

THE PATIENT ENGAGEMENT PREMIUM

Defining the Strategic Value of Patient Input in Drug Development



FLEISHMANHILLARD X Omnicom

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In a rapidly evolving healthcare environment where trust is increasingly valued and authenticity is essential, this analysis from FleishmanHillard's Global Health & Life Sciences group explores the potential impact of patient engagement on drug development.

EXECUTIVE SUMMARY

This report examines the strategic value of patient input during drug development, investigating the concept of a measurable "Patient Engagement Premium" for drug developers.

Through an analysis of FDA submissions, the following findings were observed:

- 1. Regulatory submissions are increasingly leveraging patient engagement-derived data.** Results indicate that patient input is being cited more frequently in regulatory submissions.
- 2. PRO and COA data are consistently the most common type of patient engagement input provided.** This type of patient-level data may signal an effort to systematically incorporate patient insights earlier in the drug development process.
- 3. Incorporating patient engagement is directionally associated with the inclusion of patient-centered language in FDA-approved labelling.** This may confer a commercial advantage, although additional investigation is required to fully characterize this potential benefit.
- 4. Patient-focused drug development is not constrained by company size.** Patient engagement levels appeared similar across submissions – suggesting company size is not an enabler or a barrier to patient engagement and that potential benefits are accessible to all.

It must be noted that the evidence base used in this analysis reflects what is publicly available through FDA submissions. Because these data evolve as more products are reviewed and as sponsors expand the ways they document patient experience, continued monitoring will be important to deepen our understanding of how patient engagement influences regulatory and commercial outcomes. Future data may reveal emerging trends or strengthen directional associations observed in this initial analysis, helping to further clarify whether and how patient engagement provides meaningful competitive differentiation.

INTRODUCTION

PATIENT ENGAGEMENT: FROM BUZZWORD TO BUSINESS CONSIDERATION

The pharmaceutical and life sciences industry is experiencing a shift from a research-centric model to one that is patient-centered. While this is often discussed as an ethical consideration, it is increasingly viewed as a strategic investment, with the potential to align innovation with patients' real-world priorities to improve both medical outcomes and commercial performance.

KEY DRIVERS OF PATIENT PARTNERSHIP

This movement toward patient partnership is influenced by several factors:

Regulatory & Market Access

Regulators in the US and Europe are encouraging patient involvement in R&D, recognizing patients as key stakeholders in disease experience. Health Technology Assessment (HTA) bodies are also consulting Patient Advocacy Organizations (PAOs) to inform evaluations of new therapies, which can impact market access and reimbursement decisions.^{1,2}

Strategic US Regulatory Shifts

The current US environment places a premium on genuine engagement. Increased FDA scrutiny of Direct-to-Consumer (DTC) advertising and changes in Advisory Committee (AdComm) processes are making it more important for sponsors to embed patient evidence directly into their regulatory submissions.^{3,4}

Competitive Advantage

Companies that take a patient-centered approach are seeking potential benefits such as faster clinical trial recruitment, improved retention, and stronger evidence for regulatory submissions.⁵⁻¹⁰

BRIDGING THE GAP: FROM ANECDOTE TO EVIDENCE

Despite growing interest, a gap persists in the evidence supporting patient engagement. While perception-based and anecdotal reports are common, many executive decision-makers remain cautious. This presents a clear opportunity to begin establishing a robust, measurable evidence base. The analysis that follows represents a crucial first step toward driving sustained, long-term adoption of these practices.

OBJECTIVES

This research was designed to:

- Assess whether there is an association between patient engagement and regulatory outcomes.
- Describe and quantify any observed trends to illustrate how patient input may be reflected in product labelling and the competitive landscape.

With the aim of providing evidence to inform organizational decisions relating to patient engagement.

METHODOLOGY

We used a data-driven approach to examine the relationship between patient engagement and outcomes with the US FDA, focusing on rare disease therapies. Rare diseases were selected due to the particular importance of patient engagement in these areas, given small and often dispersed patient populations.

