

Drug access in Canada

Keith McIntosh



Outline

System

Drug Development Pathway

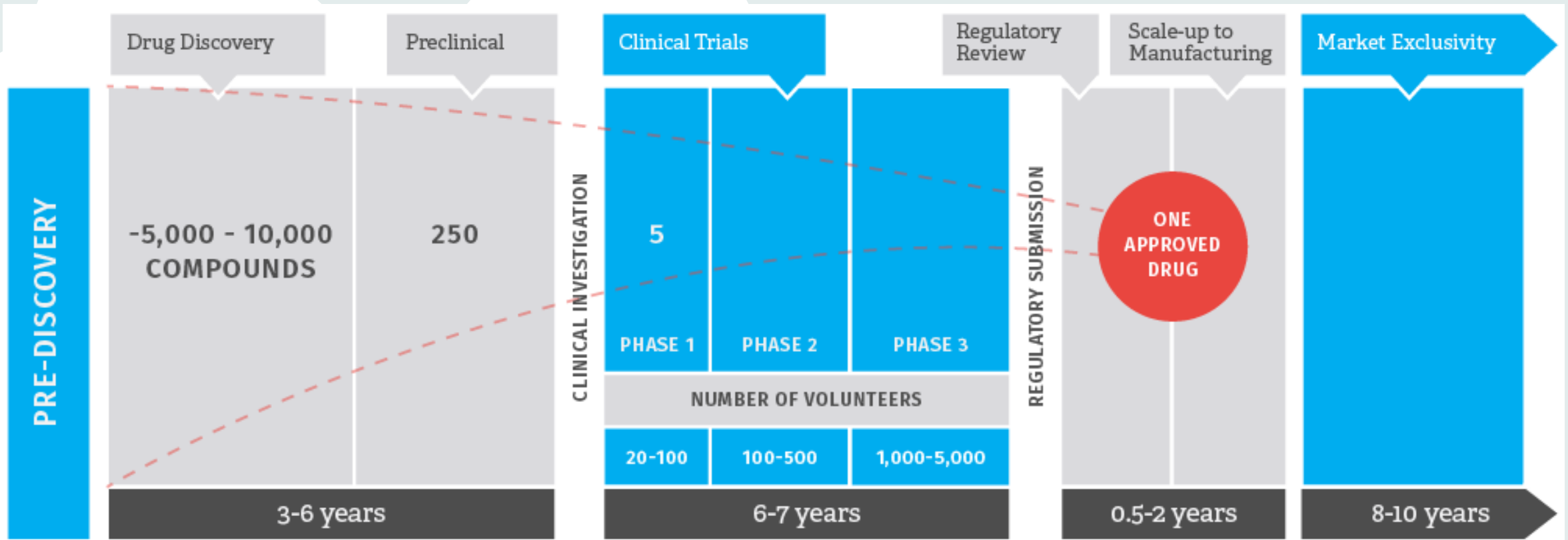
Types of Drug Coverage in Canada

Canadian Drug Reimbursement Landscape

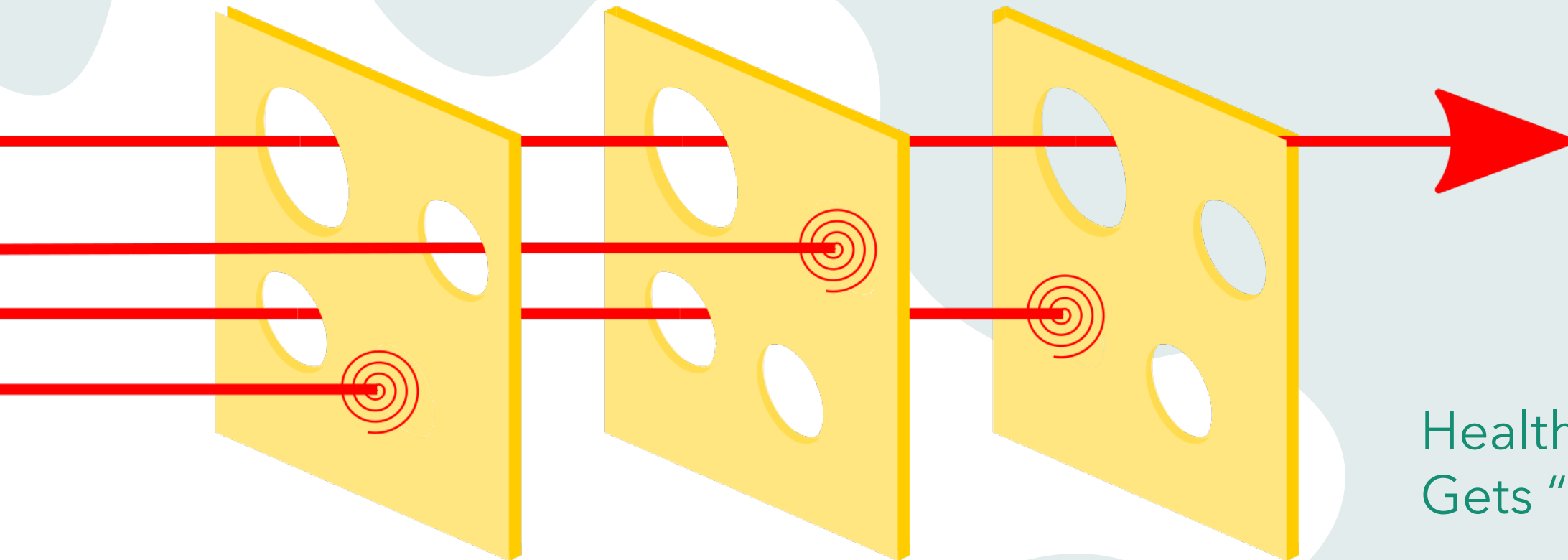
Timelines

A bit of perspective

Drug Development Process



Designed for Purpose



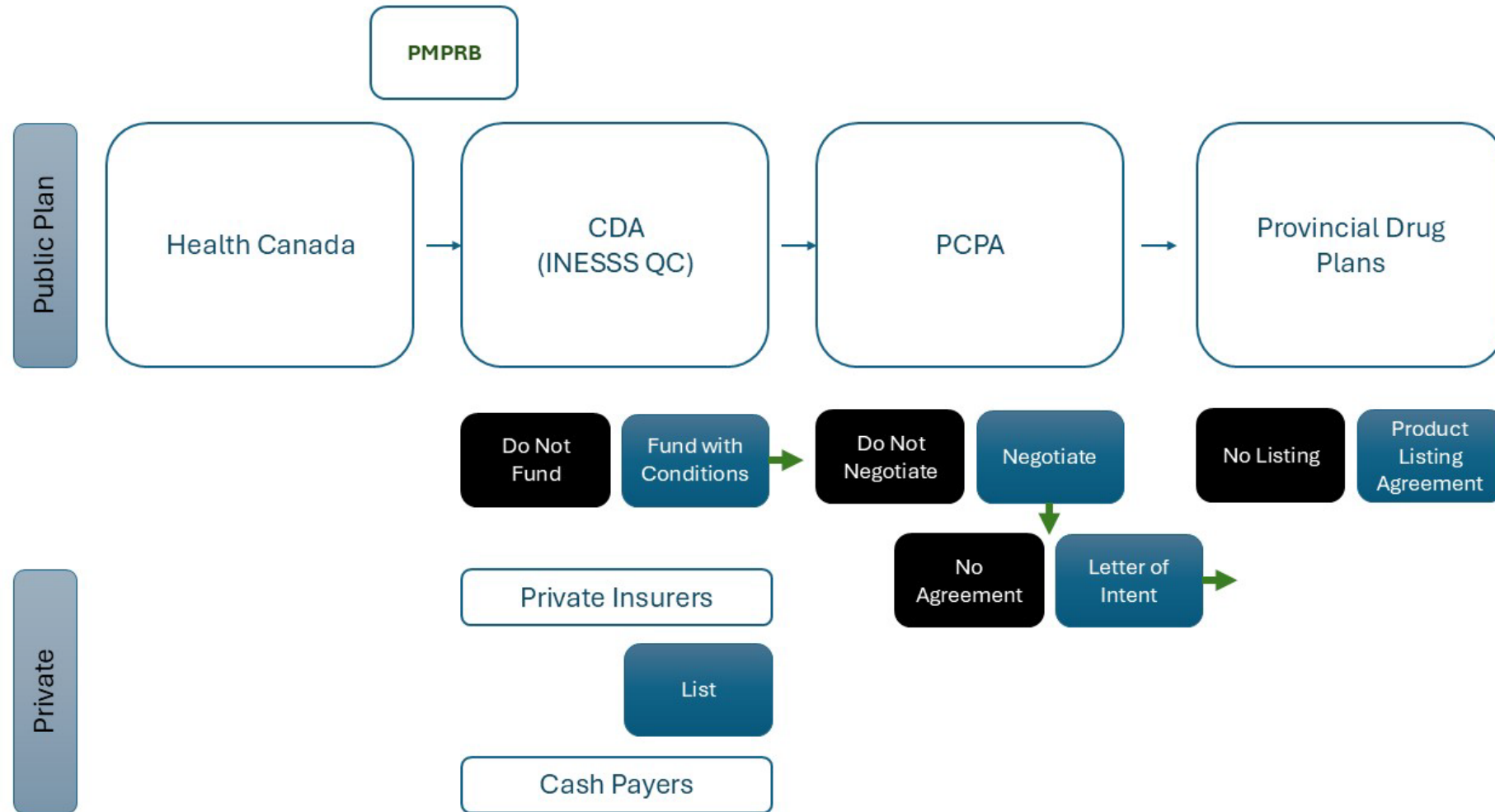
Health System
Gets "Value"

Clinical
Research

Regulatory
Review

Economic
Review/
Decisions

Drug Review System



Drug Review System – Market Authorization



Minister of Health

Health Products and Food Branch

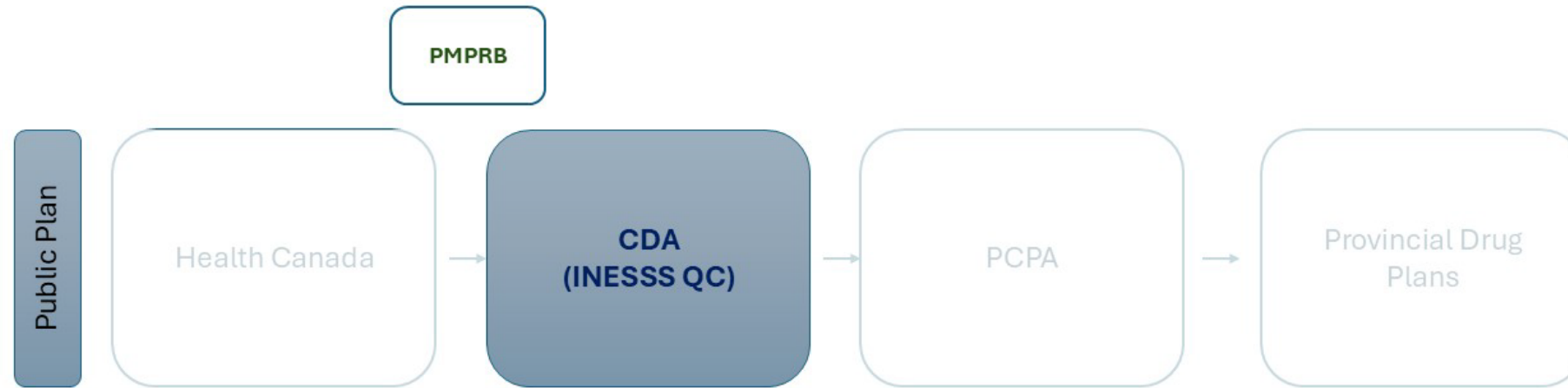
- Clinical Trial Approvals
- Approvals
- Post Market Monitoring

Drug Review

New Drug Submission

- Safety
- Efficacy
- Quality

Drug Review System – HTA



Non-profit Corporation – National Mandate

Funded: Health Canada,
Industry Fees, Provinces

Board: Provincial Drug Plans, HC, Health
System, Public

Drug Reimbursement Review

Clinical Benefit
Economic Evaluation
Drug Plan perspective

Non-Binding Recommendations

Drug Review System – Price Negotiation



Non-profit Corporation

Funded: Federal transfer*

Board: Provincial Drug Plans, Federal Drug Plans

Drug Access Negotiations

Price / Volume (rebate)
Access Conditions

Non-Binding Letter of Intent

Drug Review System – Listing Decision



P/T government drug benefit plans

Some are income-based universal programs.

Most have specific programs for populations

Seniors,

- Recipients of social assistance,
- Disease/Condition Specific
- Catastrophic Coverage

