



# How real-world evidence can enhance reimbursement decision-making for private drug plans

## Panel discussion

Moderated by Daria O'Reilly, Lead Health Economist  
TELUS Health

May 3, 2023



April 27, 2023

# Canada Life: Real-World Evidence Discussion

The role of private payers

CONFIDENTIAL



Canada Life and design are trademarks of The Canada Life Assurance Company.





## Our vision:

Customers are at the centre of what we do

## Our purpose:

To improve the financial, physical and mental well-being of Canadians





# Philosophy:

**Dual bottom line** - Balancing the health needs of plan members and the cost needs of plan sponsors

# The need for real-world evidence (RWE)

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## Growing uncertainty



### **More drugs are coming to market with limited evidence packages**

To accelerate and broaden access to treatment, more drugs are coming to market with less established clinical trial evidence. Determining value in these situations is more challenging and RWE could be a tool to confirm assumptions.

## Increasing drug costs



### **The costs of drug plans are rising unsustainably**

Drug plans need to focus on value to make the most of their benefits spend. Programs like the Canada Life SMART drug plans offer value-based management rather than strict cost-controls.

## Private plan perspective



### **The scope and priorities of private plans differ from public plans**

Private drug plans often include disability coverage and paramedical services so managing these costs are also important. Employers also highly prioritize quality of life outcomes like productivity and absenteeism.

# The potential of RWE

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Improved access



## Sharing risk improves access

Ability to expedite access with shared risk, like with an outcomes-based agreement (OBA).

Lifecycle management



## Integrating new data over time means better decision-making

Clinical trial data is often only available when a treatment is launched. Real-world evidence supports data-driven decisions throughout the drug management lifecycle.

Preventative care



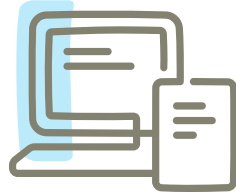
## Data insights can improve health outcomes

Predictive analytics could inform effective preventative interventions such as pre-disability support (e.g. At work services).

# Real-world data for real-life questions



Disability metrics



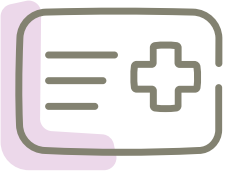
Electronic medical records



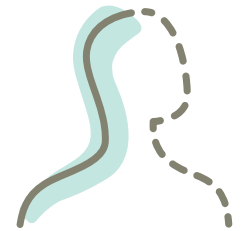
Absenteeism



Paramedical



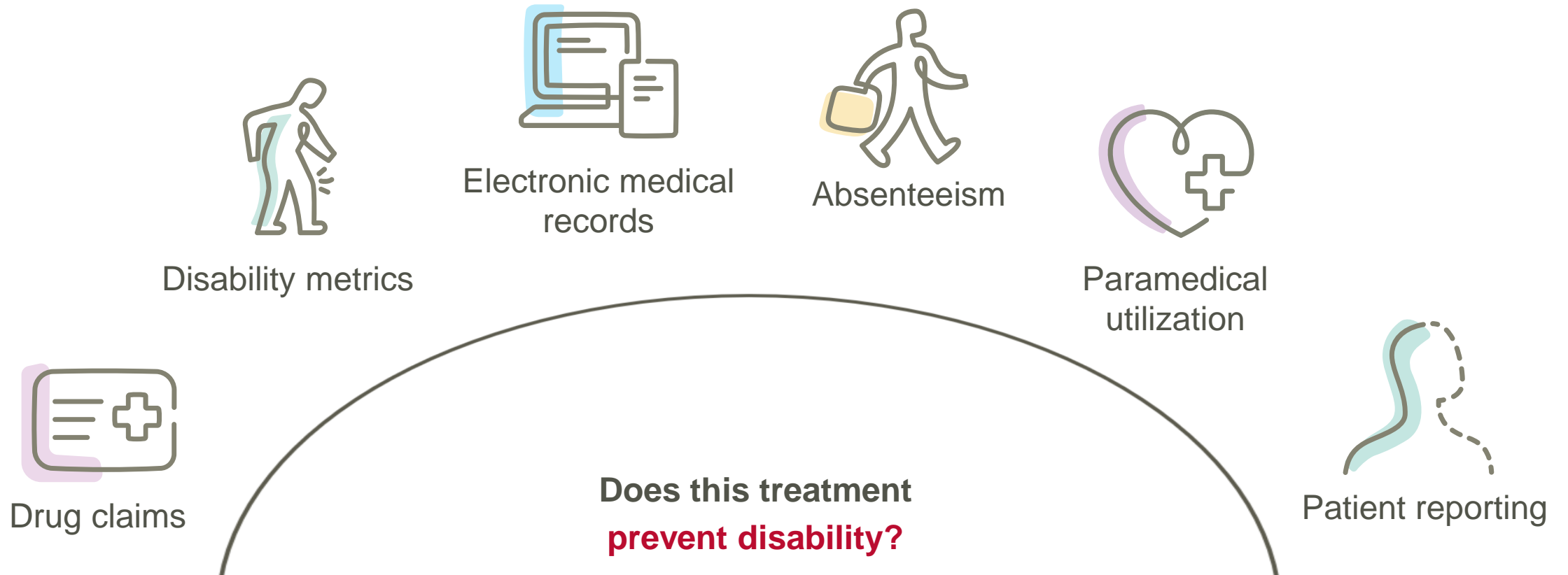
Drug claims



Patient reporting

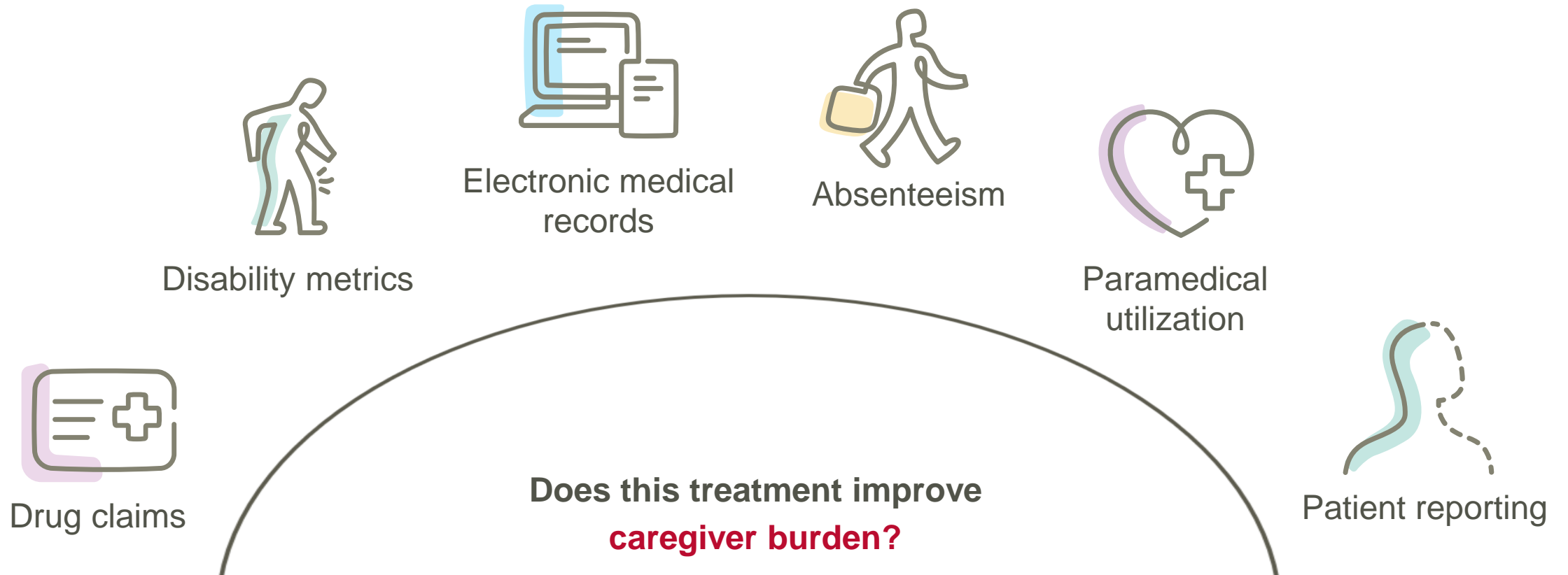
Does this treatment  
**work as well in real life?**

