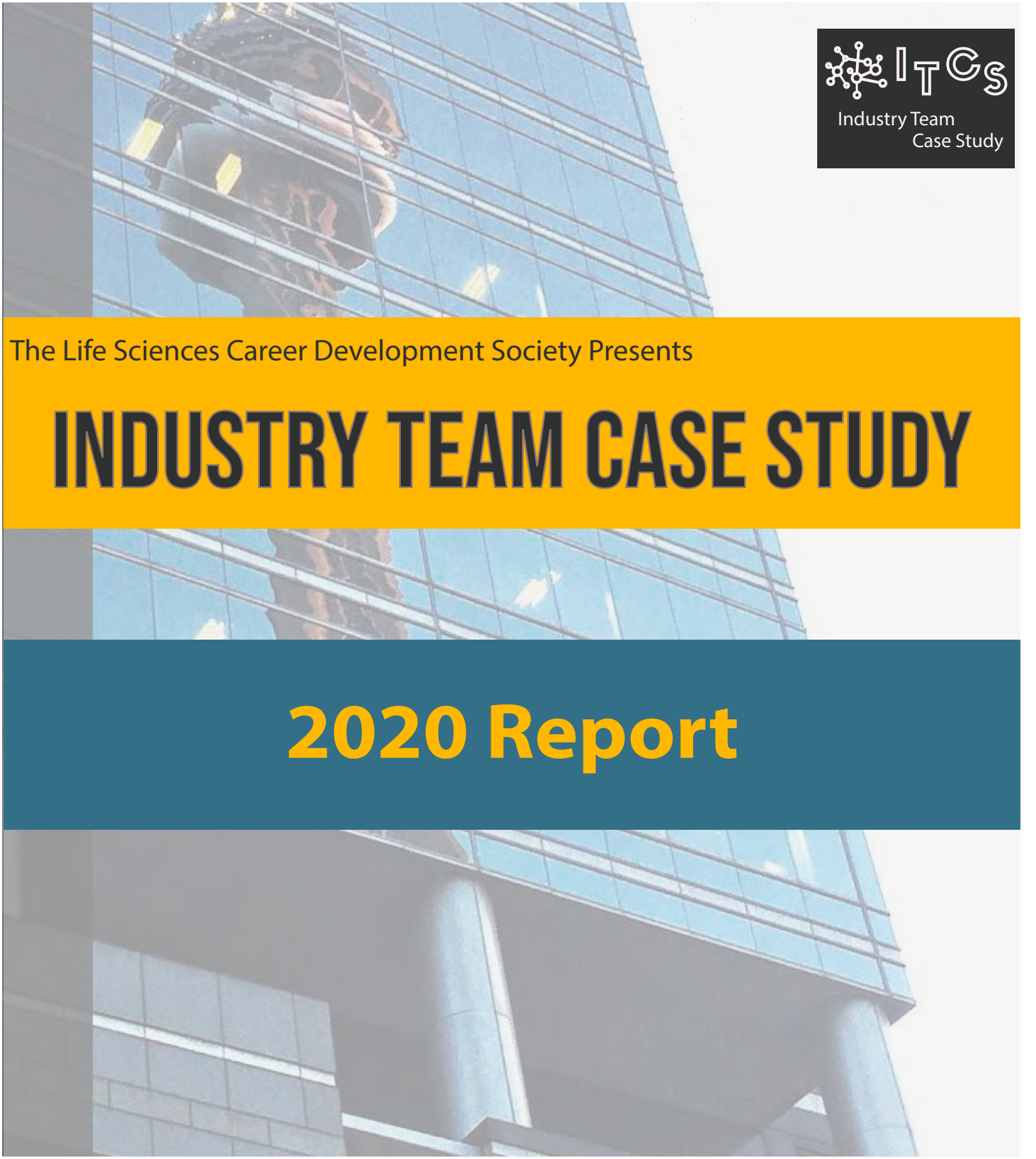

ITCs
Industry Team Case Study

The Life Sciences Career Development Society Presents

INDUSTRY TEAM CASE STUDY

2020 Report

LSCDS
LIFE SCIENCES CAREER DEVELOPMENT SOCIETY

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ITCS
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OUR MISSION

Our mission is to provide an opportunity for trainees to simulate working in the healthcare industry, enabling them to devlop their professional skills and gain marketable, relevant experience. The ITCS is part of the Life Sciences Career Development Society, which aims to bridge the gap between academia and industry by advocating for industry knowledge and helping academics network with industry professionals.

ITCS
Industry Team
Case Study

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 commercial functions. Overall, project activities included conducting surveys to determine therapeutic needs, gathering insights from key opinion leaders, 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 12, Trainees presented the highlights of their work along with key learnings to their peers in the program and a panel of industry professionals. For this 2020 ITCS 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.

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LSCDS Director

INDUSTRY PANELS

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MEDICAL AFFAIRS

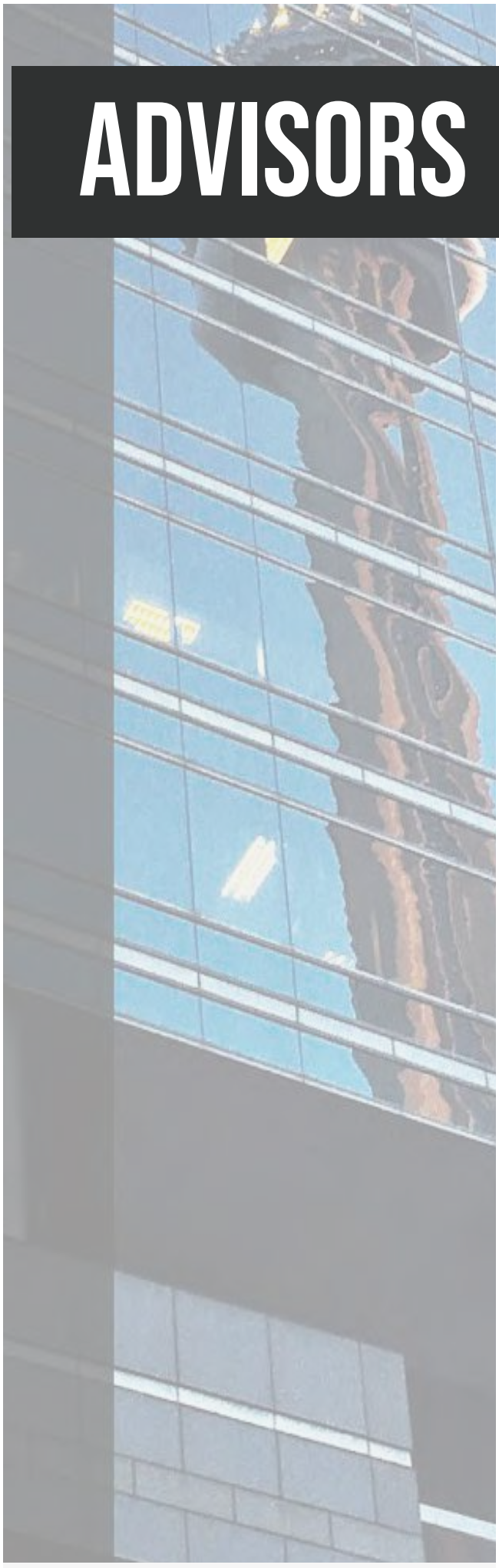
Medical Affairs professionals engage with healthcare professionals to provide medical and scientific knowledge exchange, and to develop research opportunities related to a company's products. Case study teams engaged in a variety of projects, including acting as medical science liaisons, researching the safety and efficacy of products, identifying unmet clinical needs and developing strategies to address these needs. Teams interacted with key opinion leaders through questionnaires and conversations to gain insight into research and clinical trends, and developed medical education strategies to facilitate the dissemination of information about cutting edge treatments.

