Investment Thesis Report: Voice of the Patient

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Background

Overview: *This section traces the historical evolution of the "voice of the patient" movement in healthcare, ranging from paternalistic, provider-driven models toward participatory frameworks that prioritize patient experience and input. It outlines the key legal, social, and technological milestones that catalyzed this transformation, highlighting how advocacy, regulation, and digitization have institutionalized patient perspectives within clinical research and care delivery.*

The *"*voice of the patient*"* has been a defining trend within healthcare that has evolved through an increasing recognition of the importance of incorporating patient feedback and lived experience into treatment design, delivery, and development. Historically, healthcare prioritized the perspectives of physicians, scientists, and regulators over patients themselves, but there is a growing inclusion of patient insights into the way in which treatments are designed, developed, tested, and deployed.

For much of the 20th century, healthcare was primarily centered on a paternalistic model where physicians decided on treatments without input from the patient, making the patient passive recipients of their own care rather than active participants. Patient-focused outcomes – such as pain levels or daily functionality – were secondary to quantifiable metrics such as survival rates and lab values. Drug development and deployment mirrored this approach: scientific voices and clinician judgement overshadowed patient consultation, with trials largely designed without consideration for the patient experience (Kaba & Sooriakumaran, 2006).

Several forces contributed to the gradual shift from the paternalistic model to the emphasis on the voice of the patient. The principle of informed consent, which emerged in the mid-20th century, legally obligated physicians to properly explain the full scope of risks and benefits that a patient may experience from a specific treatment, shifting the paradigm to patients

being an active advocate for their own care (De, 2004). Several landmark court cases underscored the necessity of patient awareness in treatment reception, such as *Salgo v. Leland Stanford*, which reinforced that legal action could be pursued by a patient if they were not fully educated by their provider on the extent of risks and alternatives associated with a specific treatment (Green & MacKenzie, 2007). However, this shift was also driven by the recognition that the traditional, provider-centric model often failed to meet patients' broader emotional, informational, and long-term care needs. As medical complexity increased, it became clear that effective care required not only clinical expertise but also active patient participation to ensure treatments aligned with individual values, expectations, and lived experiences.

Patient advocacy movements also served as another catalyst for greater inclusion of the patient voice. The HIV/AIDS crisis of the late 20th century served as the backdrop for developments in treatments and therapies, as advocacy groups and those afflicted with the disease used their own experience to accelerate drug approvals, increase access to experimental treatments, and trial designs that reflected their lived experience. This not only contributed to the development of life-saving therapies, but also re-shaped regulatory policy to include patient perspectives as stakeholders who could actively shape the trajectory of treatments (FDA, n.d.). Chronic diseases have also necessitated the need to look beyond traditional clinical endpoints. As survival rates have improved in cancer, cardiovascular diseases, and other rare conditions, patient-reported outcomes ("PROs") have arisen as crucial tools for capturing quality-of-life data. PROs have now become effective methods in accurately capturing the patient condition pre- and post-treatment, as well as increasingly relevant within clinical research through patient-centered approaches that are necessary for holistic perspectives on treatment impacts (Weldring & Smith, 2013).

The regulatory landscape has also been crucial in developing a patient-centric approach. The FDA's Patient-Focused Drug Development ("PFDD") initiative, which launched in 2012, instituted a framework for the agency to capture patient perspectives that have been valuable in gathering data on specific diseases and their available treatments. Stakeholders can utilize the patient voice to determine the factors that matter most to patients, the role they play in the drug development process, and their perspective on meaningful treatment benefits (FDA, n.d.).

Digitization practices within healthcare have also been a notable factor. Historically, healthcare has lagged in digital adoption compared to other industries due to a myriad of factors related to compliance, regulatory requirements, and legal challenges. Furthermore, additional elements such as skepticism related to the efficacy of technology and potential data breaches of sensitive data related to confidential patient information, have also served as barriers to digital adoption (Charalambous, 2024). However, the onset of the COVID-19 pandemic in 2020 forced healthcare organizations to digitize overnight to maintain connections to their patients. Software solutions such as telehealth, remote patient monitoring, and decentralized trial technologies demonstrated that patients were willing to engage with digital platforms, serving as the foundation for scalable channels for continuous patient input that may have taken years to establish under pre-pandemic conditions.

Introduction

Overview: *This section defines the scope and importance of the voice of the patient in today's healthcare landscape. It examines how patient insights inform clinical development, regulatory processes, and payer decision-making, while situating these dynamics within broader market forces such as pricing pressure, rare-disease growth, and value-based care models. Beyond shaping evidence generation, the voice of the patient extends across the entire drug development life cycle, informing everything from early research and clinical trial design to commercialization, market access, and post-market surveillance. Embedding patient perspectives at each stage ensures that therapies are not only clinically effective but also aligned with real-world patient needs and adoption.*

The voice of the patient is inherently multi-faceted, encompassing not only the collection of clinical outcomes such as survival or lab results, but also patient conditions and outcomes such as symptoms, treatment preferences, adverse events, and quality of life. This data shapes drug development, clinical trial design, regulatory review, and post-market evaluation, positioning it as a crucial element for making evidence-based healthcare decisions.

Drug development is both costly and risky for pharmaceutical companies. Estimates place the cost to bring a drug to market close to $1B when accounting for potential failures and capital costs (Wouters al., 2020). With 10–15 years to go-to-market and high costs of development, it is critical that pharmaceutical companies have access to the most relevant data for decision-making. Early integration of patient insights ensures that trial endpoints are meaningful, enrollment strategies are realistic, and treatments are aligned with patient expectations. Patient perspectives de-risk the R&D lifecycle and reduce potential complications that could delay development.

Far from being a static data point, the voice of the patient is a dynamic channel across the treatment lifecycle. In the early design phase, patients and advocacy groups can play an essential role in contributing to the selection of PROs, bringing experienced perspectives of the disease, symptoms, and attributes of care that can lead to effective care for future patients (Addario et al., 2019). Health plans also utilize the patient voice through real-world evidence ("RWE") when making reimbursement decisions and evaluating treatment effectiveness. RWE is intended to provide greater evidence from patients and groups about characteristics beyond those collected in randomized controlled trials (Saldarriaga, 2022).

Current market dynamics define the patient voice as a critical point of urgency. Upcoming clusters of Prescription Drug User Fee Act ("PDUFA") review dates set to occur in 2025 and 2026 are expected to accelerate the cadence of drug launches, incentivizing sponsors to avoid costly mistakes. The rise of specialty and rare-disease therapies highlight the relevance of incorporating the patient voice; a smaller and more specialized patient population requires engagement for clinical trial design and endpoints that reflect patient needs. The Inflation Reduction Act (IRA) passed in 2022 has placed pricing pressures through authorizing Medicare to negotiate drug prices, which lowers revenue on blockbuster drugs and creates less room for pricing flexibility. This has placed pharmaceutical companies under increased scrutiny from payers, prompting them for greater value creation that can be derived from patient-centered evidence (Cubanski et al., 2023).

