2020

Stories That Shaped Commercialization

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TABLE OF CONTENTS

CHAPTER 1: ACCELERATING PATIENT OUTCOMES 03

The Evolving World of Artificial Intelligence: Rare Disease Impact 04

Patient Switching Behaviors Impact on Adherence and Engagement 08

Targeted Digital Patient Engagement 16

CHAPTER 2: THE NEW GOLD STANDARD OF COMMERCIALIZATION 19

The New Gold Standard of Drug Commercialization 20

The Chronic Microcap Trap How Launch is the Escape for True Growth 22

Compliance — The Competitive Differentiator to Commercialization 28

CHAPTER 3: STRATEGIC GLOBAL PRODUCT LAUNCHES 38

Commercial Strategies for a Successful Product Launch 39

Looking to Launch or Commercialise in the US? 42

Augment Your Frontline to Boost Sales Momentum 45

CHAPTER 4: THE TRANSFORMATION OF DIGITAL THERAPEUTICS 47

Ask The Expert: The Critical Questions 48

Sharpening the Value and Definitions of Digital and RWD: 50

An Exchange Between Two Industry Leaders 50

CHAPTER 5: PIVOTING THE PATIENT EXPERIENCE 54

Advancing Beyond the Traditional Patient Adherence Model 55

Where Health Systems Are in the Shift to Value: Four Categories 59

Why Are We Settling for Mediocre Patient Services Programs? 65

CHAPTER 1:
ACCELERATING PATIENT OUTCOMES

THE EVOLVING WORLD OF ARTIFICIAL INTELLIGENCE: RARE DISEASE IMPACT

A Q&A White Paper with **Oodaye Shukla,** *Chief Data & Analytics Officer,* HVH Precision Analytics, now EVERSANA™

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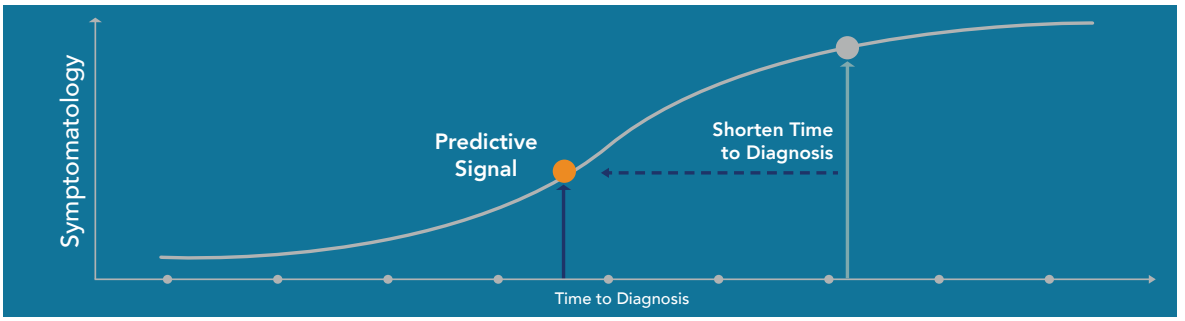
Q: From a data science perspective when we talk about analytics being used in the healthcare setting what does that mean? What is happening behind the scenes?

A: Massive volumes of healthcare data, petabytes and exabytes, are being matched with predictive and machine learning algorithms. These healthcare claims data repositories are mathematically compatible in terms of ingestion and scalability with the vast collection of machine learning and predictive algorithms available. This includes a suite of algorithms ranging from logistics regression to numerous variants of deep learning algorithms. It is the combination of a continuously growing amount of healthcare data with predictive technology that allows unexpected patterns and relationships to be uncovered. This fusion of medicine and technology has created the perfect storm for disruption in the healthcare space.

Q: How can predictive modeling impact the time and accuracy of rare disease diagnosis?

A: Searching for a rare disease diagnosis is often a frustrating process that can take many years. Applying predictive modeling techniques to healthcare data has accelerated the accuracy and speed of rare disease diagnosis. Imagine two scenarios, one where a physician (human) is diagnosing a patient and the other where a predictive algorithm (machine) trained to detect rare diseases is assisting a physician in diagnosing a patient. In first case, the lone physician relies on her medical knowledge and years of experience treating patients. But keep in mind that a physician may only see one rare disease patient (at most) in her entire career given the prevalence of rare diseases. Contrast this scenario with the one where the physician is leveraging the 'learnings' of a predictive algorithm (or model) that has been 'trained' on rare diseases. This predictive model during its training phase has learned the noisy patterns of care from the longitudinal health records of 100's of millions of rare disease and healthy patients. It can use this information to determine if the patient looking for a diagnosis matches the noisy patterns of care of a rare disease patient. During the diagnosis of a patient, this predictive model provides insights on the patient being diagnosed. The model would be able to alert the physician to the similarities of the patient to any one of 1,000's of rare diseases. Unlike the predictive model, the average physician cannot glean from her finite exposure to patients (numbering in the 1,000's) the subtle signs and symptoms indicative of a rare disease that develop over time. How can predictive modeling impact the time Q and accuracy of rare disease diagnosis? A 4 Using predictive modeling by leveraging healthcare data assets available today can significantly accelerate the accurate diagnosis of rare disease patients. With the right predictive model and data resources, it is possible to find patients hidden in healthcare databases and diagnose certain rare diseases in weeks compared to years. Imagine what this could do for patients and their families who are waiting for answers. The figure below is an illustration of the impact of earlier diagnosis with the assistance of predictive models.



Q: What are the key data sets being analyzed and signals being detected to identify undiagnosed patients? How can machine learning and predictive modelling impact this process?

A: Leveraging technology allows therapies to proactively find patients rather than patients needing to seek out therapies. Machine learning, and more specifically knowledge transfer techniques, enable the integration of seemingly disparate data sets to provide greater insight into patients' journeys and their disease progression. These data sets include healthcare administrative claims data, EMR/EHR data, genomic data, imagery, consumer, environmental and geospatial data. Building predictive models that deliver high fidelity predictions and actionable signals is of significant value. The end goal in leveraging predictive modeling is to derive a set of actionable signals that directly lead to an earlier accurate diagnosis and improved patient health. Given the current availability of large databases, machine learning and predictive modeling techniques generate insights from the data without any user bias or intervention. For example, it is now possible to determine the specific set or collection of data elements that are present months or years before a patient is diagnosed with a rare disease. These data elements are collected in an administrative claims database and are thus actionable in the sense that the treating physician can be identified who can then intervene to positively change the trajectory of a patient's health journey.

A: The amount of healthcare data collected is growing exponentially and shows no sign of slowing down. A typical analyses of healthcare data can determine the incidence and prevalence of a disease and indicate the number of patients with that specific diagnosis. However, incidence and prevalence based on real-world data now drives a number of business decisions such as, how many patients are available to support the investment required to develop the drug, execute a successful clinical trial, and bring the drug to market and whether an orphan designation can be sought for a therapy. Access to orphan drugs requires both awareness and education. The data sources and machine learning and predictive modeling tools enable the discovery of undiagnosed rare disease patients. Discovering undiagnosed rare disease patients drives efforts to increase awareness to all stakeholders. The most effective technique to raise awareness is to precisely target educational efforts that will have the greatest impact on getting undiagnosed rare disease patients on the right therapy.

Q: How are new data sources and analytic tools going to impact the way rare disease patients access orphan drugs?

Q: Technology continues to become more sophisticated and there seems to be no end in sight. Where is healthcare technology headed?

A: Technology is and will continue to be an enabler. The deployment of technology solutions will continue to accelerate. In addition, the promise of reduced healthcare costs and improved patient care will serve as the driver of technology solution adoption. Technology will allow healthcare to be conducted at the edge, meaning at home, in the community and outside of healthcare facilities. Routine health and wellness checkups will be significantly technology driven and will be a resource of patient generated data. One ubiquitous example is smartphone health applications that can capture various data points including physical activity, heart rate, ECG, blood glucose levels and measure gait. This is data that can be collected and processed continuously with the ability to provide real time feedback to patients. Overlaying this data generation and collection process, the application of machine learning and predictive modeling will enable proactive interventions reducing costly treatments. Other examples of patient generated data are digital therapeutics and potentially, smart speakers and electronic personal assistants. Healthcare technology is headed towards more patient autonomy and independence with less reliance on healthcare providers for routine care. The democratization of healthcare data is taking place that will enable, for example, the integration of personally generated data (smart home and smart personal devices) with data collected by healthcare professionals and an individual consumer's purchasing patterns. In addition, predictive modeling will enable more effective and prospective interventions that will lead to better disease management and reduced cost.

About Oodaye Shukla

Oodaye Shukla is the Chief Data and Analytics Officer at HVH Precision Analytics. He has broad experience in the Intelligence Community, Healthcare, Telecom and DoD industries spanning over 20 years.

About HVH Precision Analytics, now EVERSANA™

HVH Precision Analytics is a leading provider of advanced analytics and services utilizing global real-world data for actionable insights. Utilizing the most sophisticated defense-grade artificial intelligence and machine learning techniques, HVH is transforming the way biopharma companies identify diagnosed and undiagnosed patients and connect with providers anywhere and at any point in the product lifecycle. Powered by superior AI/machine learning systems, HVH aggregates and analyzes large amounts of disparate data to generate actionable insights to support our clients' precise requirements. We have provided actionable insights on nearly 200 diseases from ultra-rare to commonly diagnosed conditions.

PATIENT SWITCHING BEHAVIORS IMPACT ON ADHERENCE AND ENGAGEMENT:

A Predictive Analytics and Machine Learning Approach to Improving Hub Performance and Patient Outcomes

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Introduction

Today we have access to more data, from more sources than we could ever dream possible. Living in a digital world, we increasingly need the ability to efficiently and effectively process this data for insights and actions in order to be competitive. The life sciences industry can leverage this data using analytic tools and machine learning to rapidly identify patient behaviors and patterns – allowing us to predict "next best actions" in our quest to improve patient outcomes.

The key for pharma brands who increasingly play a role in supporting patients through their care journey is to think about how to implement predictions in the apparatus of patient and hub services. A prediction alone is not interesting. A prediction that enables an action and learns from the outcome of that action is what creates a high performance operation.

Problem Statement

Patient and hub services represent a significant and often ineffective spend surrounding overall patient support. How can we use data and analytics to build better patient services programs that predict next best actions and achieve improved patient engagement and outcomes across the treatment journey? As the industry continues its shift to value-based care, this challenge has never been timelier.

Company A was experiencing a universal brand challenge – lack of insight into and proof of what was working from both their product and operational sides of the business. Patients were either discontinuing use of their brand or switching to a competitor's brand after a single script. A true "One-and-Done" phenomenon had emerged. They believed that their brand challenges could be solved by investing in more Hub program services, but they couldn't tell which tactics were effective, and which were not.

We began our study by defining the challenges we wanted to solve: identifying the key drivers of a patient's switch to a competitor's brand or discontinuation of use of Company A's brand; and providing clarity on how hub efforts were affecting results. Using predictive analysis and machine learning, we would develop a model to inform personas of patients who discontinued and switched, provide data-driven predictions for patients to inform hub action, and then track how hub performance improved and the impact on hub resource utilization.

> By showcasing how the actions at each step in **ACT**ICS BY EVERSANA™ added value to the model, we demonstrated a successful process for improving patient adherence by >50%.

To train our model we selected a list of features to assess during our analysis. These features represent both clinical attributes of the patient and socioeconomic factors such as financial status, insurance coverage, and interface with the healthcare system:

- Patient Demographics: age, gender, geographic location, medical measurements (BMI, weight, etc.)
- Medical/Clinical Characteristics: comorbidities and preexisting diseases, side effects (of therapy)
- Treatment-Related Metrics: duration and number of refills when on therapy, prior drug usage, compliance

- Physician Characteristics: therapy loyalty, HCP change (during switch), physician specialty
- Insurance Characteristics: Level of copay (high, medium, low), type of insurance/payment, prior authorizations (PA), step therapy (ST)

Leveraging our secure and compliant technology platform, **ACT**ICS BY EVERSANA™, we ingested claims, hub, formulary, social determinants of health, and clinical data. We trained multiple model types (SVM, LSTM, CNN, XGBoost, Regression, and others), optimized feature selection and weighting, applied techniques such as bootstrapping and ensemble analysis, and selected the most optimized model based on train/test techniques, data splitting, and a variety of statistical measures on model performance. Details on the study's methodology will be available July 24 on eversana.com/insights under the title: *Methodology for Predicting Switching Behaviors in Patients.*

Terminology

Before we jump into the focus of this white paper let's level set on the terminology I'll be using throughout this piece. Take a look at the chart for key definitions.

Accuracy	Proportion of true results predicted, either True Positive or True Negative, by a model
Precision	Proportion of predicted positives (desired); how many are True Positives
Recall (Sensitivity)	Proportion of actual positives, how many are accurately predicted (True Positives)
F-1 Score	Measure of model's true accuracy. How well balanced the model is between precision and recall (mathematically), is a harmonic mean of the two
R-Square Value	Statistical measure that represents the proportion of the variance for a dependent variable that's explained by independent variables in a regression equation

Approach and Importance of Data Integration

In my last **paper**, I discussed the importance of knowing your data integration and analytics platform strategy and how data is used. The solutions we build must establish metric-based patient segments along with data-driven approaches to patient profiles. This is important to understand because we know that patients have different adherence issues, communication preferences, and triggers that influence their behavior. The ability to track messages and segment performance, and be supported by a learning system that optimizes engagement is key to improving health outcomes. So, in building a model to capture the valuable insights that will help us improve patient outcomes, every aspect of the patient journey must be included.

Clinical and Market Findings/Insights

The data we collected and analyzed on Company A's clinical challenge around brand switch showed us that:

- Patients with prior disease state experiences are likely to continue on therapy; however, that probability is influenced by comorbidity, side effects, insurance status and social determinants of health
- Patients with no prior disease state experiences may need more education and assistance (medical and financial) during initial days of therapy when compared with those having prior drug experiences
- Among patients who switched therapy, 16% switched back
- Higher out-of-pocket costs increases the probability of switching and discontinuing
- Patients initiated on commercial insurance or assistance programs demonstrated higher probability of discontinuation and switching
- Majority of patients who pay in cash discontinue from therapy
- 53% of patients who initiated on assistance programs (~11K), eventually switched or discontinued

> Predictive analytics and machine learning have the potential to transform healthcare by driving performance optimization for patient services, field solutions, clinical trial recruitment, and supply chain distribution.

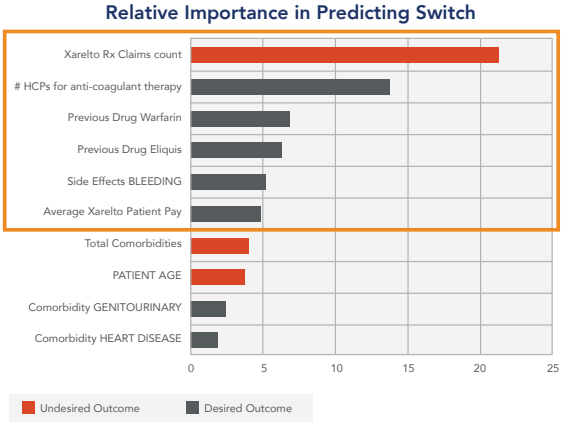
This insight provided the foundation from which we would build our model. Knowing that all of these factors impact patient behavior and action, we could then identify and create the personas that would provide a more accurate understanding of how patients are likely to engage with patient services providers and hub programs. In designing solutions, we needed to understand the environment in which our patients behave, as well as understand their coverage and affordability challenges. This insight helps us better predict next best actions and leads patient services providers to focus on customizing several different technology and engagement solutions.