REGULATORY AFFAIRS/MARKET ACCESS

Regulatory Affairs professionals guide the research and development process, engage with regulators to secure marketing authorization for healthcare products, and carry out critical compliance activities related to ensuring product labeling is updated to reflect emerging safety signals. Market Access professionals develop reimbursement strategies, and engage with health technology assessment bodies and payers to secure favorable health economic evaluations and product listing agreements. Trainees assessed therapeutic area landscapes, identified unmet needs, and developed strategies to facilitate bringing medical devices and new medicines to market.

COMMERCIAL

Commercial professionals develop and execute business development and marketing strategies to generate revenue. Teams undertook a variety of projects including developing strategies to increase sales for existing treatments and commercialize emerging treatments. In addition trainees conducted budget impact analysis and determined how to develop pricing plans for drugs prior to launch.



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ITCs
Industry Team Case Study

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COMMERCIAL

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RBX2660: Increasing patient access to microbiome restoration therapy

Katelyn Kozma, Stephanie Tran, Charles Maisonneuve

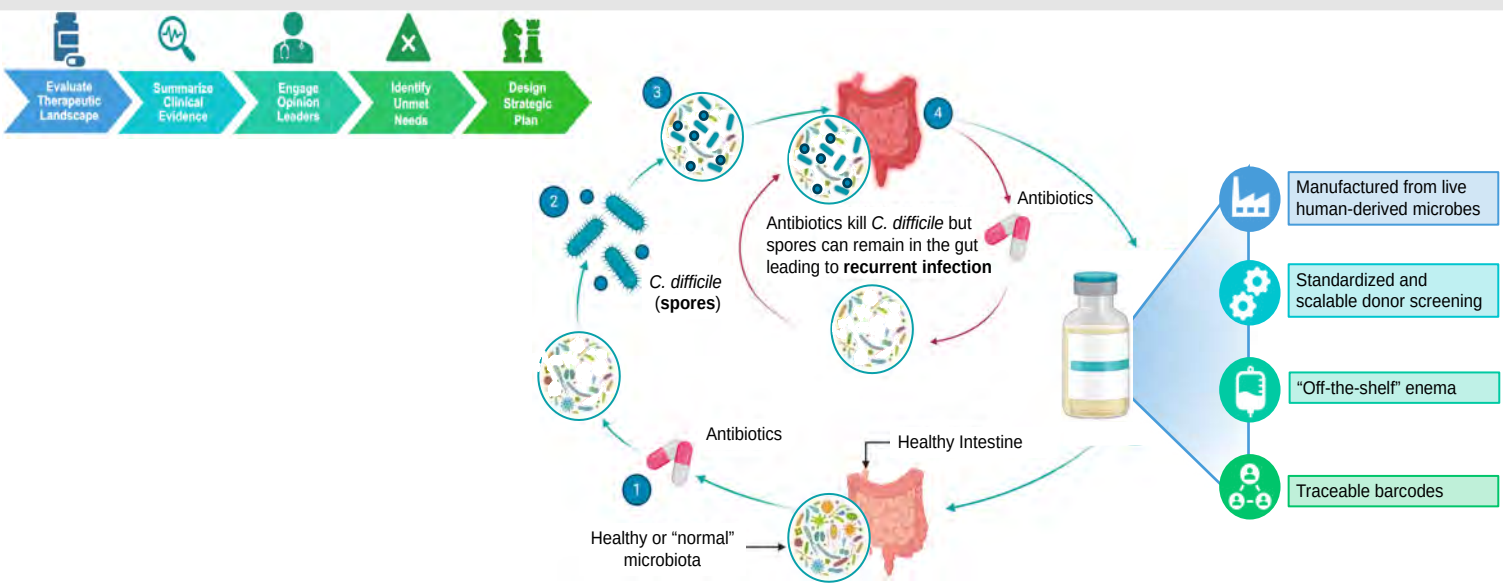
Situation: C. difficile is the most frequently diagnosed healthcare-associated infection, but frontline antibiotic treatments are suboptimal and often lead to recurrence. Fecal microbiota transplant (FMT) is an effective alternative treatment for recurrent C. difficile infections (rCDI) with a 60-90% response rate. However, this treatment is infrequently used due to lack of standardization and rigorous donor-screening processes. RBX2660 (Rebiotix Inc.) is a standardized, stabilized form of FMT that has the potential to resolve these therapeutic gaps. In anticipation of product commercialization, it is critical to assess key opinion leader (KOL) insights and ensure RBX2660 can meet both physician and patient needs. Our team goal is to determine how RBX2660 can increase accessibility of FMT treatments.

Solution: We simulated the role of medical science liaisons representing Rebiotix. We worked to engage KOLs and share safety and efficacy data for RBX2260. We gathered insights with the goal of identifying therapeutic gaps and clinical unmet needs.

Summary of Deliverables:
- Developed and implemented scientific communication strategies
- Presented key clinical evidence on product safety and efficacy to scientific thought leaders
- Engaged KOLs and gathered insights surrounding FMT use in Canada
- Quantified KOL insights using a questionnaire
- Outlined a strategic plan with three medical tactics to address unmet needs

Results: We created a medical strategic and tactical plan to support the launch of RBX2660. In this report, we summarized insights from our interactions with KOLs and identified current treatment barriers for CDI patients. RBX2660 has the potential to fill a substantial therapeutic gap for rCDI treatment. From our KOL engagements, we concluded that physician acceptance and knowledge of the product will determine patient access.

We outlined the implementation of three medical affairs tactics that will position the product to best serve patients. These include (1) medical messaging plan to describe RBX2660 and mitigate negative connotations surrounding FMT, (2) educational programming to equip physicians with extensive product information and enable them to make informed decisions about the alternative treatment options, and (3) Advisory Board formation to highlight clinical needs and gather insights throughout the product life cycle.



Post-launch clinical gap analysis for Enhertu®

Liu Zhang, Sarah Donegan, Idil Temel, Theodora Yung

Background: Post-market data generation has been increasingly important to establish a drug's long-term safety profile, increase patient acceptance, and improve the economics of its use in the real-world setting. Medical affairs teams play a pivotal role in identifying clinical gaps and in developing strategies to close these gaps. Often, these strategies involve the design of Phase IV clinical trials.

Research Statement: We are a mock medical affairs team working for AstraZeneca, in collaboration with Daiichi Sankyo, to design an effective clinical trial for the new antibody-drug conjugate Enhertu®, in the treatment of HER2+ metastatic breast cancer.