# Real-world data for real-life questions

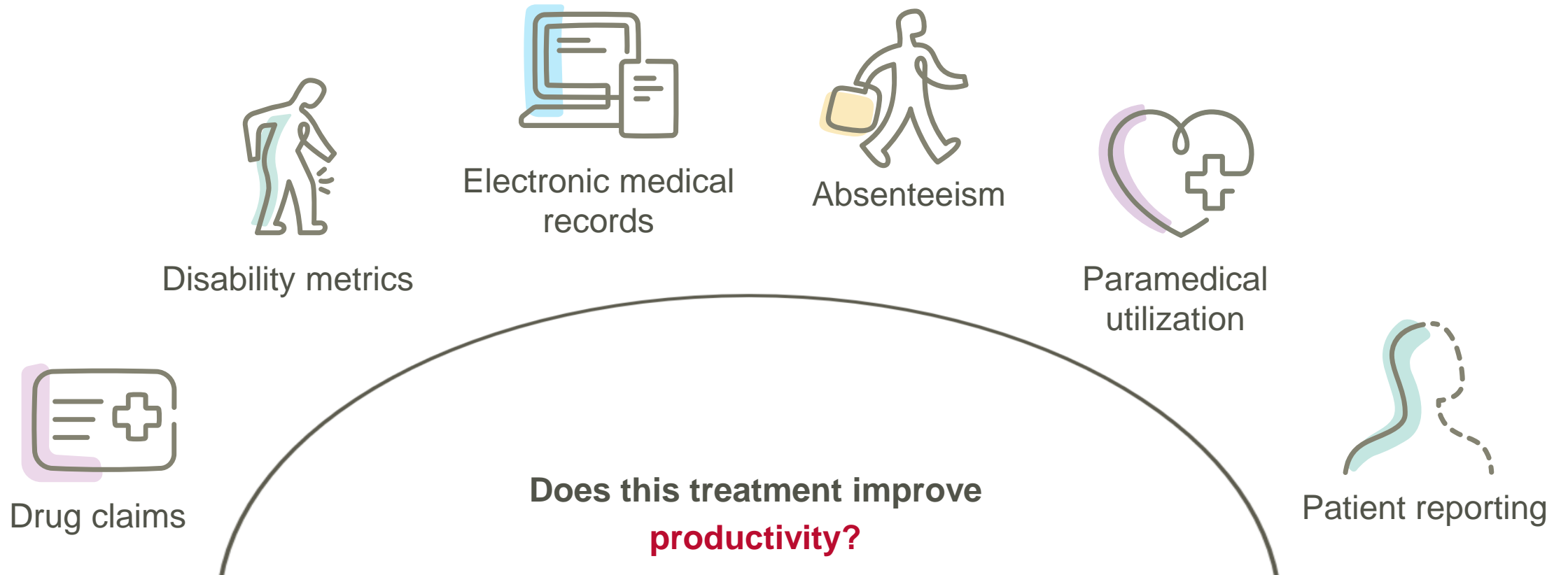




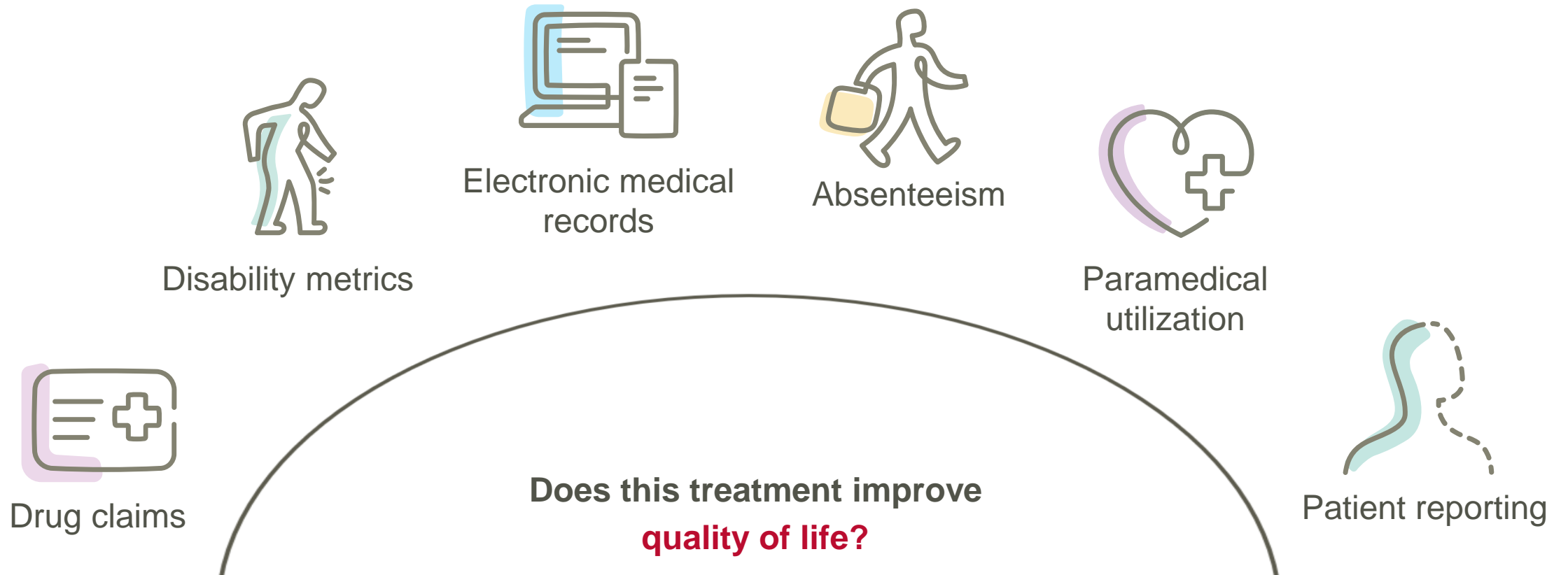
# Real-world data for real-life questions



# Real-world data for real-life questions



# Real-world data for real-life questions



# Challenges

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**Data silos** make it difficult to integrate data

**Diverse needs** require collaborative RWE study designs

Robust, **reliable data** is essential to make the results actionable



Bringing real-world evidence into drug plan management is just getting started.



# Canada Life's data expertise

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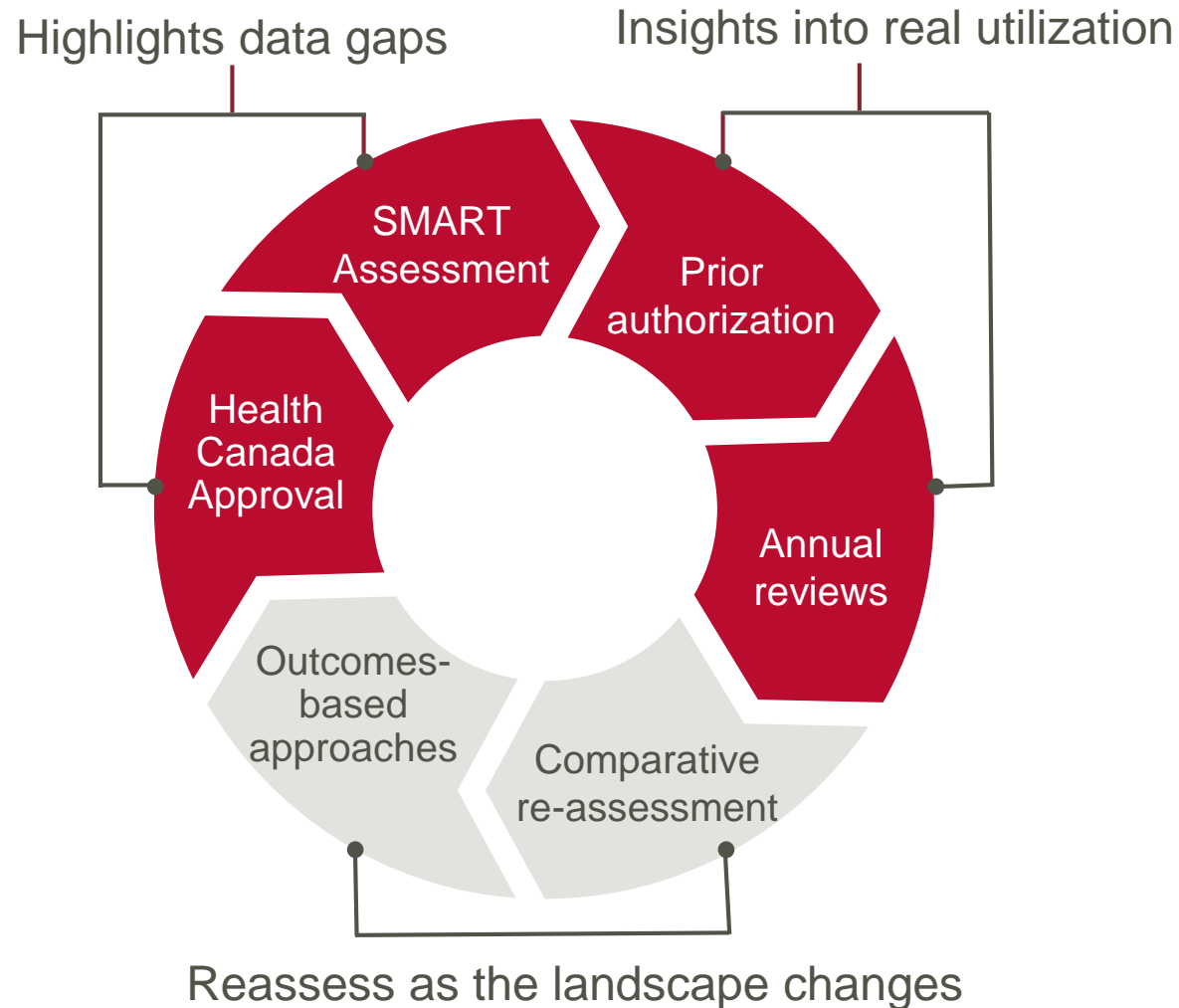


Canada Life leverages data for more efficiency and better decision-making.

Private payers data includes many measurements of health and wellness. At Canada Life, data scientists and our AI team work with our clinical and business experts to uncover valuable insights.

Data insights can drive better health outcomes.

# Drug lifecycle management



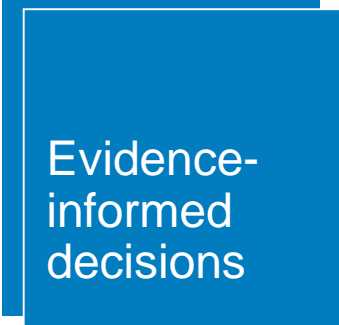
- Today's real-world data insights are the **tip of the iceberg**.
- **Technology & collaboration** can enable a full lifecycle approach

# The dual bottom line

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Better  
access for  
members



Evidence-  
informed  
decisions



Fostering  
health &  
wellness

## **The dual bottom line philosophy:**

Balancing the health needs of plan members and the cost  
needs of plan sponsors

A woman with dark curly hair and glasses, wearing a blue patterned shirt, is pointing at a laptop screen. A man in a brown blazer and blue striped shirt is looking at the screen. In the background, another man in a blue suit is visible, and a blurred office environment is shown.

