



Case Study

CF CLINICAL TRIAL FINDER



GENETIC THERAPY

Study to evaluate VX-522 in adults 18 years and older with cystic fibrosis VX-522-001 MAD (VX21-522-001)

This study will evaluate the safety and tolerability of VX-522, an investigational inhaled messenger RNA (mRNA) therapy for people with cystic fibrosis whose mutations are not responsive to CFTR modulator therapy. This study is open label, meaning all participants will receive VX-522.

AGE	MUTATION	FEV1 % PREDICTED	NUMBER OF VISITS
18 Years to 65 Years	No Copies F508del	40 to 90%	12

ANTI-INFECTIVE

Study to evaluate the standardizing of treatment for pulmonary exacerbations in children and adults with CF ages 6 and older. | STOP360-IP-22

This study will look at pulmonary exacerbations, which are a worsening of respiratory symptoms, in people with cystic fibrosis who are treated with intravenous (IV) antibiotics. It will compare treatment with one antibiotic (a beta-lactam) to treatment with two antibiotics (tobramycin and a beta-lactam) to learn whether there is a difference in lung function and symptoms between the two groups.

AGE	MUTATION	FEV1 % PREDICTED	NUMBER OF VISITS
6 Years and Older	No Mutation Requirement	No FEV1 limit	3

ANTI-INFLAMMATORY

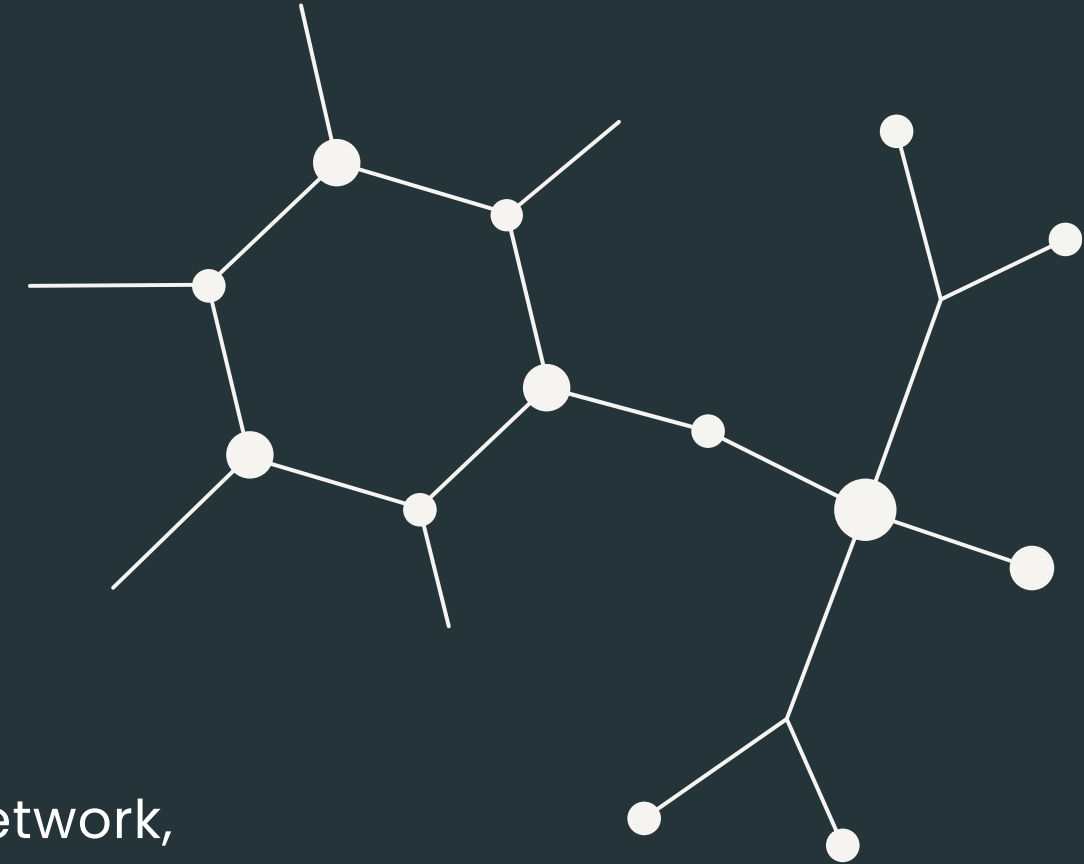
Prednisone in Cystic Fibrosis Pulmonary Exacerbations (PIPE Study)

This study will take place at various sites across Canada. It will examine the use of oral prednisone in patients with cystic fibrosis who are on long-term intravenous antibiotics for a pulmonary exacerbation and who have not returned their baseline pulmonary function at discharge.

