Session 2: **Adoption of Novel therapeutics in the Canadian healthcare system: learnings from CAR T cell therapy**

Monday October 26th, 1:40PM – 3:10PM

Virtual Conference

Session Overview:

The continued advancement of cell and gene therapies promises to transform the treatment of disease and delivery of healthcare for patients, while also fundamentally disrupting and straining Canada's traditional HTA and drug reimbursement processes. This panel will explore recent CADTH process updates related to evaluating cell and gene therapies, as well as Canadian case studies & considerations for how to tackle this exciting challenge in Canadian healthcare going forward.

Panelists	
Farah Jivraj (Moderator)	Head, Market Access, Policy and Stakeholder Relations, Biogen Canada
Sabrina Hanna	The Cancer Collaborative
Brent Fraser	Vice President, Pharmaceutical Reviews, CADTH
Scott Gavura	Director, Provincial Drug Reimbursement Programs, Cancer Care Ontario
Dr. Ralph Meyer	Vice President, Hamilton Health Sciences / Juravinski Hospital and Cancer Centre
Sophie Rochon	National Director, Health Policy and Patient Access, Novartis Oncology

adoption of novel therapeutics in the canadian healthcare system: learnings from CAR T cell therapy

patient advocate perspective

the cancer collaborative
[colab]

about colab | disclosures

the cancer collaborative is a not for profit advocacy group with a mission to bridge science, policy and advocacy to proactively identify the challenges and opportunities within oncology, prioritize them and work together to make action oriented changes on how cancer care is delivered in canada. meeting the challenges of today's cancer ecosystem with innovation and collaboration to create meaningful impact for patients and system readiness through multistakeholder engagement.

colab has recived funding from roche, novartis, astra zeneca, janssen

roomC.co

a new and unique new way to treat cancer, CAR T-cell therapy is poised to transform the outlook for children and adults with certain otherwise incurable cancers'

ASCO

CAR T – opportunities & barriers

1. new hope | personalized cures
2. complexity | uncertainty
3. cost vs value
4. ethical and equitable access

CAR T lessons learned

leadership

engagement & collaboration

long term planning

value & investment

preparedness

doing better for patients

stakeholders must learn to work together in a collaborative environment in order to bridge the gap rather than widen it

THANKYOU

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CADTH Evidence Driven.

Brent Fraser,
Vice President, Pharmaceutical Reviews

Disclosures: None

CADTH HTA reviews: cell and gene therapies

- Despite regulatory approval as a drug, CADTH chose to review the new CAR-Ts through its device pathway:
  - Implementation considerations
  - Ethics framework established
  - Reviewed by Health Technology Expert Review Panel (HTERP)

CADTH Evidence Driven.

HTA reviews: Lessons Learned

- Adjustments made to ethics review
- Need to detailed processes for review
- Understand who needs to be engaged and the needs of stakeholders
- The Health system is still learning how to use these products at the same time

CADTH Evidence Driven.

CADTH cell and gene therapy review: current status

- Requirement for an implementation plan provided by sponsor
  - Drug programs will review and determine appropriate review process
- Clinical and economics will follow usual process
- Identification of ethical considerations
- Establish an implementation panel if required
- Additional support as needed e.g., funding negotiations

CADTH Evidence Driven.

Adoption of novel therapeutics in the Canadian healthcare system: Learnings from CAR T cell therapy

Public Payer Perspective

Scott Gavura

Director Provincial Drug Reimbursement Programs

October 26, 2020

Presented at:

CAPT ACTP
Canadian Association for Population Therapeutics

Virtual Conference 2020

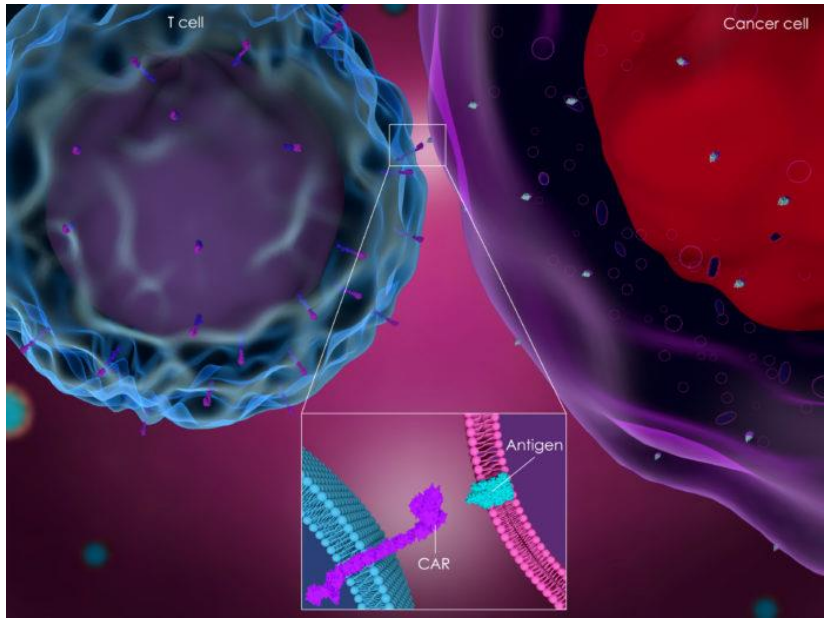
Ontario Health
Cancer Care Ontario

Disclosures

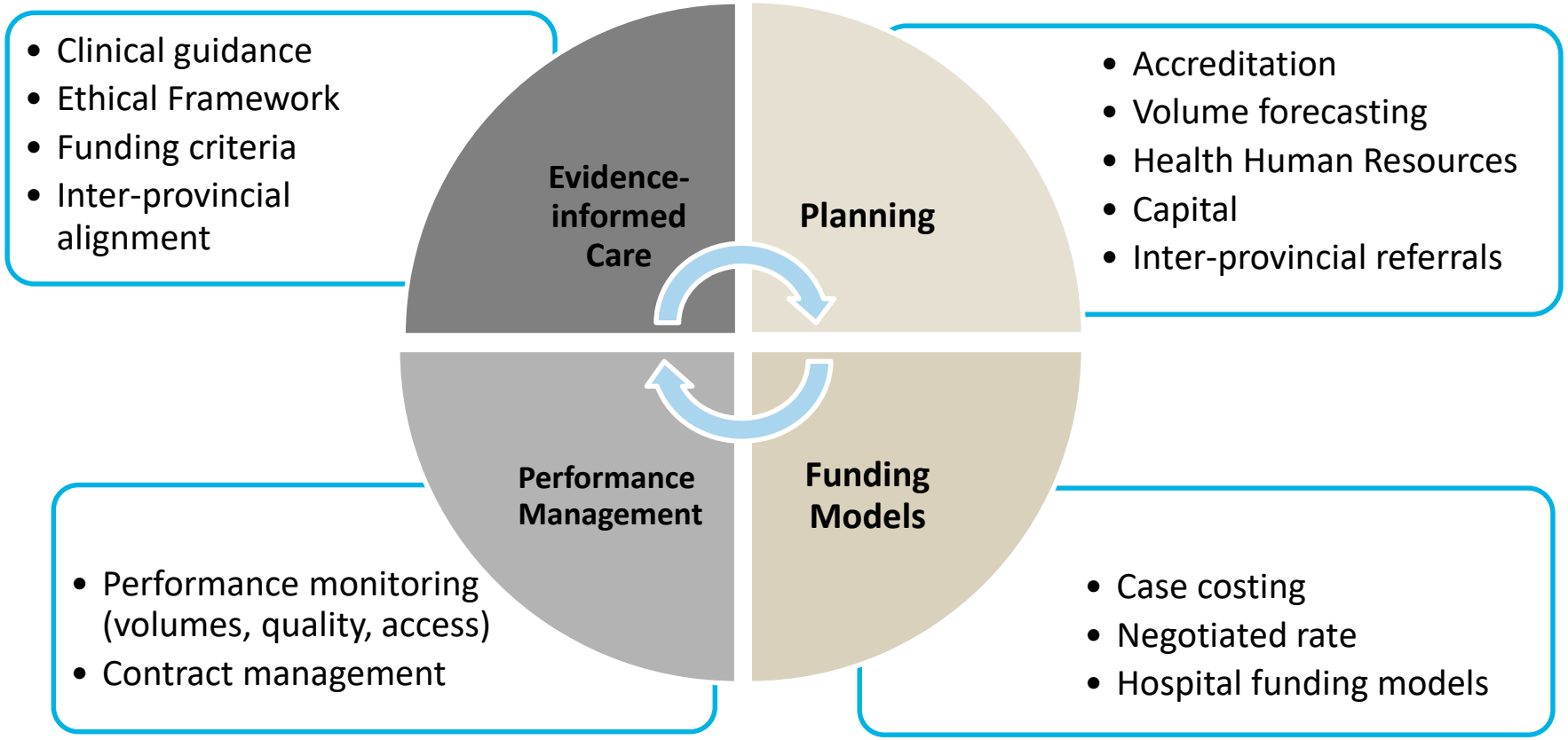
- No disclosures or conflicts of interest to report