Thank you!





Canada's Drug and  
Health Technology Agency

# Real-World Evidence at CADTH

**Dr. Nicole Mittmann**

**Chief Scientist and Vice President, Scientific Evidence, Methodologies and Resources**

**CADTH**

**[www.cadth.ca](http://www.cadth.ca)**

April 2023





# Disclosure

- **Employment: CADTH**
- **Relationship with Commercial Interest: None**
- **Grant/Research Support: Genome Canada (current), CIHR (current), Knowledge User (several)**
- **Memberships on advisory committees, boards: Research Committees and CADTH committees**
- **Speaker Bureau/Honoraria: None**
- **Consulting fees: None**



## Disclosure

- **CADTH is funded by contributions from the Canadian federal, provincial, and territorial ministries of health, with the exception of Quebec.**
- **CADTH receives application fees from the pharmaceutical industry for:**
  - **CADTH Pharmaceutical Reviews, including Common Drug Review, pan-Canadian Oncology Drug Review, and Interim Plasma Protein Product Review**
  - **CADTH Scientific Advice**






Canada's  
Drug and Health  
Technology Agency

**CADTH is a not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs and medical devices in our health care system.**




# CADTH's Role in the Access and Reimbursement Process



## ■ Health Canada

 Is it safe? Does it work?


## ■ Patented Medicine Prices Review Board

 Is the price excessive compared with some other developed countries?

## ■ CADTH

 How does it compare with existing treatment options?  
Is it good value? 

## ■ Public Drug Plans and the pCPA

 Is it needed? Is it affordable?

## Real-World Evidence

**Real-world evidence (RWE) is evidence about the use, safety, and effectiveness of a medical product, technology, or drug that is based on data from the real-world health care setting. It is playing an increasing role in health care decisions.**

## RWE Guidance

RWE  ACCESS

RWE will not replace RCT

RWE has different meanings to different people

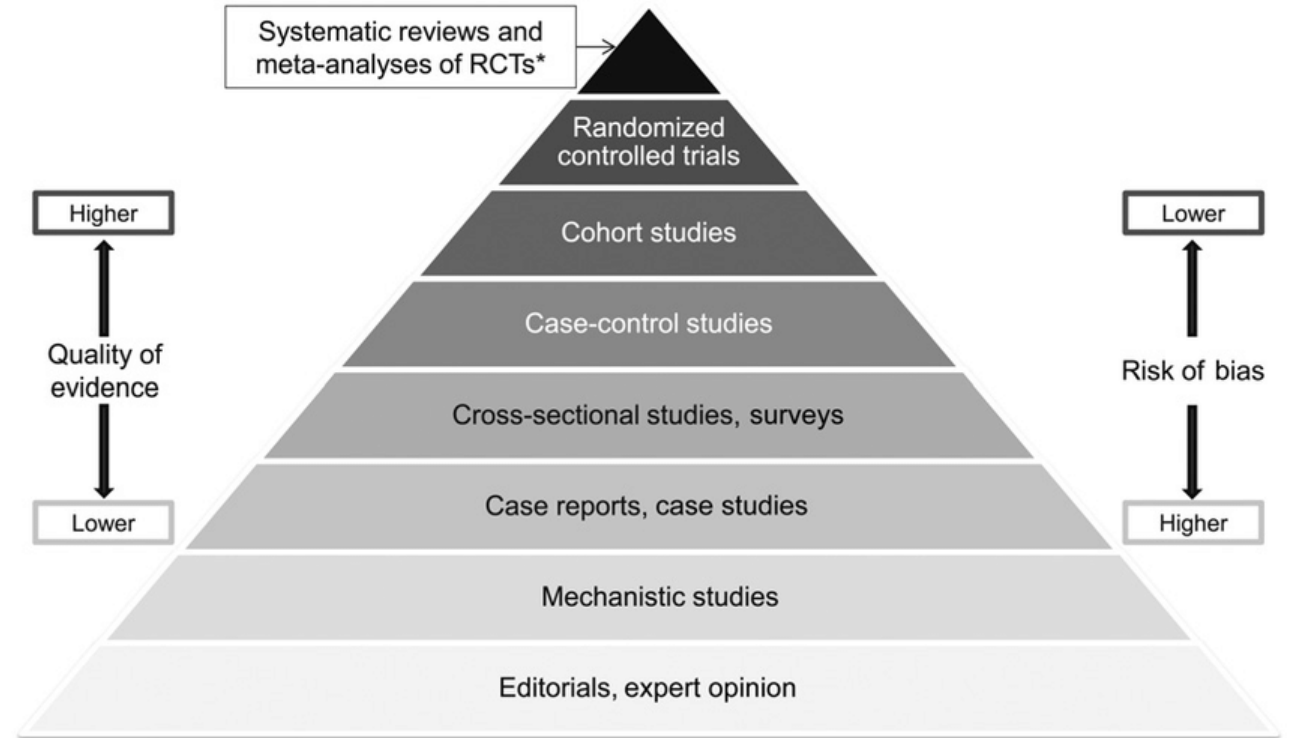
RWE does not provide causality

RWE cannot be conducted for everything

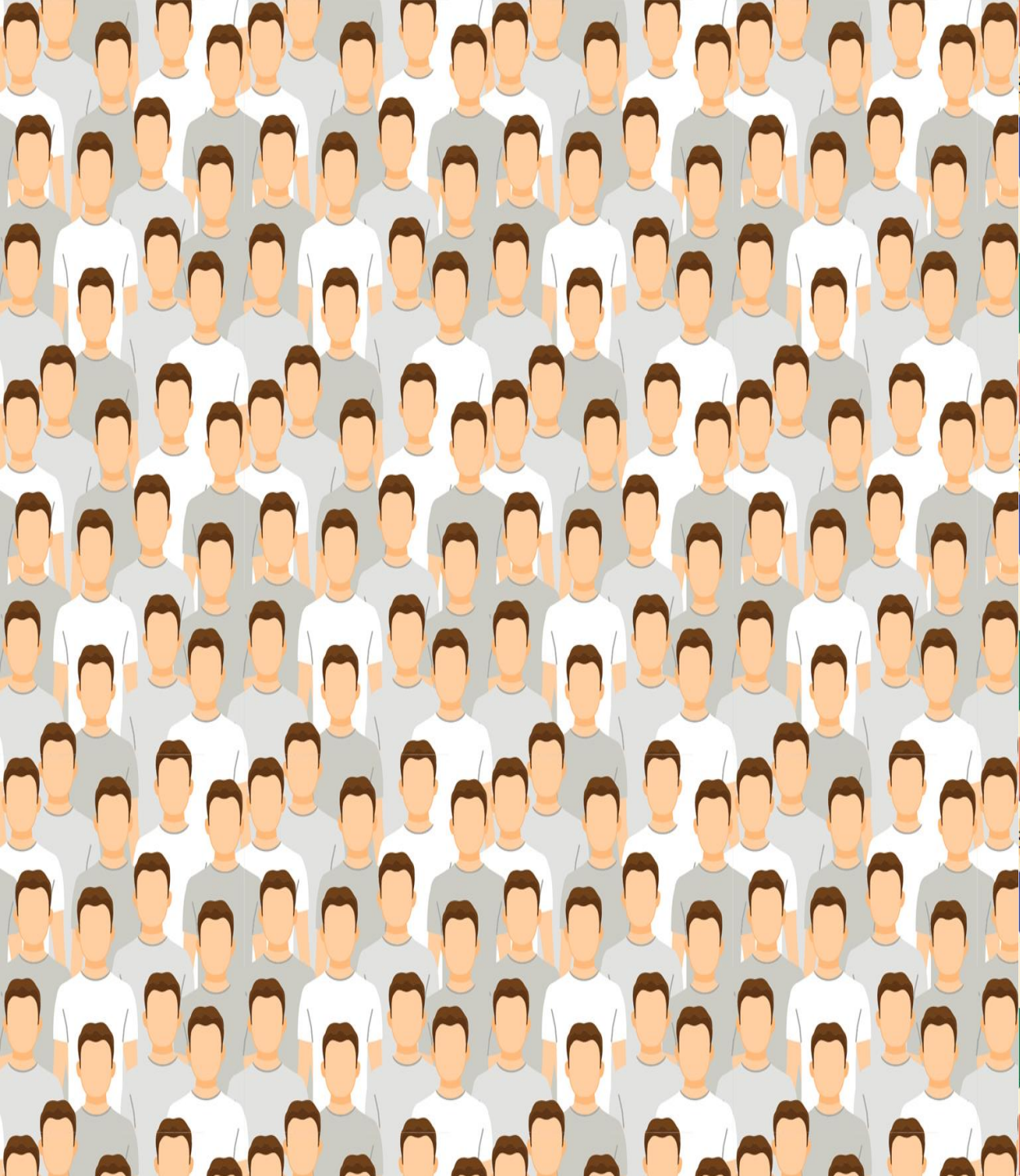
RWE is an issue being faced by all HTAs

# Expand Evidence Base

- **Fit for per purpose**
- **Evidence-based medicine principles**
- **Tools and Guidelines**









# ISPOR 2022 Top 5 out of 10 HEOR Trends



- 1 Real-World Evidence**  
RWE in healthcare decision making remains the top trend as its use and impact grows in importance
- 2 Value Assessment**  
The shift to value-driven healthcare strengthens the need for value assessment
- 3 Health Equity**  
Illuminated by the pandemic, interest in researching and addressing healthcare disparities intensifies
- 4 Healthcare Financing**  
As new and innovative technologies come to market, healthcare financing remains in the spotlight
- 5 Patient Engagement**  
Interest in infusing the “patient voice” in healthcare research remains high