Description of Model Findings

Patients fundamentally have different adherence issues – a one-adherence-solution for all patients ignores patient segments. We know that each path a patient takes during the treatment journey gives us the opportunity to build a patient persona and predict optimal adherence solutions. We segmented and described the unique persona patterns of patients who responded to existing hub services, and identified several patient persona paths including comorbidity, history of depression, no inpatient treatment, low cost of care, age, digitally engaged, and lower educational background.

FIGURE 1 showcases the results of our switching model, validating the accuracy of our AI platform. In addition to being accurate, the model had a high Negative predictive value (NPV). In simple terms the model is particularly good at predicting correctly that a patient would continue therapy. From a hub utilization standpoint this means that we could accurately determine which patients didn't need additional hub support. This translates directly to resource savings, perhaps allowing us to offer more resources to patients that we did not predict would continue therapy.

Figure 1



Key Notes

- Statistically, model contains significant predictive capacity
- More HCP switches indicate a likelihood of patient switch
- Previous anticoagulant therapy indicates likelihood of patient switch, provided there is other concerning situation (such as side effect, etc.)
- Side effects, especially bleeding, indicates likelihood of patient switch
- Higher average OOP costs indicate likelihood of patient switch

Evaluator	Value
Accuracy	93%
Precision	87%
Recall (Sensitivity)	74%
F1-Score	80%
R-Square value	60%

Actual/Predicted	Negative *(Patient Continues)*	Positive *(Patient Discontinues)*
Negative *(Patient Continues)*	42,912	1,184
Positive *(Patient Discontinues)*	2,859	8,210

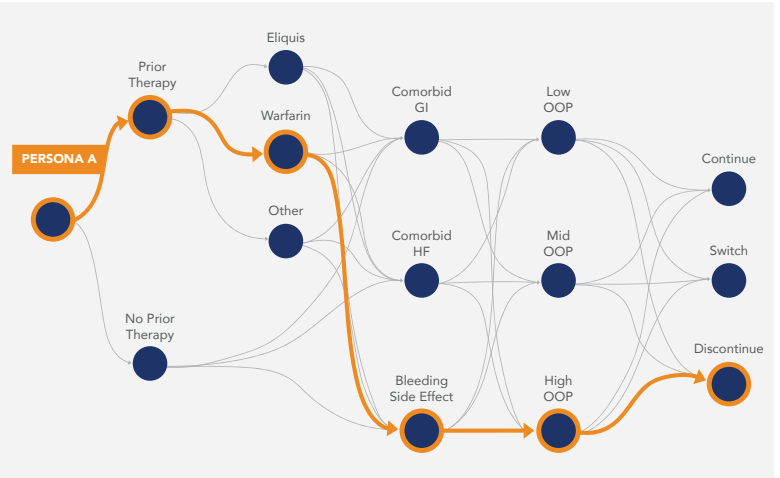
At hub intake, we have the capability to capture the following information to appropriately route each persona: comorbidity, inpatient vs. outpatient, medication expense, age, and location. We then identified that the optimal patient solutions support included app- and text-based communication and recommended physician engagement.

Taking Action From Prediction That Has Measurable Impact

There are many circumstances that compound the probability of medical adherence. We needed to accurately predict patient personas who are likely to switch, abandon, nonadhere or require financial support. By identifying the path a patient is on we can predict probability of nonadherence and measure the size of the potential impact across the product lifecycle. Data points from all aspects of the patient's health journey were gathered, analyzed and incorporated to create an authentic persona. Once the persona was created, patients were matched to similar patients that shared that persona and contrasted based on their actions and engagement to predict the path that the patient is likely to take.

Every step of the patient journey generates actionable data that enables our ability to engage patients with personalized content. We know that by finding patients early in their treatment journey and by helping them engage with treating HCPs and Hub personnel, we can have a positive impact on their journey.

Figure 2



Variable	Description	Variable Predictive Value	
Discontinue Timing	<30 days		
Initial Fill (days)	Below 14 days	High	
Initiating HCP	Therapy Loyalist (50%+ scripts are Therapy)	Mid	
Co-morbidity	Musculoskeletal Disorders High Blood Pressure High Cholesterol Non-Diabetic		Overall Model Accuracy F-1= 0.89-0.98
Payer Mix	Medicare, Assistance Programs, Commercial, Cash	1%	

- There are ~600 (0.7%) patients similar as Persona A
- The average initial Therapy fill for this cohort is 10 days
- The model can make up to 98% accurate predictions for this cohort
- This cohort is extracted from statistically significant classification exercise

Prediction enables actions to be taken and existing resources to be better utilized. In **FIGURE 2**, we trace the path of one of the personas we created, Persona A, who originally discontinued Company A's therapy. We developed a unified data set – consisting of demographics, income data, total Rx costs per year, estimated out-of-pockets, and total cost of care – to help train our model. Patients were identified from the database at the time of hub enrollment that matched Persona A and deployed/enrolled into the hub process. The results of our modeling showed a 98% accuracy rate in our ability to describe the type of patients, or personas, across the model.

Process and Resource Utilization Findings for HUB Performance

Data analysis on Company A's hub programs provided this insight:

- Current hub efforts included insurance/benefit verification, financial assistance, adherence programs, patient and physician education, and nursing support
- One and Done: Despite all programs less than 50% of patients stayed on therapy through second refill
- Targeted messages to patients with prior experiences were sent, yet pull-through was unclear, and the One and Done rate remained similar
- Increased adherence program outreach and copay coupon buy-up occurred simultaneously and the One and Done improved by 4%, but attribution was impossible and costs increased 30%

Implementing Predictions in HUB, and Predicting Communication Response

Single communication types ignore a variety of patient engagement behaviors. We found that by altering content and communication mediums, and by delivering a copay card via an app, we maximized Persona A's ability to refill his script two days ahead of scheduled refill.

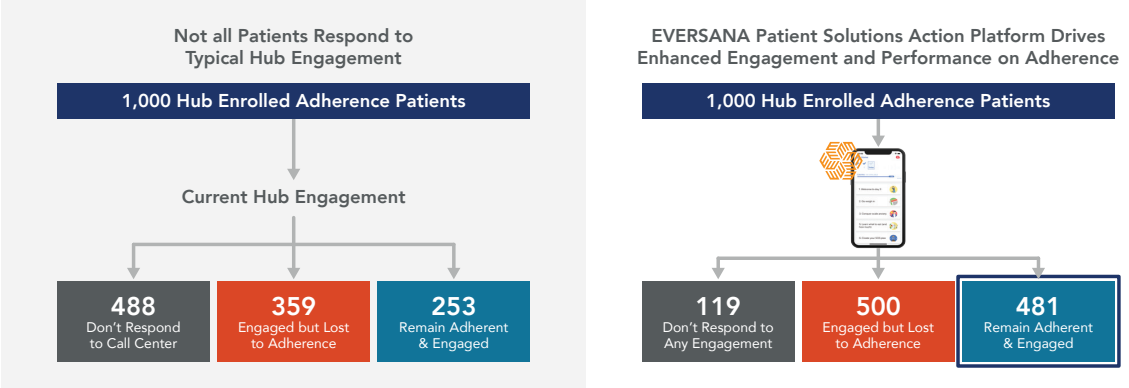
The system "learned" how well Persona A did with that action and improved its ability to predict – allowing us to successfully predict the next best action. Each persona would have a different predicted route to an optimal patient solution.

We recognize that not all patients respond to typical hub engagement, so we compared Company A's hub performance on 1000 patients against patients put through **ACT**ICS BY EVERSANA™ – a platform designed to focus on enhancing patient engagement and driving improved adherence performance. In **FIGURE 3**, you will see that EVERSANA's Platform led to a >50% patient adherence increase in just a 3-month period. Predictions on patient personas were used to drive utilization of hub resources. We took into consideration Company A's current hub activity with 253 adherent patients and we began to add:

- The adherence risk profile model increased adherence from 253 to 301
- Tailoring communications preferences predictions brought the number of adherent patients in the hub to 377
- Alternative messaging increased from 377 to 420 adherent patients
- Optimal financial support gave us a total of 481 adherent patients

Figure 3

In side-by-side comparison of 1000 hub patients we compared the effect of the EVERSANA Platform.



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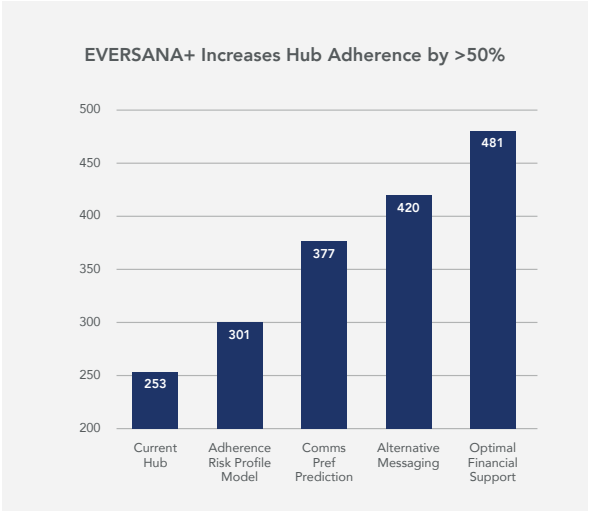
> EVERSANA's end-to-end analytics platform drives incremental value and actions across the product lifecycle and can help clients proactively improve patient identification, acquisition, conversion, and retention.

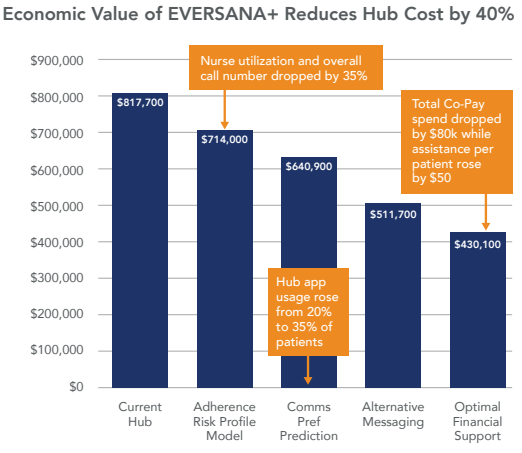
By showcasing how the actions at each step in the patient analytics platform process added value to the model, we demonstrated a successful process for improving patient adherence by >50%. **FIGURE 4** demonstrates the economic impact of **ACT**ICS BY EVERSANA™ vs. Company A's:

- Hub costs were reduced by 40%
- Nurse utilization and overall call numbers dropped by 35%
- Hub app usage rose from 20% to 35% of patients
- Total copay spend decreased by $80K while assistance per patient rose by $50

Figure 4

Improvement in adherence plus cost savings for 1000 patients





Conclusion

What we demonstrated

The goal of this study was to demonstrate how the power of technology can drive the success of patient services hub programs operations, and showcase the value of predicting the next best action in increasing the effectiveness of keeping patients on therapy. Through predictive modeling, we showcased new ways to improve and manage patient outcomes and treatment pathways, increased the value of hub performance, and demonstrated measurable economic value.

Why it is valuable

Through the accuracy of predictive analytics tools and machine learning we can identify and engage with patients across each stage of their treatment plans. These tools allow us to predict the probability of nonadherence, develop patient personas, recommend hub tactics actions, and measure the size of the potential impact. **ACT**ICS BY EVERSANA™ is designed to enable data integration and predictive actions. It drives incremental value and actions across the product lifecycle and can help clients proactively improve patient identification, acquisition, conversion, and retention.

How we enhance both insight, problem identification, process and spend

We built a predictive model to give us insight into patient switch behaviors and actions in therapy in order to improve hub utilization. We created patient personas profiles and employed **ACT**ICS BY EVERSANA™ to showcase enhanced patient engagement and improved adherence performance by routing patients to optimal solutions. Our experience has proven that the best results are achieved by understanding and optimizing each step of the process.

Ultimate brand goal

Predictive analytics and machine learning have the potential to transform healthcare by helping us identify diseases faster, decrease costs through precision therapies, improve clinical trial enrollment, and increase operational effectiveness. As demonstrated in this paper, the technology drives performance optimization, and can do the same for many services including field solutions, clinical trial recruitment, and supply chain distribution, just to name a few. We can expect the next generation of patient services will significantly improve health outcomes through high-touch patient engagement and, technology and data analytics will play a key role.

SEEKER HEALTH® BY EVERSANA:

TARGETED DIGITAL PATIENT ENGAGEMENT

eversana.com

As the patient point of care continues to change and evolve, EVERSANA has identified challenges facing how we interact with patients, and how these challenges will impact patient engagement now and in the future.

Challenges facing clinical trials

For ongoing studies, the primary concern is the safety and well-being of the participating patients. Clinical trials commonly require participation from patients that may be vulnerable to infection or need support from a caregiver, and travel to sites is a challenge.

The willingness and ability of potential patients to travel to study sites may inhibit many potential patients from participating. Increased patient anxiety and hesitancy to visit healthcare facilities and the contamination risk between patients, sites, and the community are also potential variables that will impact trial participation.

Bringing the trial to the patient

The solution to these challenges is adjusting the patient's point of care (POC). The FDA's March 2020 guidance clarifies that the safety and well-being of clinical trial patients are the primary concern of sponsors conducting clinical trials. The guidance issued by the FDA recommends that sponsors evaluate whether in-person assessments are necessary, and alternatives to in-person clinic visits and locations should be considered.

Despite this guidance, the difficulty of conducting trials in an adjusted POC model is exceptionally high. Even if companies can add virtual elements to the trial and incorporate more digital technologies to track patients and enhance data and analytic capabilities, that doesn't mean that most sponsors can do so or have the expertise to make it happen.

Permanent impact on clinical research

Sponsors will need to establish enrollment agility to manage disruption at some of their sites and identify all options and support services for enrolling more patients at study sites that can continue trial enrollment while minimizing patient risk.

Sponsors need to embrace technology and innovation; what was once considered nice to have study support tools is now mandatory. These tools, such as digital patient recruitment and screening, at-home and telehealth study visits, and direct to patient medication transport, shift the dependence of trial success away from the study site and more wholly on the patient.

These solutions are undoubtedly here to stay in study conduct, and in turn, this will open the door for smarter digital health solutions and patient monitoring apps. What was considered "remote monitoring" will become highly accurate, patient-centric data collection tools that enable cleaner trial data, less burden on site staff, and more patient compliance.

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Through the Seeker Portal™

Supporting patients and providing them with valuable information is critical in addressing these priorities. To that extent, EVERSANA has introduced and personalized multi-channel outreach campaigns to inform patients of relevant updates, safety measures and risk levels. This shift in communication focuses on maintaining effective patient engagement to ensure patients' successful participation in a trial.

To best ensure the safety of all patients, outreach campaign tactics must be transparent and include proactive decisions and modification of traditional engagement into direct patient engagement through digital channels. Our Seeker Health team has expertise in developing digital engagement channels that support clinical trial recruitment. We are equipped to make screening continuity decisions quickly, mitigating the impact on the drug development process.

Seeker Enrollment

CHALLENGE:

Finding, engaging and enrolling patients outside the traditional site-network.

OUR SOLUTIONS:

- Personalized, ongoing multi-channel digital outreach campaigns
- Fully integrated, decentralized support from recruitment to study execution
- Person-to-person call center support
- Home nursing visits integrated into the patient recruitment CRM

Seeker Outreach

CHALLENGE:

New therapy for an ultra-rare disease was released, struggling to make patients and HCPs aware of a new treatment.

