

2023 Patient Insights Annual Report

History

The Patient Insights Board began as an idea in 2019 when four patients were invited to join a group of Medidata teams in the NYC office. The success of the meeting provided the foundation for formalized patient design studios which commenced in early 2020 and have continued without interruption throughout 2023. The Patient Insights Board (PIB) currently has nine members with diverse backgrounds spanning different areas of disease focus to ensure the broadest capture of insights and experience. With its recognition as a board, formal vision and mission statements were adopted and a charter was drafted.

VISION: Create the optimal patient-centric experience in clinical research for every participant worldwide

MISSION: The Patient Insights Board recognizes patients and caregivers as equal and included stakeholders in clinical research. We amplify diverse voices to bring real-world expertise to the design of innovative digital health offerings. Empowered by Medidata, our team galvanizes the life sciences industry to meet the unique needs of every person, every day, everywhere.

Recognition by Medidata of the group as a formal board demonstrates their commitment to the patient experience and elevates the importance of the incorporation of all voices within clinical research, and throughout life sciences. This is a significant paradigm shift from focus group like involvement to a true partnership between patient experts and design teams.

By capturing the insights from the initial meetings in 2019, the internal team at Medidata quickly appreciated the importance of developing a set of guiding principles and basic tenets to incorporate into all future interactions. Using the principles of [Stanford Medicine X](#) as a foundation, Medidata maintains a commitment that is rooted in building trust, leading with empathy in all interactions, creating a sense of inclusivity among diverse groups, empowering patient partners with knowledge, and affording patient partners and patient participants with an unprecedented level of control within its product offerings.

The ongoing interaction between external PIB members and internal design teams including an anchor back to the guiding principles for all aspects, and in every project ensures Medidata is maintaining the highest level of fidelity to their award winning Patient Centricity by Design program. Together, we believe we are building tools and identifying solutions that will result in a best in class patient experience.

Internal Engagements

By sharing their stories, the challenges of navigating the healthcare system are better understood by all. The members of the PIB also bring a wealth of understanding beyond their personal experience from other areas where they may be serving, both within their communities and/or from engagements with sponsor organizations.

Throughout 2023, members of the PIB were invited to participate in several internal meetings. They joined Lunch and Learn sessions to raise awareness about the need for the implementation of proper tools to allow for accessibility for those with a myriad of challenges. Diversity initiatives were discussed by PIB members with deep ties to groups who have been historically underrepresented in clinical research. Other members were invited to join Town Hall meetings for discussions with professional service teams. Invitations were also extended by Business Research Groups including the Women in Tech BRG to talk about the need to Embrace Equity. At a Medidata sponsored Power of Her event, the eConsent process in pediatric research was an important discussion topic.

External Engagements

Providing platforms to share the expertise of the PIB outside of Medidata is paramount to the ongoing success of the Patient Insights program. In 2023, members of the PIB were included on panels at NEXT events in cities throughout the United States. At the SCRS Diversity Summit, PIB members joined Alicia Staley on a panel to discuss the importance of maintaining focus on the recruitment of diverse populations to all clinical trials. Medidata's flagship event, NEXT New York, was opened by a PIB member and several others helped to facilitate breakout sessions on eConsent, eCOA, and patient payments. Outside of conferences, PIB members were included at client engagement meetings with members of the Patient Insights and Sales teams.

In addition, members of the PIB attend many meetings throughout the year, independent of Medidata, to stay apprised of what is happening throughout the life sciences industry. Their attendance helps them better understand challenges that may be unique to specific areas or populations of people. PIB members are frequently at sponsor events, academic meetings, large oncology meetings, conferences on rare diseases, and regulatory meetings just to cite a few.

Product Development

The PIB is involved with software designers and development teams from the earliest stages. While still in the ideation phase, design studios are held to talk through the process and identify potentially burdensome areas, or areas that may be seen as stumbling blocks. All of this happens well before the creation process commences.

In fact, during the very first meeting in 2019, ideas to develop eConsent were shared with inaugural PIB members using Medidata's earliest notes. Throughout 2020, 2021, and 2022, every patient-facing tool being used by Medidata was the topic of a design studio, and prior to launch, was subsequently reviewed by the PIB. In 2023, product features that were the topics of PDS sessions included timing and types of notification delivery for participants, the onboarding process, and the eCOA build tool available to sponsors.

Emerging themes that may be employed in areas well beyond the specific design being examined are beneficial for current and future development projects. "One size fits all" is not ideal. The PIB has routinely determined that it is essential to provide preferences for participants whenever possible. Setting expectations for participants is another theme that rises to the top

during the design studios. It may not be possible to fully reduce burden, or even to reduce it to what might be considered an acceptable level. Recognizing this reality, the PIB believes that setting accurate expectations for participants might serve to mitigate some of the frustration on the part of patients and their loved ones. In addition, establishing a clear value exchange that is beneficial to both the sponsor and the participant is crucial when asking people to share information and data.

At the very heart of everything, is trust. Medidata and Dassault Systèmes, by elevating the Patient Insights Board and including them throughout each and every phase of the development process, is taking every possible step to establish their trustworthiness to the patients they are serving with all of their technology platforms.

The Process Narrative

Documenting the work of the PIB is an integral part of Patient Centricity by Design. Throughout 2023, focus was placed on creating a more formalized documentation process. After each PDS, an “At A Glance” document is created to capture the themes, suggestions, and ideas for further exploration as a project advances. Posts on Medidata Clinical Minds blog have been authored by PIB members to share their [experience at events](#) or their response to industry discussions including PIB perspectives on [Gene Therapy](#) and the [capture of post trial approval data](#). Members of the PIB have contributed to case studies and analysis of FDA’s guidance for Patient Focused Drug Development. The PIB is also developing internal sales tools to serve as a quick primer. Each of these is focused on a specific therapeutic area. A newsletter recapping PIB meetings and ongoing work is written monthly and distributed internally to the PIB and is available for all Medidata employees to access.

2024 Outlook

As the PIB has evolved, there are many opportunities for continued growth and impactful projects in 2024. Plans are in development to develop a formalized process to infuse interactions with the PIB across Medidata even more broadly and beyond the teams with whom they currently interact.

The PIB understands the importance of site burden and offers overwhelming support of this new Medidata initiative. As Amy Bohn, Director of DCT Operations at Bayer stated during NEXT NYC, “If it’s not site friendly, it will never be patient friendly,” and the PIB is eager to see the burdens of all stakeholders addressed. The PIB is also looking at processes to assess clinical trial readiness among potential participants and methods to standardize patient data return. Accruals to trials, not just overall numbers, but also participation of diverse groups that are more closely representative of the affected population is an area where we hope to anchor all to all of our interactions.

By working to reduce the time it takes to open trials and bring them to a conclusion, we will be moving with the same urgency that is experienced by the people whose needs are being served by the research. As we reflect on the transformative journey of the Patient Insights Board, we invite you to join us in embracing the insights and advancements outlined in the 2023 Annual Report. Your engagement and support are crucial as we continue to amplify diverse voices in



clinical research, striving towards creating the optimal patient-centric experience worldwide. Together, we can empower patients and caregivers as equal stakeholders in the development of innovative, empathetic technical solutions, ensuring every voice is heard and every need is met in the pursuit of excellence in patient care and clinical research.