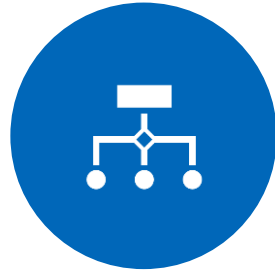
# Introduction



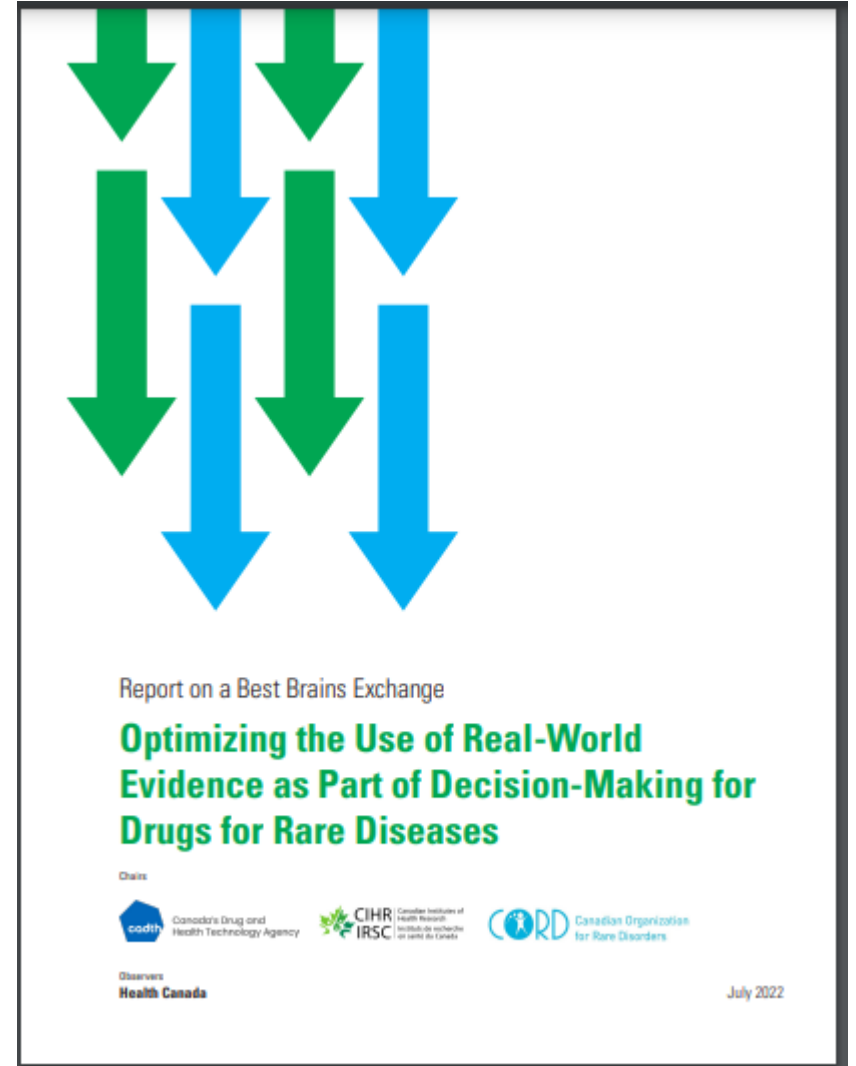
DATA



AWARENESS



COORDINATION/  
COLLABORATION





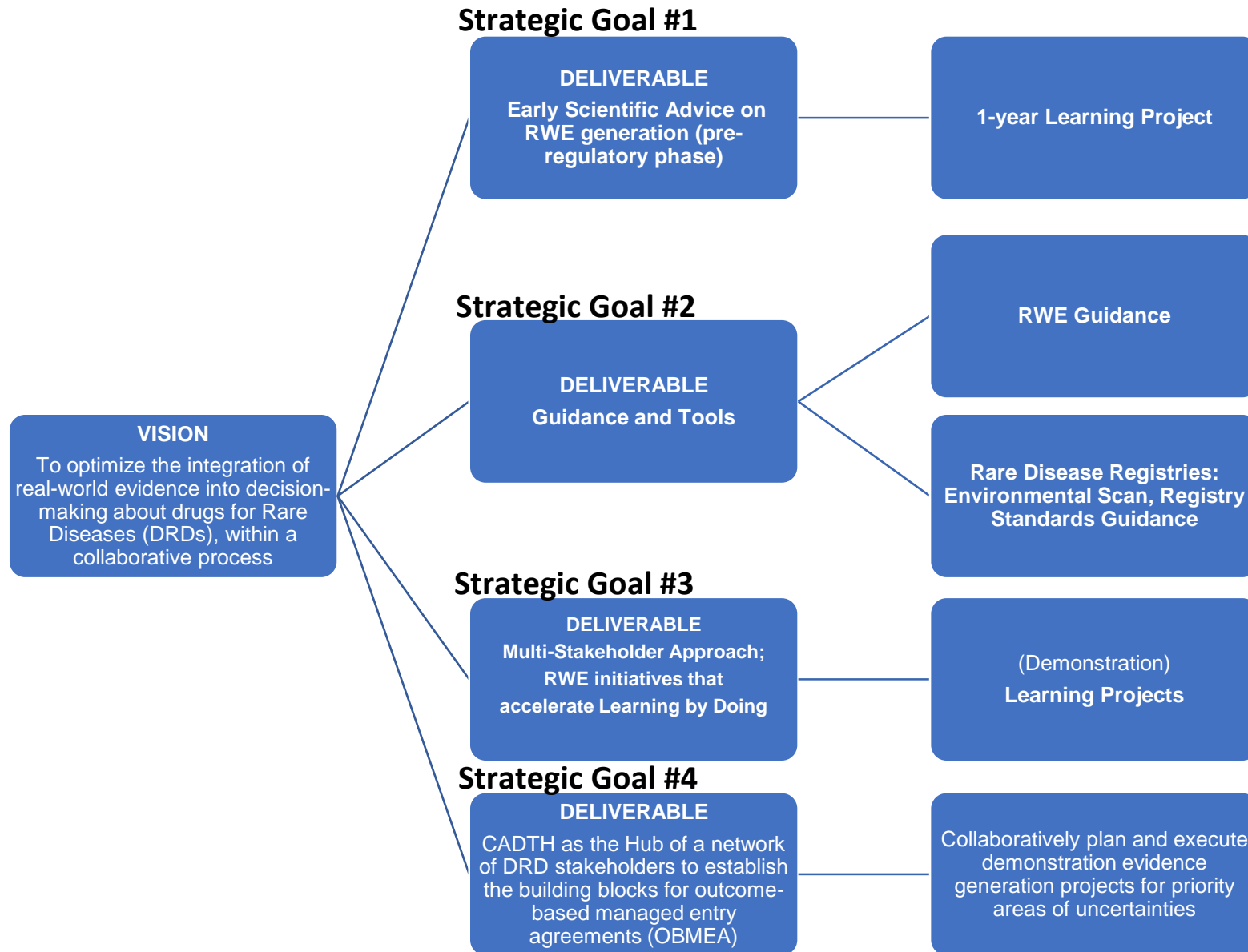
**What can RWE do?**

**What can't it do?**



## Real-world evidence

- **Fill gaps in uncertainty**
- **Does not lead to automatic approvals**
- **Still needs critical appraisal**
- **Does not provide causality**
- **Still need to provide the “O” for Outcomes before we can discuss Outcomes Based Agreements**





# Strategic Goal #1: Enhance the regulatory and HTA parallel early dialogue/scientific advice to optimize value of RWE in decision-making for DRD

<b>Program Expansion</b>	Expansion of Scientific Advice (SA) Program to include applications for advice on real-world evidence (RWE) generation plans after protocols for pivotal trials have been finalized (the pre-regulatory phase of drugs)
<b>Duration</b>	1-year learning period April 2022 – Mar 2023
<b>Offering</b>	Questions related to RWE generation plans; questions on economic modelling could be included. Priority given to Rare diseases/conditions, pediatrics. Report of Scientific Advice (ROSA) focuses on the appraisal of the RWE development plan
<b>Process</b>	Advice from CADTH alone, or in parallel with Health Canada or National Institute for Health and Care Excellence (NICE), following established SA processes





# Strategic Goal #2: Develop guidance for use of RWE

**Objective:** To develop a **Canadian RWE Guidance document** to provide recommendations for both quality and reporting standards for all RWE submissions intended for use in regulatory or health-technology submissions in Canada



## Process



May 2023

The guidance document will be most relevant to those developing submissions to regulatory and HTA bodies, as well as those who review and appraise evidence



# RWE Guidance Working Group

## Expert Panel Members - Canada



McGill



Laval University



Health Canada



UofM



IHE



Dalhousie  
Sanja Stanojevic



INESSS



UNB



CanREValue



Statistics Canada



CIHI



UBC



UofA,  
RWE Consortium

RWE Guidance Methods  
Authorship leads:  
Mina Tadrous  
Theresa Aves  
Kaley Hayes

## Expert Panel Members - International



Harvard



NICE



Oxford  
(NDORMS)



FDA

## Strategic Goal #2. Develop knowledge for generation of RWE

### Objectives

- Create an atlas of sources of information concerning rare disease: patient organizations, health care providers and institutions, research networks, registries
- Participate in international RWE initiatives to learn how to potentially address Canadian DRD decision-making challenges

### Projects

- Canadian inventory and exploration of administrative databases for rare disease
  - Standardized Requests for Data (“Protocols”) across databases
- Inventory and exploration of registries: Literature Review, Environmental scan of registries (REQueST tool)
- International RWE Initiatives: RWE4Decisions Steering Committee; ISPE RWE Appraisal Tool; ISPOR RWE SIG; CIOMS RWE Manual



