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White paper

Integrated data:
Creating a dimensional view of outcomes and cost



In so many ways, life sciences helps us and our loved ones improve our health, increase quality of life and extend lifespan. While the demand for quality health care is growing, there is enormous pressure to reduce costs and a rising need to demonstrate real sustained value.

Until now — and due mainly to availability — developing health care insights and understanding a product's real-world value proposition have been developed primarily from claims data. Additionally, research scientists have anchored much of their insight generation on the slices of information related to billable activity. While a crucial component, claims-only data is unable to provide a more complete representation of the human activity and clinical complexities that impact drug or medical device performance.

Life sciences research: At the tipping point of change.

Today, clinical data has reached the level of maturity where it can be a powerful addition to life sciences intelligence gathering. Data is now collected from electronic health records (EHR) and unstructured clinical notes across more than 100 million patient histories. This clinical information includes diagnosis codes, signs and symptoms, observations, measurements, biomarkers, lab and other test results. Natural language processing and advanced analytics pull meaning from provider notes and add a rich layer of insight into patient journeys and clinical outcomes.

Integrated data offers a dimensional view that can:

- Improve early business decisions
- Enrich research activity
- Address root-level cost
- Strengthen go-to-market strategies

Integrated data sets combine these clinical data with traditional claims information to build a more comprehensive picture of the impact that environment, demographics, patient behavior and other health conditions have on cost and clinical outcomes. And it can be useful across the entire product lifecycle. These new data bring a dimensional view that can improve early business decisions, enrich research activity and strengthen go-to-market strategies.

Traditional analysis is limited — and unable to develop a complete value story.

In the current approach, value is frequently measured on cost reduction or avoidance and the analysis is conducted leveraging a claims-only data foundation. This is understandable given the availability and familiarity of claims data. Common outcomes of interest tend to be health care utilization metrics. It is what claims data captures and therefore, what it is able to return to us as insight.

Using these data to make decisions on coverage, benefit design or other engagement models is straightforward. They can guide recommendations about shifting the site of service to less expensive locations or moving from branded to generic medications.

But it gets more difficult to assess the full impact of other decisions, such as switching medication or comparing the efficacy of treatment options. Measuring clinical benefits in these cases has usually been derived from clinical trials, which are also limited in their inputs. Clinical trials don't often compare one medication directly against another and don't collect comparative clinical results. While the assessment is valuable, it's still using only one dimension to assess impact.

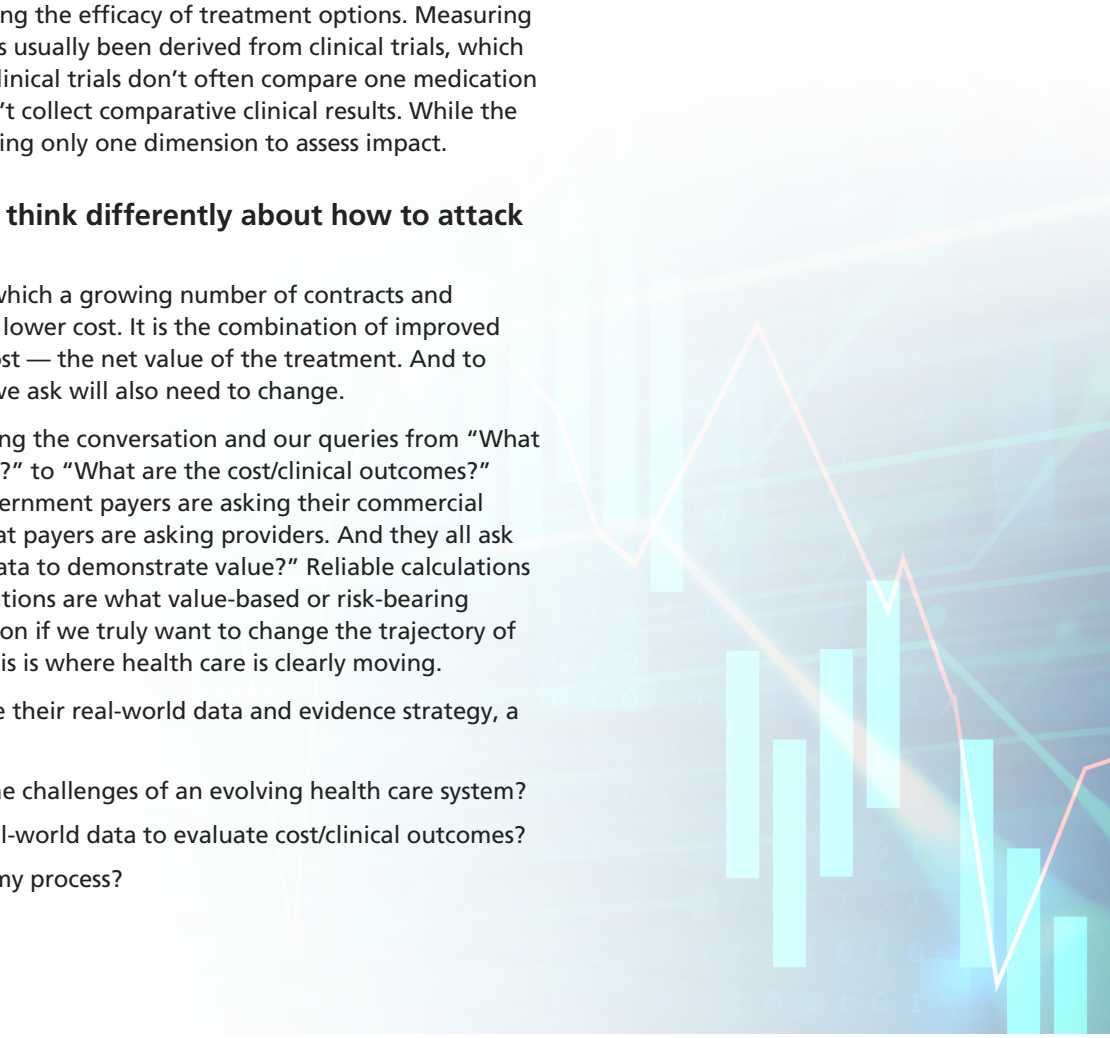
Richer insight allows us to think differently about how to attack health care costs.

