Building infrastructure to support outcomes-based agreements in Canada:

Can an outcomes-based agreement in oncology be operationalized using administrative health data?

CADTH Symposium Panel Session
November 3, 2021

Panelists: Chris Cameron, Alex Chambers, Winson Cheung, Eva Villalba
Moderator: Allison Wills

Support for the research discussed by this panel was provided by the *Real-World Evidence and Outcomes-Based Agreements Working Group*.

Moderator

Allison Wills

Partner, 20Sense, and Co-Chair of the Real-World Evidence and Outcomes-Based Agreements Working Group

Disclosure

- Employed by 20Sense.
- Co-chair of the Real-World Evidence and Outcomes-Based Agreements Working Group.
- Support for the research discussed by this panel was provided by the Real-World Evidence and Outcomes-Based Agreements Working Group.

Background

What is an outcomes-based agreement?

Definition:

An agreement between a manufacturer and a payer in which the manufacturer will issue a refund or rebate to the payer based on how well the therapy performs in a real-world patient population, measured against an agreed-upon, pre-defined set of benchmarks.

What are OBAs addressing?

- OBAs are a solution to address uncertainties that create barriers to timely patient access to therapies.
- OBAs are not a replacement for clinical trials.
- OBAs are not appropriate for all drugs. When possible, simple market access agreements are preferrable.

Panel background
Oncology, OBAs, and RWD

- With the number of promising therapies with imperfect data increasing, particularly in rare disease and precision oncology, coupled with long reimbursement timelines, timely access for patients to novel therapies has become increasingly challenging.
- Outcomes-based agreements (OBAs) are a potential solution to provide early access for patients to therapies with associated uncertainties, while mitigating the risk for payers of non-performance in the real world.
- OBAs have yet to fully gain traction in Canada. Concerns of appropriate real-world data (RWD) availability, an increase in administrative burden, and a lack of resources, infrastructure, and know-how to operationalize such agreements have been highlighted as barriers.
- In parallel, Canada's RWD infrastructure has been advancing with Alberta emerging as a health data leader, with advanced infrastructure, broad data capture, and resources to support oncology analytics (the O2 Group).

Research objectives

Operationalizing an OBA in Canada: RWD

Research questions:

Can an outcomes-based agreement in oncology be operationalized using administrative health data? Is it feasible to collect the RWD?

Objective 1:
Evaluate which health outcomes are suitable for OBAs; and determine if health outcomes can be tracked with existing infrastructure.

Objective 2:
Determine how data tracking can be operationalized for the purpose of an OBA.

Research focus and approach

Operationalizing an OBA in Canada: RWD

Research on how to operationalize an OBA, from a real-world data perspective.

✓ In scope: Oncology, Alberta, O2, and patient support program infrastructure.

× Out of scope: Actual patient or drug-specific data; drug examples.

- Core project team:
  - Dr. Winson Cheung, O2, Alberta oncologist, oncology data expert.
  - Chris Cameron, PhD, Senior Vice President, Value and Evidence at EVERSANA.
  - Arif Mitha and Allison Wills, 20Sense, Co-Chairs of the Real-World Evidence and Outcomes-Based Agreements Working Group.
  - Member representatives of the Real-World Evidence and Outcomes-Based Agreements Working Group including AstraZeneca, Bayer, BioScript Solutions, Janssen, Pfizer, Novartis, and 20Sense.

Today's panel discussion
Objectives and key learnings

Panelists will discuss key factors to be considered when operationalizing outcomes-based agreements using the health outcomes and processes identified from the research.

From this panel discussion, attendees will be able to answer the questions:

1. Which health outcomes are feasible to track to generate real-world data for the purpose of supporting an outcomes-based agreement in oncology?

2. What steps are included in the process of operationalizing an outcomes-based agreement?

3. What key factors must be considered when operationalizing an outcomes-based agreement, from the clinician, data expert, HTA, patient, and industry perspectives?

Panelists

Chris Cameron

PhD, Senior Vice President, Value and Evidence, EVERSANA

Alex Chambers

Manager, National Oncology Policy, Novartis Oncology

Dr. Winson Cheung

Principal Director at O2, Cancer Control Alberta; Professor of Medicine and Oncology, University of Calgary, Senior Medical Oncologist, Alberta Health Services.