What We Analyzed (The Cohort)

We analyzed 238 new drug approvals (New Molecular Entities [NMEs] and Biologics License Applications [BLAs]) by the FDA between 2018 and 2024. This period was chosen because the 21st Century Cures Act, enacted in 2016, began requiring companies to formally include Patient Experience Data (PED) tables in their submissions.¹¹ Of the new drug approvals, only 179 included a PED table with which to determine whether patient engagement was considered; 59 new drug approvals were missing data on whether patient engagement was included or not and were therefore excluded from this analysis.

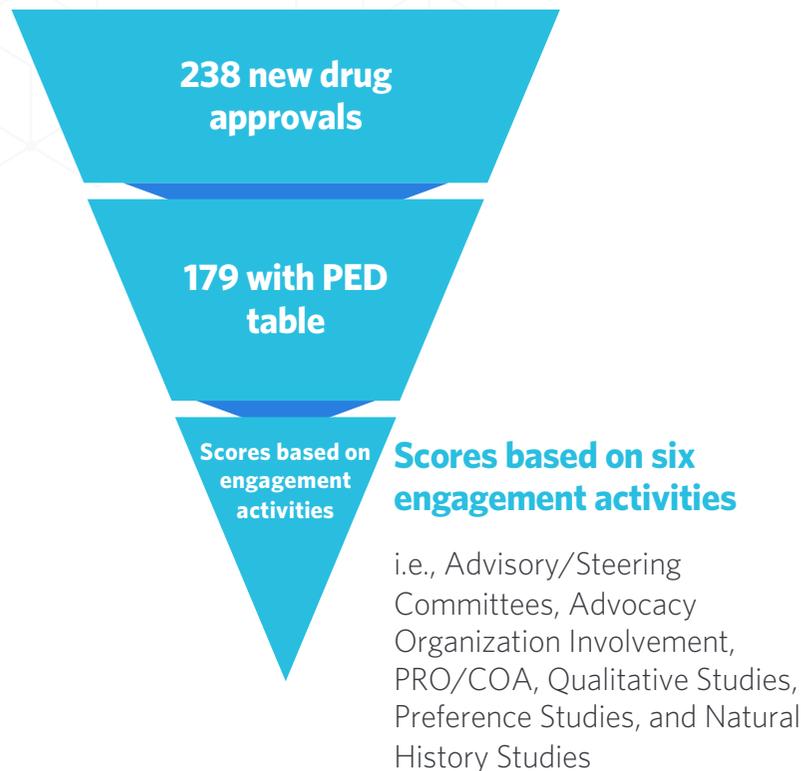
The analysis focused on the US FDA due to the availability of detailed submission data. While similar trends may exist in Europe, comparable data was not available.

Measuring Engagement and Success

Two main variables were considered:

1. The Engagement Variable: Patient Engagement Score (0-6)
2. Each of the 179 products that included a PED table was assigned a score of 0-6 based on the number of six distinct engagement activities documented. This became the Patient Engagement Score.
3. Each product received one point for every documented engagement activity (out of six types), resulting in a total Patient Engagement Score ranging from 0 (no engagement) to 6 (all six types present). While the maximum possible was six, no product received a score greater than four.

HOW THE PATIENT ENGAGEMENT SCORE WAS CALCULATED



OUTCOMES

The primary goal of the analysis was to conduct a descriptive assessment of trends related to patient engagement, with a focus on the following exploratory outcomes:

- If the final product label included a claim tied to patient input, such as a quality-of-life benefit.
- Whether the product was accepted into Expedited Programs or received First-Cycle Approval.
- If the time-to-approval was comparable between large and mid-cap companies.

The analysis did not identify directional trends linking patient engagement with expedited program participation or time-to-approval. These outcomes may require additional years of publicly available FDA data before clearer patterns emerge, but based on the 2018-2024 dataset, no associations were observed.

ANALYTICAL APPROACH

A combination of descriptive, correlational, and exploratory inferential statistical techniques was used to assess relationships between patient engagement and the outcomes above. Descriptive analyses (e.g., frequency distributions and year-over-year trend summaries) were used to characterize engagement patterns across the full cohort. Correlation analyses and group comparisons (e.g., engagement score vs. expedited program designation, label claims, and sponsor size) were conducted to identify directional associations with the data.

