The FOUNDATION FIGHTING BLINDNESS

Everything you need to know about: FFB-CANADA PATIENT REGISTRY

The Patient Registry is a secure medical database that was designed to connect people living with inherited retinal diseases (IRDs) to clinical trials, to improve patient care, and to drive sight-saving research.

Why sign up? Connecting Patients to Treatments

The answer is simple: when you join the FFB Patient Registry, you demonstrate that there are people in Canada who want and need new treatments.

Joining the Patient Registry is like putting your hand up to show that you have an inherited retinal disease (IRD) and that you support the FFB's goal to develop new sight-saving treatments. Scientists can't develop treatments without patients. The success of clinical trials depends on the participation of patient volunteers.

It is an incredibly exciting time because there are many clinical trials that are testing new treatments for people who are living with inherited retinal diseases. We are encouraged that although the majority of these clinical trials are not located in Canada, many of the trials are welcoming the participation of Canadian patients. This means that the FFB Patient Registry can do the work that it was designed to do: connect patients with clinical trials that they might be eligible to participate in. When the Patient Registry was established in 2004, the vision was to prepare for the future – that day has arrived.

In addition to connecting patients to new clinical trial opportunities, the Patient Registry is poised to play an essential role bringing new, approved treatments to Canada. When innovative treatments, such as the gene therapy Luxturna, are approved in the United States, how do they become available to Canadian patients?

The Patient Registry informs FFB's ability to communicate with government, industry, and community stakeholders about the patient need for new treatments in Canada. For example, if there were no patients living in Canada that could benefit from Luxturna, then Novartis (the global lead for this new treatment) would have no reason to bring the treatment to Canada. The Patient Registry allows us to quickly search and determine how many patients might benefit from this new treatment. But, if you are

not in the Patient Registry, you won't be counted and you won't be contacted. This is another reason why it's so important to sign up.

Because of these new clinical trial and treatment opportunities for patients – we know that we need to do more at the FFB to support the staff at the Patient Registry enrolment sites and to support the many patients who want to enrol. We are currently working to expand the FFB's Patient Registry enrolment support resources with the goal of improving the experience of patients.

How do I sign up?

If you decide to join the Patient Registry, you need to enrol at one of the growing number of regional enrolment sites across Canada. Currently, there are four enrolment sites in: Halifax, Toronto, Edmonton, and Vancouver. In 2018, to better serve the FFB community in Quebec, we are planning to add an additional site in Montreal.

At the FFB, our role is to connect you to the appropriate enrolment site. Because of this, the FFB is called a "referral site" not an "enrolment site."

FFB staff do not have access to your medical records in the Patient Registry. FFB staff cannot check if you have been enrolled on the Patient Registry.

Consent: After you are connected to your local Patient Registry enrolment site, you will learn more about how your information will be used and have a chance to ask additional questions. Staff at your enrolment site will ask you if you would like to sign a consent form to join the Patient Registry. Sometimes it is possible for this consent process to happen remotely by phone or email.

Once you have consented to join the Patient Registry, a data collection form will be used to collect the standardized information needed by the Patient Registry. If your specialist is based at the Patient Registry site, he or she will complete the data

collection form and submit it; otherwise you will be given a data collection form to take to your local eye specialist.

How does the Patient Registry work?

People who are diagnosed with an inherited retinal disease (IRD), such as retinitis pigmentosa (RP), choroideremia, Stargardt disease, Usher syndrome, Leber congenital amaurosis (LCA), achromatopsia, x-linked retinoschisis (XLRS), Bardet-Biedl and other retinal degenerative diseases agree to submit medical records to the Patient Registry.

These medical records include details of your diagnosis, personal medical and family history of eye disease and your retinal examinations, as well as any other testing, including genetic testing that you have had.

These records are filed under a reference number. Only your caregivers at the Patient Registry enrolment site (where you enroll) can link your name and contact information to this number.

Scientists studying inherited retinal diseases (IRDs) can approach the Patient Registry advisory committee to ask for access. If granted, they will be able to search the database and obtain data for use in expanding their research studies, but they will not be able to access your name or identifying information.

What research might be conducted using the Patient Registry?

The Patient Registry can be used to study how inherited retinal diseases (IRDs) develop and how these conditions can be better diagnosed and treated. For example, a scientist might search the database for the records of people with a particular genetic type of disease. They could then determine the average age at which people with this mutation had early signs of disease or major vision loss, and as a result, provide better information to doctors and families.

The FOUNDATION FIGHTING BLINDNESS

Everything you need to know about: FFB-CANADA PATIENT REGISTRY

Scientists conducting clinical trials for potential treatments are encouraged to use the Patient Registry to find participants. Many trials are currently underway. At the FFB, our goal is to showcase the Patient Registry as a gold standard resource with the capacity to encourage more Canadian clinical trials.

How does the Patient Registry connect patients to clinical trials?

Clinical trials usually require very specific groups of participants so that the study can collect clear information about the possible benefits of the therapy. People in the clinical trial must meet "eligibility criteria." For example, participants must be a specific age; have specific conditions and symptoms; and/or a particular gene mutation. In the initial stages, a scientist or clinical trial leader might search the Patient Registry database to get basic information about the number of Canadians who might be eligible for their clinical trial.

Once the clinical trial is ready to begin, FFB and Patient Registry staff can collaborate with the clinical research team to generate a list of "reference numbers" of people eligible for the clinical trial and notify the registry staff at each enrolment site. The reference number will tell the registry staff where you enrolled in the registry. You will then be contacted by your doctor and advised about the trial.

Being part of the Patient Registry does not obligate you to be part of a clinical trial. You can always say NO, but being entered in the Patient Registry will give you the option of knowing about these trials so that you can make an informed decision about participating.

Will my information be secure?

Absolutely. Many safeguards are in place to ensure that your information is only used in ways that you have agreed to and that identifying information about you cannot be released without consent. Research ethics boards associated with each enrolment site have reviewed all of the procedures and protocols and will continue to monitor the functioning of the database.

As the new enrolment sites are added to the Patient Registry, each site will undergo similar reviews. Scientists will be able to search records from all enrolment sites in a single search, but identifying information about you will only be held in the centre where you enrol.

Do I need to have genetic testing done before I join the Patient Registry?

No. However, you are encouraged to have genetic testing done, and to submit these records to the Patient Registry. If you would like to learn more about genetic testing, please review the FFB's genetic testing resources.

BE YOUR OWN ADVOCATE.

If you are having trouble getting access to a genetic counsellor and/or genetic testing, remember: you must be your own best advocate.

Explain why genetic testing is important for your care.

Explain to your doctor that a genetic diagnosis is an important part of managing your condition.

Explain that there are now over 250 different genes related to inherited retinal diseases (IRDs) and that genetic testing can potentially help secure an accurate diagnosis for you and help to connect you to clinical trials and new treatments.

Explain that you would like to join the FOUNDATION FIGHTING BLINDNESS PATIENT REGISTRY so that you can become involved if there are any Canadian clinical trials that target your specific genetic eye condition.

Print out this resource and share it.

Updated on February 6, 2018 by Dr. Mary Sunderland, Director of Research & Education at the Foundation Fighting Blindness.