Eva Villalba

MBA, MSc.
Executive Director, Quebec Cancer Coalition

Discussion:

Do you see a need for outcomes-based agreements in Canada? What is different now vs. previous years?

Panelist Introductions

Dr. Winson Cheung

Principal Director at O2, Cancer Control Alberta; Professor of Medicine and Oncology, University of Calgary, Senior Medical Oncologist, Alberta Health Services.

Disclosure

- No conflict of interest to declare.

Discussion:
Do you see a need for outcomes-based agreements in Canada? What is different now vs. previous years?

Panelist Introductions

Eva Villalba

MBA, MSc.
Executive Director,
Quebec Cancer
Coalition

Disclosure

- No conflict of interest to declare.

Discussion:
Do you see a need for outcomes-based agreements in Canada? What is different now vs. previous years?

Panelist Introductions

Discussion:
Do you see a need for outcomes-based agreements in Canada? What is different now vs. previous years?

Alex Chambers

Manager, National Oncology Policy, Novartis Oncology

Disclosure

- Employed by Novartis Pharmaceuticals Inc.
- Former CADTH staff.

Panelist Introductions

Discussion:
Do you see a need for outcomes-based agreements in Canada? What is different now vs. previous years?

Chris Cameron

PhD, Senior Vice President, Value and Evidence, EVERSANA

Disclosure

- Employed by EVERSANA.
- Shareholder of EVERSANA which is a global life sciences commercial services company.
- Former CADTH staff.

Research Results

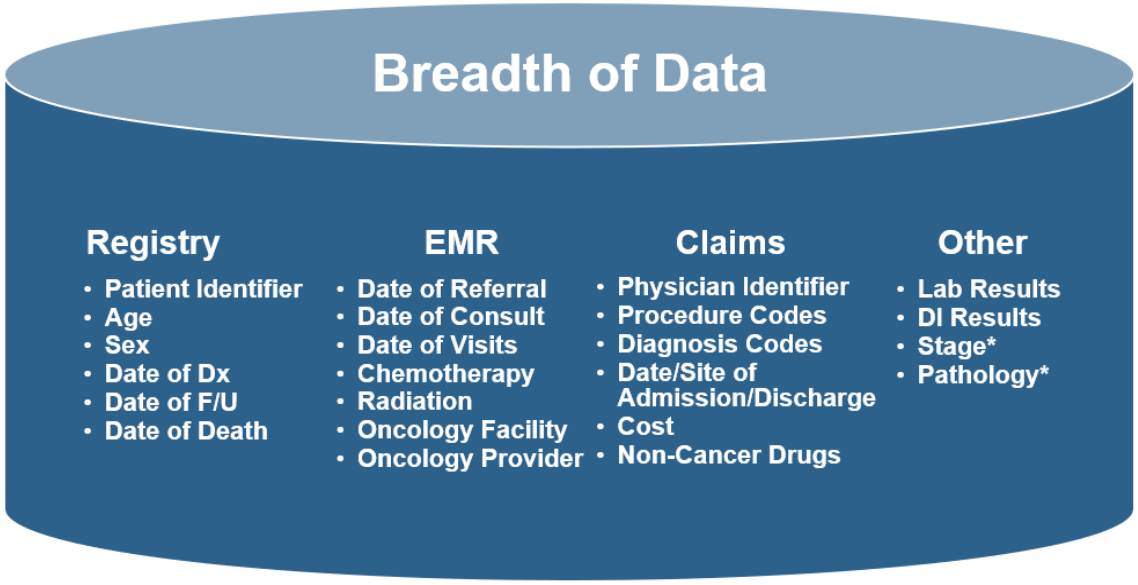
Health outcomes data suitable for OBAs

Objective 1: Evaluate which health outcomes are suitable for OBAs; and determine if health outcomes can be tracked with existing infrastructure.

Discussion:

Why conduct this research with Alberta administrative health data?