# Inventory of Databases:

## Health System; CIHI; Statistics Canada; Public; Private; Outcomes; Patient; Genetic

CATEGORY	VARIABLE	SOURCES
Drug/Medication	Public Drug Utilization	PMPRB; CIHI; HDRN -P/T; IC/ES -DAS; Reformulary; Statistics Canada-oncology; Disease Registries; Academic Groups
	Private Drug Utilization	PMPRB-NPDIUS; Reformulary; IQIVIA; P/T-BC; Private Insurers (e.g., Telus, Loblaw; CHLIA); Disease Registries; Academic Groups
	Out of Pocket Drug Utilization	PMPRB-NPDIUS; Reformulary; IQIVIA; P/T-BC; Private Insurers (e.g., Telus, Loblaw; CHLIA); Disease Registries; Academic Groups
	Hospital Drug Utilization	PMPRB; IQIVIA; Academic Group (MT)*; Private Insurers (e.g., Telus, Loblaw; CHLIA); Disease Registries; Academic Groups
	Route of administration	PMPRB; IQIVIA; Academic Group (MT)*; Private Insurers (e.g., Telus, Loblaw; CHLIA); Disease Registries; Academic Groups
Patient Information	Demographics	CIHI, Stats Can-Vital Stats; Disease Registries; Academic Groups
	Mortality	StatsCan-Mortality
	Intermediate Disease-specific Outcomes	Disease Registries; Academic Groups
	Genetics, genomics, mutations	Exactis; Flatiron; Academic clinical trial databases (e.g., OCTANE; CLEO); OICR
	Laboratory values	IC/ES- DAS; HDRN?
	Quality of Life	Disease Registries; Academic Groups
	Patient Reported Outcomes	Disease Registries; Academic Groups

CATEGORY	VARIABLE	SOURCES
Health System Outcomes	Hospitalization (admissions/discharge)	CIHI; Private Insurers (e.g., Telus, Loblaw; CHLIA)
	Emergency/Urgent Care	CIHI; HDRN -P/T; IC/ES -DAS
	Procedures	CIHI; HDRN -P/T; IC/ES -DAS;
	Physician	HDRN-P/T; IC/ES -DAS;
	Costs	CIHI-procedure/DX; HDRN-P/T; IC/ES-DAS

Data Repositories	VARIABLES	SOURCES
Canada	HDRN- drug, health system, patient outcomes; lab values	P/T administrative databases
	IC/ES- DAS	Ontario administrative databases
	Patient/Disease Registries	Registry portals
US	US data repository; based on data from insurers and HMOs; Utilization; outcomes	Aetion Portal-Clearing House
	UK data from electronic health records	Flatiron Portal-Clearing House
Europe	TBD	

Cancer Type	# in PMT	# of Stage IV in PMT	# tested for the biomarkers of interest	Biomarker	# of aberration positive cases in PMT-PR	Prevalence in PMT (%)	Prevalence in Stage IV (%)	Prevalence in tested participants (%)	Prevalence (%) reported in the literature
Lung	1736	688	894	ALK fusion	31 (25 being stage IV)	1.8	3.6	3.5	2.6 <sup>1</sup> in lung or 4-5 in NSCLC <sup>2</sup>
			957	EGFR (mutation)	163 (83 stage IV)	9.4	23.7	17	15-19 in caucasian <sup>3</sup>
			492	MET (amp + mut + fusion)	16 (14 stage IV)	0.9	2.3	3.3	2.4% for amplification <sup>4</sup> , 3% for ex14 skipping <sup>5</sup>
			462	RET fusion	3	0.2	0.5	0.6	1-2 <sup>4</sup>
Breast	2499	985	2289	Her2 expression or amplification	485	19.4		21.2	1.2-25% <sup>6</sup>
			88	HER2 mutation	3	0.1	0.3	3.4	4 <sup>6</sup>
Breast Her2- HR+	1372	701	328	BRCA1/2 germline mutation	55 (26 stage IV)	4	3.7	16.8	1-9 <sup>7</sup>
			77	PIK3CA	23 (23 stage IV)	1.7	3.3	29.9	13.3 to 61.5 <sup>8,9</sup>
Colorectal	1558	1144	607	BRAF V600E	41 (37 stage IV)	2.6	3.2	6.8	12.5 <sup>11</sup>
Prostate	914	840	NA	HRSS <sup>10</sup>	35 (35 stage IV)	3.8	4.1	NA	28 <sup>12,14</sup>
Prostate	914	840	82	BRCA1/2 mutation germline +somatic	27 (27 stage IV)	3	3.2		2-10 <sup>15,16</sup>
Pancreas	11	5	2	BRCA1/2 mutation germline +somatic	1 (1 stage IV)	9.1	20	18.2	1-8 <sup>17,18</sup>
Ovarian	628	229	NA	HRSS <sup>10</sup>	146 (64 stage IV)	23.2	27.9	NA	22.7 <sup>19</sup>
Melanoma	707	332	548	BRAF V600E/K	220 (123 stage IV)	31.1	66.3	40.1	40-50 <sup>20-22</sup>
Biliary	8	4	2	FGFR2/3 fusion	0	0	0	0	8 <sup>23</sup>
				FGFR2/3 Mutation	1 (1 stage IV)	12.5	25	50	
Thyroid	0	0	0	RET	0	0	0	0	10-25 <sup>24</sup>
Solid Tumors	7955	4318	430	NTRK1,2,3 Fusion	0	0	0	0	0.3 <sup>25</sup>

\*BRCA1, BRCA2, MRE11, RAD50, RAD51B, RAD51D, ATM, PALB2, RAD52, RAD54L, BRIP1, BARD1, CDK12, CHEK1, CHEK2, FANCL, PPP2R2A  
 1- 21P - Deasi A, Mohammed T, Gokgoz S, et al. The landscape of ALK alterations in non-small cell lung cancer. *European Lung Cancer Virtual Congress 2021* (25-27 March).  
 2- Chia, Puy Ling et al. "Prevalence and natural history of ALK positive non-small-cell lung cancer and the clinical impact of targeted therapy with ALK inhibitors." *Clinical epidemiology*, vol. 6 423-32. 20 Nov. 2014, doi:10.2147/CLEP.S69718  
 3- Zhang, Yue-Lun et al. "The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis." *OncoTarget*, vol. 7, 48 (2016): 78985-78993. | doi:10.18632/oncotarget.12587  
 4- Steriacci W, Edge M, Grogan M, Bubendorf L, Savic S, Tzankov A. MET overexpression and gene amplification: prevalence, clinicopathological characteristics and prognostic significance in a large cohort of patients with surgically resected NSCLC. *Virchows Arch*. 2017;471(1):49-55. doi: 10.1007/s00428-017-2131-1. Epub 2017 May 20. PMID: 28528511  
 5- Journal of Thoracic Oncology (2021) 16 (suppl\_4): S699-S703. S. Savic, Prince1, M. Bihl2, S. Eppenberger-Castori2, M.S. Mamer2, N. Zellweger2, S.I. Rothschild2, L. Bubendorf3



# Inventory of Databases:

Health System; CIHI; Statistics Canada; Public; Private; Outcomes; Patient; Genetic

Table 1: Data holdings available from HDRN Canada data centres

	CIHI	SC	BC	AB	SK	M B	ON	QC	NB	NS	PEI	NL	NT
Health insurance registries													
Hospitalization data													
Healthcare clinic data													
Emergency room data													
Physician claims data													
Prescription medication data													
In hospital drugs													
Home care services data									plan			plan	
Continuing or chronic care services data													
Vital statistics data (like birth and death)													
EMR data			plan										
Laboratory test results													
COVID-19 Test Results data													
COVID-19 vaccination data													
Imaging data									plan	plan			
Patient-reported data						plan							
Data from genetic tests												plan	
Health workforce													

LEGEND AND NOTES:

- = data for the whole population (or close to it; >95%)
- = data for some of the population
- plan = linkage and integration planned but not yet implemented
- = no data



# Canadian Rare Disease Registries List

Registry Name	Website URL	Attended BBE
Fighting Blindness Canada's Inherited Retinal Disease (IRD) Patient Registry	<a href="https://www.fightingblindness.ca/patient-registry/">https://www.fightingblindness.ca/patient-registry/</a>	Yes
Canadian Neuromuscular Disease Registry (CNDR)	<a href="http://www.cndr.org/">http://www.cndr.org/</a>	Yes
Canadian Cystic Fibrosis (CF) Registry	<a href="https://www.cysticfibrosis.ca/our-programs/cf-registry">https://www.cysticfibrosis.ca/our-programs/cf-registry</a>	Yes
Canadian Blood Disorders Registry (CBDR)	<a href="https://fhs.mcmaster.ca/chr/">https://fhs.mcmaster.ca/chr/</a>	Yes
Paroxysmal Nocturnal Hemoglobinuria (PNH) Registry	<a href="https://pnhregistry.com/">https://pnhregistry.com/</a>	Yes
Canadian Fabry Disease Initiative (CFDI)	<a href="http://www.the-cfdi.ca/">http://www.the-cfdi.ca/</a>	Yes
Canadian Network for Autoimmune Liver disease (CaNAL) Patient Registry	<a href="https://pbc-society.ca/canal-patient-registry/">https://pbc-society.ca/canal-patient-registry/</a>	No
British Columbia Glomerulonephritis Registry	<a href="http://www.bcrenal.ca/health-professionals/clinical-resources/glomerulonephritis">http://www.bcrenal.ca/health-professionals/clinical-resources/glomerulonephritis</a>	No
Canadian Glomerulonephritis Registry (CGNR)	<a href="https://cansolveckd.ca/gnregistry">https://cansolveckd.ca/gnregistry</a>	No
Canadian Scleroderma Research Group	<a href="http://www.canadiansclerodermaresearchgroup.org/">http://www.canadiansclerodermaresearchgroup.org/</a>	No
Canadian Inflammatory Myopathy Study	<a href="http://craj.ca/archives/2019/English/Spring/pdf/CRAJ_Spring_2019_CIMS.pdf">http://craj.ca/archives/2019/English/Spring/pdf/CRAJ_Spring_2019_CIMS.pdf</a>	No
Canadian Registry for Pulmonary Fibrosis	<a href="https://pubmed.ncbi.nlm.nih.gov/27445528/">https://pubmed.ncbi.nlm.nih.gov/27445528/</a>	No