Drug Listing Decision

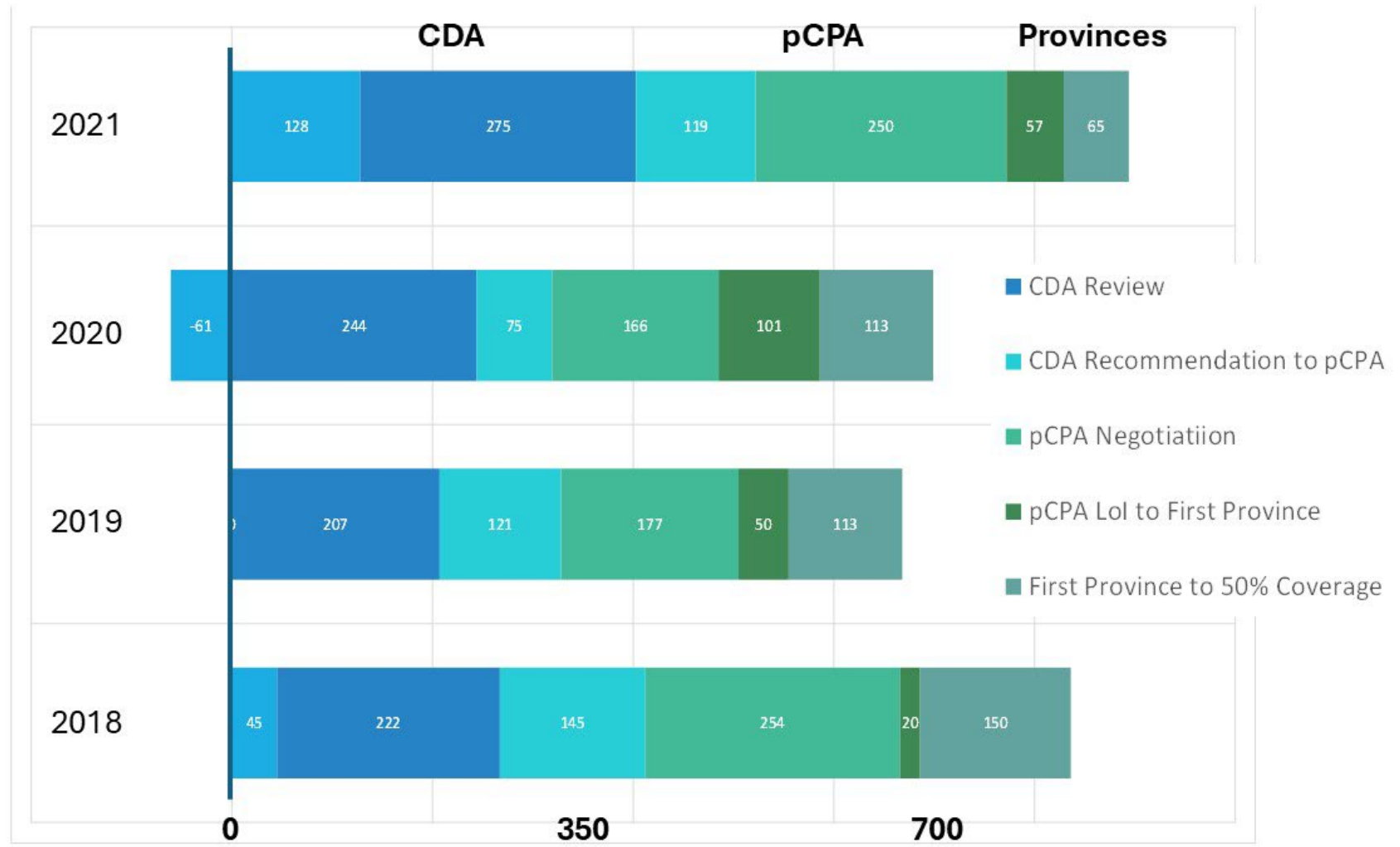
Product Listing Agreement

Standard Formulary/

Exceptional Access

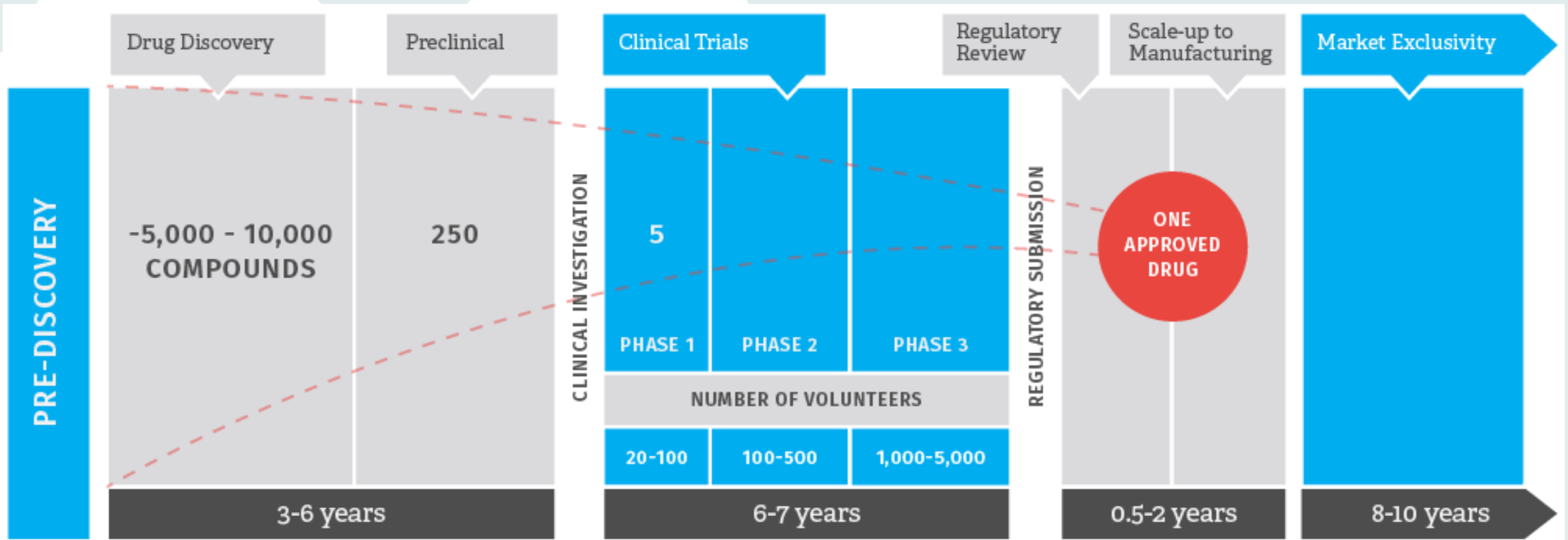
- Budget Impact
- Conditions of Access
- Place in Therapy
- Related Health Products/Services

Timelines



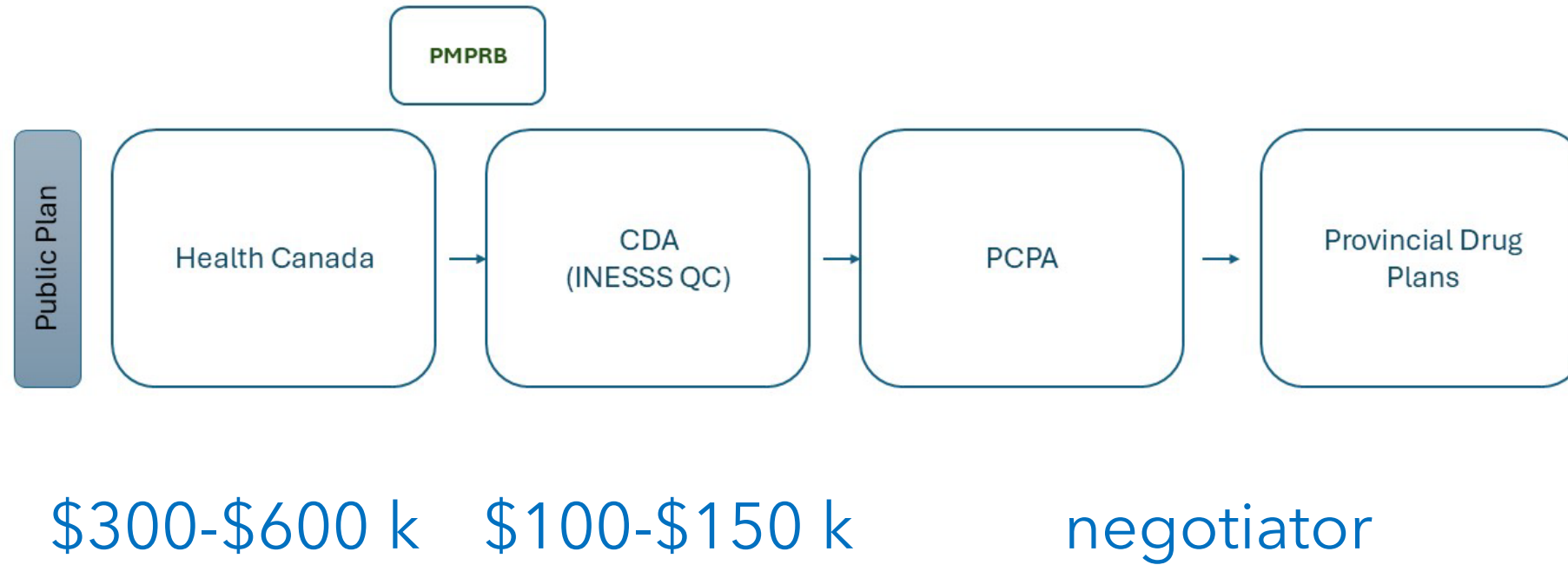
Some Perspective

Drug Development Process



Clinical use in children follows

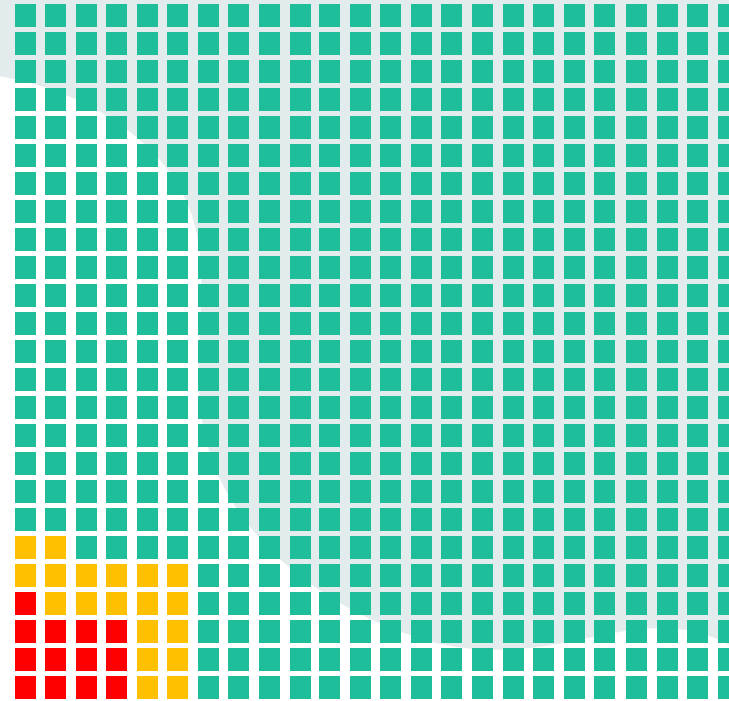
Drug Review System



Each step expects a sponsor – a drug company seeking market access.

25% of interventional cancer trials recruiting under 18 involved an industry partner

Scale – Market Authorization

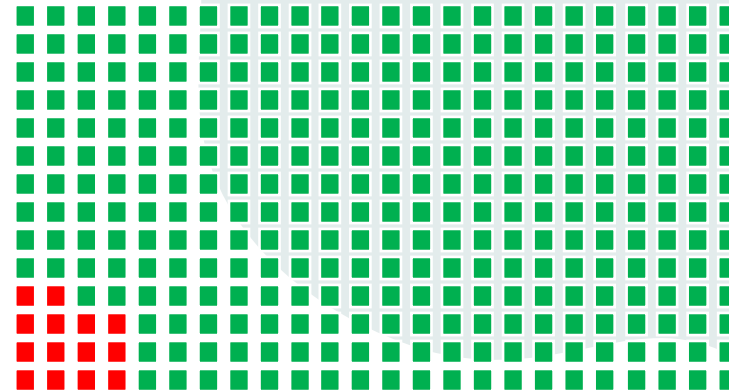


~600 unique cancer agents since 2000 (FDA)

~ 32 pediatric indications - 69% since 2015 (FDA)

Health Canada approved ~14 pediatric indications

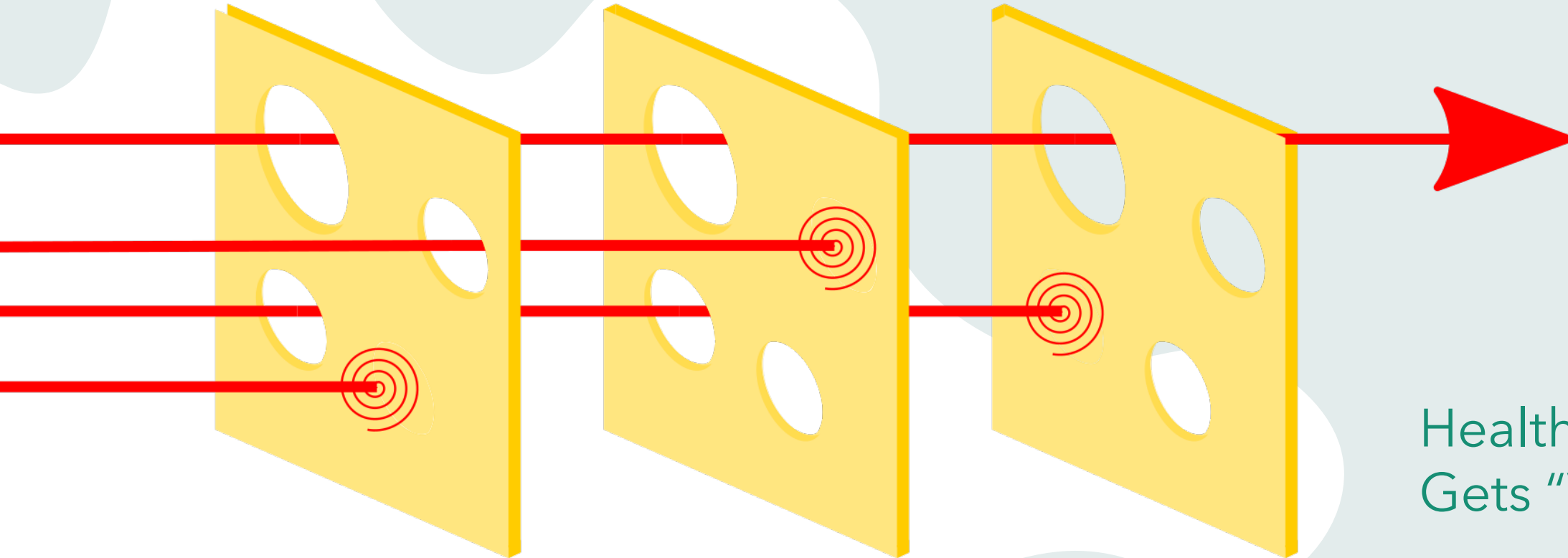
Scale – HTA



~350 cancer HTA reviews (CDA)

Ac2orn participated in 14 since 2017 (5 for blinatumomab)

Designed for Purpose



Health System
Gets "Value"

Are current configurations what we need to move medicines with evidence through the system?



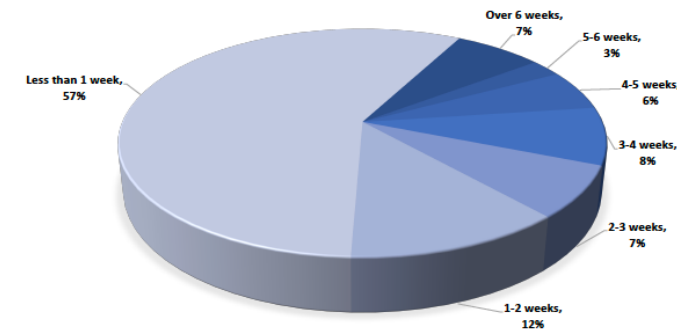
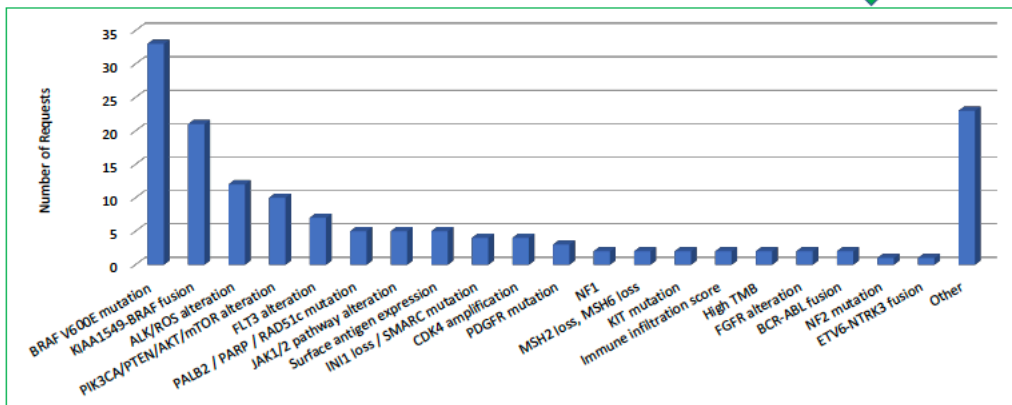
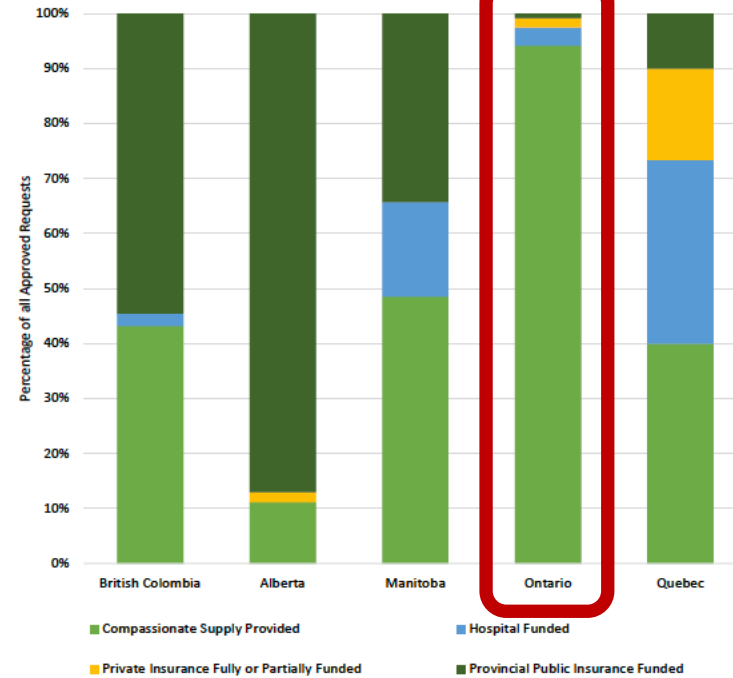
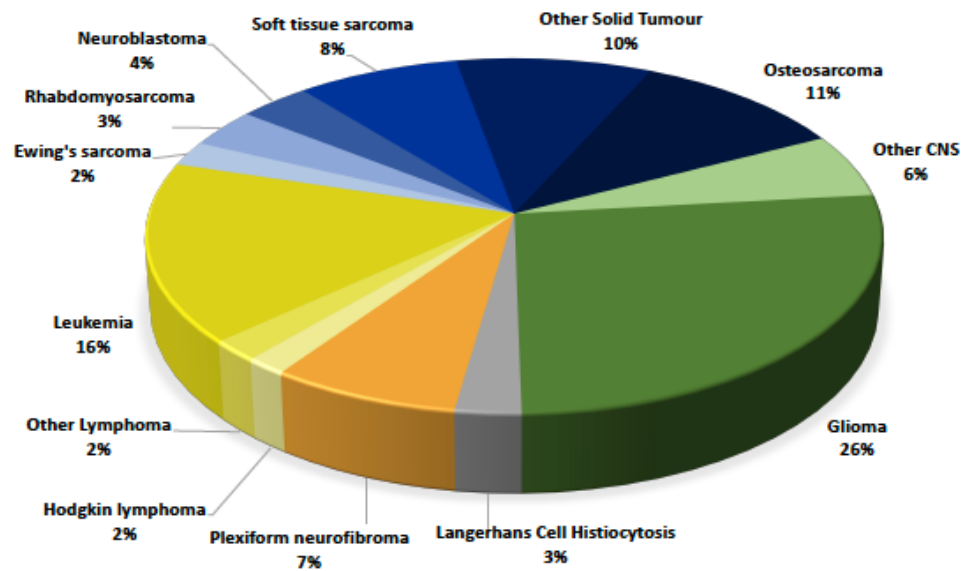
***The Problem is Big Enough, The
Problem is Small Enough:
Challenges and Opportunities in
Pediatric Cancer Drug Access***

