



WHITE PAPER

Patient Engagement at Bayer: *A Grassroots Approach*

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on behalf of
Bayer's PIE initiative



INTRODUCTION

Bayer's mission, "Science For A Better Life," encapsulates our aim to benefit people around the world in matters of healthcare and nutrition to ultimately improve their quality of life. To help achieve this goal, the Pharmaceuticals Division of Bayer fully supports initiatives designed to empower patients and their advocates, and to ensure that they have a say in the decision-making processes that affect their everyday lives.

Having witnessed revolutionary shifts in politics, culture and society over the past 150 years, Bayer places a priority on being a learning organization that reflects the changing landscape around us. Inspired by the unprecedented mobilization of today's patients and their caregivers to actively help drive the innovation of new therapies, the Pharmaceuticals Division at Bayer has adopted a novel grassroots approach to involving patients in a meaningful way from the early stages of drug development and throughout the lifecycle of our products.

By bringing together the passion and care of colleagues across all disciplines, levels and therapeutic areas, we've ignited an all-inclusive patient-engagement movement that continues to gain momentum. Driven by a strong belief that continuous patient involvement facilitates an environment for developing better drugs and improving therapeutic compliance, we are committed to expanding these efforts in the future.

Patient Partners in Drug Development: A Tipping Point in Medicine

The Pharmaceutical Industry is at a turning point in time where digital technologies, social media and global stakeholder initiatives have opened the door to patient participation and joint problem-solving across the entire drug development process.

For example, the online discussion platform Smart Patients was launched five years ago in recognition that cancer patients are among the most expert, up-to-date and motivated researchers in the world because they are fighting to stay alive. Co-founder Dr. Roni Zeiger, the former chief health strategist at Google, asserts that "the next tipping point in medicine includes tapping into the knowledge created by networks of engaged patients".¹

Patients are also embracing the surge in crowdsourcing and are donating their data to tackle some of the hardest-to-treat diseases. The National Institutes of Health *All of Us* Research Program, a key element in the Precision Medicine Initiative, is a historic effort in

which researchers are gathering data from one million or more patient partners to gain better insights into the biological, environmental and behavioral influences on diseases.² But even one patient's voice can have an important impact on the course of clinical research. During the planning phase of a landmark precision medicine trial, scientists at the National Cancer Institute sought the guidance of Nancy Roach, a cancer survivor and patient advocate. Her perspective changed a critical protocol element that may have hindered patient enrollment.³

Patient Insight is Powerful: A Global Regulatory Consensus

Over the past decade, global regulatory authorities have become more closely aligned in their approach to seeking direct patient perspectives as part of their key decision-making processes. In 2017 the U.S. Food and Drug Administration (FDA) held its inaugural meeting of the Patient Engagement Advisory Committee (PEAC) which provides the agency with patient input on the design of clinical trials for medical devices and the optimal approaches for recruiting and retaining study participants.⁴ The FDA's 21st Century Cures Act of 2016 also places a strong emphasis on soliciting patient input on the development and approval of new therapies.⁵ It builds on the agency's Patient-Focused Drug Development (PFDD) initiative introduced in 2012 to further inform its benefit-risk assessments in a given disease area by including a broader range of patient perspectives.⁶ As part of this effort, FDA is developing four guidance documents to address how stakeholders can collect and leverage valuable patient and caregiver input that can better inform medical product development and regulatory decision making.⁷

2018 marked the 12th anniversary of the European Medicines Agency's Patients' and Consumers' Working

“Patients who live with a disease have a direct stake in drug development and in the outcome of the FDA review process for new drugs. Patients are also in a unique position to contribute to an understanding of benefit and risk considerations throughout the medical product development process.”⁶

U.S. Food and Drug
Administration (FDA)

