Creating New Value from Laboratory Testing and Services in Value-Based Healthcare: Investigating Data Monetization Strategies from Clinical Laboratories

by

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Abstract

In the U.S. healthcare system, much effort is being spent to decrease healthcare costs while improving patient outcomes and improving the health of the entire population. This transition from a fee-for-service payment model to one that allows for pay-for-performance (generally referred to as Value-based payment) has been gradual but is largely recognized as a key component and strategy for the American Healthcare system. Different stakeholders in the healthcare industry are transforming their identities, organizations as well as their services to compete in the changing healthcare market.

The clinical laboratory is not usually considered a key contributor in value-based healthcare (VBHC) models, yet it is well situated to contribute in meaningful ways due to the nature of laboratory testing, the digitally native environment in which modern labs operate, and the growing acceptance of at-home testing. This thesis investigates how clinical laboratories are creating new value in the VBHC healthcare market using data-enabled, digital strategic initiatives while also validating the applicability of data monetization frameworks developed from the MIT Center for Information Systems Research (CISR). Four real-world examples of laboratory services created to support value-based care were collected through interviews with leaders of their respective laboratory companies. After analysis, all four examples were clear cases of data monetization, with the framework highlighting key factors that helped each laboratory to generate new value from their data assets. Some key factors included leadership support, an understanding of how clients create and capture value in value-based arrangements and personnel to translate laboratory data into actionable information that supports the value-based healthcare initiatives of their clients.

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DISCLAIMER

This thesis is being submitted to the System Design and Management (SDM) program in partial fulfillment of the requirements for the degree of Master of Science in Engineering and Management at the Massachusetts Institute of Technology (MIT).

The views, opinions, and conclusions expressed in this research paper are of those of the author and do not reflect the position of MIT, the SDM program, or any of the participants who participated in the interviews.

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Chapter 1: Introduction

1.1 Background

The cost of healthcare in the United States has increased drastically over the past several decades[1], while generally not providing better health outcomes for the population in comparison to other countries[2]. The reasons for this are complex, as is the American health care system, and there is no simple answer identified to remedy the issue. However, over the last decade, the U.S. government has been promoting a transition from a fee-for-service payment model to pay-for-performance models, generally referred to as "Value-Based Healthcare (VBHC).[3–6]" The transition is taking longer than many experts had hoped for and has proven more difficult than expected[7–9]. However, it continues to be championed as the best method for lowering healthcare costs while increasing quality care and promoting healthier living[10–13].

As the US healthcare market continues to embrace a transition toward VBHC, the different components of the healthcare industry are working out how to successfully operate in a VBHC environment. Healthcare providers are undertaking varied types of contracts with healthcare payers, while investing in analytics and information systems and organizing themselves to promote better physician alignment with VBHC priorities[7–9,14]. Payers are also investing in digitally enabled services to improve patient outcomes and provider performance[15,16], while entering unique relationships with providers[17,18] (even going so far as to buy and manage provider groups). The companies that supply goods and services to healthcare providers (here referred to as "healthcare suppliers") are not included in the actual VBHC contracts between providers and payers but are working towards augmenting current products and services (as well as creating new ones) to support VBHC initiatives in the provider and payer populations.

The clinical laboratory is commonly referred to as a diagnostic "ancillary service" within the healthcare system[19,20]. A clinical laboratory is not technically a supplier but is a service provider that supports the needs of physicians and patients in diagnosing, treating and monitoring patients through the analysis of body fluids and tissue. A clinical laboratory company could offer specialized testing (specialty lab), or tests for a specific environment (hospital Lab) but could also provide a wide range of tests for multiple health systems (often referred to as a reference lab). Due to the fragmented and disparate nature of clinical laboratories, as well as the fact that the laboratory does not generally engage with payers directly on value-based healthcare contracts, the narrative has been slow to evolve concerning how laboratories can benefit financially while contributing to VBHC initiatives[21].

Most VBHC initiatives by either payers or providers rely on digitally enabled services that utilize healthcare data analytics to identify opportunities to decrease the cost of healthcare while improving patient outcomes[15,22,23]. The clinical laboratory is well-suited to participate in or support these initiatives because the chief product of the modern clinical laboratory is highly structured, accurate, timely, data in the form of laboratory testing results[24–26]. There has been a focus by multiple laboratories[21,26,27] and laboratory-focused organizations[25,28,29] to find ways to participate in VBHC. As the country's health care system continues to transition towards VBHC, many expect the more laboratories to seek competitive advantage in this space[29].

This thesis is focused on understanding how laboratories are engaging in the Value-Based Healthcare market through an analysis of the data-enabled services they create. Currently, there is no standard approach to characterizing these initiatives. Because the services of interest utilize the laboratory's data asset to generate value for both the laboratory as well as the client stakeholder, it is hypothesized that frameworks from the MIT Center for Information Systems Research (CISR) focused on data monetization[30,31] are appropriate. This research aims to validate the applicability of these frameworks on real-world examples from multiple laboratories.

1.2 Purpose of the research

The purpose of this thesis to provide tools and insights generated from literature, analysis and expert interviews so that clinical laboratories can answer four main questions they face concerning Value-based healthcare (VBHC):

1. What does Value-based healthcare mean for traditional laboratory clients?
2. What does it mean for a laboratory to be engaged in value-based healthcare?
3. What kind of services can be provided by a laboratory support Value-based healthcare initiatives?
4. What kind of investments will need to be made to provide those services?

1.3 Scope and Limitations

This research is focused primarily on the business aspects of digitally enabled services of laboratories engaged in providing services to support VBHC initiatives in the U.S. healthcare system. Examples from other countries are out of scope. Specific technical topics such as new assays, software platform capabilities, data formats, and program management are out of scope. Political engagement of laboratories concerning public health/public policy engagement are also out of the scope of this research.

The analysis is based on literature review and industry data collected through interviews with laboratory leaders and executives from 4 different clinical laboratory entities. The literature review will summarize and characterize laboratory efforts in the VBHC space and is supplemented by publicly available information from those laboratories. The analysis of the interviews is to assess how these laboratories became involved in VBHC initiatives, characterize the strategic initiative, highlight necessary investments needed to provide such services, and categorize the outcomes of the initiatives.

This research is not meant to be an exhaustive study of all existing or possible VBHC services provided by clinical laboratories. It also is not an exhaustive list of every such initiative of the individual laboratories participating in this dynamic change of health care delivery.

1.4 Thesis organization

This thesis is organized into four main sections. The first chapter introduces the purpose and structure of this paper, as well as the scope and limitations of this research.

The second chapter provides background information on value-based healthcare, the role of the laboratory in the current health care market, and data monetization.

The third chapter is the result of interviews with four different laboratories, containing four real-world, illustrative examples of data-enabled services that are focused on supporting value-based healthcare initiatives.

The fourth chapter provides an analysis of the real-world examples using multiple frameworks from different domains of knowledge.

The fifth chapter is the conclusion, which includes some brief observations of the analyzed examples and the applicability of the frameworks, as well as a summary of the findings of this thesis.

Along with these chapters, there is a group of tables and figures, as well as a single appendix. Appendix A provides a structured explanation of the three approaches to data monetization that is from an online course in data monetization[32], provided courtesy of Dr. Barbara Wixom.

Chapter 2: Background information

2.1 The transition to value-based healthcare in the American healthcare system

Healthcare costs have steadily continued to increase in the United States of America, comprising at least 18% of the Gross Domestic Product as of 2020[1]. The country spends much more per capita than other countries, yet also has generally worse outcomes than many countries who spend less[2]. The increasing expenditure on healthcare without better outcomes has been a focus of healthcare research and policy reform since 2000s. Michael Porter and Elizabeth Teisberg released their book Redefining Health Care in 2006, which has been influential in introducing the definition of value in healthcare as the outcomes per dollar spent[6]. From this idea, the goal of value-based healthcare is to move from a volume-based healthcare model (where services are reimbursed by the quantity of services provided) to a model where the focus is on high-value care, reimbursing based on the value of care provided. The institute for health has also supported the idea that VBHC has a "triple aim": improving the patient experience of care, improving the health of populations, and reducing the per capita cost of care[33].

A key tool in this transition is the introduction of value-based payment models (VBPM), which were largely introduced with the Medicare Shared Savings Program (MSSP) that was introduced in the 2010 Affordable Care Act (ACA) and expanded greatly with the passing of the Medicare and CHIP Reauthorization Act (MACRA) in 2015. Before MACRA passed, VBPM comprised only 11% of payments in the United States[34], yet in 2018 it is estimated to have included 60% of reimbursement[4]. At this point, there are many different types of VBPM, but all are contracts between healthcare payers (also known as insurance providers) and contracted entities (which have many different names and structures) that links provider payments to measured outcomes of health care services. The Health Care Payment Learning and Action Network (HCP-LAN) has created four broad categories to define provider payment types in the context of VBHC: Category 1, Fee-for-Service with no link to quality of value; Category 2, Fee-for-service linked to quality and value; Category 3, Alternative payment models built on a fee-for-service architecture that hold providers financially accountable for performance; and Category 4, Alternative payment models (APMs) using population-based payment, with safeguards against limiting necessary care[4]. These categories, along with examples of each, are available in Table 1.

