IMS Health & Quintiles are now IQVIA™

10 minutes = 10 slides

R mples of Evidence

Presentation at CAPT Conference, 2018

Brad Millson, Sr. Principal, Health Access & Outcomes, IQVIA
October 2018

Agenda

+ What Is RWE?
+ Case Studies & Examples – Overcoming the “Challenges” in RWE
+ Future Outlook

A common lexicon

Real-World Data (RWD)

- Patient-level data not collected in conventional randomized controlled trials
- Examples: electronic medical records, claims data, mortality data, consumer data, registries, data collected in observational studies, chart reviews

Real-World Insights (RWI)

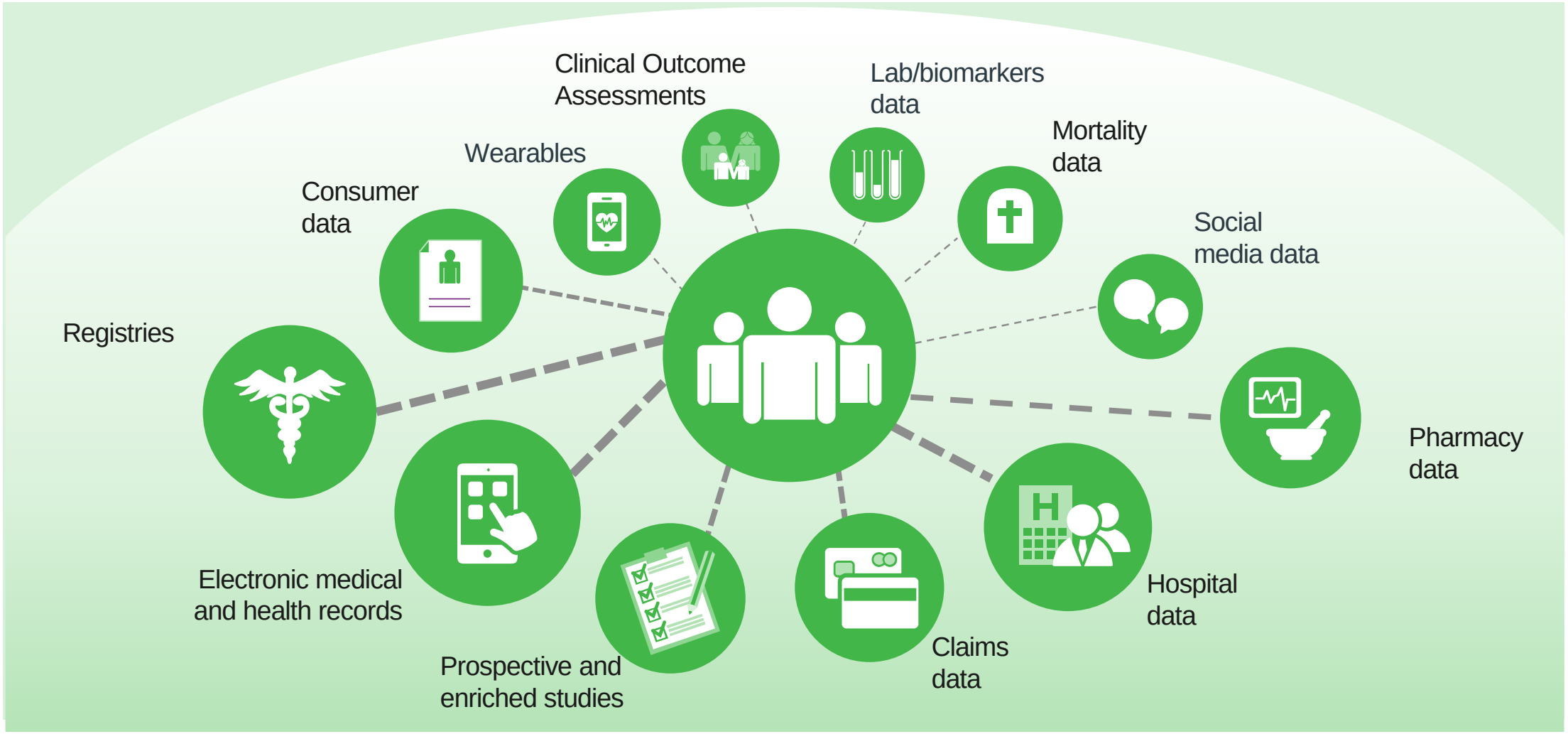
- Insights generated from RWD using appropriate scientific and/or generated commercial analytics

Real-World Evidence (RWE)

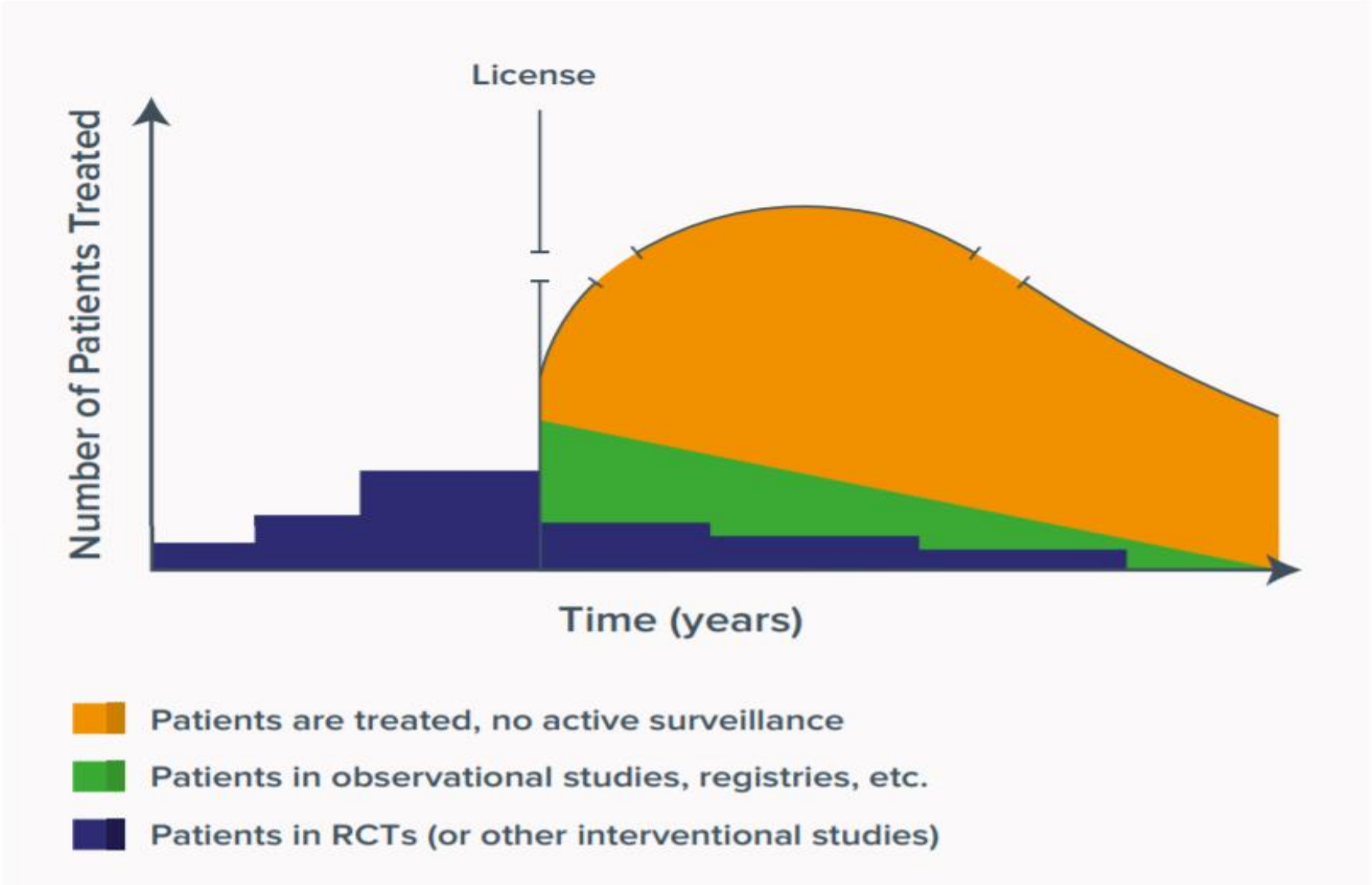
- Insights generated from RWD using appropriate scientific and/or generated commercial analytics with the intention to support a claim or belief to produce evidence for multiple stakeholders

See www.rwedictionary.com for more definitions

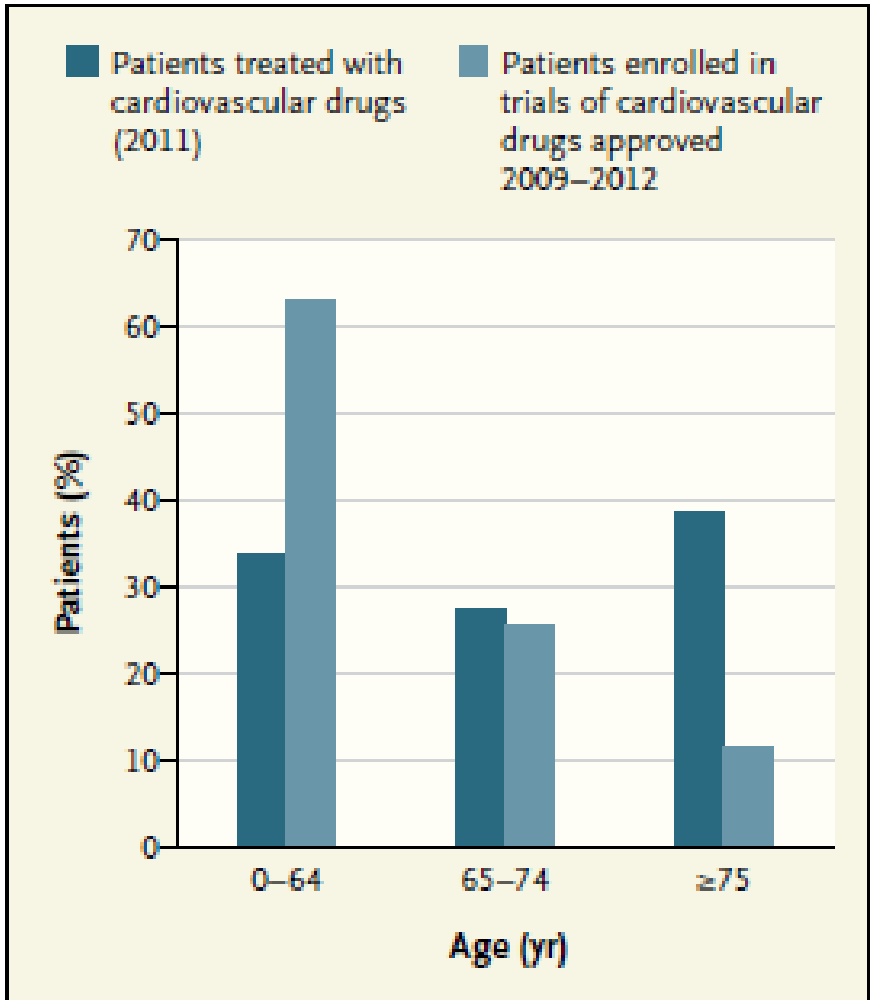
RWD is PATIENT-level data



The vast majority of data around patient exposure to interventions occurs outside of traditional clinical trials



RWE is relevant and critical, since the real world does not consist of “ideal patients”



The Example of Cardiovascular Drugs: Percentages of All Patients in a Given Age Group Treated with Cardiovascular Drugs (Italy) versus Percentages in Each Age Group Included in Cardiovascular Drug Trials (Globally).

Data on all patients treated are for 2011 and come from the Italian census and the Italian ministry of health; data on patients in clinical trials are for drugs approved between 2009 and 2012 and come from the drug-registration dossiers submitted to the EMA during that period.