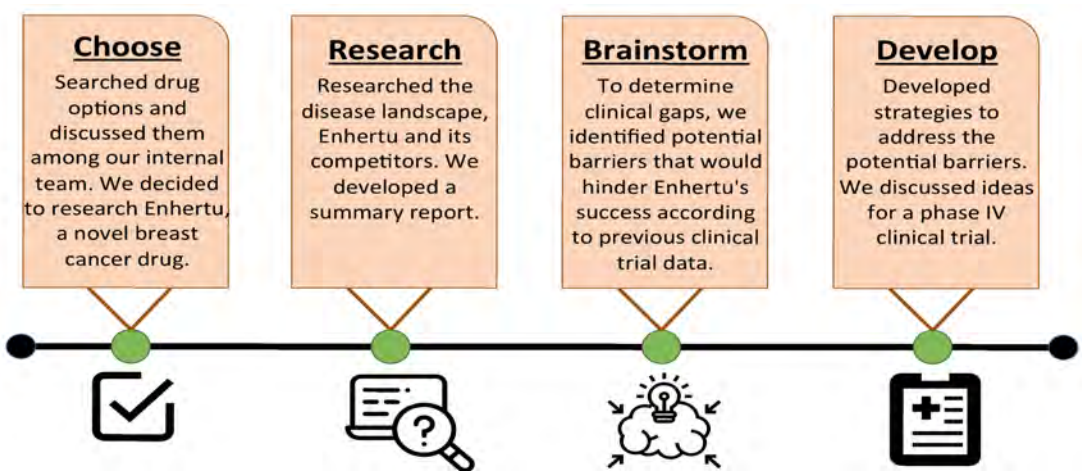
Methods: First, we assessed the disease and drug landscape. We compared pivotal trial data of Enhertu® with that of current HER2-targeted therapies, and identified the clinical barriers of Enhertu®, which included a less favorable safety profile. Next, we proposed the incidence of Interstitial Lung Disease (ILD) as a significant barrier to overcome in order to improve results of patients receiving Enhertu®. To explore possible approaches that would mitigate ILD, we brainstormed different clinical trial ideas and analyzed their benefits from a medical affairs perspective.

Results: We propose a Phase IV longitudinal surveillance study to identify risk factors for Enhertu®-induced ILD (Deliverable 1). We also provide a general strategic summary on Enhertu® (Deliverable 2).

Resources: Phase I/II trial data, Phase III trial design, conference presentation poster, general Phase IV trial protocols, public health and epidemiological articles

Key Challenges: Lack of Phase III and incomplete Phase II trial data forced us to make several assumptions when evaluating clinical gaps. Working with a new drug like Enhertu® highlighted the importance of dynamic re-assessment since new clinical trials were being announced throughout our project duration. Also, new data from current clinical trials will likely be made available, which will warrant a re-assessment of unmet needs.

Key Findings: Careful study of the design of ongoing clinical trials can reveal a wealth of information and the underlining logic of the studies. Thorough analyses of unmet needs and insight collection by the medical affairs team are critical in designing strong clinical research questions that are worthwhile to the drug sponsor and meaningful to the patient population.



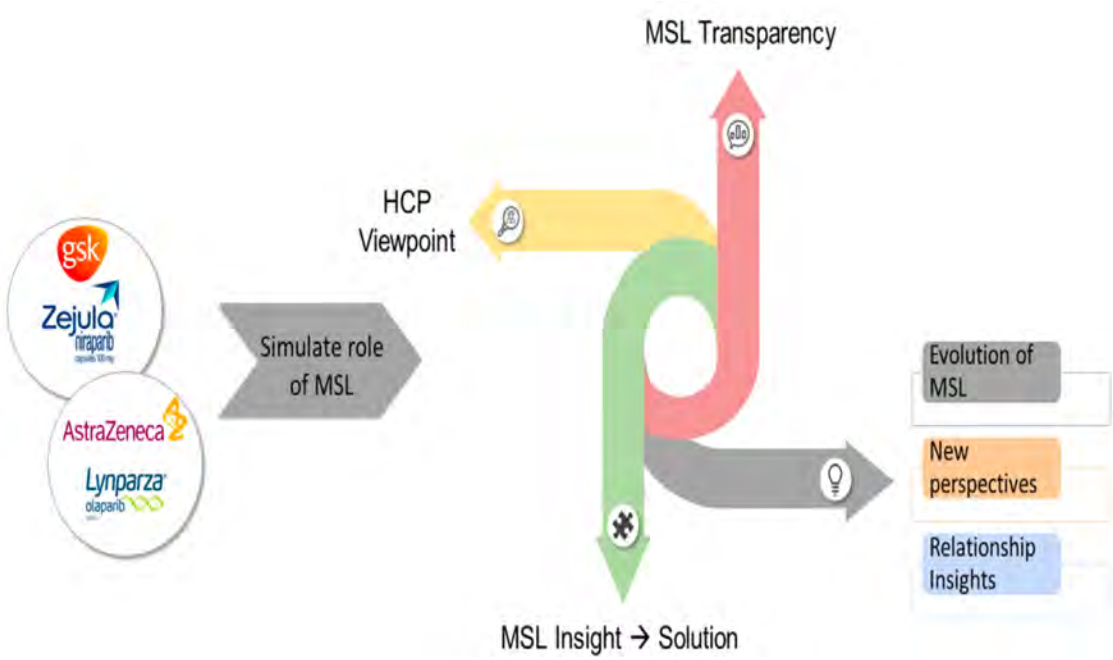
Navigating the MSL role with multiple PARP inhibitors

Corey Lourenco, Helal Endisha, Clare Sheen, Marie-Eve Di Raddo

Medical Science Liaisons (MSLs) are front-facing representatives of pharmaceutical companies that build relationships with a network of healthcare professionals (HCPs) and key opinion leaders (KOLs). As scientific experts, MSLs are expected to have a high level of knowledge on clinically important drugs relevant to their therapeutic area and employer. However, there often exists multiple competing therapeutic products that clinicians can prescribe to their patients. It is likely that each therapy has unique clinical benefits, thus as an MSL, is it possible to maintain objectivity and scientific integrity when representing one therapy over another?

The recent approvals of multiple PARP inhibitors (PARPi) in Canada are an excellent case study to examine this situation. AstraZeneca's Lynparza® (olaparib) was approved in 2016 for BRCAmut ovarian cancer patients who had complete or partial-response to platinum-based chemotherapy. This treatment is now established in treatment guidelines, is effective, and has built trust with clinicians since its approval. More recently, in 2019, GSK's PARPi Zejula® (niraparib) was also approved for the same indication. However, Zejula® was also shown to benefit patients without BRCAmut, indicating that a wider proportion of ovarian cancer patients could benefit from treatment. In this competitive landscape, how should an MSL from either company represent their drug in an unbiased manner in order to benefit patient health?