Table 1. Provider Payment Types, Adapted From HCP-LAN[4]

	Definition	Example
Category 1	Fee-for-service with no link to quality or value	Physician professional fees
Category 2	Fee-for-service linked to quality and value	Pay-for-performance (e.g., MIPS) and infrastructure improvement payments
Category 3	Alternative payment models built on a fee- for-service architecture that hold providers financially accountable for performance	Shared savings (e.g., MSSP ACOs)
		Episode-based payments for procedures (e.g., BPCI)
		Comprehensive Primary Care Plus (CPC+) Track 1
Category 4	Alternative payment models using population-based payment, with	Global capitated budgets (e.g., integrated delivery systems)
		Comprehensive Primary Care Plus (CPC+) Track 2

	safeguards against limiting necessary care Example	Prospective bundled payments for chronic conditions

The transition to VBHC has been led by the introduction of VBPM in government insurance programs (Medicare, Medicaid, and other alternative payment programs). Private insurers also have adopted VBPM[35], especially with the introduction of Managed Medicaid (where the state contracts with private insurers to provide Medicaid services to the state population) and Medicare Advantage (where approved private insurers provide services to the Medicare population[36]). Managed Medicaid is run by the individual states, which often include a requisite VBPM component in many cases[37,38]. Medicare Advantage (MA) has multiple VBPM like the MSSP. On top of these large and well-subscribed programs, the Centers for Medicare and Medicaid Innovation (CMMI) have developed and continue to develop many alternative payment models[39] that introduce new initiatives to not only increase the value of healthcare services provided but also promote health equity in the country[39].

2.2 How value-based payment models shape care provider groups

As both government and commercial/private insurers move towards VBPM, the health care delivery organizations (provider groups, individual providers, and more) have adapted to enter these payment models and engage in VBHC. First, that requires organizing providers in a fashion that they can enter into VBPM contracts. A good example is the creation of the Accountable Care Organization (ACO), which is defined as "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients"[40] but is also a formal entity that allows for entering into the Medicare Shared Savings program[41]. These ACOs are also able to enter into other VBPMs[39], such as the ACO REACH (Realizing Equity, Access, and Community Health) model recently introduced by the Biden administration.

Inside these ACOs, the organization of providers and administrators add personnel, create organizational structures, increase capabilities in data analytics, adopt new policies, and create focused committees to support their initiatives in population health (defined as the "distribution of measurable health outcomes among a defined group of individuals and the socioeconomic, environmental, biologic, and behavioral determinants of those outcomes"[6]). These practices align with the principles advocated by Porter and his colleagues for those interested in transitioning towards VBHC. These principles[5] are:

1. Organize integrated practice units
2. Measure costs and outcomes for every patient
3. Move to bundled payment for the care cycle
4. Integrate care delivery across separate facilities
5. Expand excellent services across geography
6. Enable a suitable information technology platform

Often, organizations entering into VBHC models create new or augment existing organizational structures, such as offices of quality (usually headed by a Chief Quality Officer) and offices of innovation or transformation[42]. These groups heavily invest in technology and tools to gather, analyze, track, and disseminate data and information regarding key healthcare outcomes that give insights into the value of their services[43]. For this reason, many groups have increasingly invested in technology and analytics initiatives such as standardizing Electronic Medical Records (EMRs) across the group, creating data warehouses, and investing in visualization tools and analysts[15,22,23,43]. Plainly stated, healthcare data and analytics capabilities are foundational for any entity entering into value-based contracts with any payer.

Many of the tracked outcomes chosen by the provider groups are defined by the quality measures that are required for the ACOs to report as participants of the MSSP and/or other APM. A benefit of the government leading VBPM creation is that they often share quality measures among programs[44], which creates standard metrics that are even adopted by commercial payers for their VBPMs. This is beneficial for the ACO or system engaged in population health, because they can select measures to track that are generally considered good indicators of quality[44]. Many of these shared quality measures are found in the Healthcare Effectiveness Data and Information Set (HEDIS)[45] as well as the Consumer Assessment of Healthcare Providers and Systems (CAHPS)[46].

While metrics are a crucial aspect of engaging in value-based care, focusing solely on the metrics can distract from understanding the bigger picture of what the main stakeholder is trying to achieve. In aligning providers toward a common goal, it is important to articulate the value created through any population heath/value-based care initiative[47]. Fortunately, groups engaged in VBHC research have created multiple classifications that assist in communicating and categorizing the value created in broader, more general terms. In this research, we will adopt a modified version of the classification that was created by Bruna Stella Zanotto and colleagues after systematic review of VBHC initiatives[5]. The Zanotto classification is based on published VBHC initiatives in the hospital and has 5 general domains: Financial outcome, Clinical outcome improvement, Patient-reported outcome improvement, Provider education and value culture, and Hospital management[5]. The classification has been modified to change "Hospital management" to "Management", allowing for the domain to represent management in all health care settings(Table 2). This classification scheme allows for value creation description in a way that can apply to payers, providers, and "payviders"[18].

Table 2. Value Domains of Value-based Healthcare Initiatives, adapted from Zanotto et al[5]

Domain	Sub-Domain
Financial outcome	Direct cost savings
	Indirect cost savings
	Reduced variance in cost
	Sustainable
Clinical outcome improvement	Reduced complications
	Reduced mortality
	Improved lab results and recovered from comorbidities
	Perioperative outcomes
	Reduced pharmacological treatment time
Patient-reported outcome improvement	Patient satisfaction with service
	Improved work and function relationships
	Improved well-being
Provider education and value culture	Support for innovative implementations
	Value consciousness and engagement
	Replicable
Management	Increased capacity
	Improved efficiency
	Better resource capacity allocating
	Value-office
	Improved quality through risk adjustment
	Benchmarking

While the population health initiatives of ACOs and others are defined and prioritized by administration[47], the actual initiatives are executed by the personnel of the ACO (or other VBHC organization). These personnel can include (but are not limited to) patient outreach coordinators who make contact with targeted patients, nurse educators/navigators who have specialized training and focus on supporting patients in taking care of their own chronic conditions through focused education, care coordinators who support nurse navigators in their efforts with those with chronic conditions, and referral coordinators who help schedule referrals for patients and who work to help the patients ensure coverage for the referral care[14]. The impact of these initiatives is tracked through the chosen metrics defined, and adjustments are frequently made in order to better meet the goals set by the administration[14,33,41,43]. These goals often change, due to the changing landscape of healthcare provisioning and the fact that the required measurements of VBPM are reviewed annually and can change just as frequently[48].

2.3 Laboratory support of value-based healthcare initiatives

The clinical laboratory performs a necessary role in the provisioning of healthcare. Its role is to analyze samples of tissues (urine, blood, biopsies, and more) and return information back to the provider who ordered the test[49]. The results of laboratory testing are crucial to the screening, diagnosing, and monitoring of many diseases and health conditions[50,51], but the laboratory rarely provides services that constitute as patient care. This may be the main reason that the laboratory, as well as other "diagnostic ancillary services[52,53]" (such as radiology) do not enter traditional value-based payment model contracts with payers. For example, the laboratory continues to be reimbursed for outpatient testing on Medicare patients based on the clinical laboratory fee schedule (CLFS). No testing is determined by the payer based on patient outcomes. The one challenge to that would be the concept of bundled payments for inpatient services, when a hospital is reimbursed by a payer for the entire episode of care[54]. Depending on the arrangement between the laboratory and the hospital system, there may be a case where the laboratory is not reimbursed equally by the hospital for the same testing. However, that is the result of the arrangement with the hospital and not the arrangement with the payer.

Because the laboratories are largely still reimbursed by the volume of testing provided and not by care quality metrics, they may not normally be considered a key component of VBHC initiatives. However, the modern, clinical laboratory is well situated to contribute to value-based care services due to the digital operations of the laboratory and the unique nature of the data they provide on those tested[55–59]. Many laboratories provide thousands of test results per day, if not hundreds of thousands[60,61]. They can serve one specific population (such as a hospital-based lab that only provides testing for the inpatients of that hospital) or many populations (LabCorp, a national reference laboratory, performs over 30 billion lab tests per year and has lab testing data on approximately fifty percent of the American population covered by health insurance[62]). In order to achieve this level of testing and data generation, the clinical laboratory has been increasingly run by specialized information systems[60,63–66] and robotic automation[67,68], allowing for a throughput that would have been unfathomable decades ago. In this way, laboratories are and have been digitally native for quite some time[61,66].

While laboratories employ multitudes of different methods for analyzing samples, they generally report testing results back to the patient and provider via electronic means[60,63,66,69,70]. The test results are generally captured and reported in a structured format[60,63,68,69,71], are highly replicable and accurate due to quality regulations[72], and provide granular information on the status of a patient's health in a way that diagnostic coding does not[27]. Depending on the population of patients serviced by the laboratory, the data asset generated by the test results could include important information that provides meaningful information for providers and payers. Not all laboratory test results will be useful for VBHC

initiatives, but many are tied to provider performance metrics as well as patient quality outcomes[21,24,29,73].

As the American healthcare system transitions to VBHC, laboratory leadership and researchers have discussed opportunities to engage more directly with stakeholders entering into VBPM contracts[21,24–26,28,29,57,58,73,74]. This has led to a movement commonly referred to as "Clinical Lab 2.0[21,29,73,74]", which is an agnostic approach to categorizing services created by the laboratory that create additional value to stakeholders using technology and laboratory data. The goal is to capture more value (whether it is direct funding, resources, accolades, or not directly stated) for the laboratory in an environment dominated by a fee-for-service model, with decreasing reimbursement per test performed. These laboratories look to gain or maintain competitive advantage in an ever-shifting competitive marketplace. It is thought that all laboratories[21,74] (be they owned by an integrated healthcare system or an independent lab, hospital-based or serving a many diverse facilities over a large geography) can engage in value-based care. A few laboratories have published their experiences and outcomes[27,73,74] **,** but as of yet there a common vocabulary and critical path to create successful value-generating services has not yet been achieved for these efforts.