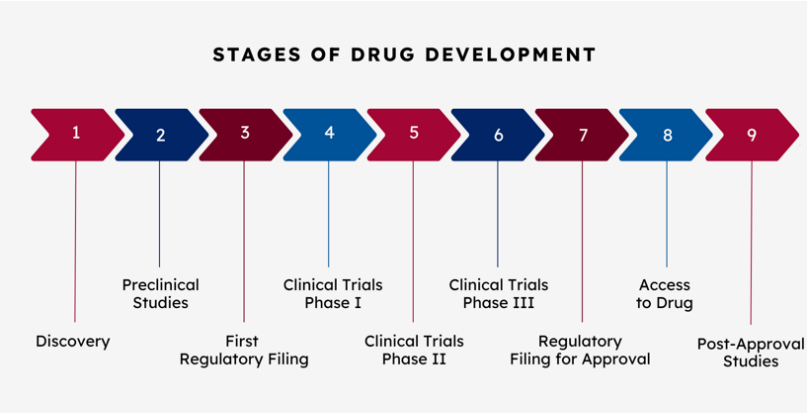
Affected Parties

Overview: *This section maps the ecosystem of stakeholders influenced by and contributing to the voice of the patient, including pharmaceutical firms, CROs, payers, regulators, advocacy groups, and technology vendors. It analyzes how each group derives value from patient data and the systemic interdependencies shaping the patient-centered healthcare model.*

Pharmaceutical & Biotechnology Companies

From the perspective of pharmaceutical and biotechnology companies, the voice of the patient is a critical component for the treatment development cycle and success in the commercial market. The current success rate for a drug beginning in the clinical trial stage and receiving market approval ranges from 10–20 percent (Yamaguchi et al., 2021). This puts intense pressure on ensuring that clinical trials are properly aligned and that the drug development cycle succeeds in as few attempts as possible. Patient insights can mitigate the risks associated with development, as patients' lived experiences form the basis for effective and meaningful trial outcomes and studies that are feasible for research participants.

Figure 1: Drug Development Stages



From Friedreich's Ataxia Research Alliance

Pharmaceutical companies can also rely on outcome-based contracts to negotiate with payers regarding drug pricing. These contracts can enable health plans to reduce costs associated with treatments that may not improve patient health, while manufacturers can appear on a list of formulary they may otherwise have been excluded from. As these models scale commercially, reliable PROs become critical for measuring real-world effectiveness and reducing disputes over performance metrics. The incorporation of standardized PRO data not only enhances the foundation of value-based agreements, but also helps manufacturers to garner payer interest through clear, patient-centered impact (Gonzales, 2019).

Contract Research Organizations (CROs) & Trial Infrastructure

CROs and clinical trial infrastructure providers are intermediaries in operationalizing the voice of the patient. Through service offerings such as electronic PRO platforms, decentralized trial solutions, and patient engagement programs, these organizations improve recruitment and retention. These patient engagement tools help minimize historical barriers in clinical research, such as dropout rates and enrollment delays that can increase the costs associated with clinical trials. The increasingly popular "patient-in-a-box" model advertised by the American Medical Association and National Institutes of Health prioritize finding patients first, then establishing trial sites. Patients are identified and gathered from several real-world data sets (e.g., EHRs, insurance, and social media) through analytics and processing tools. Patient-centric approaches at sites, such as the use of mobile apps, remote monitoring, and wearable technology, aid in increasing retention and improving convenience. These models could reshape the economics of clinical-trial operations by shifting roughly $4 billion in today's site-based activity and unlocking an additional $8 billion in new tech-enabled opportunities. The biggest drivers of this disruption

are more efficient endpoint capture, automated data collection, and simplified site setup and integration. (Bennani et al., 2024).

Payers & Health Plans

Payers and health plans can capitalize on the patient voice through the shift toward value-based care models that influence payments based on patient outcomes and satisfaction rather than pure service volume. PROs and real-world data have become critical components in determining both coverage and reimbursement levels. Value-based reimbursement strategies are more innovative solutions considered by healthcare policymakers to create a more sustainable healthcare system by focusing on the quality of care that patients receive, rather than quantity. For the delivery of patient-focused health outcomes, there is a need to prioritize the patient experience and reimburse the system through consideration of patient outcomes. Importantly, value-based care models also empower patients by aligning incentives around their long-term health rather than the quantity of procedures performed. This shift encourages care coordination, preventive interventions, and stronger patient-provider relationships, ultimately improving health literacy, treatment adherence, and satisfaction. Value-based care emerged from previous models which attempted to capture the patient experience. The capitation payment model provided a pre-specified and fixed amount of money to providers who were able to deliver comprehensive care services to a population over time while adjusting for patient care mix and care quality. The bundled payments model emerged as a method by which providers were paid for the complete cycle of care for specific clinical conditions with the potential for an incentive based on achieved outcomes. This eventually led to the Bundled Payments for Care Improvement ("BPCI") Initiative, launched in 2013 as an innovative reimbursement model supported by payers to increase both accessibility and affordability. As primary care emerged as a key facet of value-

based reimbursement strategies, it became instrumental in shifting the healthcare system toward value, but doing so requires the ability to measure costs and outcomes across the full episode of care for each patient (Etges, 2023).

Regulators

Regulatory bodies are among the most influential groups embedding patient voice and insights into frameworks guiding drug development and commercialization. Historically, there was a lack of capturing the lived experience of a patient multidimensionally across several domains (physically, mentally, etc.). In 2022, the FDA implemented the Food and Drug Omnibus Reform Act ("FDORA") to close this gap through enhancing diversity in clinical trials and accurately gathering patient data from several segments of the population. Additionally, it also stipulated guidance for greater use of real-world evidence to support drug and device applications (Congress.gov, 2022). The 21st Century Cures Act passed in 2016 also advanced the incorporation of the patient experience into drug development, biological products, and devices used in the FDA's decision-making process (FDA, n.d.). It formalized official guidance on the process of collecting and submitting patient experience data to the FDA as well as emphasized the necessity of patient engagement across several phases of data processing, including collection, reporting, management, and analysis. The Cures Act also led to stricter requirements for the FDA to draft reports based on patient experience data and reported outcomes for new approved drugs (Goble, 2018). The Patient-Focused Drug Development Initiative ("PFDD") spun-out of the legislation in the 21st Century Cures Act, cementing patient insights as a key contributor to better inform the development of medical products and regulatory decision-making. For instance, the FDA released guidance on the best methods to appropriately capture patient input – including comprehensive and representative input, methods to identify what is

most important to patients, selecting fit-for-purpose clinical outcomes assessments, and incorporating clinical outcome assessments into endpoints for regulatory decision-making (FDA, n.d.).

