Information for patients and families

Juravinski Hospital and Cancer Centre
HAMILTON HEALTH SCIENCES

Chimeric Antigen Receptor (CAR) T-Cell Therapy

Information for patients and families

"Riding the Dragon" A Cancer Journey | by Conrad Furey

About this book

Members of the Oncology Program at the Juravinski Hospital and Cancer Centre have developed this book, which is part of Hamilton Health Sciences.

Reading this book will help you learn about your CAR-T treatment. Please read the sections as you feel ready to learn. While reading this book you may come up with some questions. We encourage you to write your questions down and bring this book along with you to your appointments.

Hamilton Health Sciences is:

Smoke-free

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Wheelchair accessible

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Your health care team

You and your family are very important members of the team.

The team also includes:

- doctors
- peripheral stem cell transplant coordinator
- nurse practitioners
- nurses
- social workers
- dietitians
- physiotherapists
- home care coordinator
- pharmacists
- chaplain
- business clerks
- environmental aides

If you would like to meet with or have questions of any of these team members, let your coordinator know.

What is Chimeric Antigen Receptor (CAR-T) Cell Therapy?

CAR–T cell therapy is a new treatment to fight some cancers. It is a type of immunotherapy, which means it involves using your body's own immune system to treat your cancer. Most treatments of this kind are currently only available in clinical trials, though a limited number of Health Canada approved therapies are available for certain Cancer illnesses described below:

- B-cell acute lymphoblastic leukemia (B-cell ALL) – a form of cancer composed of some types of white blood cells that have become malignant. It can be used in children and young adults from 3 to 25 years of age with this cancer.

- Diffuse large B-cell lymphoma (DLBCL) – a form of cancer composed of some types of white blood cells that have become malignant, mostly in the lymph nodes. It can be used in adults (18 years of age or older) for whom DLBCL has returned after other treatments or when other treatments did not work.

1. How it works

The immune system is made up of specific cells and organs that protect your body from organisms that cause infection, disease, and abnormal cancer cells. CAR-T cell therapy modifies your immune system activity to improve the body's own ability to fight certain cancers.

Lymphocytes, a subtype of white bloods cells, comprise a large portion of the immune system. There are three types of lymphocytes:

B Lymphocytes (B cells) make antibodies to fight infection. T lymphocytes (T cells) and natural killer (NK) cells directly kill infected or cancerous cells and talk to other cells of the immune system using chemicals known as "cytokines."

CAR-T cell therapy changes some of your body's T cells, which are collected from your own blood.

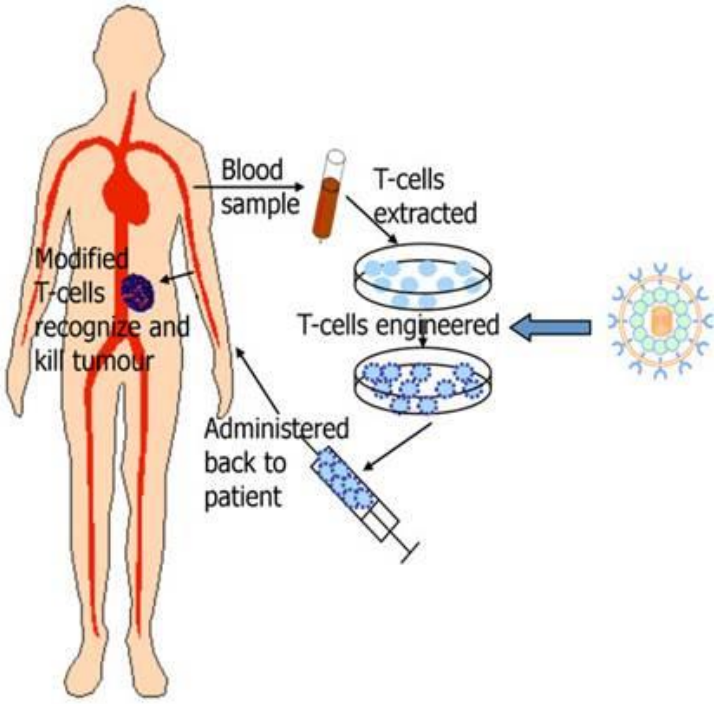
CAR-T cell therapy is an antigen receptor T cell therapy that is manufactured individually for each patient. In a laboratory, your T cells will be reprogrammed to produce special receptors called chimeric antigen receptors (CARs). When these CARs are placed back into your body through an intravenous catheter, the receptors should help your T cells find and destroy cancer cells.

