# Challenge Your Assumptions: Leveraging Real-World Patient Journeys at Scale for Clinical Trial Strategies

*Use real-world data and advanced solutions to identify clinical trial patient populations, develop recruitment, access, and support strategies, and shape trial design and execution for success.*

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## INTRODUCTION

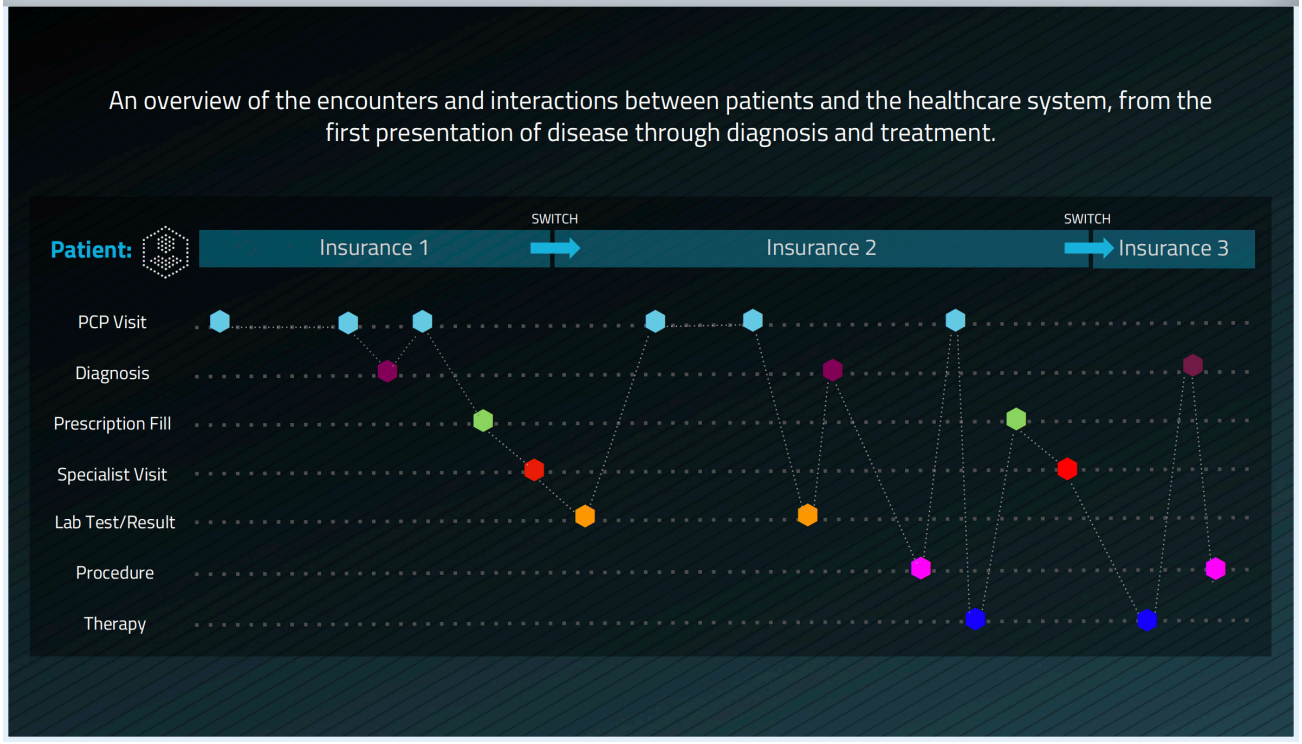
A comprehensive understanding of patient interactions and experiences with the healthcare system lays the groundwork for insights and analytics, which can inform development strategies for novel therapeutics within the clinical trial setting. However, capturing a complete picture of all these potential interactions has previously been quite challenging. In this paper, we discuss how real-world data and advanced software solutions are being used to stitch together the full patient journey, and how these longitudinal insights can be used to inform clinical trial strategies from design through execution.

## CONNECTING PATIENT DATA

The term "patient journey" refers to an overview of all the encounters that a patient has with the healthcare system at large, including initial presentation of symptoms through diagnosis, and, ultimately, treatment of a particular disease (**FIGURE 1**). These experiences may look different for different patients, but if these journeys are examined at scale across very large populations, in-depth profiles emerge over time for patients and providers at both an aggregate and individual level. These profiles enable a better understanding of the overall demographic nature of the patient population, inclusive of race and ethnicity, as well as how these demographics impact the course of treatment and the healthcare experience. Diagnostic patterns emerge, and common comorbidities or treatment patterns may be observed. Opportunity, therefore, exists across the whole healthcare ecosystem to leverage these patient data in a more strategic way, especially as related to clinical drug development.