A new funding program required for CAR-T

- An immunotherapy with a complex manufacturing and delivery process.
- Specialized resources clearly required, but many unknowns.
- Patients sent to U.S. facilities starting as early as 2014
- Initially, in-province expertise to deliver CAR T-cell therapy was lacking.



Approach to program development



Initial uncertainties

- Review process
- Pan-Canadian negotiation process
- How funding should occur
- Timelines for site readiness, impacted by
  - Capital build delays
  - Health human resources
  - Standard Operating Procedure development and agreements with manufacturers
- Limited geographic access
- Manufacturing constraints
- And then…
  - The impact of COVID-19, diverting planning resources

Where are we now?

- Two indications reviewed, negotiated, funded.
- Established referral and enrollment process. Funding criteria are posted online.
- 4 sites in Ontario and 2 in Quebec providing commercial CAR T-cell therapy
- Numerous clinical trials underway across the country.
- Ongoing data collection and evaluation of real-world effectiveness underway (OICR-funded grant)
- (Ontario): Referral to U.S. facilities if there's no capacity in Ontario for funded indication.
- Established process for review and negotiation for future drugs/indications.

CAR T-cell product	Health Canada	Indications	Ontario funding Status
Kymriah	Approved	• ALL (<25yrs) • DLBCL (adults)	• Funded in 2019
Yescarta	Approved	• DLBCL	• In negotiations
Tecartus	Pending (FDA approved)	• MCL	• Not funded

Acknowledgements

Executive Leadership
Michael Sherar
Elham Roushani
Robin McLeod
Paula Knight

Diagnosis & Treatment
Elaine Meertens
Sherrie Hertz
Gloria Chao
Christian Ceron
Tom Kouroukis
Chris Bredeson

Planning Unit
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The OH (CCO) ATI Advisory Committee

OH (CCO)'s Clinical Expert Reviewers

Clinicians participating in the Real World Evidence evaluation

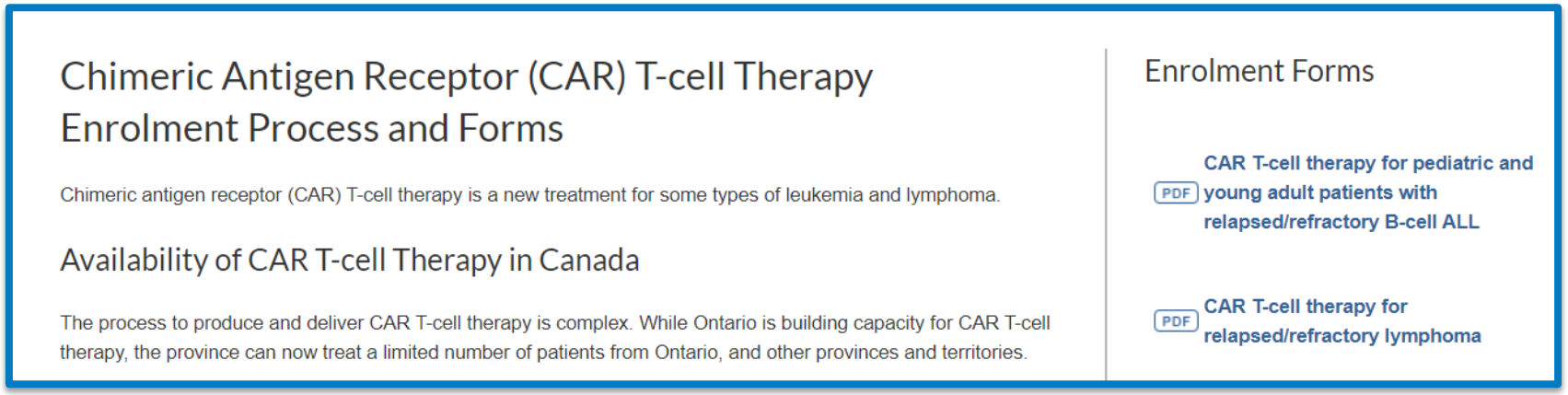
Ontario Ministry of Health
Health Services Branch
Provincial Programs Branch
Drugs and Devices Division

Delivering Institutions
The Hospital For Sick Children
Juravinski Cancer Centre
Princess Margaret Cancer Centre
The Ottawa Hospital

For more information

Email: OH-CCO_CARTSubmissions@ontariohealth.ca

Webpage:



Chimeric Antigen Receptor (CAR) T-cell Therapy Enrolment Process and Forms

Chimeric antigen receptor (CAR) T-cell therapy is a new treatment for some types of leukemia and lymphoma.

