# Timely access to novel therapies:

## Can Canada's multi-payer system be inspired by international approaches for managing evidence uncertainty related to value while providing patients with timely access to life-saving therapies?

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2CSENSE

**CADTH Symposium**

**Panel Session**
May 18, 2023

# Moderator

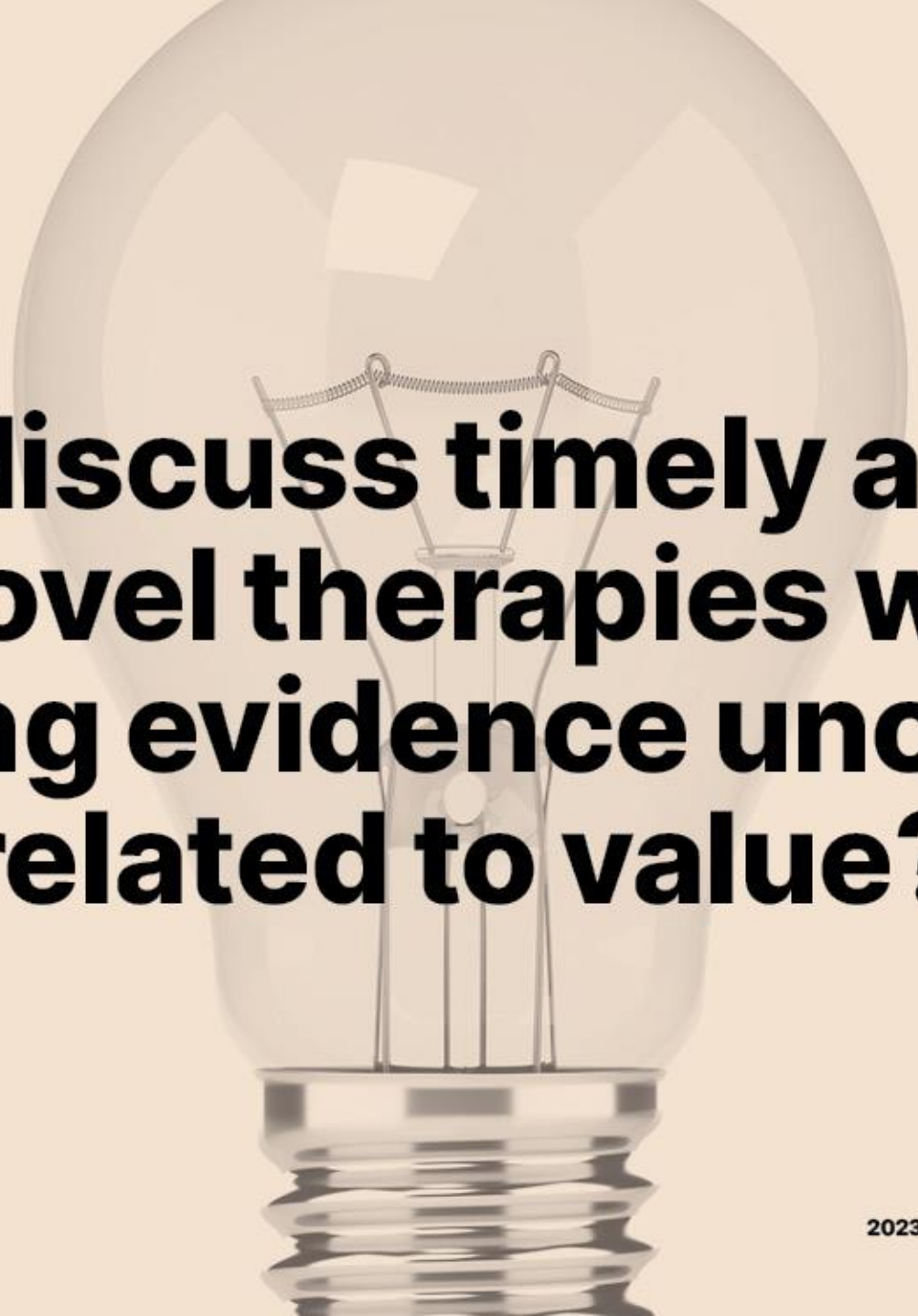
## Allison Wills

PARTNER, **20SENSE**;
CO-CHAIR OF THE REAL-WORLD EVIDENCE AND OUTCOMES-BASED AGREEMENTS WORKING GROUP.