OUR SOLUTIONS:

- Fully integrated digital customer acquisition funnel
- Direct to patient awareness campaign and HCP finder support

CHAPTER 2:
THE NEW GOLD STANDARD OF COMMERCIALIZATION

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THE NEW GOLD STANDARD OF DRUG COMMERCIALIZATION

*How EVERSANA™ **COMPLETE** COMMERCIALIZATION brings drugs to market with an end-to-end commercialization engine powered by organic connectivity and synergy*

Greg Skalicky, Chief Revenue Officer, EVERSANA

We find ourselves in a brave, new world. While institutional market sectors such as entertainment and hospitality struggle, life sciences find comfort in the promise of a growing therapeutic pipeline. However, now more than ever, we must look for ways to streamline cost and mitigate risk. When working with established pharmaceutical companies or emerging entities, we recommend turning our clients' attention away from traditional launch and commercialization approaches that may not stand the test of time.

Manufacturers spend >$125MM over three years leading up to launch, yet 66% of drugs don't meet launch expectations.[1] An unpredictable landscape, coupled with inevitable industry pressures, is forcing manufacturers to seek a more complete commercialization approach with less risk and more value.

Manufacturers wrestle with multiple industry pressures.

- **Resource Demands Constantly Fluctuate:** Fluctuations cause financial risk and unpredictability.
- **Market & Product Complexity:** Flawless operational excellence is crucial in field solutions and patient services.
- **Challenge to Identify Deep Bench:** Delays in hiring top talent reduces time to market and risks success.
- **Uncertain Technology Investments:** Data integration often lacks the necessary analytics needed to make informed decisions.
- **Raising Capital to Launch:** Launch demands millions of dollars and there are no cost-cutting alternatives.

Selling or in-licensing their product to another pharmaceutical company with an established infrastructure (e.g., field solutions, patient services and channel distribution) is a common pathway manufacturers use to commercialize. The problem with this strategy is the loss of ownership in an investment that takes years – sometimes decades – to develop. Manufacturers should not be forced to sacrifice their value just to make their life-altering drug available to patients; nor should they have to invest $125MM+ over three years to commercialize on their own. Until now, there was no other way.

The First & Only Go-To Complete Commercialization Expert in the Industry

In 2018, EVERSANA, a leading provider of commercial services to the life science industry, implemented a strategy to offer a complete, full-scale, customized model for product commercialization. Our end-to-end commercialization engine, officially referred to as EVERSANA™ **COMPLETE** COMMERCIALIZATION, gives manufacturers full access to launch strategy, execution and long-term outsourced services (including distribution, field support and patient hub services) through a contracted, multi-year model. We invested over half a billion dollars, so manufacturers and investors don't need to; plus, we continue to invest significantly year over year.

In partnering with EVERSANA, manufacturers and investors alike:

- ✓ Maintain full ownership of their asset.
- ✓ Capture full revenue potential through maturity.
- ✓ Optimize their launch performance.

With over 25 years of experience spanning all facets of the pharmaceutical industry, I believe this model enables a critical factor no company ever dared to achieve: organic connectivity and synergy throughout all

stages of commercialization. Guided by one dedicated commercialization leader and supported by a deep bench of industry experts, a manufacturer can partner with EVERSANA to maximize streamlined communications and operational efficiencies. Employing a single team with one shared goal enables a manufacturer to overcome external pressures, mitigate risk and successfully bring its drug to market; **COMPLETE** COMMERCIALIZATION is quickly becoming the new gold standard.

Unified, Predictive and Actionable Data Maximizes Growth Potential

Product launches for unique, life-altering therapies demand integrated data and analytics across the patient journey. Our investments in military-grade artificial intelligence and machine learning have strengthened our commercialization engine with the power of predictive analytics to improve patient outcomes, such as shortening the time to accurate diagnosis by years or identifying undiagnosed patients with a rare or complex condition.

Our predictive platform built on unified patient data – combined with our best-in-class patient engagement, market access and distribution solutions – affords EVERSANA the unique ability to:

- ✓ Maximize the ROI of data and analytic investments,
- ✓ Enhance decision-making, and
- ✓ Create a seamless patient journey, influence ideal behaviors and positively impact outcomes.

EVERSANA **COMPLETE** COMMERCIALIZATION breaks down traditional health care silos to deliver actionable data analytics that drive decisions: understand the complexity of disease, improve forecasting and communications with patients, design more effective clinical trials, predict trends, customize treatment pathways and so much more.

Real-World Impact: Partnership With Zosano Pharma

EVERSANA recently announced a partnership with Zosano Pharma to commercialize and distribute Qtrypta™, a first-of-its-kind transdermal microneedle therapy for the acute treatment of migraines.

"This collaboration enables us to access a comprehensive commercial organization without the significant expense and time that would have been required to build our own infrastructure. We and EVERSANA have been working closely to ensure our commercialization strategies are aligned to provide appropriate resources to enable patients to access Qtrypta if approved," said Steven Lo, president and CEO of Zosano.

With this partnership, Zosano is able to bypass fundraising for their launch and maintain the vast majority of the economic value of their product that would be lost if they licensed it out. Additionally, Zosano was able to minimize risk and exposure while reducing their up-front cash investments.

Conclusion

In my opinion, this innovative commercialization model, while groundbreaking, may in fact be the safest bet for those looking for less financial risk without compromising market impact. Our complete end-to-end commercialization model enables manufacturers to bring their drug to market at a fraction of the cost of "going it alone" or partnering with another pharmaceutical company. In a world that is ever-changing, traditional strategies demand a tune-up as well.

1. Ten years on: Measuring the return from pharmaceutical innovation, 2019. Deloitte Center for Health Solutions. Beyond the storm: Launch excellence in the new normal, McKinsey & Company.

THE CHRONIC MICROCAP TRAP

HOW LAUNCH IS THE ESCAPE FOR TRUE GROWTH

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The Chronic Microcap Trap: How Launch Is the Escape for True Growth

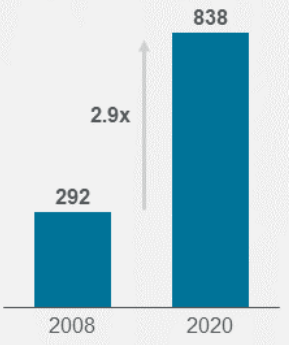
Pre-commercial pharma companies face a common choice: commercialize products independently or collaborate with another pharmaceutical company as a commercialization partner. As the C-suite leaders in these organizations wrestle with the pros and cons of this choice, one factor they must consider is the impact their decision will have on their current and future market valuation. The question is this: How much of a premium does the market put on a company that chooses to launch and commercialize its product independently? As Figure 1 suggests, that premium can be substantial. The average market capitalization of a cohort of public companies that developed paths to launch their own products (including successful and sub-optimal launches) was over six times greater than a cohort of public companies who consistently license with other pharma companies to launch their products.

Figure 1: Ratio of average market capitalization between a cohort[1] of 'Launch' and 'License' public companies

[1] The 'Launch' cohort consists of 33 companies that commercialized their own product and the 'License' cohort has 17 that partnered with larger biopharma companies

SOURCE: EVERSANA Analysis

Figure 2: Number of public biotech companies with market capitalization less than $250M



SOURCE: Nature Biotechnology Survey 2008, EVERSANA Analysis

A company that successfully launches and commercializes its product independently generates revenue and earnings that stay within the company's walls, as opposed to taking only a small percentage of royalty revenue from licensing its asset. The cash the company generates from independent commercialization can fuel further clinical development programs and acquisitions, which can set the stage for a completely different growth path. Hence, a company that is successful at commercialization commands significantly higher market capitalization estimates compared with companies that choose to license their products.

As illustrated in Figure 2, the universe of nanocap and microcap pharma companies continues to grow, creating a growing backlog of companies trying to chart the course away from being a permanent microcap company and toward becoming a mid-cap or even large-cap company. Clearly, the primary means of reaching that goal is successfully launching and commercializing products independently.

Launch Can Be Too Expensive and Complex to Execute Independently

Though an independent launch may be the "obvious" choice based on market cap impact, the harsh reality is that few companies are able to execute a launch on their own. To launch an asset with even a modest market opportunity can be a costly endeavor. On average, funding the pre-launch and five-year post-launch activities for a product can range from $200M - $450M (Figure 3). If companies underfund their launch, they risk undermining the commercial potential of the asset. Even if companies choose to allocate conservative funds for commercialization, they still face funding requirements that could exceed their current market capitalization in the nanocap and microcap space.

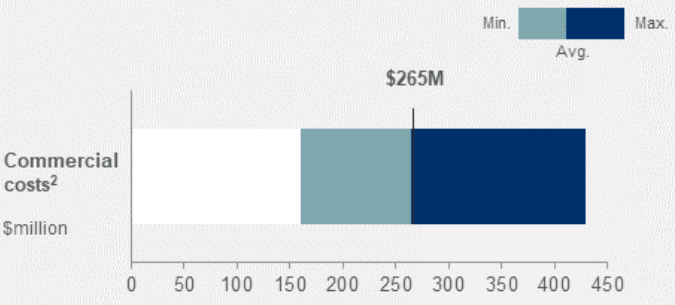
In addition to significant funding requirements, launching a pharmaceutical product requires significant and highly technical subject-matter expertise from a finite pool of talent resources who are in high demand in the pharma and biotechnology industries. You cannot fake your way through product commercialization in the pharmaceutical industry. Companies require professionals who have a strong command of the given market they are trying to serve while being able to navigate strategic, operational, regulatory and scientific issues. This is a non-trivial set of skills that cannot be established quickly or easily *de novo*.

Even when companies have sufficient funding and talent, they still face significant risks and challenges related to establishing an operational backbone of technology, supply chain and services, all of which require a high degree of orchestration of various internal and external (third-party) agencies.

Faced with these challenges, many companies are unable to justify the potential investment based on the risk and limited funding channels at their disposal. Consequently, the choice between independent commercialization and licensing skews heavily toward licensing to another pharma company that already possesses the commercial infrastructure and resources to successfully launch their product.

> **"A launch winner yields 12 times the growth vs. a license winner yielding just double growth."**

Figure 3: Range of commercial costs to launch a product ($M)



[2] Includes 12-18-month Pre-Launch costs and 5-year commercial costs

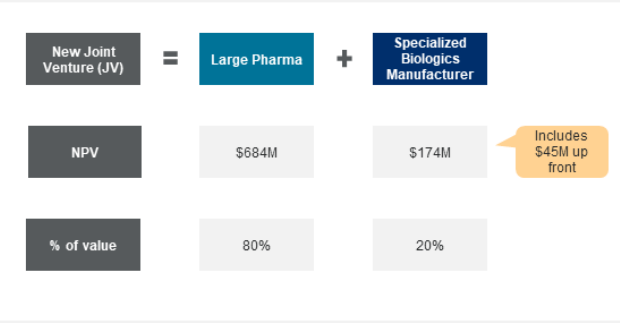
SOURCE: EVERSANA Analysis

Realizing Sub-optimal Value Creates a Microcap Trap

Once a company reaches the conclusion that the odds of successfully launching on its own are low, the company naturally turns toward licensing, partnership and co-commercialization options. The upside to these options is the ability to get the product to patients, address unmet needs, and realize the commercial value of the product. Unfortunately, the majority of the commercial value does not flow back to the company with the asset. As Figure 4 suggests, approximately 80% of the commercial value goes to the company with the commercial infrastructure.

Nanocap and microcap companies and their shareholders have been conditioned to believe and accept that this result is as good as it gets in terms of a successful outcome. However, the market recognizes the limitations of these types of partnerships and reflects those limitations in the stock price. Most nanocap and microcap companies become a permanent resident in this space. The companies that end up forming partnerships may get some increase in valuation, but that value is far below the valuation of companies that have been able to commercialize their assets and retain the majority of the commercial value. We conducted a cohort analysis to substantiate this claim.

Figure 4: Large pharma company forms alliance with a biologics manufacturer to develop and commercialize product



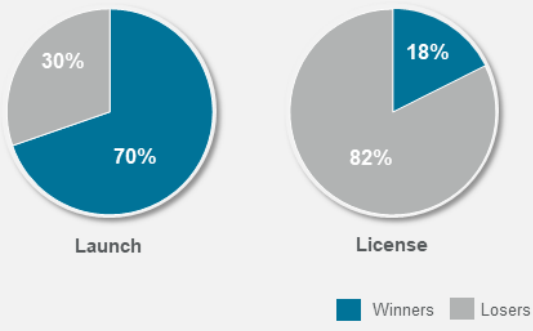
SOURCE: EVERSANA Analysis

We assembled and examined two representative sample cohorts of companies to understand the relationship between independent commercialization and partnering for commercialization.

- **Cohort 1:** "Launch" comprised companies who successfully launched and commercialized their assets independently.
- **Cohort 2:** "License" comprised companies who utilized partnering with other biopharma companies as their primary means to generate value for their assets.

We then tracked the change of market cap for each company, identifying "winners" (market cap increased) and "losers" (market cap decreased) within

Figure 5: Proportion of 'winners' in the Launch and License cohorts



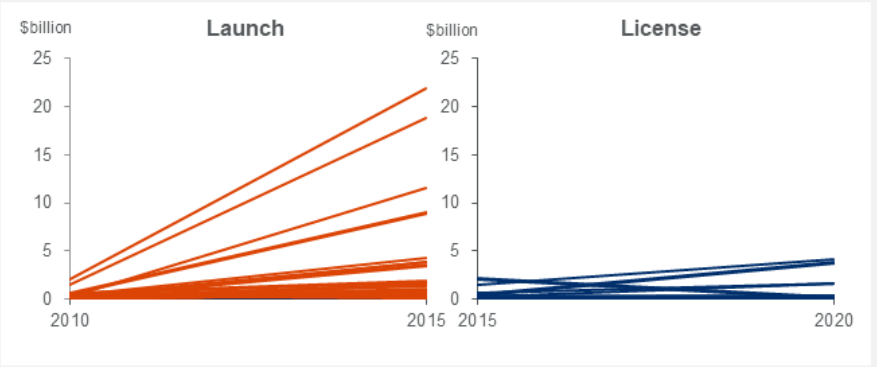
SOURCE: EVERSANA Analysis

each cohort. We also measured the change in market cap over time to understand how much of an impact/advantage independent commercialization had on the long-term market capitalization of a company.

The results were astonishing. As shown in Figure 1 of this paper, the average market cap of Cohort 1 vs. Cohort 2 had almost six times the advantage. Exploring the data further uncovered additional insights (see Figure 5); we noticed that there were far more winners in Cohort 1 than in Cohort 2. Essentially, companies who were able to launch their own products have a 70% chance of dramatically increasing the market capitalization of their company and escaping the chronic microcap trap. However, companies who license their products have only an 18% chance of escaping the trap.

In addition to more winners, the impact size of winning was far greater in Cohort 1 than in Cohort 2. Figures 6, 7 and 8 indicate how the winners in Cohort 1 saw an average 12-fold increase in their market cap. While the winners in Cohort 2 realized only double an average increase in their market cap.

Figure 6: Market capitalization trend for companies in the Launch and License cohorts over a period of 5 years



SOURCE: EVERSANA Analysis

Figure 7: Companies in the License cohort

License cohort	Market Capitalization: Initial ($M)	Market Capitalization: Current ($M)	Time period	Increase in Market Capitalization	Winner/Loser
License company 1	400	3870	6	10x	Winner
License company 2	514	1590	7	3x	Winner
License company 3	798	1370	5	2x	Winner
License company 4	142	382	7	3x	No change
License company 5	205	384	11	2x	No change
License company 6	360	550	4	2x	No change
License company 7	31	33	7	1.1x	Loser
License company 8	212	205	1	1.0x	Loser
License company 9	251	223	5	0.9x	Loser
License company 10	390	260	4	0.7x	Loser
License company 11	2950	1670	1	0.6x	Loser
License company 12	449	238	8	0.5x	Loser
License company 13	460	192	8	0.4x	Loser
License company 14	580	203	4	0.4x	Loser
License company 15	107	32	11	0.3x	Loser
License company 16	17000	4100	3	0.2x	Loser
License company 17	255	21	6	0.1x	Loser

SOURCE: EVERSANA Analysis

"Companies that launched were ~4 times more likely to become a winner (i.e., escape) vs. companies that licensed."