AGE	MUTATION	FEV1 % PREDICTED	NUMBER OF VISITS
6 Years and Older	No Mutation Requirement	0 to 100%	0



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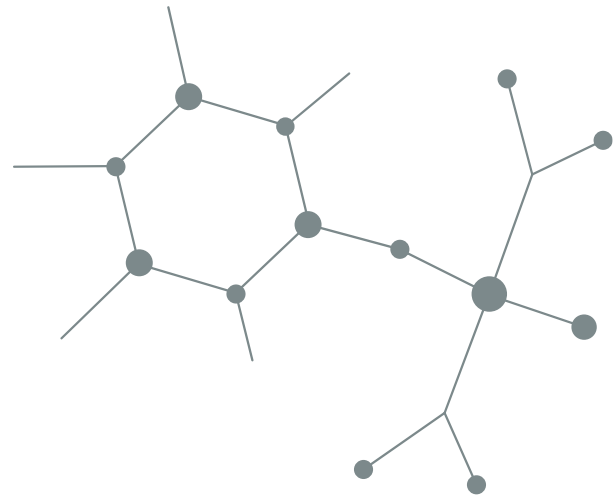
PROJECT BACKGROUND

Cystic Fibrosis Canada has established a Canadian clinical trials network, Cystic Fibrosis Canada Accelerating Clinical Trials (CF CanACT). World-class clinical trials are an integral part of the process that brings new therapeutics and better care to Canadians who are living with cystic fibrosis. The establishment of CF CanACT will help to facilitate the development of these new treatments for cystic fibrosis, as well as increase capacity and enhance participation of people with cystic fibrosis in clinical trials.

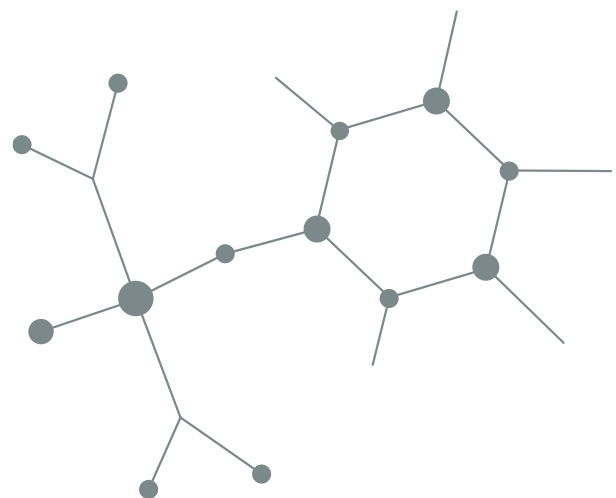
A \$30,000 grant has been issued for the development of a new online clinical trial finder. Through the use of an API developed by Cystic Fibrosis Foundation in USA, the new trial finder will draw clinical trial data directly from a source database. This will significantly reduce staff process time and mitigate the risk of inaccurate information being posted to the website.

CF Canada will need to engage the services of an external vendor to provide front -end design and a content management interface.





CHALLENGES



Timelines

- Grant money must be used in the current fiscal year; therefore, we have 4 months to select a vendor partner, establish project scope, define roles and responsibilities and launch a fully bilingual application.

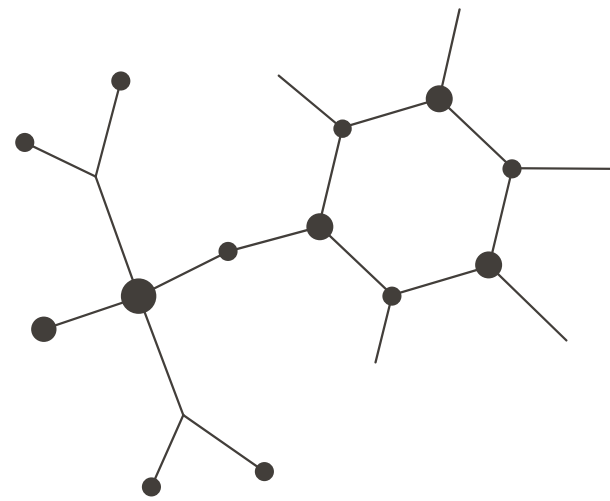
Internal Stakeholders

- Project sponsor is the Chief Scientific Officer who has little time to devote to the project and may not have insight into technical limitations. It will be important to establish and monitor expectations.
- Site will be maintained by 1 administrative staff member with limited technical knowledge; therefore, the user interface must be intuitive and easy to use.

