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Patient Focus

From Insight to Impact: Elevating Patient Engagement in Medical Affairs

WHITE PAPER

This white paper series explores how patient engagement enhances drug development—driving better research, outcomes, and innovation. Through insights and real-world examples, we highlight the value of putting patients at the center of medicine's future.

Executive Summary

In today's evolving healthcare landscape of increasing developmental complexity and ever greater commercial challenge, patient engagement has emerged as a critical component of medical affairs strategy. By incorporating patient insights into clinical research, treatment development, and healthcare decision-making, organizations can improve outcomes, enhance patient adherence, and foster trust, ultimately improving the efficiency of clinical development and long-term commercial success. This white paper explores the significance of patient engagement in medical affairs, strategic approaches for implementation, and future trends that are anticipated to shape the industry.

Introduction

More than half of the of drugs launched in the last 15 years have underperformed analysts' expectations by more than 20%.¹ However, concurrently drug development has become increasingly complicated, with more targeted therapeutic options being researched and marketed for more discrete and specific patient populations. With the costs associated with bringing these therapies to market having increased, given the complex development programmes and production requirements, the commercial demands for success are greater than ever. Pharmaceutical and biotechnology companies are therefore looking at all available routes to ensure their development and commercialisation strategies are as effective and efficient as possible.

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Traditionally, medical affairs functions have focused on disseminating scientific information and liaising with healthcare professionals, with teams structured largely to reflect this priority. However, the shift towards a more patient-centric approach has begun to redefine the role of medical affairs, driven in significant part by regulatory shifts such as the FDA's Patient-Focused Drug Development (PFDD) guidance. Engaging patients as active stakeholders leads to better-informed clinical trials, improved real-world evidence collection, and more personalized healthcare solutions. This in turn improves overall patient care and satisfaction, ultimately saving pharmaceutical and biotechnology companies' time and unnecessary expenditure, while also enhancing product sales.

It is estimated that the value of a single day of delay is worth approximately \$500,000 in unrealized or lost prescription drug sales and \$40,000 in direct daily clinical trial costs.² A 2018 study estimated that investing \$100,000 in patient engagement could equate to accelerating a pre-phase II product launch by approximately 2.5 years.³

\$100,000 invested in patient engagement could equate to accelerating a pre-phase II product launch by ~2.5 years, while a single day of delay is worth \$500,000 in unrealised or lost prescription sales.

1. Enhancing Clinical Trial Design and Recruitment

- It is estimated that the direct daily costs for running clinical trials are typically around \$40,000. Phase III clinical trials have the highest direct cost per day at \$55,716, while studies in respiratory, immunology, rheumatology, and dermatology have the highest direct costs per day.⁴
- Patient input leads to more relevant study endpoints and inclusion criteria. For example, patient-reported outcomes (PROs) have been instrumental in refining endpoints for chronic disease treatments, ensuring that trials measure factors most meaningful to patients.
- Improved recruitment and retention rates occur due to increased trust and understanding. Historically, study drop-out rates, particularly in late-stage trials, have been shown to be as high as 30%.⁵ A study on patient navigation programs found that patients who received structured support were twice as likely to complete clinical trials compared to those without assistance.⁶
- Electronic Patient-Reported Outcomes (ePROs) have been shown to enhance enrolment rates significantly. A randomized study demonstrated that using ePROs to identify eligible patients and send direct invitations resulted in a 20% enrolment rate, compared to 0% using traditional physician referrals.⁷
- Increasingly, many companies are actively incorporating patient insights into clinical development plans and Target Product Profiles (TPPs). Gaining insights into potential barriers to use and patient perspectives on risk:benefit can enhance both clinical development efficiency and long-term commercial success.

Effective patient engagement can improve study recruitment and patient retention, the cost of which can be more than \$40,000 per day for a late-stage clinical trial.