Alberta Data Overview



Population-based data

- 2 tertiary centres
- 4 regional centres
- 11 community centres

Source: O2

Results: Health outcomes data suitable for OBAs

Two health outcomes were identified as suitable

Health Outcome	Suitable for an OBA?	Data Readiness Accessible for an OBA, complete and accurate.	Data Interpretation Health outcome is clear and simple.	Data Timeframe Can be collected in a reasonable timeframe.
1 Overall Survival (OS)	Yes	• AB Cancer Registry • Data has been used in published studies	• Binary data point, easy to interpret	• 6-month time lag in AB • 12 months or longer in other provinces
2 Time to Next Treatment (TTNT)	Yes	• AB PIN database contains all Rx's dispensed in AB (all payers) • Data has been used in published studies	• Algorithm required for specific treatment pattern	• 1-month time lag in AB
3 Progression Free Survival (PFS)	No	• AB Administrative data • Incomplete: Timing of tests are not standardized	• Interpretation of results recorded in data are not standardized	• N/A
4 Patient-Reported Outcomes (PROs)	No – future potential	• AB administrative data: ESAS, EQ5D surveys. • Incomplete: Not administered to all patients. • No published studies.	• EQ5D and ESAS frequently included in HTA submissions	• N/A
5 Return to Work	No	• Data not available	• Patient may choose not to return to work	• N/A

Figure 2: Health outcomes data readiness, interpretation, and timeframes

Discussion:

Are there situations or examples that come to mind where these health outcomes could be used to support an OBA?

Health Outcome	Suitable for an OBA?
1 Overall Survival (OS)	Yes
2 Time to Next Treatment (TTNT)	Yes
3 Progression Free Survival (PFS)	No
4 Patient-Reported Outcomes (PROs)	No – future potential
5 Return to Work	No

OBA Data Tracking Example
Overall Survival (OS)

OS Details

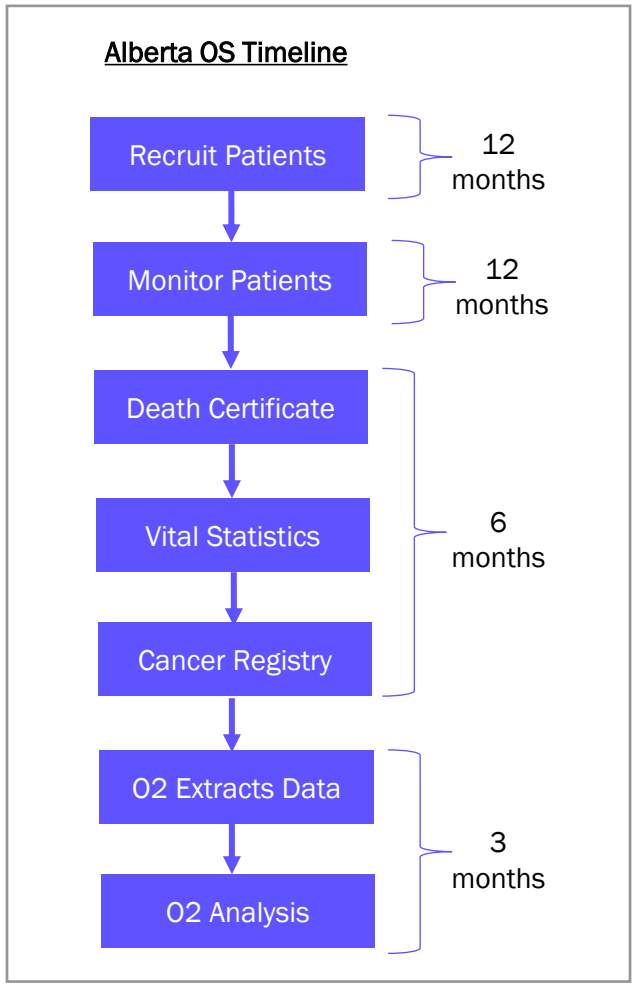
- Objective event; ease of interpretation; 1 data point.
- Diagnosis with relatively short anticipated OS could be a good fit for an OBA.