Avram Denburg, MD PhD

ACCESS AGM January 28, 2025



Innovative Cancer Drug Access Requests for Children in Canada



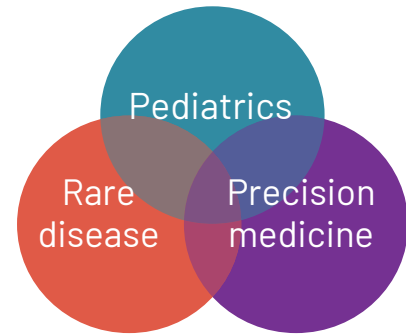
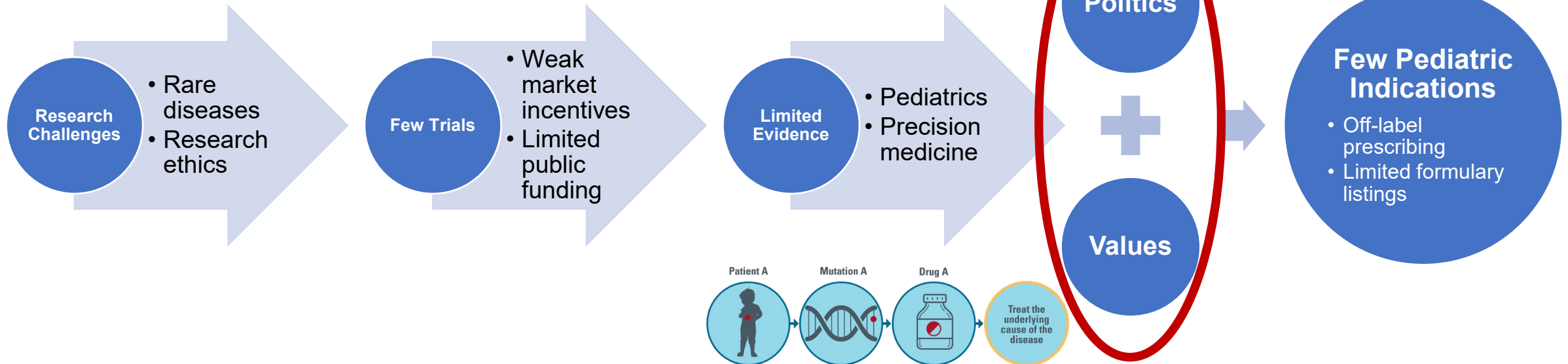
Judd et al 2023

The Pediatric Pipeline: Bends and Bottlenecks



Few innovative therapies for children and youth are **developed** and **approved** for sale and funding in most health systems

Key reasons:



Determinants of Access to Cancer Drugs for Children



Access is inequitable within and across jurisdictions. Lack of data constrains access.

ACCESS



Astronomical costs for few patients. Amid resource constraints, how do we invest fairly and sustainably?

COST



Gaps in peds evidence. Different needs and standards of regulators vs HTA vs funders.

EVIDENCE



Uncertainty of benefit as barrier to decision-making. Need to reward data generation.

UNCERTAINTY



Expanding the set of values considered. Tensions re: decision inputs and resource allocation.

VALUES

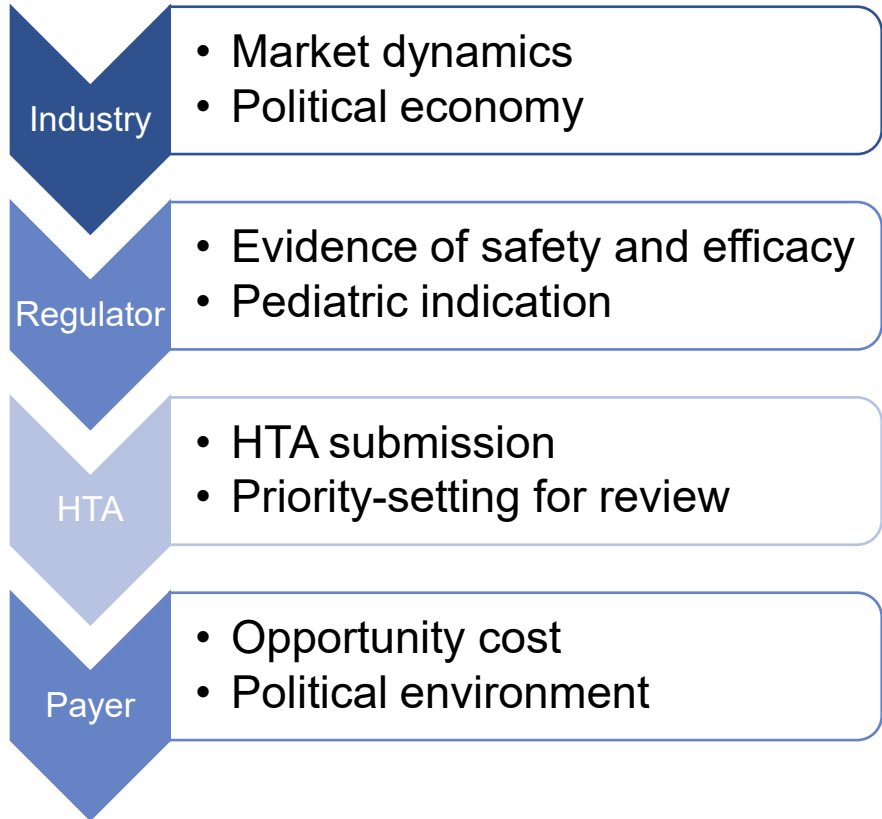


Differential power of decision-makers causes duplication and division. Need for collaboration and partnerships.

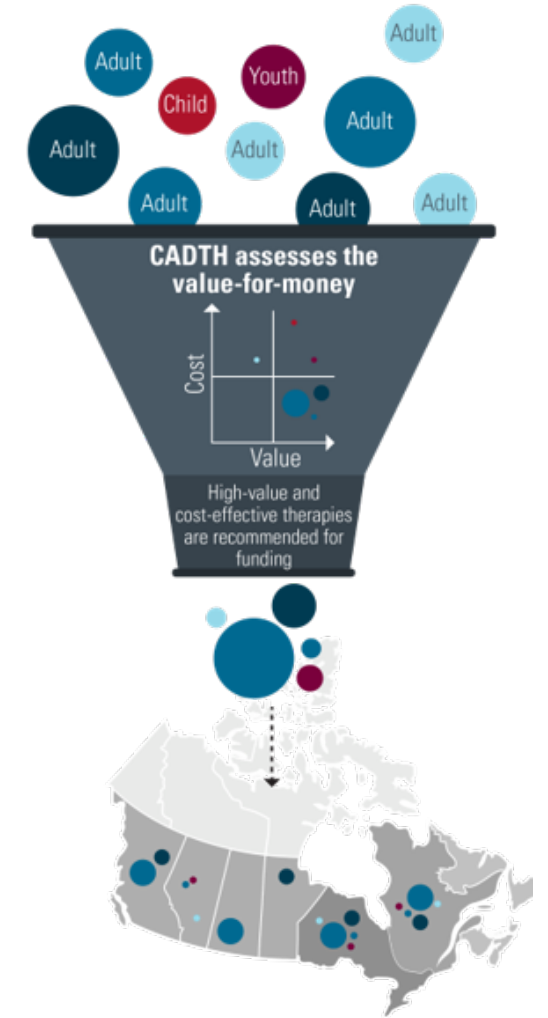
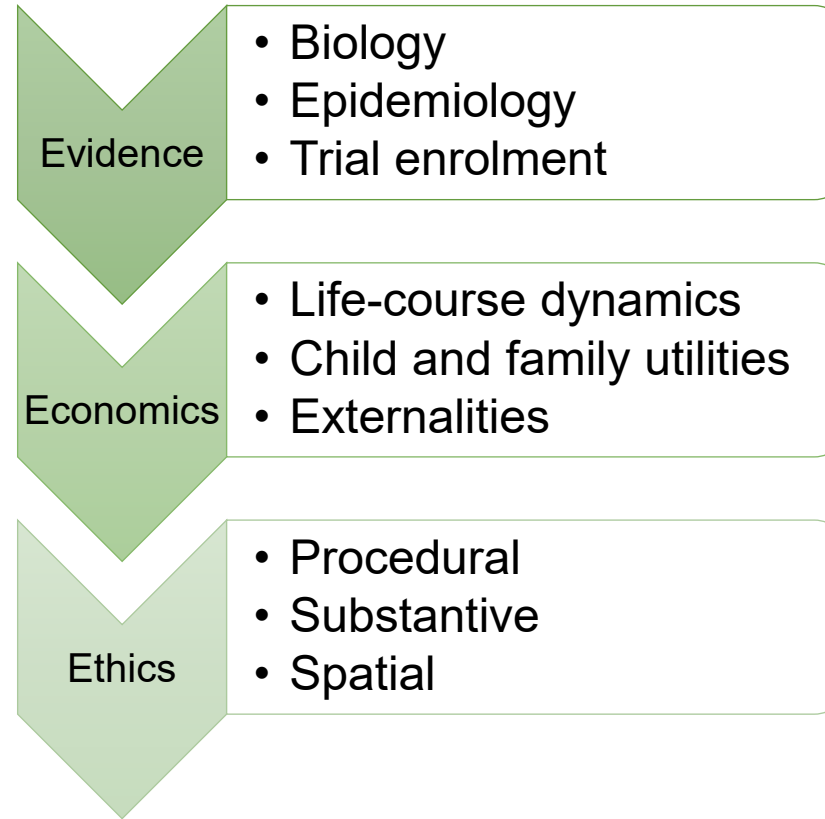
GOVERNANCE