Patients & Advocacy Groups

Patients and advocacy groups are among the most important stakeholders central to the voice of the patient. Care has evolved from patients being passive recipients of treatments that may not have been the most optimal for their condition to being a leading voice through active contribution and input of their own care. They are the heart of insights that several other stakeholder groups use to formulate and shape therapies that can properly address quality of life, functional outcomes, and treatment convenience. While patient perspectives have been making positive strides in healthcare, challenges remain in fully encompassing the voice of the patient into drug delivery models. For instance, highly specialized and rare therapies can seek to benefit the most from patient inputs.

Technology Vendors & Startups

Healthcare technology vendors and startups play a pivotal role in advancing and scaling the voice of the patient, as they are the next generation of innovative companies that can create platforms for gathering, analyzing, and deploying patient input through software-as-a-service (SaaS) models and solutions. The market size for patient engagement solutions was estimated to be $27.63 billion in 2024 and is expected to rise to $86.67 billion by 2030, with the digital patient monitoring devices market to experience a 25.2% CAGR from 2025 to 2030 (Grand View Research, 2025), but one of the greatest challenges facing healthcare is data fragmentation and silos, which can hinder patient care that can potentially impact diagnoses and treatment solutions (Fierce Healthcare, 2025).

Current Trends & Problem Identification

Overview: *This section explores both the persistent challenges preventing full-scale adoption of patient-centered systems and the emerging trends redefining healthcare's data and engagement landscape. It discusses key barriers such as data fragmentation, interoperability, clinician burden, and privacy concerns, alongside accelerating trends like AI-driven analytics, post-COVID digitization, and regulatory alignment.*

Problem Identification

The healthcare industry has begun to experience a paradigm shift toward patient-centered insights, but many of the systems, processes, and infrastructure meant to support the voice of the patient remain heavily fragmented. Stakeholder groups such as pharmaceutical and biotechnology companies recognize the importance and value of patient-reported data and insights, but the integration across data silos to improve the treatment development cycle has remained insufficient. Factors contributing to this fragmentation largely originate from a lack of standardization for PRO metrics, variable digital adoption across companies within the healthcare ecosystem, and inconsistent interoperability within existing clinical data systems. These foundational drawbacks have restrained the ability for this market to effectively scale, but the introduction of AI has enabled more efficient analysis and modeling across large volumes of unstructured data.

Fundamentally, there is a struggle in properly operationalizing patient insights efficiently, even though stakeholder groups recognize the value that it can have toward improving clinical outcomes and trial quality. The transition from traditional on-paper PROs to a digital format has been accompanied by challenges pertaining to workflow disruption, clinician burden, and cost (Mowlem et al., 2024). Although large pharmaceutical players have the resources and capacity to

include PRO endpoints when conducting major trials, smaller organizations often struggle to properly possess both the infrastructure and necessary tools needed to meet regulatory expectations. Ultimately, this contributes to a system where large enterprises have the capacity to integrate patient insights through a streamlined process, while smaller players remain reliant on insufficient methods.

Data silos also play a substantial role in compounding the problem of fragmentation. When collected, patient feedback is often located within systems that are isolated from clinical or claims data. This data is typically trapped within proprietary channels such as EHRs, outcomes platforms, or clinic-specific tools that are not capable of dynamic sharing. Although data has grown from a volume standpoint, it is ineffective if it remains in closed pools that offer minimal holistic insight. The true value of data lies in its ability to be mobilized and exchanged through integration. Beyond the challenge of silos, the next frontier involves using integrated, real-world data for dynamic modeling and demand forecasting, allowing organizations to anticipate patient needs, treatment trends, and resource utilization in real time. The ability to continuously capture and model data as it is generated connects evidence creation directly to lived patient experiences, enabling a feedback loop where clinical and operational decisions are informed by evolving real-world outcomes rather than static historical data. By breaking down proprietary barriers and activating this real-time flow of information, stakeholders can generate stronger evidence bases, drive more intentional care delivery, and uncover new revenue opportunities through predictive analytics (Bendersky, 2023). Another underlying issue preventing full data integration is measurement validity and comparability. Although the marketplace for instruments related to PROs has increased, there are few tools that have the capacity to achieve consistent cross-disease and cross-country compatibility. With a lack of standardization and normalization across

healthcare systems, different organizations use several formats and guidelines for aspects such as data entry, organization, and storage. Although there are current resources to help address standards for interoperability, such as the Fast Healthcare Interoperability Resources ("FHIR") and the Consolidated Clinical Document Architecture ("C-CDA"), data exchange between different EHRs can be impeded due to lack of adoption and implementation. By using incompatible standards, systems face difficulty in communicating with each other, leading to a substantial slowdown of data in a digestible format (Davis, 2025).

Beyond a technological standpoint, adoption barriers also originate from human factors and friction generated from the multi-faceted nature of work that clinicians perform. Within the United States, physician burnout has been increasing, with EHRs as a primary contributing factor. Besides providing care to patients, many physicians spend time performing administrative tasks, which fundamentally changes their workflow and the way they interact with patients. In a 2018 survey of 521 primary care providers, approximately half believe that "EHRs impair clinical effectiveness." Additionally, 44% simply see EHRs as data storage, rather than valuable channels to harness patient insights, as the components of EHR-related burnout can be consolidated into categories of time demands, documentation and clerical burdens, complex usability, cognitive load, and electronic messaging volume (Budd, 2023). Although the benefits of EHRs are the methods and metrics that they can capture regarding patient data, the feeling of "data overload" contributes poorly to the willingness of physicians for its usage and efficacy, as they believe that more data is not necessarily the answer for higher quality healthcare (Brown, 2024).

