

WHITE PAPER

Bridging Data & Disparities: Unlock a Complete Patient Picture With SDOH

The Role of Social Drivers of Health in Clinical Trial Diversity

Integrating social drivers of health (SDOH) into clinical trial design is essential for improving participant diversity, ensuring research findings are more representative, and addressing long-standing health disparities.

Clinical trials have a diversity problem. Despite years of effort, participants in many studies still fail to reflect the true demographics of the populations they aim to serve. The consequences are profound: limited applicability of results, missed insights, and health inequities that persist across generations. The missing piece? A deeper understanding and integration of SDOH.

Remarkably, 80% of health outcomes are influenced by a patient's SDOH, including economic conditions, education, and the physical environment.¹ By incorporating SDOH into various stages of the clinical trial life cycle, researchers can design more inclusive studies that enhance participant diversity and improve health outcomes for all populations.

Diversity at the center of clinical trials

Integrating SDOH into clinical trial planning and design is crucial for achieving health equity and improving the overall effectiveness of healthcare interventions. Despite ongoing efforts, some racial and ethnic groups, along with individuals from lower socioeconomic backgrounds, remain significantly underrepresented in clinical trials.

A 2020 report found that African Americans, who represent 13.4% of the U.S. population, made up only 8% of clinical trial participants; Hispanic/Latino individuals, who are 18.5% of the population, accounted for just 11% of trial participants.²

This disparity is exacerbated by the lack of socioeconomic status (SES) reporting in trials. Without this data, the generalizability of research findings is limited, hindering the development of tailored interventions for lower SES groups.

The importance of SDOH in clinical trial diversity

The role of SDOH in enhancing trial diversity is critical; neglecting these factors perpetuates existing health disparities and can lead to trial endpoints that don't accurately reflect

real-world outcomes. By prioritizing diversity and inclusivity throughout the product life cycle, researchers can:

- **Create relevant trial designs:** Develop trial designs that genuinely reflect the needs of diverse populations
- **Enhance patient recruitment:** Identify and engage with diverse populations to improve participation rates
- **Address barriers to participation:** Tackle the obstacles that prevent underrepresented groups from participating in clinical trials

Designing Diverse Clinical Trials

Comprehensive endpoint selection

When designing clinical trials, consider endpoints that reflect the diverse needs of the patient population. Traditional endpoints often overlook the impact of SDOH on patient experiences and outcomes, leading to a limited or misleading understanding of treatment safety and efficacy across different demographic groups.

By including endpoints that account for socioeconomic factors – such as income, education level, and access to healthcare – researchers can gain a deeper understanding of how new treatments perform in the real world and across different demographics.

For example, a trial for a diabetes medication could assess clinical outcomes as well as how socioeconomic status affects medication adherence and access to care. This approach provides a more comprehensive view of the treatment's effectiveness across diverse populations.

Flexible and accessible trial design

Diverse clinical trial designs must accommodate the realities of participants' lives. Key accommodations may include:

- **Geographic accessibility:** Selecting trial locations that are easily accessible to diverse populations
- **Flexible scheduling:** Offering appointments at varied times to fit participants' work and family commitments
- **Participant support:** Providing assistance such as childcare services or transportation options to ease participation barriers

- **Inclusive criteria:** Expanding eligibility criteria to include a broader range of patients to be more representative of the general population

By implementing flexible and accessible trial designs, researchers can create inclusive environments that encourage participation from diverse populations.

Modification of protocols

To accommodate SDOH variables effectively, researchers should be prepared to modify trial protocols as necessary. Adjusting inclusion criteria or trial methodologies based on real-world data (RWD) and SDOH factors can help ensure that studies are more representative of the populations they aim to serve.

For example, if data reveals that certain demographic groups are underrepresented due to transportation issues, protocols can be adapted to include remote participation options.

Recruitment Strategies for Clinical Trial Diversity

Building inclusive populations

Achieving diversity in clinical trials is not merely a regulatory requirement, it is a critical component of effective research. Researchers can leverage deep population segmentation data and analyze disease treatment patterns to build inclusive patient populations. This approach helps accurately identify target populations that reflect the demographic and clinical characteristics of the broader community affected by the disease.

Utilizing extensive datasets enables researchers to pinpoint underrepresented groups in clinical studies. By understanding the locations and characteristics of these populations, researchers can develop targeted recruitment strategies that are both efficient and effective.