2.4 Data monetization

As laboratories seek competitive advantage by creating useful services for those entities engaged in VBHC, they are essentially trying to create new value from the data that they generate as a clinical laboratory. They are actively pursuing "Data Monetization," a term defined by Dr. Barbara Wixom as the process of using data to generate financial returns. In her role as a Principal Research Scientist for MIT CISR, she works with senior-level executives to understand how their companies undertake data monetization. Many of the studies in this area include information from hundreds of companies and hundreds of different real-world cases of data monetization.[75–78] This research has generated many insights and multiple frameworks that can be used to understand how companies successfully create and deliver value from data.

2.4.1 Data Monetization Portfolios: Improving, Wrapping, Selling

Companies can monetize their data in three different ways[79](see Figure 1). First, they could use the data to **improve** their internal business decision making or operational processes. Second, they could "**wrap**" data and analytics around their core products or services, enhancing their value. Third, they could **sell** the data as an information solution. These three approaches are further explained through examples in Appendix A, provided from an online MIT course on data monetization courtesy of Dr. Wixom[32].

Figure 1. Three Portfolios for Data Monetization[75]

Adapted from Wixom, B. H. (2019). Generating Financial Returns from Data and Analytics — Summary of Survey Findings, 1–24.

2.4.1.1 Data wrap use cases: data, insights, action

Data wraps can be applied to any product, adding value to the customer through data analytics that changes the perceived product value in a way that increases or maintain the client's willingness to buy the product[32,76]. Wrapping data falls into three general buckets: offering the customers **data**, providing **insight** to the customers, or taking an **action** that benefits the customer. Data wraps provide data through graphs, charts, dashboards, or even data services with the hope that the data will be of use to the customer. For example, a laboratory could provide an interactive dashboard with all tests ordered in the last month which could be used to inform utilization management efforts. Data insight wraps are processed, interpreted information meant to inform the customer in an actionable way. Data insights from a laboratory could include providing a monthly list to an ACO that includes a specific list of patients with chronic kidney disease whose most recent eGFR (estimated glomerular filtration rate) indicates a progression of their disease to a worse stage. The ACO could use that list to reach out to those patients and make sure their disease is better managed and that their diagnostic coding is updated. Data action wraps are when the product uses data analytics to take an action on behalf of the customer. An example of this could be a testing cascade, where the provider sends a sample to the laboratory for thyroid testing, and the laboratory chooses which tests to perform on the test according to an algorithm set to promote best practices in testing. If the first test (thyroid stimulating hormone) is in the normal range, no further testing would be performed on the sample. However, if the first test has results that lie outside of the 95% reference interval, then a second test would be performed in the algorithm.

2.4.1.2 Data wrap design characteristics: Anticipate, Advise, Adapt, Act

Whether the laboratory provides a data wrap, insight wrap, or action wrap, it is important to know why the customer wants the product and what they would do with the information or insight in the wrap[32]. Research has shown that useful wraps have four characteristics[76]:

1. They **anticipate** the customers need
2. They **adapt** to the customers situation

3. They **advise** the customer in their decision-making
4. They **act** in a way that benefits the customer

2.4.1.3 Measuring value generated through data wraps

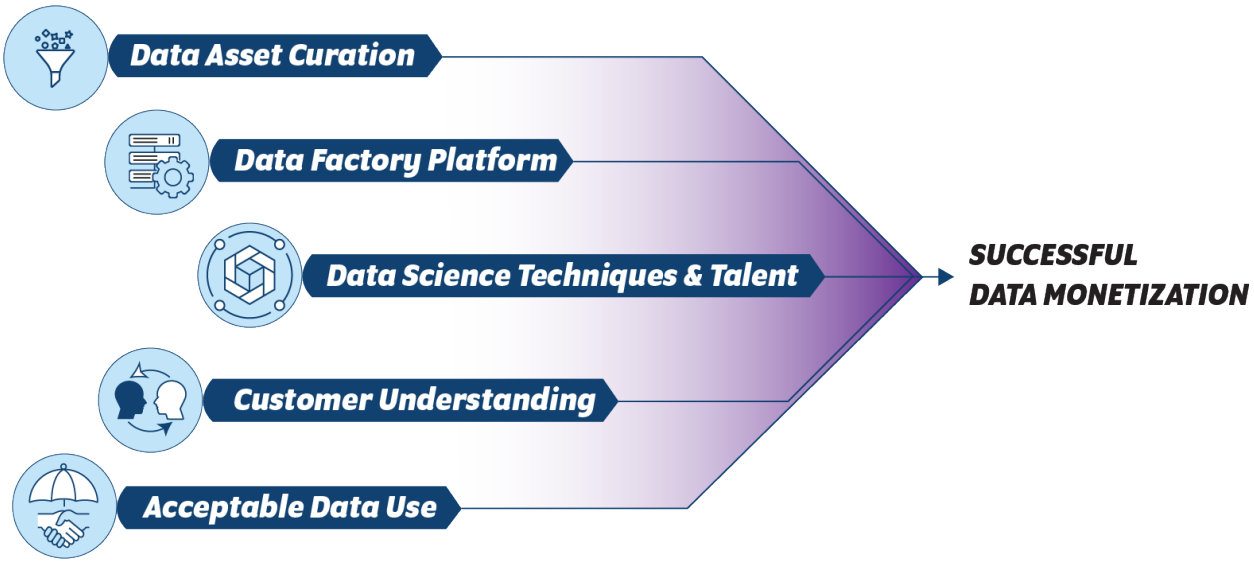
Data wrapping requires resources, which cost money. Companies will need to justify a return on investment (ROI) for the capabilities needed to wrap their products, which can be difficult due to the indirect nature of value capture in wraps[76]. Successful managers most commonly measured ROI in six general ways[76]:

1. **Margins**: an increase in revenue from charging a higher price
2. **Market share**: the wrapped product attracted new customers in the same market
3. **Wallet share**: Customers bought more products from the supplier
4. **Customer retention**: the wrap reduced customer churn
5. **New revenue streams**: Increases for charging for the wrap itself
6. **Customer satisfaction**: an improvement of customer perception of the supplier, gathered through survey

2.4.2 Data Monetization Capabilities Framework

While the "why" is clear in why companies would like to generate returns from the data they generate and accumulate, it is not always clear "what" is required to engage in data monetization. Research was conducted with 315 senior-level executives, studying the data monetization within their companies[80]. It emerged that successful companies had high levels of five capabilities. Those capabilities are data asset curation, data factory platform, data science technique and talents, customer understanding, and acceptable data use (see figure 2)[80].

Figure 2. Data Monetization Capabilities Framework[75]

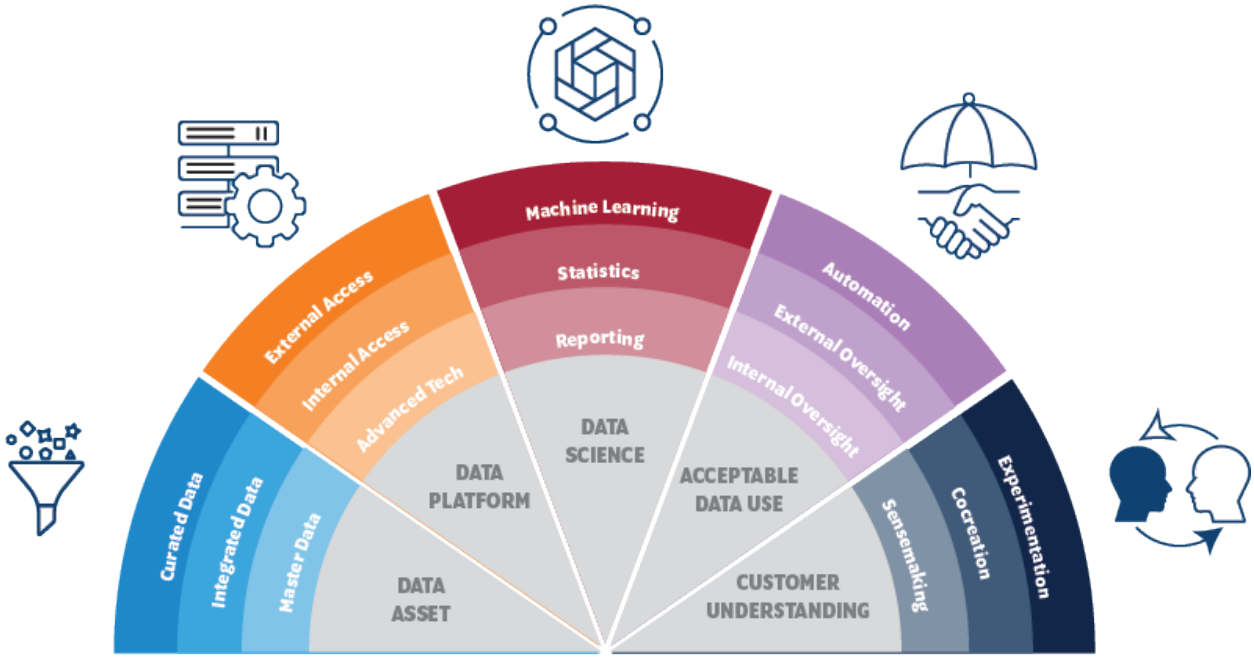


Adapted from Wixom, B. H. (2019). Genrating Financial Returns from Data and Analytics — Summary of Survey Findings, 1–24.