Throughout this process, careful measures are in place to ensure your safety and maintain high levels of quality.

2. The Process

1. T-Cells are collected from the patient's blood by means of an apheresis machine. This will take several hours.

2. T-Cells are sent to a laboratory where they are genetically engineered to produce chimeric antigen receptors on their surface. After this reengineering, the T-Cells are known as "Chimeric antigen receptor (CAR-T) cells". Chimeric antigen receptors are proteins that allow the T-Cells to recognize a specific protein on the tumor cells.



3. The CAR-T cells are multiplied in the lab and once enough cells are grown, they are sent back to hospital where the patient is being treated.

4. Some patients then receive lympho-depleting chemotherapy.

5. The CAR-T cells are infused into the patient where they multiply in number. At this point, they recognize and kill the cancerous cells that have the targeted antigen. They remain in the body long after the infusion and will guard against cancer recurrence.

Steps to CAR-T Therapy

1. Initial Assessment

You will meet with many members of our health care team this day. Plan to be here for several hours. You will be given instructions of where to meet and what time.

First, you will have several tubes of blood drawn. This is needed to clear you for the collection of your cells.

Next, you will meet with a nurse practitioner, who will perform a history and physical, and a bone marrow test (you will have to hold off taking any blood thinners). You will be given instructions on when to stop them and when to resume them prior to coming to this appointment.

A pharmacist will meet with you to review medications that you are currently taking (prescription, over the counter, supplements). Please bring these medications with you to your appointment.

A transplant coordinator will meet with you to go over any questions you may have and provide you with a potential schedule.

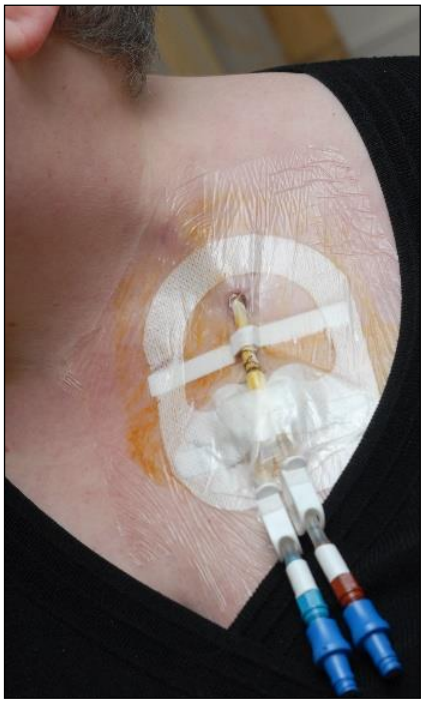
A social worker will also meet with you to go over any potential needs you may have during the CAR-T therapy. The social worker will talk to you about:

- housing
- caregiver support
- phone
- transportation
- funding sources
- personal affairs (Power of Attorney, Will)

Finally, after the results of all the testing have been reviewed, there will be a family meeting. The physician and other members of the team will sit down with you and your family and go over the potential schedule.

At this time, you will have the opportunity to ask any questions and you will be asked to sign consents. It is anticipated that within approximately 2 weeks, you will be having your cells collected.

2. Insertion of apheresis catheter



- This is an outpatient procedure
- An a*pheresis catheter* is used to collect your cells.
- A radiologist puts the catheter in your chest, below your collarbone.
- You will be given medication to reduce any pain.
- The catheter will remain in your body until after you have recovered from your CAR-T therapy.
- One end goes into a large blood vessel in your body; the other end is on the outside of your body.
- The doctors and nurses can use this outside end to take blood samples. In addition, this end will be used to give you your CAR-T cells, as well as any chemotherapy you may receive.