Addressing barriers to participation

Barriers to clinical trial participation often stem from various social risk factors that hinder healthcare access and care quality. Identifying these factors enables researchers to mitigate barriers and enhance patient care. Key challenges include:

- **Transportation issues:** Lack of reliable transport to trial sites
- **Economic barriers:** Financial burdens, such as travel costs and lost wages
- **Language barriers:** Limited English proficiency affecting understanding of trial information
- **Health literacy:** Variations in health literacy may hinder comprehension of trial protocols and risks
- **Access to information:** Lack of awareness about available trials, especially in underserved communities

Addressing the various barriers to participation is essential for fostering equitable access to clinical trials, ensuring that all demographic groups can contribute to and benefit from research advancements.

A Call for Change

Achieving true diversity in clinical trials is not just a regulatory checkbox; it's a scientific imperative. By integrating SDOH throughout the trial process, researchers can build more representative study populations, enhance data validity, and ultimately contribute to more equitable healthcare outcomes.



SDOH in Health Economics and Outcomes Research (HEOR)

SDOH have a severe impact on [healthcare outcomes](#); in response, emphasizing data challenges, economic model adjustments, and cross-sector collaboration can help improve health equity.

The importance of SDOH

Healthcare outcomes are influenced by more than just clinical care. “Only 20% of our health outcomes are actually attributed to the clinical care that we get,” said [Christie Teigland, Ph.D.](#) The other 80% of those outcomes are driven by socioeconomic factors, behaviors, and physical environment.³ Key SDOH include education, income, social support, diet, exercise, housing, and transportation.

Despite their significance, there are substantial barriers to addressing SDOH in healthcare. The primary challenge is the lack of comprehensive data access. Without detailed data on social risk factors, healthcare providers (HCPs) struggle to identify and address disparities. “For the most part, providers don’t have access to these data for most of their members and patients,” said Teigland.

While providers and pharmacists recognize the impact of SDOH, they lack the means to directly address issues like food insecurity or inadequate transportation. “If we want to close this gap, we really have to collaborate and build infrastructure at the local levels to help address these non-clinical aspects of healthcare that play an important role in outcomes,” said Teigland.

To combat this industry-wide issue, Inovalon has built a comprehensive SDOH data warehouse, [publishing studies](#) that demonstrate how factors like income, English proficiency, and living conditions affect health outcomes.

Adjusting Health Economic Models

Traditional health economic models often fail to account for the role of SDOH in healthcare outcomes. Adjusting performance metrics to reflect socioeconomic factors can provide a more accurate representation of care quality.

A prime example is the Medicare Advantage (MA) Five-Star Quality Rating System, where adherence to medications for hypertension, diabetes, and cholesterol is triple-weighted in determining reimbursement. “These measures were developed by the Pharmacy Quality Alliance (PQA),” said Teigland.

Inovalon’s collaboration with the PQA revealed that controlling for social risk factors significantly altered adherence rankings. For instance, Medicare patients who were dual-eligible for Medicare and Medicaid demonstrated lower adherence, largely due to financial constraints. Income data revealed additional disparities, proving the need for nuanced health models that capture the complexities of social drivers. “Even if you get the same quality of care, people who are low-income are less likely to be adherent,” said Teigland. “Interestingly, once we considered income in addition to Medicare and Medicaid eligibility, we found that people who are similarly low-income but don’t have dual eligibility are less likely to be adherent.” By just considering eligibility status, it is easy to miss the large population of individuals who are low-income and are not on Medicare or Medicaid.

One practical application of SDOH integration is Humana’s study, in collaboration with Inovalon, published in [NEJM Catalyst Innovations in Care Delivery](#), to address medication adherence disparities among Black MA members in Florida.³ By identifying members without a primary care visit in over a year, Humana leveraged community outreach to mitigate barriers such as childcare, transportation, and drug costs, ultimately improving adherence and outcomes.

Developing Outcome Measures

Building effective healthcare models requires a deeper understanding of how SDOH interact with patient outcomes. For example, Inovalon’s research on hepatocellular carcinoma (liver cancer) examined emergency room (ER) utilization rates. The study found that while low-income Black and White patients had similar ER visit rates, the disparity widened as income increased. Unlike White patients, higher income did not correlate with reduced ER visits among Black patients, suggesting systemic barriers beyond economic status. “You need these more sophisticated models to get at some of these hidden disparities,” said Teigland.

Similarly, Inovalon's collaboration with Humana demonstrated the necessity of multi-dimensional analysis in understanding medication adherence disparities. Initial findings indicated no significant difference in adherence rates between Black and White patients.