Availability of CAR T-cell Therapy in Canada

The process to produce and deliver CAR T-cell therapy is complex. While Ontario is building capacity for CAR T-cell therapy, the province can now treat a limited number of patients from Ontario, and other provinces and territories.

Enrolment Forms

PDF CAR T-cell therapy for pediatric and young adult patients with relapsed/refractory B-cell ALL

PDF CAR T-cell therapy for relapsed/refractory lymphoma

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/hematologic/car-t-cell-therapy-enrolment

Chimeric Antigen Receptor T-Cell Therapy (CART-C):

A Hospital Perspective

Dr. Ralph M Meyer

Vice President, Hamilton Health Sciences and Regional Vice President, Cancer Care Ontario

October 2020

Hamilton Health Sciences

Hamilton Niagara Haldimand Brant Regional Cancer Program

in partnership with Cancer Care Ontario

McMaster University

Inspiring Innovation and Discovery

Purpose and Main Messages

Purposes:

- To describe hospital processes in adopting CART-C therapy
- To advise how other stakeholders might facilitate hospital processes in advancing CART-C therapy

Main Messages:

- Hospitals and their physicians and staff enthusiastically want to advance new and better therapies
- Hospitals want to provide high-quality care, comply with authorities and partner with the private sector
- Hospitals that are to provide CART-C therapy will inevitably have a research agenda
- Hospitals are hierarchical and very operational; stakeholders should understand and respect these tenets
- Hospitals have limited abilities to take new work ; other stakeholders need to “make this easy”

Factors for External Stakeholders to Consider

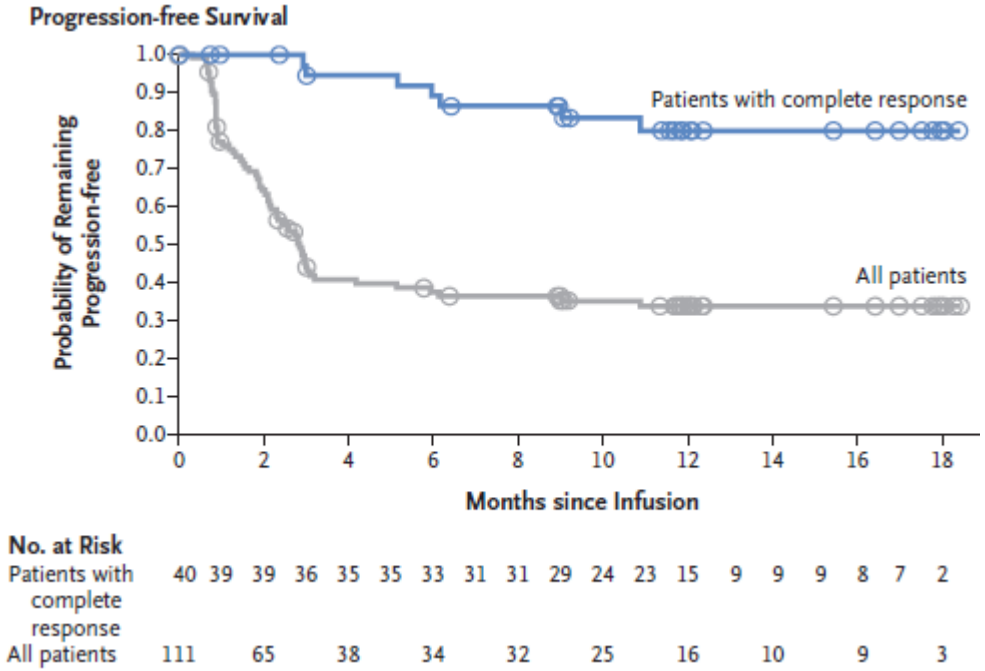
- Do you understand the Hospital's structure and how this structure should be accessed?
- What are the priorities of the Hospital related to "Complex Malignant Hematology"?
- What is the experience of the Hospital related to FACT, Health Canada and research sponsor accountabilities?
- What is the Hospital's capacity for complex project management? How might you assist this?
- What are the processes in advancing CART-C therapy that are most at risk of:
  - Delay in advancing
  - Repetitive reprocessing