## Disclosure

**I have the following relevant financial relationships to disclose:**

- Employed by 20Sense, which is a Canadian pharmaceutical consulting company.
- Co-chair of the *Real-World Evidence and Outcomes-Based Agreements Working Group*, which receives research support from members. Members currently include AbbVie, AstraZeneca, Janssen, Pfizer and Roche.



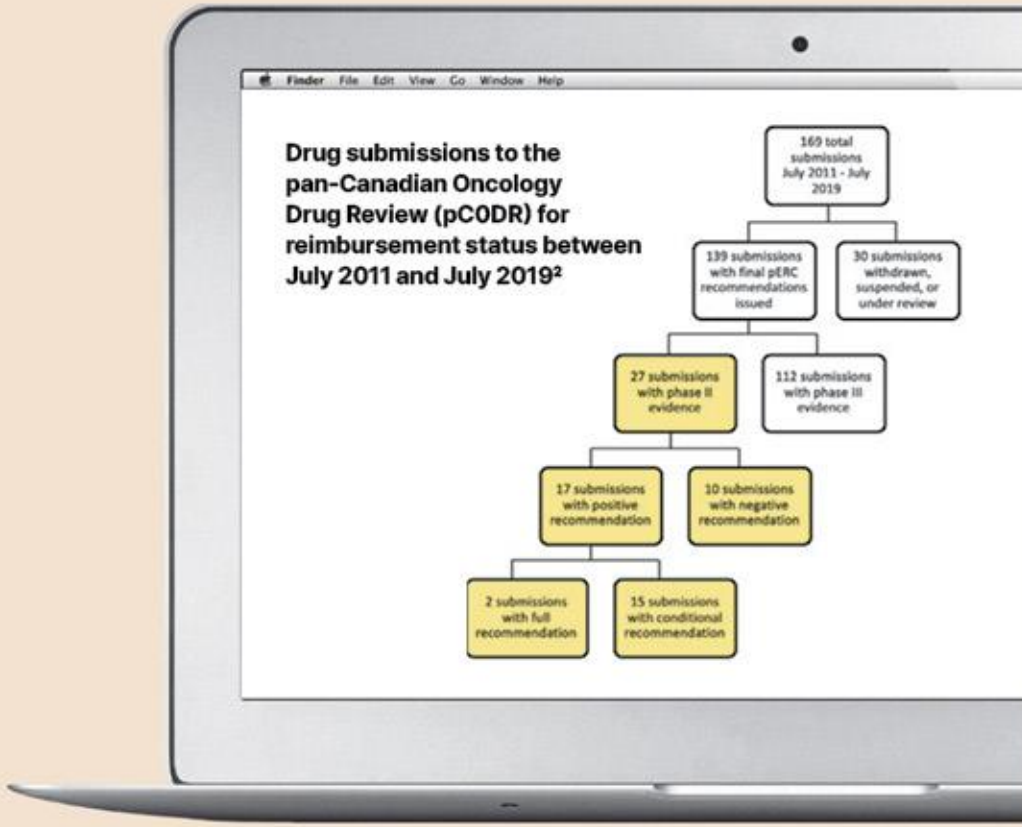
# Why discuss timely access to novel therapies while managing evidence uncertainty related to value?

# 1. Increasing challenges with access

# Phase II Data

## Phase II data are increasingly being used as primary evidence for public reimbursement, particularly for oncology drugs.