2. Improving Real-World Evidence and Outcomes

- Real-world insights enable better regulatory and market access decisions. The FDA's Patient-Focused Drug Development (PFDD) initiative has demonstrated that patient input can shape regulatory approvals. For example, in rare disease treatments, patient perspectives on quality of life have directly influenced drug approvals and label expansions, as seen in Duchenne muscular dystrophy treatments.
- The EUPATI 2023 guidance document called for increasing and equitable patient involvement in Health Technology Assessments (HTAs). While this remains an evolving area, the inclusion of patient experience data into HTAs continues to grow and have greater influence on the outcomes of technology reviews.⁸
- Incorporating patient-reported outcomes enhances data quality. For instance, in rheumatoid arthritis research, PROs provide insights into pain levels, fatigue, and mobility that traditional biomarkers alone cannot capture, leading to more comprehensive treatment assessments.
- Engaged patients who participate in clinical trials or real-world data programs contribute to better data quality and better treatment insights, which can speed up regulatory approval processes. According to McKinsey, companies that engage patients in these ways may reduce the time to market by 6-12 months, leading to faster revenue generation.⁹

Companies that effectively engage patients in clinical trials and real-world data studies may reduce the time to product commercialisation by 6-12 months.

3. Strengthening Communication and Trust

- Approximately half of the therapies launched in the last 15 years have underperformed analysts' sales expectations by more than 20%.¹⁰ While it is not possible to quantify the absolute extent to which patient communication and understanding has influenced these data, the impact of ineffective or absent patient engagement cannot be underestimated. A 2019 study demonstrated that improved adherence from effective patient support can increase medication sales by as much as 40% in some therapeutic areas.¹¹
- Transparent engagement fosters credibility between pharmaceutical companies and patient communities. A survey by the PatientView group found that companies with strong patient engagement practices ranked higher in trust and reputation among patients, particularly in chronic disease areas like multiple sclerosis and diabetes. While a 2014 Accenture patient survey found that 60% of patients are more likely to select a drug or treatment if it is paired with a strong support program.
- Addressing patient concerns early improves adherence and satisfaction. Research indicates that when patients are involved in shared decision-making, adherence rates improve significantly. For instance, in cardiovascular disease management, patient education and involvement have been linked to better medication adherence and long-term outcomes.
- A survey of 4,000 patients across the US and Europe showed that 79% were more likely to adhere to their medication/therapy when receiving engagement and support from pharmaceutical companies.¹²

79% of 4,000 patients surveyed in US and Europe were more likely to adhere to therapy when engaged and supported by pharmaceutical companies. Effective patient engagement can increase medication sales by as much as 40%.

Strategic Approaches to Patient Engagement

1. Integrating Patient Advocacy Groups and Advisory Boards

- Collaborating with patient organizations to co-develop strategies.
- Gathering direct feedback on treatment impact and unmet needs.
- Insights into patient profiles and segmentation.
- Supporting regulatory submissions with real-world data.
- Incorporating patient treatment experience into lifecycle management.

2. Leveraging Digital and Social Media Tools

- Utilizing patient forums, apps, and telemedicine for real-time engagement.
- AI-driven insights to personalize patient education and communication.

3. Ethical and Regulatory Considerations

- Compliance with GDPR, HIPAA, and other data protection regulations.
- Ensuring transparency and avoiding conflicts of interest.

Future Trends in Patient Engagement for Medical Affairs

The future of patient engagement in medical affairs is evolving rapidly, particularly with the advances in technology and the increased regulatory focus on patient-centricity. With the increased integration of real-world evidence into decision making and the personalisation of patient communications, medical affairs teams will have ever greater patient engagement responsibilities. This will require both new skills, and potentially a realignment in the composition of medical affairs teams, to maximise the effectiveness of patient interactions and utilise the evolving digital tools and models medical affairs will be expected to work with.

- Artificial Intelligence & Data Analytics: AI-powered insights to better understand patient behavior and preferences.
- Decentralized Clinical Trials: Remote patient monitoring and digital tools for broader trial accessibility.
- Value-Based Healthcare Models: Engaging patients in co-creating treatment value metrics.

Conclusion

A strategic, patient-centered approach in medical affairs is no longer optional—it is essential for improving patient outcomes and driving innovation. Organizations that prioritize patient engagement will be better positioned to succeed in an increasingly patient-driven healthcare environment. While the available data is not yet comprehensive, the financial benefits associated with earlier and effective patient engagement are increasingly convincing. From engaging patients in TPP discussions, improving study recruitment and retention, to building long-term trust, pharmaceutical and biotechnology companies can enhance the efficiency of their clinical development programmes and the long-term commercial success of their products. With the increased regulatory focus on patient-centric therapy development, medical affairs teams must proactively integrate patient engagement strategies to enhance research, development, and healthcare delivery.

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