A vicious cycle can occur with nanocap and microcap companies that initiate licensing deals. The proceeds they receive from these deals may be just enough to generate a handsome return for shareholders but are insufficient for funding meaningful growth. This lack of funding for growth keeps these companies highly dependent on larger pharma companies for further partnerships rather than being able to grow on their own. Thus, these companies become trapped in the nanocap and microcap space for much longer than they would be if a successful and viable commercialization option were available to them without surrendering so much of the commercial value.

Figure 8: Companies in the Launch cohort

Launch cohort	Market Capitalization: Initial ($M)	Market Capitalization: Current ($M)	Time period	Increase in Market Capitalization	Winner/Loser
Launch company 1	40	8600	16	215x	Winner
Launch company 2	9	940	11	106x	Winner
Launch company 3	25	1600	11	63x	Winner
Launch company 4	207	12800	11	62x	Winner
Launch company 5	88	4100	11	46x	Winner
Launch company 6	487	22500	22	46x	Winner
Launch company 7	299	12430	11	42x	Winner
Launch company 8	240	9900	11	41x	Winner
Launch company 9	222	8600	11	39x	Winner
Launch company 10	430	13100	11	30x	Winner
Launch company 11	640	18300	11	29x	Winner
Launch company 12	91	2600	11	29x	Winner
Launch company 13	601	13300	11	22x	Winner
Launch company 14	348	7600	11	22x	Winner
Launch company 15	274	5980	11	22x	Winner
Launch company 16	180	3530	11	20x	Winner
Launch company 17	167	3030	6	18x	Winner
Launch company 18	276	4400	6	16x	Winner
Launch company 19	508	7600	6	15x	Winner
Launch company 20	117	1400	8	12x	Winner
Launch company 21	2301	21600	9	9x	Winner
Launch company 22	154	764	11	5x	Winner
Launch company 23	540	2400	4	4x	Winner
Launch company 24	1316	1459	7	1.1x	No change
Launch company 25	434	427	11	1.0x	Loser
Launch company 26	574	562	14	1.0x	Loser
Launch company 27	611	509	6	0.8x	Loser
Launch company 28	910	553	4	0.6x	Loser
Launch company 29	419	244	7	0.6x	Loser
Launch company 30	259	115	11	0.4x	Loser
Launch company 31	696	234	4	0.3x	Loser
Launch company 32	3350	594	6	0.2x	Loser
Launch company 33	430	6	11	0.0x	Loser

SOURCE: EVERSANA Analysis

Launch Is the Way Out of the Trap, But It's Not So Easy

Several attempts have been made to help nanocap and microcap companies commercialize their products independently and avoid the trap of being a chronic tiny-cap company. Unfortunately, these attempts have failed or faltered for reasons that include lack of comprehensive breadth of strategic and operational capabilities, limited technology and supply chain infrastructure, poor financial wherewithal to handle funding requirements, and the risk profile of the biopharma asset.

Sometimes these attempts failed or missed expectations because they emphasized only certain aspects of commercializing a biopharma product or they focused on building capabilities that were "just good enough" rather than being forward looking and able to adapt to various launch markets and indications. Most importantly, attempts failed due to misaligned internal incentives, resulting in challenging coordination and collaboration across various disciplines and subject-matter experts. Seamless coordination and future cross-functional collaboration must be the standard rather than the exception.

These launch challenges should be acknowledged head-on and early in order to develop a successful commercialization capability. EVERSANA was founded to help companies address these challenges and realize the full value of their products.

COMPLIANCE – THE COMPETITIVE DIFFERENTIATOR TO COMMERCIALIZATION:

An Integrated Model Setting the New Global Standard

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This white paper demonstrates how integrated life sciences compliance has earned its seat at the table by demonstrating the value of increasing data-driven and technology-infused competitiveness in the successful commercialization of a new-age biopharma product. Through the lens of an integrated pharmacovigilance, medical affairs, regulatory and quality team, we'll outline the challenges manufacturers face in bringing a brand to market; detail how the integration of services, process and technology leads to increases in safety and efficiencies; and stress the importance of moving compliance from a cost center to one of value and insight. As part of a larger commercial platform, we will define how this holistic approach is fast becoming the new global standard of compliance that proves to be the competitive differentiator to commercialization.

Global Market Dynamics Create a Need for a New Compliance Model

Compliance is an integral part of the entire biopharma, medical device and SaMD (Software as a Medical Device) product lifecycle, yet it poses one of the biggest challenges for our customers: They want to focus on driving value, innovation and patient centricity but find that much of their efforts and finances are still being invested in managing regulatory obligations.

Challenges are spread across internal factors, such as obsolete and disconnected platforms, multiple silos and manual processes, to external factors like the changing regulatory landscape and increased scrutiny of regulators. Competitive forces leading to innovatively deploy the latest R&D technology to better understand and influence patient behavior throughout the patient journey add further complexities to managing end-to-end compliance.

These challenges prevent our customers from moving the needle of compliance from cost to value. **FIGURE 1** shows how we've condensed these market dynamics into the four categories – identifying the biggest challenge for customers as siloed vendors, which leads to inefficiency across operations and technology, and the inability to drive true value from data and taking end-to-end accountability for real impact on better drugs and patient centricity.

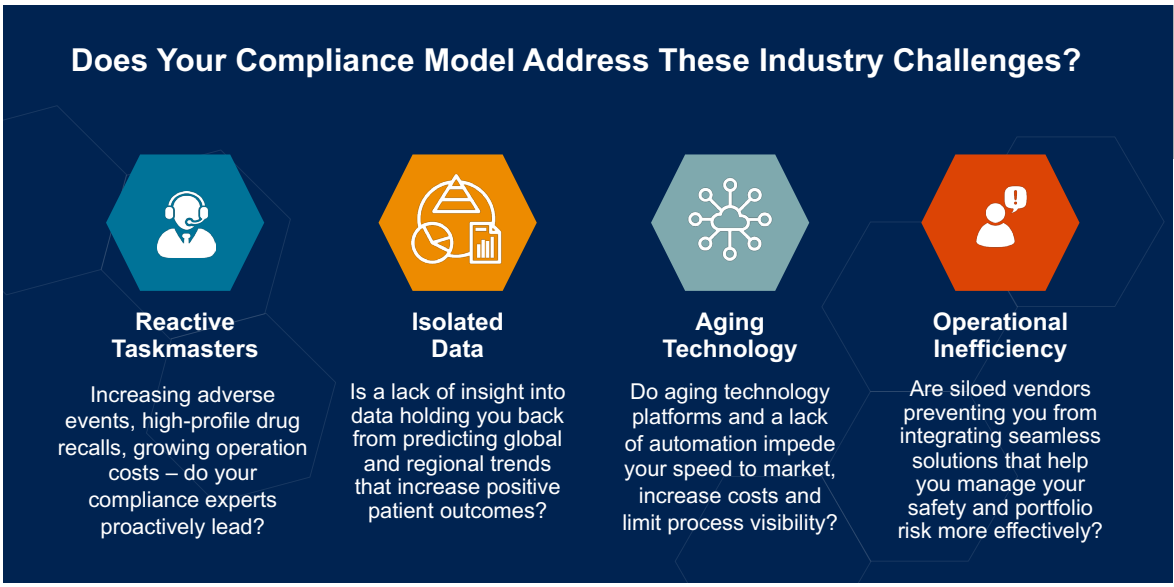


FIGURE 1

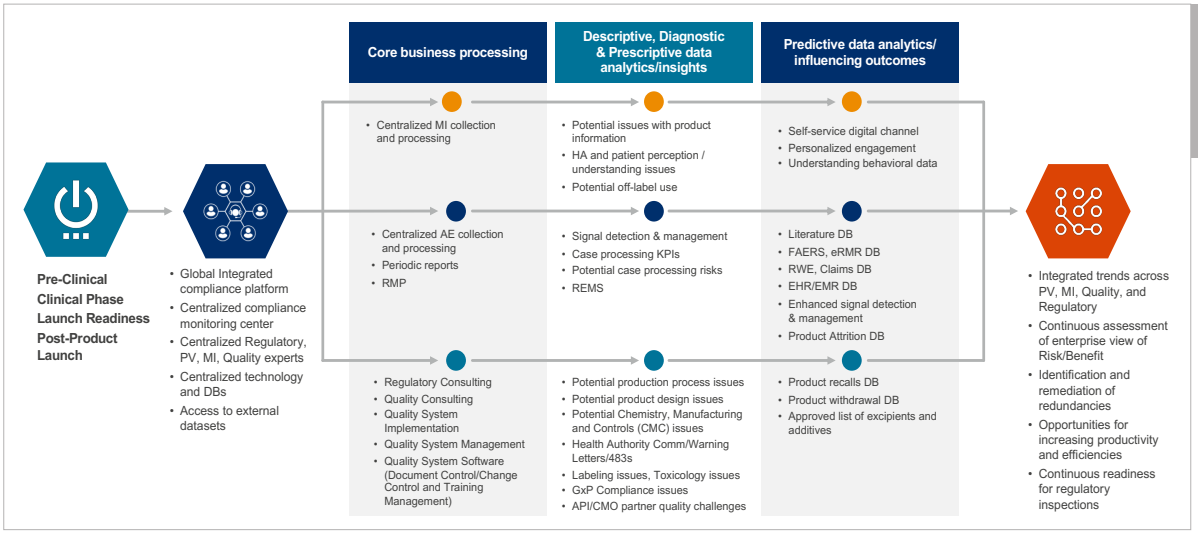


FIGURE 3

This launch model also incorporates the importance of leveraging technology that can vastly improve both efficiency and quality – namely, technology solutions in the broad categories of integration and automation. This technology can be implemented synergistically to remove most manual tasks throughout the compliance workflow to dramatically reduce overhead costs and eliminate the types of processing errors that only occur with manual processing methods and lack of system integrations.

The key outcome of any automated solution should be maximized efficiencies and cost reduction with a corresponding increase in quality and data integrity achieved through the reduction of manual tasks. With the right goals in mind, finding the "best fit" automation and integration solutions for your organization should not be difficult to achieve. A knowledge of the technologies available combined with a deep operational understanding of the processes involved in compliance workflows is often all that's needed to create a solid digital transformation roadmap. Finding the right technology partner can also help to accelerate and de-risk the innovation process, especially if your company does not have experience with automation technologies.

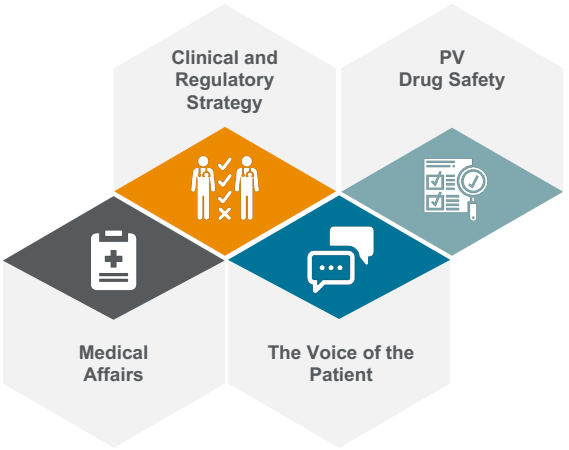
CMO Leadership and Strategy – Key to Integrated Compliance and Commercial Success

Behind any successful product launch you will find a leader who has not only helped build the scientific foundation for a product approval but one who has also provided the vision and set the tone for compliant and consistent standards needed across all medical and scientific activities. That leader is the Chief Medical Officer (CMO). The CMO provides direction for the overall clinical/scientific strategy required throughout the product lifecycle and for advancing the company pipeline. In doing so, the CMO represents the company internally and externally as the primary medical and scientific representative. This includes helping to define and develop expectations around pharmacovigilance and product safety risk management that provides for ongoing safety signal detection and benefit/risk assessment. In addition, the CMO will help to define an overall Medical Affairs Strategic Plan that supports product launch and lifecycle development and becomes the primary face of the company to the external clinical/scientific community. To achieve success, the CMO needs to be able to articulate the voice of the patient internally as the basis for decision-making when evaluating factors relevant to patients and caregivers, including aspects of quality of life.

CMO Leadership & Strategy

Provide direction for clinical strategy and for **advancing the clinical pipeline**. Represent internally and externally as a primary medical and scientific representative of the company on an interim basis

Help develop and define an overall Medical Affairs Strategic Plan and set **consistent standards** across medical and scientific activities



Help develop and define expectations around pharmacovigilance and drug safety risk management that meet standards and best practices for regulatory compliance and that **provide ongoing safety case processing** and signal detection weighing clinical benefit vs risk

Articulate the voice of the patient internally as the foundation for decision-making and when evaluating factors relevant to patients and caregivers, including aspects of **quality of life**

Medical Affairs – A Product Launch Strategic Imperative

Medical Affairs is a critical part of the strategy that helps companies ensure the successful launch of their new drug, biologic or medical device. With new product launches failing to meet corporate expectations, many companies are increasingly turning to their Medical Affairs teams to meet this challenge because they add important value through the engagement of key stakeholders in scientific information exchanges conducted in non-promotional contexts. In the age of Big Data, digital technologies, complex personalized approaches to medicine and real-world evidence generation, healthcare providers are finding it increasingly difficult to navigate the vast amounts of data needed to make the best therapeutic decisions for their patients. Medical Affairs teams equipped with extensive product and disease knowledge are well-positioned to be the conduit by which this data, along with fair and balanced scientific evidence and insights, is communicated, providing healthcare professionals and payers information needed to make informed decisions.

Companies also realize that interactions with healthcare professionals, payers and key opinion leaders provide important opportunities for insight generation that can inform market potential and patient needs, target product profile gaps and yield a better understanding of the competitive landscape. These valuable insights inform the design of clinical programs and real-world evidence generation in support of product life cycle development.

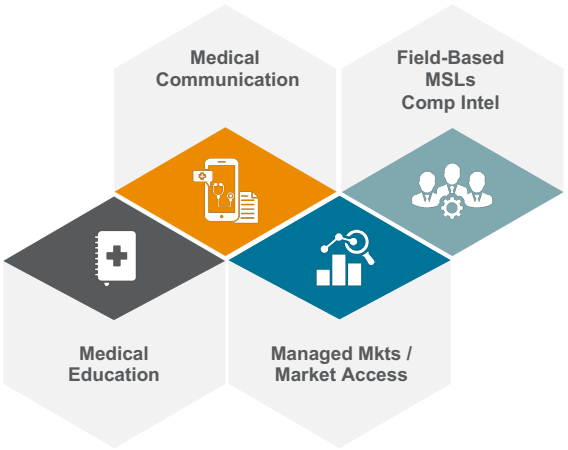
When formulating a Medical Affairs plan, a comprehensive and well-designed strategy is necessary to address key business questions and successfully commercialize a brand **(FIGURE 4)**.

FIGURE 4

Medical Affairs Strategic Plan – Key Business Questions

How will you respond to unsolicited requests for information from HCPs, **patients and consumers concerning the safe and effective use of your product**?

How will you educate physicians and other key HCPs about the overall place of your product in **treatment in order to drive adoption**?



How will you engage KOLs and bring field-derived medical insights back to your company in order to **integrate this information with key messaging**, clinical trials and real-world evidence?

How will you respond to payer needs for comprehensive information about your product in order to make formulary decisions **while meeting regulatory requirements**?