To help answer these questions, we spoke to 3 HCPs for their perspectives on how MSLs could communicate about competitive drug data and furthermore, what qualities they have identified as being necessary for a great MSL. We also gained insights on the current landscape of PARPi and how they may be used in the future. Following those discussions, we spoke with 2 Medical Affairs professionals to understand how we could turn our insights into action, as well as help establish proper guidelines for MSLs representing therapeutics in a competitive market. Overall, we learned that regardless of which PARPi an MSL is representing, the real focus is to cultivate a synergistic relationship with HCPs and KOLs to promote information sharing so that the best possible clinical and research decisions can be made for patient healthcare.



Ofatumumab in Multiple Sclerosis (MS): A medical education strategy for physicians

Keith Colaco, Sean Harrington, Meghan Wing, Pamela Xu

The aim of our project was to learn and apply our knowledge of Medical Affairs through the creation of a medical education (Med Ed) programme. As none of our group members were familiar with the field of multiple sclerosis (MS), we chose to simulate this program using the drug Ofatumumab (Arzerra®), an anti-CD20 antibody used for the treatment of relapse-remitting multiple sclerosis (RRMS).

Group members learned and studied the Innovative Medicines Canada (IMC) code of ethical practice - a set of guidelines that are used by a number of Canadian pharmaceutical companies. Through this, we realized the programme material can't be promotional and must be informative, balanced, and highlight unmet medical needs. Additionally, we learned that Med Ed/Science communications specialists will often work cross-functionally with Medical Science Liaisons (MSLs) to identify the content for these programmes. As such, our group members also consulted an MSL in the neurology space to develop a needs assessment questionnaire designed for key opinion leaders (KOLs) in the MS space.

While the original intent was to disseminate this survey to various KOL connections, COVID-19 prevented this from happening. Instead, for educational purposes, a number of Medical Affairs professionals at a pharmaceutical compnay completed our survey. From this, we identified that the unique challenge presented by COVID-19 and its effect on individuals with MS was of high importance to our survey respondents (Figure 1). Additionally, respondents identified the mechanism by which they prefer receiving a medical education programme, which allowed us to determine that the final programme should be available online (to meet physical distancing guidelines), in a lecture format, while presenting the information in as little time as possible (due to the increased demand for physician's time during this period). This resulted in group members synthesizing research from a number of reputable sources in the neurology/MS space, to be organized into an educational powerpoint programme for neurologists in the MS space.

Overall, group members gained a vast amount of knowledge in the field of MS, knowledge and application of the IMC code, experience working cross-functionally when developing various deliverables, experience creating and assessing both a needs assessment questionnaire (a tool which we have gathered is highly used in the Med Affairs space) and making evidence- and data- driven decisions when developing these programmes. Figure 2 shows a visual representation of the workflow of this project, as well as key resources that were utilized throughout.

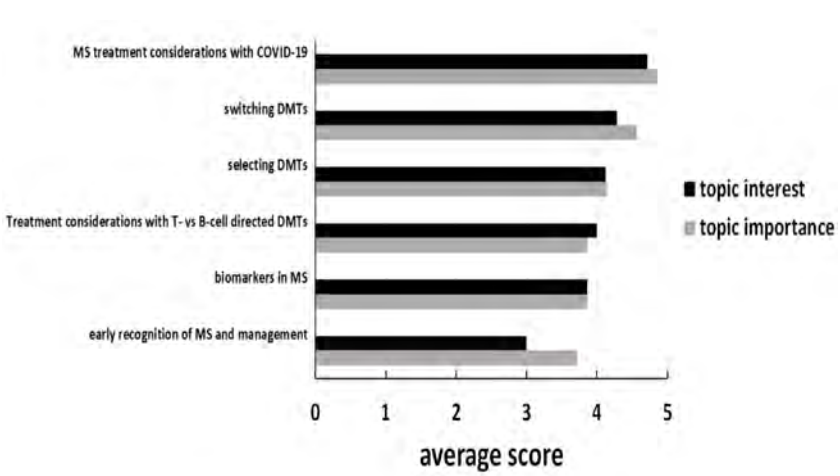
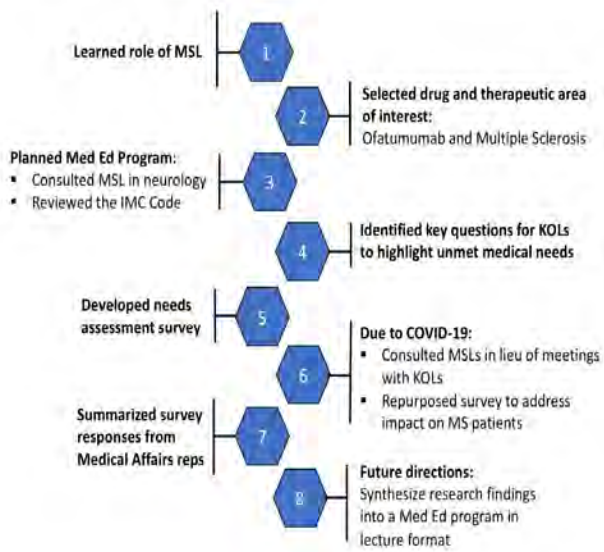


Figure 1. Summary of Mini-Needs Assessment Topic Interest Survey



A situational analysis of monoclonal immunotherapy Atezolizumab for the treatment of triple-negative breast cancer (TNBC)

Zaman Afrasiabi, Gilberto Li Feng, HoYin Lip, William Scott

Introduction: Breast cancer is the most commonly diagnosed cancer in women in Canada, accounting for 25% of all newly diagnosed cancers, and the second leading cause of cancer death in 2019. Triple-negative breast cancer (TNBC), accounting for 12–17% of all breast cancers, is a highly aggressive and metastatic subtype and is associated with the shortest disease-free survival. Due to the lack of druggable targets, chemotherapy and radiation therapy are the current standard-of-care treatment. Unfortunately, after an initial response to therapies, the cancer inevitably relapses. Recently, immunotherapy has emerged as a treatment strategy for breast cancer, specifically TNBC since it is actively engaged by the immune system. Compared to other monoclonal antibodies such as anti-angiogenic anti-VEGF monotherapy, anti-PD-L1/PD-1 monotherapy has demonstrated improved overall survival. Currently, the monoclonal antibodies atezolizumab (anti-PD-L1), pembrolizumab (anti-PD-1), and bevacizumab (anti-VEGF) are under clinical investigation to treat TNBC.