OS Timelines

Example

- Patients are recruited over 12 months.
- Survival status is monitored for 12 months.
- Data collection logistics to receive information on survival status takes approx. 6 months.
- Analysis time required takes approx. 3 months.

→ Total estimated time required an OBA data tracking: 3 years.



Discussion:

What are your thoughts on the OS data tracking example for an OBA?

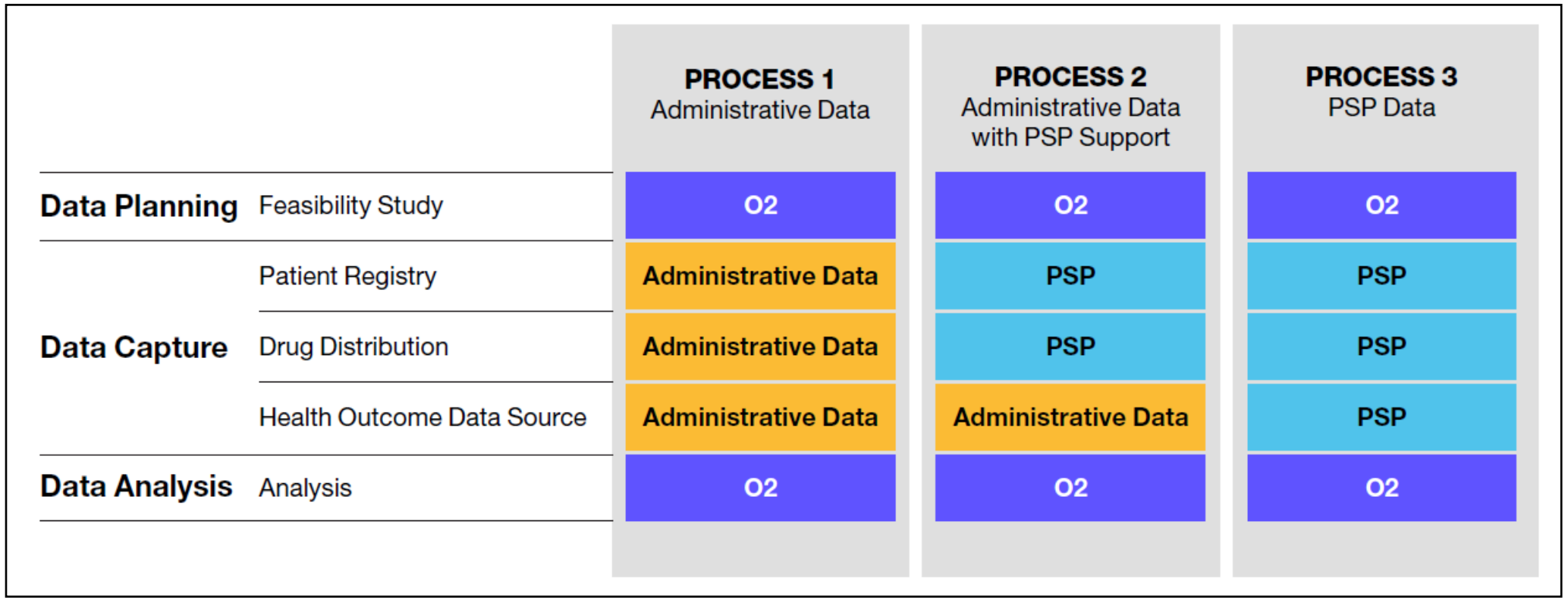
Research Results

Process to operationalize RWD for OBAs

Objective 2: Determine how data tracking can be operationalized for the purpose of an OBA, by designing an OBA data process.

Results: Process to operationalize RWD for OBAs

3 OBA data processes have been identified



		PROCESS 1 Administrative Data	PROCESS 2 Administrative Data with PSP Support	PROCESS 3 PSP Data
Data Planning	Feasibility Study	O2	O2	O2
Data Capture	Patient Registry	Administrative Data	PSP	PSP
	Drug Distribution	Administrative Data	PSP	PSP
	Health Outcome Data Source	Administrative Data	Administrative Data	PSP
Data Analysis	Analysis	O2	O2	O2

Figure 3: Process design for data collection to support outcomes-based agreements in Canada

Results: Process to operationalize RWD for OBAs

Data Planning: Feasibility study

A feasibility study is conducted to determined if health outcome data can be collected to meet the needs of an OBA?