Most companies generate data faster than ever before, yet it is crucial that companies develop the capability to curate that data and ensure that it is high in quality and reusable. A data factory platform is necessary to ingest, transform, combine, and distribute data in a way that is efficient and reproduceable. Much like a skilled chef is needed to turn raw ingredients into a delicious meal, a company needs skilled personnel to take the data and transform it in a way that creates value for the customer. To create value for the customer, the company needs to understand the needs of the customer and how they will use the services/information/product created. Lastly, information is a crucial resource with many regulations. It is important to ensure that any data monetization endeavors are compliant and safe for all stakeholders involved.

The level of these five capabilities can vary across solutions within the same company, and can increase over time as companies engage in increasingly advanced capability-building practices (see Figure 3)[78].

Figure 3. Data Monetization Capabilities can increase over time[78]



Adapted from Wixom, B., Someh, I., Zutavern, A., & Beath, C. (2020). Explanation: A New Enterprise Data Monetization Capability for AI. MIT Center for Information Systems Research (CISR), Working Paper, NO. 443.

Chapter 3: Real-world data gathered through interviews

The author of this paper contacted leadership from multiple laboratories who had published or spoken on their laboratories' value-based care initiatives. A one page brief of the research was provided via email (see Appendix B) that included the general questions that would be used during an hour-long interview. Four laboratories agreed to be interviewed for this research. Most of the laboratories asked for a brief meeting to ensure that they understood the intent of the research, to prepare them for the interview. After that, the next meeting was an interview between the researcher and laboratory and business leadership who were heavily involved in the creation of the new laboratory service/capability. The interviews were not recorded, but their responses were written and then transcribed into a draft of the illustrative examples below. The draft was then sent to the laboratory representatives for any needed clarifications or corrections. This was done to ensure that the written example is not misrepresented.

3.1 Example 1: Reducing confusion concerning testosterone testing and results

3.1.1 Stakeholders

The health system is a large not-for-profit, integrated health system that provides health services to over 12 million patients across multiple states (CA, CO, WA, GA, HA, and more). The integrated managed care organization is comprised of the health plan, the hospital group, and the provider groups. The system is considered a "closed" group-model care system, meaning that members of the health plan receive their care from the owned provider groups with few exceptions. Because of this, the majority of the system's members receive their health care services almost exclusively within the health system, allowing for tight integration of data, care, and services.

The system has invested heavily in creating an environment that pushes for innovation to deliver "high quality health care" while maximizing cost-effectiveness. As a part of that tight integration, they have a well-established group of "population health and chronic conditions management teams" (PH&CCM teams), which undertake most payer-related care management and gap-closure programs. In northern and southern California, the system also owns their own laboratories and employs laboratory directors from the provider group. Outside of California, the health system owns and operates the laboratories. The laboratories play an integral role in the PH&CCM teams; however, the teams are led by clinical providers. The role of the laboratories in these endeavors is to primarily serve as a consultant to support proactive testing, result interpretation, and follow-up.

While the lab does not lead any of the population health teams, the lab focuses on modifying testing, test ordering, and test interpretation to improve patient outcomes, reduce cost of episodes of care, and increase patient satisfaction. Although the cost per test remains important, it's not what drives decisions concerning laboratory-led initiatives and is perceived as immaterial when compared to the outcomes mentioned.

3.1.2 Problem

Laboratory leadership was informed that there was a large amount of confusion on the part of the patients as well as the healthcare providers concerning the results of testosterone testing. Testosterone testing can be performed for many indications in children, women, and men. However, there is an

increase in direct-to-consumer marketing for testosterone supplementation, which also may have increased requests for testosterone level analysis in men.

There are multiple testosterone tests, which can cause confusion on part of the ordering provider as well as the patient. A mixture of testing panels and individual tests with similar names had been viewed as a cause of providers ordering duplicate testosterone evaluations on their patients during the same visit. In evaluating testosterone levels in men, the most provided tests by the laboratory are the total testosterone test by immunoassay and the free testosterone test by liquid chromatography and tandem mass spectrometry (LC-MS/MS). This is different in women and children, and due to the lower levels of testosterone, both total and free testosterone are measured using LC-MS/MS. The total testosterone test quantifies the total amount of testosterone in the sample (both testosterone bound to proteins in the blood and the testosterone that is not bound but is "free" or bioavailable to the body). The free testosterone test only provides measurement of the bioavailable testosterone. Usually, the total test is performed first as a screening test, and the free testosterone is performed if the total testosterone is abnormal, and the clinician wants to know if the total is abnormal because the bioavailable testosterone is either too high or too low. Thus, the naming, method, and clinical importance of the testing aren't easily apparent for the physicians as they must quickly order the testing as well as interpret the testing.

There are a couple of ways in which testosterone testing has been found to be confusing for patients. First, it can be difficult for the patient to know what to do if the total testosterone test is low, but the free testosterone is normal. They may disregard the free testosterone result and be focused on the abnormal total test even though the free testosterone test is the result that indicates that the body has either too little or too much bioavailable testosterone. The differing importance regarding clinical information and necessary action is not clear in the naming of the tests. Second, the test results themselves are provided, but the reference ranges differ for children vs women vs men. Many times, a laboratory will issue a quantitative testosterone level as the result, and there will be a note in the report that lists all the reference ranges for the different patient populations. Due to formatting restrictions in the electronic medical record or print record, those notes can be incredibly confusing, and the interpretive information is buried or difficult to decipher. This interpretive challenge is compounded because each testosterone test has their own differing reference ranges. In the case of a patient who receives the results for free testosterone testing and total testosterone testing, they can have two different charts of reference ranges.

The communication to the lab leadership was that the results were difficult for patients to understand and also difficult for the organization's healthcare providers to communicate clearly with their patients. These problems were identified to stem partly from the complexity in test ordering and partly from the communicated results themselves. When analyzing issues arising from the complex ordering opportunities, it was found that duplicate testing (ordering the same test on the same patient at the same visit) was taking place. This additional problem was added to the addressable issues for the laboratory.

3.1.3 Solution

In an effort to simplify ordering, decrease repeat testing, and increase the adoption of best testing practices concerning complex testosterone testing, the laboratories replaced their long-standing menu of testosterone orderable tests with three replacement options: a diagnostic reflex test (testosterone total or free, per protocol) and two indication-specific tests. The indication-specific tests addressed the

following: one to monitor suppression (testosterone, suppression monitoring) and another to guide replacement therapy (testosterone, treatment monitoring).

The protocol-driven reflex testing simplifies the test ordering process for the clinician seeing the patient and reduces the change of incorrect testosterone test selection. This reflex testing is informed first by the patient's demographics. When a clinician orders this evaluation, the appropriate total testosterone test (and method) is automatically selected in the lab based on the patient's age and physiological sex. If the total testosterone test came back normal for the patient's gender and age group, then the laboratory information system would stop further testosterone testing and only the total testosterone level would be resulted. However, if the total testosterone was abnormal, the free testosterone test would be performed. At the end of this two-test analysis, only the free testosterone test result would be provided on the patient's results and the only reference range present in the interpretive notes would be the one that is age and sex-appropriate for that patient. In that way, the most appropriate workup would still be performed, but only the most relevant data would be provided to the patient and provider.

The automation of the initial test selection in the testing reflex pathway was created using logic built into the laboratory information system under the direction of subject matter experts in testosterone testing. The actual reflex logic (whether to order the second test in the reflex algorithm based on the results of the initial test) was created using a middleware solution between automated testing instrumentation and the laboratory information system. The logic for the patient population specific reference ranges was handled using the logic native to the laboratory information system. Once the testing logic was built into both systems and tested, then the orderable test menu was changed in the clinician's order entry system present in the clinician's electronic health record.

3.1.4 Outcomes

The introduction of the diagnostic reflex panel virtually eliminated incorrect ordering of immunoassay on females and pediatric patients and decreased the number of assays performed per patient by 18%. Unnecessary orders for free testosterone testing on males with normal total testosterone results decreased by 97%. These findings demonstrate a reduction of duplicate testing and a reduction of additional testosterone testing that is not clinically indicated.

3.1.5 Data governance approach

In this solution, the laboratories did not share new information to existing or new stakeholders. They simplified test ordering, resulting, and interpretation, yet no new compliance or regulatory issues were identified. In this way, no new data governance issues were created in the creation of their new offering and no new oversight was necessary.

3.1.6 Self-identified "keys to Success"

Instead of looking at cost per test, the integrated health system has created an environment where the laboratory is able to focus on patient outcomes and the total cost of care. Other groups (like the PH&CCM teams) have more complete, longitudinal data that supports traditional VBC efforts and metrics more than the laboratory led initiatives. Instead, the laboratory can focus on creating increased value through solutions that don't necessarily require an immediate return on investment in the lab. They can work toward solutions that speak to the total cost of care for a patient, or patient outcomes

(including patient satisfaction). This enables the laboratory to contribute and collaborate with their healthcare delivery partners in more holistic solutions.

3.2 Example 2: Closing gaps-in-care for colorectal cancer testing in a population enrolled in a Medicare Advantage plan

3.2.1 Stakeholders

The healthcare system is an integrated, not-for-profit health system that provides healthcare services through a staff of over 40,000 caregivers, primarily in the states of Utah, Idaho, Nevada, and Colorado. The health system includes clinics, a medical group, affiliate networks, hospitals, homecare telehealth, health insurance plans, and other services. Payer 1 is a wholly owned subsidiary of the health system and is the organization's insurance division. The laboratory services are fully owned by the organization as well, although the laboratory medical directors are contracted and not employed by the health system directly, with one exception.