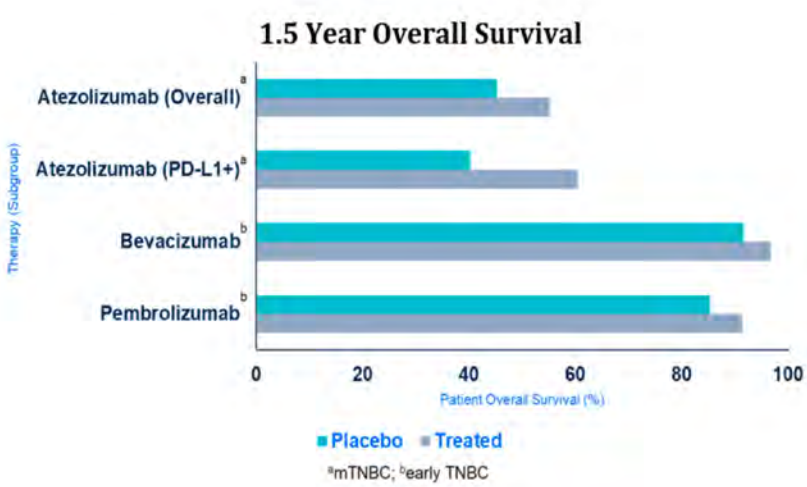
Project Aim: The aim of our project was to conduct a situational analysis of atezolizumab compared to other monoclonal antibodies. This was broken down into the following step-by-step aims: (1) investigate the therapeutic landscape for TNBC patients, (2) conduct a SWOT (strengths, weaknesses, opportunities, and threats) analysis of atezolizumab against other similar agents, and (3) provide a recommendation regarding the termination or continuation of ongoing clinical trials.

Results: The strengths of atezolizumab include improving the overall survival of advanced TNBC patients, having a good safety profile, targeting a subgroup of TNBC patients with a higher chance of responding, and addressing a narrow therapeutic area— metastatic TNBC (mTNBC).
Weaknesses include drug interactions, being unsuitable for immunocompromised individuals, drug resistance, and other factors that can affect the response to PD-L1 immunotherapies, such as high tumour mutational burden & T-cell inflamed gene expression profile. Opportunities include an emerging market, demographics, and clinical trial design. Threats include the competitor market and government policies.

Conclusion: Atezolizumab has shown promising results with treating the intended target population while maintaining a good safety profile compared to other antibodies. Atezolizumab clinical trials for mTNBC should be completed and the drug should be brought to market to treat mTNBC. Atezolizumab clinical trials for operable TNBC should also continue.

SWOT Analysis of Atezolizumab for TNBC

Strengths	Weaknesses
-Improved OS -Targets TNBC subgroup -Predicted toxic effects/ safety profile -Addresses narrow therapeutic area -Company experienced in mAb cancer therapy	-Response dependent on other factors -Drug interactions -Not suitable for immunocompromised patients -Drug resistance
Opportunities	**Threats**
-Emerging market -Demographics -Competitors & market share -Clinical trial design	- Competitor market - Policy



Medical education strategy: Rybelsus® for type 2 diabetes

Alaa Alsaafin, Avery Brydon, Lauren LeMay-Nedjelski, Mila Mirecta

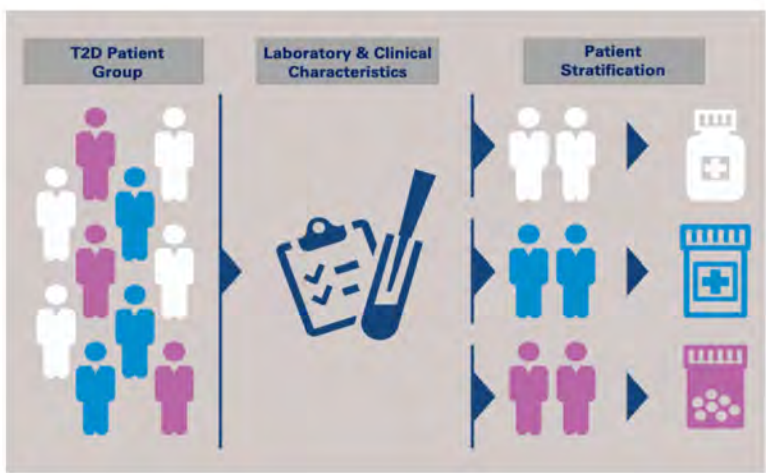
Background: Type 2 diabetes (T2D) affects millions of Canadians, and its rising prevalence, as well as lack of individualized treatment strategies, highlights the importance of education in this field. Low patient adherence to treatments continues to be a barrier, especially as patients often take several medications concurrently, including oral tablets and injectables, in an effort to maintain tighter glycemic control. Rybelsus® (semaglutide; Novo Nordisk), the first oral GLP-1 receptor analogue (RA) on the market, has been approved by Health Canada* for the treatment of T2D. Rybelsus® aims to fulfill a current unmet need in the T2D landscape, increase patient adherence, improve both short- and long-term clinical outcomes, and enhance quality of life.

Rationale: T2D is a heterogeneous disease that requires personalized treatment regimens based on specific laboratory and clinical characteristics of each patient to mitigate their risk of future complications. A recent study published in The Lancet (Diabetes and Endocrinology) by Ahlqvist et al. (2018) focused on this heterogeneity in patients with T2D and identified five novel subgroups within T2D. It is suggested that this new sub-stratification may help to tailor treatment regimens for patients and represent a step towards precision medicine in T2D.

Objective: Develop a multi-pronged medical education strategy to educate primary care physicians, endocrinologists, and RN diabetes educators within the University Health Network (UHN) regarding this novel stratification approach for patients with T2D and the use of Rybelsus® and other therapeutics in each strata.

Deliverables: The three medical education methods of delivery will include 1) one-on-one interactions between medical science liaisons and HCPs, 2) Novo Nordisk's presence at national diabetes conferences, and 3) a non-accredited medical education webinar within a large online conference series available for on-demand viewing. This patient- focused medical education webinar will detail the findings of the Ahlqvist et al. (2018) paper and define optimal treatments based on strata characteristics, which will include information about Rybelsus®. This medical education strategy will educate HCPs regarding the use of this novel GLP-1 RA, address a learning gap in the medical sciences community, and help improve the treatment and management of T2D today.

*While the product has been approved by the FDA and not yet by Health Canada, we are stating it has been for the purposes of our presentation.



Padcev™: a mUCh needed treatment

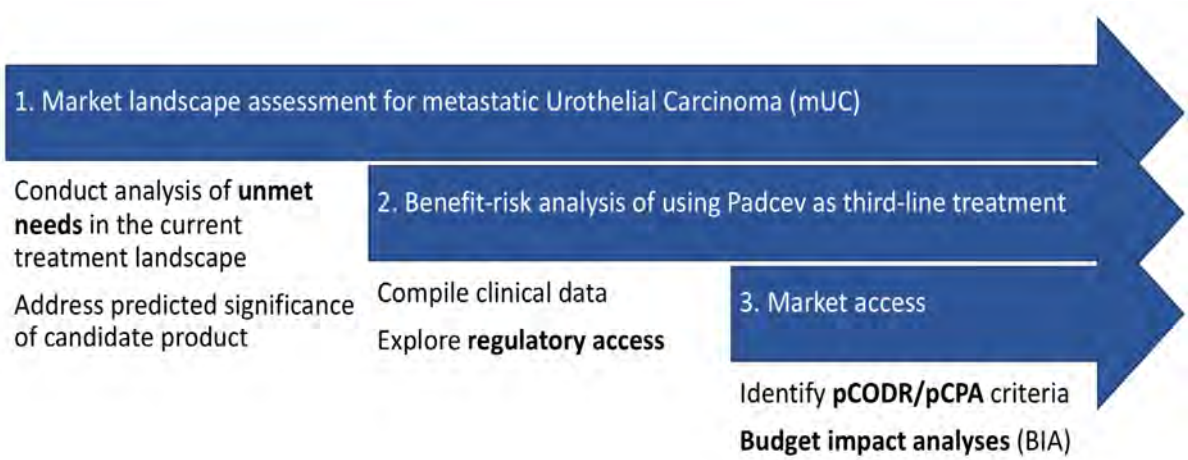
Daniel Wang, Alice Xue, Anthony Ku, Shruthi Venugopal