Engagement patterns and sponsor size were also evaluated across the 2018-2024 period to explore whether the use of patient input has shifted over time. Sponsor size is not an FDA-reported variable and was therefore classified using publicly available company information. Companies were grouped as follows:

- 01 Large sponsors: Annual revenue greater than \$1 billion, or a large employee base (typically several thousand employees).**
- 02 Mid-cap sponsors: Annual revenue between \$100 million and \$1 billion, or a workforce ranging from several hundred to approximately 1,000 employees.**
- 03 Small sponsors: Annual revenue below \$100 million, or fewer than approximately 200 employees, including emerging or early commercial-stage firms.**

This classification was used solely for comparative analysis and does not represent a precise financial or operational measure.

KEY FINDINGS

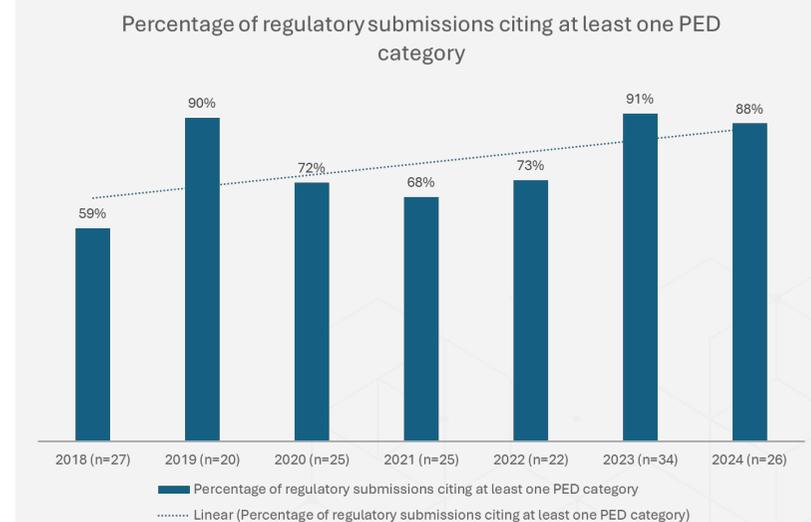
Our analysis of documented patient engagement suggests the presence of a 'Patient Engagement Premium' across three dimensions, though the evidence is primarily associative based on currently available data, and further studies are required to definitively link involvement and outcome.

1 REGULATORY SUBMISSIONS ARE INCREASINGLY LEVERAGING PATIENT ENGAGEMENT-DERIVED DATA.

Results indicate that patient input is being cited more frequently in regulatory submissions. The proportion of regulatory submissions that explicitly cite at least one Patient Engagement Activity Category (PED Category) has increased over the last six years and was especially pronounced over the last two with roughly 9 in 10 submissions including at least one such category (see Figure 1).

Note that the pattern observed from 2020-2022 could be interpreted as a temporary aberration, reflecting the operational impacts and constraints of the global COVID-19 pandemic or an artifact of slow adoption/reporting of patient outcomes given report PED reporting originated in 2017. Additional historical data and future timepoints will be needed to confirm this observation.

Figure 1: The proportion of submissions explicitly citing patient experience is increasing



KEY FINDINGS

2 PRO AND COA DATA ARE CONSISTENTLY THE MOST COMMON TYPE OF PATIENT ENGAGEMENT INPUT PROVIDED OVER TIME

This type of patient engagement-derived data may signal an effort to systematically incorporate patient insights earlier into the drug development process (see figure 2).

The increase in PRO/COA inclusion from 2018 to 2024 is particularly striking and mirrors the larger trend in inclusion of patient engagement-derived data.

There appears to be a slow but steady inclusion of qualitative study data, particularly in 2023 and 2024. Despite not achieving statistical significance, this increase could indicate clinical importance. And as these types of evidence are the most rigorous to collect, they may indicate greater investment in patient engagement in the existing drug development process.