F. Cerrata, HG Eichler, G Rasi: Drug Policy for an Aging Population — The European Medicines Agency’s Geriatric Medicines Strategy NEJM 2012:36;1972-1974

Quintiles + IMS Health, integrating evidence generation

imshealth™

Largest real world data company (secondary collection)

Bridging Clinical with Real World Evidence

QUINTILES®

World's largest clinical research organization (primary collection)

IQVIA™

Smarter evidence design & execution:

- Enriched Study (aka Hybrid Study, Enhanced Study)
- Evidence Platforms & Technologies (aka Evidence Hub)
- Low Intervention Clinical Trial *(aka Minimally Interventional Trial)*
- Predictive Analytics
- One-Armed Study with External Comparator
- Pragmatic Randomized Trial

Challenges in using RWE

Data Access & Sharing

Methodology

Technology

Standards

Human & Financial Resources

Governance & Privacy

Innovating Solutions

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

OMOP Common Data Model

PRIVACYANALYTICS
Data Anonymization Solutions

ISPOR
INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOMES RESEARCH

Sentinel Initiative

e360™
REAL-WORLD INSIGHTS

Innovation = Change

Models of Innovative Evidence Generation in Regulatory Setting

Combining Primary with Secondary sources of information opens up new options

PURE PRIMARY

Randomization Clinical Trials

Prospective research (registries)

Blend & Extend the use of Secondary data

Drug Use & Disease Prevalence

Mosaic studies

Enriched studies

PURE SECONDARY

Admin Database studies

Evidence Platforms

1 EXTENSION In time

RCT data collection ends — *agent + comparator* → LINK → *Direct to patient* and / or *Secondary data*

- *Low-cost follow-up for long-term safety & effectiveness*

2 AUGMENTATION with comparators

Primary data collection (*agent*) + *Secondary data* (*comparator*)

- *Comparative evidence for product registries or single-arm clinical trials*

3 ENRICH with more data sources

Primary data collection (*agent + comparator*) + *Secondary data* (*agent + comparator*)

- *Improved efficiency of data capture to address several research questions*
- *Accelerated evidence generation*

CASE STUDY
Extension study

Extend follow-up after a clinical trial

Understanding long-term benefits of treatment through direct-to-patient research

Why RWE:

- Can measure long-term benefits / risk
- Much lower cost than extending follow-up through RCT framework:
  → < $5k >$15K per patient, + enhances RCT investment
- Bulk of budget is directed to following up potential CVD events (not all patient information)
- Reduces number of sites needed, simplifying operations

The Approach:

- Direct to patient follow-up for effectiveness (up to 10 yrs)
- Follow-up both treated and placebo patients
  - 10,000 patients from 100 sites
  - Patients are consented before trial ends by RCT sites
  - Single investigative site per country
- Selected clinical validation for events of special interest
- Link to administrative datasets for long-term follow-up

Extension study:

RCT ends

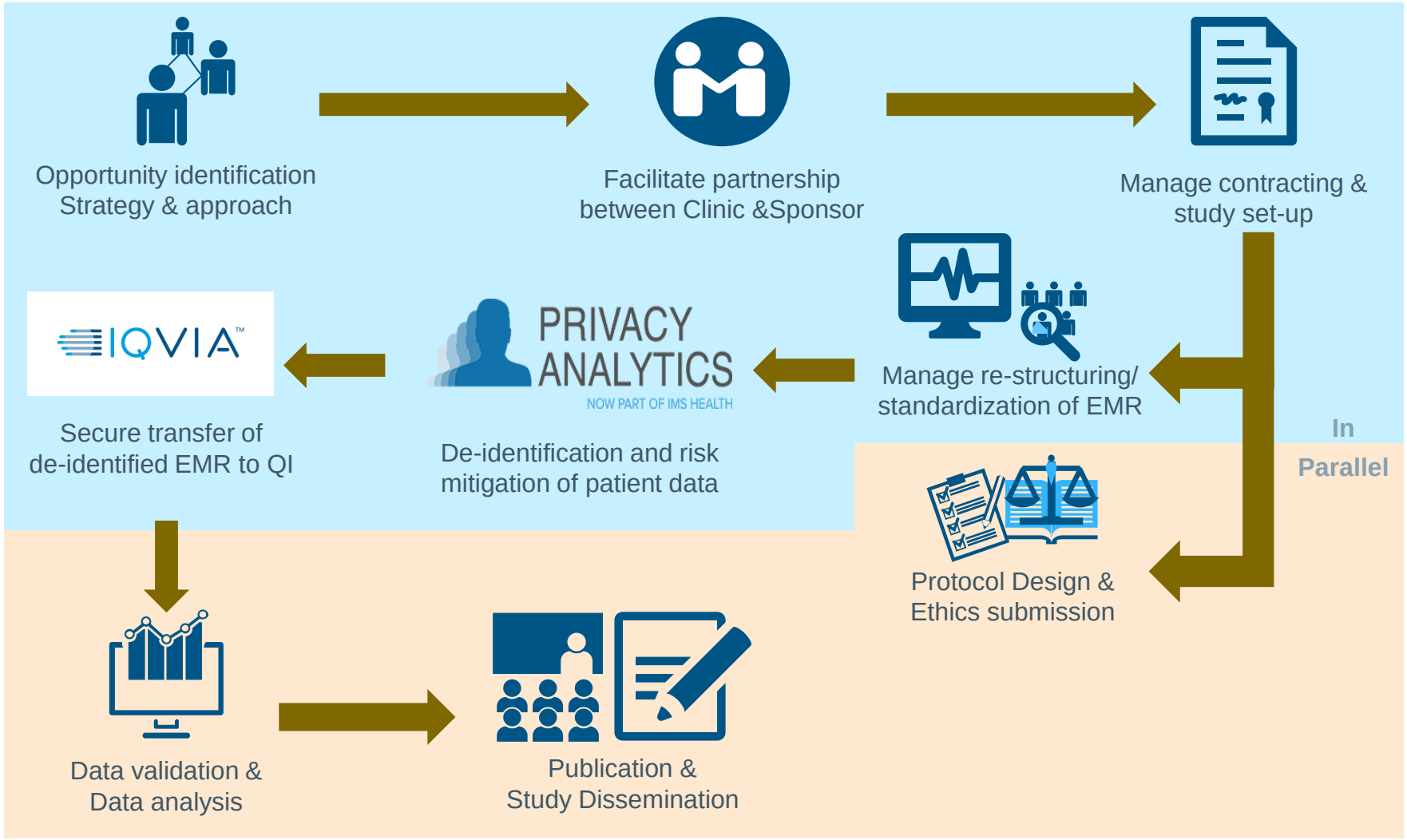
Agent + comp.

LINK

Direct to pt.

Secondary data

EMR Chart Audits simplify and greatly reduce the time required for data collection and generation of real world insights



Liraglutide Real World Study – A Multi-Stakeholder Approach

Study Objective: What is the real world clinical effectiveness of liraglutide 3.0mg for weight loss?

Collaborative Approach

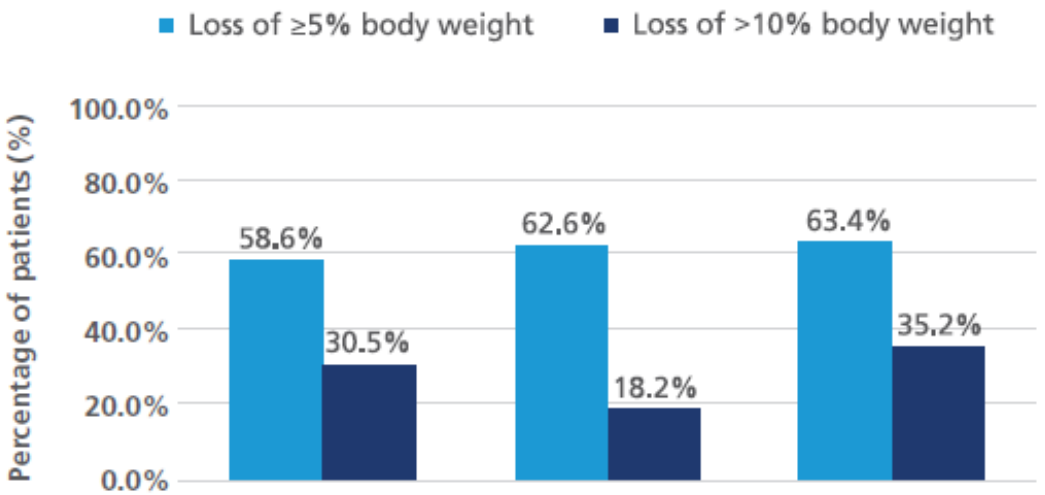
WHARTON MEDICAL CLINIC WEIGHT & DIABETES MANAGEMENT

novo nordisk®

PRIVACY ANALYTICS

IQVIA™

Figure 3b: Categorical Percentage Weight Loss



	All Subjects	≥4 months	≥6 months
N (n)	*311 (203)*	*210 (187)*	*167 (145)*

Key Findings:

- Characterization of real-world patient population
- Significant improvements in
  - Weight reduction
  - HbA1c
  - SBP
- Results in-line with clinical trial results

Source: **Real-World Clinical Effectiveness of Liraglutide 3.0mg for Weight Management in Canada** S. Wharton et al. Value in Health; May 2018, Volume 21, Supplement 1, Page S246: https://doi.org/10.1016/j.jval.2018.04.1668

IQVIA™

The Engage platform – How it is employed on a study

Fully enabled real-world data collection and reporting

PROs | QOL | eDiaries | Study EDC integration

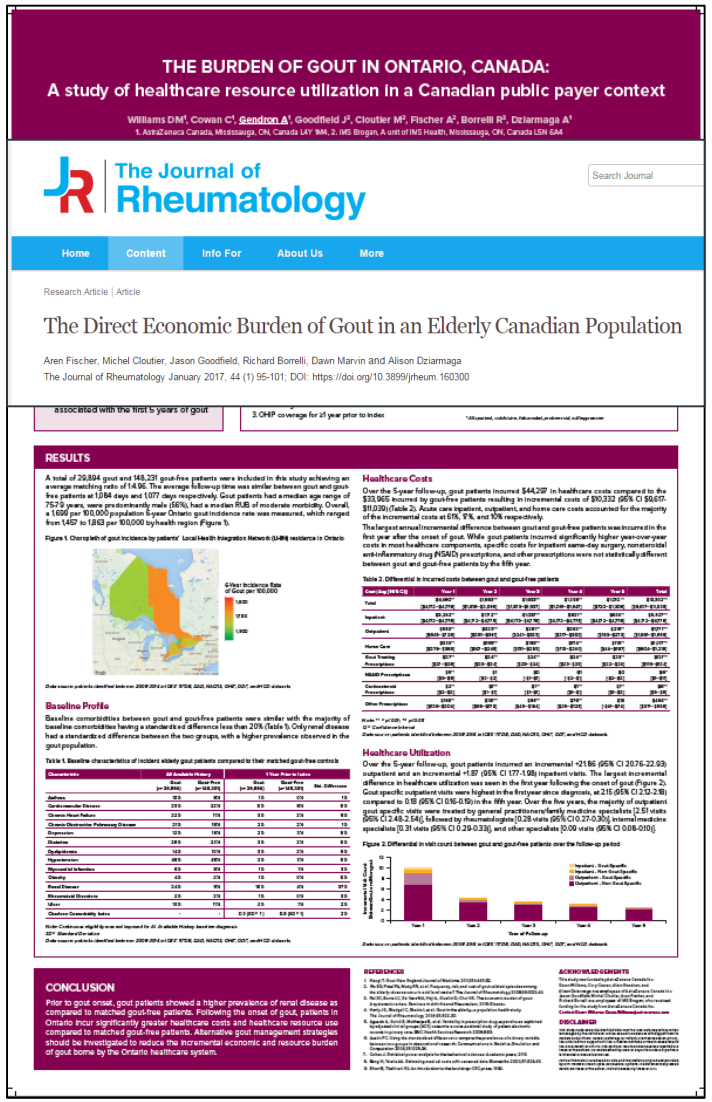
Outcomes
Adherence, persistence, health outcomes, quality of life

Engagement
Satisfaction, feedback, interactions

Utilisation
Visits, tags, hits, favourites

Patient Engagement Platform | IQVIA™

Partnering with ICES real world data to understand the treatment landscape and burden of disease



THE BURDEN OF GOUT IN ONTARIO, CANADA:
A study of healthcare resource utilization in a Canadian public payer context

Williams DM[1], Cowan C[1], Gendron A[1], Goodfield J[2], Cloutier M[2], Fischer A[2], Borrelli R[2], Dziarmaga A[1]
1. AstraZeneca Canada, Mississauga, ON, Canada L4Y 1M4, 2. IMS Brogan, A unit of IMS Health, Mississauga, ON, Canada L5N 6A4

The Journal of Rheumatology

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The Direct Economic Burden of Gout in an Elderly Canadian Population

Aren Fischer, Michel Cloutier, Jason Goodfield, Richard Borrelli, Dawn Marvin and Alison Dziarmaga

The Journal of Rheumatology January 2017, 44 (1) 95-101; DOI: https://doi.org/10.3899/jrheum.160300

associated with the first 5 years of gout

3. OHIP coverage for ≥1 year prior to index

RESULTS

Healthcare Costs

Baseline Profile

Healthcare Utilization

CONCLUSION

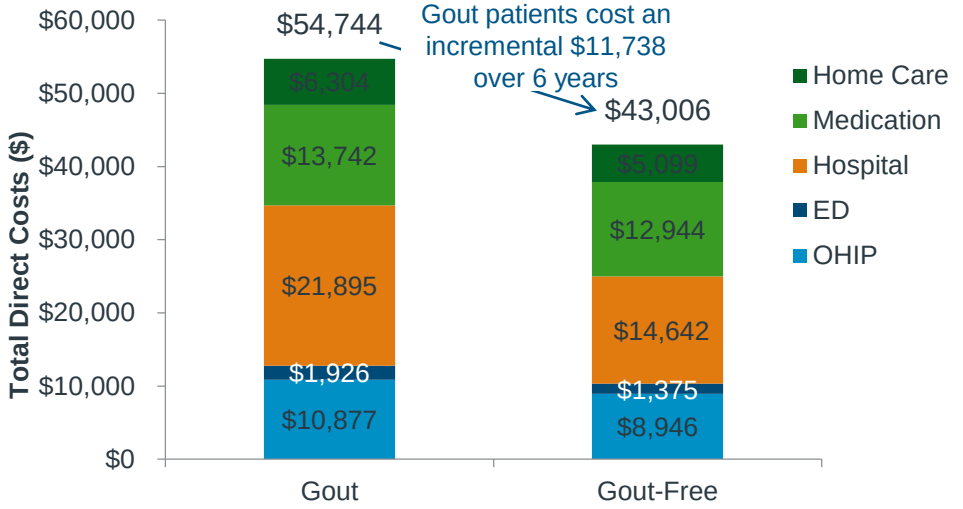
Prior to gout onset, gout patients showed a higher prevalence of renal disease as compared to matched gout-free patients. Following the onset of gout, patients in Ontario incur significantly greater healthcare costs and healthcare resource use compared to matched gout-free patients. Alternative gout management strategies should be investigated to reduce the incremental economic and resource burden of gout borne by the Ontario healthcare system.