Care of your apheresis catheter

- The catheter needs to be "flushed" weekly with a citrate solution and covered by a sterile dressing. This dressing will be changed once a week by a nurse.
- A nurse will flush the catheter and change your dressing, either at home or in a clinic.

Call the doctor or nurse right away if you notice:

- **Signs of infection** – pain, puss or redness around your catheter, or a temperature of 38^{O}C or 100^{O}F or more. This is a fever. **Do not take Tylenol, Aspirin, ibuprofen or anti-inflammatory medications without checking with your team first.** They may cause bleeding and may hide a fever. Call if you need medication for pain.
- **Signs of a clot -** swelling in your arm on the side of your catheter and having trouble flushing the catheter

3. Apheresis collection

The collection takes place in the Apheresis Suite. The Apheresis Suite is located in Oncology Day Services on B4.

Before each visit to the Oncology Day Services, you must first check in at Patient Registration, which is located on the 1st floor of the Juravinski Hospital, at the front entrance.

A nurse will be with you during the day and will monitor your care.

- You should not feel any pain during the collection
- Some people get a tingling feeling around their mouth or in their arms or legs. You may be given calcium to decrease this tingling.
- Your apheresis catheter will be hooked up to an apheresis machine.
- Your blood is spun in this machine and the layer of mononuclear cells is collected in a bag.
- The other line returns the rest of your blood to you.

Apheresis machine

Suggestions for your harvest day

- ❒ You will come to the Apheresis Suite early in the morning so it is important to eat breakfast before coming to the unit. Please bring your lunch, fluids and medications you need for the day. It takes about 6 to 8 hours to collect your cells. If you need assistance with taking your medications, please bring someone to assist you with this.

- ❒ You may bring a friend with you for the day to keep you company.

- ❒ You may also want to bring a book, videos, radio, or a hand held device.

4. Manufacturing of CAR-T

The collected cells are sent to a specialized lab where the CAR-T cells will be manufactured. This will take several weeks. During this time, you will return to the care of your referring physician. It is possible you will require chemotherapy during this time to control your disease. This will not interfere with the planned CAR-T therapy.

5. Assessment for lympho-depleting chemotherapy and CAR-T infusion

Lympho-depleting chemotherapy is a special chemotherapy regime that you will receive a few days prior to the CAR-T infusion. Your CAR-T physician and nurse practitioner will assess you prior to this regime at a pre lymph-depleting appointment. Blood work will be drawn and a nasal pharyngeal swab done to assess you prior to receiving your

Lympho-depleting chemotherapy. You will be given a schedule for your chemotherapy (if required) and CAR-T infusion. Please bring all your medications (prescription, over the counter, supplements) to this appointment. This appointment may be lengthy.

6. Lympho-depleting Chemotherapy (Not all patients require this step)

You will be seen in Oncology Day Services, Ward B4 of the Juravinski Hospital. Before each of your daily visits to the Oncology Day Services, you must first check in at Patient Registration, which is located on the 1st floor of the Juravinski Hospital, at the front entrance.

You will receive your chemotherapy through your Apheresis line over the next few days. This is an outpatient unit. Please bring your lunch, fluids and medications you need for the day. You may bring a friend or family member with you.

7. CAR-T Infusion

You may be seen in Oncology Day Services, Ward B4 of the Juravinski Hospital after the completion of your chemotherapy. Within 2 to 5 days after the completion of the chemotherapy, your CAR-T cells will be infused.

- For a period of 12 months after your CAR-T infusion, 2 methods of birth control must be used (oral, injected or implanted hormonal contraception and condoms or occlusive cap with a spermicidal foam/ gel/ film or vaginal suppository).
- A caregiver must be present with you at all times throughout the first 30 days following the CAR-T infusion.
- You or your caregiver should carry the CAR-T patient information card to alert all healthcare providers of the treatment (i.e.

Avoidance of steroids, chemotherapy and the risk for infection) and physician contact information.