Finally, one of the largest challenges pertaining to problem identification are the sentiments surrounding privacy and governance concerns, which can serve as a bottleneck to

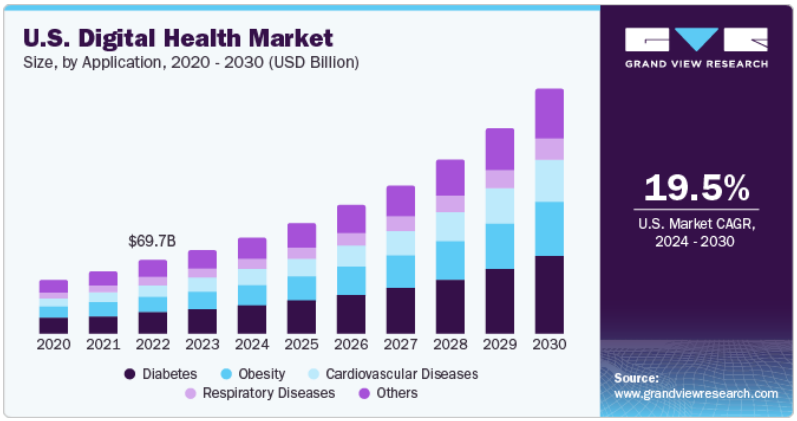
integration and access of patient insights. At its core, the voice of the patient involves the handling of highly sensitive data that could reveal patient information such as specific conditions, treatment adherence, and personal data. Within the United States, the U.S. Department of Health and Human Services governs data privacy through the Health Insurance Portability and Accountability Act ("HIPAA"), which requires measures related to access restrictions, encryption protocols, and breach notifications for health information electronically protected. Although these frameworks are robust, there is still substantial risk associated with increasing integration of EHRs and digital tools (Conduah et al., 2025). A collaboration between the American Medical Association and the Savvy Cooperative sought to explore patient perspectives related to privacy of medical information. This led to a 1,000-participant study aimed at capturing patient perspectives, confirming that there is deep concern among patients regarding a lack of security and the inability to ensure confidentiality of their data. Patients are most comfortable with providers having access to their data, and least comfortable with data access for social media sites and big technology companies (Alder, 2022). To properly establish patient trust and institute robust governance models to certify that patient insights will be properly harnessed, it is imperative that licensing or subscription frameworks are utilized to minimize sentiments that could threaten integration and adoption across data systems.

Current Trends

Digital Health Implementation and Post-COVID Adoption

With the onset of the COVID-19 pandemic in the beginning of 2020, the digitization of healthcare faced a transformational acceleration as patients and providers transitioned to outlets such as remote communication, telehealth, virtual monitoring, and mobile data collection.

Figure 2: U.S. Digital Health Market Size



From Grand View Research

As the effects of the pandemic began to cool, these services began to normalize, leading to lower barriers for gathering patient insight and engagement data. Necessity was the driver for these new innovations, as the pandemic illustrated a large spike in the amount of telemedicine adoption by consumers. For physicians, telephone and video channels experienced an overnight rapid rate of adoption, growing from 20 percent to 80 percent and normalizing digital care. While healthcare has historically lagged in digitization compared to other industries, the impact of technology in the healthcare landscape has demonstrated its effective uses. Even after the pandemic, most physicians surveyed stated they would continue the development of digital innovations (Torre, 2021). Patients became more comfortable with digitally reporting outcomes and experiences using their personal devices, supercharging the ability for the voice of the patient to be collected more efficiently.

Value-Based Care and Outcome Reimbursement

As healthcare systems begin to deviate from fee-for-service reimbursement models, there has been a trend in the integration of PROs into value-based care models. Instead of primarily using treatment or service quantity as a metric, there have been incentives to focus on the

outcomes that are most impactful to the patient: quality of life, satisfaction, and functional improvement. The Centers for Medicare & Medicaid Services designed the Hospital Inpatient Quality Reporting Program, which was intended to increase PRO measures by rewarding hospitals for the quality of care that they provide to patients, and requires data submission on quality measures (CMS.gov, n.d.). With this strategic alignment between payments PROs, there is an incentive to capture and report high-quality patient data. Providers can demonstrate superior performance through value-based care, while payers can realize outcomes that extend beyond clinical efficacy. Life sciences companies can form outcome-based agreements with payers, which provides a link between drug pricing and real-world patient benefits. As value-based care continues to expand, the ability to capture and validate patient experiences will be a distinction point.

Artificial Intelligence and Advanced Analytics

Artificial intelligence and natural language processing models have been instrumental in shaping the voice of the patient landscape by converting unstructured patient data into clear and actionable intelligence. With patient data being generated on a massive scale through channels such as surveys and digital platforms, manual interpretation is no longer feasible. AI has the capacity to enable real-world sentiment analysis, theme clustering, and predictive modeling to unlock correlations between experiences, symptoms, and outcomes. One of its most impactful applications lies in patient journey mapping through building detailed patient profiles early in the clinical cycle and tracking them from pre-clinical research through commercialization. This longitudinal view allows stakeholders to better understand evolving patient needs, identify intervention points, and design more patient-centric therapies. AI can also be leveraged in the context of mobile health assessment tools that span the entire patient journey, assisting in

identifying potential causes of symptoms. Advanced analytics appear in consumer wearables that screen undiagnosed patients for signs of disease and enable providers, through digital diagnostics, to successfully monitor patients remotely (IQVIA, 2024). Beyond analytics capabilities, generative AI also has use cases for automating regulatory reporting by summarizing patient narratives and mapping them to validated instruments, thereby reducing both the cost and time required for submissions. This technology expands voice of the patient vendors from being data collectors to insight providers, enabling them to differentiate on the depth of analysis rather than the volume of data alone.

Regulatory Alignment and Patient Insight Institutionalization

Regulatory formalization and patient experience data has been critical for the incorporation of the voice of the patient into drug development and approval. The U.S. first instituted this shift through the PFDD Initiative, detailing the extent to which PROs and patient insight data should be collected, validated, and leveraged to inform labeling of end benefit-risk decisions. The FDA's update in 2024 not only emphasized that patient data must be captured using standardized processes, but also compels sponsors to use voice of the patient platforms for compliance initiatives.

Globally, other nations have also begun this movement toward institutionalization. The framework of the European Medicines Agency ("EMA") has emphasized the importance of supporting access to patient experiences and promoting the collection and use of evidence-based patient experience data. Health Canada launched a Patient Involvement Pilot Project that was used to assess how input from patients and advocacy groups could be utilized within the drug submission review process (Klein et al., 2016). These regulatory frameworks have transitioned the patient voice from being a consideration to an expectation. This can create consistent demand

for voice of the patient platforms, making patient experience data and insights mandatory components of regulatory and market-access submissions.

Monetization of the Patient Voice

Overview: *This section analyzes how patient insights are being commercialized through scalable, tech-enabled models. It breaks down the major monetization strategies: SaaS platforms, patient data licensing, outcome-based contracts, and professional services, which convert patient engagement into sustainable business value and recurring revenue.*

The commercialization and monetization of the voice of the patient has grown rapidly as healthcare has shifted toward the inclusion of patient-centered insights. The ability to scale and package these insights lies in innovation platforms and solutions that can capture raw patient data through channels such as surveys, ePROs, and engagement data that is converted into digestible and actionable value for stakeholders such as pharmaceutical companies and payers. Rather than acting as a complement to existing platforms, voice of the patient solutions have the opportunity to become integral to the execution of clinical trials, regulatory approval, reimbursement practices, and long-term patient adherence. Among the many solutions available, the most promising business models are SaaS-based with the opportunity to be licensed to sell datasets and validated PRO tools, outcome-based contracts, and services linked to accessibility and adherence.