Pediatric Cancer Drug Access: Major Dynamics and Challenges

Health system challenges



HTA challenges



Limited and inequitable access

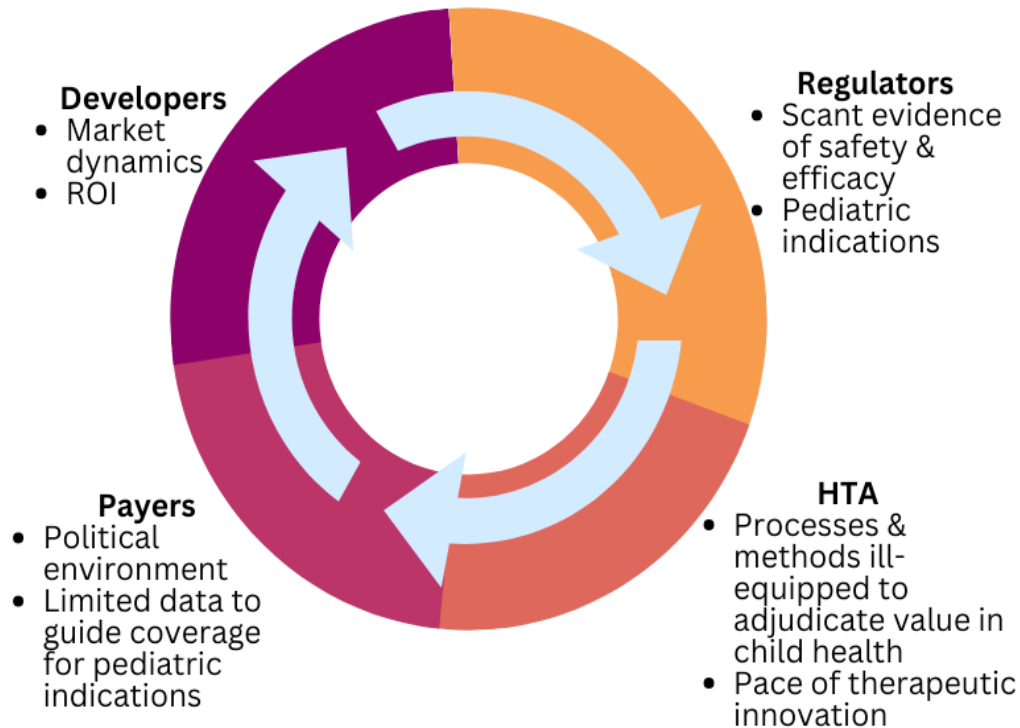
Drug Archetypes

1. Developed in adults, and often later for pediatrics for the **same indication** (e.g. Brentuximab vedotin)

2. Developed in adults and children for a **different indication** (e.g. Crizotinib)

3. Developed **only for pediatrics** (e.g. Dinutuximab)

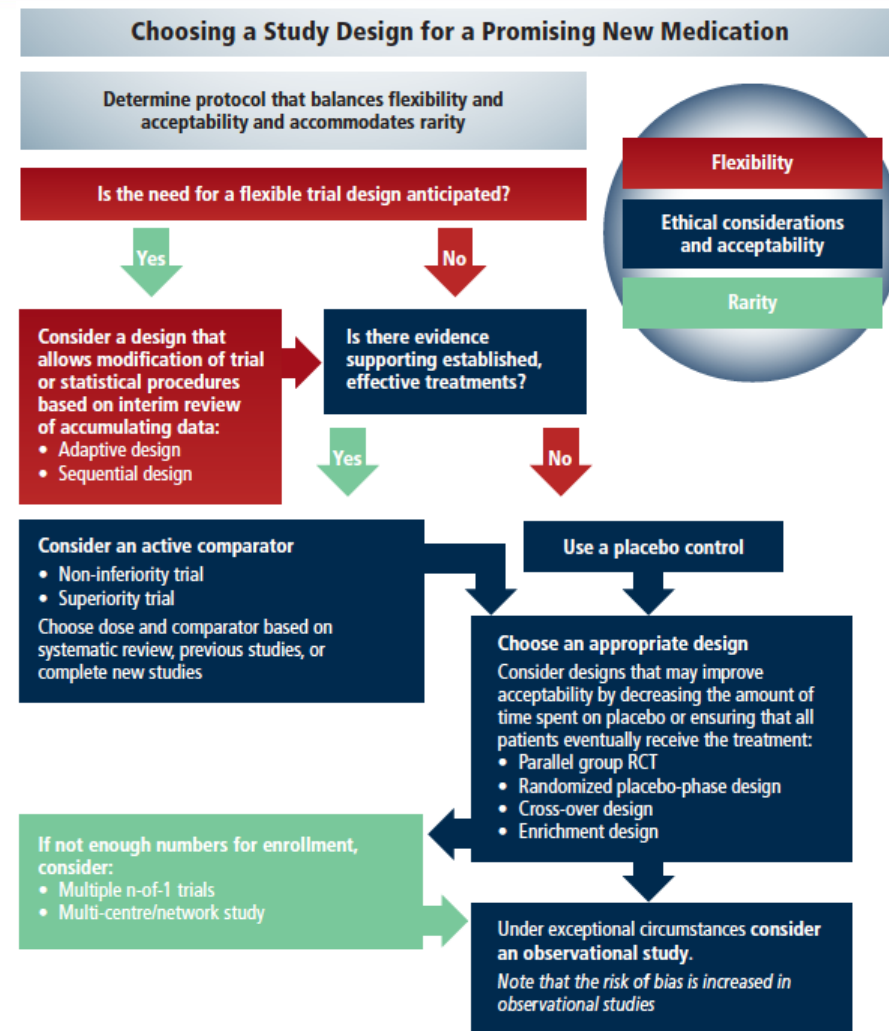
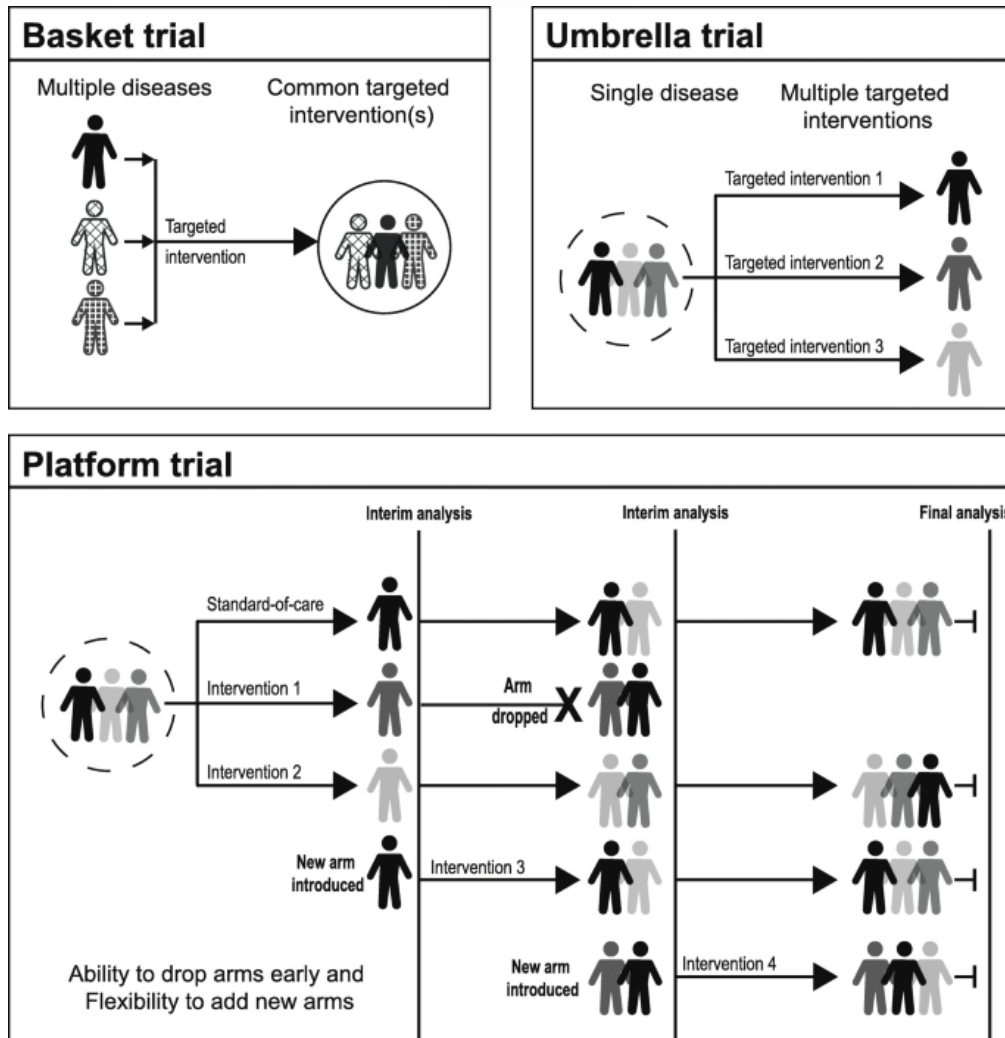
Shared and Distinct Challenges



Public drug approval and funding pathway in Canada		Child and youth perspective	
3-6 years	Step 1: Research and discovery		
	Step 2: Pre-clinical research	Problems	Potential solutions
6-7 years	Step 3: Clinical trials	Few innovative therapies targeting children and youth	Regulations to optimize inclusion of children and youth
6 months - 2 years	Step 4: Regulatory approval Health Canada <i>Should the drug be sold in Canada?</i> Assesses for safety, quality and if they work as intended, but does not consider cost or effectiveness compared to other approved therapies.	Few innovative therapies approved	Regulations to optimize inclusion of children and youth
	Step 5: Value/pricing assessment Canadian Agency for Drugs and Technologies in Health & Institut national d'excellence en santé services sociaux <i>Does the drug offer value for money?</i> Conduct health technology assessments to evaluate the clinical benefits and cost of drugs. Issue recommendations for or against public funding.	HTA frameworks don't fully account for the unique dimensions of children and youth	HTA frameworks tailored to children and youth
	Deciding which drugs to cover Pan-Canadian Pharmaceutical Alliance <i>Can we negotiate a lower price?</i> Jointly negotiates drug prices and coverage criteria with manufacturers on behalf of public drug plans.	High cost	Improved information generation, collection and management Tailored HTA
lifetime	Public Drug Plans <i>Will we cover this drug for our beneficiaries?</i> Consider factors such as needs of those served by their drug plan and a drug's potential budget impact to determine whether to add it to the plan's formulary.	Differences in funding and coverage across Canada	Improved information generation, collection and management Tailored HTA
	Step 6: Post-market surveillance		

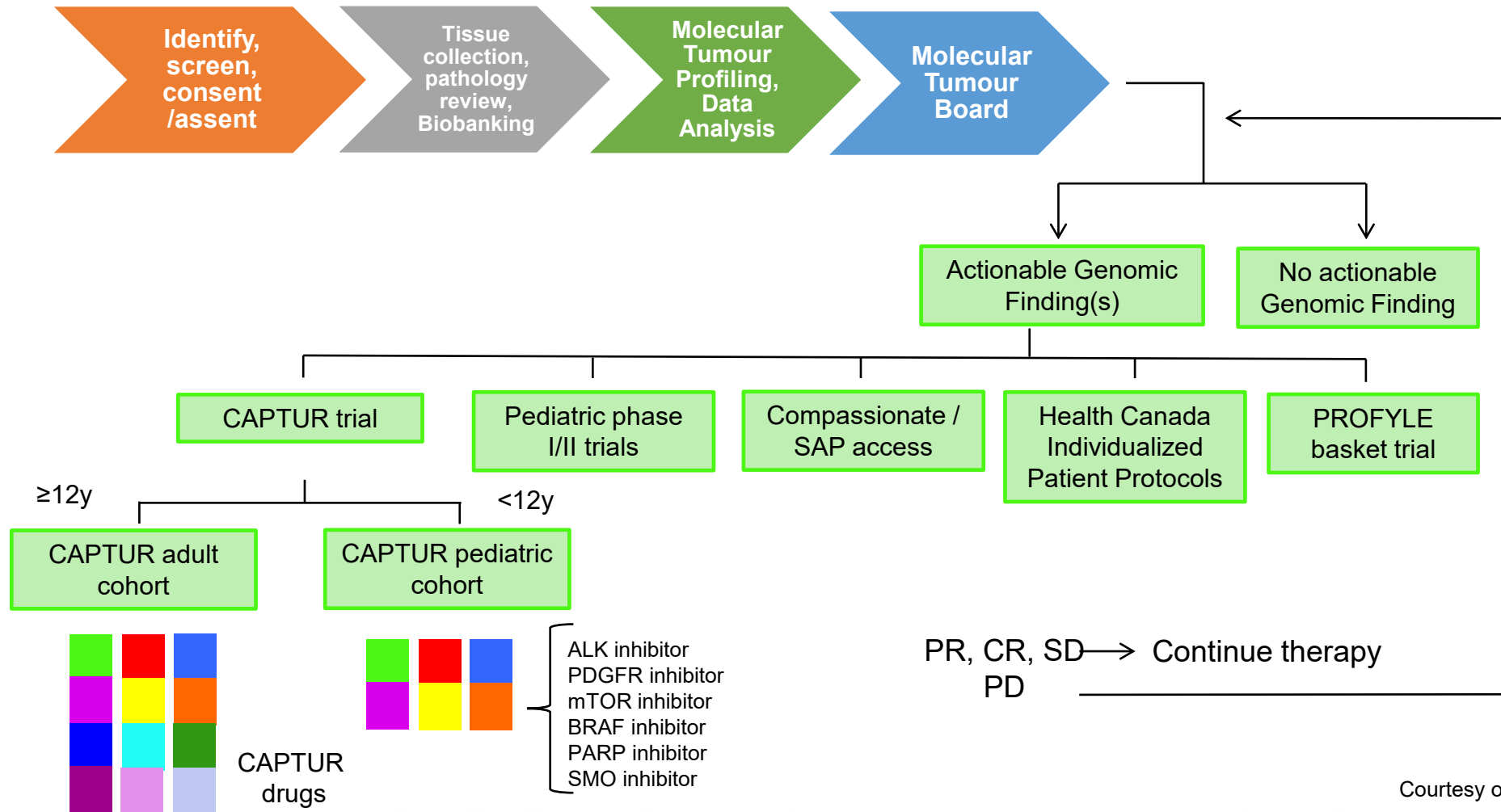
Adapted from: <https://aphm-inc.com/drug-review-approval-process>
©in-canada-am-infographic/
<https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharm-act/reports.html>

Adapting to Uncertainty: Innovation in Pediatric Trial Design



CCA 2014

Precision Oncology in Pediatrics: Trial Innovation in Practice



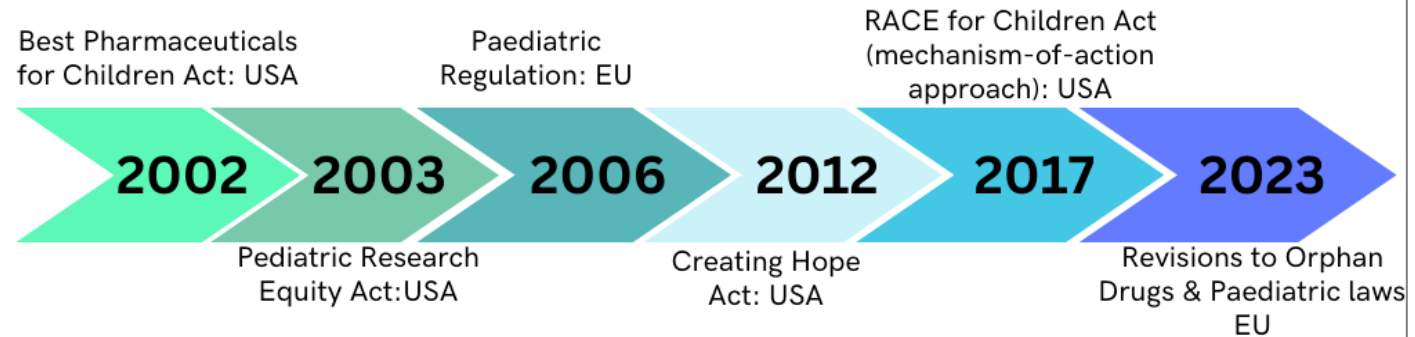
Courtesy of R Deyell. PROFYLE 2020



International approaches to these challenges:

Pediatric-specific regulatory reform

Legal frameworks for paediatric drug development



Incentives to submission of paediatric data:

- Market exclusivity
 - EU & UK: 6-mos if paediatric investigative plan (PIP) is completed + 2yr extension for orphan designation
 - CAN: 6-mos paediatric extension for innovative drugs
- Reduced fees and review time

Conditions:








- EU & US: Paediatric data submitted within specific timelines (e.g. end of adult phase 1 trial)
- US: If molecular target is relevant to paediatric cancer, trials in children are required



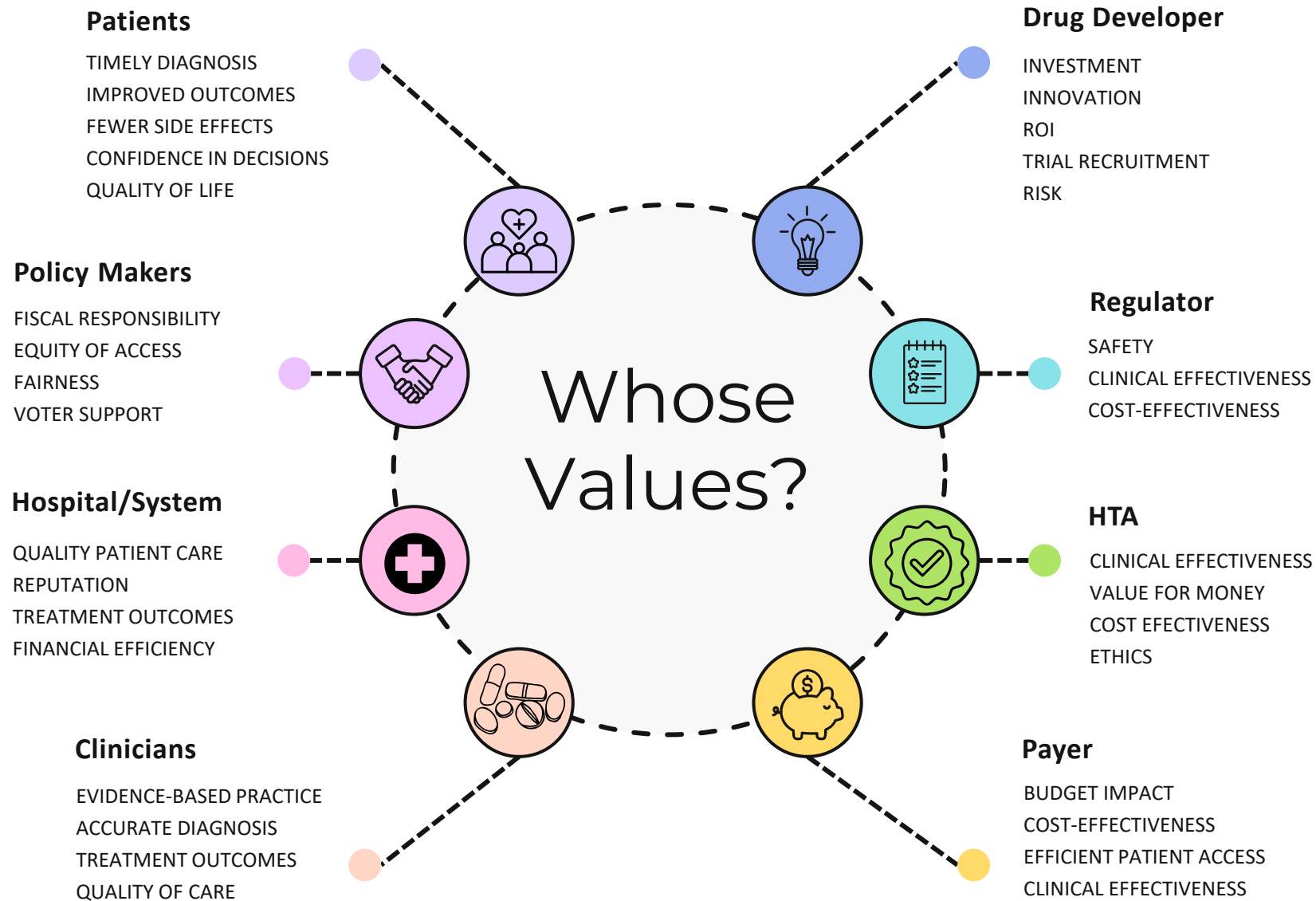
Impact: dramatic increase in % of submissions including paediatric data

Same Problems, Different Framings, Distinct Architecture...