External Stakeholders

- The Cystic Fibrosis Foundation in the US has partnered with CF Canada to provide the API that will allow the site to be operated. Because they are offering this at no cost, it is essential to cultivate a non-demanding working relationship. But as their support is necessary for the project to succeed it will require considerable maneuvering to achieve project success.

VENDOR SELECTION



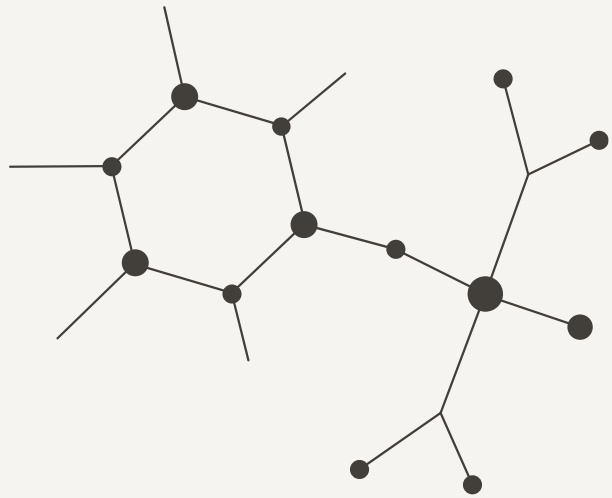
Requirements

- Transparent pricing structure and no hidden costs.
- Strong project management skills and methodologies
- Strong focus on user experience
- Expertise in accessibility and AODA compliance
- Willingness to tailor solutions
- Previous experience with Non-Profits, and healthcare applications

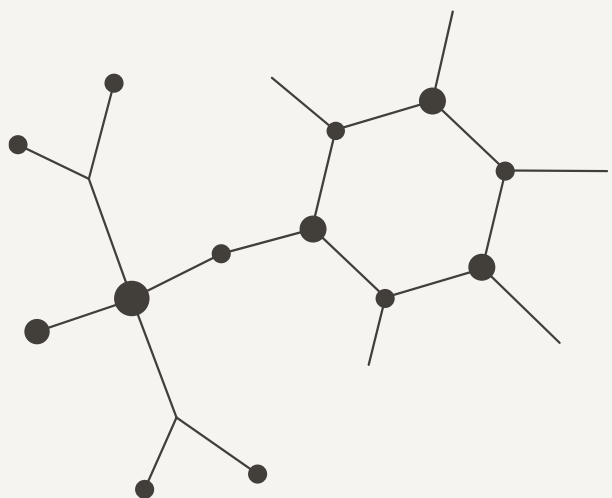
Selection

Through vendor interviews and internal stakeholder feedback I was able to select a vendor that met the project requirements and timelines.

As CF Canada was planning a corporate website redesign project in the next year, I positioned our agreement with the vendor as a “trial run” for a potential partnership for the larger project. I was able to get a significant discount for the current project and also establish the groundwork for the future partnership.



SOLUTION



- To solve the **time constraints** challenge I suggested breaking up the project into two phases. The first phase would include interface design, and APi integration for the English site with the French version to be launched in the next quarter.
- To solve the **internal stakeholders** challenge, I scheduled regular updates and clearly communicated highly technical information into easy-to-understand concepts. I worked with the vendor to ensure a highly intuitive interface and confirm that extensive documentation and training materials would be available prior to launch.
- To solve the **external stakeholders** challenge, I coordinated communication between CF Foundation developers and vendor developers to workout bugs and facilitate knowledge transfers. I established regular communication with CF Foundation Project Managers and IT staff during the project and setup a feedback loop for any changes or updates to the API going forward. This mitigated risks and ensured CF Canada would be notified of down-time or outages.



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Project Success

Using clear communication, effective stakeholder management, and in-depth knowledge of both technical and end-user requirements, I managed the successful launch of the Cystic Fibrosis Canada Clinical Trial Finder, both on-time and on-budget. The Trial Finder continues to enhance participation of people with cystic fibrosis in clinical trials and bring better care to Canadians who are living with cystic fibrosis.

<https://trialfinder.cysticfibrosis.ca/>