Registry Name	Website URL	Attended BBE
Canadian Organ Replacement Register	<a href="https://www.cihi.ca/en/canadian-organ-replacement-register-corr">https://www.cihi.ca/en/canadian-organ-replacement-register-corr</a>	No
Canadian Home Parenteral Nutrition (HPN) Registry	<a href="http://www.bchomenutrition.org/Canadian-HPN-Registry.html">http://www.bchomenutrition.org/Canadian-HPN-Registry.html</a>	No
Canadian Fontan Registry	<a href="https://canadianfontan.com/registry/">https://canadianfontan.com/registry/</a>	No
MitoCanada's Patient Contact Registry	<a href="https://mitocanada.org/patient-contact-registry/">https://mitocanada.org/patient-contact-registry/</a>	No
National Spinal Cord Injury (SCI) Registry	<a href="https://praxisinstitute.org/research-care/key-initiatives/national-sci-registry/">https://praxisinstitute.org/research-care/key-initiatives/national-sci-registry/</a>	No
Canadian Open Parkinson Network	<a href="https://copn-rpco.ca/research/">https://copn-rpco.ca/research/</a>	No
CDKL5 International Patient Registry	<a href="https://www.cdkl5canada.ca/cdkl5-international-patient-registry">https://www.cdkl5canada.ca/cdkl5-international-patient-registry</a>	No
Myelodysplastic Syndrome (MDS)-CAN Database	<a href="https://www.mds-can.ca/">https://www.mds-can.ca/</a>	No
Pediatric Oncology Group of Ontario Networked Information System (POGONIS)	<a href="https://www.pogo.ca/research-data/pogonis-childhood-cancer-database/data-anatomy/">https://www.pogo.ca/research-data/pogonis-childhood-cancer-database/data-anatomy/</a>	No
Cancer in Young People in Canada (CYP-C)	<a href="https://www.canada.ca/en/public-health/services/chronic-diseases/cancer/cancer-young-people-canada-program.html">https://www.canada.ca/en/public-health/services/chronic-diseases/cancer/cancer-young-people-canada-program.html</a>	No
Canadian Registry for Amyloidosis Research	<a href="https://amyloidregistry.ca/login">https://amyloidregistry.ca/login</a>	No



## Strategic Goal #3.

### Objectives for Learning Projects

1. Establish a process for Multi-Stakeholder dialogue;
2. Complete demonstration / Learning Projects to collaboratively begin answering the following questions for each DRD proposing to enter Canada's healthcare system:
  - *What are the decisions to be made and by whom?*
  - *What are the questions which need answering to make those decisions?*
  - *What evidence is needed to answer those questions?*
  - *Is the necessary evidence to inform decision-making already available, in Canada or elsewhere, or are there important gaps?*
  - *If not already available, can evidence be generated to respond to the identified uncertainties?*
  - *What is the best way to provide the necessary evidence in a timely, feasible way?*



# Approach to Learning by Doing Projects

	Review of existing information		Multistakeholder Input		Real-World Evidence Development/Generation		
	(Literature) Review of existing evidence	International information / Data scan	Multi-stakeholder engagement	Multi-stakeholder meeting	Registry appraisal	Registry data analyses	Admin data analyses
Pediatric Low-Grade Glioma	x		x	x	x	x	
Pediatric Spinal Muscular Atrophy	x	x	x	x	x	x	x
Amyotrophic Lateral Sclerosis			x		x	x	x
Pediatric Cystic Fibrosis			x		x	x	x
NOC/c: OCALIVA	x	x	x		x		

**Strategic Goal #4:** Establish the building blocks for the new CANRWE4DRD framework, including those needed to use outcome-based managed entry agreements (OBMEA)

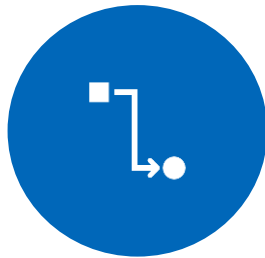
**Collaboration, early and iterative dialogue amongst stakeholders to efficiently plan and act on evidence generation for priority areas of uncertainties**



## RWE Work

- Expand Evidence Base
- Enhance Deliberation
- Improve Communication

# Opportunities



**Increase evidence base through integration of RWE into HTA**



**Standards & Guidance: RWE, Registries**

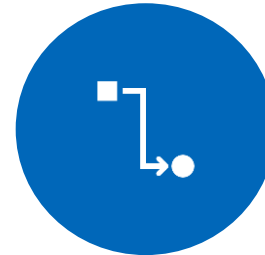


**Pan-Canadian Partnerships**



**International Collaborations**

# Specific to Rare Diseases



**Expand HTA appraisal to all drugs and devices for RD**



**Collaborate with data holders to address current limitations / gaps e.g.: standard core outcomes sets to be collected prospectively**



