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| **Applications will be accepted from:** [ ]  Both MD & non-MD Undergraduates [x]  MD undergraduate students only [ ]  non-MD undergraduate students only |
| **Project Duration:** [ ]  Suitable for either a 4 or 8 week project (Only Yr 3 MD students are eligible to apply for 4-week projects) [x]  Only suitable for an 8-week project [ ]  Only suitable for a 4-week project  |
| **Additional information for potential student partners:** Please send an updated CV with your expression of interest. Please include prior experience performing statistical analysis in R or other statistical programs.      |

## PROJECT INFORMATION

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| **Project Title:** Real-worldimpact of elexacaftor/tezacaftor/ivacaftor (Trikafta) on medication adherence and respiratory outcomes in adults with cystic fibrosis       |
| **Hypothesis or Research Question being addressed (400 character limit, ~55 words):** Among adults with cystic fibrosis, does initiation of ELX/TEZ/IVA therapy lead to changes in medication adherence and does this influence pulmonary outcomes following one year of treatment?      |
| **Keywords:** **Provide approximately 5 key words that describe the proposed research project.** Cystic fibrosis, CFTR modulator, medication adherence, lung function, pulmonary exacerbations  |

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| **Project Attributes and Benefit to the Student**Please review the [online adjudication criteria](http://www.med.ubc.ca/current-learners/summer-student-research-program/adjudication/) carefully prior to completing the next two sections to ensure your application is addressing the adjudication criteria outlined in “Project Attributes and Benefits to the Student”. |
| **A) Background and Summary of Proposed Research. Summarize the proposed project including the rationale for the project, the context within the relevant field of research, the proposed research approach and the expected project outcomes.** *If this is an ongoing project of >8 weeks duration (or 4 weeks for MD 2022 students) clearly distinguish the expected project outcomes at the end of the FoM SSRP funding period from the overall project objectives.* **Please write in lay terms for a non-specialist audience.** **Character Limit: 3050 characters (~430 words)**     **Background**: Cystic fibrosis (CF) is a genetic disorder caused by mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene which results in disturbances in CFTR protein activity. The disease affects multiple organ systems but primarily affects the lungs and pancreas. CFTR modulators are drugs that increase CFTR activity, thus treating the disease at its root. The most recent modulator therapy, elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA; ETI), has been shown to significantly improve patients’ disease outcomes in clinical trials. **Rationale:** A prior pilot study (n=20) conducted by our research team demonstrated that CF patients with more advanced lung disease who accessed ETI via a compassionate access program (before Health Canada approval) stopped some or all of their nebulized maintenance therapies (e.g. nebulized antibiotics, nebulized mucolytics) following the initiation of ETI due to its dramatic effectiveness, despite encouragement from the CF care team to continue with all standard of care therapies. ETI has since been approved by Health Canada for use in all patients >= 6 years old with the F508del mutation. By the summer of 2023, 150 CF patients followed at the St. Paul’s Hospital Adult CF Clinic will have received treatment for 1 year. The primary objective of this study is to evaluate how ETI initiation impacts adult CF patients’ use of other nebulized maintenance therapies across a wider range of lung disease and to examine its impact on respiratory outcomes at 1 year. **Approach:** During the funding period, a retrospective chart review of ~150 patients who have received at least 1 year of ETI at the St. Paul’s Adult CF Clinic will be performed. The following data has been collected pre and post ETI initiation as part of routine care: medication refills and pulmonary outcomes. First, the student (TS) will compare changes in the number and frequency of nebulized medications refilled 1-year pre vs. post ETI initiation. Approximately 10% of CF patients are not eligible for ETI and they will be included as a control group. Next, TS will compare lung function and pulmonary exacerbation events following 52 weeks of ETI in patients who do vs. do not remain adherent to their other nebulized maintenance therapies. Near the end of the SSRP period, TS will begin manuscript writing and present their findings at the Centre for Heart Lung Innovation (HLI) Summer Student Research Day.**Expected Outcomes:** The present study will to add to the growing body of evidence on the real-world effects of ETI, and will provide new insights on how medication adherence to other previously relied upon nebulized maintenance therapies impact post-ETI pulmonary outcomes among adults with CF. |