However, further stratification by dual-eligible status – Medicare beneficiaries who also qualify for Medicaid, often used as a proxy for low income – revealed a stark contrast. While Black and White non-dual eligible members had similar adherence rates, Black dual-eligible members exhibited significantly lower adherence compared to their White counterparts.³ This suggests that economic status alone does not fully explain disparities in medication adherence and that a broader range of SDOH factors must be considered to develop equitable healthcare policies and interventions.

Engaging Policymakers and Payers

While Inovalon does not directly engage in policymaking, the company's research has influenced federal healthcare strategies. Its studies comparing [Medicare Fee-for-Service \(FFS\) with MA](#) challenged prevailing assumptions about healthcare efficiency. Contrary to previous research favoring FFS, its findings demonstrated that MA enrollees – who often face greater social risks – achieved better health outcomes due to managed care interventions. This evidence is crucial for shaping policies that support equitable healthcare access.

“Some of our work focuses on helping policymakers and payers zero in on the biggest problem areas,” said Teigland. “This provides a big incentive for payers to address SDOH more as a financial strategy.” Missed medical appointments cost the healthcare industry \$150 billion annually and can increase the need for escalated care. Hospitalization is one of the most expensive aspects of healthcare, and reducing those hospitalizations is a clear way to save money in the long run.

Furthermore, studies indicate that social factors like food insecurity elevate the risk of chronic conditions such as diabetes, significantly increasing long-term costs. Humana found that food-insecure members were 50% more likely to develop diabetes. Addressing transportation, childcare, and similar barriers such as food insecurity could reduce these expenses and improve preventive care utilization.³

The Centers for Medicare & Medicaid Services (CMS) has taken steps to integrate health equity into reimbursement models. By 2027, the Excellent Health Outcomes for All (EHO4all) will be incorporated into MA five-star ratings, incentivizing plans to improve outcomes for socially at-risk beneficiaries. This initiative underscores the growing alignment between policy and data-driven healthcare interventions.

Utilizing SDOH Data Effectively

The effectiveness of SDOH data hinges on its granularity. Traditional studies rely on broad geographic groupings such as counties or ZIP codes. “There are only 42,000 5-digit ZIP codes,” said Teigland. Understanding the shortcomings of this approach, Inovalon’s SDOH data warehouse refines this approach by incorporating ZIP+4 level data, covering approximately 32 million micro-geographic areas. This precision helps better identify social risk factors and their direct impact on individual health outcomes.

Partnerships with data and technology firms like Inovalon can help with the integration of SDOH into healthcare decision-making and embed SDOH insights into clinical and pharmaceutical research.

Collaboration for Health Equity

Achieving health equity requires cross-sector collaboration. Traditionally, pharmaceutical companies, healthcare providers, and insurance plans have operated in silos. Inovalon helps bridge these gaps by providing real-world data and analytics that inform targeted interventions.

One of Inovalon’s most impactful contributions is equipping life sciences teams with actionable insights. By integrating SDOH data with clinical outcomes, Inovalon helps providers identify disparities and implement evidence-based solutions.

For example, the company’s software tools enable pharmaceutical representatives to present data-driven insights to healthcare providers, fostering meaningful discussions beyond product promotion. This approach has proven instrumental in boosting provider engagement and aligning efforts to reduce health disparities.

“Our unique perspective comes from a lot of experience integrating healthcare policy, data analytics, RWD, and evidence,” said Teigland. “Our work emphasizes not just collecting and analyzing the data, but translating that data into actionable insights that can drive change.”

Driving Patient Engagement Through SDOH Data

Leveraging SDOH data helps life sciences companies segment patient populations into distinct archetypes, allowing for personalized strategies that improve access, adherence, and engagement – ultimately leading to more equitable healthcare outcomes.

One-size-fits-all approaches no longer suffice to meet the complex health needs of diverse patient populations. Life sciences companies must recognize that patients differ in their clinical profiles and in their social and economic contexts, which significantly influence health outcomes. Yet, many organizations struggle to understand and meet these diverse needs, leading to gaps in patient access, adherence, and engagement.

SDOH data enables companies to segment populations into distinct archetypes, each defined by unique characteristics and challenges.

This level of insight allows for the design of targeted strategies that resonate with individual patient needs, ensuring that interventions are effective and equitable.

Exploring Patient Archetypes

Life sciences companies can enhance patient engagement by segmenting populations into distinct archetypes, each representing unique intersections of social, economic, and health-related factors.