Objective: Describe the Burden of Illness of Gout

1. Describe the demographic and comorbidity profile of incident gout patients in Ontario

2. Estimate the incremental resource utilization and healthcare costs associated with the first 6 years of gout

Total Average 6-year MD/ Facility Visit Count by Healthcare Touch Point



- Data source: patients identified between 2008-2014 in ICES' RPDB, DAD, NACRS, OHIP, ODP, and HCD datasets .

IQVIA Canada utilized EMR data and predictive analytics to undertake a new analysis on the prevalence of CHF in Canada

Patient flow chart used in developing and testing predictive model

Starting with adult patients that have at least 2 visits and 1 prescription

EMR records available for study
N = 317,478

Patients removed during cleaning
N = 207,617

EMR records available after cleaning
N = 109,861

Patients not treated with a cardiovascular product
N = 83,612

Patients treated with a cardiovascular product
N = 26,249

Randomly removed non-CHF patients
N = 24,734

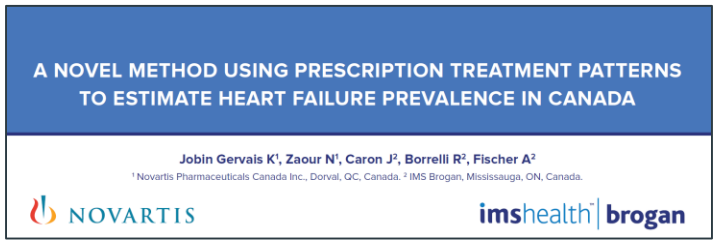
Final cohort available for Modeling
N = 1,515

CHF patients
N = 675 (574 to teach, 101 to test)

Non-CHF patients
N = 840 (716 to teach, 124 to test)

We taught the predictive model only using patients treated with a cardiovascular product, because we are predicting *treated* CHF patients. Therefore, if a patient is not receiving a cardiovascular product, then they are not a treated CHF patient.

Source:



Using predictive analytics to leverage smaller, richer datasets to apply insights to larger, national data

Diagnosed treated CHF patients

Predicted treated CHF patients	True **CHF Dx**	True **No CHF Dx**
Pred **CHF Dx**	505 True Positive	3,171 False Positive
Pred **No CHF Dx**	170 False Negative	22,403 True Negative

The prediction model has a 87.3% accuracy

- To evaluate the overall model, we tested it against all available patients in the EMR with a cardio treatment.
- The model has:
  - 87.3% accuracy
  - 74.8% positive predictive value (PPV)
  - 87.6% negative predictive value (NPV)
- The method used by Blais *et. al.* has a PPV of 55.6%[1]

$$PPV = \frac{\text{Number of True Positives}}{\text{Number of Patients With a CHF Diagnosis}}$$

$$NPV = \frac{\text{Number of True Negative}}{\text{Number of Patients Without a CHF Diagnosis}}$$

Note: Of the 3,171 patients incorrectly predicted as CHF, 25.3% have a pre-CHF diagnosis (Hypertensive Heart Disease, Old Myocardial Infarction, Mitral Insufficiency Or Stenosis, Pulmonary Embolism with Infarction)

Data source: EMR patients within selection period Jan 2006 – Jan 2015

Using data within a patient support program to understand patient outcomes: The COMPANION Study

Companion
Canadian study of outcomes in Adalimumab patients with support of adherence

In IBD patients receiving ongoing care coach calls, **12% more patients achieved remission** (according to HBI score) after 6-18 months

Objective

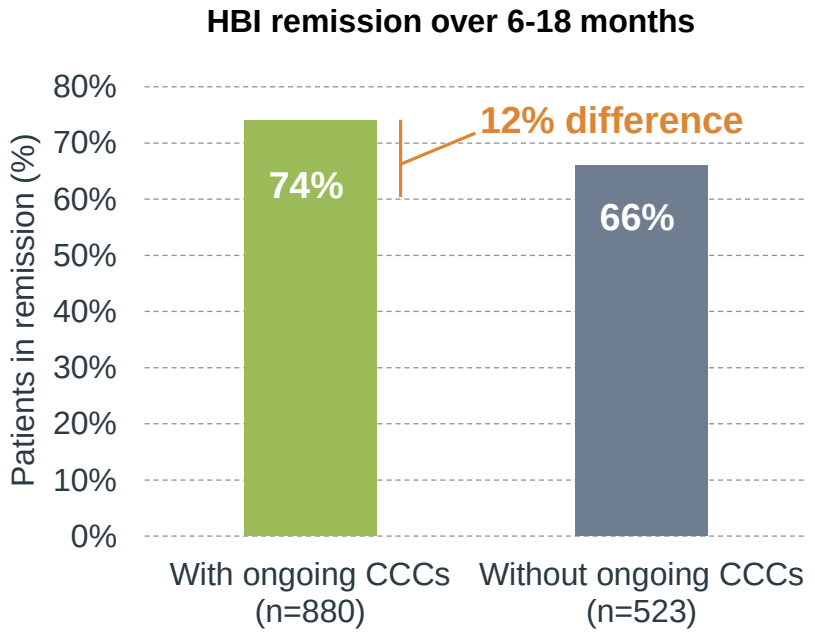
To evaluate the impact of the services provided by the HUMIRA® AbbVie Care PSP on the adherence, persistence and clinical outcomes of patients within the program

Methodology

- Pharmacy-level longitudinal data (LRx database from QuintilesIMS) was linked to the AbbVie Care PSP dataset
- Patients were matched using an externally validated algorithm based on a combination of variables

abbvie care + QuintilesIMS™ LifeLink Longitudinal Insights (LRx)

n = 10,857 patients



In remission (HBI < 5) vs. not in remission (HBI ≥ 5):
Hazard ratio (HR): 1.12, CI: 1.04-1.21, p=0.003

PSP: Patient support program

HBI, Harvey-Bradshaw index; IBD, inflammatory bowel diseases
Source: Marshall et al. J Crohns Colitis 2017; 11 (Suppl 1):S438-S439

IQVIA™

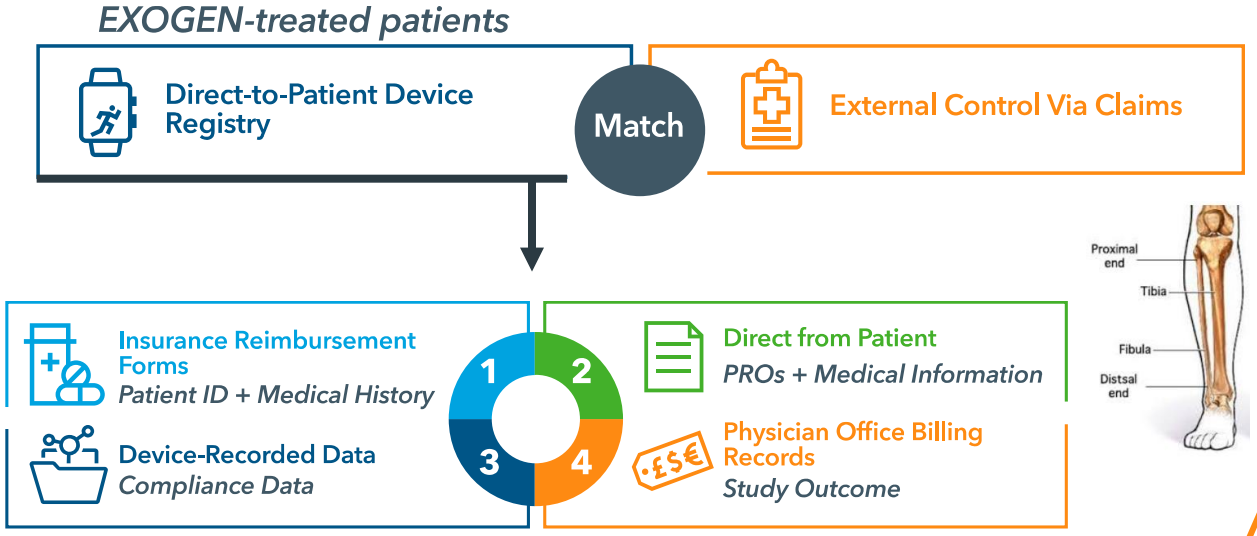
Breaking barriers: RWD as registry comparators for FDA label expansion

CASE STUDY
External comparators

Value Points:

- Design was discussed and agreed upon in advance with FDA after close, collaborative consultations.
- Sourcing comparators from claims reduces enrollment risk by 50%
- External comparator study design merges many data sources

  → Methodologic complexities + Innovative operational solutions



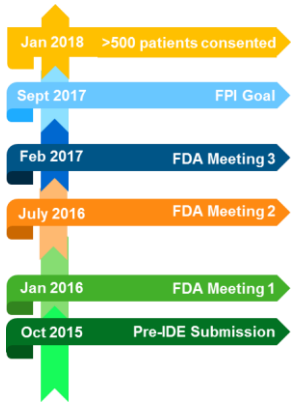
Clinical setting enabled innovative design:

Rare outcome (~5%) – Required sample size too large for site-based RCT + Infeasible and arguably unethical to recruit patients into placebo group → Observational Study

Safe device marketed for >20 years + Broadly prescribed and reimbursed off-label → External comparator

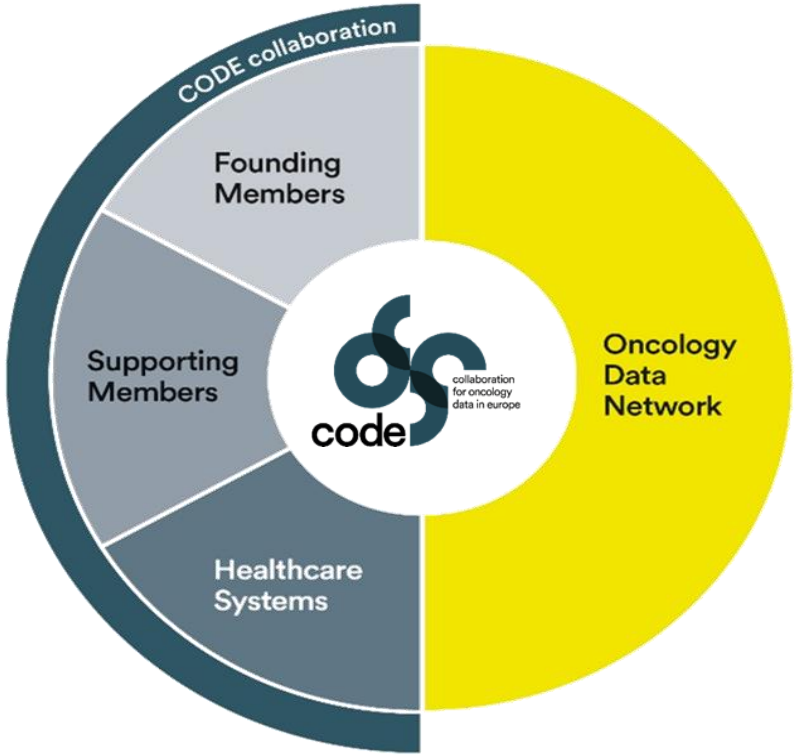
Regulatory Timing:

The 21st Century Cures Act (US)



CODE is a broad Collaboration aiming to connect the European Cancer Community with data in powerful ways

CODE Lead: IQVIA



Pharma

"Do we have to build access to these data and the infrastructure ourselves?"