Party, the agency's formal platform for incorporating patients' real-world disease and treatment experiences into its key scientific discussions.⁸ Another notable initiative is the European Patients' Academy on Therapeutic Innovation (EUPATI), a public-private consortium of European organizations that offers expert-level training in medicines research and development to people managing various diseases.⁹ The European Patients' Forum (EPF) and EUPATI are also co-leading a public-private initiative called PARADIGM (Patients Active in Research and Dialogues for an Improved Generation of Medicines) which is addressing the inconsistency which still exists in terms of who should be engaged, how and when at different points along the drug development lifecycle.¹⁰

Such programs in the U.S. and Europe have supported a growing global consensus about the value of patient participation in the development and approval of new medicines. For example, the Ministry of Health, Labor and Welfare in Japan provides training for patients to enable their participation in research activities, especially in oncology. The International Alliance of Patients' Organizations provides guidance to patient groups in Latin America, where they have formed strong community networks to positively shape regulatory policies that directly impact patients.¹¹

Bayer's "Patient Insights & Engagement" (PIE) Program: *An All-inclusive Grassroots Movement*

The "Patient Insights & Engagement" (PIE) network was created at Bayer in 2016 as an innovative approach to ensuring that key learnings from the company's patient engagement activities are leveraged cross-functionally on a regular basis, and thus, to providing an official framework for the process of patient insight generation within the Pharmaceuticals Division. The program now connects to Consumer Health, Radiology and even non-customer-facing functions like Finance.

Kicked off as a grassroots effort, the initiative is built on the philosophy that patient engagement should be the core interest of everyone, not a duty of a single department, because each function interacts externally in different ways. As such, no employees are assigned or required to join the PIE network. The only requirement is a passion to be involved in amplifying the patient's voice within Bayer.

"Top-down approaches to fostering patient engagement in a company are not always ideal," said Matthias Gottwald, Head of R&D Policy and Networking at Bayer AG. "You



listening
understanding
acting
responding

can't force people to behave in a way that they don't think is important. The PIE model is a more promising long-term strategy because it's driven by colleagues with a true passion for patient engagement and fully supported by senior management."

The PIE network has grown six-fold in only two years and its self-motivated members are effectively linking colleagues from different levels, disciplines and therapeutic areas across Bayer. Recognizing that teams may be genuinely interested in patient engagement but unclear about the proper steps and ultimate goals of their involvement, the first priority of the PIE movement was to create a vision and framework for working cross-functionally to benchmark, connect and share expertise. The framework was built on four pillars for achieving "Science For a Better Life": **listening, understanding, acting, and responding.**

"These four guiding principles remind us that we need to understand the needs of patients beyond their symptoms and disease experience, and take a customer-centered approach to our development process in order to truly improve their healthcare experiences," said Pooja Merchant, Head of Patient Partnerships and Engagement at Oncology Global Medical Affairs and former leader of the PIE movement at Bayer. "We invite patients to share their experiences, try and understand their concerns and

*"My personal commitment for patient engagement is that it's actually happening automatically [in that] we don't have to 'push' patient engagement within industry, with the regulators, within the HTA environment, and with the healthcare professional community as well ... that it's an automatic reflex that makes absolute sense in terms of better outcomes for patients but also in terms of the sustainability of quality health systems of the future."*¹²

Nicola Bedlington, Special Advisor and former Secretary General at EPF

unmet needs, work with them to embed this knowledge into our Research & Development processes, and close the loop by making them aware of the outcomes.”

Through ongoing workshops, a growing Knowledge Hub, an eXperience eXchange platform, and a “Slice of PIE” newsletter, the program offers a bird’s-eye view of the spectrum of projects in the Bayer organization and helps everyone to see the synergies and think differently about collaborating with patients and their caregivers.

“There is no more noble cause than taking care of improving a patient’s situation and ensuring their voice is being heard.”

Dr. Jörg Möller,
Head of Research &
Development, Bayer AG,
Pharmaceuticals Division

..... **Bridge2Patients**

One of the latest PIE offerings is Bridge2Patients, a novel internal service platform designed to remove as many hurdles as possible to actively engaging with patients.