- YES/NO
- The result of the feasibility study will be a key input when the payer and manufacturer are designing the OBA.

Feasibility study questions to answer:

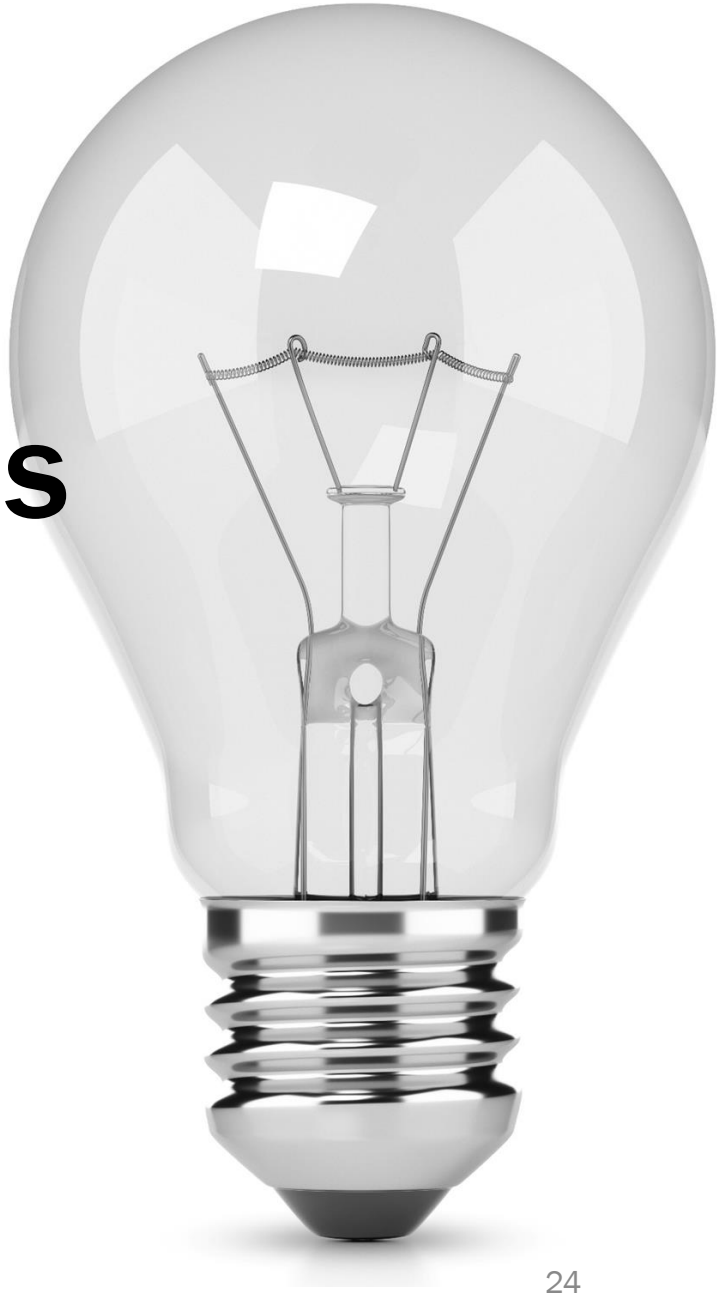
1. Which health outcomes are possible for the drug?
2. Is the RWD available? Data source?
3. Is the patient population sufficient?
4. What is the anticipated timeline to complete the data portion of the OBA?

Feasibility study process:

1. Data expert engaged for perform feasibility study.
2. Timing of feasibility study.
3. Ethics Committee approval to access data for feasibility study, and for the OBA.

Discussion:

What other considerations come to mind about the OBA RWD feasibility study?