The system is heterogeneous in terms of providers and insurance. While the healthcare system does have their own insurance products, they accept insurance from other payers as well. Also, the system's medical group includes 1,600 physicians and advanced practice clinicians, but also works with over 3,000 affiliated providers. In this sense, it is not a closed healthcare system, and its members can and do receive health care services from physicians that are not directly employed by the health system. The data and healthcare services are not as tightly integrated as the health system from illustrative example 1.

3.2.2 Problem

In 2018, the insurance group was looking for a solution to increase the colorectal cancer screening rate for patients enrolled in their Medicare Advantage (MA) plan. The required, reported metric for MA plans is a HEDIS measure for Colorectal Cancer Screening which concerns how many adults aged 50 to 75 have current and appropriate screening for colorectal cancer. Accepted screening includes annual fecal occult blood test (a lab test), flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, a "Virtual colonoscopy" (computed tomography colonography) every 5 years, or a stool DNA test every 3 years. This screening is important because catching and treating colorectal cancer early on can lead to a 90 percent survival rate after five years.

80% of the group's Medicare Advantage population were up to date regarding their colorectal cancer screening, which was well above the mean rate of the national Medicare HMO rate (71.1% in 2018) and Medicare PPO rate (75.2% in 2018). Despite their above average results, the insurance group leadership wanted to increase the number of patients with current screening results. While this would not necessarily increase their reimbursement with improved performance, it could possibly catch early-stage colorectal cancer in the remaining 20% of patients, thereby reducing the morbidity and mortality caused by colorectal cancer. It was stated that this approach (focusing on maximizing all patient outcomes, not only focusing on benchmarked averages for reimbursement) was indicative of the overall health system's mission to "Help people live the healthiest lives possible."

The insurance plan's leadership wanted to create a direct-mailing campaign using fecal occult blood testing in the form of a fecal immunochemical test (FIT), closing the gaps in care for that remaining 20% of MA patients. They had found a vendor who would manufacture the testing kits, mail the kits to the

patients, and prepare and send reminder letters. The payer group then approached the health system's laboratory services to see if the lab would perform the FIT in the laboratory. To strengthen their relationship with their owned health plan, the laboratory began to work with the payer in implementing a solution.

3.2.3 Solution

Once they began their internal collaboration, the laboratory and insurance group realized that some important components would need to be addressed to create the desired service. For a FIT kit to be sent to a patient, the testing would have to be ordered by a physician first. The results would then also have to be sent to the patients and appropriate providers. The groups approached medical leadership from the provider organization and the health plan organization, yet none would participate in the project. At that time, the laboratory proposed a laboratory-run solution that expanded their role from merely testing the FIT kits inhouse. The proposed solution included the following:

1. Preparing and mailing introductory letters to the program
2. Ordering the tests for the patients eligible for the program and preparing the requisitions
3. Assembling and mailing the kits to the patients
4. Running the tests and reporting the results
5. Calling members with positive results
6. Notifying primary care physicians of positive results
7. Sending results to all members tested
8. Preparing and sending reminder letters to those who did not send back their kits for testing
9. Preparing campaign progress summaries

The proposal was accepted, and the service was created. The resultant system created for this service was digitally enabled through various data assets and tools. First, the insurer provided a list of patients who were considered not to be current on their colorectal cancer screening. The list was then compared to the laboratories' data to see if any tests had already been performed that would qualify. If so, that information was shared with the health plan to update their database. Next, the introductory letters were mailed to the 6953 patients on the list. Due to mail response, the FIT kits were then mailed to the 6693 patients still on the list. 129 undelivered kits were returned, and the lab received 2074 specimens back for testing for a 31% participation rate. Of those patients, 148 (7.1%) had positive results, and those patients were contacted by the medical director of the laboratory, who also notified the patient's primary care provider. Due to the integrated nature of the laboratory, the test results were also available in the patient's electronic healthcare record and patient portal at the time of resulting. 49 of those patients underwent colonoscopy, and 23 of them had abnormalities found.

3.2.4 Outcomes

The laboratory charged the health plan a flat fee per participant for the service provided to the patients enrolled in the program. This fee was lower than the third-party vendor, yet it provided more services than the vendor would have provided. In this way, the health plan saved thousands of dollars from the while simultaneously receiving a more comprehensive set of services. Anecdotally, the health plan was "thrilled" with the participation rate of the mail-order campaign. The laboratory felt that the offering

increased visibility of the lab to senior executives in the health system and the project was seen as a model of cooperation between the healthcare delivery side of the system and the payer side. As a result of the outcomes of the first campaign, the health plan increased the budget for the following year's campaign and there was discussion of expanding the service to members that do not yet qualify for Medicare.

3.2.5 Data governance approach

The developed solution did not experience many issues from a data governance perspective. The health plan provided a list of patients in a secure manner to the laboratory. The laboratory compared that list to their laboratory information system, using the patient's system-wide medical record number available from the payer-provided list. The requisitions were created in a way that allowed each mailed FIT kit to be identified in the laboratory system as a participant of the mail-testing campaign. The information was managed internally on spreadsheets, and periodic updates were shared back to the health plan via secure file transfer. Providers received notification of positive results from the medical director of the lab, and results were placed in the system electronic medical record with a note. All participating patients received a copy of their results. In this solution, no additional digital system created to handle any aspect of this service.

3.2.6 Self-identified "keys to Success"

In order to create a solution, the laboratory had to first understand why the health plan was involving the laboratory in their efforts. In working together while solutioning the problem, the laboratory was able to learn and translate the needs of the health plan into a service that could be primarily provided by the owned laboratory. Another perceived key to success was that of having "principle-driven leadership" throughout the health system. Because the principles are reinforced throughout the system, the insurance group and the laboratory were supported in their endeavor to further increase the colorectal cancer screening efforts in an area that was already considered above average. Third, because the health plan and laboratory services are owned by the same health system, both stakeholders were able to use the common enterprise medical record number for matching patients, keeping track of patients, communicating with providers, and providing electronic results.

3.3 Example 3: Improving patient outcomes by improving fill volumes for blood culture testing

3.3.1 Stakeholders

The health system is a nonprofit healthcare network in the northeastern United States, with 23 hospitals, over 830 outpatient facilities, and more than 16,000 affiliated physicians. The system does have an Accountable Care Organization (ACO) and has participated in various innovative care programs (such as the CMS Direct Contracting Model). It is not a closed system, and it accepts many commercial providers as well as Medicare and Medicaid members. The system owns their laboratories, which service the inpatient and outpatient providers and patients throughout the system.

However, the illustrative example of data-driven services provided by the laboratory is not focused on a specific payer-captive population, but on all patients being tested in the hospital.

3.3.2 Problem

The Chief Quality Officer (CQO) and Chief Medical Officer (CMO) for the health system asked the laboratory to standardize the phlebotomy process concerning sepsis testing. Blood stream infections (also known as sepsis) are a leading cause of hospital patient readmission in the United States and contribute significantly to inpatient cost of care. Blood cultures are the main tool used to detect the cause of sepsis, but a large proportion (28-49%) of patients with severe sepsis have blood cultures with negative test results. For the testing to be as sensitive as possible (reducing the chance of false negatives in cultures), it is necessary to have enough blood in the sample taken from the patient. The measurement is called the Blood Bottle Fill Volume (BBFV). It is a common problem in laboratory testing that the BBFV isn't high enough in samples sent to the lab to ensure enough sensitivity for accurate detection. The CQO and CMO approached the laboratory to improve the BBFV in the hospitals and hopefully reduce patient morbidity by detecting and treating the infection as early as possible. This would hopefully reduce the length of stay for affected patients as well as reduce the number of readmissions due to sepsis.

3.3.3 Solution

Laboratory leadership had invested in new equipment and software that automated the monitoring of blood volume for blood cultures. Because of these investments, they were able to monitor all blood culture samples coming to three of their laboratories from a total of 4 tertiary hospitals and 6 community hospitals. The laboratory used this background information and the data collected from the samples to create several educational and operational strategies in the different hospitals. Educational interventions included retraining managers, in-service training with medical nursing staff to promote best practices, and wider seminars on the importance of BBFV. Procedures concerning collection for blood cultures were updated at the local and system level. The monthly fill volume rate was visualized and distributed in staff common areas (referred to as "glossies on the wall" by lab leadership) to support the educational initiatives and promote competition towards desired BBFV.

3.3.4 Outcomes

Throughout the three-year exercise, the average BBFV increased from 2.7 mL to greater than 8 mL (with the suggested BBFV being 8-10 mL). Skin contaminates causing false positives (an important issue) decreased and positivity rate of patients with sepsis increased. The time to a positive result decreased by 24 hours due to improved BBFV, which allows for quicker detection and treatment of the causative agent.

3.3.5 Data governance approach

In this solution, the laboratories did share new information to the provider and nursing staff in the form of printed, visualized data for BBFV. While the BBFV data was available through the laboratory-owned automated monitoring software, no stakeholder outside of the laboratory had access to the individual patient data. Thus, no protected health information was distributed during the initiative and the nature of the provided information was such that no new governance approach was necessary.

3.3.5 Self-identified "keys to success"

It was thought that this initiative would have been too painstaking to perform ten years ago. The automated monitoring of fill volume, as well as the automated monitoring of the cultures for detection purposes enabled the laboratory to collect, analyze, and provide actionable information back to the

organization. Leadership felt that widespread dissemination of updated, printed "glossies on the wall" created high visibility for the initiative throughout the organization. Another perceived key to success was that the laboratory was able to engage the health system at multiple levels (local, as well as system wide) which allows for visibility and support from health system leadership. The laboratory's exclusive testing arrangement for the organization's hospitals allowed for a value-added solution that extends throughout the enterprise.