- Your temperature should be taken twice daily for the first 14 days. Call your healthcare team promptly with any fever for possible hospitalization.
- You will require many, sometimes daily visits in Oncology Day Services following the infusion of your CAR-T cells.
- You and your caregiver may be required to relocate closer to the hospital during this time.

8. Potential side effects

Things that may occur during CAR- T cell infusion **(hours or days after).**

Cytokine release syndrome.

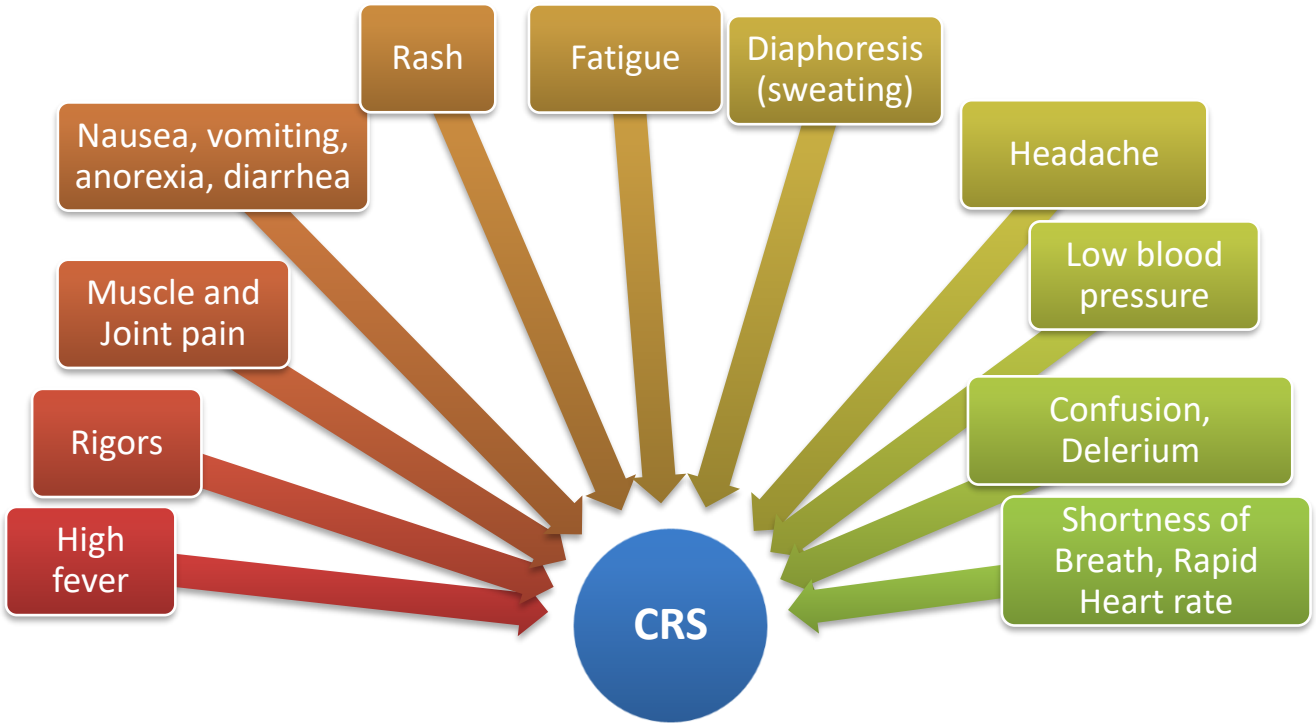
In some patients, the immune system may become activated as the CAR- T cells travel through the body. Substances called cytokines release into the system. This can make you feel like you have the flu, with a high fever and/or chills. Other symptoms that may occur include low blood pressure, difficulty breathing, or confusion. These symptoms can be mild or severe. Your team will monitor you frequently to help control these problems. You may need oxygen, intravenous fluids, and/or medicines (including steroids) to keep your fever down. In severe cases, you may receive medicines designed to stop the effect of the cytokines. Talk with your clinical team about the likelihood that you could have any of these symptoms.

Changes in neurologic status.