- In some cases, randomized trials are not possible – when the patient populations under study are too rare.[1]
- HTA entities may struggle to determine the value of products with phase II data, and therefore making recommendations is more challenging.[1]
- When compared with HTA submissions for public reimbursement having phase III data, oncology drug submissions with phase II data are less likely to be recommended by CADTH.[2]





1. CANCER TREATMENT: CANADIANS DON'T HAVE ACCESS THEY EXPECT AND DESERVE, ONCOLOGY MEDICINE ACCESS ROUNDTABLE, A.DUBUC, APR. 2022.
2. Y.Y.R. LI, MD, ET AL., REIMBURSEMENT RECOMMENDATIONS FOR CANCER DRUGS SUPPORTED BY PHASE II EVIDENCE IN CANADA, CURR ONCOL. OCT. 2020

# >1.5 years

**In Canada, it takes more than 1.5 years for Canadian patients to get access to a new drug in public plans.**

- From NOC to first listing, access to oncology therapies takes approx. 580 days, and for orphan drugs 670 days.
- Canada is among the slowest of the OECD20 countries to reimburse innovative new medicines through its public plans, based on the time from first global launch to public reimbursement (18th of 20; 926 days vs. median of 519 days).


SOURCES: HOSKYN S., INNOVATIVE MEDICINES CANADA, EXPLAINING PUBLIC REIMBURSEMENT DELAYS FOR NEW MEDICINES FOR CANADIAN PATIENTS, 2020.; AND IQVIA MARKET ACCESS METRICS DATABASE, SEPT. 2021.

1. Increasing challenges with access
2. International approaches to managed access

# 1 or more early access pathway

Many countries, including England and Wales, France, Germany, Italy, and Australia, have established pathways for publicly-funded early access, where patients can receive treatment while evidence collection is ongoing.

# 0 early access pathway

Canada does not have a formalized early access program.

SOURCE: EARLY ACCESS TO INNOVATIVE MEDICINES, MEDLIOR HEALTH OUTCOMES RESEARCH LTD., CORD CONFERENCE PRESENTATION, MAR. 2023.

# 86%

## England's experience with managed access agreements[1]:

- 86% (19 out of 22) of technologies re-evaluated by NICE following a period of managed access were recommended for routine use in the NHS.
- 20 out of 22 were treatments for cancer.
- While 19 out of 22 involved real-world data (RWD) for the guidance update,[1] when examining CDF review appraisals only, the main evidence has been from clinical trial data (21 of 24 appraisals).[2]

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*"Managed access is an established mechanism in England for early patient access to promising new treatments, where significant evidential uncertainty remains...without managed access, these technologies would most likely not have been recommended for routine use within the NHS in England."*



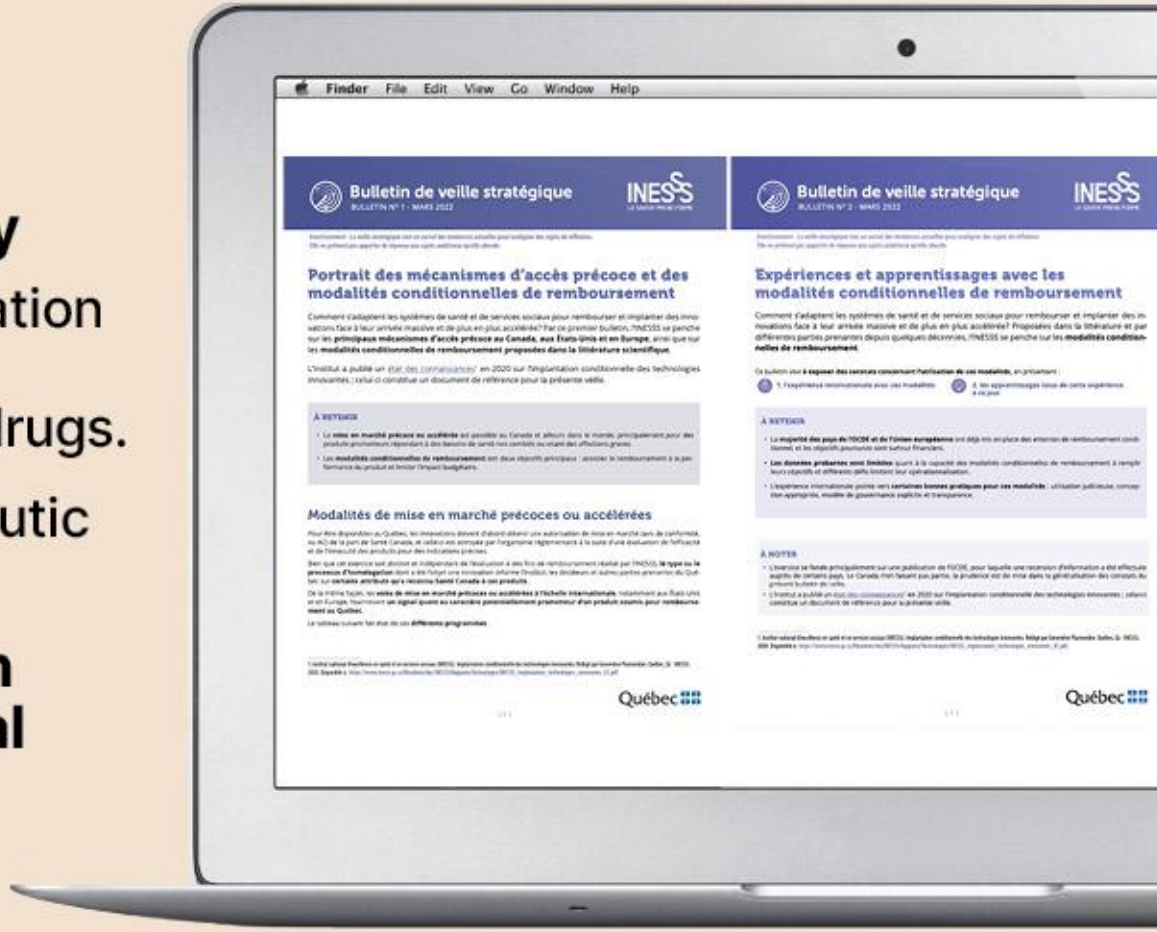
SOURCES:

1. WHAT GOES IN MUST COME OUT: AN ANALYSIS OF NICE RECOMMENDATIONS FOR DRUGS EXITING MANAGED (EARLY) ACCESS IN ENGLAND, NICE, 2022.
2. USING ADDITIONAL DATA TO REDUCE UNCERTAINTY REGARDING ONCOLOGIC DRUGS PROVIDED THROUGH MANAGED ACCESS AGREEMENTS IN ENGLAND, PHARMACOECONOMICS, SEPT. 2022.

1. Increasing challenges with access
2. International approaches to managed access
3. The current Canadian approach

INESSS
LE SAVOIR PREND FORME

- **Quebec's 2017-2027 life sciences strategy**
  - Outlines objectives to further integrate innovation into the health and social services network, including expedited access to promising new drugs.
  - Enabled INESSS to take a "promise of therapeutic value" approach.
- **Ongoing strategic intelligence research on timely access mechanisms and conditional reimbursement schemes**

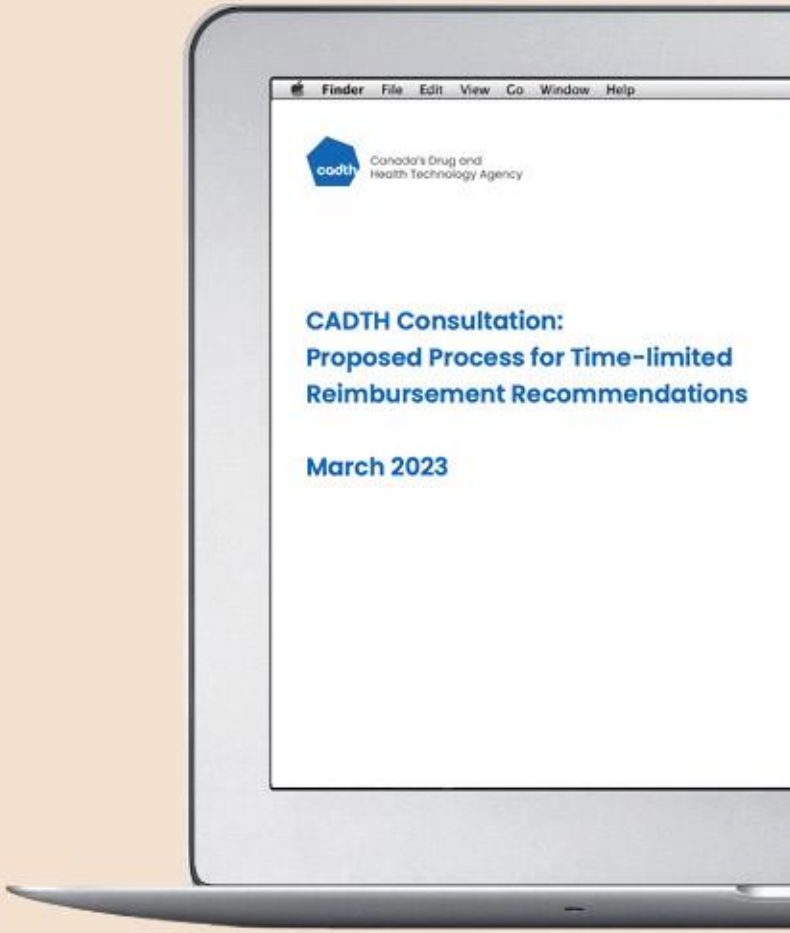