One major challenge has been a lack of connection across the healthcare system, where the data tend to exist in silos. Komodo Health has addressed this challenge

**FIGURE 1:** What is longitudinal patient journey?

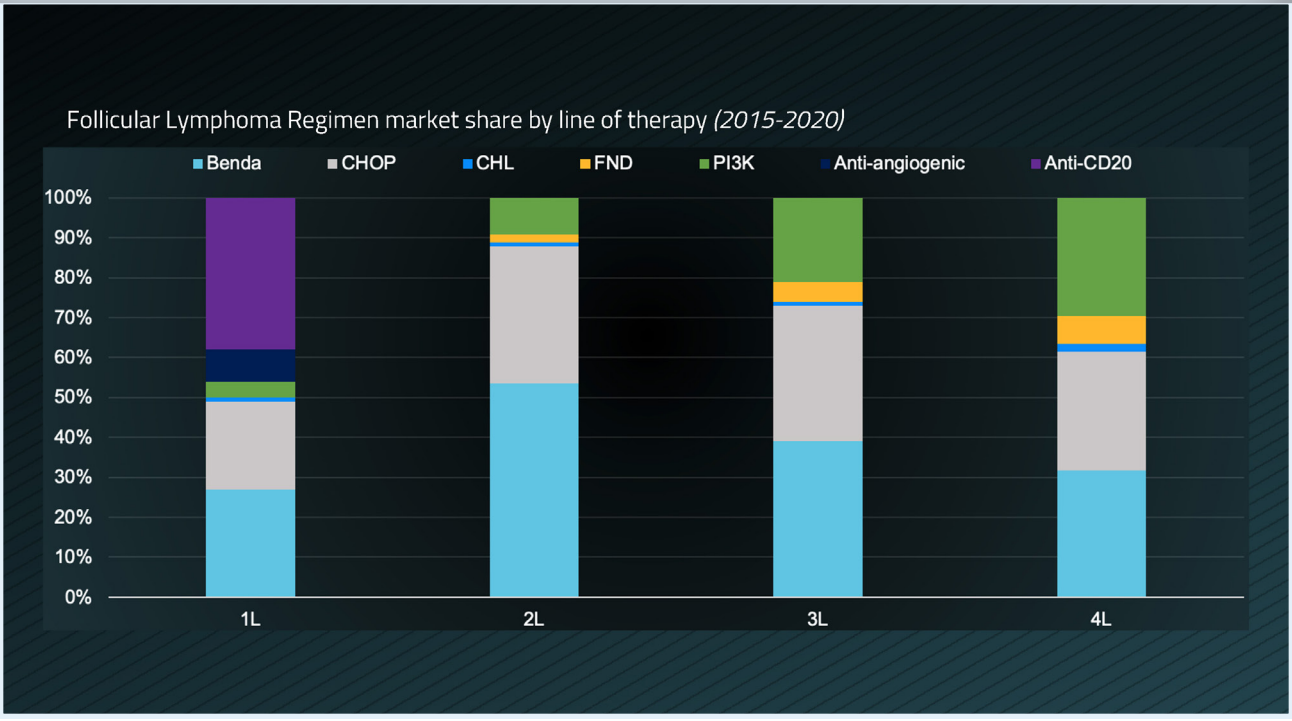



by connecting multiple novel datasets together, capturing the patient journeys of 330 million patients across the United States in a "healthcare map" that includes race and ethnicity data for 225 million patients. These demographic data are key for those in clinical development because they relate not only to ensuring trials are representative of the patients affected by a disease, but also ensure support of trial diversity. Accurate patient journeys are critical in supporting trial design, execution, and patient support, and require not only breadth, depth, and completeness but also longitudinality, security, and flexibility (1). The Komodo Healthcare Map™ contains a massive volume of continuously updated, high-fidelity data sourced directly from multiple provider and payer sources, including patient electronic health records, billing and claims data, pharmacy records, and laboratory and diagnostic data. It has also been designed to be linkable to other data sets, such as clinical trial records or omics data, to elevate the insights that can be generated. Importantly, all patient level data are de-identified through tokenization, maintaining patient privacy.