Link  
Leverage  
Liberate  
Learn





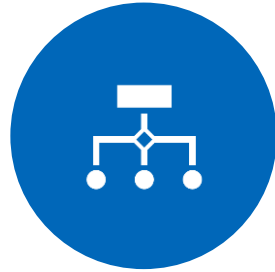
# Introduction



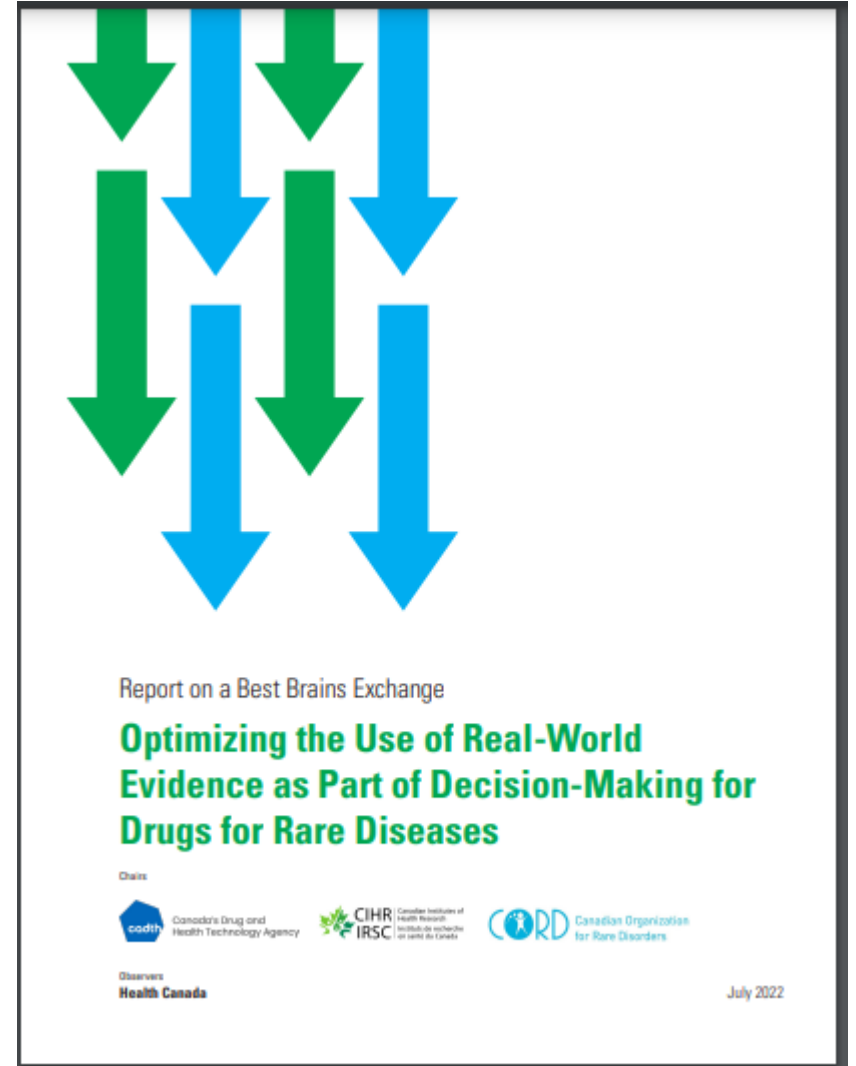
DATA



AWARENESS



COORDINATION/  
COLLABORATION



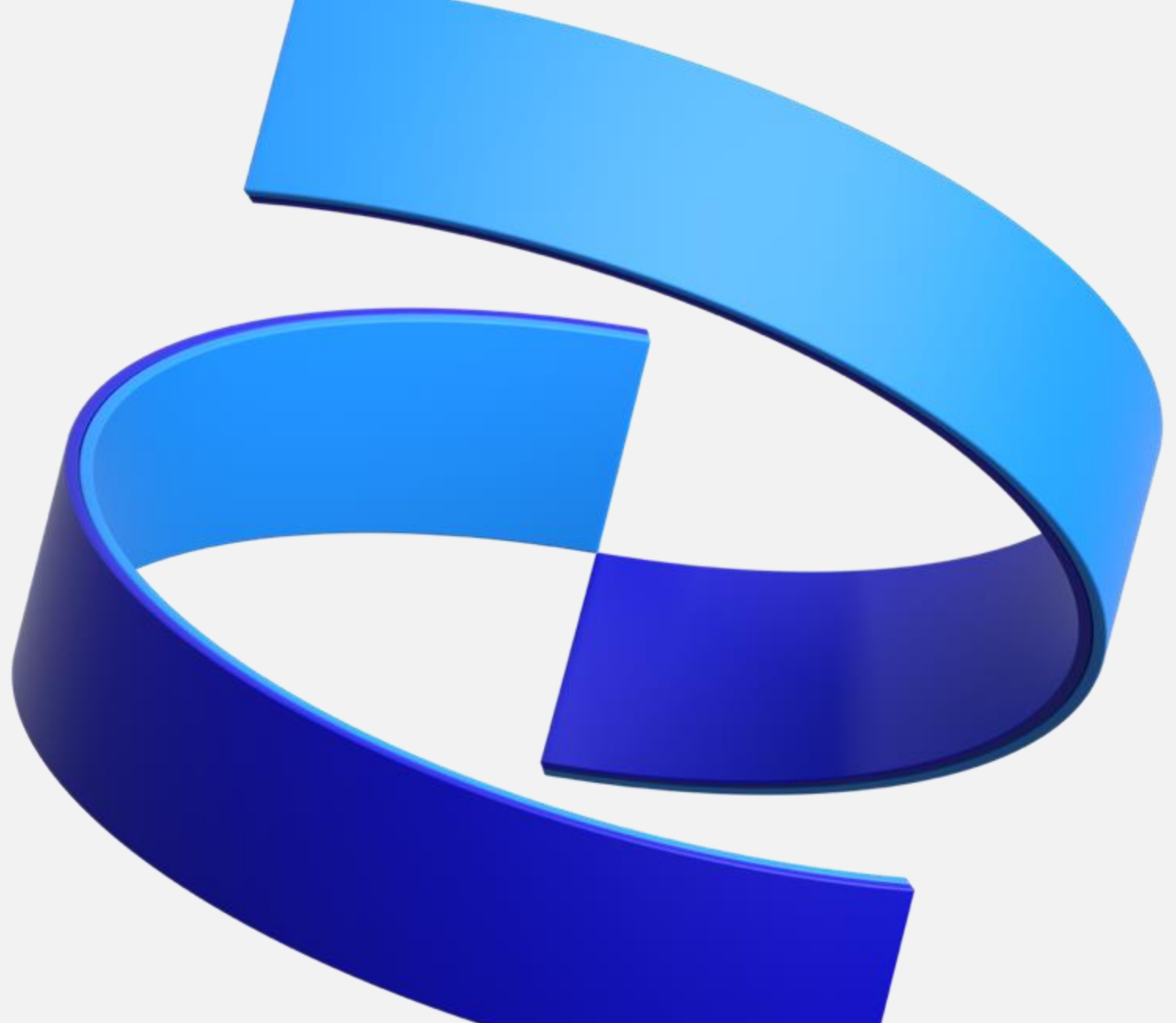
Thank you





# RWE to Enhance Decision Making

Karine Grand'Maison  
Vice-President, Access and  
Government Relations



# Private Benefits and Real-World Evidence (RWE)

**Where to invest resources into RWE to enhance coverage decisions and enable innovative contracting?**

Overall, RWE is an avenue to:

- Enhance ability to **assess value** for plan sponsors/ members
- Understand the needs of plan **members (patient) preferences**
- Enable **innovative contracting**
- Support **timely and appropriate** access of innovation for Canadian workforce

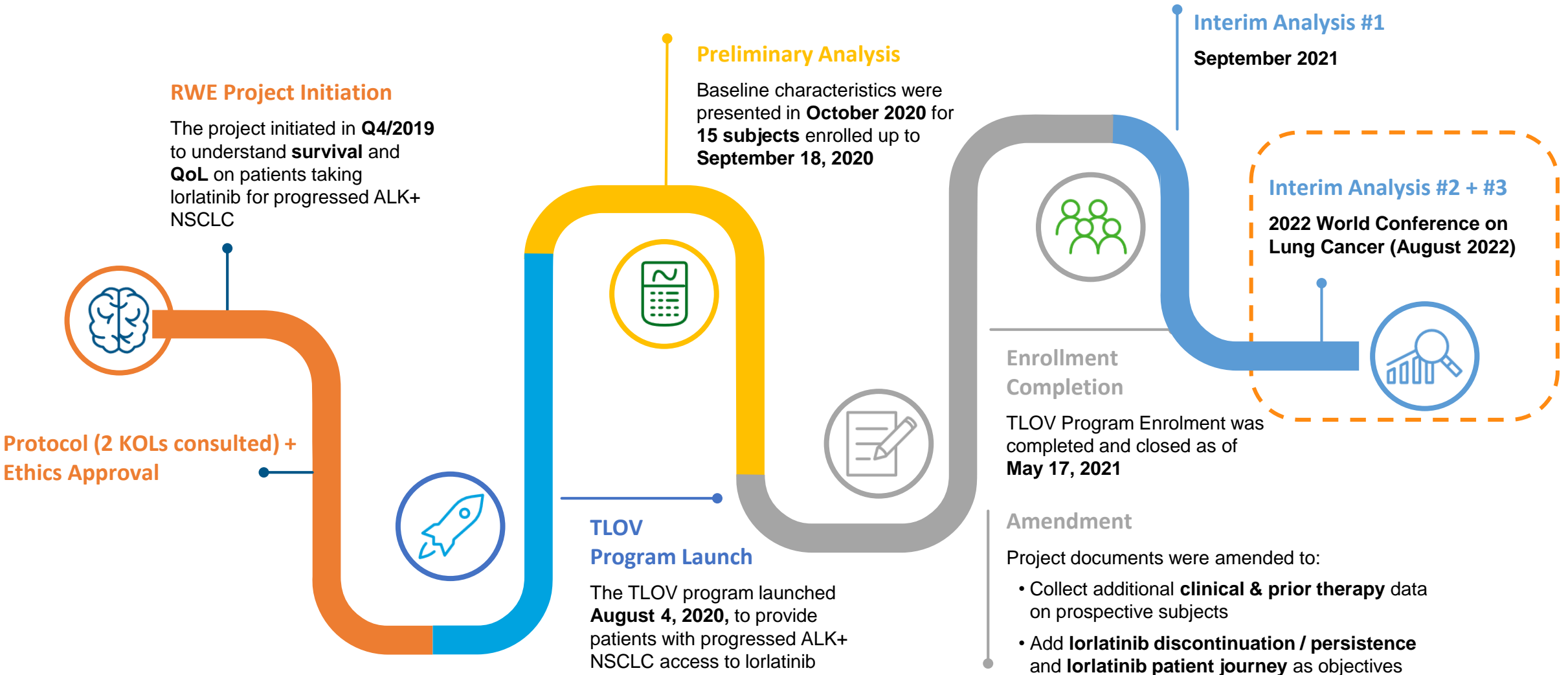


# RWE Activities @ Pfizer

How can RWE reduce uncertainty and place plan members interests at centre of access decisions?

- **RWE teams**
- **Burden of Chronic Disease**
- **Productivity / Demographics**
- **Outcomes or Value Based Coverage**
  - Canada
  - US

# Leveraging PSP to gather RWD to supplement HTA



# PREPARED: A RWE Master Class

- Pfizer Global initiated and funded a non-product oriented, educational event to facilitate the conversation around RWE and Health Technology Assessment
- Included many global and Canadian private payers, public payers and patient association groups (PAGs) for advancing Real World Evidence Decision-Making


Real-world Evidence Master Class  
Course Faculty  
PayerR  
Education  
Program  
Advancing  
Real-world  
Evidence & Decision-making



**Chris Cameron**  
MSc, PhD, P. Stat

*"The excellent curriculum presented at the most recent edition of the RWE Master Class generated informative and useful discussions with payers and participants from around the world."*

**Chris Cameron**  
Expert



*"The RWE Master Class offered by Pfizer was an excellent opportunity to learn from globally recognized RWE experts on how RWE is used to assess humanistic, clinical and economic outcomes, and what the future opportunities and challenges are for the generation and use of RWE."*

**Robert Bick**  
Co-Lead  
CanCertainty Coalition



# Using Real-World Evidence to Enhance Reimbursement Decision-Making for Canadian Payers

Consultant's Perspective

May 3, 2023



# Consultant's Perspective

PeriPharm is a Canadian consulting company specializing in health economics and market access

- In-depth knowledge of the Canadian health care system and payers' requirements.
- Established expertise in pharmacoeconomics and outcomes research for 20 years.
- Involved in numerous submissions to Canadian public and private payers.
- Diverse clients: from local to global pharma leaders.



## Clients

Pharma companies seek market access in Canada for a drug.



## Consultant

Develop key components of the submission dossier.



## Payers

Evaluate the submission dossier to issue reimbursement recommendations.



Provinces  
Private Payers

# Canadian Reimbursement Landscape

## ■ Clients' Need

Obtain public and private reimbursement to maximize market access.

## ■ Payers' Need

Make informed decisions to enhance access to innovative drugs to patients.