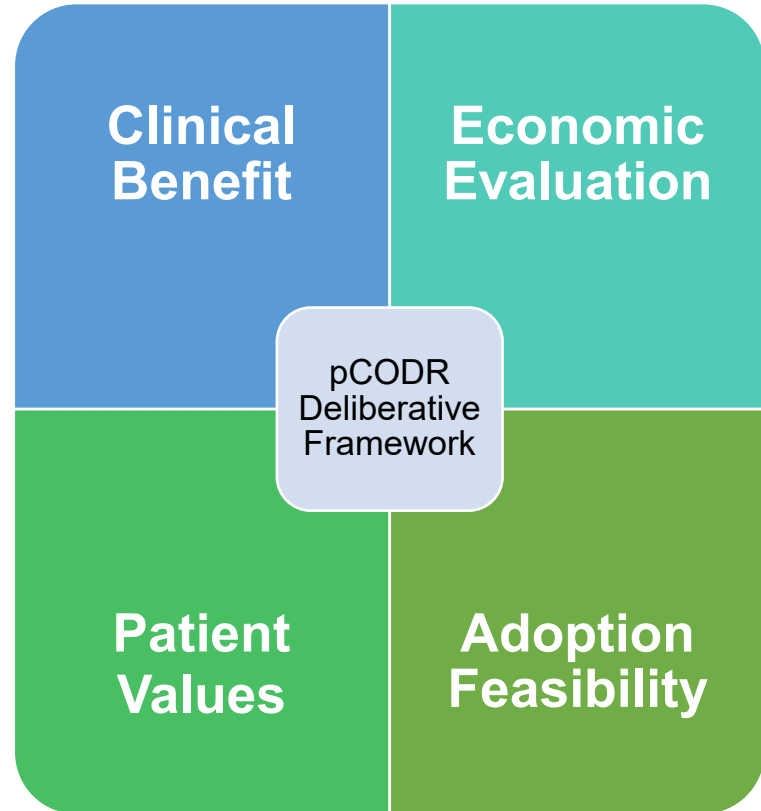
Jurisdiction	Regulator	Existing pediatric legislation	Regulatory pathways for pediatrics or rare disease (RD)	HTA body	Special provisions for peds or RD	Binding Recommendations	Special funding for peds or RD
Canada	Health Canada	 *Pilot underway	Special Access Program Precision Regulation: Reliance Authority	CDA (National), INESSS (Quebec)	RD parameter in deliberative framework, FMEC 'sandbox'		Varies by province/territory
EU	European Medicines Agency (EMA)		Paediatric Investigative Plan (PIP) requirement Orphan designation	Member states *Transitioning to EU-level joint clinical assessment	No	Varies by Member State	Varies by Member State
UK	Medicines & Healthcare products Regulatory Agency (MHRA)		PIP Orphan designation Promising Innovative Medicine Designation	NICE (National)	Highly Specialized Technologies Appraisal		Innovative Medicines Fund Cancer Drugs Fund
Australia	Therapeutic Goods Administration (TGA)		Orphan designation	MSAC & PBAC	No	 *Contingent on Ministerial approval	Life-Saving Drugs Program

Value in an Era of Precision Medicine

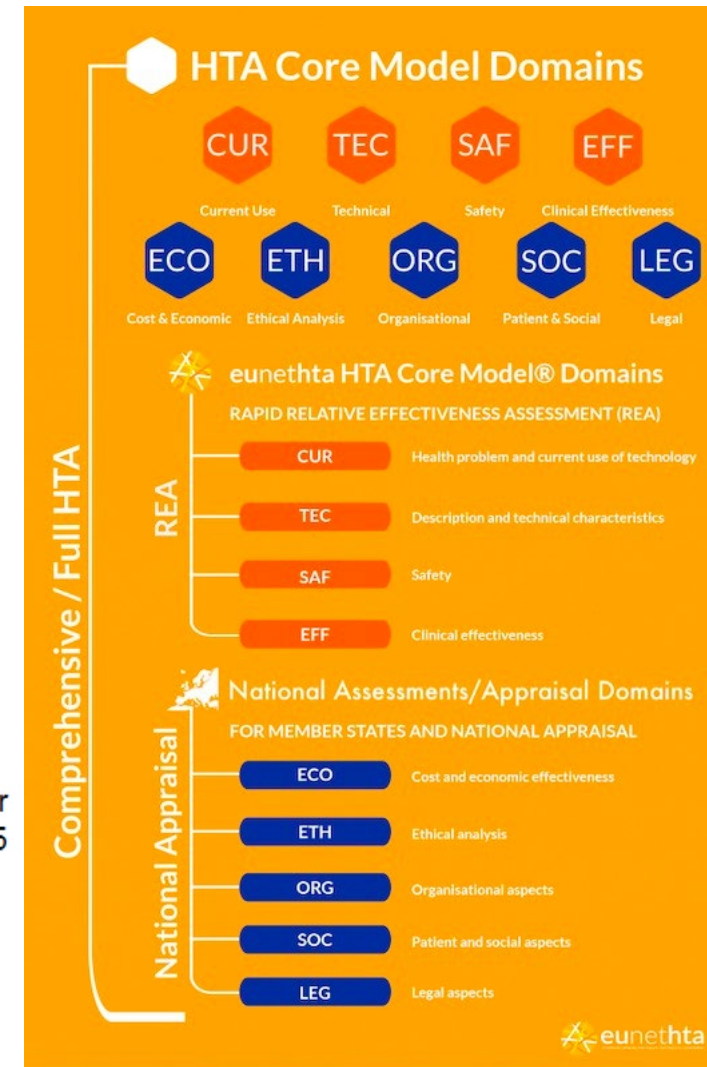
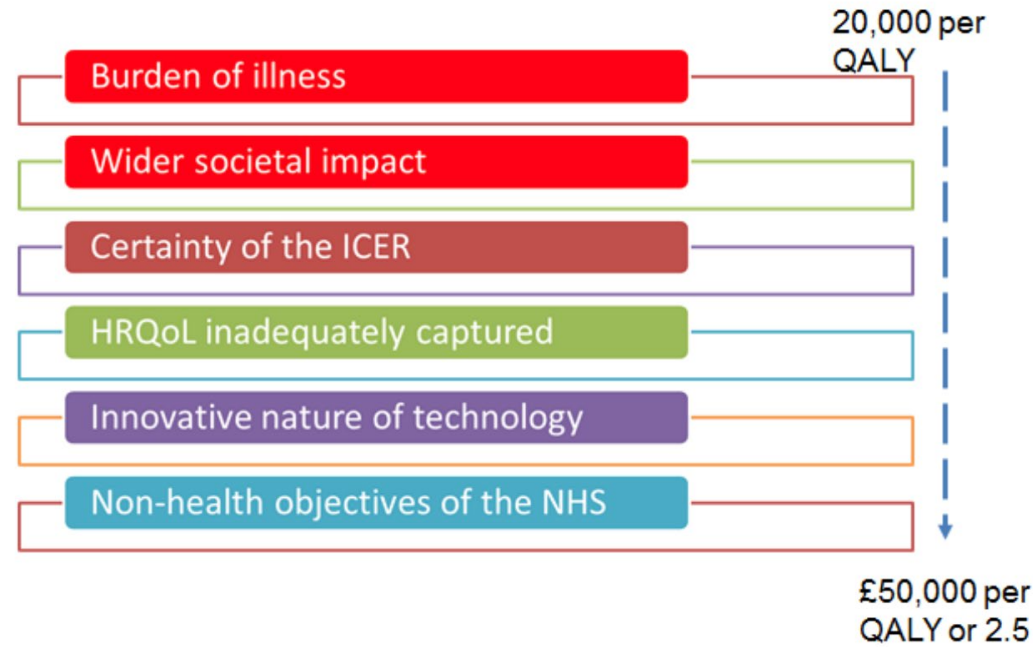


Value Frameworks: Deliberating on Uncertainty

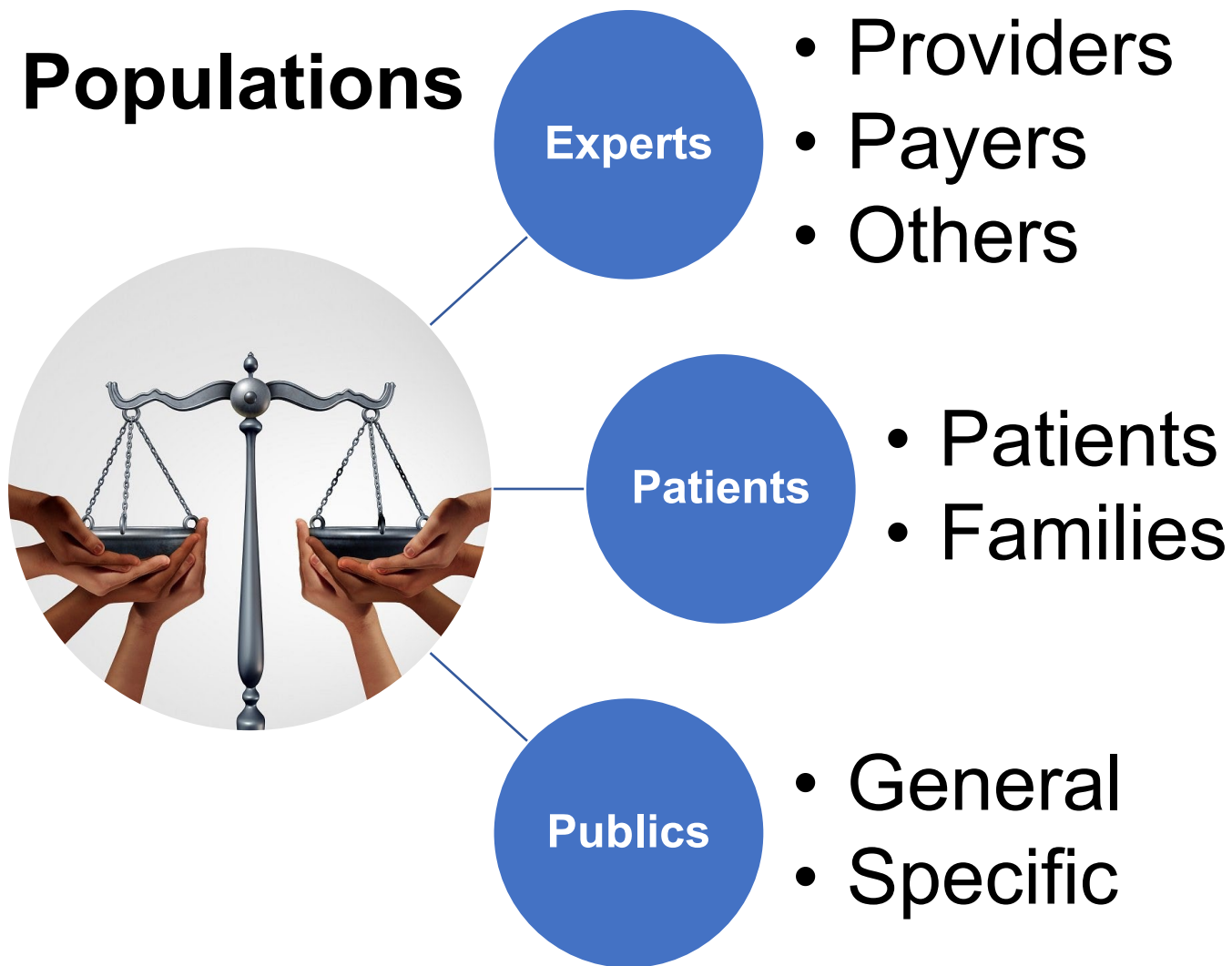
CADTH



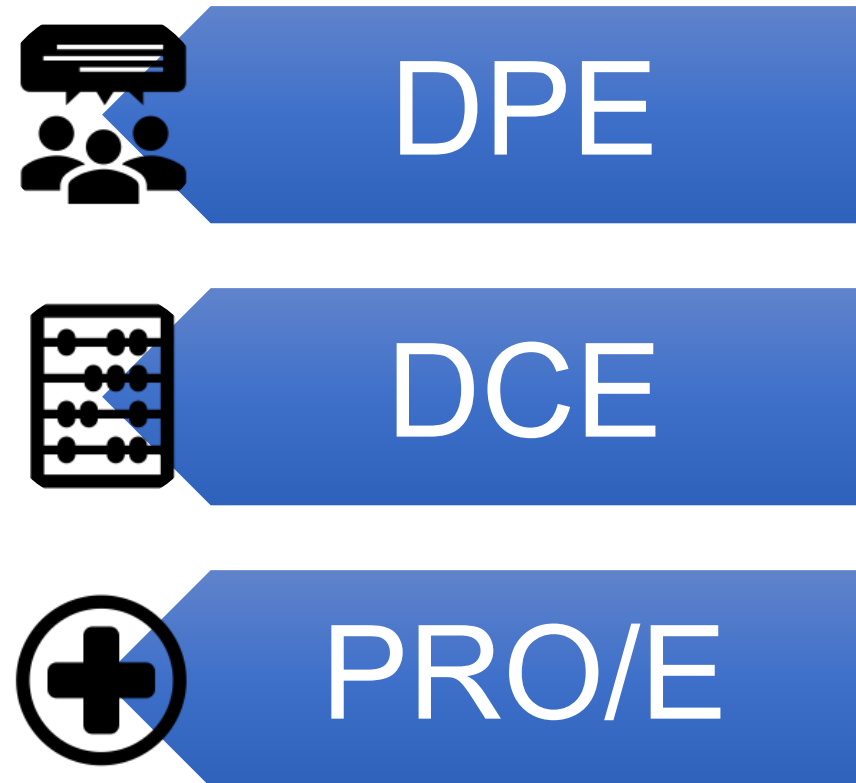
NICE National Institute for Health and Care Excellence