Bladder cancer represents the fifth most common type of cancer in Canada, of which urothelial carcinoma (UC) accounts for over 90% of all cases. Patients with metastatic UC (mUC) have poor prognosis, with 5-year survival rates as low as 5%. Given the high prevalence of bladder cancer among Canadians, and its status as the most expensive type of cancer to treat, there is an urgent need for new innovations to bring better treatment options to UC patients. Padcev™ (Enfortumab vedotin), developed by Astellas Pharma USA in collaboration with Seattle Genetics, is a breakthrough antibody-drug conjugate that has shown strong clinical potential, with no direct competitors as a third-line treatment strategy.

We represent the regulatory affairs and market access strategy team at Astellas Pharma Canada, proposing to obtain Padcev™ approval from Health Canada and negotiate a subsequent launch into the Canadian mUC treatment market.

First, we conducted a market landscape assessment to identify unmet needs in the target population and to characterize existing competitors for Padcev™. Our goal was to request an expedited regulatory assessment of Padcev™ by Health Canada based on the drug's superior safety profile and clinical efficacy, thus far demonstrating a 44% overall response rate in phase II clinical trials. We next simulated a health technology assessment for Padcev™, identifying and addressing key criteria for reimbursement including relevant patient-related and clinical factors, alongside cost-effectiveness metrics. We then proposed a price negotiations strategy for Padcev™ with a focus on pharmacoeconomics, funding risk mitigation and patient input. Finally, we performed a budget impact analysis (BIA) to illustrate the financial consequences of bringing Padcev™ into the mUC treatment market.

Our BIA projects the introduction of Padcev™ will result in an increase in annual drug budget of up to a total of $41.6 million over the course of three years, and it can enhance survival up to 339 patients per year. Overall, based on favourable clinical evidence and the urgent need for novel mUC therapies in the third-line setting, we anticipate that Padcev™ would successfully obtain conditional regulatory and reimbursement approval. For subsequent price negotiations, we advise on proposing a market rate for Padcev™ as part of an outcomes-based contract.



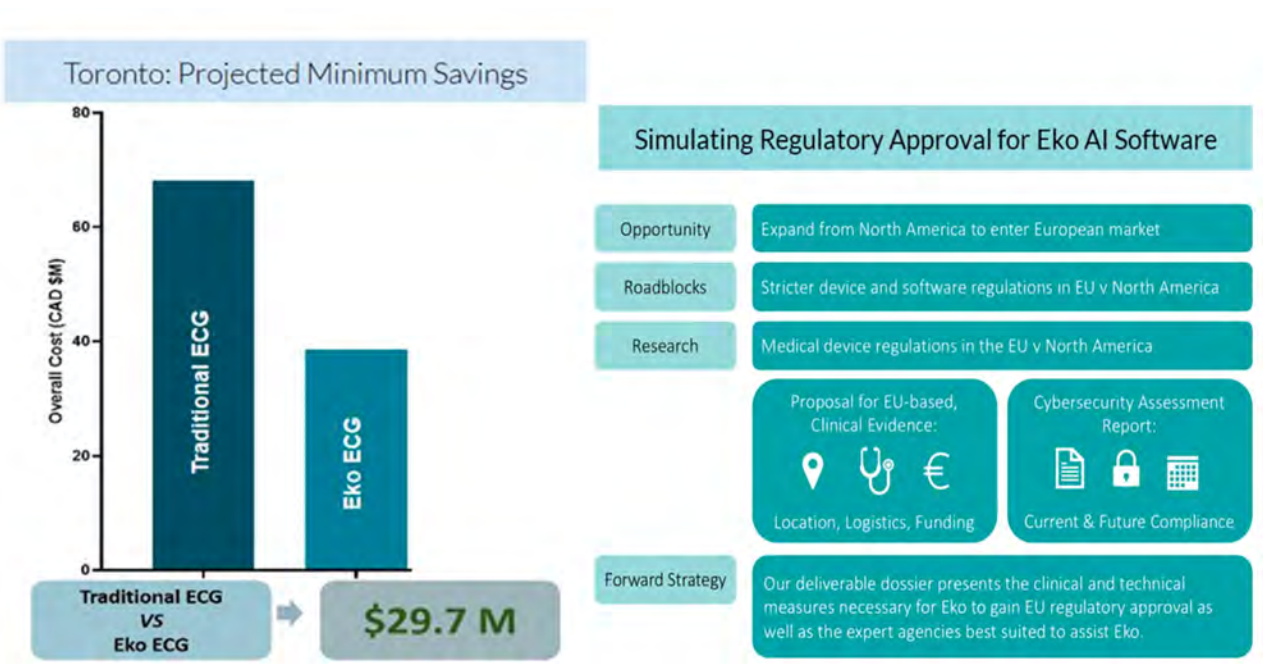
Innovation in heart health by Eko Duo®

Navkiran Verma, Anusha Ratneswaran, Bushra Yusuf, Ernesto Ramos

Eko Duo® and AI, is an electronic stethoscope and one lead ECG paired with artificial intelligence which has been developed through a partnership with the Mayo Clinic. It measures auscultation (heart sounds), as well as ECG signals, and currently has US FDA approval. It is capable of detecting heart failure through specialized algorithms with greater sensitivity and specificity than physicians. It is simple to use with recording and analysis by the AI taking a total of 15 seconds. Results can also be shared with other health-care practitioners for seamless patient monitoring, remote care, and second opinions.

Our goals were to commercialize Eko Duo® in the Canadian market as well as obtain regulatory approval in Europe. We conducted a consumer engagement survey to assess interest in the product, quantified the time and money Eko Duo® could save patients and GPs as well as the money it could save the healthcare system, and predicted gross revenue in Canada based on different models of sales strategy and uptake. We found that medical students and physicians were interested in Eko Duo®, but unsure about integration into practice. We also found that Eko Duo® implementation would save approximately 70 hours per test, and could save up to 30 million dollars in Ontario, and the company could make between $1-6 million dollars in the first year.

Eko Duo® is in prime position to obtain EU regulatory approval for its AI software due to existing connection to an established notified body and up-to-date cybersecurity practices in line with EU recommendations. However, further outstanding EU requirements necessitate the involvement of European clinical and technical experts. Accordingly, we focused on these challenges for Eko Duo® AI software approval. Firstly, we designed an EU-based study to satisfy the requirement of clinical evidence for Eko Duo® AI software. Secondly, we compiled a cybersecurity report to compare the cybersecurity standards that Eko Duo® currently aligns with to those required by the EU. Our research also identified legislative factors that would make an EU data server necessary in the future and proposed a proactive server strategy.



