WHITE PAPER

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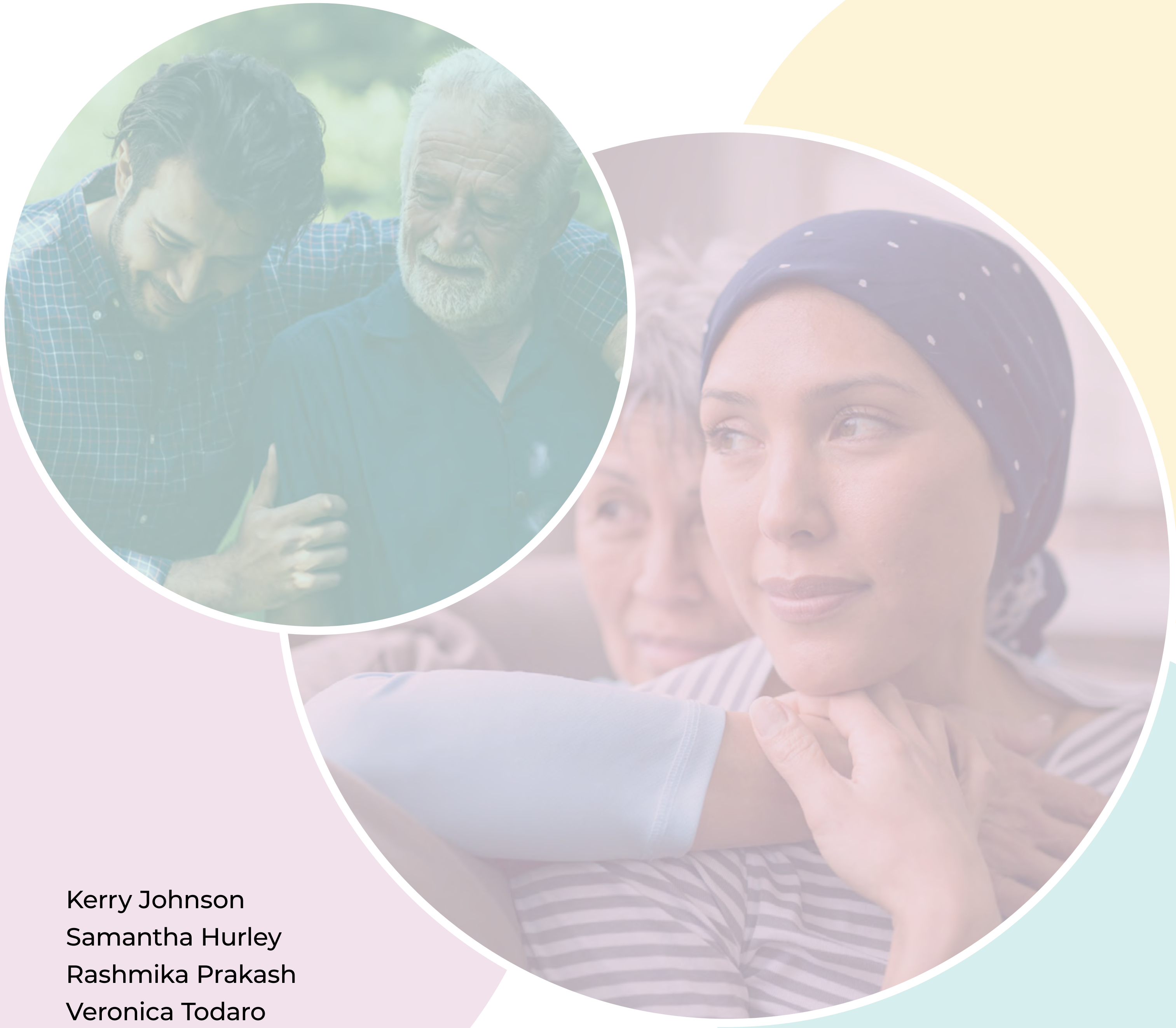
Embedding Sustainable Patient Engagement in R&D: A Grassroots Effort to Organization-Wide Change at Incyte Corporation



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Engaging patients and care partners can positively impact the drug development lifecycle through **avoiding costly protocol amendments, improving enrollment, adherence, and retention in clinical trials**, supporting timelines and diversity goals, and advancing a patient-centric culture. Though its value is irrefutable, committing to and integrating a framework for authentic patient engagement at a mid-size biopharma company with a robust pipeline presents a unique set of challenges. How does a company like Incyte build, pressure test, and operationalize patient engagement within R&D practice without slowing its efforts?