"A medicines company, not a data/information company"

Healthcare Systems: Payers/Providers

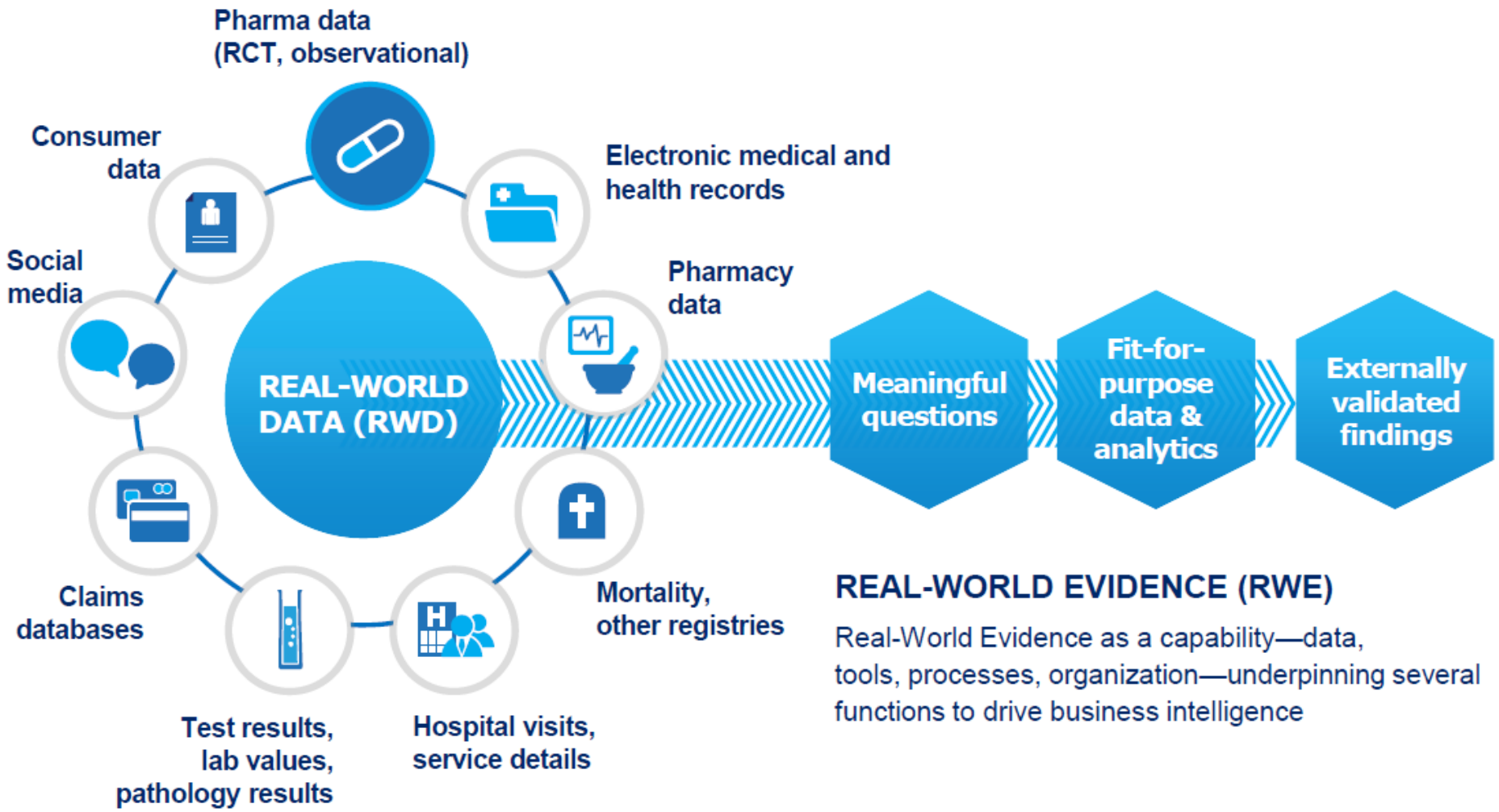
"Dealing with single companies creates challenges for us – not least in terms of the inefficiencies and compliance paperwork"

"There is a growing number of product-related requests for data collection and form filling. This is fast becoming problematic"

Founding Members: Bristol-Myers Squibb, Lilly, Pfizer, Merck, AstraZeneca, Amgen

IQVIA

RWE is here to stay, and holds the promise to greatly improve healthcare decision-making



REAL-WORLD EVIDENCE (RWE)

Real-World Evidence as a capability—data, tools, processes, organization—underpinning several functions to drive business intelligence

RWE holds the promise of improving healthcare

Where we need to apply RWI

What is the health value of the

$370 Billion

total worldwide increase in medicine spending 2017-21

What can we do to address

$500 Billion

in avoidable annual medical costs globally because medicines are not used responsibly?

Can we increase adherence of the

60%

of patients on chronic therapy who are not refilling their prescription after 6 months?

Can we reduce the

$2.1B

development cost for a drug today, and ultimately lead to lower drug prices?

Can we find the

20-40%

of Canadians diabetics who are undiagnosed and untreated?

Can we prevent the

4,000-8,000

Canadian deaths due to diagnostic errors every year?

IMS Health & Quintiles are now

IQVIA™

Questions?

Improving the Use of Real World Evidence in the Regulatory Environment: Where Are We Heading in Canada?

Rhonda Kropp
Marketed Health Products Directorate, Health Canada
rhonda.kropp@canada.ca

Health Canada: Context for Regulatory Reform

- 2015 Mandate Letter Commitment for the Canadian Minister of Health:
  - Engage provinces and territories in the development of a new multi-year Health Accord, including **improved access** to necessary therapeutic products

- January 2016 Health Ministers Meeting:
  - Commitment to improve **the affordability, accessibility and appropriate use** of therapeutic products

- 2016: Health Canada's Health Products and Food Branch (HPFB) launches Regulatory Review of Drugs and Devices (R2D2) initiative
  - Delivers on elements of this commitment, in particular those pertaining to therapeutic product access

- R2D2 forms the umbrella under which work is underway in three areas:
  - Expanded Collaboration with Health Partners
  - More Timely Access to Drugs and Devices
  - **Enhanced Use of Real World Evidence (RWE)**

Enhanced Use of RWE Projects: What are they?

Goal

- To improve Canada's ability to assess and **monitor safety and effectiveness** across the health product life cycle by optimizing the use of RWE through engagement with key stakeholders

Objectives

- Understand the **key information gaps** across the product life cycle
- Understand how RWE can be used to **inform regulatory decision making**
- Determine potential **return on investment for use of existing/new RWE sources**
- To implement the **strategic use of RWE** across the product life cycle
- **Collaborate with partners** to explore access to, and use of, RWE

Desired Outcomes

- The health-related risks to Canadians associated with use of drugs and devices are minimized, while the benefits are maximized
- Accessibility, affordability & appropriate use of drugs & devices are improved

Current Status in Canada: We already use RWE…..

- Pre-Market:
  - Where a **conventional RCT was unfeasible or unethica**l & RWE was therefore submitted and assessed in lieu
  - Where a **product was previously approved and marketed in a foreign jurisdiction** and RWE from clinical registries in the foreign jurisdiction was used in the Canadian submission

- Post-Market:
  - Submitted to address requirements in the **Risk Management Plans (RMP)** to address residual risks
  - **Monitor for adverse reactions and signals** domestically and internationally
  - **To inform change in indications, monograph or label revisions** for products already marketed in Canada

– Can **ask/compel MAH to develop the evidence:**
  – Minister of Health can require holders of drug product (and establishment) licenses to perform tests or other monitoring related to their products (but not NHPs) where…
    – Significant uncertainties exist about the drug's harms or benefits (or activities of license holders)
    – Company is unable to provide the needed information, & it is not available through other regulatory powers

– Can undertake or solicit **research:** Canada's Drug Safety and Effectiveness Network **(DSEN)**
  – CIHR and Health Canada have partnered to establish the DSEN to increase..
    » …evidence on drug safety and effectiveness available
    » …capacity within Canada to undertake high-quality post-market research in this area.
  – Health Canada, and others, work with DSEN to formulate research questions and gather information on safety & effectiveness of pharmaceuticals used by diverse patient populations outside of clinical trials.

…but there is much room to improve….

Areas to Improve (1)

Address challenges to collaboration domestically and with international partners

- Privacy legislation
  - Domestically, privacy legislation differs between the Federal government, Provinces and Territories (PTs).
  - When agreements for sharing between PTs, and between the PTs and Federal government, are achieved, there are economies of scale in capitalizing on that arrangement rather than putting in place multiple arrangements
- Variability in data sources and analytic approaches: lack of standardization
  - Domestically, within Canada, health information solutions vary between PTs
  - Need to ensure that when collaborating we are not comparing apples and oranges
- Everyone is busy….very busy
  - Need to dedicate time to explore and operationalize collaboration; time dedicated will payback via increased efficiencies in the longer term
- Trust and accountability
  - Trust in each other's scientific capacity, rigor of each other's work, etc….

Areas to Improve (2)

Address challenges to partnerships with research community

- Issues of data 'ownership'
  - Publish or perish culture challenging when ownership of data is not outlined through a contractual approach
- Research umbrella involves Research Ethics Board approvals which vary
  - Time to coordinate REBs is not aligned with regulatory safety questions that are urgent
  - Research or public health imperative? Requirements differ…..
- Research culture and regulatory culture mis-alignment
  - Questions required to answer a regulatory question may not be of greatest interest to research community
  - Timing needed/proposed by research community may not be aligned with regulatory needs

Way Forward

Moving forward, HC will publish a strategy outlining how we will optimize the use of RWD/RWE across the product life cycle. Snapshot of the approach….

1. Developing Guidance for Industry and Data Partners
   - Publishing principles and guidance for industry and data partners on the key data elements needed for decision points across the product life cycle and how HC and Industry can work together to optimize RWE use early on in submission discussions

2. Developing and Implementing a Transparent Approach to Assessing Quality of Evidence
   - Documenting the approach to assessing quality of evidence submitted across the life cycle to support data producers in collecting the right data of sufficient quality to inform regulatory decision making

3. A Phased Approach to Implementation
   - Health Canada already accepts RWE as part of submissions across the life cycle, however, with the Guidance and Quality of Evidence (QoE) approach clarified, we will work with willing partners to phase in deliberate use of RWE starting with product lines for which use of RWE provides clear value-add to the health system and to Canadians. Lessons learned will be used to optimize the approach for future phases.

4. Working with Partners to Optimize Data Availability
   - Collaborating with partners to support the development/sharing/optimization of sources with greatest Return on Investment (RoI) for Canadians.
   - Monitoring the safety and effectiveness of medical devices on the market requires data, both to identify signals and proactively assess for potential issues
     - Regulatory and non-regulatory solutions will be assessed

Improvements Underway!

Domestically, making changes and partnering to ensure we are…

- Asking the right questions at the right times, and addressing these through the right venue(s)
- Increasing transparency in our short & longer term post market plans, and consulting with key users on those plans
- Taking lessons learned through the DSEN-Health Canada partnership and adjusting
- Updating our IT and HR capacity to meet current and future needs
- Learning from, and aligning work, with our partners
- Aiming to provide clear guidance to Industry on how RWE will be used for decision making across the life cycle, how quality of evidence will be assessed, and the QoE required for use in different regulatory decisions
- Working closely with our HTA colleagues to align our efforts and where appropriate our approaches

Internationally, we are partnering….

- Collaboration between US FDA Sentinel Network and CNODES
  - Common Data Model (CDM): standardized data structures and code/programs
  - Goal: implement Sentinel's CDM in four Canadian provinces (ON, MB, SK, NS)
  - Can be used for queries on drug utilization (general and specific demographic cohorts) and cross-tabulations

- Collaboration between European Medicines Agency (EMA) and CNODES
  - Proof of concept to demonstrate how collaboration on a study could occur between regulators
  - Study of interest: *Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU*

…but can we do more in Canada between our Research, Patient, Health Care Provider, Data Holder, Industry and Federal Decision Maker communities?

Opportunities: Individually and Together

Can we better collaborate across disciplines and organizational boundaries to….

1. CLARIFY OUR QUESTIONS?
   - Can we define key safety and effectiveness questions that are of interest to multiple partners across the life cycle in Canada?

2. OPTIMIZE DATA COLLECTION, USE AND SHARING IN CANADA?
   - Different pieces of the story being held across the country.
   - Can we share our data or findings? Improve our sample size and analytic power through collaborative work within Canada and internationally?

3. DEFINE STANDARDS?
   - Can we advance in standardizing approaches, data analysis methods to optimize comparability?
   - Can we define how RWE will be used in decision making in Canada, and see if standardization might be possible in terms of quality of evidence review approaches across the life cycle?

4. SHARE WORK?
   - Can we divide/partner, capitalize on each others strengths, and conquer?

We can, and we are…

Meetings, such as this, which allow for collaborative discussions across disciplines are important venues to discuss potential economies of scale in our common objective to protect and support the health of Canadians.

Thank you!

Disclosure

- CADTH is funded by federal, provincial, and territorial ministries of health.
- Application fees for three programs:
  - CADTH Common Drug Review (CDR)
  - CADTH pan-Canadian Oncology Drug Review (pCODR)
  - CADTH Scientific Advice

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Life-Cycle HTA: Unlocking the Potential for Real World Evidence in Support of Health Technology Management

Tammy J Clifford, PhD
Chief Scientist and Vice-President, Evidence Standards
@TammyJClifford

CAPT 2018
October 22, 2018

CADTH Evidence Driven.

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  - CADTH Scientific Advice

CADTH

is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence about the optimal use of drugs and medical devices.

2018–2021 Strategic Plan

Transforming How We Manage Health Technologies

CADTH Evidence Driven.

Mission

CADTH consistently delivers credible scientific evidence and management strategies that enable the appropriate use of health technologies.

Vision

Canada has a world-class system for assessing and managing health technologies to achieve better outcomes and value for Canadians.

Values — These foundational values guide CADTH decision-making and activities at all levels.

Excellence
CADTH is trustworthy, delivers what it promises, and exceeds expectations by focusing on impact to drive better health, better patient experience, and better value for Canadians.

Responsiveness
CADTH understands and meets the needs of its customers in a timely fashion.

Collaboration
CADTH creates and nurtures partnerships with those who produce, acquire, deploy, and use health care technologies to promote their appropriate use.

Transparency
CADTH makes timely and user-friendly information about its programs, processes, and performance widely available, with a special emphasis on engaging key stakeholders.