[This segmentation approach](#) highlights the diverse challenges patients encounter and helps identify engagement strategies that can lead to better outcomes.

Five key archetypes and strategies

1 High-Income Isolated

This archetype combines high income and health literacy, but individuals in this group often lack strong social support networks. Despite their financial stability and knowledge of health information, they struggle with feelings of social isolation, which can lead to lower likelihood of adhering to treatment plans.

Targeted interventions like digital health tools that provide emotional support and connect them with similar individuals can be particularly effective.

2 Underserved Communities

Members of this group typically struggle with low income and health literacy, compounded by a higher risk of depression. They face significant healthcare access barriers and often mistrust the healthcare system.

Engagement strategies for this archetype require culturally sensitive communication, simplified educational materials, and robust support systems to improve health literacy and access.

3 Stable Cautious

This group is financially and educationally stable but are hesitant about proactive health management. Members in this archetype may be resistant to new treatments and slow to change health behaviors.

Strategies to engage this group should emphasize clear, evidence-based information and the long-term benefits of proactive health management.

4 Passive Unaware

Characterized by low income and low health literacy, patients in the Passive Unaware archetype are often unaware of the health risks they face. This lack of awareness can lead to poor treatment adherence and adverse outcomes.

Prioritizing educational interventions that focus on the importance of medical advice and regular follow-ups can help improve this group's engagement and overall health.

5 Non-Traditional Advocates

The Non-Traditional Advocates archetype consists of well-informed individuals who prefer alternative medicine and may be skeptical of conventional treatments. To successfully engage with individuals in this group, respectful communication is key.

Engagement requires acknowledgment of individual preferences, coupled with balanced information about the benefits of conventional medical approaches. Integrative strategies that combine traditional and alternative treatments can appeal to their proactive health management style.

Prioritizing High-Risk Groups

Certain patient archetypes demonstrate heightened vulnerabilities that require immediate and specific interventions.

For instance, the Passive Unaware group requires the most immediate attention due to its vulnerability and lack of awareness. Targeted education and support can significantly improve their outcomes.

Similarly, the High-Income Isolated, while generally better informed, can benefit from focused interventions that address their specific need for social and emotional support.

By leveraging SDOH data to understand and segment patients into these archetypes, life sciences companies can develop more effective and personalized strategies to improve access, adherence, and overall patient engagement.

Implementing a targeted approach enhances patient outcomes and drives commercial success by aligning resources with the areas of greatest need.

Improving Patient Access

SDOH data provides critical insights into the challenges patients face when trying to access therapy. A recent study revealed that factors like distance to treatment centers, age, gender, and socioeconomic status significantly influence treatment adherence, emphasizing the necessity for targeted interventions.⁴

By understanding these barriers, life sciences companies can develop tactics that ensure equitable access across diverse populations, including:

- **Tailored access strategies:** By identifying patients facing the greatest access challenges, companies can deploy targeted solutions like financial aid for low-income patients or transportation for rural residents
- **Engaging relevant stakeholders:** By informing healthcare providers and pharmacies of patient-specific barriers, companies can promote personalized care and advocacy for better access solutions

Maximizing Therapy Adherence

Adherence to therapy is a significant challenge, especially when patients face social or economic barriers.

A recent study highlights the significant impact of socioeconomic factors on diabetes medication adherence. The research found that individuals who could not afford balanced meals were 44% more likely to be non-adherent to their diabetes medication compared to those who could afford balanced meals.⁵

SDOH data can help life sciences companies identify these hurdles and offer strategies to keep patients on therapy, such as:

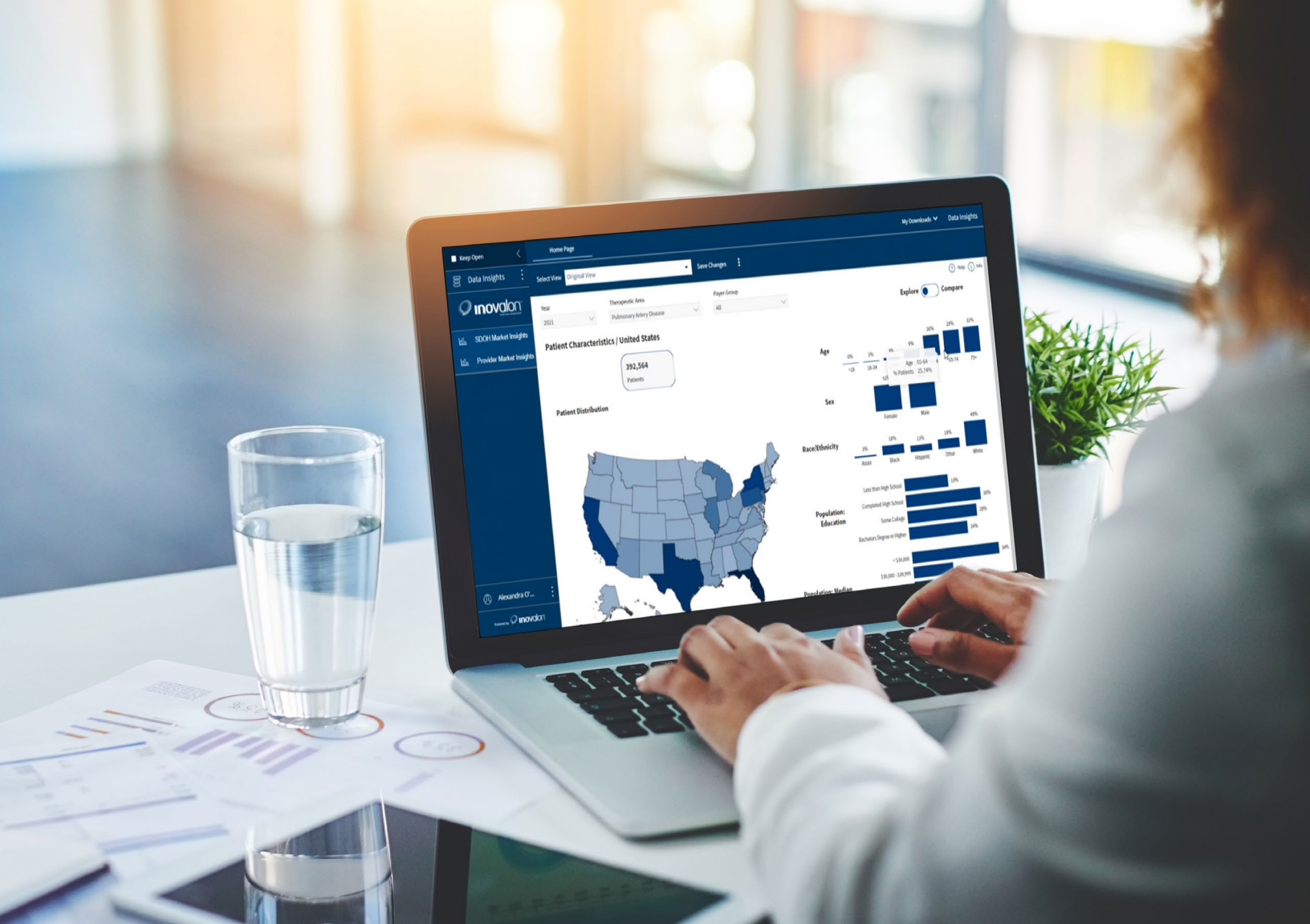
- **Designing adherence programs:** By creating targeted programs that address the unique obstacles of each patient archetype, such as providing educational efforts for the Passive Unaware or personalized support for the High-Income Isolated, companies can improve patient adherence.
- **Improving engagement:** By directly engaging patients with educational materials and reminders, or indirectly through healthcare providers, companies can enhance adherence rates and foster better health outcomes.

Engaging Patients for Better Outcomes

Effective patient engagement is at the heart of successful commercial strategies.

SDOH data enables life sciences companies to connect with patients in ways that resonate with their unique circumstances. This includes:

- **Personalized communication:** By tailoring messages to deliver meaningful, patient-specific information and simplifying complex medical terms, companies can improve patient understanding and engagement in their care
- **Empowering healthcare providers:** By equipping providers with SDOH insights to foster more effective patient interactions, companies can help drive better adherence and health outcomes



Advancing Patient Care With SDOH Data

Harnessing SDOH data empowers life sciences companies to develop deeply personalized strategies that address the unique barriers each patient faces.

By segmenting populations into distinct archetypes and tailoring interventions accordingly, companies can enhance patient engagement, adherence, and access, ultimately driving equitable and effective healthcare outcomes for all.

Enhance Patient Care

About us

Inovalon is a leading provider of cloud-based SaaS solutions empowering data-driven healthcare. The Inovalon ONE® Platform brings together national-scale connectivity, real-time primary source data access, and advanced analytics into a sophisticated cloud-based platform empowering improved outcomes and economics across the healthcare ecosystem. The company's analytics and capabilities are used by over 50,000 active, licensed customers.

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