This white paper outlines the journey of patient engagement at Incyte, aligned to key challenges and learnings, from inception to a forward-looking vision.

THE JOURNEY BEGINS:
AN INTERNAL CHAMPION WITH A VISION

Though no specific business unit was responsible for patient engagement, Dija Atta, Executive Director, now Incyte's Head of Regional Clinical Operations for North America, and Stephanie Lyke, Director, Sr. Clinical Trial Head, had a vision of creating a sustainable structure for incorporating patient and care partner insights, as experts in their lived experiences, into clinical development. While Incyte was gathering feedback from individual patient advisors on an ad hoc basis early on, there was a desire to move to a more longitudinal, streamlined approach reflective of multiple diverse perspectives. This model would also incorporate the organization, centralization, and seamless transfer of relationships across functional areas, specifically Public Affairs and Clinical Development, creating a coordinated approach to partnering with patient advocacy organizations as potential treatments advance through the development lifecycle.

> “While the value of patient feedback has always been clear, the key to maximizing its impact lies in **systematic implementation**. Transforming our patient feedback process from ad hoc interactions into standardized processes allows us to systematically harness these crucial insights while maintaining organizational efficiency.”
>
> — **DIJA ATTA, HEAD OF REGIONAL CLINICAL OPERATIONS FOR NORTH AMERICA, INCYTE**

With a modest budget and the go ahead for a pilot project, Dija and Stephanie launched the Incyte Patient Council at the end of 2021, engaging patient experts with various hematology, oncology, myeloproliferative neoplasms (MPNs), and dermatology and autoimmunity (IAI) disease-related conditions. Early on in the pilot, it was a priority to recruit patients and care partner experts that represented racial, ethnic, geographic, age, and gender diversity. Given the Incyte project leads were leading this initiative in addition to their roles in Clinical Operations, the decision was made to engage VOZ Advisors (VOZ) to provide strategic and tactical support throughout the pilot project.

> "Our partnership and collaboration with VOZ has been invaluable with not only our launch of this initiative but also in our ability to grow and sustain it."
>
> — **STEPHANIE LYKE, DIRECTOR, SR. CLINICAL TRIAL HEAD, INCYTE**

The one-year pilot brought the group of expert patient/care partner advisors together for seven engagements, which gave them the opportunity to provide input on study protocols and informed consent forms (ICFs), a plain language summary, a dosing diary for a dermatology study, and to discuss their preferred methods for accessing information on clinical trials.

This small but productive pilot initiative resulted in tangible benefits to Incyte R&D such as:

- Dermatology/IAI study protocol and ICF updates
- Plain Language Summary Publication improvements
- Dosing diary updates and considerations
- Clinical trial website update recommendations
- Input on use of Google Ads as a method for clinical trial awareness

To share the news about the project expansion, the Incyte project leads organized a Lunch and Learn for the entire Clinical Development team across all indications. The Lunch and Learn focused on highlighting the importance of patient engagement in R&D via two case studies, the protocol and ICF reviews, and introduced a streamlined, online process for the study teams to request engagement with the Incyte Patient Council for feedback on various aspects of their trial (protocols, ICFs, trial burden, etc.). Beyond the prescriptive impact the pilot council had, Incyte gathered key learnings that helped refine and expand this grassroots initiative in its next phase.

The Journey Begins: Key Learnings

Benefits of a targeted grassroots approach: In response to the positive impact of the pilot Patient Council on the Clinical Development team, a Patient Engagement Playbook was drafted to share information, build excitement, and create buy-in across all R&D therapeutic areas to engage patients in development activities. The Incyte project leads also hosted a Lunch and Learn to socialize the playbook and Patient Council, offering the recording of the presentation to all teams. **The aim was for this effort to spark widespread uptake across the organization; however, a single one-hour Lunch and Learn was not able to generate the level of shared understanding and uptake needed** to truly embed patient engagement into the DNA of Incyte's clinical development work.

The team quickly realized they needed a more targeted and relational approach – seeking opportunities to engage with study teams one-on-one, facilitating the patient engagement exercise, and building their "grassroots" base of internal champions to promote incremental change.

