulatory approval for eli-cel. To improve the global reach of eli-cel, we recommended applying to Health Canada as their next step. A submission to Health Canada comes with several competitive benefits: the regulatory structure in Canada is similar to the EU and USA; Canada has a well-understood treatment population, frameworks to support the approval of gene therapies, and accredited cell therapy administration sites; the Canadian market provides up to 8.5 years of market exclusivity and up to 2 years of supplemental data protection; and New Drug submissions (NDS) submitted to Health Canada enable access to 4 additional international regulators through the Access Consortium.

We proposed two routes to achieve market authorization in Canada. First, we recommended that bluebird bio apply for Priority Review when submitting an NDS to Health Canada, which will reduce the review process from 345 days to 205 days. Alternatively, if bluebird bio is seeking a greater global footprint, we recommended they apply for regulatory approval through the Access Consortium. The Access Consortium is a collaborative effort between 5 regulatory bodies, including Health Canada, aimed to help increase the international reach and timely access to safe therapeutic products.

In summary, we have developed a comprehensive submission strategy for bluebird bio to seek regulatory approval of eli-cel in Canada. We have catered our submission strategy to align with the immediate goals of bluebird bio, recommending an application to Health Canada through Priority Review or through the Access Consortium.

Regulatory Approval Process of PTX-COVID19-B Vaccine

Jean Tang, Sofiia Ivantsiv, Shadi Zarei, Alaa Alsaafin

Advisor: Rodrigo Iglaesias

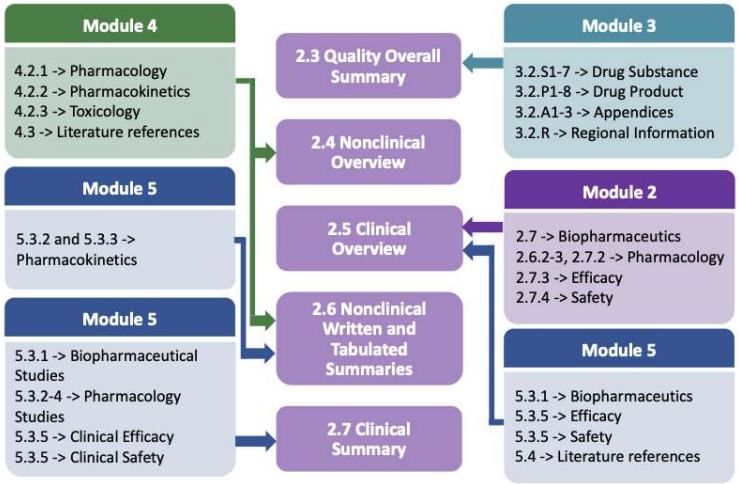
Situation: Currently, there are four COVID-19 vaccines approved for emergency use by Health Canada: Pfizer-BioNTech, Moderna, AstraZeneca and Janssen. Despite their approval, their manufacturing and supply still could not meet with the Canadian and immense global demand. This is particularly important for Canadians given that Canada does not have domestic vaccine production and is heavily relying on Europe and America. To help mitigate the shortage of the COVID-19 vaccines and potentially address the emergence of different virus variants, Providence Therapeutics, a private Canadian Biotechnology company, has expanded its focus from oncology vaccines to developing an mRNA-based COVID-19 vaccine, PTX-COVID19-B. They have recently completed their Phase I clinical trial and will commence their Phase II and III trials over the summer of 2021.

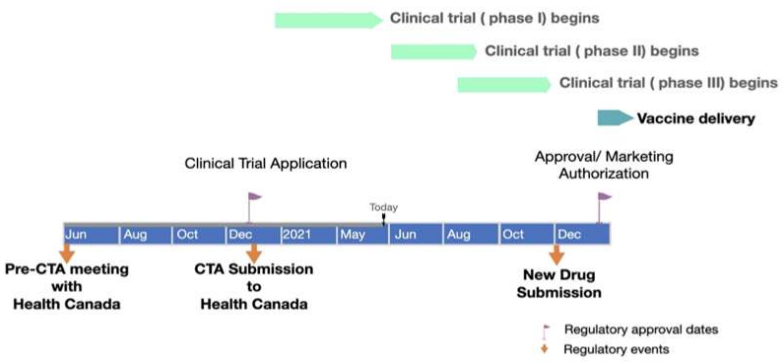
Objective: Our goal was to assist Providence Therapeutics as a regulatory affairs consultation company, JASS, to have their New Drug Submission (NDS) application approval in time before the end of the fiscal year. Their approval by Health Canada will prioritize the needs of Canadians and help with the vaccine shortage.