In some patients, the immune activation after CAR- T cell infusion may alter the brain and neurologic system temporarily. These changes can present as confusion, difficulty with talking or memory, or even in severe cases loss of consciousness. Your team will monitor you

frequently and may give you special medications to help prevent or control these problems.

If your symptoms are severe, you must page your CAR-T doctor at _____ and go to the Juravinski Hospital Emergency Room.



- high fever
- rigors
- muscle pain
- joint pain
- nausea
- vomiting
- diarrhea
- rash
- fatigue
- diaphoresis (sweating)
- headache
- low blood pressure
- headaches
- confusion
- delirium
- shortness of breath
- rapid heart rate

Tumor Lysis Syndrome.

CAR –T cell therapy is designed to target your cancer cells. In some cases, this process may destroy a large amount of tumor. When these cancer cells die, the contents of the cells are released into your bloodstream. This can result in shifts of fluid and minerals, and/or kidney damage. Your team will have a specific treatment plan for you, if needed. This may include chemotherapy prior to T cell therapy, IV fluids, and or medicines to help the body clear these excess fluids and protect the kidneys.

Directions and parking

1. Getting to the Juravinski Hospital and Cancer Centre, 699 Concession Street, Hamilton, Ontario

From St. Catharine's

Take the QEW to the Centennial Parkway/Red Hill Valley Parkway exit.

Follow the sign for the Red Hill Valley Parkway exit.

The parkway becomes the Lincoln Alexander Parkway (LINC).

Exit onto Upper Gage. Turn right on Upper Gage and travel north to Concession Street. Turn left on Concession Street. Travel several blocks. The hospital and Cancer Centre are on the right.

From Cambridge

Take Hwy #52 to Hwy #403 and exit at the Lincoln Alexander Parkway (LINC).

Follow the LINC exit to Upper Wentworth Street.

Travel north on Upper Wentworth Street.

Turn right on Concession Street. The hospital and Cancer Centre are several blocks up on Concession Street on the left.

From Brantford
Take Hwy #403 and exit at the Lincoln Alexander Parkway (LINC).

Follow the LINC exit to Upper Wentworth Street.

Travel north on Upper Wentworth Street.

Turn right on Concession Street. The hospital and Cancer Centre are several blocks up on Concession Street on the left.

From Toronto
Take QEW to Hwy 403.

Exit onto the Lincoln Alexander Parkway (LINC).