Software-as-a-Service ("SaaS")

With a SaaS-based model, patient voice platforms can digitize collection of ePROs and other forms of proprietary raw patient data collection to then license and sell to other parties such as pharmaceutical organizations, contract research organizations, and health systems on a subscription basis. Contracts can be negotiated on a per-study, per-patient, or enterprise-wide model with different tiers of pricing based on the needs and scale of the organization. ePROs have distinct advantages over traditional paper-based collection because of features such as real-

time reporting and streamlining of workflows that enhance the differentiation of SaaS adoption (Gwaltney et al., 2008). SaaS models also offer a more predictable business model through recurring revenue, making it an attractive opportunity for potential investors and those looking for scalability. However, SaaS solutions are highly competitive, meaning a moat must be established through ease of integration into existing systems or advanced analytics capabilities (Gnanasakthy, 2019).

Patient Data Aggregation and Licensing

Besides purely subscription-based monetization models, another solution involves the creation of large, de-identifiable, longitudinal sets of data that can be sold to institutions such as pharmaceutical companies and CROs. These datasets can provide unique insights into components such as treatment adherence, symptom patterns, and patient quality of life that can be difficult to capture through traditional clinical trial endpoints alone. The commercial value proposition of this method of monetization is that it directly addresses a need that many pharmaceutical companies and CROs face: the need for condensed trial timelines, trial design improvement, and support for post-market surveillance. But to command the premium pricing that these sets of data will be marketed at, there must be evidence of clear quality, representativeness, and defensibility of datasets while continuing to remain compliant within the constraints of data privacy frameworks such as HIPAA (Gibbons et al., 2016).

Another strategy within aggregation and licensing is the commercialization of validated PRO instruments. Solutions that can house and cultivate libraries of disease-specific PROs can license these tools directly to sponsors or CROs. Additionally, there can also be service offerings such as translation, cultural adoption, psychometric validation, and regulatory documentation. Within the context of regulators such as the FDA increasingly expanding the expectation of

validated and patient-centered endpoints within clinical trial endpoints, this monetization model has a distinct advantage (FDA, 2022). Platforms that provide access to validated instruments not only succeed in streamlining adoption, but also enhance stickiness among clients. Through embedding these instruments in digital platforms, companies can powerfully combine the capabilities of licensing fees with usage fees, leading to multiple streams of revenue associated with the same asset.

Outcome-Based Platforms

Patient-centric platforms can also be interwoven with models that reward positive outcomes, where fees are generated through a relationship with measurable performance metrics such as greater trial retention rates, lower participant attrition, and improved adherence. These models are similar to other platforms in healthcare that are designed to maximize patient outcomes based on quality, rather than the number of treatments and services administered. Outcome-based models can be fundamental in not only improving the quality of care administered to a patient, but also reducing the financial strain on the healthcare industry by driving cost-saving initiatives and contributing to a financially stable healthcare ecosystem (Latkovic, 2013). For instance, a platform may elect to form a contract with a sponsor to guarantee a specific improvement in ePRO completion rates compared to historical benchmarks. If the platform can deliver the results based on the terms of the contract, it can receive performance incentives, while if it does not, it may be subject to certain penalties. This model has potential to be attractive to sponsors because it mitigates upfront risk and mirrors incentives between the platform and the sponsor. However, it does require advanced attribution methodologies to isolate the impact of the platform from other confounding variables, as well as continuous monitoring and audibility to preserve trust and authenticity.

Besides direct monetization strategies, value can be derived from patient-centered platforms by improving accessibility, adherence, and equity. A lingering challenge within clinical trial design and execution is preserving diverse and representative patient populations for all of those impacted by a disease. Dropout rates are often skewed toward cohorts that have fewer barriers to entry and participation. Platforms that can enable multilingual interfaces, chatbot or speech-based reporting, low-bandwidth mobile apps, or offline capture tools are better positioned to capitalize on patient populations that may have otherwise been excluded from clinical trials. Patients prefer platform accessibility, speed, and convenience, leading to higher completion rates for ePROs (Golden, 2023). Through enhancing adherence and reducing dropout rates, these platforms can improve trial efficiency and power, creating intrinsic value that sponsors are willing to pay a premium for. Furthermore, as both regulators and payers demand greater diversity in clinical trials, platforms that can provide greater inclusion will have a more competitive advantage.

Additional Services

Additional services and integration solutions also provide several avenues to monetization. Several platforms have pricing models tied to integration with electronic health records, clinical trial management systems, and regulatory reporting pipelines. Others provide services related to advanced analytics packages that utilize natural language processing and machine learning for raw patient engagement data, turning it into actionable and quantitative insights. These models not only increase the amount of revenue for a given client, but also embed the platform deeper into client workflows, thereby decreasing the amount of churn and increasing the likelihood of renewal. Through offering professional services such as training and

implementation support, these solutions can derive competitive value from being comprehensive platforms rather than single-point vendors.

Alternatives & Adjacent Markets

Overview: *This section identifies the broader ecosystem of adjacent or competing markets that intersect with the voice of the patient. It highlights overlaps with digital health, engagement platforms, and patient communities, emphasizing opportunities for integration, differentiation, and defensible growth strategies within a rapidly converging industry.*

While tools directly related to the voice of the patient occupy a distinct role in the aggregation and capture of structured patient experience and insight data, there are also several adjacent markets and alternative solutions that have potential overlap or serve as natural extensions for current vendors. An understanding of these adjacent markets is crucial for positioning, defensibility, and upside.

One of the closest alternative markets is broader patient engagement platforms. These systems place an emphasis on communication, reminders, educational content, symptom tracking, and portal interactions rather than a deeper dive into PRO and ePRO capture and data analytics. These engagement platforms may possess features such as surveys or feedback, yet typically lack the validated instrument libraries or regulatory alignment factors that a voice of the patient platform can provide. Many of these leading patient engagement platforms place an emphasis on chatbots, appointment reminders, and telehealth integration, which are adjacent functions that are less specialized than traditional voice of the patient tools. For instance, platforms such as Simbie AI are cutting-edge tools that leverage the capabilities of voice-based artificial intelligence to revolutionize the methods that healthcare practices use to manage administrative tasks and interact with patients. These clinically trained AI agents can handle a variety of tasks, such as routine appointment scheduling to complex prior authorizations and personalized patient education (Simbie, 2025). These solutions may increase competition for the

same budget lines in provider or payer organizations, leading to potential limitations in the willingness to invest in specific voice of the patient tools unless clear and distinct differentiation can be identified.