Methods: As PTX-COVID19-B is fourth to market in Canada, first we reviewed available documentations regarding approved COVID-19 vaccines in Canada (with the caveat that PTX-COVID19-B has just completed its clinical phase I). We performed a landscape analysis for all four approved COVID-19 vaccines, including clinical and non-clinical and quality assessment. We then examined the requirements for each module in the Electronic Common Technical Document (eCTD), relevant module subsections for the vaccine (vs. drugs in general) and the relationships between the modules in the CTD. We also studied the product monographs of Pfizer-BioNTech and Moderna and utilized them as a reference for building the document structure of PTX-COVID19-B's product monograph. Finally, we assessed the requirements for approval under the interim order and outlined the responsibilities of Providence Therapeutics once the pandemic is over.

Deliverables:
Tentative regulatory timeline for Providence Therapeutics (based on newsroom articles)
Submission content plan with key milestones
Product monograph for PTX-COVID19-B

Key Challenges: As Providence Therapeutics has recently completed their Phase I trial for their vaccine, it was a challenge to perform a comprehensive landscape analysis and to assess their key differentiation points. While the approval process for COVID-19 vaccines is dynamic, this motivated us to frequently monitor the data on the Health Canada website for updates.





Market Access Strategy: Tepotinib

Aaron Jackson, Christopher Go, Carly Thrower

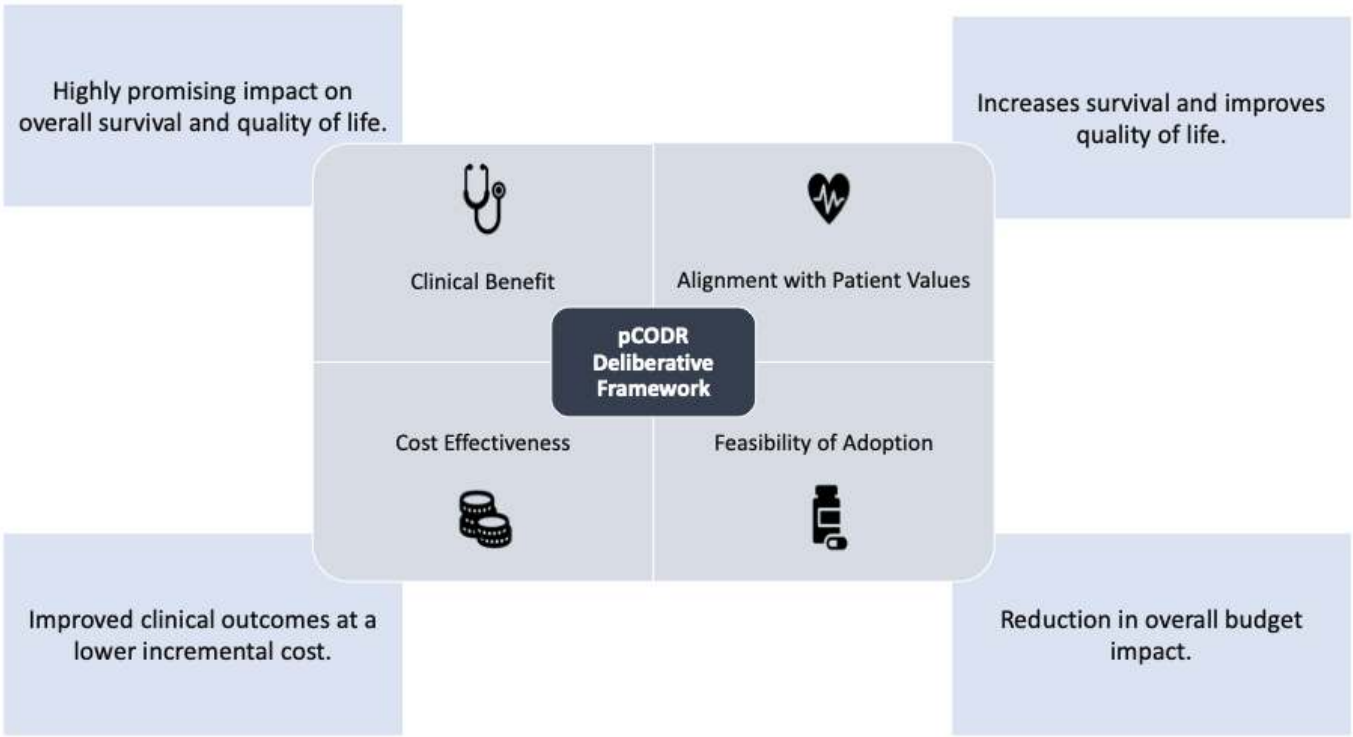
Advisor: Tahir Feroz

Background:
Our team has taken the role of a Canadian market access team at Merck. Our team is working with Tepmetko (tepotinib), a therapeutic for metastatic non-small cell lung cancer (NSCLC) that targets the MET exon 14 Skipping Mutation. Late-stage NSCLC can be a devastating diagnosis with poor survival and significant reductions to quality of life. Current 1st line treatment in Canada can modestly improve survival and quality of life yet is costly and requires uncomfortable and frequent IV administration.

Aim:
We are working to provide a rationale for bringing tepotinib to the Canadian market, considering the clinical benefit, cost-effectiveness, patient values and feasibility.

Results:
Tepotinib is a once daily oral therapy for NSCLC patients with MET exon 14 skipping mutations that has been shown to significantly improve survival as well as quality of life. Indirect cost-effectiveness analyses show that Tepotinib is a dominant therapy that not only improves clinical benefit but does so at a lower cost. Adopting tepotinib into the Canadian healthcare system will have a positive impact on the budget although there are barriers to easy adoption of tepotinib. Genetic screening for MET exon 14 skipping mutations is required yet is only available sparsely throughout the Canadian healthcare system. However, given the increase in targeted cancer therapeutics throughout the oncology space, there is likely a future for standardized and reliable genetic testing across Canada.

Conclusion:
Given the considerable clinical benefit, cost-reductions, feasibility, and alignment with patient values, tepotinib should be recommended in Canada for 1st line treatment of late-stage NSCLC patients with MET exon 14 skipping mutations.



Evaluating the reimbursement feasibility of Lynparza (olaparib) in Ontario for mCRPC

Maria Z Miranda, Sarah Simon, Sanghavy Sivakumaran

Advisor: Adrian Turner

Background: Prostate cancer accounted for 10% of cancer related deaths in Canadain men in 2020. The end stage of prostate cancer is mCRPC, a terminal disease requiring palliative care drugs to improve patient outcomes. Lynparza (olaparib) has recently received approval as the first PARP-inhibitor treatment for mCRPC in Canada, specifically targeting patients with homologous recombination repair (HRR) mutations. Lynparza serves as an additional second-line treatment that can be used after developing resistance to current treatment lines. Lynparza was recently reviewed at CADTH (final recommendation published April 2021), and our project evaluates the clinical and budgetary implications of Lynparza into Ontario's mCRPC standard of care.

Objective: To determine whether Lynparza, for mCRPC, should be covered in Ontario

Approach: For our clinical evaluation, we assessed clinical trial data for Lynparza and contrasted this with standard of care practice and expert opinions found in the literature to evaluate the efficacy data presented.
For our Budget Impact model, we incorporated patient population size, market share, and drug costs to model the cost of Ontario funding Lynparza over a 3-year horizon. Considering multiple scenarios forecasting variations across 3 years regarding relative market share, eligible population and pricing factors.