SOURCES: 2017–2027 QUEBEC LIFE SCIENCES STRATEGY: INNOVATION COMES TO LIFE, GOVERNMENT OF QUEBEC, 2017, ACCESSED MAY 2023.

ÉVOLUTION DES MODALITÉS D'ACCÈS, DE REMBOURSEMENT ET DE SOUTIEN À L'IMPLANTATION DES INNOVATIONS, INESSS WEB PAGE, ACCESSED MAY 2023.

Canada's Drug and Health Technology Agency

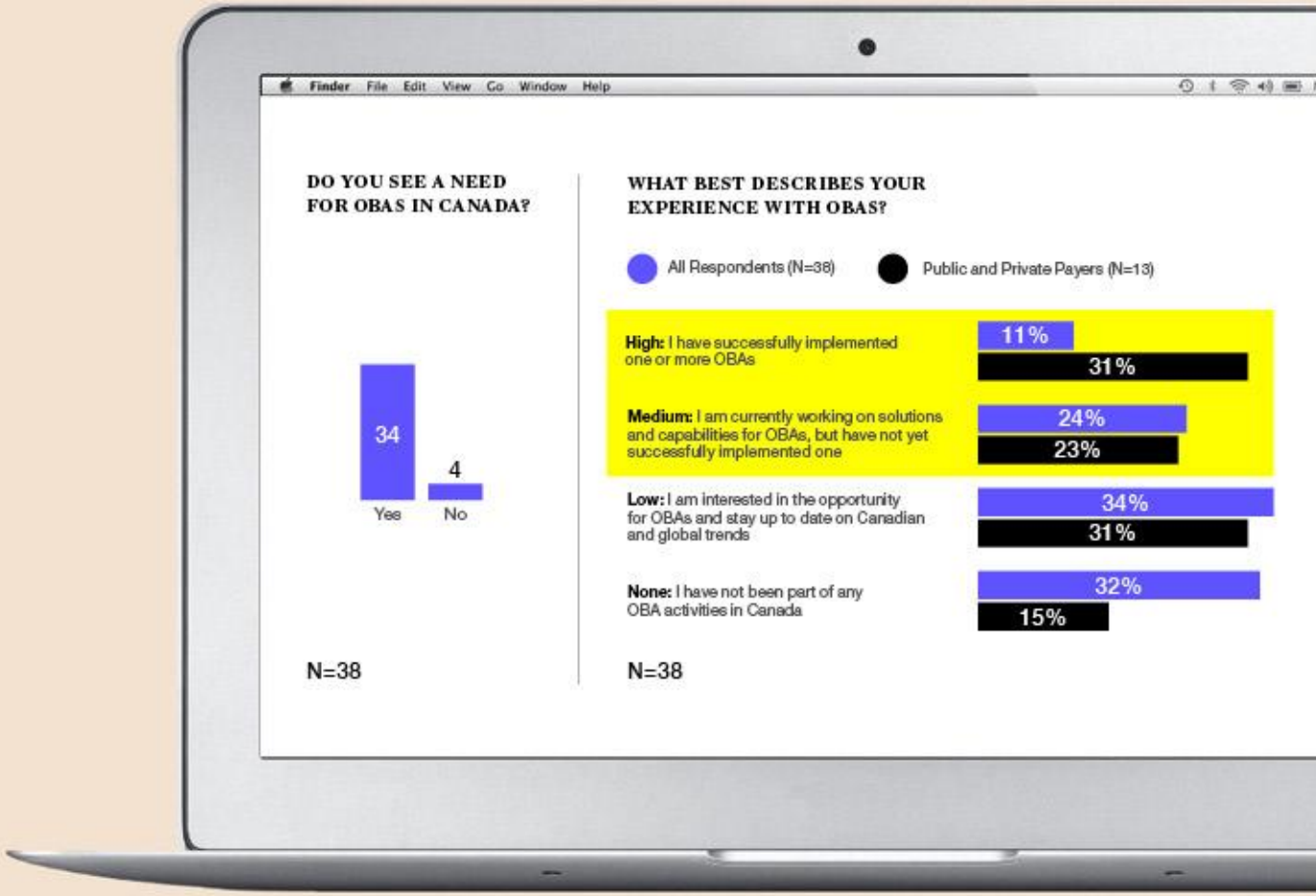
- **Proposed process for time-limited reimbursement recommendations for drugs which receive Notice of Compliance with Conditions (NOC/c) regulatory approval.**
- ***"Time-limited reimbursement recommendations are recommendations that would be issued in favour of reimbursement in a manner that is time-limited and contingent on a future reassessment of additional evidence that addresses the uncertainty with the comparative clinical benefit and cost-effectiveness for the drug or drug regimen under review."***