True value, and the value upon which a growing number of contracts and formularies are based, is not just lower cost. It is the combination of improved clinical outcomes and reduced cost — the net value of the treatment. And to prove that value, the questions we ask will also need to change.

Assessing true value means shifting the conversation and our queries from "What are the cost/utilization outcomes?" to "What are the cost/clinical outcomes?" These are the questions that government payers are asking their commercial partners — and the questions that payers are asking providers. And they all ask life sciences, "Do you have the data to demonstrate value?" Reliable calculations of the cost/clinical outcome equations are what value-based or risk-bearing arrangements should be built upon if we truly want to change the trajectory of health care expenditures. And this is where health care is clearly moving.

As researchers continue to evolve their real-world data and evidence strategy, a few key questions arise:

1. Does our approach address the challenges of an evolving health care system?
2. Do I have the right sets of real-world data to evaluate cost/clinical outcomes?
3. What will it mean to amend my process?



Let's explore these questions:

1. **Does our approach address the challenges of an evolving health care system?**

   Where the government leads, commercial payers soon follow. Lives under Medicare, Medicaid and Veterans Administration programs are growing significantly, as are budgetary pressures. Health plans and providers serving these segments are required to cost-effectively manage vulnerable populations with chronic, complex and often multiple conditions. The FDA also recognizes the use of EHR data to improve accuracy and clinical trial efficiencies.* Every stakeholder feels the heightened demand for better outcomes and lower costs — a demand that is driving a shift from fee-for-service to fee-for-value. But to participate in these new payment arrangements, health organizations must be able to predict clinical and financial performance. They look to their life sciences partners and the products and services they provide to contribute to their ability to manage that risk.

2. **Do I have the right sets of real-world data to evaluate the cost of achieving improved outcomes?**

   By their nature, today's most common approaches can provide only limited insight. They do not include information captured in a clinical environment, such as disease severity, symptomology, health measurements or laboratory values. The current standard approach cannot help you best prepare for head-to-head clinical trials, recognize changes in clinician behavior or measure clinical outcomes. Without these inputs, it is nearly impossible to calculate a path to the most improved outcomes at the lowest cost.

3. **What will it mean to amend my process?**

   The process of using integrated data is not dramatically different from the current approach. Working with clinical data does add a new layer of information, and therefore, another layer of evaluation and complexity. But it builds rationally on the current claims-only approach. Let's look at the following examples.