## GENERATING INSIGHT FOR CLINICAL DEVELOPMENT

Connecting previously siloed patient data is a core aspect of the Komodo Healthcare Map™, but the true value of these data lies in moving the data into a space where assumption-challenging insights are generated and leveraged to drive impact at the patient level. This involves developing an understanding of patients relevant to a study, highlighting differences across the key cohorts, and uncovering common patterns in healthcare encounters prior to a diagnosis. The paths patients take across providers are then followed to identify how patients are treated and highlight the differences among those treatment protocols, including outcomes and healthcare costs. The potential applications for these analyses are numerous, but areas where software is being used in conjunction with patient journey data to specifically inform clinical drug development include clinical trial design and evidence generation, site and investigator selection, trial recruitment, and patient support.

**FIGURE 2:** Understand treatment patterns to inform control arm design.




## GUIDING CLINICAL TRIAL DESIGN

There are many considerations in designing a clinical trial, but all trials rely on accurate design of an appropriate control arm. Real-world patient data can be used to challenge assumptions regarding the patient experience and to design the most relevant control arm and its clinical endpoints. One drug developer used Komodo's Healthcare Map™ data to inform a control arm in a follicular lymphoma trial. Investigation into patient data revealed treatment patterns across different lines of therapy, including differing relative proportions of treatments that patients were typically receiving (**FIGURE 2**). These data were illuminating, both in designing a trial that was relevant to the actual experience of patients with that disease, but also for investigating the potential of positioning the new drug as a first-line versus second-line or later therapy. The ability to analyze real-world, patient-level data in this therapeutic area not only guided what clinical timelines and endpoints would be needed to create a compelling clinical trial, but significantly shaped their control arm design.

Another key element of any clinical trial is the inclusion and exclusion criteria, which define the target patient population that will be eligible for a particular study. There are many factors to consider in setting these criteria, but it is also extremely important to understand the potential impact of a given set of inclusion/exclusion criteria in terms of patient availability. Understanding the patient journeys at scale across the population can position clinical scientists to better understand these ramifications, particularly with regard to unexpected, disproportionate impacts to different racial or ethnic groups. Where particular inclusion/exclusion criteria may be unavoidable due to a drug mechanism of action or specific therapeutic area, knowing what disproportionate impacts exist can inform the development of a trial operation strategy to mitigate this impact once the trial is in its recruitment phase. Importantly, the patient journeys can also be analyzed to understand the influence of factors such as relative rates of diagnosis for various comorbidities (**FIGURE 3**) to better characterize the target patient population and inform strategies for mitigating risk associated with the trial design or execution.