A well-designed Medical Affairs plan has become a product launch strategic imperative and generally includes the following:

1. Medical information contact/call center support responding to unsolicited request for information
2. Field-based medical science liaisons, advisory boards and speaker programs
3. Congress planning, support and participation
4. Scientific content development, publications and publications planning
5. Managed market/market access and compendia listing support
6. Grant review and support for independent medical education and investigator-initiated trials
7. Health economics outcomes research and real-world evidence generation

Medical Affairs teams are well-positioned to engage healthcare professionals and payers in scientific discussions that clarify product benefits and risks and drive early adoption. Leveraging the full potential of a Medical Affairs team is no longer an option, but a requirement for successful commercialization.

Medical Information Contact Center: Key to Successful Pre- and Post-Commercialization

The Medical Information (MI) Contact Center provides a communication channel with the healthcare professional prescribing and recommending the product to patients and with consumers who are interested in receiving more information regarding the product. Most Medical Affairs Strategic Plans include preparing

the MI Contact Center to address unsolicited medical information inquiries post-launch. We recommend establishing a live contact center prior to commercial launch to add greater value to key customers by providing early access to information and insight about the product or disease state. The MI Contact Center provides important product launch information and can assist with the recruitment efforts of ongoing clinical trials. In addition, the MI Contact Center can be an access point in providing information on any compassionate-use and expanded-access programs prior to product launch.

When considering an integrated structure for supporting a product launch, the MI Contact Center plays a central role by establishing a well-defined and seamless workflow between the center and any patient services or hub support contact centers. This integrated approach increases successful customer experiences while maintaining compliance and provides customers a clear route to report adverse events and product quality complaints.

In addition, the system integration of sales customer relationship management platforms with the MI system is essential to ensure a direct channel for healthcare professionals to receive important information to unsolicited inquiries, especially for providing information that is not addressed in the product labeling (off-label information).

Selection of a robust and compliant MI system is paramount to the success of an MI Contact Center operation. Detailed and strategic collection of information from MI interactions will provide valuable data and metrics to inform a unique narrative of the product usage, safety profile and considerations from customers. The MI system must also establish that full compliance measures, including those that meet GxP regulatory compliance and FDA's 21 CFR Part 11 requirements, have the ability to establish country-specific data privacy rules for considerations of HIPAA and GDPR as well as reporting features to meet Sunshine Act reporting needs. Finally, the MI system needs to have an intuitive user interface to allow the MI specialists to perform their tasks with ease so they remain focused on providing the highest-quality service and delivering the best customer experience.

MI is a key customer-facing unit of the product brand, and the MI contact center must embody a strong culture of service to ensure the highest-quality response to medical and clinical inquiries with a steadfast focus on the patient. This translates to every MI specialist understanding that each MI interaction with a customer is another opportunity to demonstrate this value.

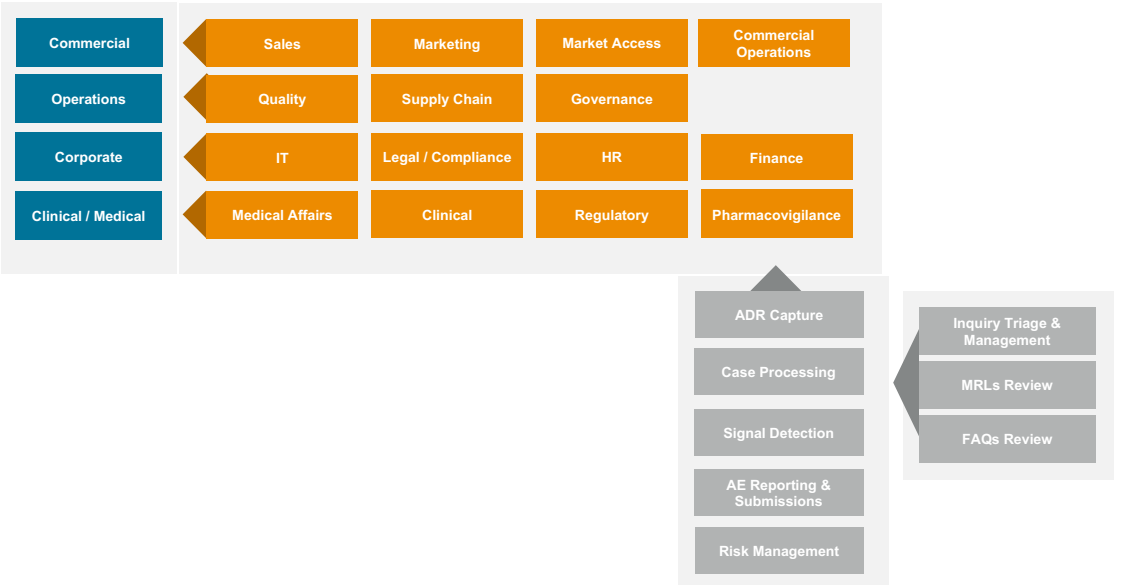
Pharmacovigilance: Product Launch Critical Success Factors

Managing the safety profile of a product is key to the overall compliance strategy for an organization looking to launch a biopharmaceutical product. A pharmacovigilance (PV) plan and execution strategy that incorporates all aspects of the product's safety profile provides the strong foundation for an effective and efficient approach that also meets all compliance requirements.

Implementing the PV plan includes detailed step-by-step tactics on who will manage the following responsibilities: what will be managed within the organization vs. outsourced, what oversight will need to be in place for any outsourced activities, and what systems will be utilized for safety reporting and managing safety trends. It must also provide details on how the plan and systems will meet the requirements for all countries targeted for product approval. The PV plan needs to efficiently and seamlessly coordinate all safety activities across medical information, quality management and regulatory affairs functions successfully in order to drive the goal for 100% compliance.

FIGURE 5

Integrated Pharmacovigilance Strategy



A robust PV plan not only allows for a review of a product's safety at key post-launch milestones but also includes an ongoing safety monitoring plan to evaluate any potential trends to proactively take action as needed for Commercial and Medical Affairs teams.

To achieve a successful product launch and subsequent commercialization, the PV plan should include:

- A thorough process for documenting and reporting adverse events per country-specific regulations and/or guidance.
- Clear channels for reporting safety events from any source, including reconciliation with these sources.
- Distribution of safety information to the required parties for awareness and/or action, considering any in-license/out-license asset agreements for safety data exchange.
- Ability to scale up resources for safety management due to unforeseen circumstances, i.e., product recalls or product withdrawals.
- Accurate and current information for product safety that is captured in validated safety systems to allow the data to be reported in health authority databases.
- Signal detection and evaluation plans for trending of any potential safety concerns as part of ongoing review of safety profile that can impact product label.

Quality Assurance: Differentiating Product Launch Success

The ability to identify the appropriate quality and regulatory strategy early in the product lifecycle provides the appropriate scope and framework to reduce time, regulatory/business risk and overall cost to launch – key differentiating factors for a successful commercialization. Some high-level Quality Strategy elements needed to achieve the key ROI and major benefits, indicated in **FIGURE 6**, include:

- Company goals and structure.
- Outsourcing strategy.
- Exit or growth strategy.
- Intended market.
- Product type and classification.
- Regulatory strategy and overall route to market.
- Intended launch timeline.
- Pre-market and post-market tactics.
- Implementation, execution and maintenance.

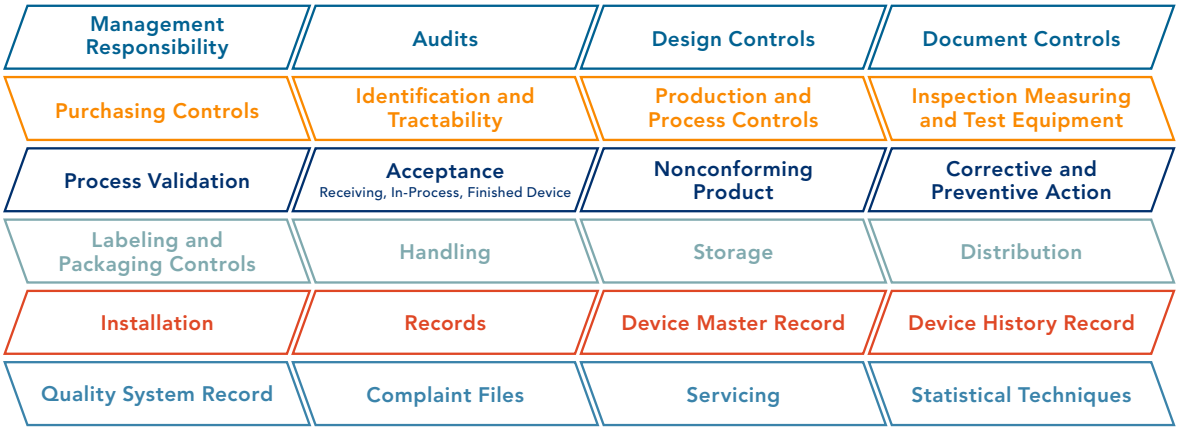
FIGURE 6

Manufacturers are well aware that the costs of noncompliance can be significant and compounding. Many of the serious challenges below can either delay or derail the commercialization of a product:

1. Rejected product and/or adulterated product leading to complaints, leading to adverse events, leading to recall and agency action
2. Remediation of agency action ranging from the hundreds of thousands of dollars to millions of dollars
3. Product recall and remediation never planned or staffed for; significant internal and external resource burden required

To cover the elements of quality for a medical device, pharmaceutical, biologic, tissue or combination product, it is important to establish a Quality Management System (QMS) that outlines and governs each element as it relates to the company and the product.

A phased approach to this implementation or the implementation of key elements as they become relevant/required should also be part of the overall Quality Strategy. The chart below highlights many of the elements critical to success.



Having access and control of the QMS is essential for any size business. Selection of the appropriate eQMS software should also be identified during the Quality Strategy process. Selecting the right platform for the overall company strategy and future state is crucial to short- and long-term success. Software can be a great tool in this area, or it can become a burden if not understood and is sized only for the task at hand.

Establishing a strategy is a great start to kicking off the Quality Assurance program; however, vision without execution is just a hallucination. EVERSANA supports not only the development of the quality strategy but execution of all activities required to run a successful quality department. The above elements – Quality Strategy, Quality Management System and Quality Management Software – should be acknowledged early to achieve successful commercialization. As part of an integrated compliance model, addressing these challenges helps clients realize the full value of their products at launch.

Regulatory: Critical Milestones for Successful Commercialization

There are many regulatory factors to consider in successfully launching a product. These factors could be considered the "pillars" of regulatory launch readiness, and within each of these pillars are various activities and milestones that must be achieved. The six key pillars are below; and for this white paper, we'll address the first two:

1. Regulatory strategy
2. Regulatory project management
3. Product label management
4. Regulatory intelligence
5. Submission management
6. Registration management

The key to properly addressing a regulatory strategy that supports product development is to start early – years before expected product approval. This strategy should be written to address product launch and post-market necessary cross-functional areas, such as reimbursement, marketing, legal, etc.; so when product launch is imminent, those ancillary factors are accounted for. It is important to note that the regulatory strategy is a living document; and as policy, regulations and guidance evolve, so must the regulatory strategy. An out-of-date regulatory strategy is catastrophic to product launch.

As timing of product launches becomes increasingly more critical, it's imperative to develop the regulatory strategy to eliminate these timing risks. The strategy must include establishing positive and constructive relationships with the review team so that when the product is under review, the team is more collaborative – positively impacting the timeline. Additionally, be sure to take into account any specialty programs or designations that may be applicable to the product, such as orphan designation, fast-track designation, breakthrough designation, RMAT designation or accelerated approval. These designations facilitate streamlined development and review timelines, given options for rolling review and priority reviews.

Regulatory project management cannot be overlooked, as this pillar is responsible for establishing critical internal processes and systems to support everything from the marketing application to post-market program maintenance. Comprehensive timelines and project plans defining key activities, assignments, deadlines, milestones, etc., need to be developed. A system should be established to ensure that both internal and external communications regarding the product are defined and controlled. This system needs to take into account laws and regulations, such as the False Claims Act, Anti-Kickback Statute and the Health Insurance Portability and Accountability Act (HIPAA). The Target Product Profile (TPP) must be developed and finalized to be the foundation of subsequent label and labeling development.

Additionally, establish a system to set up a promotional material review committee (PMRC) or equivalent, as well as a process for submission of promotional material to the regulatory authorities as appropriate. The PMRC should comprise various relevant functions, such as regulatory, clinical/medical, commercial, marketing, operations, etc. Ensuring cross-functional review and approval is critical to not only compliant product labeling but also product labeling that will differentiate the product from its competition and/or properly communicate the product's value to patients and providers at product launch and throughout commercialization.

Regulatory is a major component of an integrated product launch solution. A deficient regulatory strategy can single-handedly derail a product launch and/or compromise prosperous commercialization, and it's critical to ensure the regulatory factors are identified, addressed early on and updated throughout development to account for the ever-changing global regulatory landscape.

Conclusion

Advancing Life Sciences Compliance to Deliver Safer Products

In building an integrated compliance platform that moves the needle of compliance from cost center to value center, EVERSANA has addressed the market dynamics that challenge clients' ability to provide real insight to products, innovation and patient centricity. Integrating processes, technology and people is essential for successful commercialization and leads to increased efficiency, reduced costs, reduction in manual errors, faster processing time and, ultimately, increased safety, quality and compliance. EVERSANA's holistic model advances life sciences compliance to deliver and commercialize safer and better products, allowing customers to stay focused on what matters most: helping patients live healthy lives.

CHAPTER 3:
STRATEGIC GLOBAL PRODUCT LAUNCHES

INCREASE YOUR SPEED TO MARKET:

Commercial Strategies for a Successful Product Launch

Mike Ryan,
Executive Vice President,
Europe and Asia Pacific, EVERSANA

With the launch of new blockbuster drugs becoming less frequent, there is increased scrutiny on the importance and success of clinical trials, mandatory to determining the safety and efficacy of a developing product. The road to commercialization is daunting – the process of bringing a product to market is long and the failure rate high, ultimately impacting the price of products that do make it to market.

Pharmaceutical and biotechnology companies assume the risk of these failed investments, and there are numerous market factors determining this failure rate, including: complex trial design and failure to meet endpoints; low patient recruitment, adherence, retention and consistent access; disparate safety data and lack of validation; and regulatory burdens and unexpected changes.

Let's build a better road to commercialization by recognizing there is value in accelerating clinical trial timelines with qualified patients – from earlier regulatory filing and launch to growth stages of commercialization. To succeed in today's market, companies need to mine the value that can be found in the time and insights created between post-clinical and pre-commercialization. **Do this by:**

- Building relationships with patients and gathering behavioral data early, then embrace innovative digital technology to find and engage patients
- Demonstrating value by adding health economics outcomes research earlier in the clinical development process to garner better evidence to support pricing arguments
- Planning for the delivery of integrated patient services that include comprehensive HUB, specialty pharmacy, and distribution strategies much earlier in the development process
- Mitigating risk and ensuring product safety and efficacy with integrated pharmacovigilance that spans the clinical/commercial divide
- Preplanning medical communication strategies to formulate better results from the quality data gathered in order to achieve better product claims and provide ongoing support and assurance to patients and caregivers.

> "Let's build a better road to commercialization by recognizing there is value in accelerating clinical trial timelines with qualified patients – from earlier regulatory filing and launch to growth stages of commercialization."

EVERSANA™

To advance clinical trial performance, companies need a global partner with an integrated commercialization model designed to expedite the clinical trial process, achieve high economic value, deliver best-in-class patient services, and manage the unexpected.

Expedite the Clinical Trial Process

It's time to transform current clinical trial practices by including commercialization strategies into clinical development plans. Knowing that patient recruitment is a major cause of trial delay, start by putting patients at the center of the process. Build relationships with patients earlier in the trial planning process by tapping into the growing online influence of engaged patients. Understand the forces impacting their journeys by gathering data on their experiences, fears and concerns. Then harness this powerful data to influence trial design at the earliest stages, improve early regulatory review protocols, co-create recruitment and educational content, and share and raise awareness.