Figure 2: The types of patient experience data included in submissions are becoming more varied

	2018	2019	2020	2021	2022	2023	2024
Advisor/Steering Committee with Patients	4%	20%	0%	12%	0%	12%	4%
Advocacy Org Involvement	4%	0%	12%	0%	0%	15%	8%
PRO/COA used	59%	90%	72%	64%	73%	85%	88%
Qualitative Studies (interviews/focus groups)	15%	15%	12%	12%	14%	18%	19%
Patient Preference Study	0%	0%	0%	0%	5%	3%	0%
Natural History Study	4%	10%	12%	8%	0%	15%	8%

KEY FINDINGS

3 INCORPORATING PATIENT ENGAGEMENT IS DIRECTIONALLY ASSOCIATED WITH THE INCLUSION OF PATIENT-CENTERED LANGUAGE IN FDA-APPROVED LABELLING, BUT NO OBSERVABLE ASSOCIATION WITH EXPEDITED PATHWAYS OR TIME-TO-APPROVAL (2018-2024)

Drugs that had label claims tied to patient input trended towards higher average numbers of PED categories included in their submission than those that didn't (1.4 vs 1.0 PED category). Label claims tied to patient input were a relatively uncommon outcome within the new drug approvals with only nine submissions (out of 179) including this outcome.

This may confer a commercial advantage, although additional investigation is required to fully characterize this benefit.

The analysis did not identify directional trends linking patient engagement with expedited program participation or time-to-approval. These outcomes may require additional years of publicly available FDA data before clearer patterns emerge, but based on the 2018-2024 dataset, no associations were observed.



KEY FINDINGS

4 PATIENT-FOCUSED DRUG DEVELOPMENT IS NOT CONSTRAINED BY COMPANY SIZE

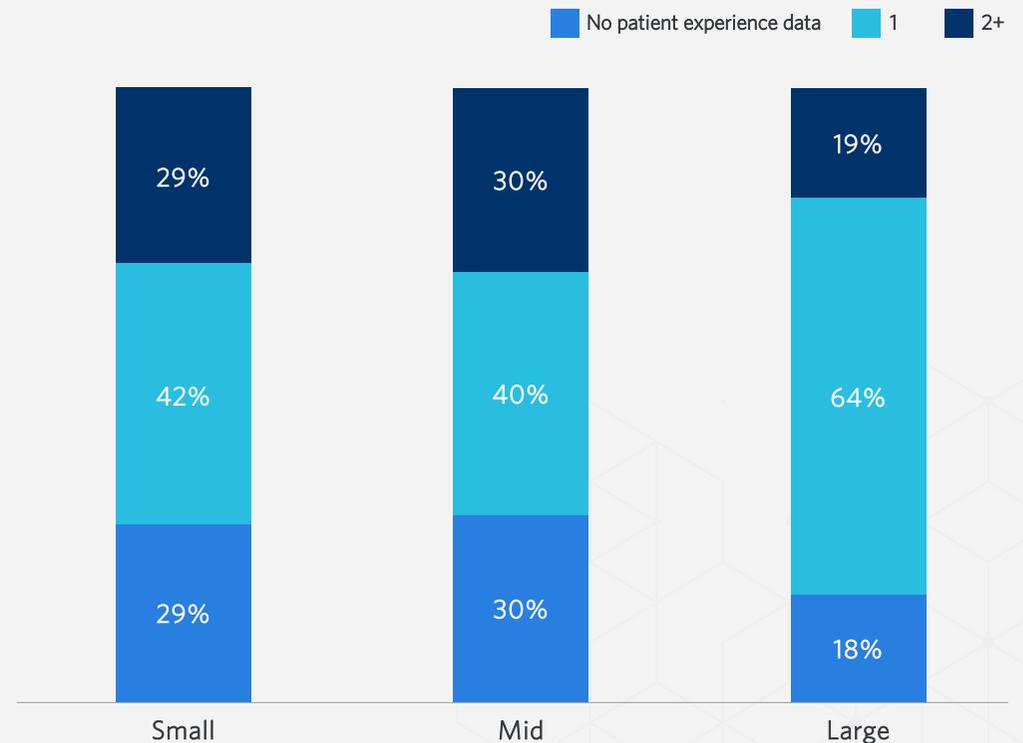
Engagement levels were found to be similar across company sizes — with mid-cap sponsors engaging in patient-centered activities nearly as much as large pharmaceutical companies, despite the pattern of patient engagement appearing slightly different for large versus mid-cap sponsors (see Figure 4).