# Canadian Payers' Requirements

## THERAPEUTIC VALUE

- Unmet therapeutic need
- Clinical evidence (e.g., phase III clinical trials)
- Place in therapy of the new drug

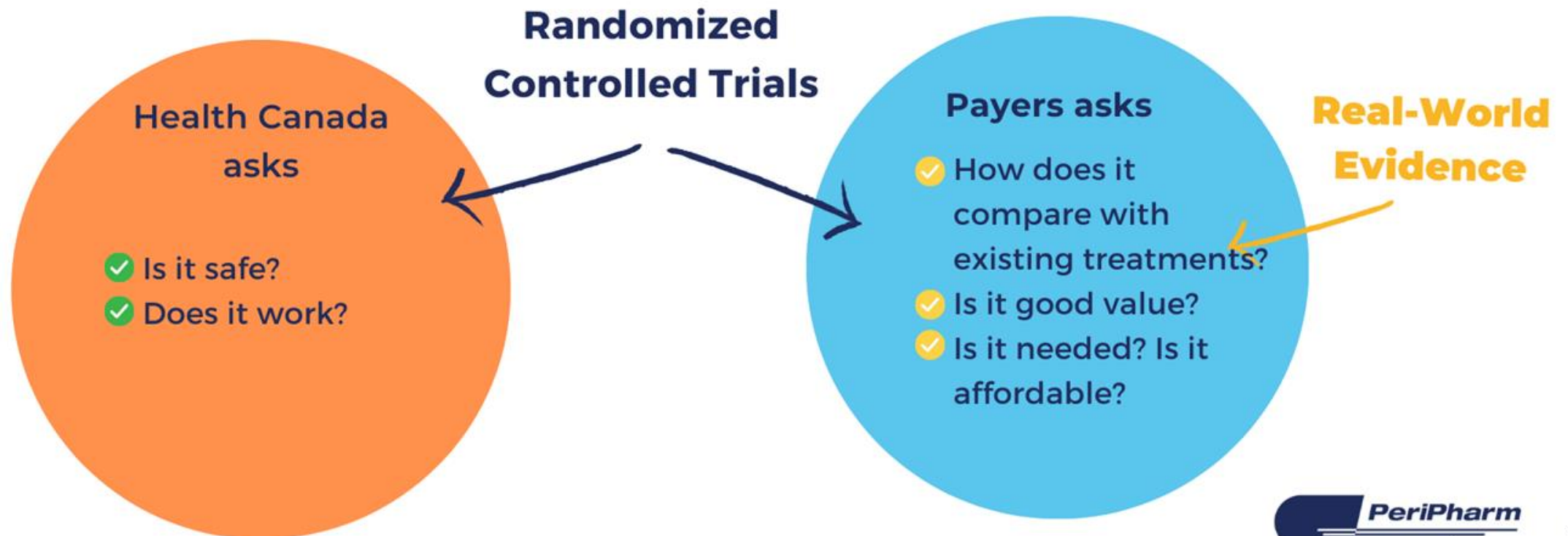
## ECONOMIC VALUE

- Economic evaluation assessing the cost-effectiveness of the new drug
- Budget impact analysis estimating the financial impact of listing the new drug



# Our Experience with Submission Dossiers Development

Submission dossiers are prepared using best available evidence



# Case Study 1



## CONTEXT

Client sought reimbursement for an approved **oral treatment in women's health** where the standard of care is an injectable.

## ISSUE

Advantages of the new drug were beyond the clinical efficacy. **Treatment convenience, patients' satisfaction** and increased **adherence to oral treatment** was anticipated, but no evidence was available to support this statement.

## IMPACT ON DECISION-MAKING

**No recognition of the therapeutic value of innovation** by payers.



# Case Study 2



## CONTEXT

Client sought reimbursement for an approved **new drug in mental health**.

## ISSUE

**Work productivity and caregiver burden** data were obtained from other countries, but no Canadian evidence were available.

## IMPACT ON DECISION-MAKING

**Increased uncertainty** in economic evaluations and payers' assessments.





# Case Study 3



## CONTEXT

Client sought reimbursement for an approved **new drug in rare disease**.

## ISSUE

Limited Canadian evidence was available. Data from another disease were used to estimate **patients' quality of life, health state utility values** and **healthcare resource utilization**.

## IMPACT ON DECISION-MAKING

- **Increased uncertainty** in economic evaluations and payers' assessment.
- Key concern in the context of **high-cost drugs**.



## Gap in Evidence

- Limited Canadian data on disease burden to demonstrate the clinical and economic value of a new drug.
- Few Patient Reported Outcomes data in Canada



Réseau  
**PROxy**  
Network

An initiative of PeriPharm Inc.

# **The Patient's Voice at the Core of Health Care Decisions**



**Our goal is to help generating patient-centered evidence to inform decision-making**



**Innovative Research  
Network**



**Allows Conducting  
Real-World Studies**



**High Standard for  
Confidentiality and  
Security of Data**

# Innovative Real-World Evidence Platform to Collect Data Directly from Patients and Caregivers

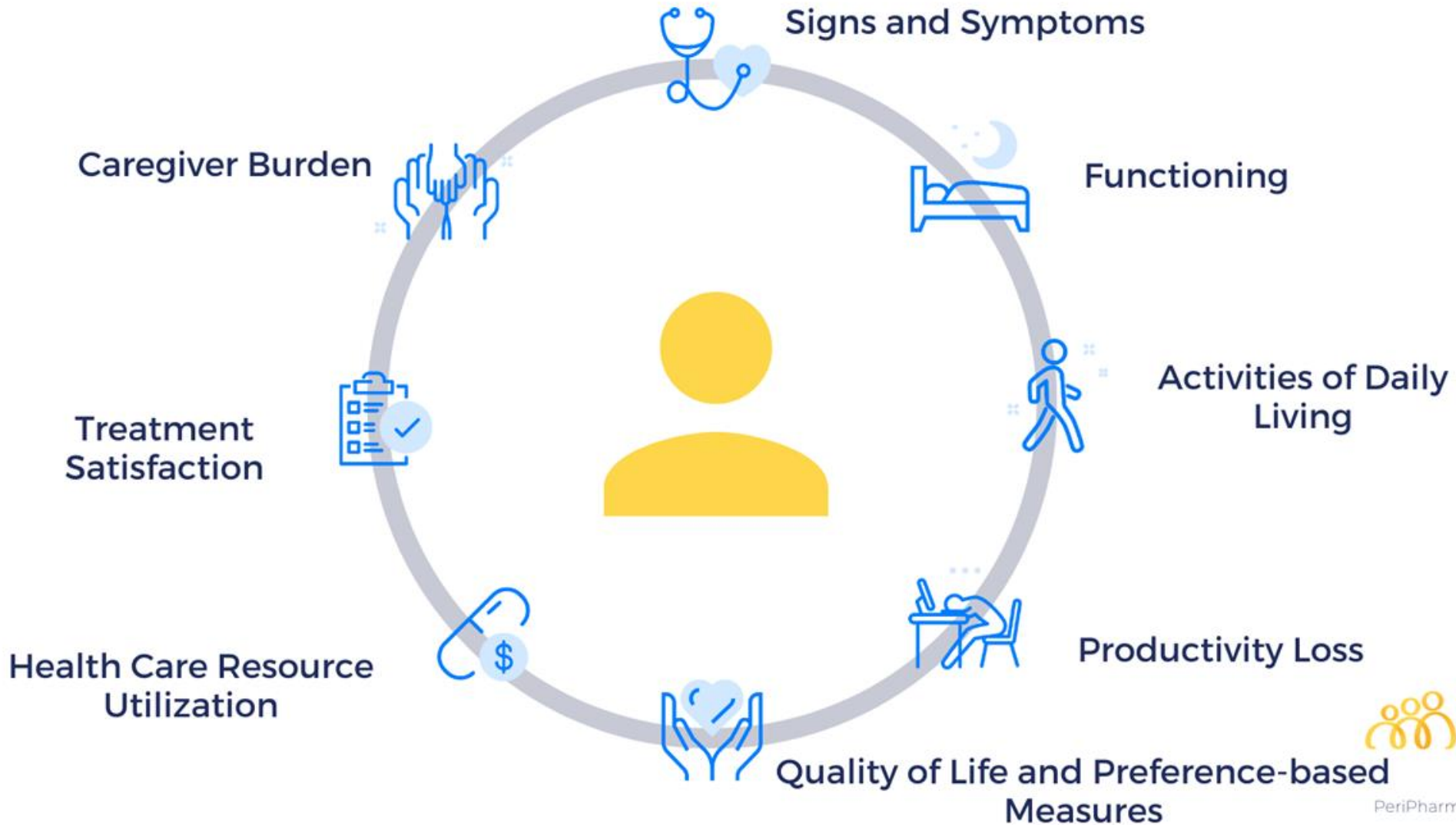
## COMMUNITY PHARMACIST NETWORK

Established network willing and ready to participate in a study. Role of the pharmacy team is to identify eligible patients for a study.

## PATIENTS' ASSOCIATION

Patients can also be identified through patients' association.

# Patient-Reported Outcomes Collected







# The Impact of Migraine on Canadians' Work Productivity

## OBJECTIVE

- To estimate the impact of migraine on work productivity and activity impairment in adults being treated with a triptan.

## STUDY DESIGN

- Cross-sectional, observational, community pharmacy-based study.

## STUDY POPULATION

- 100 adults with migraine treated with a triptan identified by the pharmacist (new script or renewal in the last 3 months).

## PRIMARY OUTCOME

- Work and activity impairment, using Migraine Impairment Disability Assessment Scale (MIDAS).



# Take-Home Message

- Canadian payers need comprehensive evidence on the therapeutic and economic value of a new drug.
- Available data does not always provide the full picture of the impact of a drug.
- Gap in evidence: Canadian based patient-centered data.



## RWE Offers the Opportunity to Better Inform Decisions

- Patients deserve to be at the core of health care decisions.
- Although RWE will never replace RCTs, it undoubtably brings value to drug assessment for Canadian payers.
- Considering the increasing cost of specialty drugs and drugs for rare disease, RWE will become a pillar in healthcare decision-making.

**QUESTIONS**



Thank you