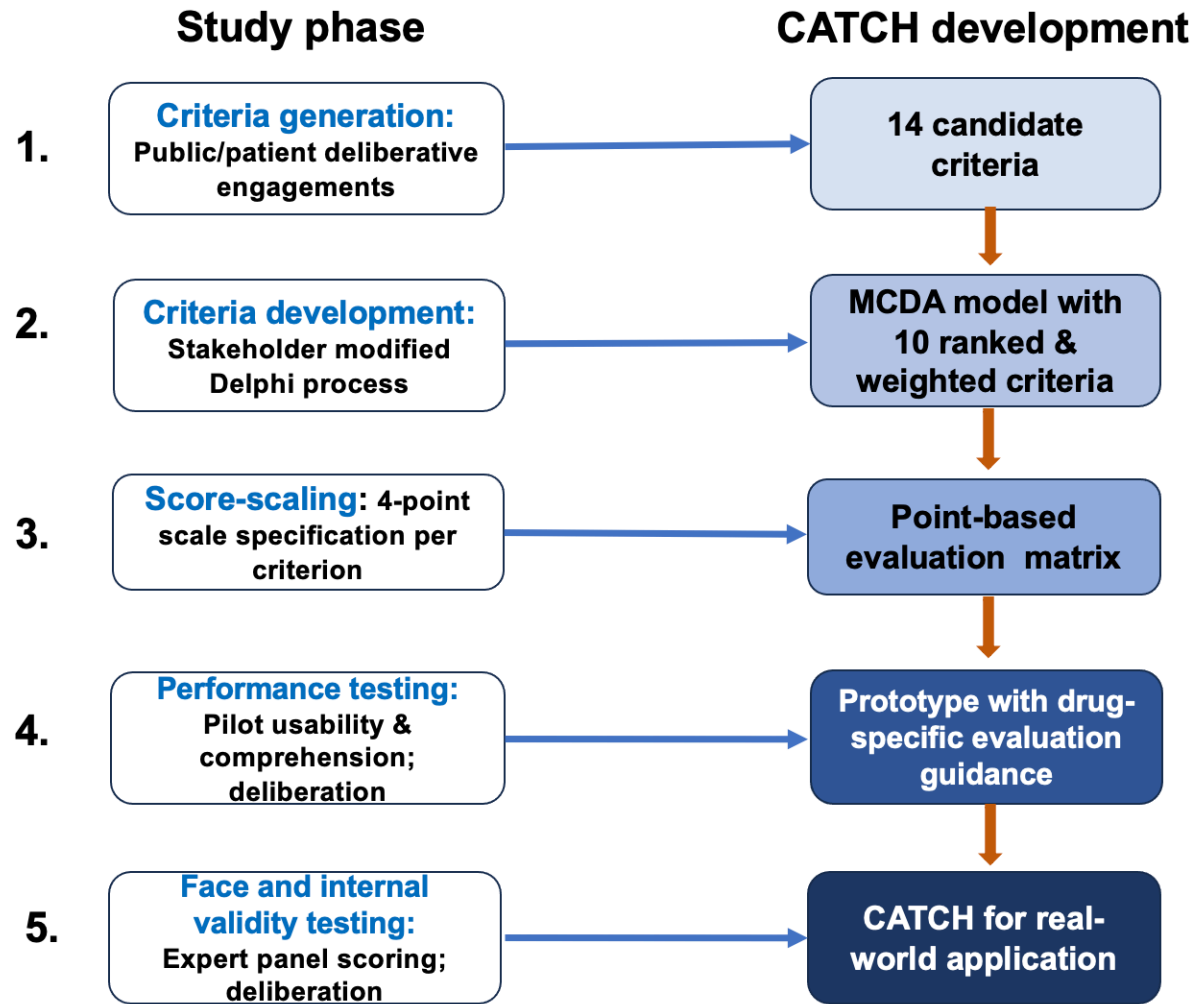
Populations



Methods



Making HTA Child-Sized: Value Framework Innovation



Final criteria and weights

Effectiveness	19	Equity	10
Child HRQOL	18	Family Impacts	9
Disease Severity	17	Childhood Development	3
Unmet Need	11	Rarity	2
Therapeutic Safety	10	Fair Innings	1

PROs in Practice: Role in Regulatory Approvals

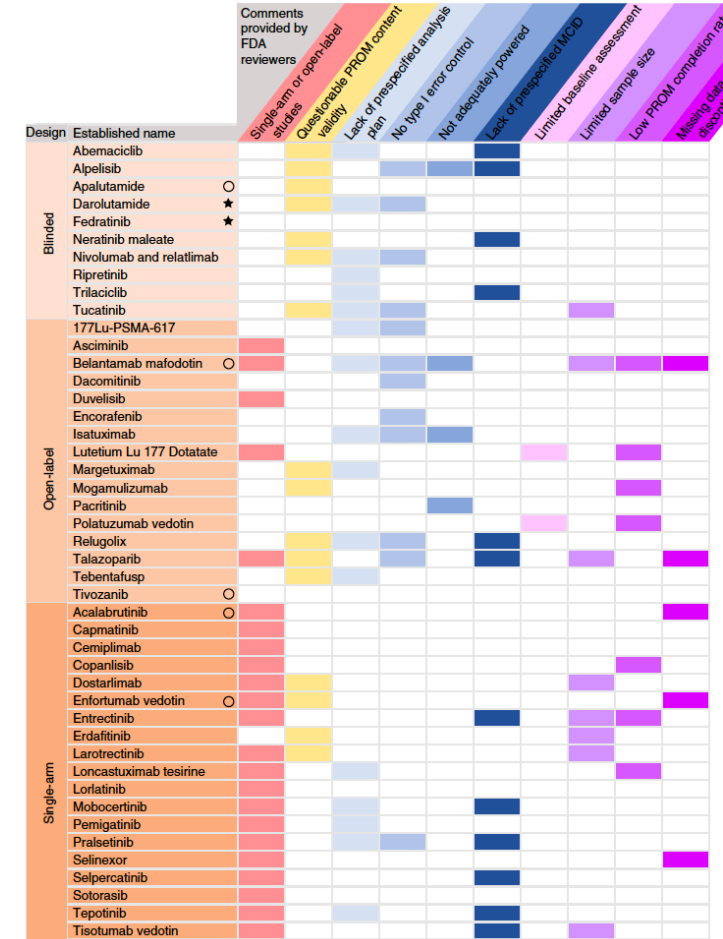
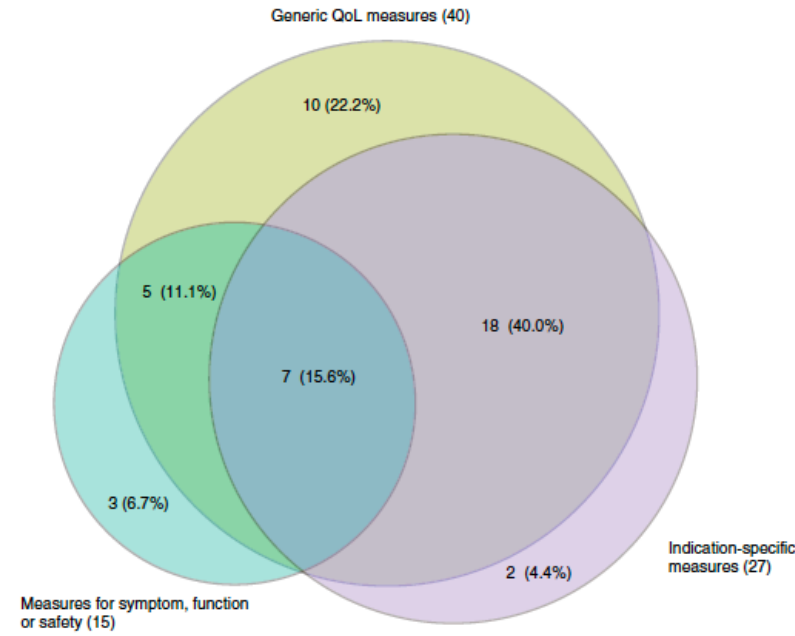
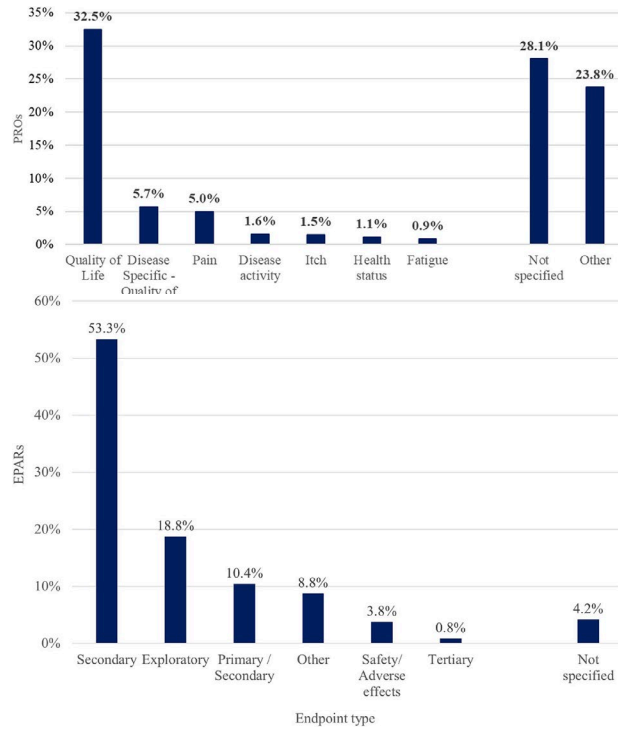
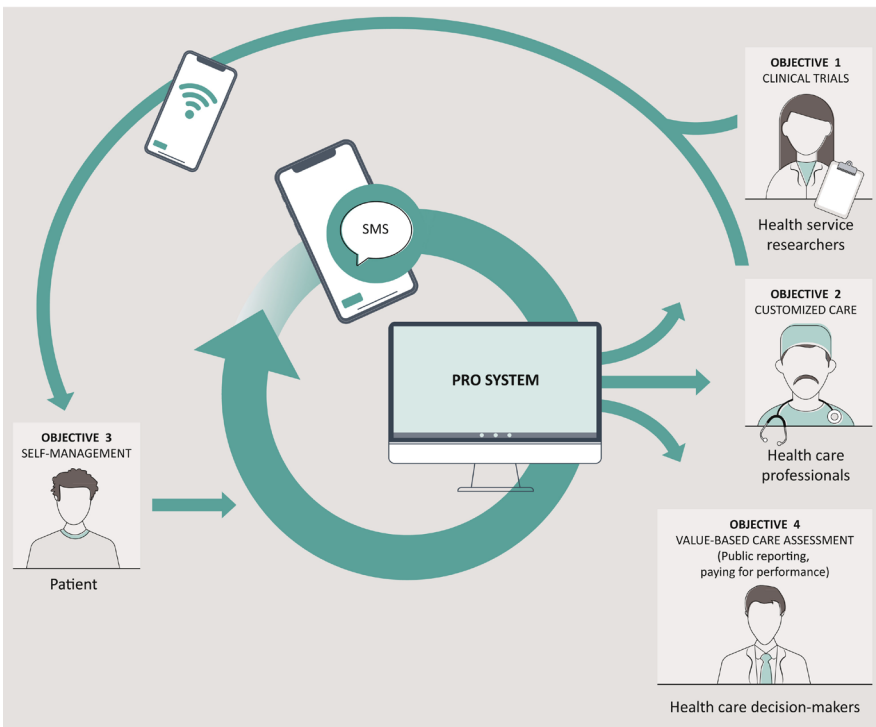


Table. Summary of PROMs Consideration Included in EMA New Marketing Authorizations in Oncology, 2017-2021

EMA new oncology marketing authorizations ^a	2017 (n = 15)	2018 (n = 22)	2019 (n = 13)	2020 (n = 23)	2021 (n = 30)	Total (N = 103)
Biosimilar, No. (%)	2 (13)	5 (23)	1 (8)	3 (13)	4 (13)	15 (15)
Generic, No. (%)	0	5 (23)	5 (39)	7 (30)	8 (27)	25 (24)
With PROMS, No. (%)	12 (80)	10 (46)	7 (54)	9 (39)	14 (47)	52 (51)
With PROMS excluding biosimilar and generic, No./total No. (%)	11/13 (85)	10/12 (83)	7/7 (100)	8/13 (62)	14/18 (78)	50/63 (79)

Ge et al., 2023; Ciani et al., 2023; Meregaglia et al., 2023

PROs in Practice: Evidence for Expanded Value Assessments

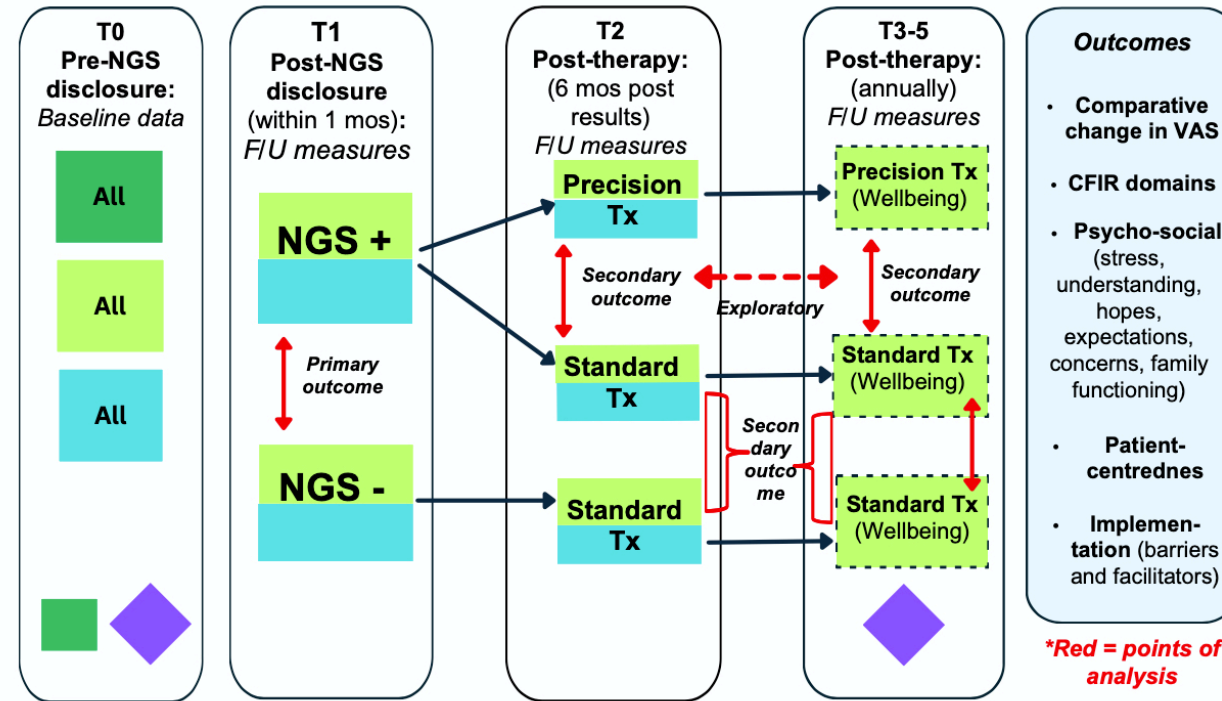


AIM 1: Patient & Care-giver Experience

- Demographic survey
- Psychosocial Surveys (incl. Pt./proxy EQ-5D-Y; Distress thermometer; Experiences & impacts; P-GUIDE)
- Interview

AIM 2: Healthcare professional experience

- ◆ Interview



**Red = points of analysis*

1. **Coordinate** review processes at regulatory and HTA stages
2. **Harmonize** standards and principles across regions
3. **Engage** multiple stakeholders upstream
4. **Amplify** the patient voice and **expand** decision-making tables

REDESIGNED HTA

HTA has to encompass more than just the patient as an adult [...] **Kids are dependent** on their surroundings and their support system, and those people are impacted, and their quality of life is impacted." -*Pharmacist*

REGULATORY REFORM

We have to...**anticipate needs at a very early stage**. Ideally, we would want to agree on a PIP [pediatric investigative plan] that actually takes into consideration HTA needs, whether it's through PROs, or other quality of life measures, which we might already request to satisfy the HTA decision-making. -*Regulator*

PATIENT VOICE

I think NICE is an exemplar for patient enrollment because they've got patients and clinicians at the table so they're able to make the submission together. And they're at the table when the topic is scoped, which is really important, so **they can say what outcomes matter**. And they're there when the uncertainties are discussed." -*HTA*

EVIDENCE GENERATION

There are uncertainties, and you're never going to really align regulatory and payer requirements, because they are different decisions. So the only resolution is to **reward data**, and that needs very early engagement, and we need to be all agreeing what the key outcomes are. -

HTA

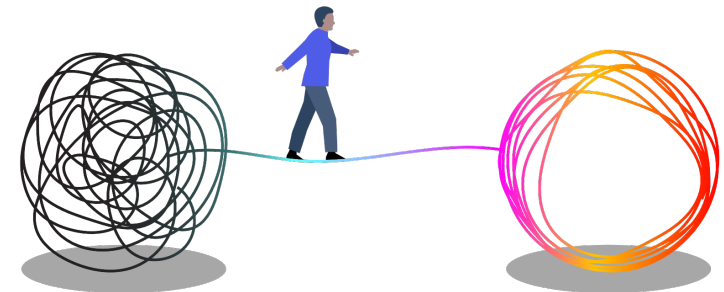
Policy Implications:

1. Pediatrics as a unique and neglected space
2. Oncology as a place to pilot innovative reform
3. Evolving policy landscape as context for findings

"The problem is small enough and the problem is big enough"

(Denburg et al., 2020)