Work with a trusted partner who understands how streamlined communication and innovative engagement methods foster faster recruitment in order to design a clinical trial that reduces complexities, avoids oversights, closes the time gap between phases, and lowers cost. Leverage a comprehensive digital patient-finding platform that has the ability to successfully find and convert qualified patients to participate in clinical trials, patient databases, and market research, and can also manage patient prescreening, registration and tracking, helping companies accelerate enrollment. The platform's database should also provide companies the ability to find, educate, and onboard patients faster post-launch, increasing time to revenue creation.

Achieve High Product Economic Value

Health economics and outcomes research (HEOR) and real world evidence (RWE) are essential strategies needed in demonstrating the economic and clinical value of improving patient outcomes. Integrating both earlier into regulatory phases allows companies to identify unmet needs and support the value of healthcare interventions, as well as inform payers on new therapies' total cost of care. HEOR experts, using RWE and technology like artificial intelligence (AI), can improve clinical trial certainty by modeling who will receive the most benefits.

Breaking down the complexity of reimbursement and cost-to-coverage dynamics using the HEOR and clinical data collected early in the trial process, coupled with a pricing strategy that includes comparative and cost effectiveness studies, will help increase payer acceptance. Working with experts who understand the payer landscape and the product launch environment will ultimately help stakeholders in patient care make better decisions. The use of health economics evidence is increasingly being used through post-launch in developing value-based contracts to demonstrate how effective disease-state management lowers cost.

Patient-Centered Program Modeling

As with the halcyon days of blockbuster drugs, the one-size-fits-all patient services solution is no longer a relevant option. Companies need to advance beyond traditional HUB models to achieve greater value and this approach includes customized patient education and support services, like clinical nursing and the use of digital behavioral influence tools, to enhance adherence and health outcomes. An integrated access and affordability solution – HUB, co-pay and patient assistance programs – plays a role in navigating complex onboarding processes, overcoming pricing barriers to manage cost, and increasing market share.

Optimizing a product launch for commercial success includes developing a distribution strategy to address unique patient populations, therapies and channel/network needs. Work with a trusted partner to develop an integrated and customized distribution solution that includes direct-to-patient and global channels to ensure that patients have access to the therapies they need when and where they need them.

> "Integrating HEOR and RWE earlier into regulatory phases allows companies to identify unmet needs and support the value of healthcare interventions, as well as inform payers on new therapies' total cost of care."

Preemptively Mitigate Risk

As patients demand increased drug safety, companies must address disparate safety data and lack of validation, as well as regulatory burdens and unexpected changes. If the goal is to proactively design clinical trials that provide patients with safe and effective drugs, the approach must include the ability to deliver congruent data aggregated in one place to ease cross database analysis, improve safety and speed decision time.

Delivering high-quality medical information helps mitigate patient and caregiver concerns and decreases the potential financial risk a company could be exposed to. As the front line contact to patients and key stakeholders, ensure you work with a trusted medical communications team that compliantly addresses questions from healthcare professionals and patients. Partnering with experts who know the day-to-day impact of regulatory changes and who have a robust post-market monitoring process increases the probability of market success prior to and post-launch. It's important that the team is compliant with all pertinent regulations governing patient outreach of any kind.

> "If the goal is to proactively design clinical trials that provide patients with safe and effective drugs, the approach must include the ability to deliver congruent data aggregated in one place to ease cross database analysis, improve safety and speed decision time."

Conclusion

Time matters in protecting investments and achieving greater market success. Let's advance clinical trial performance by increasing opportunities to demonstrate value in the post-clinical and pre-commercialization timeframe. Build a seamless approach that begins with transforming patient insights into powerful messages and enrolling and retaining qualified patients for clinical trials. Evidence-based understanding, pricing strategies and payer insight are needed to execute a comprehensive market access strategy that enables payers, providers, and patients to make better decisions about treatments. Having a patient services ecosystem – that delivers best-in-class experiences through enhanced patient education and affordability programs, along with an integrated distribution strategy – in place prior to launch – helps companies achieve value across the entire lifecycle of their brands. Earning credibility with patients and providers and maintaining compliance throughout the product lifecycle helps reduce risk and protect the safety and efficacy of therapies.

By choosing the right partner with an integrated commercialization model specifically built to achieve high economic value earlier, manage risks, and immediately provide the ability to scale up for launch – companies are better prepared to increase the speed to market and achieve full market potential.

LOOKING TO LAUNCH OR COMMERCIALISE IN THE US? START WITH THE RIGHT COMMERCIAL PARTNER.

Mike Ryan, Executive Vice President, Europe & Asia-Pacific, EVERSANA
David Holloway, Vice President, Global Strategic Accounts, EVERSANA

Launching a product is a serious undertaking, requiring a seamless approach to building a commercialisation strategy that includes all the variables needed to maximise the investment across the product's lifecycle. Nowhere is this more true than the world's largest market, the United States (US). We know that a successful product launch is critical to maximising revenue potential, and this success is contingent on understanding and managing a multitude of factors including legal and regulatory, speed and success of clinical trials, market access and reimbursement, value and evidence, data and analytics, patient support services, channel management, risk mitigation and monitoring – the list goes on.

The bottom line is that regardless of whether you are a small to mid-size biotechnology or a large pharmaceutical company, bringing a product to market in the US is fraught with many challenges. In today's patient-centric, value-based landscape, biotechnology and pharmaceutical companies now have a larger ecosystem of stakeholders to collaborate with – patients, physicians, payers, and policy makers – and to consider when building commercialisation strategies that succeed in-market.

So how does a European company successfully commercialise a product in the US? Usually by asking a series of critical questions that identify unmet needs such as:

Do I build my own presence?

Do I partner with pharma or work with a commercialisation partner?

How do I define a pricing strategy or build a sales force team?

How will I manage importation supply chain and warehousing?

Then, look for a full-scale commercial partner in the US that can provide solutions to all of your challenges.

> From clinical trial recruitment to product distribution, a partner representing every facet of commercialisation brings together experts across fully integrated solutions to address key stakeholders on issues that matter most to them.

> Choose the right partner with an integrated commercialisation model specifically built to achieve high economic value earlier, manage risks, and immediately provide the ability to scale up for launch.

I've outlined three scenarios that illustrate how a full-scale commercial partner can make the ultimate difference in your US market launch success:

Full Commercialisation

Scenario: A small to mid-sized pharmaceutical company in Europe with a few compounds in Phase 3 development and without an established affiliate in the US or resources to bring the product to market has traditionally had two paths to commercialisation:

1. **OUT-LICENSING –** In this option, the emerging biotechnology company gives another company the opportunity to complete the development of the product. A downside to this option is the loss of control over sales, marketing, packaging, distribution and cost, and the inherent risk that the larger company may not ever produce the product

2. **CO-MARKETING –** This option allows the product to be co-marketed with another pharmaceutical company. Finding the right partner and the right time to partner are two of the biggest hurdles to success in this complex model, and the lack of ability to negotiate a successful strategy impacts the ability to maximise value.

Now, there is a **third option** – partner with a fully established commercialisation organisation in the US. This gives the pharmaceutical or biotechnology company the ability to expand globally within the US, supported by an end-to-end complete commercial solutions partner that eliminates the traditional service silos that stand in the way of healthcare transformation.

From clinical trial recruitment to product distribution, a partner representing every facet of commercialisation brings together experts across fully integrated solutions to address key stakeholders on issues that matter most to them:

Patient Services: designed to significantly improve health outcomes through high-touch patient engagement and behavioral health technologies

Import, Warehousing, Distribution and Logistics: designed to be agile and dedicated to investing in the facilities, technologies, and processes that meet the growing, complex distribution needs for novel, branded and generic therapies

Field Solutions: designed to be value-driven and provide services beyond traditional sales territory mapping, target lists, training and tactical value propositions to provide clinically-oriented and data-driven solutions that both describe value and capture the data to measure value for all patients, payers, and providers

By choosing the right partner with an integrated commercialisation model specifically built to achieve high economic value earlier, manage risks, and immediately provide the ability to scale up for launch – companies are better prepared to increase the speed to market and achieve full market potential.

Pre-Clinical Market Research and Insight

Scenario: A small to mid-sized global emerging biopharma company in Europe with a few compounds in Phase 1 and Phase 2 development, backed by either a venture capitalist or funded by a larger pharmaceutical as a successful spin-off, will benefit from working with a US-based end-to-end commercial partner who has the ability to provide a deep understanding of market potential throughout the US and Asia-Pacific.

Partner with a company whose global experts support every phase of the product's development, can overcome the complexities of new regulations on contract development and address the challenges in growth maximisation.

Management Consulting: designed to use evidence-based data and analytics to maximise product value, and provide strategic market insights into product commercialisation, growth maximisation, and pricing and market access

Regulatory and Compliance: designed to navigate the ever-changing global regulatory and quality landscape and deliver customised solutions and strategic guidance to expedite approvals, increase speed to market, and maintain or regain compliance

Revenue and Finance: designed to reduce revenue leakage, understand the technology and government compliance issues impacting the industry, and the ability to streamline Medicaid claim payments to optimise value

Maximise ROI through optimal pricing strategies, market penetration and adherence support with reduced cost of sales and increased margins. By working with a fully integrated commercial partner companies increase their abilities to provide value to their products and better understand the unique business, regulatory, and cultural intricacies of the global marketplace.

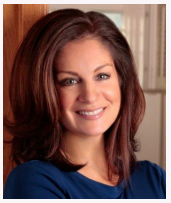
Customised Solutions

Scenario: A small to mid-size European pharmaceutical company with a limited portfolio, a legal presence in the US, with some functional abilities in place but lacking the typical infrastructure needed to achieve full in-market success. Identifying this need allows a full-scale commercial operation to provide a customised solution to complete the company's commercialisation footprint in the US.

> "EVERSANA has taken the lead in building an integrated ecosystem providing the most cost effective and dynamic commercial solutions to achieve optimal market access and deliver outcomes that matter."

Whether this solution involves a full-service healthcare marketing agency focused on reaching patients, providers and payers, or a suite of global HEOR capabilities that include economic modeling, evidence synthesis, value communication and reimbursement strategies, the commercial partner is prepared to provide a solution that allows the pharmaceutical company to better focus on bringing innovations to market that positively impact patient outcomes. And, keep control of their IP, product, brand and revenue streams.

Access to the world's most lucrative market can indeed be daunting, but having a complete commercialisation partner in the US avoids the risk and complexity of multiple vendors and this is a game changer for many companies. EVERSANA has taken the lead in building an integrated commercial ecosystem providing the most cost effective and dynamic solutions to help you achieve optimal market access and deliver outcomes that matter. Our commercial solutions are designed to optimise your asset portfolio and existing infrastructure while maximizing the return on investment. **We have both the expertise and experience to help you define the optimal strategy for your product in the US market.**



THE 2020 PLAYBOOK ADDENDUM: AUGMENT YOUR FRONTLINE TO BOOST SALES MOMENTUM

Krista Pinto
Executive Vice President, Commercial

In the midst of a global pandemic, the role of commercial field teams evolved right before our eyes. "Nice to have" sales tactics like digital sales aids and tele-detailing instantly became mandatory as brand teams and sales trainers scrambled to modernize Provider-Rep engagement. Now that field teams are starting to master these virtual interactions and settle into "the new normal," pharmaceutical manufacturers are turning their attention to the next phase: make up lost sales.

Fortunately, this initial shift to virtual engagements and supporting infrastructure (e.g., technology) enables manufacturers to complement field promotions with more personalized services for providers and patients. Augmenting your frontline with three proven strategies will create value for these stakeholders, and ultimately, boost sales momentum.

1 Boost Prescription Volume

New safety protocols, limited staff interactions, and appointment-based meetings will redefine the "total office call" for field teams permitted back into the office. Accordingly to a recent survey by EVERSANA, many providers expressed their preference to maintain virtual interactions and receive digital patient education and co-pay cards. Provider-Rep engagement will evolve as teams determine the right mix and frequency of promotional touchpoints for each audience segment.

Now is the time to take advantage of two factors: providers' new acceptance of virtual engagements and your new set of PRC-approved digital materials. Territory lines and mileage are no longer contributing factors to which providers you engage and how frequently. Consider contracting with an inside sales team to expand into new territories or complement the promotions of existing ones. In spite of best efforts, brand awareness and new-to-brand prescriptions significantly decreased over the past three months. Amplifying share of voice can reinvigorate the brand story and generate more writers, compounding your effort to increase prescription volume.

2 Boost Product Affordability

As new changes in insurance coverage and policy adjustments are implemented, providers and patients will face yet another set of access barriers. Prescription abandonment will likely increase due to complexity, financial constraints, or unfamiliarity of affordability programs. It's vital the field team is quick to understand and communicate these changes to providers.

Additionally, manufacturers can deploy an affordability program model that streamlines copay claims

"Amplifying share of voice can reinvigorate the brand story and generate more writers, compounding your effort to increase prescription volume."

processing, benefit verification, and prior authorization handling. For patient assistance programs, secure websites can be utilized for "self-serve" patient submission that automates the intake process, provides instant eligibility determination, and uses e-signature to confirm patient approval. Continuing to invest in digital solutions will not only eliminate providers' burdens, it will increase speed to therapy and ensure every prescription is managed properly.

3 Boost Therapy Adoption

The dramatic shift from in-person medical care to telehealth is here to stay. According to a recent survey by EVERSANA, nearly 93% of primary care providers transitioned to telehealth to treat chronic conditions in the midst of COVID-19. Widespread acceptance of telehealth from all stakeholders – patients, providers, payers and even regulatory groups – coupled with the "patient-as-consumer" culture is driving demand for readily accessible medical care. Patients are now embracing new ways to manage their diseases and therapies.

A powerful catalyst for innovative healthcare has been ignited and it's time to rethink how to improve therapy adoption through alternative distribution models. Whether your product is a brand, generic or specialty therapy, consider offering direct-to-patient dispensing through a specialty pharmacy. Convenient, dependable, and fully customizable, direct-to-patient dispensing enables you to manage the patient experience right out of the box. Additionally, specialty pharmacy teams routinely connect with patients to ensure compliance, assist with reimbursement, and issue refill reminders. Keeping patients engaged with your brand is a key component to securing adoption and building loyalty.

Healthcare will never be the same post-COVID-19 and we should all be so grateful. It's time to rethink how to share our brand story with providers and the role we play in enhancing the patient experience. By embracing the new reality and creating catalysts for change, we can dramatically improve the lives of our patients… **all because we had the courage to lean in.**

Consider these key trends when revamping your playbook:

Routine doctor visits are estimated to decrease by 10-20%.

We predict >70% of details will remain in-office and <30% will be virtual.

Significant shifts will occur in covered lives, patient insurance coverage, and eligibilities for affordability programs.

A rise in patient out-of-pocket costs will cause high prescription abandonment rates.

Increase of sample delivery via mail order and less handing by reps and staff.

Significant decrease of in-person conference attendance for the remainder of 2020 and potentially into early 2021.

CHAPTER 4:
THE TRANSFORMATION OF DIGITAL THERAPEUTICS

ASK THE EXPERT: **DIGITAL IN PHARMA**

The Critical Questions

GET THE ANSWERS

Ed Cox, Executive Vice President, Strategic Alliances
& Global Head of Digital Medicine, EVERSANA

"Not every drug needs to have digital tools or wrap-arounds, but every drug needs to know how digital could maximize its value."

Does every drug really have to have a digital strategy?

ED: Absolutely. These are sometimes multimillion or multibillion-dollar assets. The idea that, in a modern world in which every part of our lives has a digital component to it, an asset of that value would not have any digital involvement, it is highly unlikely. Not every drug needs to have digital tools or wrap-arounds, but every drug needs to know how digital could maximize its value. So, Yes, every single therapeutic asset should at least have a digital strategy.