**FIGURE 3:** Scenario model: impact of inclusion/exclusion criteria.

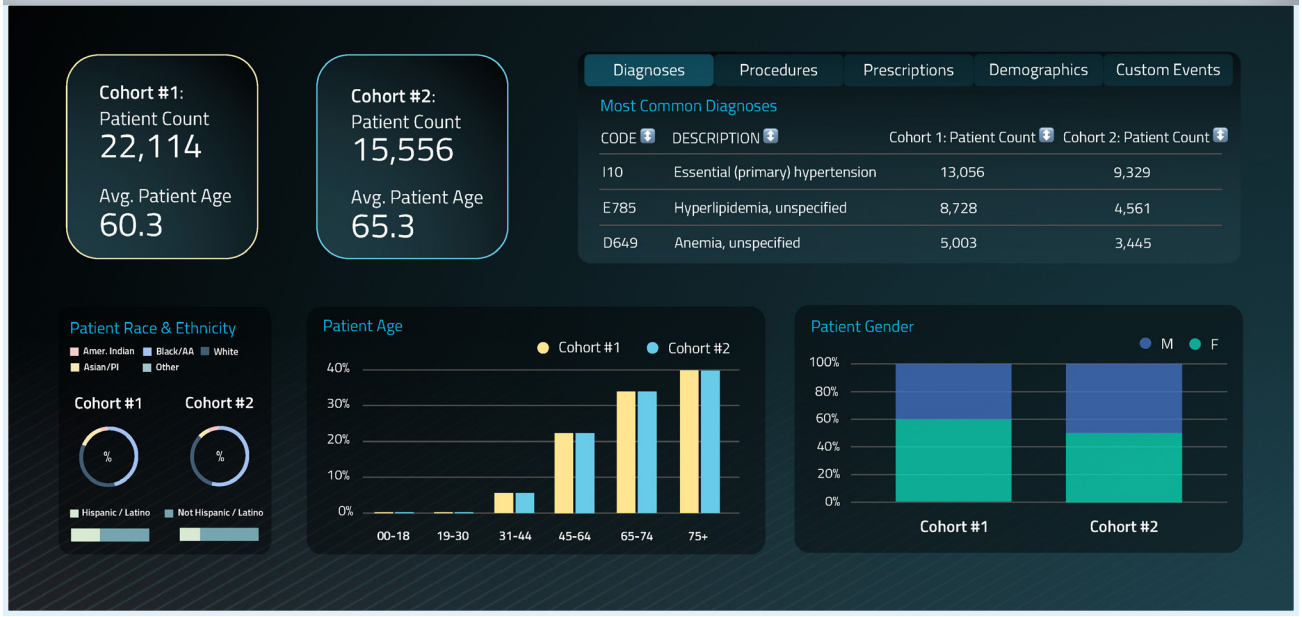
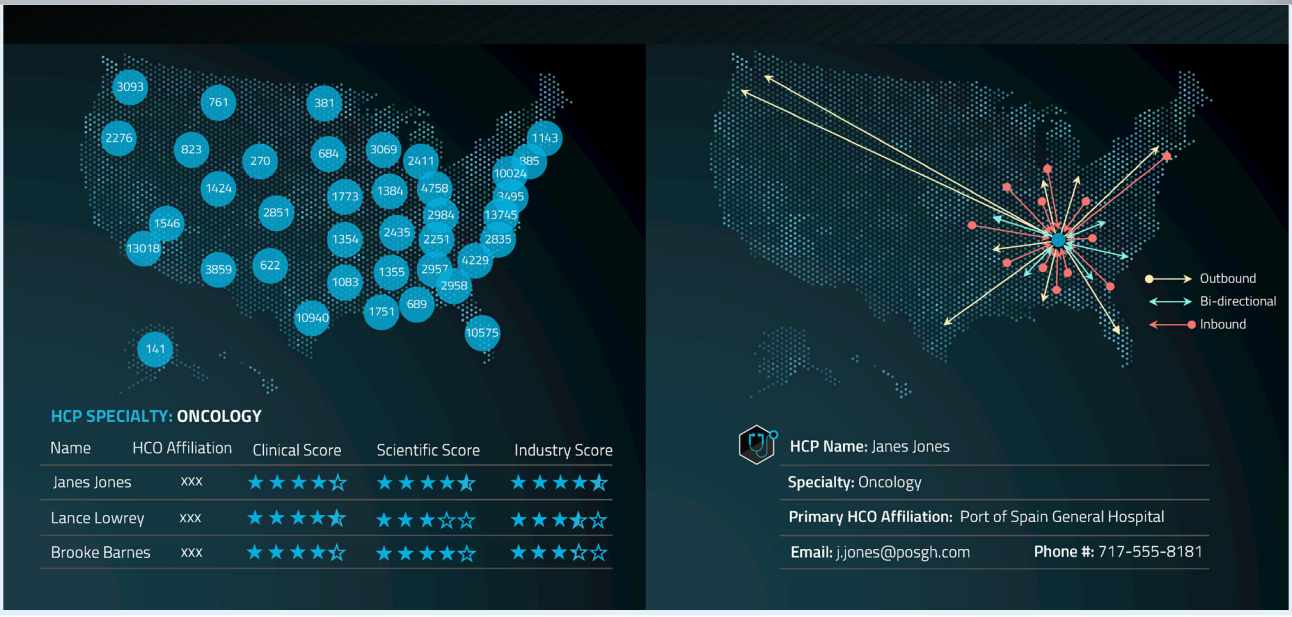



**FIGURE 4:** Understand provider treatment and referral patterns to inform site and investigator selection.




## INFORMING SITE AND INVESTIGATOR SELECTION

Another key component of clinical trial design where real-world data analyses can be used is the selection of sites and investigators for a particular trial. In addition to investigating patient journeys from the perspective of their interaction with the healthcare system, the Komodo Healthcare Map™ enables indexing of providers and healthcare organizations that interact with specific patient populations. Understanding the characteristics of these providers can challenge assumptions regarding which sites

and providers are best suited to participate in a trial. For a given therapeutic area, the volume of patients treated by providers across different specialties are indicated by an assigned clinical score. The extent to which these providers are involved in clinical trials or scientific publications is indicated by a scientific score, and the extent to which they are engaged with the biopharmaceutical industry in terms of payments for engagements is indicated by an industry score (**FIGURE 4**). Additionally, referral patterns are mapped to identify providers who are central nodes in a network of other providers. Providers can then be selected to provide patients for a particular trial, or identified as a key source of referrals for patient participants.