Similar inclusion of patient engagement suggests that company size is not a barrier or enabler of patient engagement.

The average number of PED categories per business size is 1 for large/mid-size companies and 1.1 for small.

It is possible that the potential benefits of patient engagement may be accessible to companies of all sizes, independent of scale or resource base.

Figure 3: Average Patient Engagement Score by Sponsor Size



KEY FINDINGS

LIMITATIONS



Observational Design

While the associations identified are directional, sample size limitations prohibit more robust attributions. Further, the current analysis does not meet the requirements to establish causal attribution (e.g., establishment of temporal precedence and the ability to rule out possible confounds).



Documentation Bias

Our approach relies on explicit mentions in public regulatory records. Some companies may have conducted engagement activities that were not included in their public filings, or kept private, potentially leading to an underestimation of overall engagement.



Heterogeneity in Patient Input

The methods and quality of patient engagement vary widely. Our coding distinguishes the explicit documented presence of input but cannot fully grade methodological rigor across all submissions.



Scope

Our ability to measure advantages of patient engagement is limited by what data are available. There are unmeasured outputs that may benefit from patient engagement, such as enhanced brand trust and better patient experience.

IMPLICATIONS

Although the evidence base is still developing and observed associations should be viewed as directional rather than conclusive, these findings suggest that patient engagement is evolving into a strategic consideration for drug developers.

The trend toward increased engagement following the 21st Century Cures Act highlights the growing importance of patient-centered strategies. Early-stage investment in patient evidence is becoming more common, with companies increasingly prioritizing structured, quantifiable patient engagement data for FDA submissions, specifically PRO/COA data.

However, companies appear to be focusing narrowly on this single pathway while underutilizing other available options, such as input from patient organizations and patient preference studies. By failing to leverage these additional forms of evidence, sponsors miss the opportunity to develop a comprehensive understanding of patient needs and preferences. This selective approach suggests that structured investment in the full spectrum of available patient evidence could represent an untapped competitive advantage.

While the data indicate a potential business impact from documented patient engagement, realizing that value at scale will require ongoing research and the further development of tools and methods. Smaller companies not yet integrating patient perspectives should consider structured engagement to gain a competitive edge, while larger companies that under-invest in patient input risk losing ground to more patient-centered rivals.

WHO WE ARE

In an era where policymakers, payers, and patients are reshaping how innovation is valued, patient engagement is becoming a prominent consideration. At FleishmanHillard, we view patient engagement as a catalyst for positive change and a critical capability within our broader public affairs practice.

Our patient engagement capability is focused on integrating patient insights for market advantage. We combine regulatory and communications expertise with data science and AI tools, enabling us to generate and test patient-preference insights at speed and scale. We help companies operationalize patient input across every stage of the product lifecycle—from early R&D to policy shaping and communications planning—ensuring that the patient voice strengthens both market access strategies and broader policy engagement.

We help our clients

Connect real-world patient priorities to innovation.

Ensure the patient voice informs evidence of generation for regulatory and payer submissions.

Build communication strategies that treat patients as partners and foster trust.

We help clients establish patient engagement as a core capability that integrates and empowers all functions, ensuring their innovation is positioned as human-centered and evidence-driven.

Find out more

To discuss how our Strategic Patient Engagement expertise can unlock value for your organization, please contact:

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FleishmanHillard: Global Health & Life Sciences

FleishmanHillard is one of the world's leading strategic communications firms, with nearly 80 offices in more than 30 countries across the globe. We specialize in reputation management, public affairs, and brand marketing, delivering data-driven intelligence and bold creativity that achieves measurable impact. As part of Omnicom Group Inc. (NYSE: OMC), we bring unparalleled scale, integrated capabilities, and deep local market knowledge to our clients.

The Global Health & Life Sciences sector is one of our largest and fastest-growing, comprising a vast network of experts who provide unique understanding of the complexities facing pharmaceutical, biotech, and health systems today—from regulatory shifts and market access challenges to rapidly evolving patient and policy environments.

AUTHORS

Barry and Laura are responsible for shaping FleishmanHillard's patient-centric consulting services worldwide.