CART-Cell Therapy and Lymphoma

ORIGINAL ARTICLE

Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma

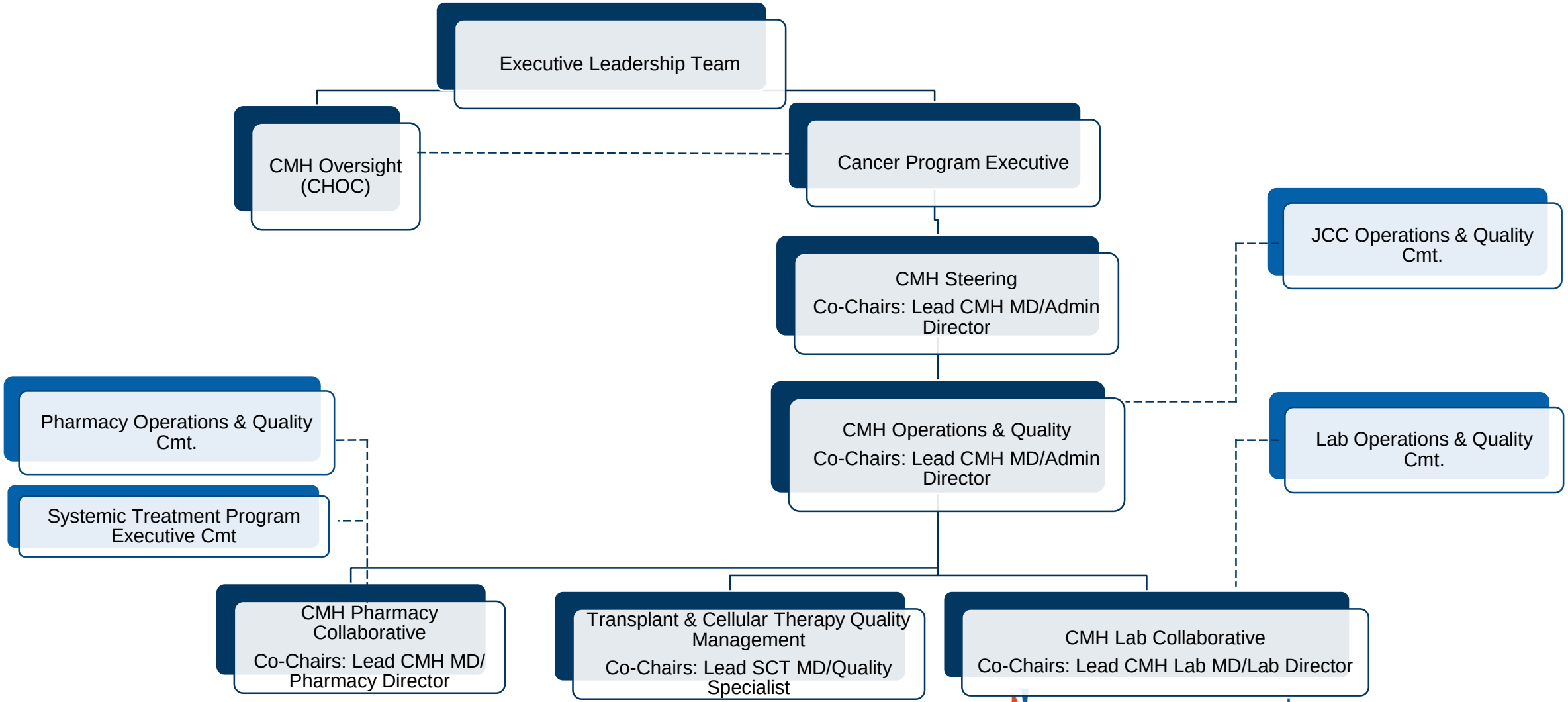
Stephen J. Schuster, M.D., Michael R. Bishop, M.D., Constantine S. Tam, M.D., Edmund K. Waller, M.D., Ph.D., Peter Borchmann, M.D., Joseph P. McGuirk, D.O., Ulrich Jäger, M.D., Samantha Jaglowski, M.D., Charalambos Andreadis, M.D., Jason R. Westin, M.D., Isabelle Fleury, M.D., Veronika Bachanova, M.D., Ph.D., S. Ronan Foley, M.D., P. Joy Ho, M.B., B.S., D.Phil., Stephan Mielke, M.D., John M. Magenau, M.D., Harald Holte, M.D., Ph.D., Serafino Pantano, Ph.D., Lida B. Pacaud, M.D., Rakesh Awasthi, Ph.D., Jufen Chu, Ph.D., Özlem Anak, M.D., Gilles Salles, M.D., Ph.D., and Richard T. Maziarz, M.D., for the JULIET Investigators*