Similarly, indexing of healthcare providers can challenge assumptions regarding treatment patterns in various specialties. For example, one drug developer used these real-world patient data to understand treatment patterns across specialties for patients with chronic kidney disease and varied albumin levels. They were particularly interested in specialties that disproportionately prescribed glucagon-like peptide (GLP) receptor agonists since this was a key attribute of the inclusion/exclusion criteria. The analysis revealed endocrinologists were the leading source of GLP treatment, regardless of patient disease stage or albumin levels (data not shown), a finding that helped support decisions regarding investigator selection for the clinical trial.

## ACCELERATING TRIAL RECRUITMENT

Once a trial begins actively recruiting, key moments exist across a patient journey that are precursors to a patient becoming eligible for screening for inclusion in a particular trial. Trial recruitment can therefore be accelerated by identifying those key moments as a source for potential trial participants. Such moments may include a new diagnosis with specific health history, testing for a new disease or undergoing a procedure that is generally a precursor to diagnosis, starting a specific therapy that is a key part of the inclusion/exclusion criteria, or even continuing a therapy where progression to another treatment regimen is common (**FIGURE 5**). This can be accomplished in near real-time through the setting of software alerts on the Komodo Healthcare Map™, and providers who treat these patients can then be contacted for additional referrals into the trial.