Outcome: Our clinical evaluation found that Lynparza stalls cancer progression and improves survival outcomes for BRCA1/2 or ATM mutated patients with mCRPC. Despite limitations in the PROfound study design, Lynparza is likely to be adopted as clinical standard practice in Ontario. Regarding reimbursement feasibility, a 3-year net budget impact of Lynparza's Ontario market entry ($918,428,828) is considered cost-ineffective. Thus reimbursement within Ontario is expected to be highly conditional based on clinical need and negotiations regarding pricing.

Recommendation: Lynparza is likely to be reimbursed in Ontario, with conditions: (1) Patients must exhibit exclusive need for Lynparza vs ARAT and chemotherapy comparators, and (2) Ontario advocates for a price reduction to make the drug more cost-effective in comparison to current and upcoming comparators.

Vyepti: Journey To Market

Chris Onderisin, Liu Zhang, Doorsa Tarazi, Sarah Ashton

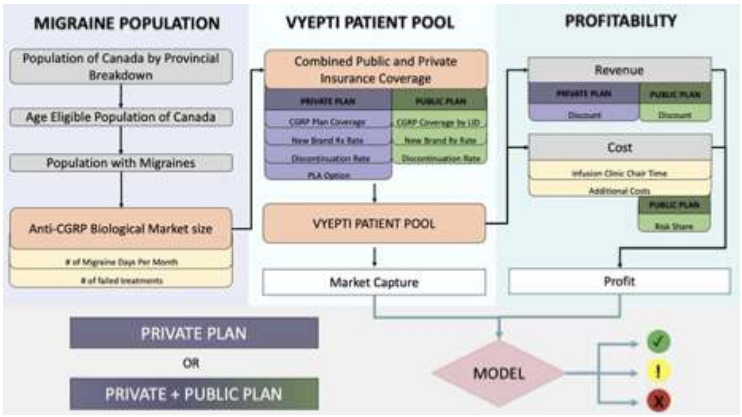
Advisor: Kavisha Jayasundara

Background:
Chronic Migraine affects hundreds of thousands of Canadians each year. Standard of care, until recently, has consisted of expanded-label use of medications such as antidepressants, antiepileptics, and botox. These drugs are typically ineffective for many patients leading to polytherapy for symptom management. Vyepti - made by Lundbeck - represents the latest entrant into the market for a new class of preventative migraine biologics, trailing Aimovig, Emgality, and Ajovy. These biologics targeting the CGRP protein/receptor represent a new wave of preventative relief for migraine patients, offering new opportunities for patients not seen in over a decade.

Objectives:
1) To provide a market landscape assessment for Lundbeck, detailing the chronic migraine space in Canada, focusing on the profitability of pursuing a public reimbursement strategy in Canada.
2) To explore market access strategies beyond pCPA-negotiated discounts for payers, including Risk-Sharing and Preferred Product Agreements.
3) To prepare a Budget Impact Analysis for Lundbeck in preparation of pursuing public reimbursement.

Approach:
Utilizing clinical trial data from each of the four anti-CGRP migraine biologics, published literature on chronic migraine prevalence & incidence rates, CADTH & INESSS reports, and key insights gleaned from interviews with patient advocacy groups, reimbursement & market access consultants, pharmacists, & physicians, a user-customizable Excel model was created. We model the Canadian population of chronic migraine patients over four years from 2021 to 2024, estimating growth of the CGRP biologic market, as well projecting the Vyepti patient base, and expected revenues, costs, and profits for the launch of Vyepti in Canada. The model took into consideration age- and gender-specific prevalence rates, public-private payer splits, CGRP biologic market shares, new brand prescription rates, drug discontinuation rates, unique costs associated with intravenous drug administration, and patient support program costs.

Outcome:
We predict that public reimbursement of Vyepti is modestly profitable over 4 years, earning total profits of $74.5M and $84.5M under likely and unlikely reimbursement criteria, respectively (>8 migraine days per month & 2 failed drugs, vs. >4 migraine days per month & 2 failed drugs). Targeting >5.35% of private drug plans for a Preferred Product Agreement (PPA) wherein Vyepti is offered at 25% discount will yield additional profits, with $133.4M in profits attainable at 25% private market coverage for PPAs. Incorporation of sponsor Risk-Sharing can yield additional profits at public discount rates below 72.4%. Ontario is expected to incur $143M-$288M in additional costs with public reimbursement of Vyepti over the base case scenario.