Regulatory feasibility assesment for FARYDAK® market authorization in Canada

Hyeyeon Kim, Bei Yan, Christina Schiza, Maisha Syed

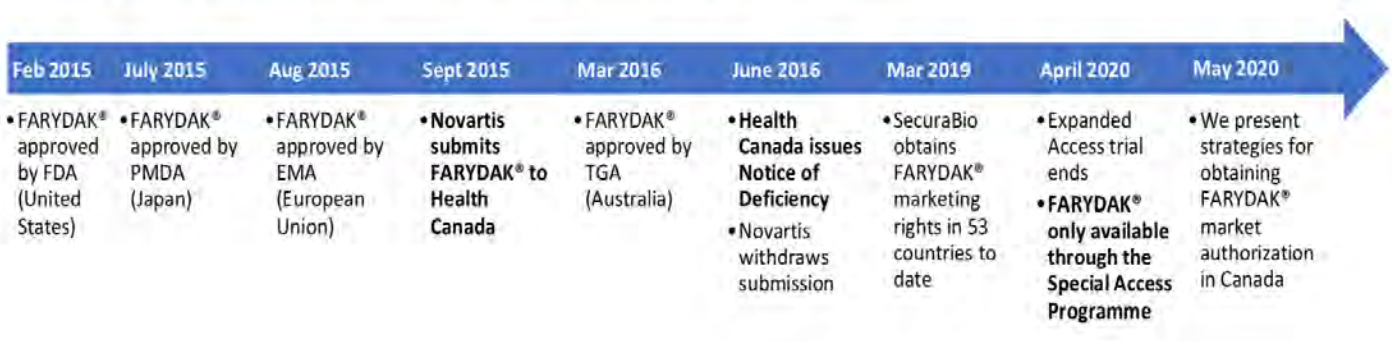
Multiple myeloma (MM) is the second most common blood cancer with about 3,000 cases diagnosed in Canada annually. Despite the availability of treatments including immunomodulatory drugs (IMiDs) and proteasome inhibitors (PIs), MM remains incurable, as most patients relapse and/or become refractory to treatment. FARYDAK® (panobinostat) is a drug with a novel mechanism of action. FARYDAK® received market authorization by the FDA in February 2015, followed by other jurisdictions in 2016. However, Health Canada identified major deficiencies, as the proposed indication was not sufficiently supported by clinical data, resulting in submission withdrawal by the sponsor.

Our team simulated the role of Regulatory Affairs advisors at Secura Bio, as we explored the deficiencies in the previous FARYDAK® submission and made recommendations to facilitate market authorization in Canada. First, we reviewed reports generated by regulatory authorities upon the approval of FARYDAK®. We identified all registered clinical studies and evaluated safety and efficacy data. We then explored the treatment landscape for relapsed/refractory MM and performed a comparative analysis between FARYDAK® and five existing MM therapies, to identify the specific patient group with the most positive benefit/risk balance for FARYDAK®.

We identified that FARYDAK® significantly increased the progression free survival of MM patients. Compared to other therapies, FARYDAK® is less expensive, is conveniently administered, and serves as an alternative option by targeting a novel pathway. However, FARYDAK® induces grade 3/4 adverse events in most patients, which may lead to the deterioration of quality of life and increased death rates. Notably, the effect of FARYDAK® on overall survival was not statistically significant. Based on these assessments, we recommend FARYDAK® for a subgroup of MM patients who have relapsed or become refractory after at least 2 lines of therapy, including Bortezomib and IMiD drugs. These patients have a poor prospect for a cure, thus the benefit of FARYDAK® may outweigh the risks.

We propose two approaches to achieve market authorization in Canada. A cost-effective approach includes the assessment of post-marketing data in a retrospective Phase 4 trial to validate the safety and efficacy of FARYDAK® in authorized jurisdictions. Additionally, a supplementary Phase 3 trial should be conducted to support the proposed indication, with a focused recruitment of the subgroup of MM patients as stated above. Phase 3 trials are expensive and time-consuming, however, they remain the most ideal approach to confirm drug efficacy in the target subgroup and improve approval success rate by Health Canada.

Figure 1. A Timeline of the FARYDAK® Regulatory Approval Process



This project was completed by Trainees through ITCS (LSCDS, University of Toronto). Trademarks are property of their respective owners.

Gilotrif® in USA: three pronged strategy

Zoey Li, Julie Marocha, Varun Balaji, Aravind Rajendran

Our team learned about the role of a Life Science Consultant. Our project focused on devising a strategy to increase the sales of a therapeutic drug: Gilotrif® by Boehringer Ingelheim.

This drug treats for non-small cell lung cancer (NSCLC) and is a tailored therapy for patients with somatic EGFR genetic mutations. In order to effectively market Gilotrif®, we conducted a competitor analysis, identifying the advantages and disadvantages of the drug, including the safety, efficacy, indications, and price. Given that Gilotrif® is the only therapeutic drug approved for three rare EGFR mutations, in addition to other common mutations, it fulfills a unique unmet need in the treatment of patients with these mutations. We found that the rate of NSCLC EGFR mutations is highest among the East Asian population (up to 50%) compared to the population worldwide (10-20%).

As a pilot, we devised three strategies to increase the sales of Gilotrif® in the United States, a market whose healthcare system is well-understood. Our first strategy involves increasing physician education to spread awareness of EGFR-related NSCLC and its treatment. Our second strategy involves developing a physician-facing app to increase diagnosis of EGFR mutations among NSCLC patients. Our third strategy involves increasing awareness of the Gilotrif® brand among Chinese-Americans through a social media platform called WeChat. In conclusion, we think utilizing the three-pronged strategy would enable us to increase the sales of our drug, Gilotrif® in the US.

Lastly, our key challenges during this project were coordinating the team, being able to price a drug, as drugs on the market are already priced, and being unable to launch our strategies overseas since a pilot study in the U.S. would inform strategies abroad.

Budget impact analysis: five year reiumbursement costs to the Ontario drug benefit program

Chris Ondersin, Alisa Ugodnikov, Christy Yeung, Xiaoyan Chen

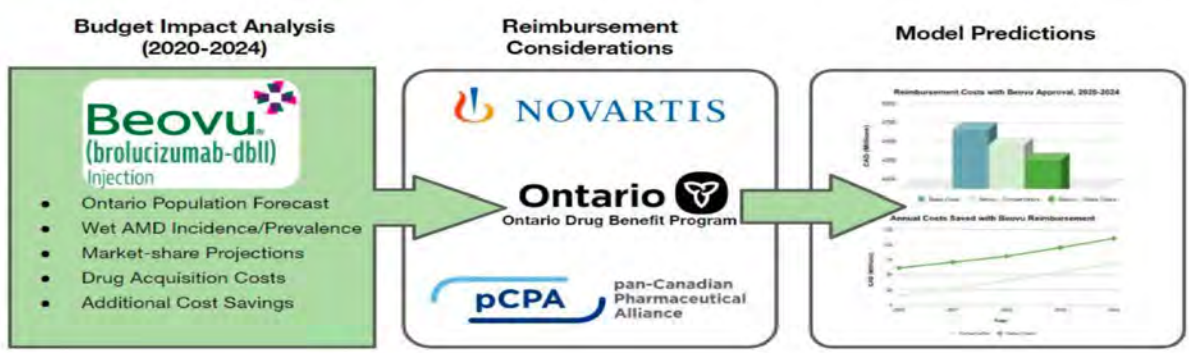
Background: Wet Age-Related Macular Degeneration (Wet-AMD) is a form of progressive vision loss caused by leakage of fluid into the central retina. The current drugs available for treatment are Lucentis® (Novartis) and Eylea® (Bayer, Regeneron). Beovu® is a newly FDA-approved treatment for wet AMD developed by Novartis, and is poised to enter the Canadian retinal anti-VEGF market, which exceeds $456 million.