Exposure to patient engagement drives critical buy-in: Providing an opportunity for members of the study teams to hear directly from patients via the council meetings built empathy, changed misperceptions about study design and trial education approaches, and **shifted the mindset of those involved from viewing patient engagement as a "nice to have" to recognizing it as a critical factor for a study's success.** Team members at the peer and leadership levels joined the council meetings as observers and left as champions.

> “I think we need to do this for all of our studies regardless of where they are at – having used it on one Ruxolitinib cream study, I think every single Ruxolitinib cream study should have this.”
>
> — HOWARD KALLENDER, ASSOCIATE VP, CLINICAL RESEARCH SCIENTIST, INFLAMMATION & AUTOIMMUNITY, INCYTE

Importance of collaborating across functions: Seeking to identify and recruit patients to participate in the council, Dija and Stephanie had the opportunity to engage with their cross-functional colleagues. This allowed an important partnership to emerge between Clinical Operations and Public Affairs, the function that manages the relationships with the patient groups at Incyte. **By establishing a coordinated, single source of contact approach to outreach for council recruitment through the Public Affairs team, Incyte presented itself to patient groups as working as one and the risk of overburdening patient groups via multiple contacts was eliminated.** This facilitated the successful recruitment of underrepresented communities, engaged individuals for the pilot council and set a framework for internal collaboration that benefits the growth of patient engagement across all functions at Incyte.

THE EVOLUTION: **MATURING AND GAINING TRACTION ACROSS INDICATIONS**

The first-year pilot of the Patient Council demonstrated the value of incorporating patient perspectives in clinical development by providing a discrete set of insights that improved study materials and processes, while also fostering the cultivation of internal champions. The pilot project was granted increased resources, which formalized its structure and allowed for heightened focus on operationalization and expanded reach.

Efforts to expand the remit of the council beyond patient experts to include lay patient perspectives were underway. Leveraging the successful internal partnership with Public Affairs, the team recruited individuals from additional therapeutic areas representative of Incyte's pipeline.

Together, this group of patient experts, lay patients, and care partners were consulted as a full group to advise on materials and topics that would impact many or all therapeutic area studies, and were engaged in smaller groups to review clinical trial materials or discuss disease-specific topics. An example of this dynamic in motion was the Incyte ICF Template Update project. The full council reviewed the standard ICF template, a notoriously dense but important document, and provided realistic suggestions for improving the layout of information, language, graphic elements, and more. Their goal was to better inform potential study participants of key information and expectations, and in turn, support recruitment, retention, and adherence within the trial. **The council reviewed a few iterations of the ICF Template before finalizing an updated version that is now implemented as the standard template for use across all studies at the company.**

Another key element of the Patient Council's evolution was the organization of patient and care partner insights into an accessible repository. Following each engagement, learnings were categorized by topic and added to a continuously updated document. This repository grew to serve multiple purposes as more study teams sought to engage the council. The document, openly available to all Incyte team members, allows users to review previously generated insights, thus limiting the risk of soliciting the same type of feedback multiple times from the council. It also helps Incyte identify the types of feedback most requested over time.

Finally, Incyte committed to providing the council with clear feedback after each engagement, detailing how and where their insights were applied, or explaining why certain suggestions were not implemented. This "feedback loop" aided in building trust and demonstrating the value of their time and perspectives during the evolution of the initiative. To consistently execute this effort, VOZ Advisors followed up with study teams one month after their discussion with the council to take stock of the utilization of insights and then communicated the updates back to the council members, along with Incyte's gratitude for their contributions.

> "You and your team have done a fantastic job in ensuring our voices are heard and our suggestions are granted. Fabulous job!"
>
> — **ASHLEY L., INCYTE PATIENT COUNCIL MEMBER**

The Evolution: Key Learnings

If you build it, they will (not necessarily) come: Though Incyte set up a framework for study teams to submit study information and request meeting with the Patient Council via an online submission form, there was very little use of this tool. In hindsight, this should have been expected, based on multiple competing priorities typically faced by clinical development teams, as well as the lack of familiarity of the value gained from patient engagement.