Another adjacent market is digital health platforms and marketplace ecosystems. These platforms broadly aggregate several health services, including telehealth, wellness apps, device integration, and clinical decision support into one singular ecosystem. The global digital health market is one that is primed for substantial growth in the coming years, with an expected growth CAGR of approximately 22.2% from 2024–2030 (Grand View Research, 2025). Voice of the patient offerings have the potential for integration or can serve as valuable targets for acquisition to further consolidate patient-facing experiences, administrative tools, telemedicine, and remote patient monitoring.

Besides direct alternatives to patient-facing tools, social and patient community networks are also platforms which operate on the periphery of traditional voice of the patient solutions. For instance, platforms such as PatientsLikeMe or HealthUnlocked primarily offer a patient-centered community and data-sharing network, which has historically had monetization paths through aggregated data licensing, scientific partnerships, and research contracts (PatientsLikeMe, n.d.). Although these platforms function more as community-oriented solutions rather than traditional regulatory-grade patient engagement capture, they do compete for patient attention and insights, especially for chronic and rare disease segments. HealthUnlocked, which is a large patient community network based in the U.K., provides a suite of services including peer support, content curation, and symptom tracking across hundreds of different disease communities, enabling a seamless path for patient-generated data to be used as a byproduct of engagement and providing a direct source of first-party data inputs and insights.

Given these adjacent markets, another opportunity lies in voice of the patient vendors to partake in expansion markets where their core capabilities can confer an advantage. Through patient segmentation and market research, voice of the patient platforms can extend into support for marketing, real-world evidence strategy, and payer marketing by supplying patient preferences, burden profiles, and quality-of-life metrics that inform market segmentation and messaging. Another capability is health economics and outcomes research modeling, a voice of the patient tool that captures outcomes data to build modules for modeling utility values, cost-utility analysis, and reimbursement scenario simulation. Another adjacent space is clinical decision support, which is tied to patient-reported signals, such as triggering alerts or care pathways that are based on patient-reported symptom or recovery patterns. Since voice of the patient systems already have the capability to collect symptom and functional data, they are extremely well-positioned to feed or integrate with clinical decision support modules, particularly in the context of chronic diseases.

Based on research of these adjacent markets, it is critical for a voice of the patient vendor to refine its strategy within a defensible moat. There must be considerations over whether it should choose to remain specialized or horizontally expand into engagement, remote patient monitoring, analytics, or community ecosystems. Each adjacent expansion opens avenues for growth but also increases the risk for more intense competition or dilution of positioning. A defensible path can lie in modular partnerships, where voice of the patient platforms are embedded into broader ecosystems, yet remain autonomous over the capture of patient experience, instrument validity, and data governance. In this fashion, the vendor can expand into adjacent markets but retain its control over the value core – direct access to inputs that support the commercial and brand performance of prescribed drugs and therapeutics.

Potential Investment Areas

Overview: *This section synthesizes the voice of the patient landscape into key investable segments, from data analytics infrastructure to patient networks and real-world evidence providers. It highlights notable players, scalable business models, and strategic tailwinds that make the sector attractive for early-stage healthcare investors.*

The voice of the patient intersects regulatory compliance, data analytics, and patient engagement; healthcare has begun to recognize patient insights as a core component for treatment development, regulatory submission, reimbursement frameworks, and care optimization. The current market is fragmented, composed of technology vendors, research networks, analytics firms, and patient communities that attempt to capture, structure, and monetize patient-generated data.

From a top-down perspective, the voice of the patient landscape is broadly defined within four different segments: data infrastructure and analytics firms that normalize and aggregate patient data, online patient communities and engagement platforms serving as collection channels, research and recruitment networks facilitating studies, and educational solutions to convert patient engagement into scalable insights. Although these segments collectively capture, curate, and monetize the patient voice, they each have their own business models and unique pressures, playing a role in patient supported services and giving patients a platform to share their voice and experiences.

The large-scale data and analytics providers such as IQVIA and Komodo Health specialize in mining data and aggregating it into digestible frameworks and populate a substantial part of the value chain by offering integrated datasets that can combine clinical, claims, and PROs. IQVIA's patient-centered solutions division leverages patient feedback to

design and support clinical trials that maximize value for patients and access treatments faster (IQVIA, n.d.). Komodo's health data solutions platform provides access to a "Healthcare Map," which contains a comprehensive and real-time patient journey of over 300 million unique individuals (Komodo, n.d.). These firms are critical partners for regulators, CROs, and payers by positioning themselves as irreplaceable to patient-centered insight distribution.

Digital health communities such as Health Union, The Mighty, and Health Central represent another layer of the ecosystem. These platforms have capabilities to generate real-world narratives through patient dialogue, curated disease content, and peer support. They not only serve as a community that can connect patients with similar backgrounds but can also create qualitatively rich datasets for licensing to pharmaceutical and market research partners. Similarly, firms such as Rare Patient Voice and Liberating Research can connect sponsors with verified patient populations for advisory boards, qualitative interviews, and real-world data collection. These organizations fill a crucial need to generate a bridge between patient insights and monetization, closing the divide between anecdotal experiences and regulatory-grade evidence.

Despite there being momentum for the voice of the patient, the broader ecosystem is positioned between consolidation and convergence. Larger players are seeking to acquire smaller organizations to bolster patient networks and access authentic data streams, and community-driven solutions seek partnerships to leverage data interoperability and compliance. This convergence suggests that the voice of the patient market is entering a phase where scale, proprietary data assets, and integration will determine the longer-term winners.

Patient Data Platforms and Analytics Infrastructure

One of the investable layers within the voice of the patient landscape is data infrastructure and analytics platforms that are a critical component for patient-generated insights. These systems have capacity to collect and standardize PROs, integrate them with clinical data, and deliver comprehensive analytics to life science and pharmaceutical clients.

IQVIA remains a market leader in this space, leveraging global data assets and regulatory partnerships to provide services from instrument design to analytics integration. The patient experience solutions division is built to accommodate the needs of regulatory bodies such as the FDA regarding standards for patient experience data, which enables sponsors to integrate patient insight metrics into clinical trial design and submission. Other competitors such as Komodo Health and Definitive Healthcare are commercializing similar services with cloud-native infrastructure and real-time analytics pipelines. Firms such as dQ&A bring targeted expertise in disease-specific areas, including diabetes, enabling organizations to capture more nuanced and specialized patient-reported data.