SOURCE: CADTH CONSULTATION: PROPOSED PROCESS FOR TIME-LIMITED REIMBURSEMENT RECOMMENDATIONS, MAR. 2023.

# Innovative market access agreements

Given the lack of formalized managed access programs in Canada, some payers and manufacturers look to innovative market access agreements, such as outcomes-based agreements and others, to support early patient access to therapies while managing evidence uncertainty.




SOURCE: CANADIAN OUTCOMES BASED AGREEMENTS EXPERIENCE AND PERCEPTIONS: SURVEY RESULTS, RWE & OBA WORKING GROUP, OCTOBER 2021.

# Can Canada's multi-payer system be inspired by international approaches for managing evidence uncertainty related to value while providing patients with timely access to life-saving therapies?

# Panelists

## Sylvie Bouchard

DIRECTOR OF DRUG EVALUATION AND TECHNOLOGY ASSESSMENT FOR REIMBURSEMENT, **INESSS**

## Carole R Chambers

PHARMACY DIRECTOR, CANCER SERVICES
**ALBERTA HEALTH SERVICES**

## Martine Elias

EXECUTIVE DIRECTOR, **MYELOMA CANADA**

## Thomas Strong

INTERIM ASSOCIATE DIRECTOR, MANAGED ACCESS, **NICE**

# Disclosures

Panelists have confirmed that they have no actual or potential conflicts of interest in relation to this topic or presentation.

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DIRECTOR OF DRUG EVALUATION AND TECHNOLOGY ASSESSMENT FOR REIMBURSEMENT, **INESSS**

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# Session Objectives

1. Discuss successes and challenges related to adapted HTA and listing pathways.
2. Explore how such approaches could be applied in the Canadian multi-payer context, to help manage evidence uncertainty related to value while providing life-saving therapies to patients.
3. Identify potential solutions that could be applied in Canada. What immediate opportunities and next steps are there? What barriers need to be overcome?

# Managed Access – A UK perspective

Thomas Strong
Associate Director – Managed Access
Thursday 18 May 2023

NICE National Institute for Health and Care Excellence

# Medicines in England

56 Million People

National Institute of Health and Care Excellence (NICE)