"There are no universes in which life sciences will become less digital or scenarios in which digital is not a significant component."

Is there a need to accelerate our digital understanding and strategy as a result of COVID-19?

ED: There are no universes in which life sciences will become less digital or scenarios in which digital is not a significant component. Digital is expanding rapidly and it is a permanent and irrevocable shift – virtual, telehealth and all the other things that fall under digital are here, and they will never go away. Because of COVID-19, digital went from a critical element that you needed to be aware of…to an existential threat to not having.

COVID has opened the door for telehealth and easier paths to reimbursement. The fact is that the pandemic has cleared the pathway to digital healthcare and accelerated it – if you are now not exploring this, then you are not doing your company justice.

Would my company require third-party support or expertise to do this?

ED: That is a great question, and it depends on your firm. What is happening in the healthcare landscape is changing so rapidly and so radically and in so many ways that the likelihood that any company has all of these capabilities internally is extremely unlikely. But what is also true is it's hard to find many outside service providers that have the expertise to understand the nuances of digital through the lens of a company that is intimately familiar with every stage of the commercialization journey within the life sciences or pharma business. That's a real challenge.

In a recent survey conducted with top pharma companies, we asked how critical digital was to their business – most of the companies surveyed listed digital in their top three critical business needs. Still, most of them also had less than ten people working on it across their company. This gives you a better understanding of the importance pharmaceutical companies are now putting on digital but also the significant gap in people that can help move it forward.

"The healthcare landscape is changing rapidly [...] the likelihood that any companies has all [digital] capabilities internally is extremely unlikely."

Am I behind the curve?

ED: Here are the key questions to ask yourself to determine if you are behind the curve:

- Does every single one of my drugs have a digital strategy?
- Have all the critical components of my business been evaluated through digital lenses?
- Is my organization investing in digital? And is it enough to impact the success of our brand?

Request a 1-hour FREE workshop with Ed and his team to discuss your digital strategy.

SCHEDULE MEETING

Brigham H.

Ah yes, the GIF(JIFF) vs. GIF(GIF) debate of health tech. Let me parry at least a glancing blow at this debate of buzz words. In my world, Real-World Data is patient-level data that can be clinically validated against the current gold standard "controlled clinical trials." I won't give an oral history of the evolution of the FDA, but there is substantial research about the importance of data collection methodologies and statistical approaches to clinical trials. RWD definitions require careful analysis through this lens. I also think there is an important element of auditability, currently governed by 21 CFR Part 11 compliance in clinical trials that drives much of the evidence validation in healthcare.

Ed C.

 I'm tracking! Keep going.

Brigham H.

So for me, RWD has to be A) auditable; B) validated against Control Trials; and C) statistically valid and appropriate. Today the RWD that meets that measure includes "Regulatory grade EMR [electronic medical record]" registries, and increasingly digitally-captured biometrics captured on 510k validated devices (Apple Watch, etc.). I think the unfortunate thing about my definition is it tends to leave out the voice of the patient experience which could be so well captured by other digital means. But I do think it helps us draw a distinction between "digitally collected patient data" (that may or may not be RWD depending on the above) and "digital interventions or therapeutics."

Ed C.

As a patient focused organization, I understand your dilemma about the patient voice. There are many ways I can include this in my work.

Brigham H.

You will notice I have a pretty strict definition of RWD. This sort of implies that there is other health data that might not meet my definition of RWD. As this relates to real-world evidence, I view it as something you can use RWD, or non-RWD, to create. The term evidence implies measurement and comparison. The survival curve, the cox regression, the hospitalization rate, the cost of care, the summary table of model feature importance, these to me are all RWE. RWE is essentially aggregation and analysis of RWD and non-RWD health data.

Ed C.

If I'm understanding you correctly, RWD has defined sources and everything else is non-RWD.

Brigham H.

I think there can be a whole range of "evidence" and inherently there will be weak and strong evidence. In some ways that is the caveat emptor of RWE and healthcare evidence in general. In terms of grades: Prospective double-blind randomized control trials in humans is Grade A RWE / RWE based on Regulatory grade RWD is Grade B (and perhaps rising) / RWE based on non-RWD Health data Grade C / Grade F, I guess, would be yoga studio Instagram likes or something.

For my loved ones I would want a decision being made or value being assessed on the basis of Grade A and Grade B. I think there are limitations to control trials, in particular the lack of diversity, coverage of women and children, overall size of the study arms, and the lack of considerations for differences in healthcare delivery. RWE based on RWD solves for a lot of these issues and standards and methodologies are maturing.

Ed C.

Nothing against yoga studios, of course, and I think your delineations are spot on!

Brigham H.

To hit it back to you I will pose this question that I have been mulling: Do Digital Therapeutics need to have their digitally collected RWD data points validated against classic clinical endpoints, or should it be enough just to have the intervention itself perform better against SOC [standard of care] in control trials? Sort of regardless of how it got there?

Ed C.

Brigham, I think that's an awesome explanation and actually very helpful.

To answer your question about what is the correct order for Digital Therapeutics – Getting them approved by preexisting endpoints (probably PRO or collected by clinician... on paper), or going out and validating the digital endpoints, which are already collected by the products themselves and then try to get DTx approved based on those evolved endpoints. I'm going to take a pretty strong position on the former.

Brigham H.

I agree with your position.

Ed C.

There are many indications where the endpoints, although not ideal, are well-established and well-accepted by the regulators and the clinicians. DTx needs to get a beachhead of approved (cleared) products before we start trying to rewrite the way everybody else measures things.

Plus sometimes a product designed to drive behavioral or biological change is driving towards a different goal than a tool designed to collect clinical data. If you're trying to build something to grab clinical data, one might forget to actually build something that actually has a therapeutic effect.

Brigham H.

I think what this comes down to is clinical validation. Could we run a trial of an app vs. a drug? What would be the standards? The methods? The labels?

Ed, your last comment about "focus" in digital health really resonated with me. It feels like some investors push digital health companies into becoming data collection engines as opposed to focusing on the technical strength of their intervention. It's sort of understandable given that the tech giants of today tend to be the ones who got engagement and data collection right. Almost as an ever spring strategic advantage. It feels like therapeutics are different, and maybe health tech in general, in that the focus needs to be on algorithmic and clinical validation. I also find most digital health companies are collecting such a narrow slice of data (disease area, behavior, experience, etc.) that it's not really a viable strategy anyway.

Phew, that was a lot but I feel like we are getting somewhere. Care to take a swing at digital health/ digital medicine buzzword definitions or should we cap off with a speed round of burning questions?


Ed C.
Well since it's clear to me this is probably going to become a recurring project, I'm going to wait on the definition of digital therapeutics and digital medicine until our next exchange. That's a rabbit trail… Or is it rabbit hole? Anyway, that's an entire conversation in itself.
Let's go straight to burning questions!
Burning question for you: Which therapeutic indication has the greatest chance to be fundamentally reshaped because of data? Go!
Brigham H.
Ed, overall pediatrics, RWD/E is desperately needed in pediatrics who are heavily underrepresented in clinical trials today. I will also throw in oncology (the tip of the spear in regulatory grade RWD), and immunology which has the biggest need to find proxies for efficacy and patient experience from the real world.
Last one for you: Which therapeutic/disease area will have the first digital intervention to surpass SOC drug intervention on efficacy?
Ed C.
Brigham, great question, but wow. As a general rule I think about DTx being used alongside drugs or in the absence of a drug, so trying to think of winning a head-to-head efficacy comparison is generally not the way I think about it.
But to try to sort of answer the question, I'm going to cheat a little and say Alzheimer's disease specifically and CNS generally. I personally believe the Therapeutic Area that can benefit the most from digital therapeutics is CNS and Neuro but in many ways that's because there are so few drugs and the standard of care is generally very limited.
Well this was a blast. Let's try to make this a regular thing.
iMessage
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CHAPTER 5:
PIVOTING THE PATIENT EXPERIENCE

ADVANCING BEYOND THE TRADITIONAL PATIENT ADHERENCE MODEL

Maria Kirsch, *Senior Vice President, Head of Patient Services Operations*

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Delivering value in the era of empowered patients renders the one-size-fit-all patient services program obsolete. Not every treatment journey is consistently linear within a disease state because patients take different paths to medication adherence. For example, one patient may be compliant when prompted by a smartphone notification while another relies on a caregiver for their daily reminder.

There are **three main issues** with current adherence programs:

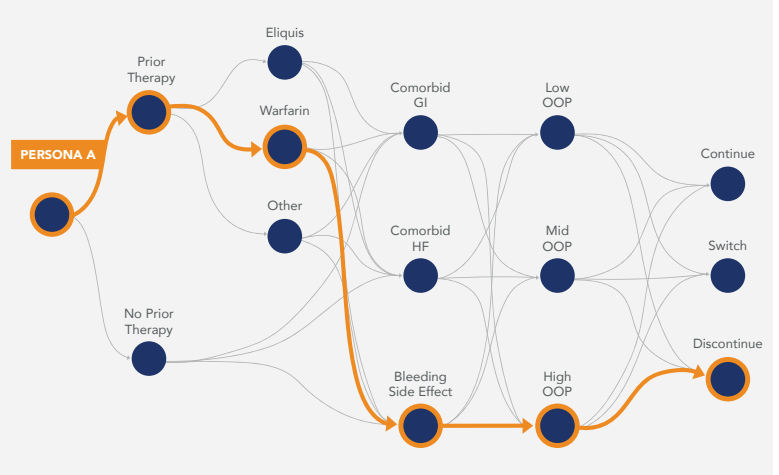
1. Patients have fundamentally different adherent issues
2. Patient issues change over time
3. Metrics ignore patient subgroups

Patients demand more personalized services, yet current offers fail to meet their expectations set by standards from other industries. Just as music and TV streaming services have become hyper-personalized, we envision customized patient experiences can improve health outcomes.

Patient Insights Inform New Model For Support Services

Earlier this year, EVERSANA elevated its next generation patient services with predictive analytics that inform "the next best action" along the patient journey. By identifying where the patient is in his/her treatment journey, we predict probability of nonadherence, provide effective corrective actions, and measure the size of the potential impact. **FIGURE 1** showcases how the EVERSANA team uses predefined personas to determine if a patient prescribed an anticoagulant will continue therapy, switch, or discontinue.

Figure 1



Variable	Description	Variable Predictive Value	
Discontinue Timing	<30 days		
Initial Fill (days)	Below 14 days	High	
Initiating HCP	Therapy Loyalist (50%+ scripts are Therapy)	Mid	
Co-morbidity	Musculoskeletal Disorders High Blood Pressure High Cholesterol Non-Diabetic		Overall Model Accuracy F-1= 0.89-0.98
Payer Mix	Medicare, Assistance Programs, Commercial, Cash	1%	

- There are ~600 (0.7%) patients similar as Persona A
- The average initial Therapy fill for this cohort is 10 days
- The model can make up to 98% accurate predictions for this cohort
- This cohort is extracted from statistically significant classification exercise

In his recently published white paper, *"A Predictive Analytics and Machine Learning Approach to Improving Hub Performance and Patient Outcomes,"* my colleague Brigham Hyde, PhD, President of Data and Analytics describes in further detail how the results of our model generated a 98% accuracy rate in our ability to describe the types of patients and the personas. By showcasing how the actions at each step in the patient analytics platform process added value to the model, we demonstrated a successful process for improving patient adherence by >50%.

> "By integrating Noom's proven behavioral health technology with EVERSANA's best-in-class patient service programs, we will help manufacturers give their patients the personalized support they have long needed and deserved."

Another important factor to the EVERSANA model is our one-on-one relationship with the patient and the multitude of channels we can engage them with. Whether it's technology based through an app or a text message, or a dedicated Patient Services Coordinator they connect with in person, phone or video chat, the EVERSANA care team is continuously trained to ensure patient empathy and coordinate additional therapies as needed throughout the treatment process.

"We're not just worried about the shipment and the time and the delivery date," shares Victoria Butler, Director of Clinical Care Delivery. "That's incredibly important, but we also care about where the patient is in their disease journey and what they're facing. Building relationships and helping to overcome barriers empowers patients and enhances their success with medication therapy."

The approach also helps manufacturers understand potential issues with the therapy itself that could be impacting adherence. For example, patients might share that taking a drug in many small doses is challenging, and that they would stay more adherent if they could take the drug in fewer, larger doses. Manufacturers also cite fewer adverse event challenges, thanks in large part to proactive patient outreach based on research cited concerns in the therapeutic journey.

Continuity of Rare Care

Patients not only need assistance with adherence challenges, but with managing required lifestyle, nutritional or physical modifications that are necessary for patient compliance – behaviors that are difficult to influence, track or control. Oftentimes patients do not know how to make long-lasting changes to their everyday life that would best benefit their therapy.

EVERSANA recently partnered with Noom, the world's leading behavior change company, to increase medication adherence and improve health outcomes for the millions of patients suffering from rare diseases. Noom's program is based on cognitive behavior therapy that leverages human coaches and artificial intelligence. The partnership combines EVERSANA's fully integrated patient services model with Noom's digital therapeutic platform to give patients the personalized support they need to create life-changing habits and generate positive outcomes.

"Despite a long road to diagnosis, adherence to therapy falls to 50% – 80% for patients with complex diseases who routinely deal with difficulties handling side effects, navigating lifestyle changes, and finding the education and resources needed to understand their disease and care," said Jim Lang, CEO, EVERSANA. "By integrating Noom's proven behavioral health technology with EVERSANA's best-in-class patient service programs, we will help manufacturers give their patients the personalized support they have long needed and deserved."

The Economics of Patient Understanding

As cited in Evaluate Pharma's 2019 Orphan Drug Report, "by 2024, orphan drugs are expected to reach $242 billion and capture one-fifth of worldwide prescription sales." Increasing reputational and payer pressures will require the industry to create more value through better outcomes. Improving adherence, through precision patient support via behavioral technology, will lower cost while helping manufacturers recoup their investment after years of research and development – all to the ultimate goal of better rare disease patient care.

At EVERSANA, we believe manufacturers can achieve greater adherence by advancing beyond the traditional model to building a program that focuses on the unique needs of each patient. Our new adherence solution yields a best-in-class experience brought forward by one-on-one interactions; timely communication and resolution of access and affordability; and at-home product delivery and nursing care. This one ecosystem of integrated services not only keeps patients informed but generates positive outcomes to demonstrate therapeutic success.

WHERE HEALTH SYSTEMS ARE IN THE SHIFT TO VALUE: FOUR CATEGORIES

Dr. Richard Stefanacci, Chief Medical Officer, EVERSANA™ ENGAGE

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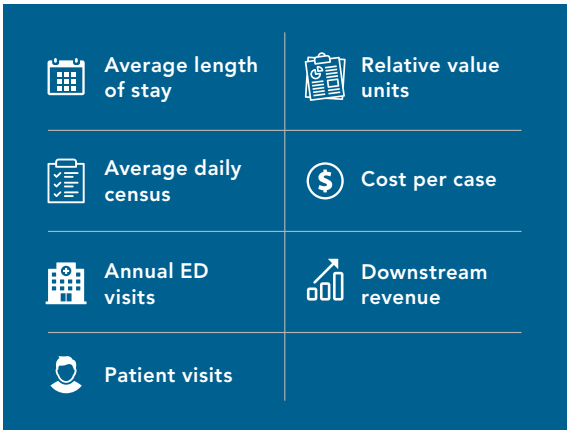
One could make the argument that there are four situational categories under which all health systems now fall on the journey toward more value-based care and away from the fee-for-service model. Assisting health systems in successfully transitioning to value-based care and delivering improved clinical and financial outcomes for their patient populations depends on very different approaches depending on where they fall on the spectrum. Appreciating these differences is critical to understanding how to approach each group of health systems when articulating value to achieve high-quality clinical and financial outcomes.