Company Logo	Recent News	Company Description
patientIQ	PatientIQ raised a $20 million Series B in 2022 to accelerate growth, enabling new partnerships with orthopedic and specialty practices to expand its PRO analytics network.	PatientIQ provides a cloud-based outcomes platform for health systems to collect and benchmark patient-reported outcome measures. It integrates with EHRs to help providers track post-treatment quality-of-life and satisfaction metrics.
VIDERA HEALTH	Videra Health has raised $8.6M across two seed rounds, including a 2021 $3M Seed to scale remote behavioral health monitoring and a 2024 $5.6M Seed II to advance its AI mental health assessment tools and expand deployment of its video-based screening and monitoring platform.	Videra Health is an AI-driven video assessment platform for behavioral health and life sciences that gathers structured quantitative and qualitative patient data to detect risk earlier, monitor outcomes between visits, and power real-time safety and efficacy signals for research.
morf	Morf raised a $3 million Seed round in late 2023 to expand its platform, which is designed to reconcile and activate patient data across the tech stack.	Morf syncs and unifies patient data across a provider's tools and EHR systems. By automating data workflows and eliminating tedious manual entry, it helps clinics maintain a comprehensive, up-to-date view of each patient's records.

Patient Communities and Digital Networks

Online patient communities and social platforms have become crucial tools for data generating, converting daily conversation into scalable healthcare intelligence. These organizations act as moderators for ecosystems where patients can discuss symptoms, treatments, and experiences, leading to qualitative patient engagement data at a larger scale.

Health Union, which manages several platforms for complex health conditions, such as *Chronic-Hives.com*, *Heart-Failure.net*, and *Lung-Cancer.net*, curates condition-specific discussions that capture both structured and unstructured data that can inform clinical trial recruitment, brand strategy, and patient support programs. Other platforms, such as The Mighty, connect millions of users across hundreds of different communities, providing outlets for patient feedback and discussion.

Platforms such as HealthCentral focus on crafting medically reviewed content and bridging patient stories with educational materials to improve health literacy and treatment adherence. These platforms have gained commercialization through a combination of advertising, data licensing, and sponsored content partnerships. These data sets, which are foundationally rooted in real-world patient dialogue and sentiment, offer a collection of unique insights that can complement the qualitative outputs produced by larger analytics firms.

Company Logo	Recent News	Company Description
myHealthteam	MyHealthTeam raised a Series C round to grow its advertising and data licensing services, which allow pharma clients to glean real-world patient insights from its active user forums.	MyHealthTeam develops social networking apps for over 40 different conditions. Each network is a dedicated space for patients to ask questions and share experiences with others who have the same diagnosis
Stuff That Works.	StuffThatWorks raised a $9M Seed round to scale its crowdsourced patient-experience platform and expand its condition communities as a real-world treatment-effectiveness dataset.	StuffThatWorks hosts AI-powered patient communities that crowdsource treatment experiences across chronic conditions, creating structured patient-reported data that helps members identify effective therapies and supports research-ready insights.
patientslikeme®	PatientsLikeMe raised $26M in 2021 to expand its community platform and data/insights offerings for clinical research and partner programs, building on prior strategic activity that embedded PLM more deeply into the healthcare ecosystem.	PatientsLikeMe operates large, condition-based patient communities where members track symptoms, share patient-reported outcomes, and learn from peers. The platform supports real-world evidence generation and study recruitment for life sciences by synthesizing de-identified lived experience.
PatientPartner	PatientPartner raised a $7M Seed round in 2024 to scale its mentor-driven patient engagement platform, enhance its technology, and expand into new treatment areas and healthcare verticals.	PatientPartner is a digital health communication platform that leverages the power of real-world patient experiences to personalize the patient journey and drive market awareness for pharmaceutical and medical device companies.

Research and Recruitment Networks

Research and recruitment networks serve as a middle-ground between grassroots patient engagement and enterprise analytic solutions. They provide sets of patients and caregivers for qualitative research, focus groups, and advisory boards. This area has become relevant in the context of rare and chronic diseases, where locating and engaging the right patient populations creates a bottleneck.

Rare Patient Voice, which maintains a comprehensive panel of over 100,000 patients and caregivers spanning hundreds of conditions, has become a source for sponsors seeking perspectives on rare diseases. Liberating Research, another organization headquartered in the United Kingdom, mirrors a similar model which emphasizes ethical compensation and patient empowerment.

From an investment standpoint, the model that these businesses follow are attractive from the perspective of scalability and margin profile. Their assets, which are verified participant panels and proprietary databases, require low capital expenditure to maintain and can be integrated into larger voice of the patient or real-world evidence platforms. As decentralized trials become more commonplace, recruitment networks specializing in digital engagement and patient retention will see rising demand from players such as CROs and biopharma companies.

Company Logo	Recent News	Company Description
	Savvy Cooperative closed a 2023 Seed funding round to enhance its platform, which matches client projects with patient "advisors." It also launched an initiative to ensure more diverse patient representation.	Savvy Cooperative is unique as a patient-owned co-op that empowers patients to share their experiences with healthcare innovators.
	In 2025, Trially secured a $4.7 million Seed round led by Flyover Capital and launched an AI assistant ("Margo") that not only finds matches but also engages and enrolls patients through automated outreach.	Trially was founded to match patients with studies faster; the system reads clinical trial protocols and integrates with electronic health records to identify eligible patients in real time.
	Power exited stealth with a $7M Seed round to expand patient access and increase diversity in clinical trials, further developing its patient-friendly platform that connects people directly with research teams across therapeutic areas.	Power is a consumer-facing clinical trial marketplace that simplifies discovery and pre-screening for patients while enabling sponsors to drive patient-led recruitment. It focuses on usability, speed to match, and transparency.
	Javara raised a $3.78M Series A in 2019 to scale its integrated research organization model and deepen partnerships with physician groups and health systems. They have raised approximately $60M, with $9M currently outstanding in a note.	Javara is an integrated research organization that partners with large physician groups and health systems to attract clinical research studies from pharma and manage the expensive and complex clinical trial process.
	Thrivable raised a $6M round in 2023 to build out its patient experience data platform, enhance data monitoring capabilities and product offerings.	Thrivable offers medical device companies access to a leading marketplace of diabetes patients for the purposes of research and development.

Healthcare Media, Education, and Engagement Platforms

Healthcare media and education platforms represent an adjacent but strategically critical category within the voice of the patient value chain. Companies in this category exercise patient engagement by providing content, decision aids, and wellness tools, which effectively function as patient voice collection points.