Central Single Payer: NHS England

2021/22: £17.2B on medicines and Health Tech

2 Managed Access Funds: CDF and IMF

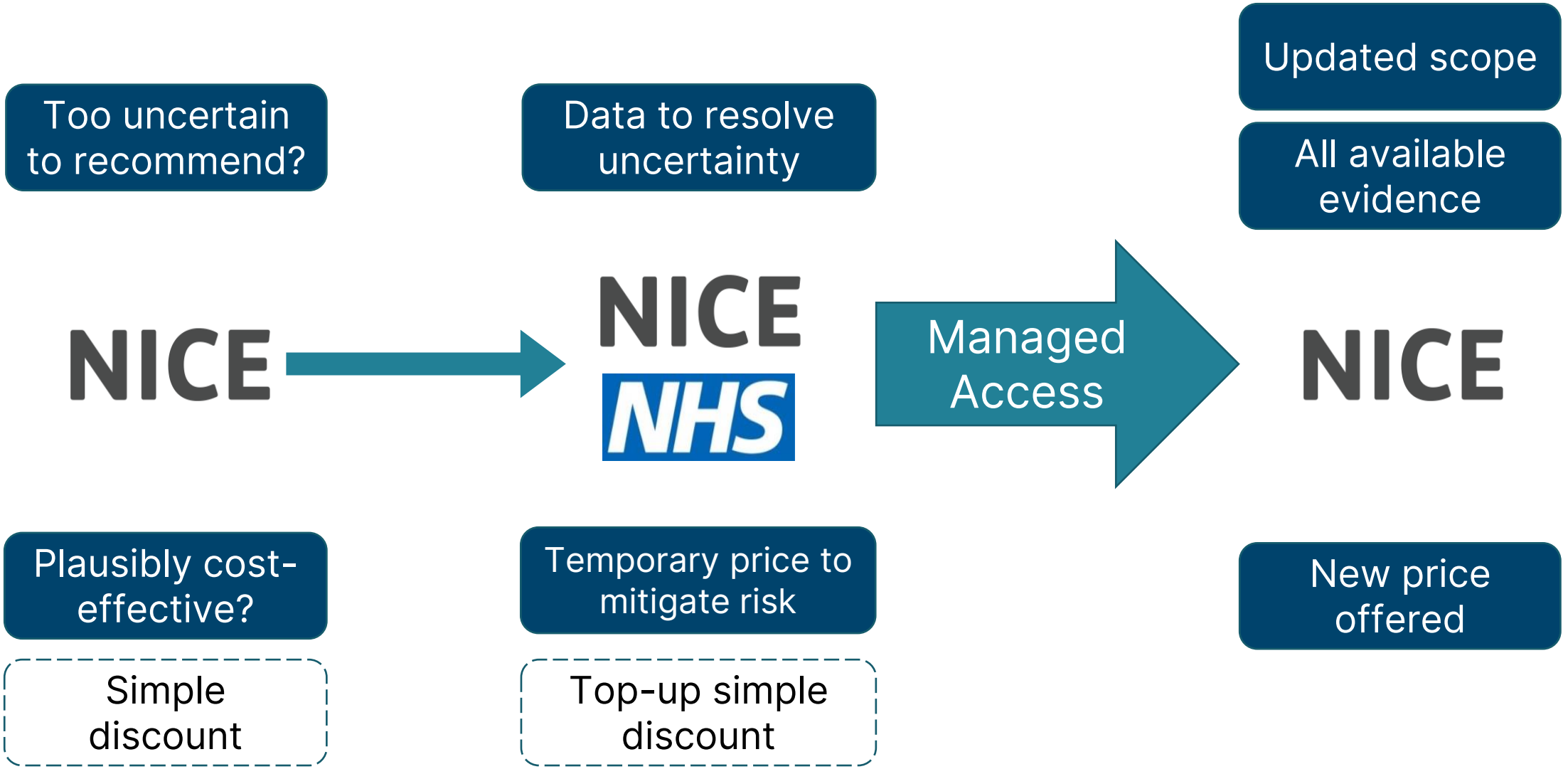
NICE

# What is ‘Managed Access’?


- **A Managed Access Agreement (MAA) is a time limited arrangement to:**
- Enable patient access while further data is collected to address key uncertainties identified by NICE
- Ensure the NHS still pays a cost-effective price, through a commercial access agreement (CAA)

**NICE**

# Managed Access: An outcome-based agreement?



# Managed Access: CDF - a success?

55 CDF MAAs since 2016

28 Exited

86% positive

96% immature data

39% generalisability

26% treatment duration

Median 3 years of data collection

87% clinical trial

78% RWE, however mostly supportive

NICE

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NICE

# Managed Access: What have we learnt?

Define the purpose and principles of managed access

How will the technologies exit?