3.4 Example 4: Pre-defined population health dashboards for payers using laboratory analytics

3.4.1 Stakeholders

The laboratory is an independent, regional, not-for-profit, clinical laboratory that provides testing for a large portion of the New Mexico's population. It provides lab services for many different systems and providers throughout the state (including the 3 largest hospital systems in the state). It also accepts payment from many payers (government and commercial) and is estimated to have provided testing on at least 60% of the state population covered by health insurance.

New Mexico is unique in that approximately 65% of the population are covered by Medicaid and Medicare insurance (43% of the state in Medicaid programs, and about 21% by Medicare)[81,82]. The laboratory has a large test menu, with less than 2% of the testing being sent to outside laboratories. With its large regional market share, the lab provides comprehensive testing for a good proportion of the population of New Mexico. The laboratory has also invested heavily in innovation, such as by acquiring a company which provides information technology solutions, consulting, and other services for laboratories and health systems. The extensive testing footprint, confluence of insurers engaged in value-based care reimbursement, and digital capabilities have allowed the laboratory to develop data-enabled solutions for their clients, patients, and new stakeholders throughout the state.

3.4.2 Problem

New Mexico Medicaid services (known as Centennial Care[81]) contracts with managed care organizations to provide Medicaid services throughout the state for children, low-income adults, and non-dual eligible aged adults. Centennial care has made VBC projects and payment plans an important part of these contracts. Because a large proportion of the population in New Mexico is covered through Centennial Care contracts, it means that a large proportion of the population is covered through MCOs who have entered value-based care contracts with the state. Centennial care requires its MCOs to report HEDIS and CAHPS data to the state to adequately reimburse the MCOs concerning their performance-based contracts and shared savings/risks contracts. A key population for these contracts is the diabetic population, and two key HEDIS measures for this population are the number of diabetic patients with a hemoglobin A1c test (which generally indicating the control of blood glucose in diabetics) and those that have their annual albumin creatinine ratio (ACR) test performed (which provides insight into chronic kidney disease, a major comorbidity of diabetics). The state has a requirement that MCOs must increase their HEDIS compliance rates by 2% or be penalized 2% of the total amount paid for managing physical health. Traditionally, the MCOs rely on insurance claim information to understand their population, perform services to improve outcomes, and establish the VBHC initiatives. For example, an MCO would use claim data to identify diabetics and perform care management services to increase current HEDIS measures for this population. However, claim information is not as timely in that it can lag up to 6

months from the time of the patient visit. Claim information also has limitations in that it is limited to diagnostic codes submitted by health care providers. In contrast, laboratory testing information is timelier in that results are available days after the sample is taken and that the results provide more granular and definitive insights into the state and severity of many diseases (like diabetes and chronic kidney disease).

One of the MCOs involved in managed Medicaid collaborated with the laboratory to see if their laboratory testing results could augment the plan's diabetes care management services and improve their performance on diabetes related HEDIS measurements which would help them avoid contractual penalties.

3.4.3 Solution

The health plan provided their Medicaid enrollment file to the laboratory to analyze the Hemoglobin A1c test results and identify diabetics for those covered patients. The lab accomplished this by using their Enterprise Master Patient Index (EMPI), that creates a unique laboratory identifier for each patient tested in the laboratories and matched them based off the demographic information supplied by the payer. Of these matched patients, a hemoglobin A1c of greater than 6.4% was used by the laboratory to indicate if a patient has diabetes. A random sample of 600 of the matched patients with diabetes were identified, with half (300) being provided back to the health plan to perform care management services. The other half were not provided on the list back to the plan and were treated as the control population. After a set amount of time, both groups were compared to see how many patients were current on their A1c testing and their ACR test.

3.4.4 Outcomes

More patients in the sample group were current on their A1c test (25%) compared to the control group (18%). The number of patients from the managed sample who received their ACR test (14%) was also greater than the sample group (9%). Because the information provided was deemed helpful, the laboratory developed a service for payers/MCOs. The MCOs would provide a list of their attributed patients and select to receive population health reports purposefully built to provide disease surveillance (on multiple conditions/diseases) on the population who receives testing from the laboratory. The laboratory then created a subsidiary with a "clinical innovations" division to turn this project into a business model where the MCO/payer would pay a per-member-per-month fee for each report/condition that they subscribe to. The client can then securely access the reports, which are automatically updated every night, through a proprietary portal.

3.4.5 Data governance approach

This new service requires data sharing agreements between payer organizations and the laboratory. The payers have right to the raw test results data under 45 C.F.R. § 164.506(a)(4), commonly known as Limited Healthcare Operations. Thus, the payers were already receiving the raw data without interpretation for no cost. However, the payers do not usually have resources with expertise in understanding or analyzing laboratory data in the context of population health. The data sharing agreement includes not only the raw data, but the analyzed data in the form of interactive dashboards that provide interpretive data at the population health level for the MCO's care management services. The laboratory provides an online portal for access to the data which has security and protections for

protected health information, ensuring that MCO personnel only access the information for their matched members. The remainder of the communications and data involved occur through previously established and secured channels.

3.4.6 Self-identified "keys to Success"

The laboratory believes that the data and technology has been in a place where this kind of service could have been possible ten years ago, yet the incentive wasn't there for the MCOs that would lead them to pay for this information service from a laboratory. In contrast, the government health plans are heavily determined by health metrics tied to VBHC that laboratory data at a population health level can be a new tool that enables their success. The laboratory's investment in the technology such as data warehousing, EMPI, analytics tools, and visualization tools greatly enabled them in their initial efforts with the health plan. In addition to the technology, the lab perceives having specialized personnel as necessary for these endeavors. They see it necessary to have staff who can interpret lab data in a way to find health conditions and outcomes at a population level, which allows the lab to take the raw testing data and provide actionable information for their stakeholders. These investments in personnel and technology served as the foundation for turning this project into a suite of products and services they can offer to additional clients.

Additionally, the laboratory's data asset is unique in that they have an extensive outpatient and inpatient testing footprint. They have enriched that data through building interfaces with the health systems that allow the laboratory more than the bare minimum information required for a testing interface. The results are not only drillable to the organization and facility level, but even to the hospital department and room. Additionally, because they are an independent laboratory, they receive billing information for a good portion of their testing. This allows the laboratory to further enrich their data in with diagnostic codes, which help stratify patient populations by comorbid conditions that would not be apparent through laboratory test results alone.

Lastly, the laboratory sees that perseverance in these initiatives is necessary. The laboratory leadership strongly stated that survival as an independent laboratory requires providing more than the traditional, transactional testing model. They support these initiatives through investment in the resources previously mentioned, but also publish the results of many of their initiatives as well as participate in national discussions concerning how the laboratory can contribute to VBHC.

Chapter 4: Analysis

4.1 Analysis methods

The interviews provided raw information regarding four real-world examples from laboratories. Multiple frameworks were applied to create more transparency into the context of the new laboratory-based services.

First, a matrix was created to categorize the participants in relation to the population of patients affected by the VBHC initiative. The matrix includes the following:

1. The geography of the population
2. The payer(s) involved in taking care of this population
3. The type of contract using the HCP-LAN categories (Table 1)
4. The contracted entity responsible for providing the care to this population
5. The site of the care provided (inpatient vs outpatient)
6. The characteristics of the population receiving the services
7. The laboratory creating/adapting services
8. The percentage of the client's defined population that is serviced by the lab.

Second, the laboratory's client was identified, the client's high-level goal was written as a sentence, and the specific issue that can be addressed by the laboratory was identified. Then, a table was created to distinguish the value creation from the value capture, and both were categorized using the modified Zanotto classification (table 2).

Third, the laboratory's mission statement was placed into the structured form of "To, By, Doing" and a separate table was created to understand the client value creation and client value captured enabled by the laboratory's services/products as well as the value creation and value capture for the laboratory itself.

Lastly, to allow for a common vernacular in the laboratory space for characterizing the services created, a few key data monetization frameworks were used to understand the nature of the services created:

1. The solution was categorized by data monetization strategy as either improving business processes and decisions, data wrapping products, or selling information solutions[77].
2. If the solution created was considered a data wrap (as many were), the use case was defined as providing data, insights or action as well as further described by how the data wraps anticipate, advise, adapt and or act[76].
3. To understand how the clinical laboratories have created their services, the solution was described in reference to the data monetization capabilities[78,80]
    a. data asset curation
    b. data factory platform
    c. data science techniques and talent
    d. customer understanding
    e. acceptable data use.

The results of the analysis of each case are described in the following pages.

4.2 Illustrative Example 1: Reducing confusion concerning testosterone testing and results

Laboratory	Health system owned laboratories
Laboratory Client	Integrated health system

Client goal:

To increase or maintain market share (for all contracts), the integrated health system must increase or maintain high levels of patient satisfaction as well as physician retention.

Client value creation and capture with VBHC value domain classification:

	Value Creation	Value Capture
Description	Increase patient satisfaction with health care services while reducing unnecessary work for providers	Increase or maintain market share, increase reimbursement in VBPM contracts that include patient satisfaction as a metric
Zanotto classification[5]	**Patient-reported outcome improvement**: Patient satisfaction with service	**Financial outcome:** Sustainable

Client problem: The traditional means of ordering and interpreting testosterone testing has caused patient confusion as well as increased physician workload.