Health systems are at varying stages and levels of focus when it comes to shifting their care delivery to a model emphasizing value. Although many health systems have painted a rosy picture of their transition from fee-for-service (FFS) to value-based care, the reality of the situation is far different. One could make the argument that there are four varying situational categories under which all health systems now fall. Some health systems are still firmly grounded on the FFS deck, while others have made it into the value-based boat. Many believe that most health systems fall somewhere in between—with one foot on the dock (FFS) and the other on the boat (value-based care), straddling the space in between. There is also a fourth scenario in which a health system has failed to transition, figuratively falling into shark-infested waters, where some systems will go under/die out naturally and others will be eaten by the competition. It is important to appreciate each of these four situations to better understand how to approach a health system regarding value so as to produce the highest level of clinical and financial outcomes.

Grounded on the FFS Dock

Despite the fact that the world has been fixated on the shift to value-based care for some time now, there are several types of health systems that are content with being firmly grounded on the FFS dock. This includes for-profit hospitals and those fortunate enough to be considered designation health systems that can demand what they want due to their prestige, such as the Hospital of the University of Pennsylvania and the Children's Hospital of Philadelphia, for example. Because these health systems are such a draw to patients, they can simply focus on their volume and demand whatever price is needed to cover their costs plus. As a result, these systems focus on volume and their costs of operation in areas such as length of stay; they are not at all focused on investing in efforts to reduce readmissions or keeping patients out of their beds, as this is solely where their revenue is generated. Value to these health systems is defined as filling their beds and reducing their cost of care **(Box 1)**. Other objectives are not priorities for these systems and, as such, value must be articulated to them purely in these terms. These health systems will be rarer in the future, but some may survive the transition to value-based care because they are seen as a valuable part of the current health care system that provides superior specialized care to unique populations.



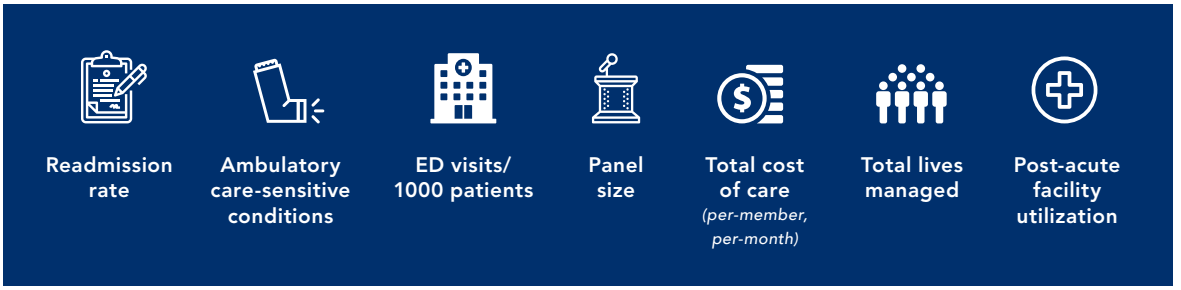
Box 1: Fee-For-Service Measures of Value

In a Shaky Value-Based Boat

Some health systems have boarded the value-based care boat; however, the stability of this situation is highly variable based in part on those value-based contracts signed and their ability to deliver on clinical and financial outcomes. These systems are focused not on filling their beds but rather the exact opposite—keeping individuals healthy far outside of their walls. For systems like Kaiser Permanente, which has been in the full-risk provider

game for years, the boat appears to be fairly stable. Changes in the healthcare system that require improving the health of members benefit full-risk providers like Kaiser, thanks to programs that focus on the most common chronic diseases to prevent filling hospital beds. With this model, all decisions are not only clinical but also financial, and the goal is to maximize value through overall cost of care rather than maximizing patient health outcomes in all circumstances. Some may question the greater number of more specialist providers, as they may be seen as a cost driver in a full-risk model. The Mount Sinai Health System (New York, New York) illustrated the priorities of systems implementing value-based care in an ad with the caption, "If our beds are filled, it means we've failed."[1] Quite the opposite view from those standing on the FFS dock.

For full-risk providers, the focus is on total cost of care, so investing to decrease their service volume is critical. Articulating value to these health systems means focusing on reducing total cost of care in areas such as prevention, delaying initial admissions, and reducing readmissions **(Box 2)**.



Box 2: Value-Based Care Measures of Value

An important point to consider is that health systems that follow the FFS model and those that focus on value-based care share one common area of focus: market share. Both groups are interested in capturing as much of the market as possible, since their revenue stems from their market volume.

Straddling the Two Worlds of FFS and Value-Based Care

There are, of course, health systems that are not fully on the FFS dock or firmly in the value-based boat, but instead find themselves straddling these 2 worlds. These health systems, such as Jefferson Health (PA/NJ), find themselves growing through hospital acquisitions, as well as by purchasing their own health plans. This situation takes providers like Jefferson Health and places them in the dual role of payer as well. Such health systems face a conflict between filling their beds and investing in keeping individuals healthy in the community; finding a balance between the two can be especially difficult when these systems find themselves investing in efforts that reduce their revenue. Articulating value to these systems depends greatly on whom one is speaking to. For example, the pharmacy group may be siloed as being responsible for drug costs. But if they are armed with information on the impact of increasing the pharmaceutical spend that would reduce their total cost of care, they could win the argument with their chief financial officer and medical director—although this can be an uphill battle at times. These organizations are preparing to make a successful transition from FFS to value-based care, while finding a balance between maximizing care from specialists and primary care providers within the health system.

Falling in the Water

Finally, there are those health systems that will not succeed in the current shifting environment. Instead, they will fall into shark-infested waters where competitors will be looking to gobble them up in an acquisition or they will simply "die." Systems like rural hospitals or those like Hahnemann University Hospital (Philadelphia, Pennsylvania), which have failed to exist in either the FFS or value-based worlds,[2] may fail primarily due to their payer mix. Alternatively, systems may invest heavily in value-based care but fail to achieve cost savings—they only spend funds to reduce their revenue and do not receive savings—or worse, they may have to write a check to the Centers for Medicare & Medicaid Services (CMS) for spending above their benchmark. It is especially difficult for health systems that remain operationally focused on hospital revenue while still taking on risk. Then there are those health systems that own their market. These health systems may be forced to reduce their revenue to achieve reductions in total cost of care. It will be much easier on those health systems that can reduce other health system use for the patients for whom they are responsible, thus cutting others' revenue rather than their own, gaining a percentage of these savings.

Unfortunately, failing health systems will be more prevalent given the ever-increasing risk levels in the face of higher Medicare Part B expenditures, especially for new innovative biologics that have not been calculated into the benchmark total cost of care. As a result, through no fault of their own, simply providing appropriate use of a new diagnostics or treatment could force these health systems to miss their target and, as a result, write a check to CMS. Other factors forcing these failures is the fact that patients are becoming increasingly demanding even while being limited in their own ability or desire to manage their health. This increased demand in the face of crumbling support around social determinants of health is forcing some health systems to fill an increasingly widening gap without being reimbursed for these services.

The other reasons for these failures has been described by The Institute of Healthcare Improvement (IHI), which grouped these failed change efforts into 3 categories: failure of ideas, failure of will, and failure of execution.[3] The failure of ideas refers to the situation where ideas fail because they do not effectively diagnose the problem or generate a set of solutions that would work. Failures of will occur when everyone, from leadership to front-line staff, lacks the motivation to effectively engage in the process of developing and implementing solutions. Finally, the failure of execution occurs when new solutions are not implemented in a way that works.

For these systems, avoiding the failures of ideas, will, and execution may be too difficult, too little, or too late. Supporting them requires the knowledge and tools to ensure successful action; despite these efforts, many will fail. The only opportunity for outsiders is to stand on the sidelines to see how these systems are acquired, or if they are not acquired, to determine how their failure may impact nearby systems with a domino effect of more failures in systems that are unable to adapt.

Successfully Making the Move to Value

So how does a health system successfully make the move from FFS to value-based care? While it is too late for those that have already failed, there are still those that are caught between the two worlds of FFS and value-based care; they will either fail completely or retreat back to the safety of the dock—at least for now.

For these health systems to succeed, successful execution of Kotter's 8-step change process is required.[3]

These 8 steps include the following:

1. Establishing a sense of urgency
2. Creating the guiding coalition
3. Developing a vision and strategy
4. Communicating the change vision
5. Empowering employees for broad-based action
6. Generating short-term wins
7. Consolidating gains and producing more change
8. Anchoring new approaches in the culture

Wagner's Chronic Care Model provides an outline of how systems can integrate these steps into care delivery.[4] Under this model, health systems can move toward value-based care delivery by implementing the following tactics:

An example of these principles being put into action can be seen in the work of Bill Frist, MD. With a strong background in health systems as a heart and lung transplant surgeon and founding family of Hospital Corporation of American as well as policy expertise as a Senator Majority Leader from 2003 to 2007, Dr. Frist was well equipped to establish the not-for-profit organization NashvilleHealth with a mission to substantially improve the health and well-being of Nashville, Tennessee, residents. With the goal of value-based population health, NashvilleHealth established the objectives at **Table 1**, achieving these by tracking against specific measures.[5]

OBJECTIVES	MEASURES
1. Convene diverse groups of key local stakeholders 2. Identify specific and measurable community health indicators 3. Develop a comprehensive and practical health roadmap 4. Leverage and align Nashville's relevant resources (ongoing) 5. Engage academic partners to measure ad monitor outcomes 6. Strengthen the community-wide integration of health services 7. Scale evidence-based, countrywide success to state and national level	• Adhere to the Office of Disease Prevention and Health Promotion's Health People 2020 goals, with a 2022 goal date for NashvilleHealth • Create specific equity goals for each area of focus to reduce racial disparities and create a culture of health citywide • Consider process metrics, such as the number of individuals or grips involved in the work, along with media reach • Develop processes for measuring the quantifiable outcomes of each individual program as they are developed for each focus area

Table 1: NashvilleHealth Objectives, Measures for Improving Nashville Population Health

Final Thoughts

Assisting health systems in successfully transitioning to value-based care and delivering improved clinical and financial outcomes for the population they care for depends on very different approaches depending on where they fall on the spectrum. Appreciating these differences is critical to understanding how to approach each group of health systems when articulating value in order to produce the highest level of clinical and financial outcomes. It is not an easy journey from the safety of the dock to getting into the boat—without help, many will fall.

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WHY ARE WE SETTLING FOR MEDIOCRE PATIENT SERVICES PROGRAMS?

Maria Kirsch, Senior Vice President & Head of Patient Services Operations

Meet Dorothy:

mother of twin 12-year-old girls who inherited her natural talent and love for tennis. Every weekend she coaches their junior team and analyzes each match on their way to get pizza. Dorothy thrives on the tennis court next to her girls; she feels energized and empowered.

Monday mornings, on the other hand, don't have the same effect on her. Three weeks away from reaching her two-year anniversary of being the office manager of Riverside Pediatric, she pulls into the office parking lot precisely one hour before their first appointment. She's hoping to get a head-start on the day's task list. A quick glance over to the office's gray door and her mind takes off like a freight train:

- *Call the specialty pharmacy to check the status on young Edward's prescription – he should have received his medication three days ago, and his mother already called twice to check on the status.*
- *Touch base with Jenn – did she schedule Mrs. Kline's daughter's consult? I really hope she doesn't have asthma.*
- *Calculate the final tally of cancellations last month – did it improve from the previous month? Dr. Nguyen is going to have a fit if we lose any more patients.*

In a busy pediatrics office with three providers, Dorothy provides support for more than 50 patients per day.

From the time a prescription is written to the day the patient begins treatment, she is responsible for managing their health insurance journey for each medication. Each one requires their own benefit verification process, enrollment program, payment option and distribution channel.

Getting medication to patients is a never-ending cycle that cuts into her main responsibilities: patient care and office management. Dorothy never feels caught up. Normally, she can muster enough strength to power through, but lately she is overwhelmed. Back inside the car, her body tenses with every new task, physically holding her back from opening the door. **"I don't think I can I do this job much longer,"** she quietly says to herself.

Between patient care and office management, Dorothy is responsible for:

Patient Services Programs Are Falling Short

To give credit where credit is due, pharmaceutical manufacturers make a tremendous – and well-intended – effort to alleviate the product access obstacles and burdens patients and providers often endure when a new medication is prescribed. While interactive wellness apps, generous co-pay card offerings and essential patient assistance programs make a brand appear "patient-centric" and "easy to prescribe," these programs fall short on the back end. Complex business rules and lengthy intake forms, coupled with progress notes and medical history documentation, are creating mountains of paperwork and dozens of phone calls. The worst part of this reality? It's completely avoidable.

As you evaluate your own patient services program for an upcoming launch or your 2021 brand strategy, I urge you to ask yourself:

- **How am I helping PROVIDERS prescribe my brand?**
- **How am I helping MORE PATIENTS access this necessary medication?**
- **How am I helping DOROTHY to make it all possible?**

At EVERSANA, we deliver a standardized process enabled by a single integrated platform that connects prescribers, payers, pharmacies (retail and specialty) and manufacturers to provide real-time visibility into insurance benefits, patient support programs, timing of delivery/pick-up and associated costs to patients. Sitting on top of the latest technology to safely and securely capture specific payer requirements and individual patient data, EVERSANA's platform ensures the quickest route to patient access with minimal steps and a fast, two-way flow of communication.

Patient services programs need a refresh to deliver a better brand experience and increase speed to therapy. Here are three proven ways to be THE BRAND doctors eagerly prescribe, office managers easily manage benefits and patients stay adherent:

Leverage Artificial Intelligence (AI), Machine Learning, and Data and Analytics to Improve the Patient Journey

Of all product launches, 66% do not meet expectations.[1] With increased competition, complex patient behaviors and higher operating costs, patient services programs now demand integrated data and analytics across the patient journey to model value-based care. More importantly, manufacturers need to implement behavioral interventions to increase patient adherence. By leveraging the power of AI and machine learning, we can identify where the patient is in their treatment journey and maintain engagement throughout each stage. Through unexpected trends and patterns, manufacturers can then predict the next best action and probability of nonadherence to provide effective corrective actions.

Establish Process Automation and Streamlined Workflows

Prescription abandonment is often caused by complexity, financial constraints or unfamiliarity of affordability programs. Manufacturers can deploy an affordability program model that streamlines co-pay claims processing, benefit verification and prior authorization handling. For patient assistance programs, secure websites can be utilized for "self-serve" patient submission that automates the intake process, provides instant eligibility determination and uses e-signature to confirm patient approval. Investing in digital solutions will not only eliminate providers' and office managers' burdens; it will increase speed to therapy and ensure every prescription is managed properly.

Utilize a Specialty Pharmacy to Get Therapy to Patients Faster

Whether your product is a brand, generic or specialty therapy, consider offering direct-to-patient dispensing through a specialty pharmacy. Convenient, dependable and fully customizable, direct-to-patient dispensing enables you to manage the patient experience right out of the box. Additionally, specialty pharmacy teams routinely connect with patients to ensure compliance, assist with reimbursement and issue refill reminders.

Fortunately for all of us, Dorothy's passion to help patients keeps her going, even on those dreadful Mondays. But her sheer willpower (I'd go so far to call it a superpower) shouldn't be her only crutch. She should be able to depend on us to provide a best-in-class experience that allows her the bandwidth to care for her patients.

When we do more for Dorothy, we do more for patients.

1. Ten years on: Measuring the return from pharmaceutical innovation 2019. Deloitte Center for Health Solutions. Beyond the storm: Launch excellence in the new normal, McKinsey & Company

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About EVERSANA™

EVERSANA is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science solutions for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through LinkedIn and Twitter.