Results: Process to operationalize RWD for OBAs

Process 2 and 3 leverage PSP infrastructure

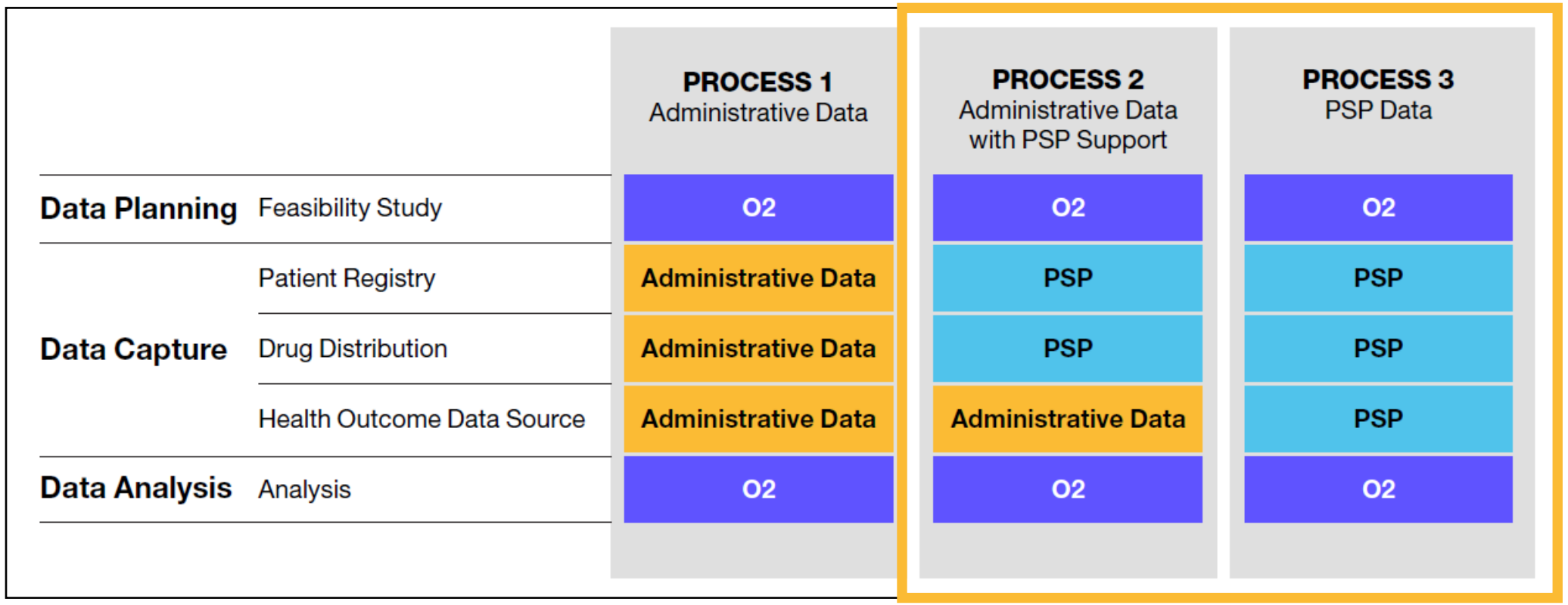


Figure 3: Process design for data collection to support outcomes-based agreements in Canada

Discussion:

What are the pros and cons of leveraging the PSP infrastructure for OBAs (vs. administrative data)?

Research Results
Summary of Results and Key Insights

Operationalizing an OBA in Canada: RWD

Summary of Results & Key Insights

RWE AND OBA WORKING GROUP

1. It is feasible to collect RWD to support OBAs, using Alberta administrative health data in oncology: OS & TTNT.
2. Minimal additional resources and infrastructure are required from the public system to collect data to support OBAs.
   - In some scenarios, administrative data infrastructure is already in place; and PSP infrastructure and data could supplement, where appropriate.
3. The total estimated timeframe required to collect RWD and report for OBAs is 2.5 – 3 years.
4. The recommended first step when considering an OBA is to perform an RWD feasibility study by a data expert.

Final thoughts:

Can an outcomes-based agreement in oncology be operationalized using administrative health data? Yes

Q&A

Panelists

Chris Cameron

PhD, Senior Vice President, Value and Evidence, EVERSANA

Alex Chambers

Manager, National Oncology Policy, Novartis Oncology

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