Reimbursement Submission for Xofluza in Canada

Mehrnoosh Neshatian, Moushumi Nath, Karen Fung, Sophia Li **Advisor:** Tayyab Pirzada

Background: Influenza is a significant contributor to lost workday, hospitalizations, and deaths in Canada. Antiviral medications are used to alleviate influenza symptoms. Currently, the main antiviral drugs on market are the neuraminidase inhibitors oseltamivir and zanamivir. However, in 2020, Health Canada issued a notice of compliance for baloxavir marboxil (Xofluza®), a novel anti-viral cap-dependent endonuclease inhibitor.

Objective: Our objective was to produce a health technology assessment (HTA) product for Xofluza by examining its clinical effectiveness relative to comparators, and its budget impact. This HTA product was designed according to the Canadian Agency For Drugs And Technologies In Health (CADTH) guidelines.

Methods: For the examination in clinical effectiveness, a critical assessment of peer-reviewed publications, including clinical trials and meta-analyses, was conducted. For the budget impact analysis, the National Centre for Pharmacoeconomics Budget Impact Model Template was used, taking into consideration eligible population, market trends, and drug costs.

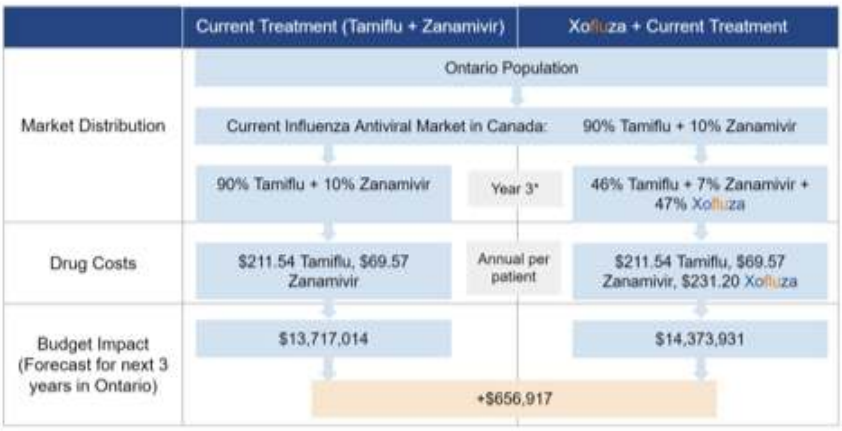
Outcomes: In terms of clinical effectiveness, Xofluza use was associated with a reduced time to symptom and fever alleviation compared to placebo, but comparable to comparators, and more rapid decrease in viral titer and viral shedding compared to both placebo and comparators. In terms of budget impact analysis, the introduction of Xofluza into the Ontario population is expected to decrease the market shares of oseltamivir and zanamivir and have a net budget impact of $656,917 over the next 3-years.

Conclusion: Xofluza has clinical advantages relative to both placebo and comparators, and has a limited impact on the budget. Reimbursement for this drug would therefore constitute a minor health budget use for Ontario, for increased clinical benefits for the population.

Figure 1. Clinical Effectiveness of Xofluza in comparison with Tamiflu and Placebo.

Outcome	Baloxavir Marboxil (Xofluza) vs. Oseltamivir (Tamiflu)	Baloxavir Marboxil (Xofluza) vs. Placebo
Time of Symptom Alleviation	Comparable	Shortened
Time of Fever Resolution	Comparable	Shortened
Viral Shedding	Shortened	Shortened
Decline in Viral Titre	Greater	Greater

Figure 2. Budget Impact Analysis of Xofluza.



Orgovyx in Canada: Launch plan for the first oral ADT for advanced prostate cancer

Kali Iyer, Jessica Mo, Harsha Murthy, Keyue Chen

Advisor: Kiran Dharandi

Prostate cancer is the most diagnosed cancer among Canadian men, accounting for 20% of all cancer cases and 10% of all cancer deaths. Given that 1 in 9 Canadian men will develop prostate cancer in their lifetime, there is a need for innovative treatments.