Example 1

Here we begin with claims data, and can easily summarize costs for a commercial patient population from Optum de-identified data. As illustrated below, we can now view the distribution of cost in deciles to identify the most expensive patients:

Average annual cost (PMPY) per patient — 2017				
Decile	**Medical cost**	**Medication (medical)**	**Specialty Rx cost**	**Retail Rx cost**
1	$524,005	$19,776	$22,455	$12,984
2	$144,859	$10,038	$17,767	$10,696
3	$72,423	$5,295	$13,549	$9,358
4	$44,500	$3,121	$8,840	$7,665
5	$29,920	$1,625	$4,713	$6,361
6	$20,639	$784	$1,776	$4,976
7	$13,423	$356	$644	$3,723
8	$8,058	$154	$320	$2,596
9	$4,167	$61	$150	$1,521
10	$716	$9	$18	$219

Further analysis can delve into which conditions are driving cost and their relative contribution to the overall total cost of care as follows:

Any malignancy	Rheumatologic disease	Mild or moderate diabetes	Meta solid tumor	Pulmonary disease
2.1%	2.78%	3.9%	.25%	4.6%
50%	11.7%	11%	7.2%	3.9%

**Commercial only

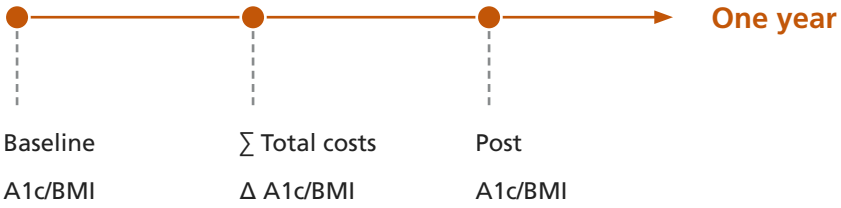
We can then refine the analysis to identify the specific types of activity that are impacting costs and look for ways to remove cost where appropriate. However, this misses a key question on the potential impact to patient health as measured by clinical metrics.

This is where we shift the inquiry to examine cost/clinical outcomes.

It is at this point when existing models need to evolve to take advantage of a new combined data foundation.

Example 2

Let's examine diabetes. Integrating claims and clinical data allows us to sort data from the previous example into deciles and still ground our analysis in cost. But we can simultaneously look at two clinical health measures over the time period for which cost is calculated to assess the clinical benefit derived from that spend. This can be illustrated as follows:

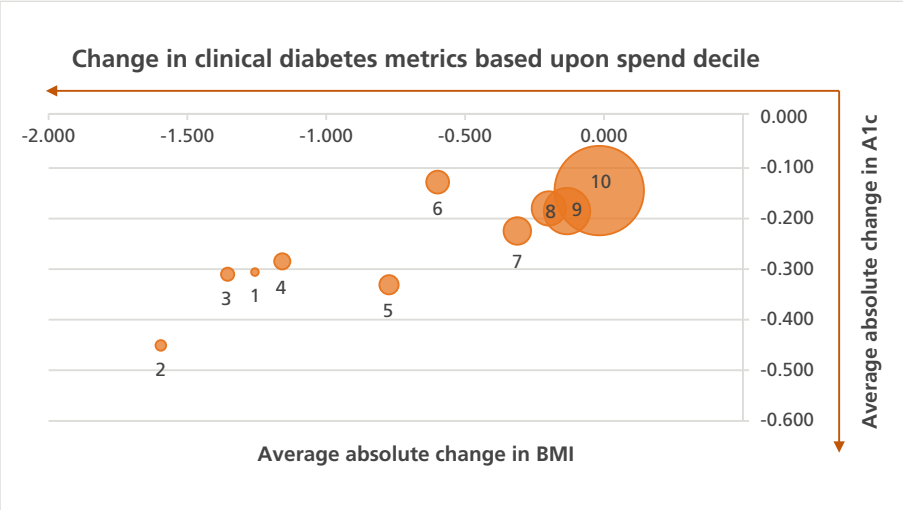


Working with clinical data adds a new layer of **information, evaluation and complexity.**

Now we can start to ask new questions.

What is the benefit of our health care expenditures on the control of diabetes and weight for patients with diabetes?

Let's take a look below at each decile of spend in 2017 for a diabetic population and the average change in A1c and BMI over the year.



As the above graphic shows, higher costs (decile 1) may not always correlate with better clinical outcomes. This invites us to investigate further and consider what we might learn as a result of altering our data foundation. It opens up new ways to track and address the health care cost issue and what actions we can take to better manage costs and population health. It opens the door to new models of explanation and the potential development of new solutions to manage health.

Imagine what else can be uncovered over the next few years for high cholesterol, immunological conditions, oncology, COPD/asthma — the possibilities are nearly endless. And so are the opportunities for life sciences.

The availability of data is the key. Many data scientists have ideated on alternative solutions to health care's issues, but a lack of data at the point of intervention or sufficient sample sizes has prevented those alternatives from reaching their potential.

Integrated data has now reached a gold standard.