Strategic Goals and Objectives

Close the Gap Between Evidence, Policy, and Practice

1. Provide customized implementation support.
2. Strengthen engagement with patients, clinicians, and other stakeholders.
3. Enhance analytics and performance measurement.

Adopt a Life-Cycle Approach to Health Technology Assessment

4. Align drug and medical device review processes with federal, provincial, and territorial priorities throughout all phases of the technology life cycle.
5. Implement programs for reassessment and disinvestment.
6. Advance initiatives across the health technology life cycle that will improve access, appropriate use, and affordability.

Anticipate Health System and Technology Trends, and Develop Agile Management Strategies

7. Advance initiatives that anticipate, influence, and manage technological advancement and health system evolution.
8. Focus on health technologies that have the most potential to meet patient and health system needs.
9. Align CADTH efforts and investments with federal, provincial, and territorial priorities for health improvement.

https://cadth.ca/sites/default/files/corporate/planning_documents/CADTH_2018_2021_Strategic_Plan_Overview.pdf

HEALTH ECONOMICS
Health Econ. **23**: 379–383 (2014)
Published online in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/hec.3034

EDITORIAL

BREAKING THE ADDICTION TO TECHNOLOGY ADOPTION

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[b]*Centre for Clinical Epidemiology & Evaluation, Vancouver Coastal Health Research Institute, Canada*
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[d]*Yunus Centre for Social Business & Health, Glasgow Caledonian University, UK*

ABSTRACT

A major driver of cost growth in health care is the rapid increase in the utilisation of existing technology and not simply the adoption of new technology. Health economists and their health technology assessment colleagues have become obsessed by technology adoption questions and have largely ignored 'technology management' questions. Technology management would include the life-cycle assessment of technologies in use, to assess their real-world performance; and monitoring of technology indication creep. A rebalancing of focus might serve to encourage a more self-critical and learning culture amongst those involved in technology evaluation analysis. Further, health economists and health technology assessment analysts could make a more significant contribution to system efficiency through rebalancing their efforts away from technology adoption questions towards technology management issues.

Original Article

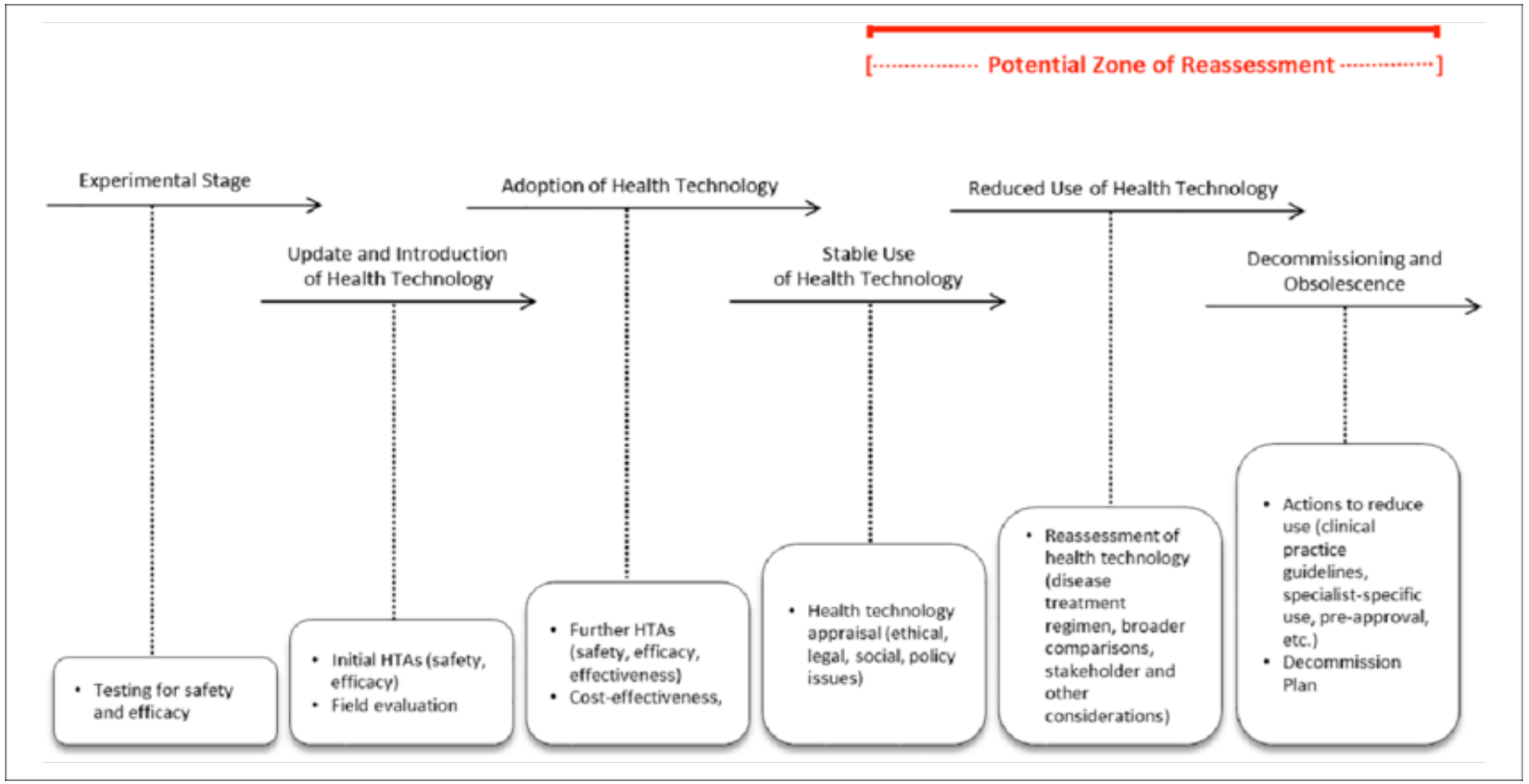
SAGE Open Medicine

Achieving optimal technology use: A proposed model for health technology reassessment

SAGE Open Medicine
Volume 5: 1–7

DOI: 10.1177/2050312117704861
journals.sagepub.com/home/smo
SAGE

Lesley JJ Soril[1,2], Gail MacKean[1,2], Tom W Noseworthy[1,2], Laura E Leggett[1,2] and Fiona M Clement[1,2]

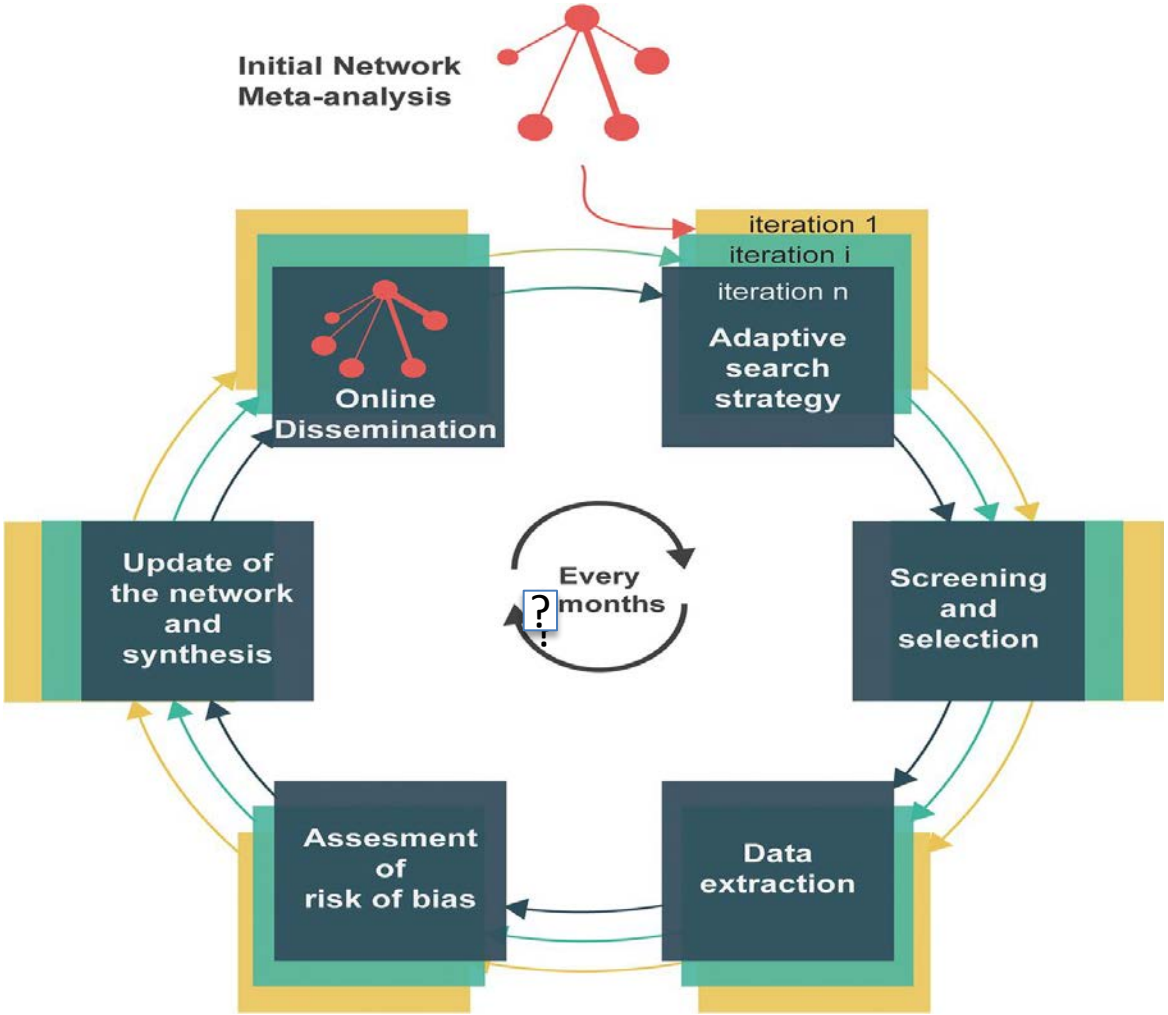


A life-cycle approach …

- **Development/R&D**
  - Scientific Advice/Early Dialogues
    - Joint with regulator +/- other HTA
- **Market Access & Initial Reimbursement Recommendation**
  - Regulator – safety, efficacy, quality
    - NOC, NOC/c
  - HTA – comparative effectiveness, value for money
    - Possibility for conditional coverage recommendation
      - Conditions specified re: additional data collection
  - Opportunities for parallel review & joined up data collection requirements
- **Reimbursement Decision**
  - Payers
- **Implementation**
  - System
- **Reassessment →**


Real World
What does the evidence say?

Living Systematic Reviews



http://bmjopen.bmj.com/content/6/8/e011841

https://www.cadth.ca/dv/guidelines-economic-evaluation-health-technologies-canada-4th-edition

Current and emerging health knowledge ecosystems.

Elliott JH, Turner T, Clavisi O, Thomas J, Higgins JPT, et al. (2014) Living Systematic Reviews: An Emerging Opportunity to Narrow the Evidence-Practice Gap. PLOS Medicine 11(2): e1001603. https://doi.org/10.1371/journal.pmed.1001603
http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001603

PLOS | MEDICINE

RWE - Challenges & Opportunities

- Not a replacement for comparative RCT data
  - Different questions require different data
    - What type(s) of evidence for which decisions?
- Need “good” data on the outcomes that matter
  - Quality, timeliness, efficiency
    - Require collaboration & linkages
      - use data collected by others
      - inform subsequent data needs
        - e.g., HC, CIHI, CIHR
- Appetite to re-visit decisions in light of new evidence?

CADTH Evidence Driven.

ACMTS Preuves à l'appui.

Myeloma Canada
Bringing Research to Patients

Martine Elias
Executive Director

MYELOMA CANADA
MAKING MYELOMA MATTER

Why patients matter

Aldo Del Col
Co-founder & Chairman

As the only national organization exclusively devoted to the Canadian myeloma community, we have been making myeloma matter since 2005.

How We Make Myeloma Matter

As a patient organization, Myeloma Canada promotes its commitment to patient-focused clinical research in collaboration with the Myeloma Canada Research Network (MCRN).

MYELOMA CANADA
MAKING MYELOMA MATTER

- Education
- Awareness
- Access & Advocacy
- Community Engagement

GOAL:
Accelerating access to treatments

MYELOMA CANADA
RESEARCH NETWORK
MAKING MYELOMA MATTER

- Clinical trials
- Peer-reviewed consensus statements
- National database

Collaboration

Myeloma Canada Scientific Roundtable September 2018

- An incubator for clinical trial ideas and developing made-in-Canada trials
- The patient voice has a seat at the table!

2017 Scientific Roundtable

The MCRN is comprised of 27 centres in 9 provinces across Canada

Bringing more clinical trials, to more patients,
in more centres across Canada

Database: Goals

1. Evaluate **the health outcomes** of multiple myeloma patients
2. Identify the **differences across Canada** in the treatment of multiple myeloma
3. Identify the **strengths and weaknesses in the management** of multiple myeloma inn centres across the country
4. **Understand the regional needs** to provide adequate care to multiple myeloma patients
5. Support the **development of centres of excellence** in multiple myeloma research
6. Understand the **impact of novel therapeutic** strategies on outcome of multiple myeloma patients
7. Inform **future clinical trial** activity of the MCRN and beyond for patients

8. **Generate PWE** to inform HTA and funding bodies

Database Steering Committee Evaluation Criteria

Is the research question original?