Orgovyx (relugolix) by Myovant Sciences is the first FDA-approved oral androgen deprivation therapy (ADT) for advanced prostate cancer. It more rapidly suppresses testosterone levels as a GnRH antagonist compared to the leading competitor, Lupron (leuprolide). Furthermore, its oral administration makes it a more convenient treatment that can be administered in an outpatient setting.

Myovant Sciences has hired our consulting group to assess the market landscape and create a launch plan to support the marketing of Orgovyx in Canada. First, we examined the current Canadian prostate cancer market, which has a population size of 356,808 and is projected to grow at a CAGR of 9.8% to $18.2B by 2025. With this, we suggested a Canadian list price of CAD$1368.15 - $1734.75 per month as a starting point for negotiation. Using CAD$1734.75 per month as the reference price for Orgovyx, the incremental cost-effectiveness ratio (ICER) in comparison to leuprolide was calculated to be CAD$17125.84/QALY, falling within the acceptable ICER range.

Secondly, we constructed a $3.23 million marketing strategy along with core messaging materials for Canadian physicians. Given the current climate, we proposed an entirely virtual launch, focused on journal advertising, conference booths, and virtual visits. This would utilize a sales team of 8 who would initially target major prostate cancer centers for the greatest impact before expanding across Canada with the help of peer-peer education.

Lastly, we developed a framework for a patient support program to provide resources and engage with patients and their families. This includes connecting with local patient advocacy groups (for instance, Prostate Cancer Canada), providing financial and administrative assistance to cover provincial co-pays and navigate reimbursement, engaging patients and families with regular newsletters, and raising awareness for prostate cancer..

Through analyzing Orgovyx's efficacy, current market, and pricing, we determined it demonstrates substantial clinical and financial advantage over its competitors. Effective physician education and patient support will aid in the successful uptake of this therapeutic. We project that by following this launch plan, Orgovyx is poised to recoup USD$57 million in revenue over the first two years, greatly disrupting the Canadian market.

Launching Lupkynis for Patients with Lupus Nephritis in Canada

Keith Colaco, Claresta Adityani, Vincent Lee

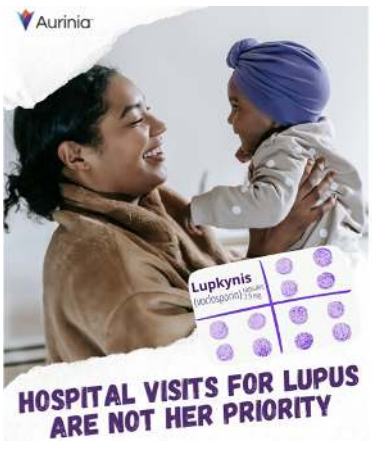
Advisor: Veda Maharajh

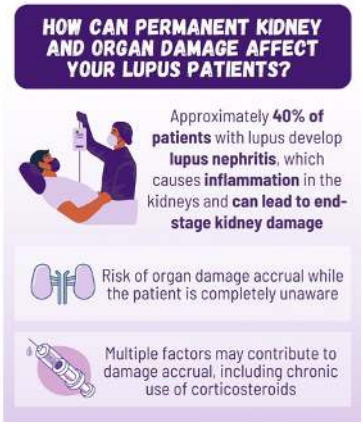
Background & Objective: Lupus nephritis (LN) is an inflammatory condition of the kidneys that can lead to permanent and irreversible tissue damage of the kidneys, and affects primarily young women. Currently, the typical standard of care consists of treating patients with multiple non-specific high-dose corticosteroids to suppress the immune system, but with high toxicity, leaving patients with side effects, such as fatigue and joint pain. Our team simulated a product launch of Aurinia Pharmaceuticals' Lupkynis (voclosporin) for the Canadian market to treat LN.