The Patient Council team decided to take a more **proactive approach** of identifying studies in the pipeline that were headed towards a critical phase (for example, a protocol submission) and contacting the study team directly. Incyte's partnership with VOZ created the person power needed to execute on this "high touch" approach. Study team contacts were provided with examples of engagement and insights gained from Patient Council engagement (changes made to patient-facing materials, protocol, informed consent forms, etc.). This **high-touch education and outreach resulted in an increase in Patient Council engagement** from 7 engagements in the first year (2022) to 20 engagements over the second and third years (2023 – 2024).

A central, shared source of patient insights is key: The Incyte project leads recognized that the key to demonstrating value and fostering creative thinking about Patient Council engagement was to create a central source of information for common topics and insights generated by the council across clinical study focus areas and disease indications.

This repository, created and managed by VOZ Advisors, also included the questions that had been asked to date, along with sample questions that could be used to generate patient insights. This database of questions and insights also helped avoid asking the advisors the same/similar questions multiple times, or revisiting topics insights had already been gleaned on, ensuring each engagement was a fresh start. Incyte's proactive commitment to valuing council members' time created a positive environment at council meetings.

The insights repository was utilized during the proactive outreach to study teams to bridge the gap in understanding how patient engagement can offer solutions to challenges they are facing, for example, recruitment, retention, or education.

Embed patient engagement into organizational goals: Cultivating buy-in from leadership is integral during the evolutionary phase, not only because it supports increased budget and headcount towards patient engagement initiatives, but also because it opens the door to instituting organizational change. Advocating for the implementation of goals related to patient engagement at the programmatic level ensures it is a responsibility held across R&D.

CURRENT STATE AND LOOKING FORWARD: **EXPANDING THE VISION**

Fast forward to 2025, where the Incyte Patient Council is comprised of patients, care partners, and patient advocacy leaders representing multiple therapeutic areas and diverse walks of life. The council is agile and engaged, often broken out into smaller disease-specific cohorts to review materials relevant to their condition but still brought together occasionally as a full group to discuss disease-agnostic "big picture" topics such as patient support services or decentralized clinical trials. To date, the Patient Council has participated in 16 full-session group meetings and 17 study-specific offline engagements. This growth is the result of ever-expanding internal buy-in and recognition of the value of patient engagement in R&D. This value was not only recognized by clinical development teams, but by leadership, who witnessed improvements in study materials and as a result called for organization-level change. **Incyte now requires 100% of studies to have directly engaged the Patient Council or thoughtfully incorporated relevant patient insights from the repository.**

Beyond the new requirement to integrate the patient voice into critical study materials, patient engagement as a practice has expanded into other business areas, both within the US and globally. Studies with global sites have requested the geographic expansion of patient advisors to include individuals from the UK and, additionally, the EU. Incyte team members leading efforts to make clinical trials more representative and inclusive are seeking patient insights on study support materials specifically for underrepresented communities. Initiatives are underway to create opportunities for health care providers and patients to come together to share perspectives and build on insights through the expansion of what has, to date, been single stakeholder healthcare provider councils.

The future-state vision is to move towards engaging patients and care partners in real time with study teams in a more agile manner, utilizing innovative asynchronous platforms. This approach will allow patients to act as co-partners in trial development, co-create patient-facing materials, and help pressure-test elements of trials, such as patient support services offerings. The composition of the council will also change to create space for new perspectives and an evolving pipeline, while retaining the original council members as trusted ad-hoc advisors to Incyte.

There is no one “right way” to integrate patient engagement into R&D. Some approaches are top down and some are “grassroots”; some have a full complement of dedicated resources and some are small pilots. All require champions with a vision to understand the needs of internal stakeholders and demonstrate how engaging patient stakeholders in drug development is beneficial to both the company and the patient communities we serve, ultimately resulting in therapies that are more accessible and effective for patients. The Incyte “grassroots” to organizational change model highlights the impact that a modest yet intentional multi-year effort can have on driving uptake of patient engagement throughout R&D.

> VOZ Advisors is honored to have had the opportunity to partner with the Incyte team and contribute to the impact and success of this “organic” approach to patient engagement.

About VOZ Advisors

VOZ Advisors in a global consulting firm to pharmaceutical and biotech companies specializing in bringing the patient experience into medicines development. For more than 30 years, we have partnered with clients across drug discovery, development, and commercialization to build mutually beneficial and sustainable patient advocacy and engagement relationships with patients and care partners, patient organizations, and professional groups.

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