Does the research question confirm prior known information?

Would there be enough clinical data available in the database to answer the question?

If one or more comparison groups are used are they concurrent comparators or is the use of historical comparison group(s) justified?

RWE questions

What have we accomplished

- 14 centres that are committed
- 4589 retrospective patient data uploaded
- New patient data being captured
- Number of lines of treatments, stem cell and non stem cell
- One presentation at ASH2018
- Two presentations at EHA2019

Insights

- Quality of data capture templates
- Looking at prospective studies and how to enter the data in a consistent manner across centers
- Credibility of the data – somewhat dictated by the quality of the data coordinator
- Toxicity measures are different from clinical setting to those of clinical trials
- Collaboration with governments is required

Education – Patient at the table

Patient empowerment:

- Adapting the CCTG patient input process to the MCRN system
- Training on clinical trials – PaCER (Patient and Community Engagement in Research)
- Educating our patient representatives on PROMs and REW

THANK YOU!

JOIN OUR COMMUNITY

www.myeloma.ca

CONTACT US

Myeloma Canada
1255 TransCanada Highway, Suite 160
Dorval, QC H9P 2V4

Tel: 1.888.798.5771
Email: contact@myeloma.ca

Building Capacity for Real World Evidence

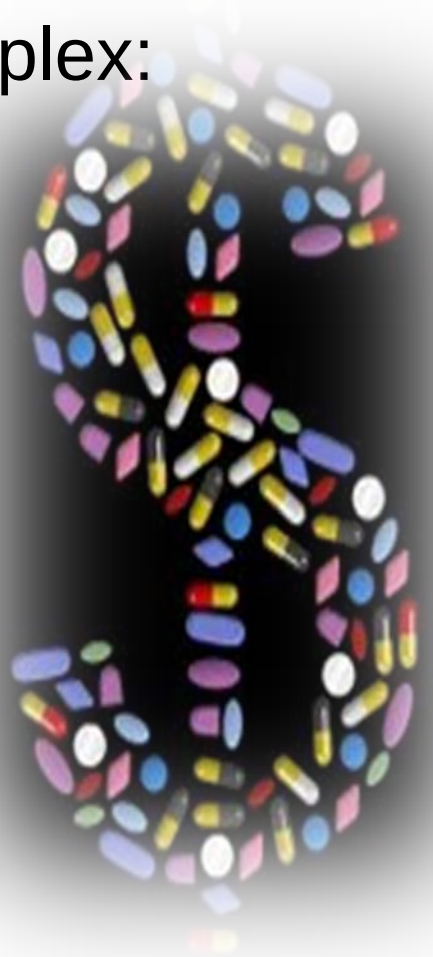
Winson Y. Cheung, MD, MPH, FRCPC
Director of Health Services Research & Real World Evidence
Cancer Control Alberta
@winsoncheung

Overview

- Main reasons for a provincial cancer program in real-world evidence (RWE)
- Creating the necessary infrastructure and building future capacity for RWE
- Barriers, facilitators, and lessons learned

Need for RWE

- Cancer care is increasingly complex:
  - Access and disparities
  - Follow-up and survivorship
  - Costs and resources
  - Quality of care
  - Models of care
  - Real world “effectiveness”



Reasons for a Provincial Program

- Healthcare is provincially administ
- Population-based research
- Data are already collected
- Cost-effective study method
- Variations in care based on geography/centre
- Provincial data enable and facilitate larger national and international collaborations

Current Provincial RWE Programs

Key Items for a Provincial RWE Program

- Data are readily available, accessible, and high quality for patients across the entire province
- Use of data for research is strongly encouraged
- Release of data is relatively expedient
- Expertise in data cleaning and analyses
- Critical mass of researchers
- Leaders invested in RWE generation

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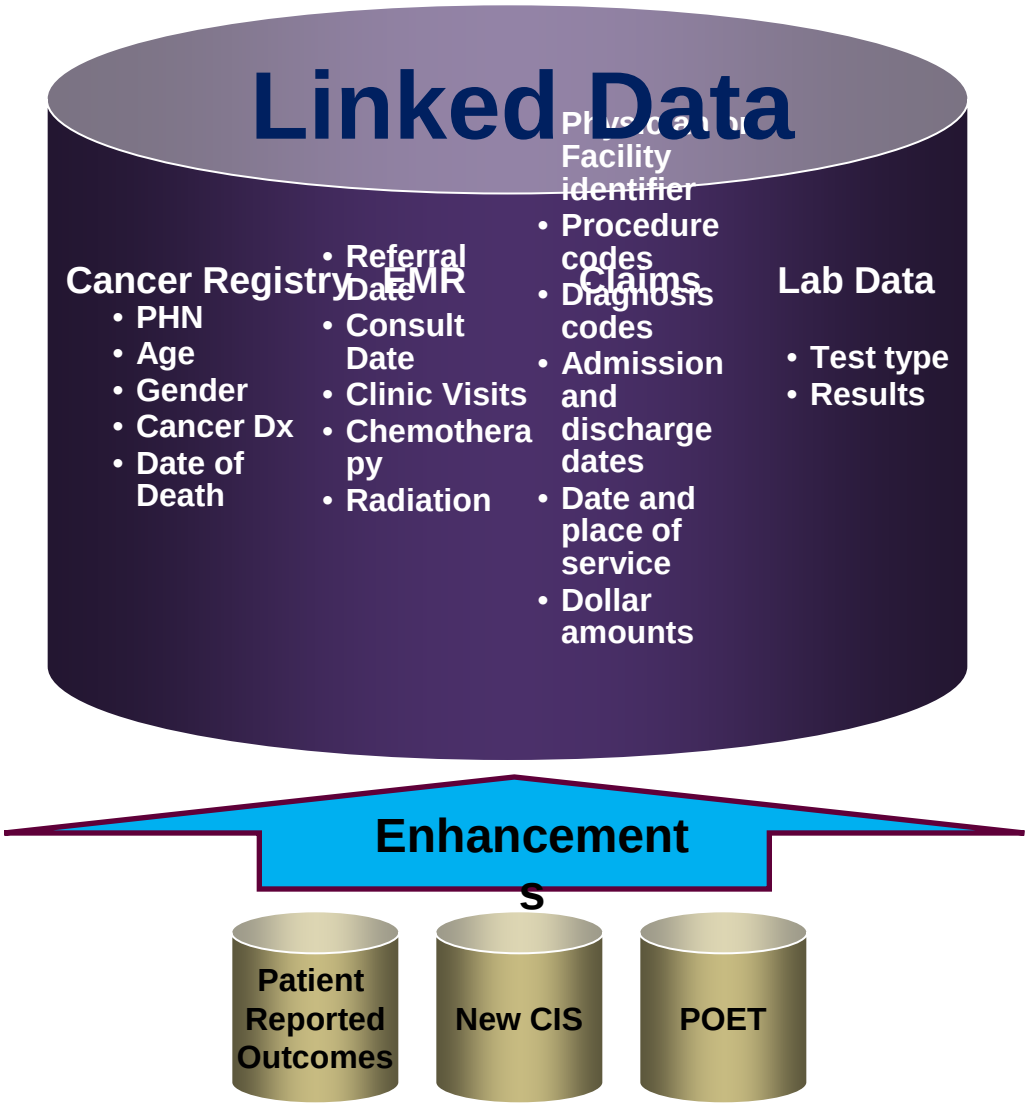
Data Environment in Alberta



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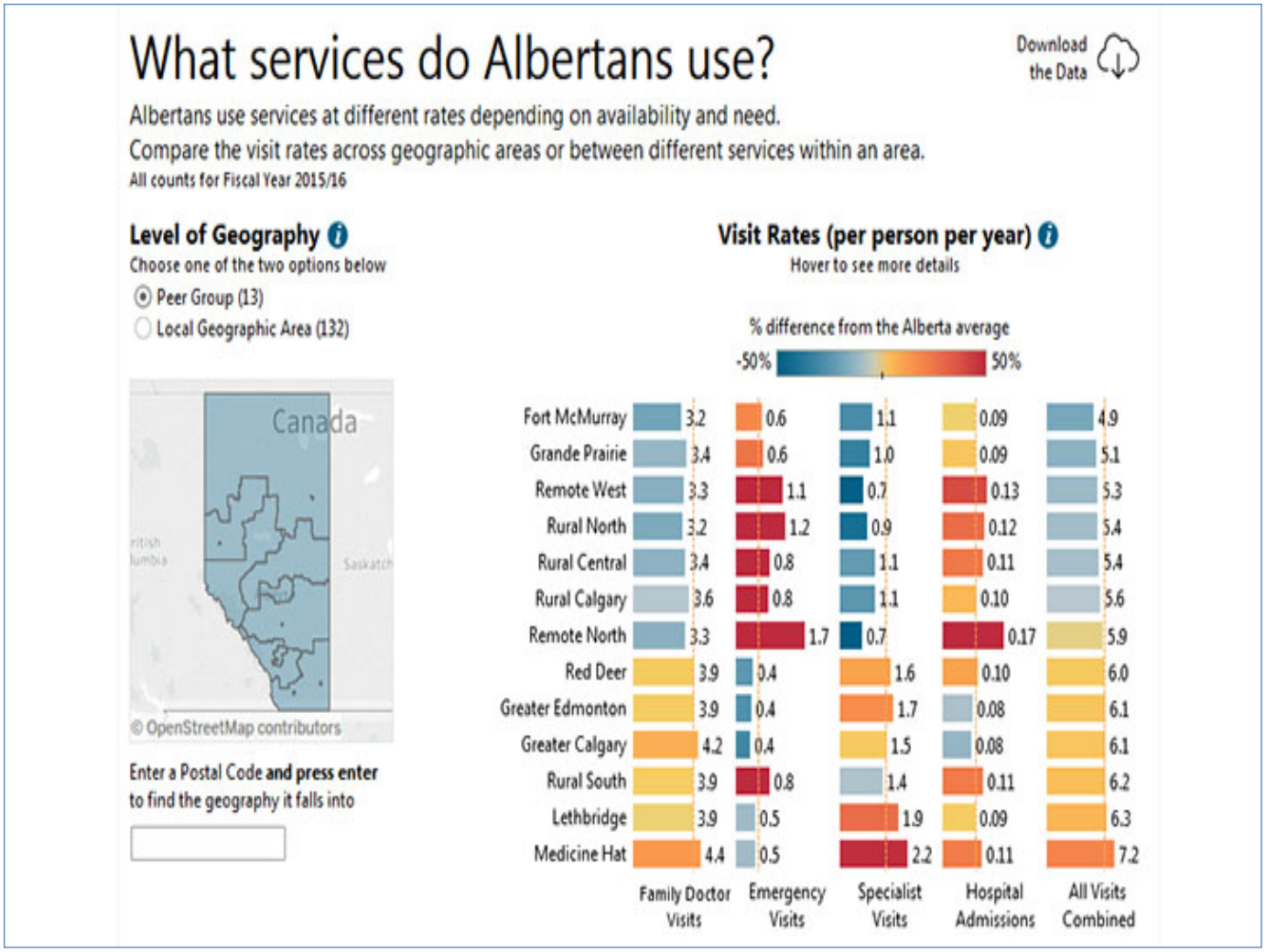
Secondary Use Data Project (SUDP)

- SUDP is a provincially led initiative to facilitate the enhanced and advanced secondary use of health data for the health and socioeconomic benefit of Albertans
- Still in formative stages of planning and development
- Initial focus on non-cancer patients

ACCESS HEALTH DATA

Alberta Health Services

Secondary Use Data Project (SUDP)