Population definition matrix:

Region	Payer(s)	Contract Type (HCP-LAN Categories[4])	Contracted Entity	Site of Care	Target Population	Laboratory	Est. % of pop tested by lab
Northern California, Southern California	Owned Health Plans (Commercial)	All Contracts (Categories 1-4)	Integrated Health System	Outpatient	Patients evaluated with testosterone testing	System owned laboratories	>98%

4.2 Illustrative Example 1 Continued

Lab solution mission statement:

To	By	Doing
To improve patient satisfaction with client services by decreasing patient confusion concerning interpretation of testosterone test results	By simplifying test ordering to a reflex test based on age and sex specific reference ranges as well as reporting only the most applicable results for each patient's demographics	Using lab test automation software and reporting rules in the laboratory information system

Two-sided table of value creation and capture from solution:

	Client Value Creation	Client Value Capture	Lab Value Creation	Lab Value Capture
Description	Decreased reports of patient confusion and physician burden	Improved efficiency for employed physicians	Simplified test ordering and interpretation for testosterone evaluation	Maintain exclusive relationship with health system and become visible part of organization that contributes value above traditional role
Zanotto classification[5]	**Patient-reported outcome improvement**: Patient satisfaction with service	**Management:** Improved efficiency, better resource capacity allocating	**N/A**	**Provider education and value culture:** Support for innovative implementations

Data Monetization Strategy[75]	Data Wrap
Data Wrap type[76]	Insight and Action

Data wrap characteristics[76]:

Anticipate	The new testing anticipates what the patient wants to know concerning testosterone testing and removes extraneous information in the results
Advise	The result does not directly advise the patient or healthcare provider
Adapt	The results are tailored to the patient's age and sex, and only provides those reference ranges
Act	The reflex test will automatically order a free testosterone test if the total testosterone test is abnormal and will not perform it if the total test is within normal range. This reduces required provider ordering and reduces cost of testing of the second test is not clinically indicated

4.2 Illustrative Example 1 Continued

Data monetization capabilities[75,78]:

	Type	Description
Data Asset	Master Data	Patient-specific data generated through exclusive testing arrangement with healthcare providers.
Data Platform	Advanced Tech	Connected system of automated specimen analyzers, rules-based middleware software, rules-based laboratory information system, and electronic healthcare record.
Data science	Statistics	Demographic-specific rules are created based on reference ranges generated by statistical analysis. Clinical talent is needed to generate appropriate reference intervals.
Customer Understanding	Sensemaking	Laboratory modified current solution without direct collaboration with stakeholders
Acceptable Data Use	Internal oversight	Only internal resources were used, which may be a result of the client being considered internal as well.

4.3 Illustrative Example 2: Closing Gaps in Care for colorectal cancer testing in a population enrolled in a Medicare Advantage plan

Laboratory	Health system owned laboratories
Laboratory Client	Health system owned health plan

Client goal:

To increase the percentage of the Medicare Advantage population that have current colorectal cancer screening

Client Value Creation and Capture with VBHC value domain classification:

	Value Creation	Value Capture
Description	Increase percentage of population screened, potentially catching colorectal cancer at an earlier, more treatable stage	Reduce downstream costs of cancer caught at more advanced stage, improve population-based metric of MA contract
Zanotto classification[5]	**Clinical outcome improvement**: Reduced mortality	**Financial outcome:** Indirect cost savings

Client problem:

Approximately twenty percent of their MA patients were missing current colorectal cancer screening.

Population definition matrix:

Region	Payer(s)	Contract Type (HCP-LAN Categories[4])	Contracted Entity	Site of Care	Target Population	Laboratory	Est. % of pop tested by lab
Utah	System owned health plan (Commercial)	Population-based payment (Category 4)	System health plan contract with CMS	Outpatient	MA Patients needing current colon cancer screening	System owned laboratories	>80%

4.3 Illustrative Example 2 Continued

Lab solution mission statement:

To	By	Doing
To decrease the number of Medicare Advantage patients without appropriate colon cancer screening	By ordering, sending, and performing home testing kits to patients without current screening results	Using patient matching technology, home kits for fecal immunochemical testing, automated analyzers, laboratory information systems, traditional lab resulting channels, and secure file transfer

Two-sided table of value creation and capture from solution:

	Client Value Creation	Client Value Capture	Lab Value Creation	Lab Value Capture
Description	More necessary patient visits that can reduce morbidity of advance cancer	Saving thousands of dollars by using internal lab instead of third party	Increase number of patients screened for colorectal cancer	Flat per patient fee, high visibility in organization concerning VBHC initiatives
Zanotto classification[5]	**Clinical outcome improvement**: reduced mortality	**Financial outcome:** Direct cost savings	**N/A**	**Provider education and value culture:** Support for innovative implementations

Data Monetization Strategy[75]	Data Wrap
Data Wrap type[76]	Insight and Action

Data wrap characteristics[76]:

Anticipate	The service does not anticipate the needs of the plan
Advise	The service contacts the primary care physician of patients with abnormal results to advise them to follow up
Adapt	The service adapts to send only to those patients without record of preexisting FIT and those with a viable address
Act	The service does order testing, send kits to matched patients, and send reminders for MA to patients who have not returned their kits for testing

4.3 Illustrative Example 2 Continued

Data monetization capabilities[75,78]:

	Type	Description
Data Asset	Master Data	Data set includes a list of health system patients contracted to system's Medicare Advantage plan.
Data Platform	Advanced tech	Though not extremely advanced, the data is processed and provided to the client using visualization tools, spreadsheets, and secure file transfer.
Data science	Reporting and Statistics	Data is reported at the patient level, with population level statistics providing insight into project progress.
Customer Understanding	Cocreation	The laboratory created the service in collaboration with the client.
Acceptable Data Use	Internal oversight	Only internal resources were used, which may be a result of the client being considered internal as well.

4.4 Illustrative Example 3: Improving patient outcomes by improving fill volumes for blood culture testing

Laboratory	Health System owned Hospital Laboratories
Laboratory Client	Health System Hospitals

Client goal:

To improve patient outcomes while reducing the length of hospital stay and reducing patient readmissions.

Client value creation and capture with VBHC value domain classification:

	Value Creation	Value Capture
Description	Improve patient outcomes while reducing costs	Increase margin through reducing length of stay and reducing preventable readmissions
Zanotto classification[5]	**Clinical outcome improvement**: Reduce complications, Reduce mortality **Financial outcome:** Direct cost savings, Indirect cost savings	**Financial outcome:** Indirect cost savings, Sustainable

Client problem: Providers commonly provide substandard blood specimens for blood culture testing in patients with sepsis. Those substandard specimens lead to reduced sensitivity (leading to false negative results) and increased time to results (delaying treatment).

Population definition matrix:

Region	Payer(s)	Contract Type (HCP-LAN Categories[4])	Contracted Entity	Site of Care	Target Population	Laboratory	Est. % of pop tested by lab
All system Hospitals	All payers/ All plans	All Contracts (Categories 1-4)	Health System Hospitals	Inpatient	Patients with suspected Sepsis	System owned labs	>98%

4.4 Illustrative Example 3 Continued

Lab solution mission statement:

To	By	Doing
To improve care of septic patients	By increasing the sensitivity of blood cultures through increasing the Blood Bottle Fill Volume (BBFV) toward established standards	Using automated software and hardware to monitor sample BBFV as well as monthly distributed reports of performance to promote competition and awareness of BBFV performance

Two-sided table of value creation and capture from solution:

	Client Value Creation	Client Value Capture	Lab Value Creation	Lab Value Capture
Description	Earlier identification of Bacteremia; Reduce Time-to-Effective-Treatment	Reducing hospital length-of-stay and readmissions due to untreated infections, improve quality ratings	Increase BBFV, increasing test sensitivity and reducing turn-around-time	Maintain exclusive relationship with health system and become visible participants in quality-related initiatives
Zanotto classification[5]	**Clinical outcome improvement**: reduced mortality, reduced complications	**Financial outcome:** Indirect cost savings	**Management:** Improved efficiency	**Provider education and value culture:** Support for innovative implementations

Data Monetization Strategy[75]	Data Wrap
Data Wrap type[76]	Insight

Data wrap characteristics[76]:

Anticipate	The reporting service does not anticipate the need of the provider
Advise	The reporting service advises the provider to improve performance through competitive, public data reporting
Adapt	The reporting service does not adapt to the needs of the provider
Act	The service does not act for the provider

4.4 Illustrative Example 3 Continued

Data monetization capabilities[75,78]:

	Type	Description
Data Asset	Master Data	Provider-specific data on historic BBFV.
Data Platform	Advanced Tech	The automated specimen monitoring machinery and hardware generates the data, but it cannot be accessed outside of the laboratory.
Data science	Statistics	Basic techniques are required to calculate statistics of performance over time.
Customer Understanding	Sensemaking	Laboratory modified current solution without direct collaboration with stakeholders.
Acceptable Data Use	Internal oversight	Only internal resources were used, which may be a result of the client being considered internal as well.

4.5 Illustrative Example 4: Pre-defined population health dashboards for payers using laboratory analytics

Laboratory	Independent, regional, reference laboratory
Laboratory Client	Commercial health plan with Managed Medicaid patients

Client goal:

To sustainably provide Medicaid services to the children and impoverished in the state of New Mexico.

Client value creation and capture with VBHC value domain classification:

	Value Creation	**Value Capture**
Description	Provide access to quality health care services for Medicaid patients	Increase or maintain marketshare, avoid penalties in VBPM contracts
Zanotto classification[5]	**Clinical outcome improvement:** Reduce complications, reduce mortality	**Financial outcome:** Sustainable

Client problem: The diabetic population experiences difficult and costly complications from the disease. It is hard to identify diabetic patients in a timely manner using only claims information.