N Engl J Med 2019

Complex Malignant Hematology (CMH) Committee Structure

Approved by CPE October 2018
Endorsed by CHOC December 2018



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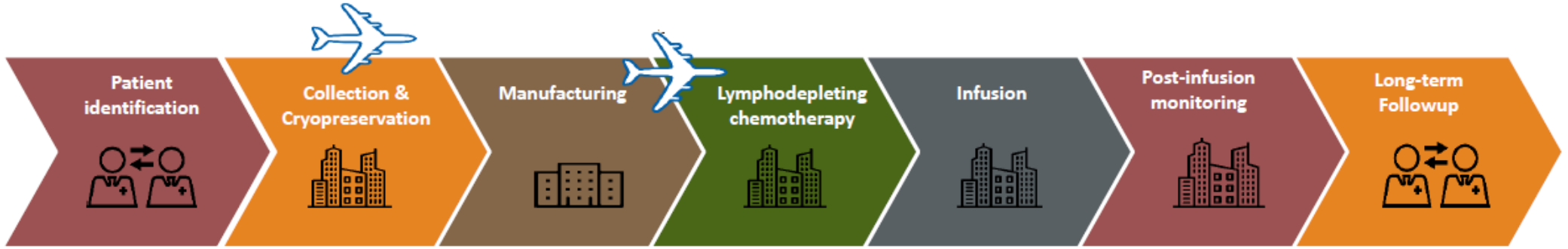
Slide made by Kim Alvarado, Director, Hamilton Health Sciences

Hospital Program Processes in Adopting CART-C Therapy



• Referral criteria • Process thru JCC NPR • Flow of referral package • Consultation process • Coordinator role & responsibilities • Social work support for out of town patients	• Peripheral access • Collection processes • RN competencies • Flow thru lab • Lab procedures • Transport processes	• Understanding of process and responsibilities of JH while product in transport • Process for Health Canada approvals	• Patient care pathways (IP, OP, ICU, ED) • Regime protocol • Order sets • RN assessment	• Infusion protocol • Patient care pathways	• Protocols and order sets for key symptoms such as CRS and neurotoxicity	• Follow-up protocol • Shared care model • Disease progression

SOP, Policies and Procedures to support patient care

Education: (1) Staff, MD for C4, ODS, Clinics, ICU, ED and (2) Patient/Family

Data required for reporting and quality improvement

Targeted communication (Messages to JH, LHIN, Partner Hospitals, community, etc)

Conceptualization and slide led by Kim Alvarado, Director, Hamilton Health Sciences

Summary

- CART-C therapy is potentially transformative
- Rapid adoption is occurring
- Growth will include indications and private sector expansion
- There are recognized risks:
  - Patient care is specialized and requires close relations between Programs*
  - Provincial / national referral / catchment is expected; Canada abides by universal care principles
  - Relations with the private sector are unique
  - Regulatory implications are substantial

* Clinical, Critical Care, Laboratory, Pharmacy, Quality, Legal

Novartis Oncology

Adoption of novel therapeutics in the Canadian healthcare system: Learnings from CAR T cell therapy

The industry perspective

presented at the CAPT virtual conference October 26 2020

Sophie Rochon
National Director Health Policy and Patient Access

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“We’re making the immune system do things it never could... it’s unlike anything the pharmaceutical industry has ever done.”

Carl H. June, MD
Richard W. Vague Professor of Immunotherapy at the Perelman School of Medicine and Director of the Center for Cellular Immunotherapies at the Abramson Cancer Center, University of Pennsylvania

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We are focused on reimagining the future of cancer for patients in need

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CAPT ACTP

Canadian Association for Population Therapeutics

Session 2: **Discussion and Q&A**