**FIGURE 5:** Understand and intervene at specific patient journey moments that matter for trial recruitment.

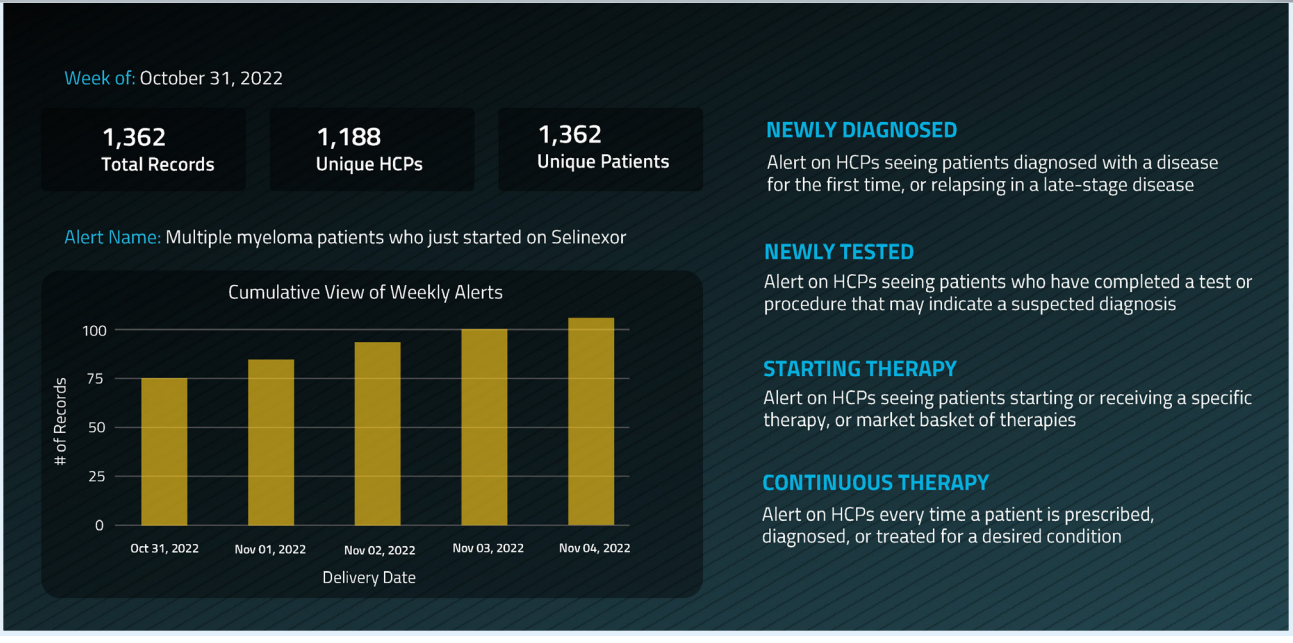
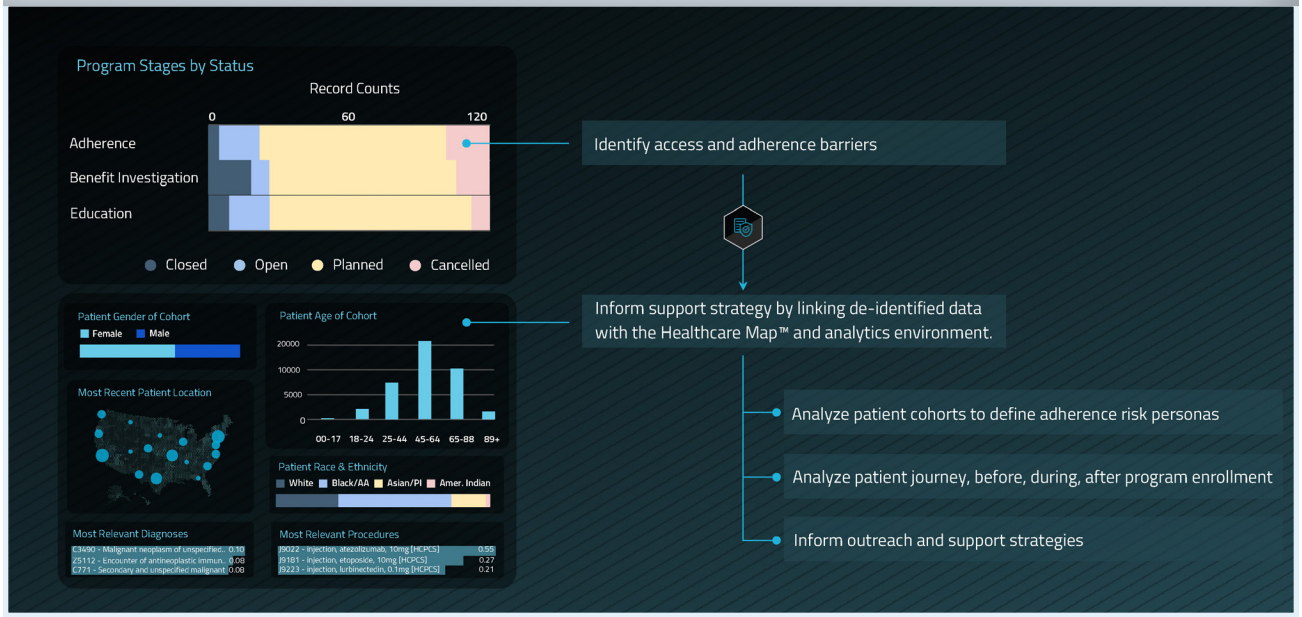


**FIGURE 6:** Drive patient outcomes by reducing time to access and maximizing adherence.




## REMOVING BARRIERS WITH REAL-WORLD DATA

The inclusion/exclusion criteria that was used to set the stage for a particular clinical trial are very well defined, but once a drug is approved the discipline of those criteria does not always translate into the labeling. This can directly impact patient experience with the drug as well as the drug's long-term therapeutic and market success. Mid- and long-term follow-up using real-world data after completion of a clinical trial can track efficacy and safety without the need for additional clinical trials and enables companies to challenge assumptions regarding access to their drug (**FIGURE 6**). Real-world data that reveal the entire patient journey, from prior to diagnosis through treatment, and even track clinical outcomes following changes in therapy can enable both qualitative and quantitative insights that can identify access and adherence barriers and inform outreach and support strategies to remove those barriers.

## CONCLUSION

An understanding of patient-level healthcare journeys informed by comprehensive, connected, real-world data creates a bedrock knowledge base that can inform clinical drug development strategies from design all the way through execution. Assumptions regarding patient experiences, trial populations, providers and specialties, and barriers to access can be challenged using analysis of these real-world data, yielding insights that can enable companies to identify gaps in care, accelerate research, better position their clinical trials for success, and enhance patient support even after a trial is completed.

## REFERENCES

1. Miksad, R.A.; Abernethy, A.P. Harnessing the Power of Real-World Evidence (RWE): A Checklist to Ensure Regulatory-Grade Data Quality. *Clin. Pharmacol. Ther.* 2018, 103, 202-205. DOI 10.1002/cpt.946