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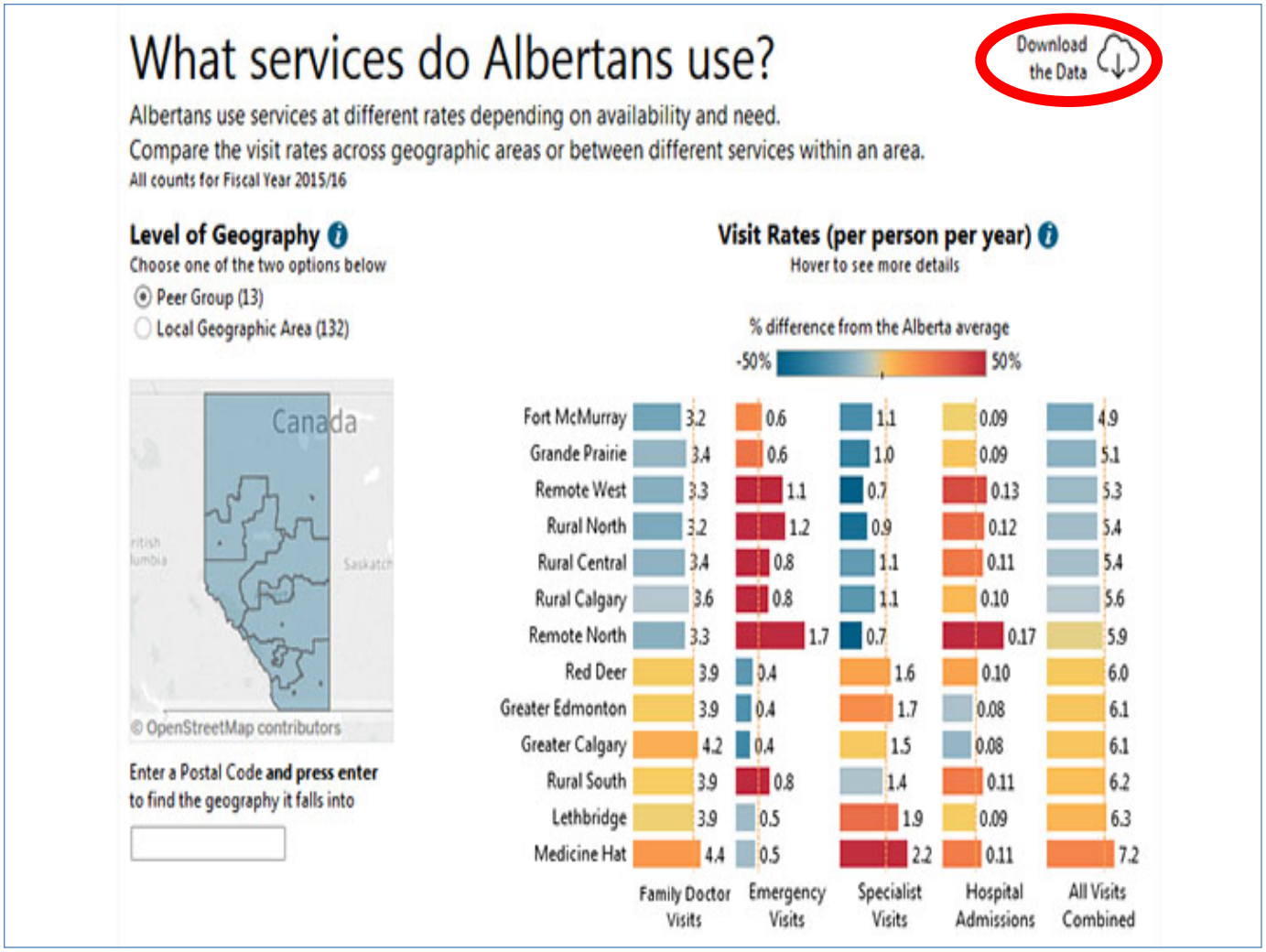

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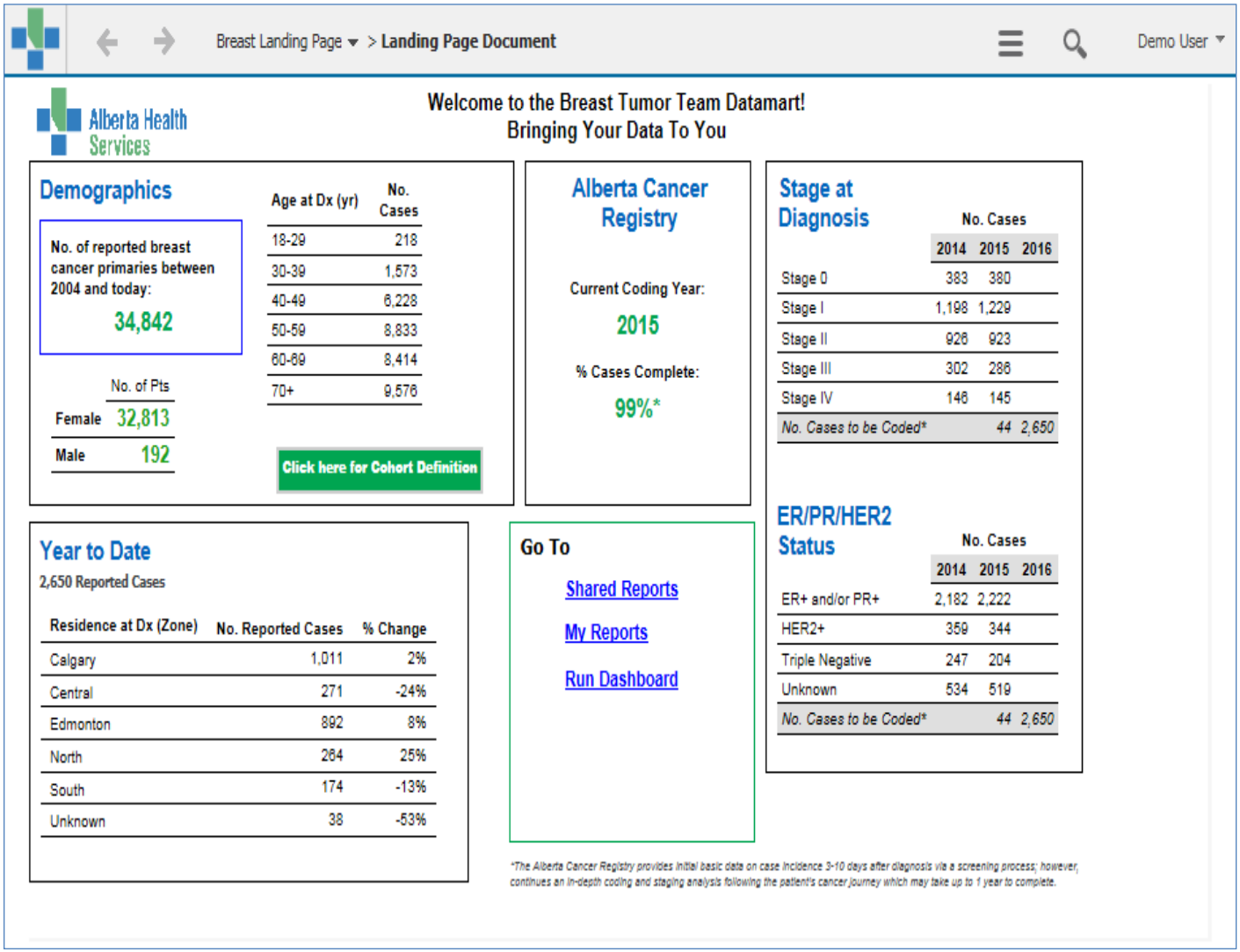
“CDI”

CDI provides clinicians and researchers on demand access to a minimal dataset of cancer information, including demographics, diagnosis, treatment, and outcome data, to enable some preliminary analysis

CDI



Breast Landing Page > Landing Page Document

Demo User

Alberta Health Services

Welcome to the Breast Tumor Team Datamart!
Bringing Your Data To You

Demographics

No. of reported breast cancer primaries between 2004 and today:

34,842

	No. of Pts
Female	32,813
Male	192

Age at Dx (yr)	No. Cases
18-29	218
30-39	1,573
40-49	6,228
50-59	8,833
60-69	8,414
70+	9,576

Click here for Cohort Definition

Alberta Cancer Registry

Current Coding Year:

2015

% Cases Complete:

99%*

Stage at Diagnosis

	No. Cases		
	2014	2015	2016
Stage 0	383	380	
Stage I	1,198	1,229	
Stage II	926	923	
Stage III	302	286	
Stage IV	148	145	
*No. Cases to be Coded**		*44*	*2,650*

Year to Date

2,650 Reported Cases

Residence at Dx (Zone)	No. Reported Cases	% Change
Calgary	1,011	2%
Central	271	-24%
Edmonton	892	8%
North	264	25%
South	174	-13%
Unknown	38	-53%

Go To

Shared Reports

My Reports

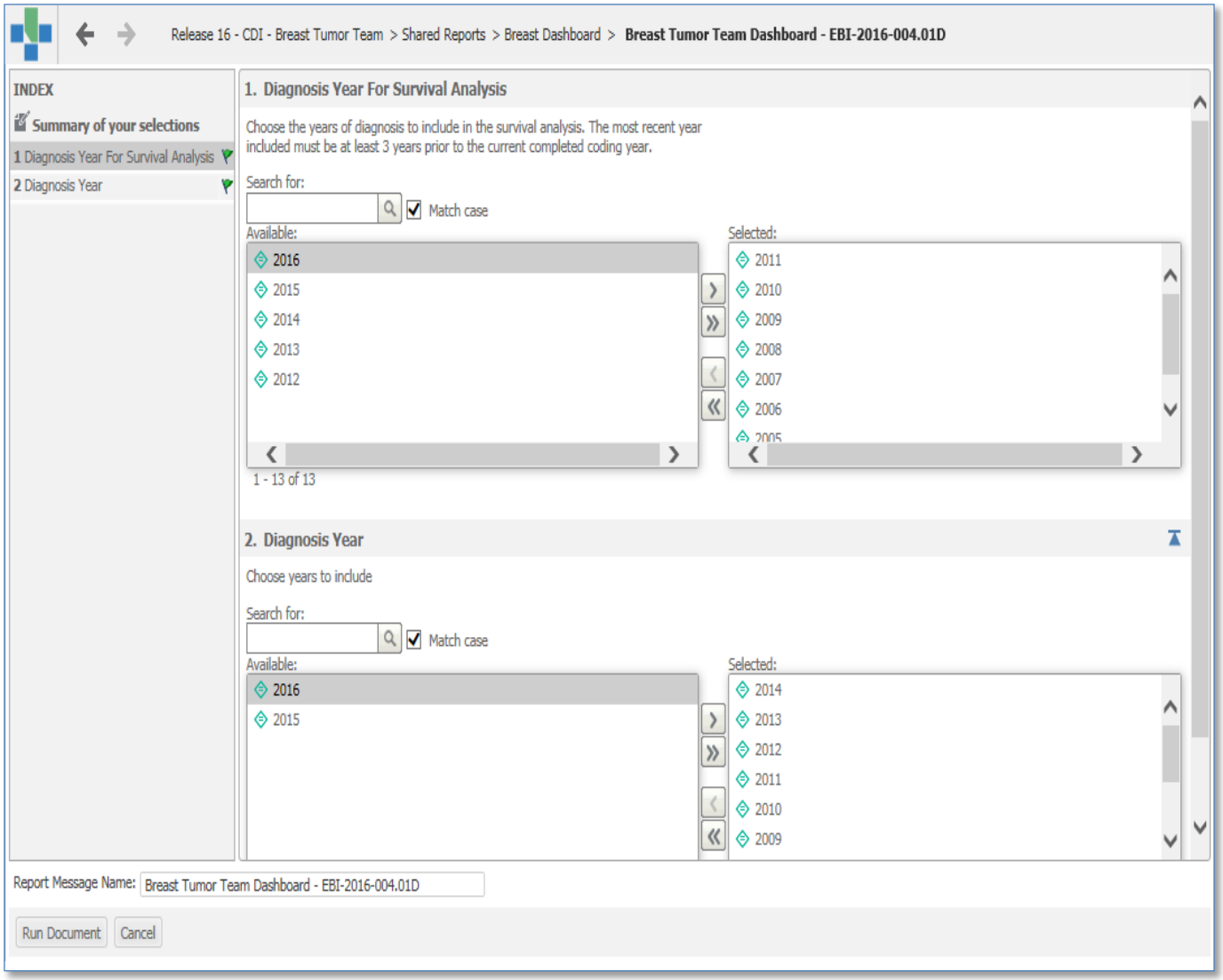
Run Dashboard

ER/PR/HER2 Status

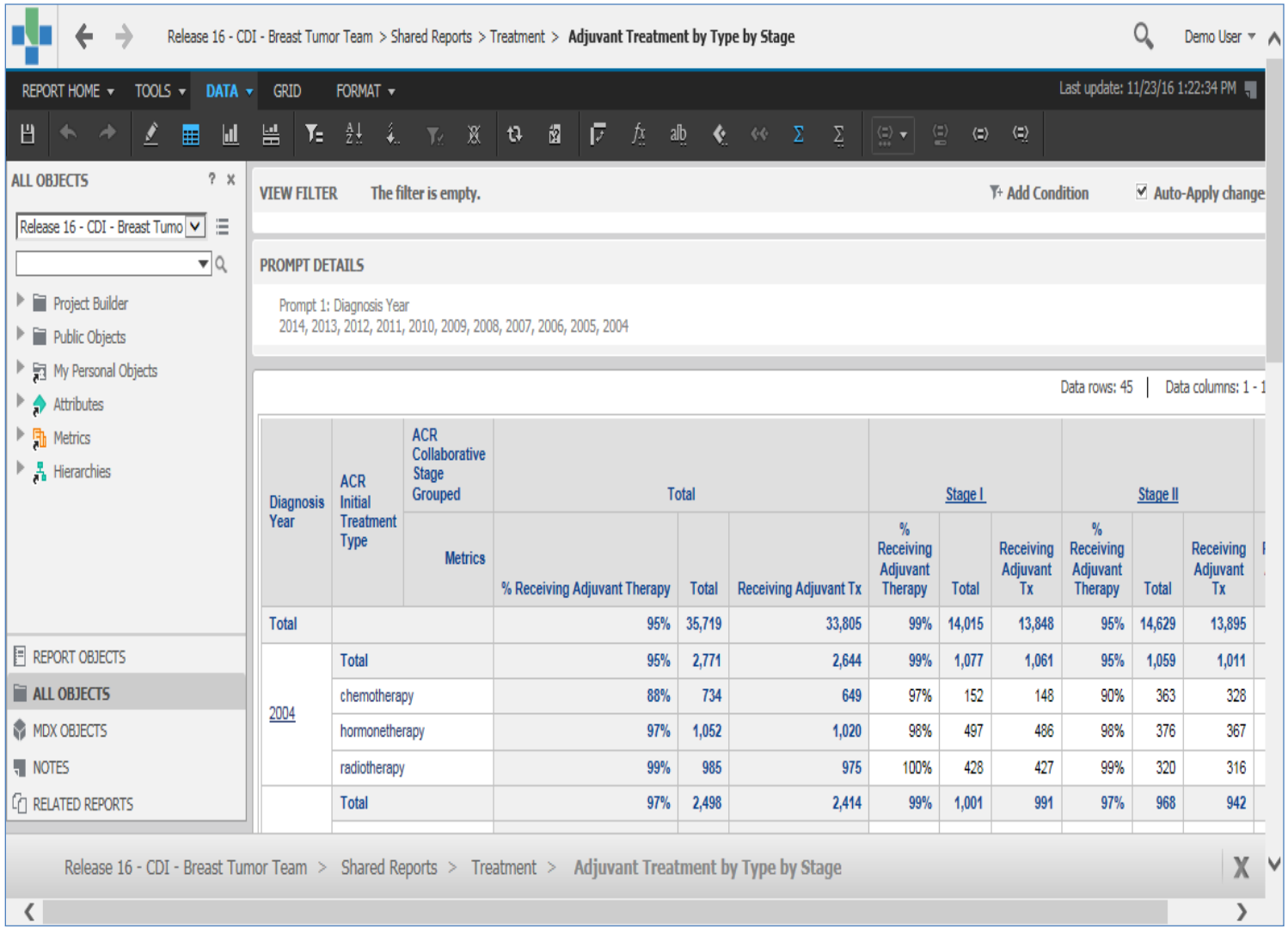
	No. Cases		
	2014	2015	2016
ER+ and/or PR+	2,182	2,222	
HER2+	359	344	
Triple Negative	247	204	
Unknown	534	519	
*No. Cases to be Coded**		*44*	*2,650*