Population definition matrix:

Region	Payer(s)	Contract Type (HCP-LAN Categories[4])	Contracted Entity	Site of Care	Target Population	Laboratory	Est. % of pop tested by lab
New Mexico	Commercial MCO with Managed Medicaid	All Contracts (Categories 1-4)	Commercial MCO	Outpatient	Diabetic patient	Independent reference laboratory	At least 50%

4.5 Illustrative Example 4 Continued

Lab solution mission statement:

To	By	Doing
To support MCO in contacting and reaching out to their diabetic population	By providing timely identification of diabetic patients for client outreach services	Using laboratory test results for Hemoglobin A1c testing, interactive dashboards, and a secure client portal

Two-sided table of value creation and capture from solution:

	Client Value Creation	Client Value Capture	Lab Value Creation	Lab Value Capture
Description	More efficient use of care coordinator resources, leading to increase in number of diabetics with current A1c tests	Preserved margin due to increased performance	Identify diabetic patient population from lab testing	Monthly per-member-per month fee from MCO
Zanotto classification[5]	**Management**: Better resource capacity allocating	**Financial outcome:** Indirect cost savings	**N/A**	**N/A**

Data Monetization Strategy[75]	Data Wrap (of an existing, free information service)
Data Wrap type[76]	Insight

Data wrap characteristics[76]:

Anticipate	The reporting service does not anticipate the needs or actions of the payer
Advise	The reporting interprets the test results of their patients to identify which have diabetes and advises the payer to make contact with those specific patients
Adapt	The reporting service does not adapt to the payer's specific situation
Act	The service does not order any testing or provide any specific actions for the client

4.5 Illustrative Example 4 Continued

Data monetization capabilities[75,78]:

	Type	Description
Data Asset	Integrated Data	Data set includes information from MCO as well as data on those patients in the laboratory information system, enabled through patient matching algorithms.
Data Platform	External access	Self-service, secure portal with interactive visualizations.
Data science	Statistics	Population-level dashboards populated by analysis of demographic information and laboratory result data. Clinical talent is needed to generate appropriate interpretive rules. Data scientists needed to turn analysis into interpretive, interactive information.
Customer Understanding	Experimentation	Laboratory entered an experiment with MCO to prove value of service.
Acceptable Data Use	External oversight	A data sharing agreement was formulated to allow for transmission of protected health information.

Chapter 5: Discussion and Conclusion

5.1 Discussion

After analysis, it was observed that all the examples gathered through interviews are cases of data monetization in the form of data wrapping. The nature of the data wraps varied greatly, with most having an element of insight wrapping and a few having action wraps as well. In the case of example 4, the preexisting service to the payer was a free data wrap, providing raw data to the commercial insurer upon request. By improving their monetization capabilities, they were able to modify their data wrap into an insight wrap which showed enough value to the client that they became willing to pay for it.

By investigating the data monetization capabilities of each example, it was shown that the main data asset is the data generated as result of the laboratories preexisting arrangements with providers and payers. It seems that payers are willing to engage with laboratories concerning data products and data-enabled services when there is a substantial overlap in the populations that both sides serve. In those cases, a means of creating an enterprise master patient index for patient matching was considered necessary for success. There were wide differences concerning the data factory platforms that the laboratories used to power their initiatives. While all laboratories had laboratory information systems (LIS) for creating laboratory results and distributing those results to clients and patients, most of the data-enabled services were created by platforms that exist outside of the LIS. In terms of data science techniques and talent, multiple interviewers stated that they needed personnel who could translate the laboratory data into population-based clinical insight for the clients. This is not an area of traditional training for laboratorians, and there have been groups of pathologists who have advocated for the advancement of specialized training in informatics to include this area of focus[84]. Outside of core capabilities, many participants credited culture and supportive leadership as helpful in creating these new and unfamiliar initiatives in their laboratory.

While it was felt that the two-sided value capture and value creation tables illustrate how both sides of the business-to-business (B2B) arrangements benefit in the context of value-based healthcare, there was difficulty in applying the Zanotto classification to both sides in all cases. First, there were no clear and direct ways to classify improved screening or monitoring performance, as the value is created indirectly and downstream from the lab in the value chain. Second, the Zanotto classification is limited when categorizing financial benefits in that the subcategories are limited to savings (either direct or indirect). There may not have been enough published cases in the healthcare literature that chose increased financial revenue (through market share, or wallet share, or other means) as an outcome of their VBHC efforts. If the Zanotto classification is to be used in classifying these laboratory endeavors, it may need to be modified further to increase its applicability.

5.2 Conclusion

Due to the nature of laboratory operations and services, most laboratories are already digitized and have amassed large data assets that can be used to create additional value. As the nation's health care system continues in its transformation towards value-based reimbursement, laboratories continue to find ways to use that data to change and enhance their services and products to help their customers create new value. When investigating and describing these initiatives, laboratories should consider their efforts as forms of data monetization. The existing body of research in data monetization provides a standardized vernacular for understanding how companies create value from their data assets and capabilities and the resulting frameworks have been shown to be applicable in the four illustrative examples in this research paper. By adopting these frameworks as well as standardizing the description of the business arrangements of the laboratories with their clients and clearly describing the shared

patient population served, the research in “laboratory 2.0” will allow for the industry to share best practices more clearly. By becoming more familiar with data monetization research, laboratories may learn best practices from other industries as well.

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Appendix A: Three Approaches to data monetization[32], provided courtesy of Dr. Barbara Wixom

Three approaches to data monetization at a glance:

	 **IMPROVING**	 **WRAPPING**	 **SELLING**
Data Monetization Approach	Improving generates financial return indirectly by **using data to positively change the economics of work and then removing or redirecting the resulting slack**. Data first creates value by helping to make operational processes better, faster, and cheaper, or by boosting decision-making quality.	Wrapping generates financial return indirectly by **using data to positively change the economics of products and then raising prices or selling more products**. Data first creates value by helping to enhance the customer value proposition of products.	Selling generates financial return directly by **using data to generate new revenues**. Data can take many forms, including raw data, packaged insights, and information solutions.
Common outcomes	Slack created from better, faster, cheaper production and delivery of services Slack created from better assessment of and response to customer demands Slack created from better assessment of and response to marketplace and macroenvironmental shifts	Product sales lift created from higher prices Product sales lift created from larger customer market basket Product sales lift created from larger market share Avoidance of sales erosion from by customer retention or ability to maintain prices	New revenue streams

		Increased margins by reducing costs to produce or service offering	
Top value creation risk	Action risk. If the organization fails to act on an improving initiative, then there is no created value to be captured.	Service-level risk. If the organization deploys a wrapping initiative that falls below the customer's service expectations, then the product's value proposition can deteriorate.	Sustaining competitive advantage. If the organization does not sense and respond to dynamic market shifts and evolving customer demands, then selling initiatives will fail to produce information offerings that customers will pay for or stay for.
Top value capture risk	If the organization does not remove or redirect the slack created by efficiencies or quality hikes that an improving initiative produced.	If the organization fails to extract revenues from the marketplace created by the increase in customer value proposition that a wrapping initiative produced.	If an organization fails to charge a price for their selling initiative that justifies the expense or risk of the exchange.
Ideal Owner	Process owner	Product owner	Information solution owner

Source: Wixom, Barbara and Jeanne Ross. (December 2015)

Appendix B: One page research brief for informing participants before agreeing to be interviewed

Research Topic: Investigating Laboratory-Led Population Health Services

A Laboratory-led Population Health service (LLPHS) is a novel laboratory service that relies on data from clinical laboratory testing as well as other digital resources to create and capture economic value for health care entities (especially those engaged in Value-Based contracting). These initiatives are specific products or projects, not large-scale strategic efforts (e.g., digital transformation). They rely on a core of digital resources, and they are executed to achieve competitive advantage for a clinical laboratory. A key LLPHI digital resource is the **digital data asset,** which we define as ***data that is modularized, governed and shared in a highly scalable manner*.**
In this study, we explore how clinical laboratory companies **identify, design and deploy a LLPHI and** what contributes to their progress and impact on value.

Research methodology: The principle investigator will conduct a series of 1-hour interviews by video conference with business leaders from clinical laboratory companies engaged in LLPHI creation.

Confidentiality: With approval from participants, information from interviews will be collected and transcribed. All interview data are confidential and available only to the research team, all of whom are bound by MIT confidentiality rules and procedures. The case study will be reviewed by the participant to ensure that the information is represented accurately. The final report will contain information in the form of an illustrative example.

Benefits to participants: For many participants, the main benefit of participating in an interview is the opportunity to reflect on and share experiences and expectations, and then to read how their practices are described by researchers who have expertise in the domain area. All participants will receive a copy of study deliverables, and will be seen by other participants in the study. There is no cost to participating firms or respondents.

Research team: Dr. Chris Garcia (cagarcia@mit.edu) MIT SDM Masters candidate, with Faculty sponsor Dr. Barbara Wixom **(**bwixom@mit.edu**)** MIT CISR Principal Research Scientist.

Sample interview questions:

1. Have you been engaged in creating Laboratory-led Population Health Services, as described in the intro?
2. Could you please describe a Population Health Service that you have created?
3. How is it that you chose this Population health initiative?
4. What is the nature of the data that you use in this initiative?
5. Could you please describe the key technologies and processes you found necessary to develop and execute the data asset component of the Value Based Care Initiative?
6. How is data governance handled for your asset and your service?
7. What are the critical resources that the data asset requires (particularly as a live resource)?
8. Would this initiative have been possible 10 years ago?
9. How is your data asset unique from your competitors' data assets?
10. What outcomes can you share and describe from the operation of your LLPHS?
11. What do you think contributed to the impact of your LLPHS?