- **Opportunities to strengthen access:**
 1. Policy recommendations on precision oncology implementation for policymakers internationally
 2. Child-focused HTA value framework
 3. Patient- and program-level PRO data for national precision oncology platform
- **Parallel work:**
 - Health system implementation of precision diagnostics in Canada and internationally



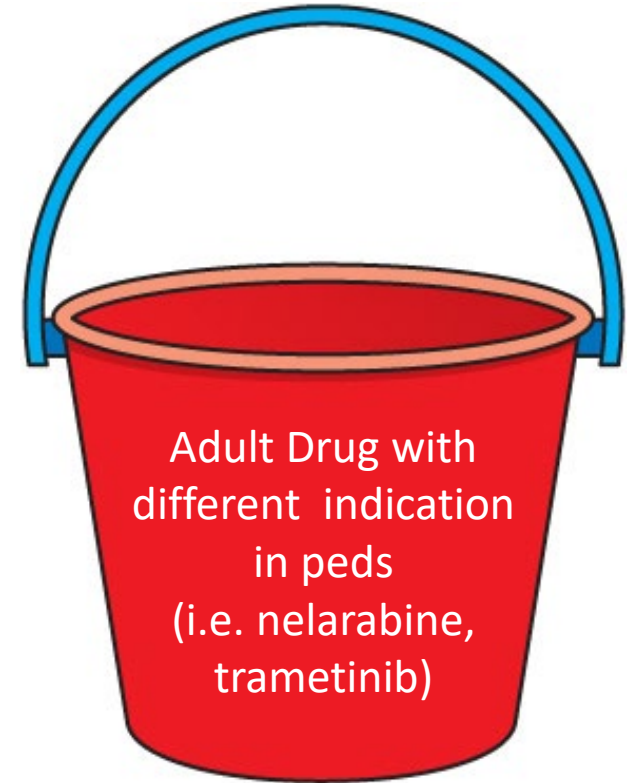
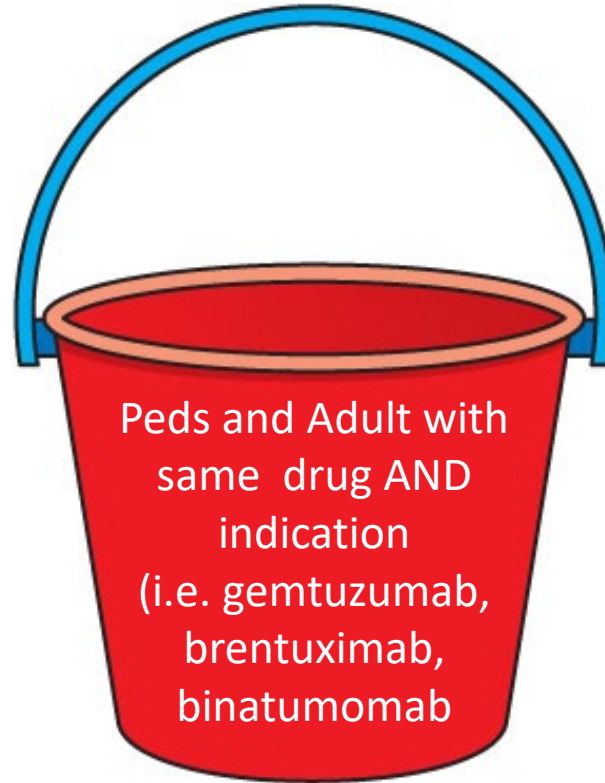
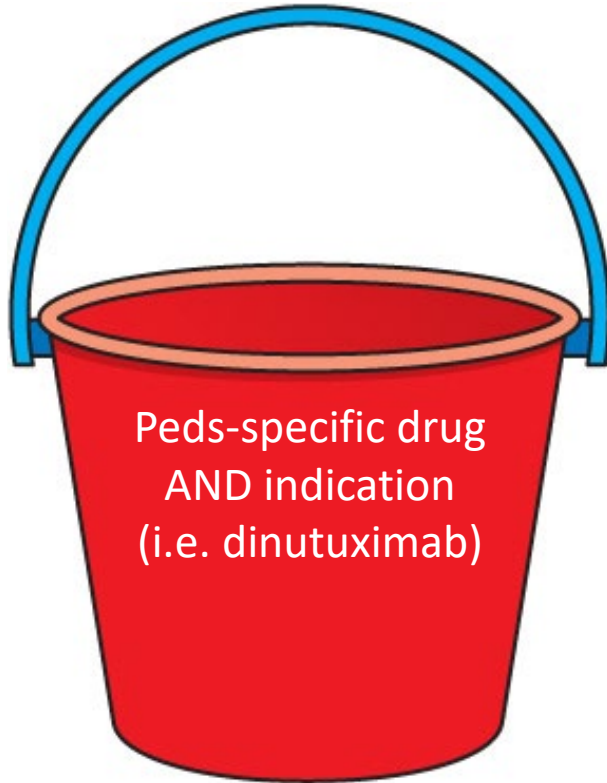


Making your voice heard: Stakeholder engagement in Health Technology Assessment

Drug Access in Canada Panel

January 28, 2025

'Buckets' of Challenges in Canadian Drug Funding



The NEW ENGLAND JOURNAL of MEDICINE

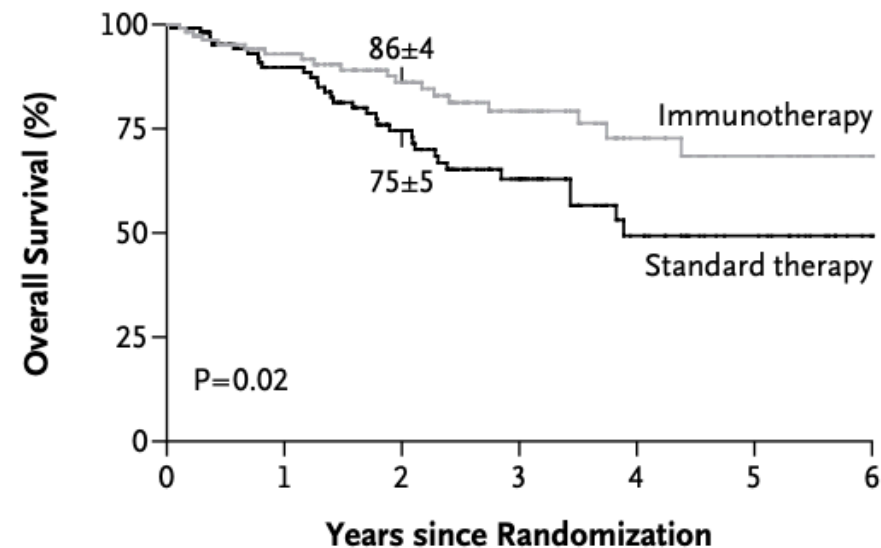
ORIGINAL ARTICLE

Anti-GD2 Antibody with GM-CSF, Interleukin-2, and Isotretinoin for Neuroblastoma

Alice L. Yu, M.D., Ph.D., Andrew L. Gilman, M.D., M. Fevzi Ozkaynak, M.D., Wendy B. London, Ph.D., Susan G. Kreissman, M.D., Helen X. Chen, M.D., Malcolm Smith, M.D., Ph.D., Barry Anderson, M.D., Judith G. Villablanca, M.D., Katherine K. Matthay, M.D., Hiro Shimada, M.D., Stephan A. Grupp, M.D., Ph.D., Robert Seeger, M.D., C. Patrick Reynolds, M.D., Ph.D., Allen Buxton, M.S., Ralph A. Reisfeld, Ph.D., Steven D. Gillies, Ph.D., Susan L. Cohn, M.D., John M. Maris, M.D., and Paul M. Sondel, M.D., Ph.D.,
for the Children's Oncology Group

2010

B Overall Survival



No. at Risk

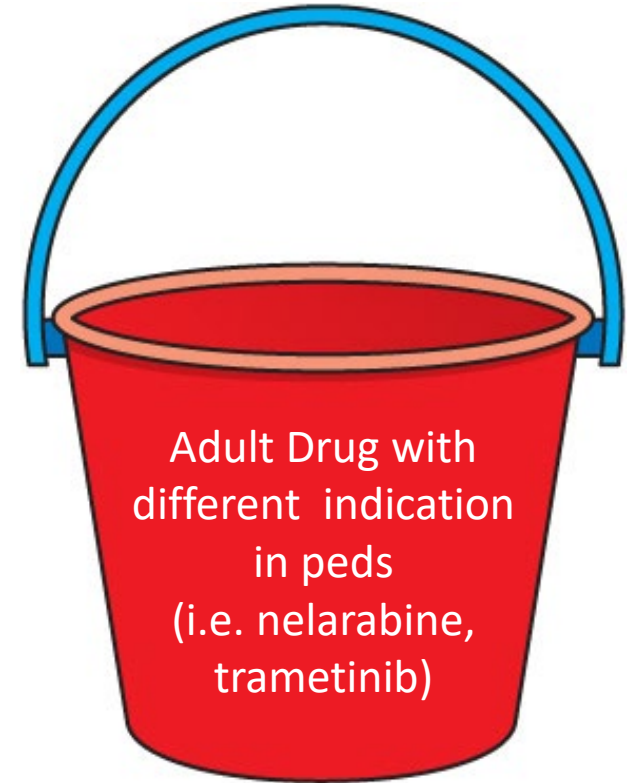
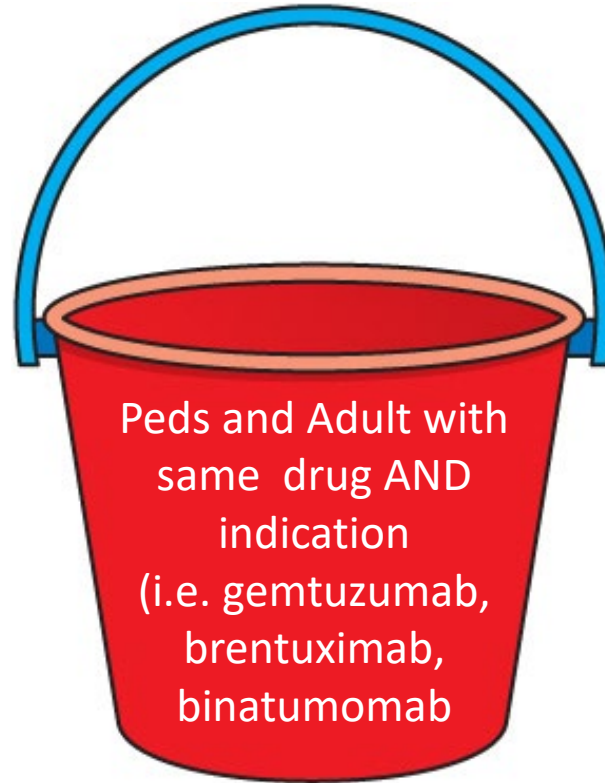
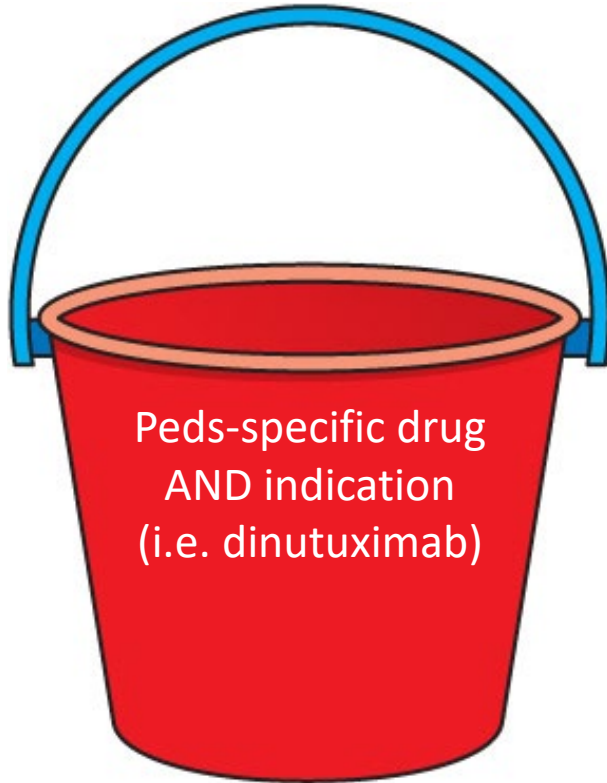
Immunotherapy	113	77	59	37	20	10	3
Standard therapy	113	79	51	26	12	9	1

CADTH/pCODR Dinutuximab Review

- Combined Submission(Ac2orn, CORD, OPACC)
 - “The Committee deliberated on the joint patient advocacy group input submission and concluded that dinutuximab aligns with patient values in that it offers a possible impact on the disease. pERC commended the efforts of this joint input submission that brought significant light to patient and family challenges and values in this uncommon disease setting.”
- 4 Registered Clinician submissions

Drug: Dinutuximab Submitted Reimbursement Request: To be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and retinoic acid (RA) for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multi-agent, multimodal therapy	
Submitted By: United Therapeutics Corp.	Manufactured By: United Therapeutics Corp.
NOC Date: November 28, 2018	Submission Date: October 1, 2018
Initial Recommendation: March 7, 2019	Final Recommendation: March 26, 2019

'Buckets' of Challenges in Canadian Drug Funding



Gemtuzumab Ozogamicin in Children and Adolescents With De Novo Acute Myeloid Leukemia Improves Event-Free Survival by Reducing Relapse Risk: Results From the Randomized Phase III Children's Oncology Group Trial AAML0531

Alan S. Gamis, Todd A. Alonzo, Soheil Meshinchi, Lillian Sung, Robert B. Gerbing, Susana C. Raimondi, Betsy A. Hirsch, Samir B. Kahwash, Amy Heerema-McKenney, Laura Winter, Kathleen Glick, Stella M. Davies, Patti Byron, Franklin O. Smith, and Richard Aplenc

2014

- In 2019: Pfizer submits for use in upfront AML for 15+

- POGO Clinician Group Submission
- Leukemia Lymphoma Society Submission

- pERC noted that the eligibility criteria in the ALFA-0701 was patients who were 50 to 70 years old; however, that the approved Health Canada indication is for adult patients. pERC agreed with the CGP that for patients aged 70 years and older with an absence of adverse cytogenetics, they should be eligible for gemtuzumab ozogamicin. Given the Health Canada approved indication is for adult patients, pERC did not recommend gemtuzumab ozogamicin for patients under 18 years of age. pERC considered this out of scope but acknowledged the COG AML 0531 trial, which examined the safety and efficacy of gemtuzumab ozogamicin in children and young adults using a different chemotherapy regimen.