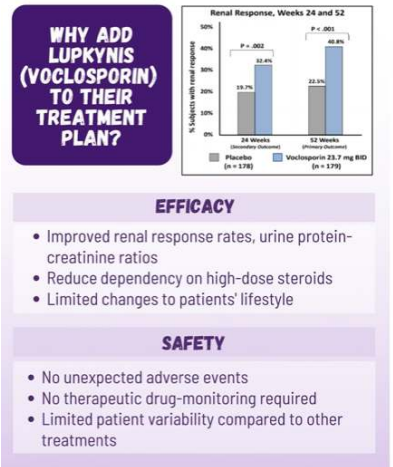
Approach: Lupkynis is currently the only FDA-approved oral treatment for LN. Through our competitor analysis, Lupkynis has superior efficacy, safety profile, and delivery compared to other LN therapeutics. With a strategic product launch, we aim to capture the LN market in Canada, which is currently dominated by non-specific high-dose corticosteroids for standard of care. The reduction in the number of pills and side effects with Lupkynis fulfills the need for young women have an improved quality of life, enabling them to take charge of their schedules.

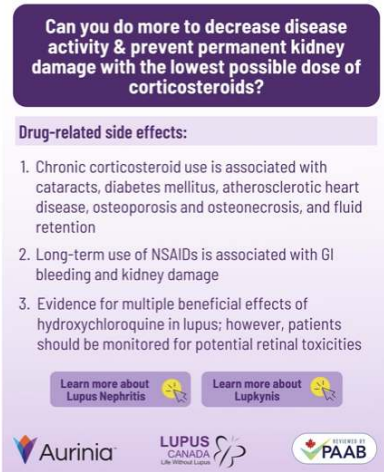
Outcome: Through interviews with rheumatologists, we identified drug efficacy and safety as important traits when marketing to rheumatologists, who are most likely to interact with LN patients and prescribe treatments. We narrowed down the target population to influential early adopters in large cities to start launching the drug, hoping to capture rheumatologists interested in providing their patients with a novel treatment. Our team also designed and developed a starter kit to provide rheumatologists with information on the disease, as we plan on distributing it as part of our promotional strategy, which includes rheumatology conferences and journals. In conclusion, our strategy of targeting early adopter rheumatologists with a focus on improved drug efficacy and safety would enable us to have a successful product launch in Canada.

Future Directions: Pending approval from Health Canada, examine the impact of Lupkynis on the Canadian market. Given that lupus is an autoimmune disease, it will be important to incorporate newly emerging evidence on the impact of COVID-19 disease and vaccines on patients' lives and treatment plans.









How To Get Involved

JOIN THE TEAM

If you are a trainee and want to take a leadership role in the 2022 program, join the ITCS Executive team. Recruitment: Summer, 2021.

BECOME AN ADVISOR

We are always looking for industry professionals to volunteer as Advisors. If you would like to return as advisor or know any colleagues that would like to join the program, please do not hesitat to reach out!

BECOME A TRAINEE

If you are interested in participating in the program as a Trainee, please look out for information November 2021.

To find out how recent ITCS alumni have used their case study projects to get noticed by industry employers, check out:

Yung et al. Getting hired in industry – life science graduate students use case studies to get noticed by employers. OSF Preprints doi: 10.31219/osf.io/x6fny

Kozma, Meyer-Miner, et. al. "Developing an industry job simulation program for graduate & postdoctoral trainees in the life sciences" Canadian Journal of Career Development. In press 2021.

Stay in touch!

e:*casestudy@lascds.org*

w:*https://lscds.org/events/industry-team-case-study/*

On behalf of the ITCS Executive Team

THANK YOU

ITCS continues to serve as a platform for life science trainees to prepare for the job market. This year 46 highly motivated Trainees were selected to participate based on their readiness to engage in a case study project and interest to pursue a career in industry.

The ITCS Executive team was extremely impressed by the quality and detail of this year's Trainee projects. We commend Trainees on their dedication, collaboration, and ability incorporate feedback throughout the program. We hope that this program has provided Trainees with an introduction to industry deliverables as well as an opportunity to develop professional relationships with their peers and industry professionals.

The program would not have been possible without the generosity and mentorship of our Advisors. Throughout the program they provided invaluable support to trainees, helping them refine their projects and offering guidance on career paths. We hope this has been an enriching experience for them, and we look forward to continuing to engage industry professionals in the coming years.

We are looking forward to welcoming the next cohort of participants in 2022.

~ ITCS Executive Team