| **B) Outline the student’s role in the project and describe how they will benefit from their involvement.** This section must address how involvement in this project will help the student gain an understanding of how high quality research is conducted. This includes addressing the opportunities to learn new skills in the context of the relevant learning objectives listed in the [adjudication criteria](http://www.med.ubc.ca/current-learners/summer-student-research-program/adjudication/); their anticipated interactions with other researchers and the available resources that will contribute to a beneficial experience.*Clearly indicate which items will be completed during the FoM SSRP funding period and which (if applicable) will be completed before or after the funding period if the student and supervisor have chosen to also work together outside of the funding period. Project feasibility is considered during the adjudication process; 4-week and 8-week projects will be adjudicated separately, with appropriate consideration given to each.***Character Limit: 3800 characters (~540 words)**The student (TS) will be involved in this project from start to finish. TS will conduct a literature review to briefly summarize the literature in order to place the current research within the context of existing work. TS will critically review the literature throughout the project to keep up to date with new knowledge on the effects of ETI, CF medication adherence, treatment burden, and other relevant topics. TS will review various statistical analysis methods and will develop a statistical analysis plan with the help of a PhD student in the supervisor’s lab.In the 6 weeks before the SSRP funding period, and once ethical approval is obtained, TS will receive appropriate training on working with patient information and obtain the necessary approvals to access patient chart data remotely. TS will have the opportunity to organize the collected clinical data in a way that will facilitate statistical analysis. During the SSRP period, TS will be involved in data analysis and begin manuscript writing. After the funding period, TS will finish any uncompleted research activities and continue to draft the manuscript. Throughout the entire research process, TS will receive support and guidance from the members of the study team: the supervisor, the PhD student, and the CF pharmacist. TS will have access to resources required for conducting research activities outlined above and have regular and timely communication via email and/or zoom with the study team. TS will have access to all seminars and training sessions (e.g. ethics, presentation skills, manuscript writing) offered to summer students based at the Centre for Heart Lung Innovation.In addition to learning how to conduct high-quality research, TS will also benefit from learning more about the complex and multi-disciplinary nature of CF care, the pharmacology of CFTR-modulator therapies, how to interpret lab values (spirometry, sputum microbiology, sweat chloride etc), become familiar with different medications used in CF care, and the impacts of ETI on CF patients’ lives. The concurrent clinical exposure will allow TS to link classroom knowledge with actual practice. TS will also get the chance to learn about ethical research practices, and the process of novel treatment research, review and approval. In summary, this research experience will allow TS to meet the following learning objectives:1. Understand all aspects of conducting a retrospective chart review study
2. Understand common statistical analysis methods and be able to interpret statistical data relevant to this study
3. Participate in scientific communication in the form of an abstract presentation and manuscript writing
4. Gain knowledge about CF care and current research in this field.
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| **Please indicate if your project requires the following and indicate their status as appropriate.** This will help clarify the scope of the project for potential student partners. |
| **This project requires ethics approval (human or animal):**[x]  Yes [ ]  NoIf yes please indicate if you:[ ]  Already have approval [x]  Will obtain approval before the SSRP funding period [ ]  Intend for ethics application to be a focus over the funding period\*Please note that as ethics approval can be a lengthy process it is recommended that this be obtained well in advance of the funding period unless the intention is for this activity to form a major part of the FoM SSRP-funded portion of the project.**This project requires access to electronic medical records:**[x]  Yes [ ]  NoIf yes please indicate if you: [ ]  Already have approval [x]  Will obtain approval before the SSRP funding period [ ]  Plan to obtain approval during the SSRP funding period**This project requires operational/institutional approval:**[x]  Yes [ ]  NoIf yes please indicate if you: [ ]  Already have approval [x]  Will obtain approval before the SSRP funding period [ ]  Plan to obtain approval during the SSRP funding period |

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| **Research Location (As applicable, indicate where the project will be conducted.)** |
| City or Region: VancouverResearch Centre: UBC Centre for Heart Lung Innovation      Hospital: St. Paul’s Hospital      Program or Unit: Medicine      Additional information (building, lab etc.):       |
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| **Supervisor’s Information** |
| **Supervisor Last Name:** Quon      | **Supervisor First Name:** Bradley |
| **FoM Department/School (Main FoM Appointment):** Medicine     | **UBC FoM Division (if applicable):**Respirology |
| **Preferred contact method (for students)****[ ]** Phone supervisor**[x]** Email supervisor | **[ ]** Phone alternate contact**[ ]** Email alternate contact |
| **Preferred Phone:** 604-682-2344 (Ext 62762) | **Supervisor Rank (Instructor, Professor etc.):**Associate Professor |
| **E-mail Address:** bradley.quon@hli.ubc.ca |  |
| **Optional Alternate Contact** (e.g. co-supervisor, research/lab coordinator, assistant etc.) |
| **Contact’s Name:**       | **Contact’s Role:**       |
| **Contact’s Phone Number:**      | **Contact’s E-mail Address:**      |