Set risk appetite

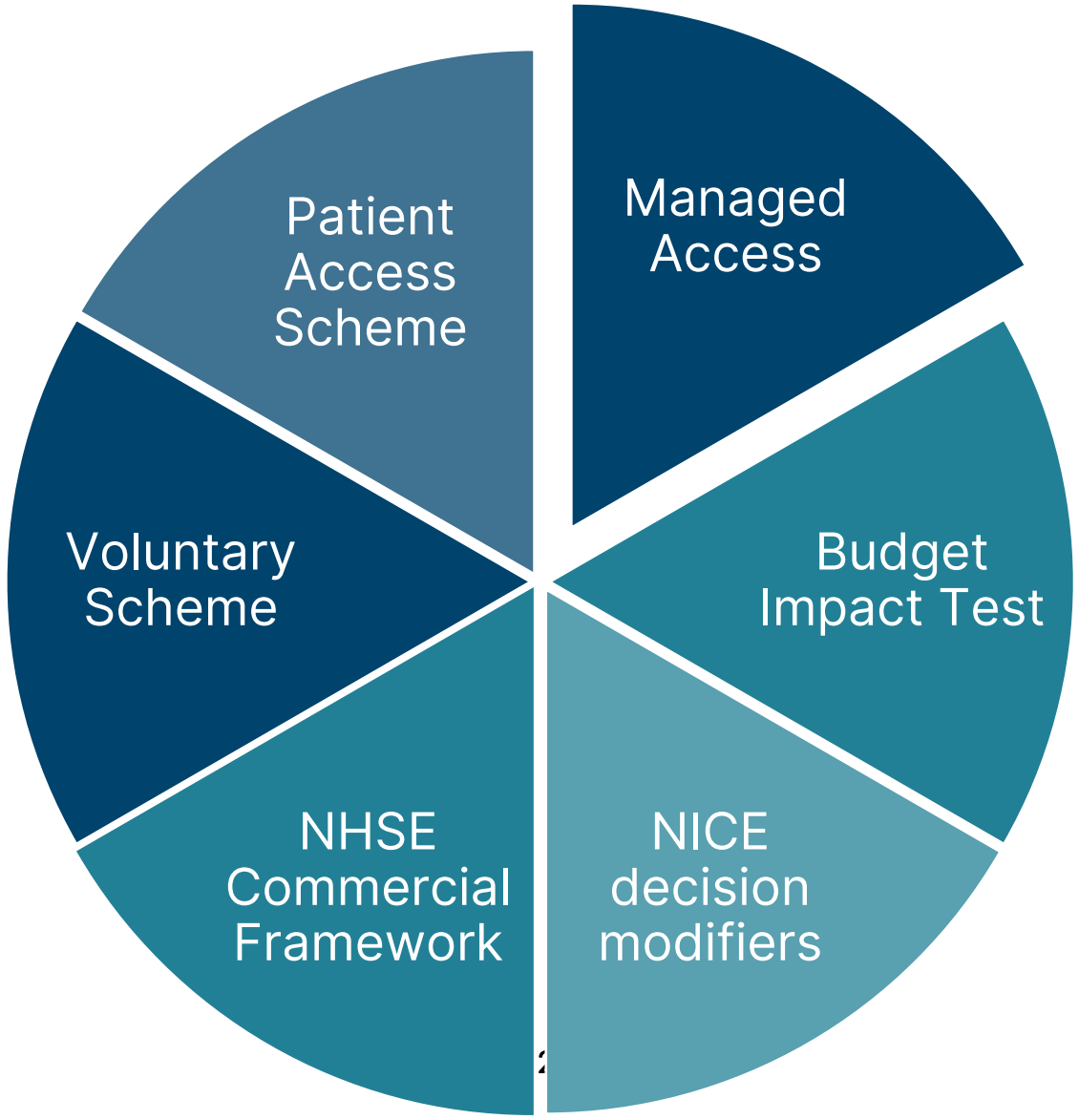
Focus on the data that matters most

Consider resource and burden on all parties

Keep it simple

NICE

# Managed Access: Not the answer to everything




NICE

# Panel Discussion

Can Canada's multi-payer system be inspired by international approaches for managing evidence uncertainty related to value while providing patients with timely access to life-saving therapies?

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**Allison Wills**

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# Audience Q&A

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