WebMD, one of the largest publishers of digital health content, reaches millions of monthly users and partners with pharmaceutical companies for engagement and education initiatives. In contrast, Healthcasts targets healthcare professionals yet increasingly integrates patient-centered analytics into educational offerings.

These platforms have potential as strategic acquisition targets for larger data analytics firms seeking direct access to patient and clinician traffic. Their core asset, which is the ability to generate continuous, first-party engagement data, positions them as gateways for collecting and contextualizing patient feedback at scale.

Company Logo	Recent News	Company Description
Mytonomy	Mytonomy announced a partnership with the American Heart Association in 2025 to co-create video content for cardiac rehab patients, following a $25M Series B funding round to grow its content library and analytics capabilities.	Mytonomy produces short, tailored educational videos for specific conditions and delivers them through a digital platform to patients' devices. This helps healthcare organizations scale consistent education while reducing staff burden.
Healthcasts	In August 2024, Healthcasts announced a major update to its clinician collaboration and research tool, extending AI features that highlight critical scientific attributes and context for decision-making.	Healthcasts is an HCP collaboration and education platform built for point-of-care utility: clinicians search real-world cases, validate decisions via a physician-driven intelligence engine, and keep up with breaking updates and trials.
IMPIRICUS	Impiricus raised a $3M Seed round in 2022 to further strengthen its team and scale provider acquisition to meet pharma demand for new go-to-market solutions on its HCP-pharma engagement platform.	Impiricus provides a software platform for pharmaceutical companies to engage with physicians for brand-specific insights, enabling unparalleled connectivity. Hyper-relevant health care provider (HCP) education is realized through evidence-based resources such as clinical data, patient outcomes, and updated guidelines.

Real-World Evidence and Integration Specialists

As regulators and payers increasingly rely on real-world data and real-world evidence, the ability to integrate patient-reported data into these broader evidence frameworks has become a key investment area. Companies that specialize in linking voice of the patient data with clinical, genomic, or claims information are emerging as critical partners in the evidence-generation ecosystem.

Definitive Healthcare, for example, is an analytics platform that integrates provider, claims, and patient-level datasets to generate insights into treatment outcomes and quality performance. These platforms serve as a connective point for enabling patient insight data to influence market access, reimbursement, and regulatory policy.

Investment in this segment provides broad exposure to the highest layer of the voice of the patient ecosystem, which is the translation of patient-reported data into measurable outcomes that drive economic decisions. As value-based care and outcomes-based contracting expand, the demand for integrative analytics will rise sharply, which will position real-world evidence players as critical enablers for voice of the patient scalability.

Company Logo	Recent News	Company Description
SEQSTER™	SEQSTER raised a $12M Series A to accelerate adoption of its healthcare data interoperability technology and expand its multi-dimensional RWE platform for patients, providers, payers, and life-science partners.	SEQSTER creates unified, longitudinal patient records by integrating EHR, genomic, wearable, and claims data into a single research-ready dataset. It enables sponsors and researchers to link patient-generated information with clinical and real-world sources through a consented, privacy-preserving data infrastructure.
folia HEALTH	In late 2025, Folia raised a $10.5 million Series A to scale its patient-driven RWE platform. The data collected has informed FDA discussions, treatment guidelines, and studies in lupus, sickle cell, cystic fibrosis, and more.	A Boston-based startup pioneering “home-reported outcomes” to turn patients’ day-to-day health experiences into structured real-world evidence. Folia’s app empowers patients to track symptoms, treatments, and outcomes and share that data for research.
ATROPOSHEALTH	Atropos Health raised a $33M Series B in 2024 to scale its evidence-generation platform, broaden its clinical data partnerships, and accelerate development of AI tools that generate timely, high-quality RWE for providers and biopharma.	Atropos Health generates on-demand real-world evidence by transforming large networks of de-identified EHR and claims data into rapid, queryable analyses. Its platform enables clinicians and life-science teams to answer specific clinical or research questions using structured observational data, producing fit-for-purpose RWE to guide decisions.

Strategic Outlook & Recommendations

Overview: This section concludes by evaluating the long-term trajectory of the voice of the patient and its implications for investors and healthcare stakeholders. It emphasizes the enduring shift toward transparency, accountability, and patient-driven innovation, offering recommendations for identifying and capturing value in this evolving ecosystem.

Although the voice of the patient is a fairly recent phenomenon, it will continue to be a dominant force within healthcare. The landscape has structurally shifted as patient engagement, insight, and perspective have noticeably shaped the treatment development cycle and the approach taken by pharmaceutical companies, regulators, payers, and health systems. This growing emphasis on patient insight reflects a lasting structural priority that will continue to shape strategy and decision-making across biopharma and the life sciences.

The broader macroeconomic landscape has several positive tailwinds that will positively influence the voice of the patient. As value-based care models continue to propagate how providers interact with patients and the way that payers use reimbursement models to more effectively prioritize patient outcomes instead of quantity of service, patient engagement and perspectives will play a central role in streamlining and shaping these operations. Simultaneously, the digitization of healthcare following the COVID-19 pandemic has enabled the normalization of virtual care models such as telehealth, remote patient monitoring, and digital data collection from patients. With the advent of AI and natural language processing models, there will be a distinct advantage for companies that are able to unite data across different silos and gather proprietary insights on patient data at scale. Collectively, these

developments indicate that voice of the patient solutions will continue to grow as healthcare moves toward greater transparency, accountability, and patient-driven decision-making.

From an investment perspective, the voice of the patient offers an opportunity for investors to capitalize on a movement before it scales. The most compelling opportunities are those with platforms that can utilize SaaS models with proprietary datasets or solutions that can generate recurring revenue on a contracted basis. Furthermore, platforms with direct reimbursement pathways can benefit from higher adoption potential and scalability. Solutions with PRO enablement, decentralized trial participation, and advanced patient engagement analytics are well-positioned among the intersection of healthcare compliance, software, and data. As pharmaceutical companies continue to outsource non-core functions and seek greater efficiency, there will be more agility in decision-making and openness to new technologies that can assist with these processes. As these trends accelerate, the voice of the patient is emerging as a strategic asset shaping innovation priorities and creating new avenues of value across the life sciences.

FCA Venture Partners is a venture capital firm investing in early-stage healthcare technology and technology-enabled healthcare services companies that improve patient care, reduce costs, and increase efficiency. FCA manages over $285M and invests across the Seed to Series B stages. Our firm brings portfolio companies valuable healthcare insights, connections, and board-level experience to accelerate growth and build disruptive and sustainable businesses. Based in Nashville, the epicenter of healthcare innovation, with a strategic network in Charlotte and Winston-Salem, NC, our team has a decades-long track record including more than 60 investments in the rapidly changing healthcare industry.

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