Integrating data at scale is growing easier with advances in de-identification software, development of certified data models to protect privacy, and cloud-based computing. However, the adoption of these new integrated data sources has lagged — often due to questions of sample size and completeness. We have now reached a point where those concerns have been significantly reduced which is enabling broader adoption.

Altering our data foundation opens up the potential for **new solutions to manage health.**

The gold standard is **controlled eligibility, integrated pharmacy, medical claims** and **EHR data.**

This allows researchers to feel comfortable that they have a complete picture of patients during the desired period and in sufficient amounts to power robust analytics.

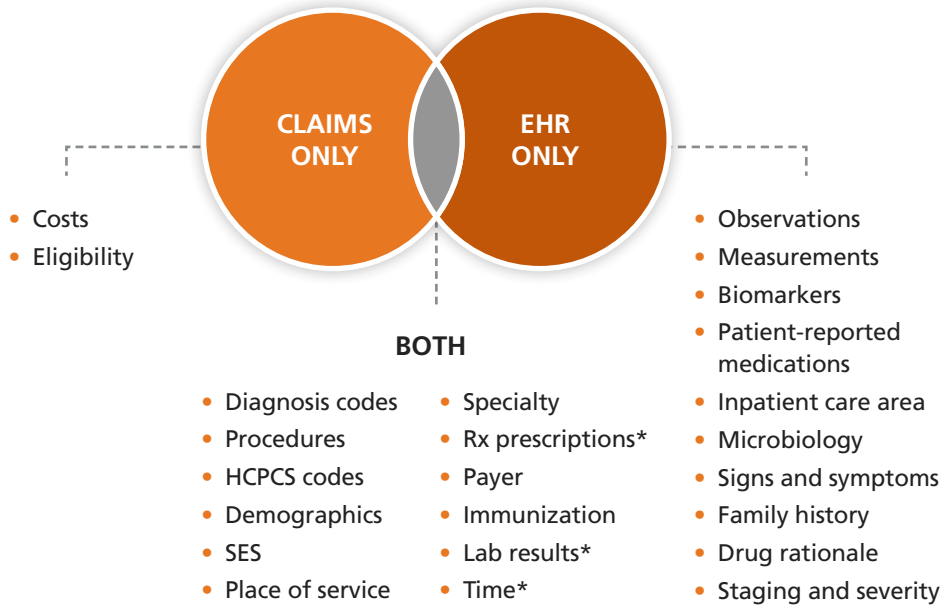
Find the factors that drive clinical outcomes and address cost at root level

The most logical next step is a more refined model assessing the contribution of other attributes — in addition to spend — on the clinical outcomes of interest.

- What other factors are contributing to better A1c and BMI levels in these patient populations, and how does that relate back to cost?
- Could we build simulations from those models to game what interventions and modifications to policy or formulary changes may be most impactful?
- Could we carry this forward to targeted interventions at a patient level?

The answers are "yes" to all. And as researchers continue to explore these data, their queries will become more sophisticated and more targeted.

The range of potential data domains to be used with integrated data goes far beyond our traditional claims data or our more recent EHR data sources. As the figure below illustrates, we get the best of both worlds with integrated data, a set of common data domains, plus those data domains found only in claims or only in EHR.



With integrated data, models can continue to evolve into the realm of cost-effectiveness for treatments, again with the appropriate covariates to help explain additional variation.

Imagine a rank order of diabetes medications based upon their impact on A1c as a function of their cost. How could that change how we reimburse for medications or make investment decisions during clinical development?

Imagine you have clinical and cost insights on treatment dynamics before you start clinical trials. Think how much more targeted you could be in your research. The potential impact that integrated data can have on the issues plaguing the health care system is significant.

And the system is at a tipping point. The pressure to reduce cost and improve outcomes is present in every conversation. Integrated data is now available to use at scale. It is a powerful new tool that can help us collect the level of insight needed to make more precise business decisions, create more comprehensive value stories, and do our part to deliver the low-cost, quality outcomes that the market demands.

If you are curious about how this might apply in your organization, we can help you make an assessment. We can discuss how you might:

- More accurately size your market opportunity
- Base clinical trials on the most complete clinical data
- Identify risk earlier in product development
- Better address drug safety
- Prove the impact on both clinical outcomes and cost
- Expand your value proposition
- Prepare to negotiate risk-based arrangements
- Refine strategic decisions across the product lifecycle

See how integrated data solutions from Optum can impact your performance at every phase of development.

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* FDA. Use of electronic health record data in clinical investigations. Published July 2018. Accessed April 23, 2021.

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