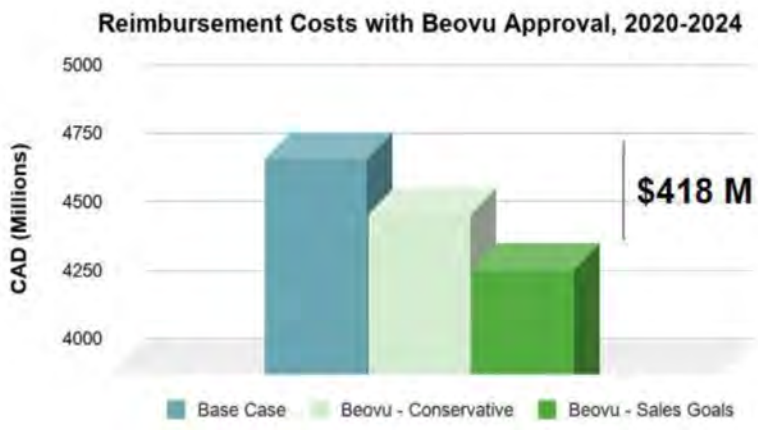
Objective: To determine the budgetary impact for public reimbursement of Beovu® by the Ontario Drug Benefit (ODB) program over a 5-year period, 2020 - 2024.

Approach: A budget impact analysis (BIA) model was developed, which compares the budget impact of introducing Beovu as a publicly reimbursed option for wet AMD treatment, vs. a base case scenario, where Lucentis® & Eylea® remain the only drugs reimbursed. The analysis took into consideration patient population, market share, drug acquisition costs, and additional costs.

Outcome: Following the assessment of these inputs, a conservative market share estimate put total costs saved at $206 million between 2020-2024. Using a sales goals market share estimate, the BIA indicated that the ODB would realize cost savings of up to $418 million over this same 5-year period.

Recommendation: Ontario Drug Benefit (ODB) program cover Beovu® with limited use authorization period of 1 year, renewable each year.





This project was completed by Trainees through ITCS (LSCDS, University of Toronto). Trademarks are property of their respective owners.

IBSRELA® commercialization strategy

Ryan Smith, Stephanie Tran, Laura Campbell, Dory Abelman

Irritable bowel syndrome with constipation (IBS-C) affects 1.2 million Canadians and is a highly costly disease. Individuals with IBS-C spend upwards of $150 per month on treatments and often miss work due to pain, cramping, and constipation. Accordingly, IBS-C in Canada has a direct cost of $56 million per province per year, and an indirect cost of approximately $500 million per year. Despite its impact on both Canadians and the economy, 80% of IBS-C patients remain underserved by current options available to manage their symptoms.

IBSRELA® (tenapanor) by Ardelyx is a first-in-class NHE3 transporter inhibitor recently approved by the FDA for IBS-C symptom management. It prevents dietary sodium uptake to reverse osmotic flow into the intestinal lumen, softening and reducing stool transit time.

Given the economic importance of effective IBS-C management in Canada, our team wondered if it would be viable to commercialize IBSRELA® in Canada. To address this, our team assessed three factors that would ensure the commercial success of IBSRELA® in Canada: IBSRELA®'s position relative to its competitors, its ability to be publicly listed, and whether IBSRELA® could generate substantial revenue.

We first demonstrate IBSRELA® has superior clinical effectiveness, relative to its competitors currently in the Canadian market, with 37% of patients reaching clinical trial endpoints versus 34% from Constella® (Linaclotide) treatment and 25% from Resotran® (Prucalopride) treatment. Next, our team investigated the process to be listed on public insurance plans in Canada to determine whether IBSRELA® could be accessible to a large number of Canadians. While Constella® and Resotran® failed their bid to be publicly listed due to a poor incremental cost effectiveness ratio and weak clinical support, IBSRELA® can propose lower prices for its product to overcome these challenges. Finally, our team created a number of revenue projections for sales of IBSRELA® in Canada. Our most conservative estimates suggest IBSRELA® will generate over $100 million in revenue if it reaches its entire potential market. Our most bold estimates put the revenue at over $1 billion dollars, provided IBSRELA® establishes a dominant position in the market.

Collectively, our analyses demonstrate that IBSRELA® is in a superior clinical position relative to its competition, and with a carefully defined pricing scheme, it can access a large portion of the Canadian IBS-C population, leading to high revenue generating potential. Accordingly, our team believes that IBSRELA®'s entry in the Canadian market will be profitable and help improve the lives of Canadians.

GETTING INVOLVED

ITCs
Industry Team Case Study

JOIN THE TEAM

If you are a trainee and want to take a leadership role in the 2021 program, join the executive team. Recruitment for the incoming ITCS executive team will occur summer-fall 2020.

BECOME AN ADVISOR

We are always looking for industry professionals to volunteer as Advisors. If you or any of your colleagues would like to participate as an Advisor, please email the ITCS team.

BECOME A TRAINEE

If you are interested in participating in the program as a Trainee, please look out for information November 2020.

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

STAY IN TOUCH!

e: casestudy@lscds.org
w: https://lscds.org/events/industry-team-case-study/

THANK YOU

ITCs
Industry Team
Case Study

Now in its 5th year, the 2020 ITCS program continues to deliver meaningful development experiences to prepare life science trainees for the industry job market. This year, more than 140 students expressed interest in the program, and 48 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 team is grateful for the dedication demonstrated by participants in seeing their case study projects through to completion despite the challenges that COVID-19 has imposed. Their efforts are well-represented in the quality of work showcased in this report. We hope that the experience and knowledge participants gained will help them as they pursue careers in industry.

This program would not have been possible without the generosity and commitment of our Industry Advisors. We hope this has been an enriching experience for them, and we look forward to continuing to engage industry professionals in the coming years.

Thank you to the generosity of our spoansors, Centre for Community Partnerships and Graduate Life Science & Education at the University of Toronto, who made it possible to run this program.

We are looking forward to welcoming the next cohort of participants in 2021!

~2020 ITCS Executive Team

LSCDS
LIFE SCIENCES CAREER DEVELOPMENT SOCIETY

UNIVERSITY OF TORONTO
FACULTY OF MEDICINE
Graduate and Life Sciences Education

STUDENT LIFE
Centre for Community Partnerships