With a combined 30+ years of experience in pharmaceuticals and consulting, they lead the firm's approach to translating patient-defined value into tangible business outcomes. Laura specializes in developing global market and regulatory strategies, ensuring patient input drives commercial success. Complementing this, Barry spearheads the firm's European engagement and is a Market Access & Payer Specialist. They focus on navigating the region's complex regulatory (EMA) and payer environment, using patient experience data to build robust value dossiers and secure favorable coverage decisions from payers and Health Technology Assessment (HTA) bodies, linking patient needs to label differentiation in key markets.



**Laura
Musgrave**



**Barry
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Patient Engagement Specialists

TEAM EXPERTISE



Mary Kosinski
Regulatory & Public Affairs Strategist

Mary focuses on integrating patient narratives into regulatory submissions and public affairs campaigns to enhance reputation and manage stakeholder alignment.



Jennifer Martin
Research & Data Expert

Jennifer designs and manages qualitative and quantitative research programs, ensuring methodological rigor and data integrity in all patient evidence generation.



Claire Wood
Data Methodologist

Claire focuses on applying specialized data techniques and modelling to transform complex qualitative and quantitative data into high-value, defensible insights for strategic use.



Richard Sherrington
Strategist

Richard pairs a deep technical understanding of the life sciences pipeline with the high-level strategic acumen gained at McKinsey, allowing him to bridge the gap between scientific innovation and commercial execution.



Joyce Higgins
Digital Expert & AI Architect

Joyce leads the development and application of our Synthetic Audience and AI-driven data tools, ensuring ethical, scaled, and timely generation of patient-preference insights.



Bia Assevero
Strategist & Storytelling Expert

Bia specializes in developing compelling narratives that translate complex patient evidence into accessible, impactful stories for policymakers, payers, and consumers.



Emma Cracknell
Health Policy Advisor

Emma specializes in analyzing European legislative and policy trends to anticipate how patient advocacy shapes future regulatory requirements and reimbursement frameworks.



Jennifer Westphal
Clinical Trial Recruitment Specialist

Jennifer provides expertise in integrating patient insights to improve protocol design, resulting in more efficient and patient-centric trial recruitment and retention.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the dedication and analytical expertise of the FleishmanHillard Global Health Data & Analytics team, specifically Jennifer Martin and Claire Wood, for their rigorous work in building the custom dataset and applying the analytical methodologies used in this report. We also extend our gratitude to the broader Global Health & Life Sciences team at FleishmanHillard as well as the Leadership Team in London for their guidance and commitment to advancing our offering and strategic thought leadership in patient engagement.

AI tools were used solely to enhance clarity and accelerate initial content refinement; all core research, analysis, and conclusions remain the independent work of the agency team.

REFERENCES

- FDA. [FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making](#). March 2025
- EMA. <https://www.ema.europa.eu/en/patient-experience-data-ped-reflection-paper>. September 2025
- HHS. <https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency-fact-sheet.html>. September 2025
- Pink Sheet. <https://insights.citeline.com/pink-sheet/product-reviews/us-advisory-committees/with-us-fda-adcomm-meetings-disappearing-sponsors-see-other-outlets-for-patient-voice-HJBQ653M6FHK5BX3WAVZYYS5OM/>. October 2025.
- Meskó B, Radó N, Gyórfy Z. [Opinion leader empowered patients about the era of digital health: a qualitative study](#). *BMJ Open* 2019;9.
- Pharma Exec (2022). [The role and recruitment of the Chief Patient Officer](#)
- Bertalan Meskó (2025) writing on LinkedIn. [What Pharma Executives Secretly Think About the Future \(But Won't Admit Publicly\)](#)
- Pushparajah DS. [Making Patient Engagement a Reality](#). *Patient*. 2018 Feb;11(1):1-8.
- Piil K, Jarden M. [Patient involvement in research priorities \(PIRE\): a study protocol](#). *BMJ Open* 2016;6.
- Crowe, S., Fenton, M., Hall, M. et al. [Patients', clinicians' and the research communities' priorities for treatment research: there is an important mismatch](#). *Res Involv Engagem* 2015;1:2.
- Congress.gov. <https://www.congress.gov/bill/114th-congress/house-bill/34/text>. December 2016