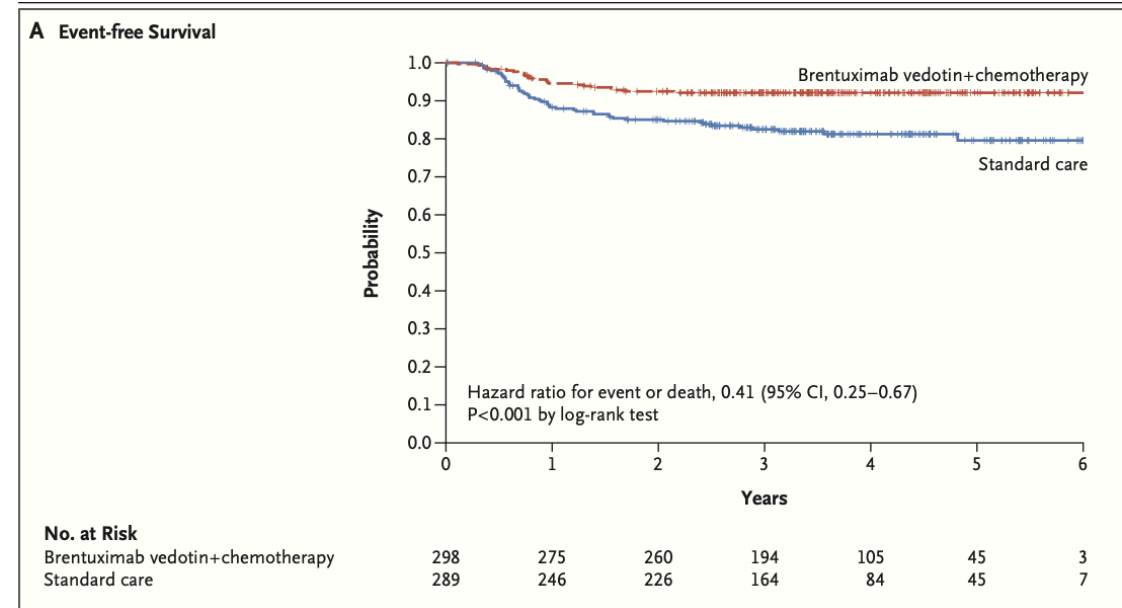
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Brentuximab Vedotin with Chemotherapy in Pediatric High-Risk Hodgkin's Lymphoma

S.M. Castellino, Q. Pei, S.K. Parsons, D. Hodgson, K. McCarten, T. Horton, S. Cho, Y. Wu, A. Punnett, H. Dave, T.O. Henderson, B.S. Hoppe, A.-M. Charpentier, F.G. Keller, and K.M. Kelly

ABSTRACT



2022

- In 2023, A CDA submission was made for the use of brentuximab with an 'adult' backbone as per ECHELON-1 results

Brentuximab in Hodgkin Lymphoma

- 1 patient group submission (Lymphoma Canada, no pediatric experience represented)
- 2 Clinician Groups (POGO and CCO-Hematology)

June 14, 2023

RE: CADTH Review of Adcetris

Dear Dr. Gibson:

I am writing to acknowledge that we recently received your input on Adcetris (brentuximab vedotin for injection) for the treatment of previously untreated patients with advanced stage Hodgkin lymphoma, in combination with doxorubicin, vinblastine, and dacarbazine (AVD). As always, CADTH sincerely appreciates the participation of POGO in the CADTH drug review process.

We thank POGO for drawing our attention to the use of brentuximab vedotin in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (AVEPC) for pediatric patients. CADTH has consulted with the sponsor and the participating drug programs, and we have expanded the scope of the ongoing review of brentuximab vedotin to include use in combination with AVEPC for pediatric patients.

What Is the CADTH Reimbursement Recommendation for Adcetris?

CADTH recommends that Adcetris be reimbursed by public drug plans for the treatment of patients with previously untreated advanced stage Hodgkin lymphoma (HL) if certain conditions are met.

Which Patients Are Eligible for Coverage?

Adcetris should only be covered to treat adults aged 18 years or older with advanced stage classical HL or children and adolescents aged 2 years or older with high-risk HL who are in relatively good health. Adcetris should not be covered to treat patients with nodular lymphocyte-predominant HL, severe sensory or motor peripheral neuropathy, cerebral or meningeal disease, or a neurologic disease that affects their daily activities.

- Spring 2024, Amgen is preparing an ADULT submission for blinatumomab based on E1910 Study

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Blinatumomab for MRD-Negative Acute Lymphoblastic Leukemia in Adults

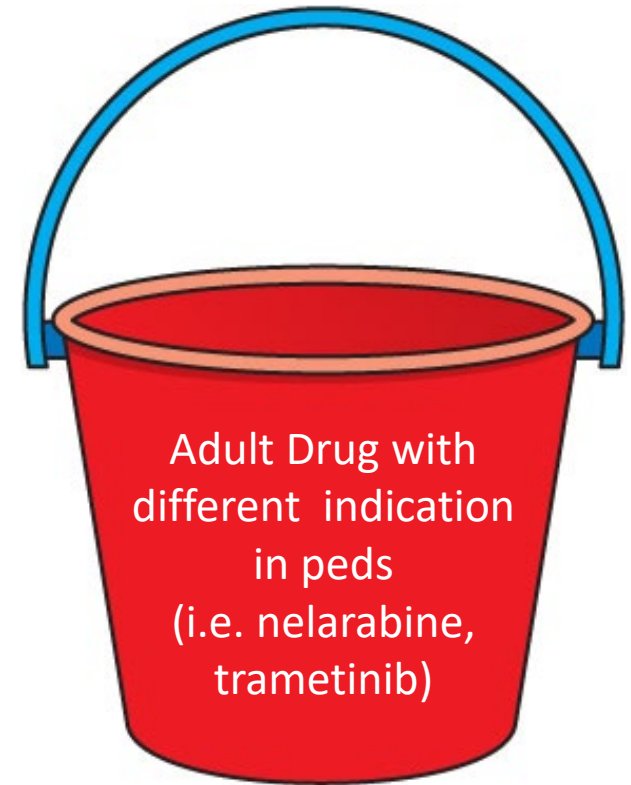
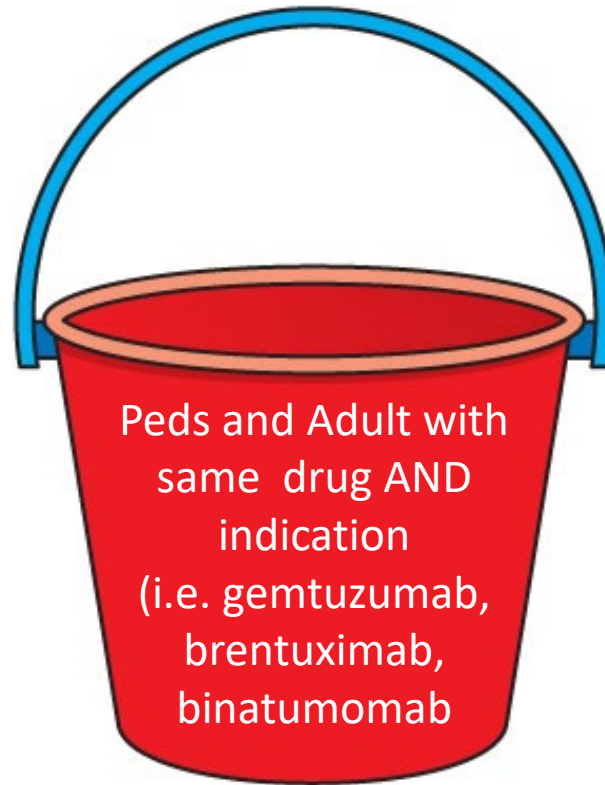
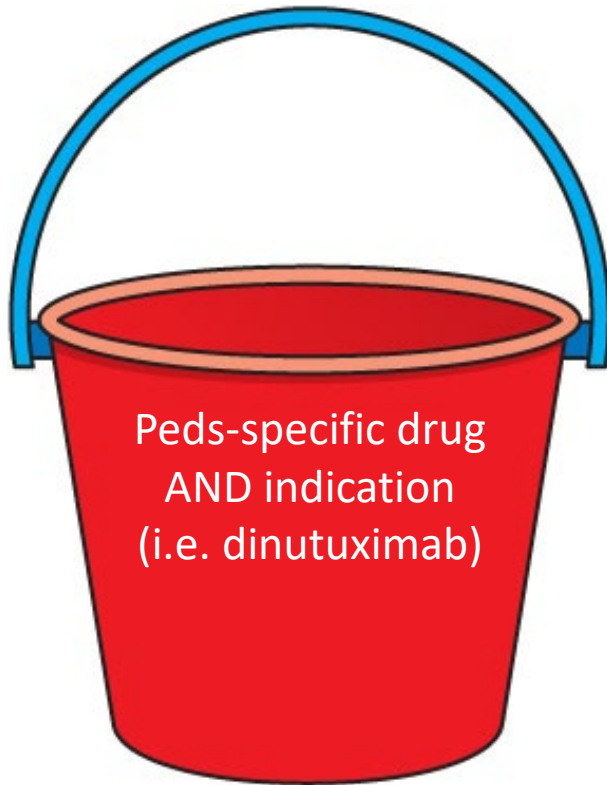
M.R. Litzow, Z. Sun, R.J. Mattison, E.M. Paietta, K.G. Roberts, Y. Zhang, J. Racevskis, H.M. Lazarus, J.M. Rowe, D.A. Arber, M.J. Wieduwilt, M. Liedtke, J. Bergeron, B.L. Wood, Y. Zhao, G. Wu, T.-C. Chang, W. Zhang, K.W. Pratz, S.N. Dinner, N. Frey, S.D. Gore, B. Bhatnagar, E.L. Atallah, G.L. Uy, D. Jeyakumar, T.L. Lin, C.L. Willman, D.J. DeAngelo, S.B. Patel, M.A. Elliott, A.S. Advani, D. Tzachanis, P. Vachhani, R.R. Bhave, E. Sharon, R.F. Little, H.P. Erba, R.M. Stone, S.M. Luger, C.G. Mullighan, and M.S. Tallman

ABSTRACT

Blinatumomab in 1st Line B-ALL

- July 2024: COG informs members of results of AALL 1731, results confidential until planned release at ASH in December
- August: COG releases confidential results document for “regulatory agencies and insurers”
- Amgen agrees to alter current planned submission to include pediatric data
- CDA agrees to ‘Rolling Assessment’ (Taking adult data first, Peds data when released)
- Feedback: LLSC, Ac2orn, OPACC, POGO
- Results?

'Buckets' of Challenges in Canadian Drug Funding



'Repurposed' Drugs in Pediatric Cancer

- As the age of greater biologic and genetic insight in tumours continues to advance, many agents initially approved and marketed for more common adult malignancies are finding roles in pediatric cancers
- Examples
 - Nelarabine in T-Cell ALL
 - Crizotinib, lorlatinib in neuroblastoma
 - Regorafenib, cabozantinib in osteosarcoma
 - Dabrafenib, trametinib in low grade gliomas

'Clinician Driven' Submissions to CDA

- When pharma does not submit a drug/indication for assessment at CDA, clinician groups may choose to prepare an 'unsponsored' submission
- These rare submissions require most of what usual submissions by pharma include:
 - Summary of evidence/systematic review
 - Comparison with alternatives
 - Pharmaco-economic review

original reports

Children's Oncology Group AALL0434: A Phase III Randomized Clinical Trial Testing Nelarabine in Newly Diagnosed T-Cell Acute Lymphoblastic Leukemia

Kimberly P. Dunsmore, MD¹; Stuart S. Winter, MD²; Meenakshi Devidas, MBA, PhD³; Brent L. Wood, MD, PhD⁴; Natia Esiashvili, MD⁵; Zhiguo Chen, MS⁶; Nancy Eisenberg, MPH⁷; Nikki Briegel, BPharm, GradDipClinPharm⁸; Robert J. Hayashi, MD⁹; Julie M. Gastier-Foster, PhD^{10,11}; Andrew J. Carroll, PhD¹²; Nyla A. Heerema, PhD¹¹; Barbara L. Asselin, MD¹³; Karen R. Rabin, MD, PhD¹⁴; Patrick A. Zweidler-Mckay, MD, PhD¹⁵; Elizabeth A. Raetz, MD¹⁶; Mignon L. Loh, MD¹⁷; Kirk R. Schultz, MD¹⁸; Naomi J. Winick, MD¹⁹; William L. Carroll, MD¹⁶; and Stephen P. Hunger, MD²⁰

2020

Nelarabine in T-ALL

Generic Name: nelarabine	Brand Name: Atriance
Project Status: Complete	Project Line: Reimbursement Review
Therapeutic Area: T-cell acute lymphoblastic leukemia	Project Number: PC0307-000
Manufacturer: N/A	Call for patient/clinician input closed: March 27, 2023
Call for patient/clinician input open: January 30, 2023	Tumour Type: Leukemia
	NOC Status at Filing: N/A

- POGO Clinician Submission
- LLSC feedback included Ac2orn, OPAC, CCC
- BCCH, Janeway feedback

CADTH Reimbursement Recommendation

Nelarabine (Atriance)

Indication: Nelarabine (Atriance) for addition to front-line multiagent therapy of pediatric, adolescent, and young adult patients (aged 1 year to 30 years at diagnosis) with intermediate- or high-risk T-cell acute lymphoblastic leukemia

Sponsor: Pediatric Oncology Group of Ontario

Final recommendation: Reimburse with conditions

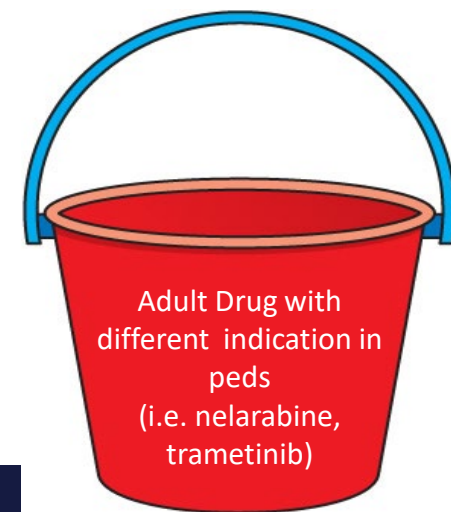
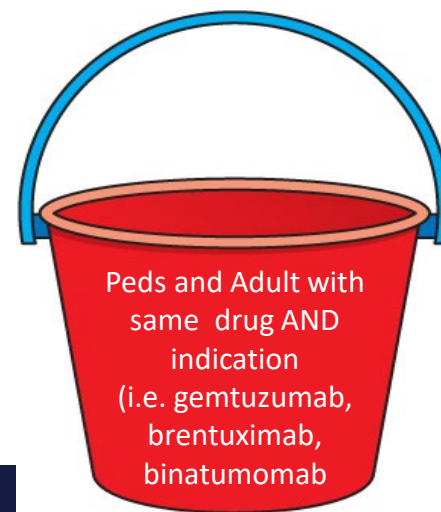
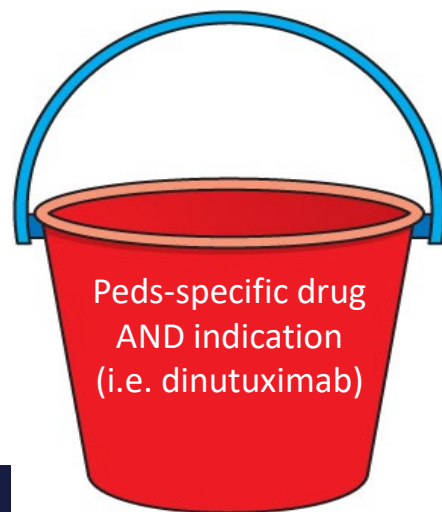
- Lessons Learned
 - It's POSSIBLE
 - Its incredibly time consuming and not sustainable for the variety of agents needed for small populations in pediatric cancer

When Pharma Doesn't Submit: The Future?

- CDA recently launched Formulary Management Expert Committee (FMEC)
 - Non-Sponsored Reimbursement Reviews evaluate a **single drug that is later in its life cycle** with evidence to support the drug's use in a previously unfunded indication.
 - Streamlined Drug Class
 - Therapeutic Reviews

Drug	Indication	Current State
Blinatumomab	1 st relapse in B-ALL	<ul style="list-style-type: none">• Draft recommendation in December, awaiting final and ? Implementation
Dabrafenib and Trametinib	V600E mutated Low Grade Gliomas	<ul style="list-style-type: none">• Feedback submitted, meeting in March 2025
Regorafenib	Metastatic Osteosarcoma	<ul style="list-style-type: none">• Feedback submitted, meeting in March 2025
Nivolumab	High Risk Hodgkin Lymphoma	<ul style="list-style-type: none">• Feedback due January 2025, meeting in May 2025

- The process of ensuring access and funding for pediatric cancer therapies remains a challenge
- In the absence of transformational approaches at the HTA and reimbursement levels, we should continue to advocate for pediatric cancer patients in the current systems
- PWLE and clinician voices must be active in the process to use existing tools to optimize access and reimbursement equitably across Canada





Thank you
Merci

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Panel Discussion: Drug Access in Canada

- Avram Denburg
- Paul Gibson
- Keith McIntosh
- Supriya Sharma
- Ross Wallace (moderator)



Interested in participating in discussions about next steps in pediatric cancer drug access?

Complete this survey!

Thanks // Merci

Link will be shared again in a communication after the Annual Meeting