**The Alberta Cancer Registry provides initial basic data on case incidence 3-10 days after diagnosis via a screening process; however, continues an in-depth coding and staging analysis following the patient's cancer journey which may take up to 1 year to complete.*

CDI

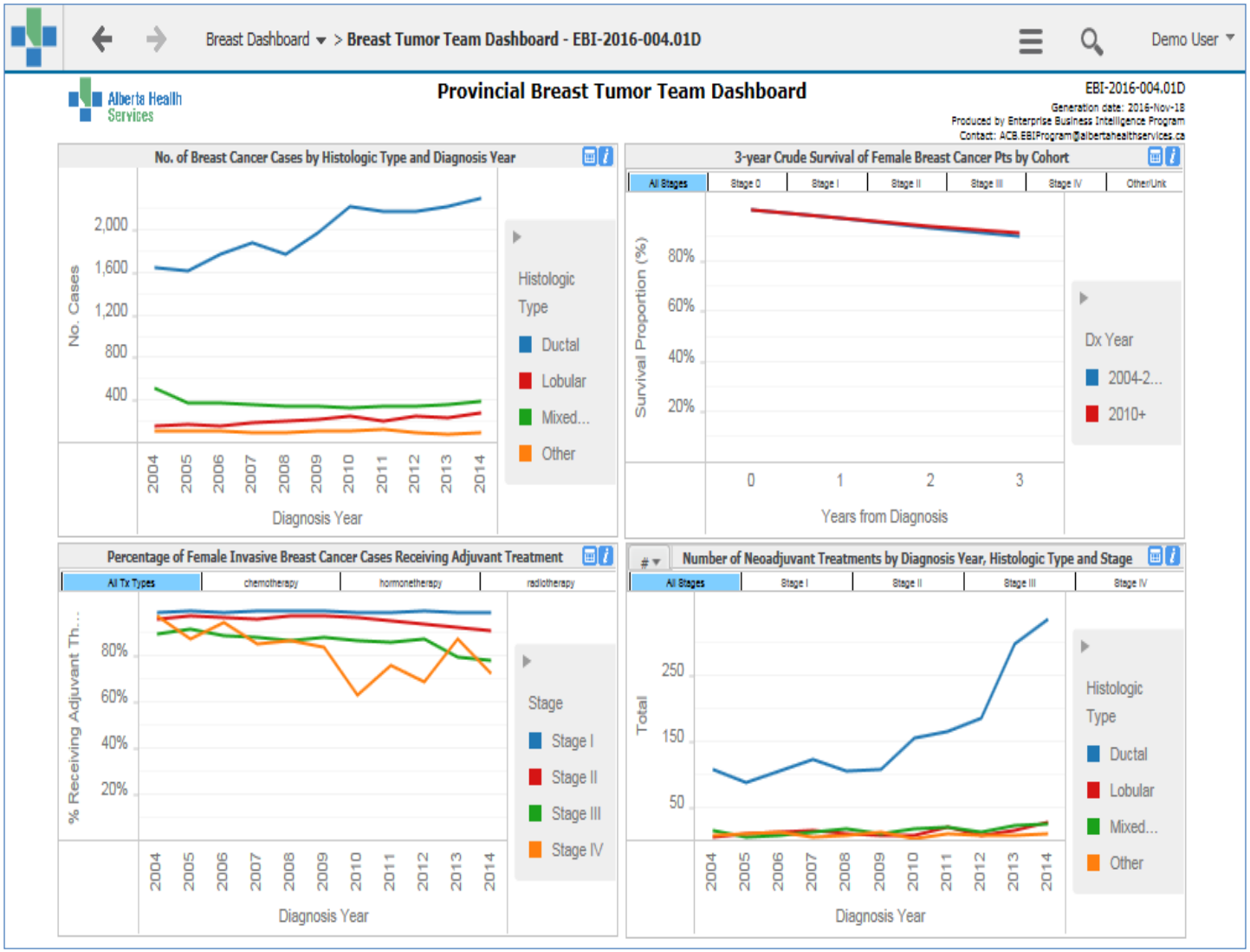

Release 16 - CDI - Breast Tumor Team > Shared Reports > Breast Dashboard > Breast Tumor Team Dashboard - EBI-2016-004.01D
INDEX
Summary of your selections
1 Diagnosis Year For Survival Analysis
2 Diagnosis Year
1. Diagnosis Year For Survival Analysis
Choose the years of diagnosis to include in the survival analysis. The most recent year included must be at least 3 years prior to the current completed coding year.
Search for:
Match case
Available:
2016
2015
2014
2013
2012
Selected:
2011
2010
2009
2008
2007
2006
1 - 13 of 13
2. Diagnosis Year
Choose years to include
Search for:
Match case
Available:
2016
2015
Selected:
2014
2013
2012
2011
2010
2009
Report Message Name:
Breast Tumor Team Dashboard - EBI-2016-004.01D
Run Document
Cancel

CDI



Diagnosis Year	ACR Initial Treatment Type	ACR Collaborative Stage Grouped / Metrics	Total: % Receiving Adjuvant Therapy	Total: Total	Total: Receiving Adjuvant Tx	Stage I: % Receiving Adjuvant Therapy	Stage I: Total	Stage I: Receiving Adjuvant Tx	Stage II: % Receiving Adjuvant Therapy	Stage II: Total	Stage II: Receiving Adjuvant Tx
Total			95%	35,719	33,805	99%	14,015	13,848	95%	14,629	13,895
2004	Total		95%	2,771	2,644	99%	1,077	1,061	95%	1,059	1,011
	chemotherapy		88%	734	649	97%	152	148	90%	363	328
	hormonetherapy		97%	1,052	1,020	98%	497	486	98%	376	367
	radiotherapy		99%	985	975	100%	428	427	99%	320	316
	Total		97%	2,498	2,414	99%	1,001	991	97%	968	942

CDI


Breast Dashboard > Breast Tumor Team Dashboard - EBI-2016-004.01D
Demo User
Alberta Health Services
Provincial Breast Tumor Team Dashboard
EBI-2016-004.01D
Generation date: 2016-Nov-18
Produced by Enterprise Business Intelligence Program
Contact: ACB.EBIProgram@albertahealthservices.ca
No. of Breast Cancer Cases by Histologic Type and Diagnosis Year
No. Cases
2,000
1,600
1,200
800
400
2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014
Diagnosis Year
Histologic Type
Ductal
Lobular
Mixed...
Other
3-year Crude Survival of Female Breast Cancer Pts by Cohort
All Stages
Stage 0
Stage I
Stage II
Stage III
Stage IV
Other/Unk
Survival Proportion (%)
80%
60%
40%
20%
0 1 2 3
Years from Diagnosis
Dx Year
2004-2...
2010+
Percentage of Female Invasive Breast Cancer Cases Receiving Adjuvant Treatment
All Tx Types
chemotherapy
hormonetherapy
radiotherapy
% Receiving Adjuvant Th...
80%
60%
40%
20%
2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014
Diagnosis Year
Stage
Stage I
Stage II
Stage III
Stage IV
Number of Neoadjuvant Treatments by Diagnosis Year, Histologic Type and Stage
All Stages
Stage I
Stage II
Stage III
Stage IV
Total
250
150
50
2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014
Diagnosis Year
Histologic Type
Ductal
Lobular
Mixed...
Other

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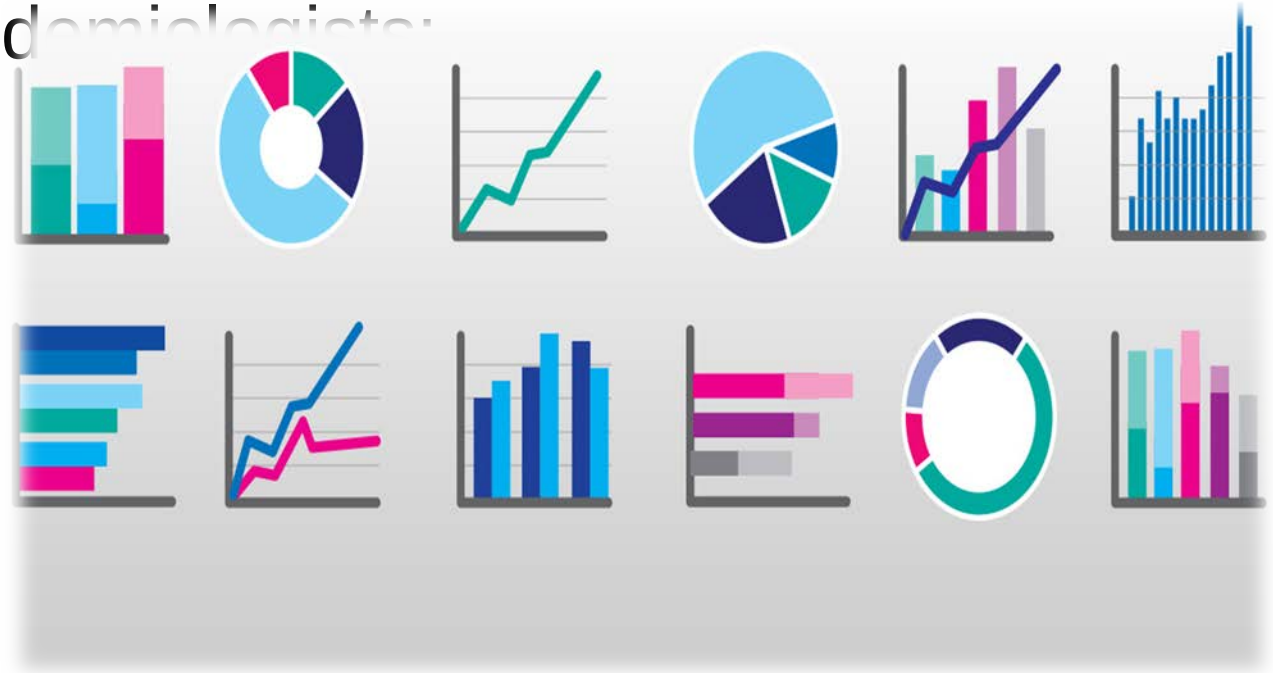
Methodologists

- Forging strong partnerships with biostatisticians data engineers, and epidemiologists



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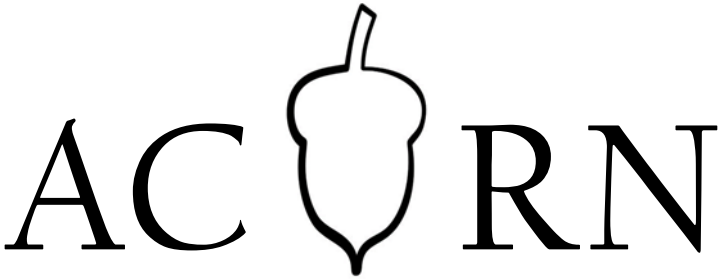

Alberta Cancer Outcomes Research Network

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Provincial Pillars of Research

Early Successes

- Provincial projects:
  - Patterns of care and outcomes in Indigenous cancer patients (access and disparities)
  - Urban vs. rural differences in post-treatment surveillance (follow-up care)
  - Adoption and impact of new drug therapies on outcomes (quality of treatment)
  - Health services utilization and costs during different phases of cancer care (resource use)

CHORD
CONSORTIUM

Lessons Learned

- Barriers:
  - Data and research silos
  - Lack of analytical support
  - Ownership and authorship guidelines
  - Unrealistic expectations of data quality and complexity

Facilitators for Moving Forward… The 3 C's

CONNECTING people and researchers

CREATING support and solutions

CATALYZING projects and priori