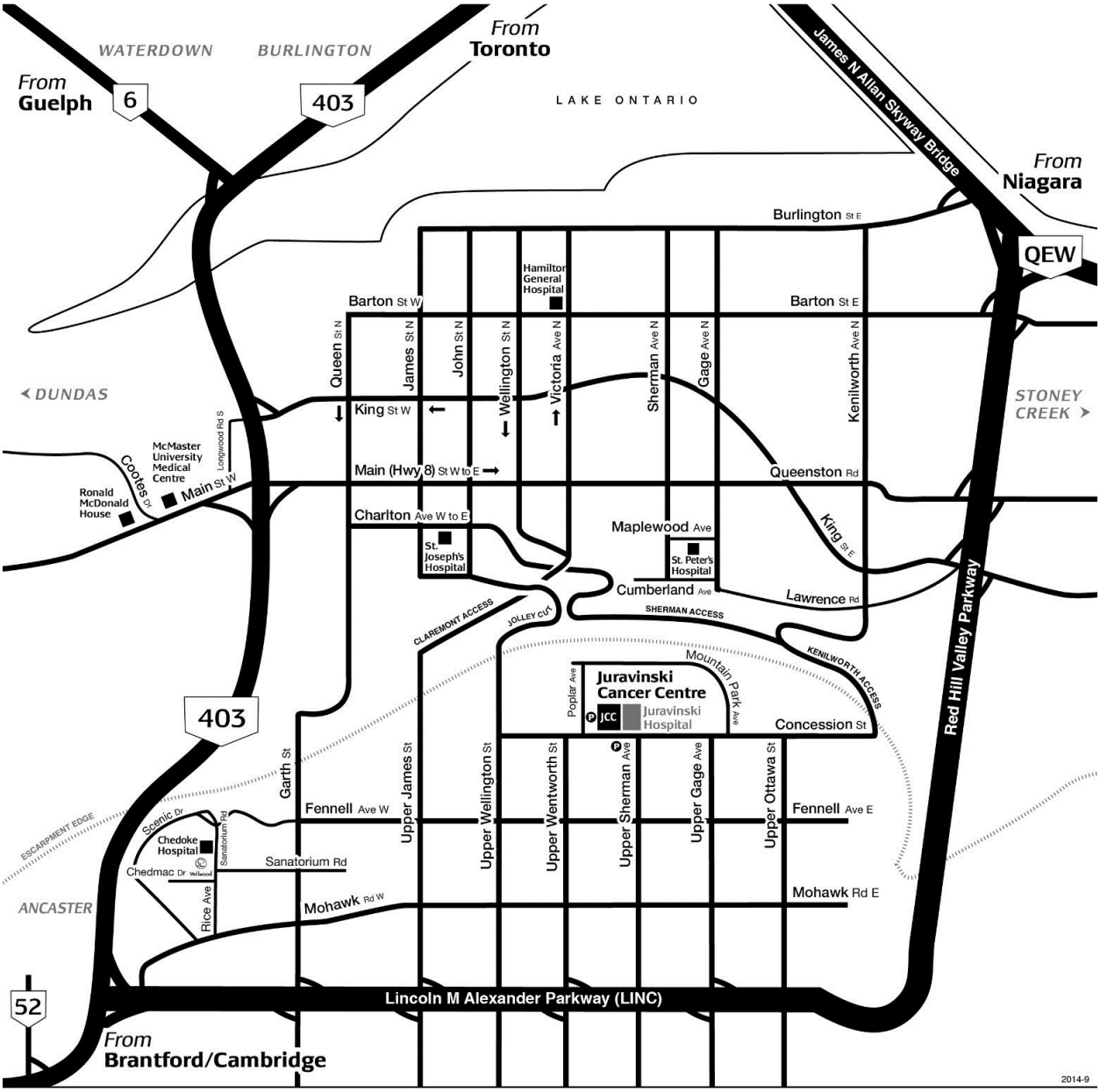
Follow the LINC exit to Upper Wentworth Street.

Travel north on Upper Wentworth Street.

Turn right on Concession Street. The hospital and Cancer Centre are several blocks up on Concession Street on the left.

From Guelph
Take Hwy #6 to Hwy #403.

Exit onto the Lincoln Alexander Parkway (LINC). Follow the LINC exit to Upper Wentworth Street. Travel north on Upper Wentworth Street. Turn right on Concession Street. The hospital and Cancer Centre are several blocks up on Concession Street on the left.



Important:

1. The Juravinski Hospital and Cancer Centre has 2 entrances. The Cancer Centre is **Entrance J** at 699 Concession St. and the Hospital is **Entrance A** at 711 Concession St.

2. Juravinski Innovation Tower (Charlton St.) and Juravinski Centre for Integrated Healthcare (West 5th) are part of St. Joseph's Healthcare and ***not*** related to the **Juravinski Hospital and Cancer Centre**.

2. Parking instructions

There are two parking lots near the Juravinski Hospital and Cancer Centre. One is on Concession Street right across from the hospital.

The other is on Poplar Avenue right next door to the Cancer Centre.

Family support

You and a caregiver will be required to live **within 45 minutes** of the Juravinski Hospital for approximately 6 weeks around the time of the infusion and follow-up care.

The social worker with the health care team can give you information about places to stay and their costs.

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Front Mural: *"Riding the Dragon"*
by Conrad Furey

Riding the Dragon is a 30 foot mural created in 2006 by renowned Hamilton Artist Conrad Furey. The images in the mural reflect Conrad's personal experience with cancer, his valued relationships with the staff who cared for him, and pays special tribute to the Knot-a-Breast dragon boat team. The mural hangs in the atrium of the cancer centre and provides, comfort and reflection to patients, staff and visitors.

Juravinski Cancer Centre
HAMILTON HEALTH SCIENCES

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