In a short amount of time there’s been a huge demand for the Bridge2Patients program, which fills a gap for guidance about direct patient engagement that is distinct from large-scale market research and traditional patient-advocacy interactions. Pilot interactions have already taken place in early research, development and post-launch phases. Employees appreciate the hands-on support and the efficiency provided by standardized processes and templates. Their daily work is also being enriched by the meaningful two-way discussions with patients and the important insights they’re uncovering.

“Bayer’s approach to patient engagement is in step with what we see happening with regulatory authorities and patient advocates around the world,” said Dr. Michael Devoy, Chief Medical Officer and Head of Medical Affairs and Pharmacovigilance for the Pharmaceuticals Division at Bayer AG, and early champion of PIE.

“Pursuing science that puts patients first has always been at the heart of Bayer’s corporate mission. For many employees, exposure to patients is limited and therefore the ultimate impact of their efforts on improving people’s lives may not be easily recognized. PIE is changing that.”

The Future of Patient Engagement at Bayer

We have made important progress with the PIE movement but there is much more to learn and do to formalize patient engagement as a long-term strategy and to fully anchor patient engagement in the Bayer organization. We are committed to growing the PIE network, expanding our reach to include new and different partners, and to creating more awareness both internally and externally. We aspire to one day build upon the Bridge2Patients platform by creating a pathway for easy, direct and compliant access to Bayer for patients interested in collaboration.

All of our current patient engagement efforts support an ambitious long-term vision in which patients co-create and embrace the services, education, clinical research programs, and medical innovations provided by Bayer; they measurably trust us to be patient-centric; and we can ensure that patients' needs are truly met and that our offerings make a meaningful difference in their lives.

Patient Engagement in Action at Bayer: Case Studies

RESEARCH: To better understand what it's like to be a person undergoing cancer treatment and what patient expectations are for oncology research, Bayer conducted its first "Cancer Patient Interaction Day" in 2017. The pilot event was attended by 100 of Bayer's oncology researchers who interacted directly with patients from different cancer patient organizations. The forum provided an important opportunity for researchers and patients to directly engage in a dialogue about the clinical research process, including what patients experience when they participate in a clinical study and how much they want to know about a research program.

"People are so much more than their disease or illness. When we think about the patient experience, what if we consider their needs holistically and not just in terms of their "sickness?" In doing so, we have the opportunity to not only provide a pill, but to significantly improve the lives of patients. We need to get to the point where we help patients with appropriate support – for example, education on their condition, impact of medication adherence and resources for their families and healthcare providers to navigate their disease state."

Dr. Sebastian Guth, President,
Bayer Pharmaceuticals, Americas
Region

Bayer's PIE vision:

*Patients inspire
and motivate us.*

*Together, we create
products & services*

that are relevant

for a better life

by following these

guiding principles:

- **Listening:** *Inviting patients to share their healthcare experience*
- **Understanding:** *their needs, concerns and challenges*
- **Acting:** *Infusing this knowledge into solutions that meet patients' needs and develop these solutions together with them*
- **Responding:** *Let patients know about the outcome & embed this feedback process in all programs*

DEVELOPMENT: Diffuse systemic sclerosis (dSSc) is a rare autoimmune disease that causes painful fibrosis of the skin and internal organs. To better understand the level of disease burden on patients' daily lives, we created an innovative program to map the dSSc Patient Journey and evaluate the physical and emotional impact on the patient outlook. The research enabled us to walk in patients' shoes and get a much deeper disease understanding from the patient's perspective. For example, patients illuminated the fact that they would like to see the symptoms of joint pain and fatigue included as study endpoints in the clinical assessment of new products. This important feedback will inform potential future Bayer trial designs in this indication. The team embarked on a separate patient-engagement effort to further explore dSSc patient views on priority endpoints that should be included in development studies and patient-reported outcomes. Recognizing that there seems to be a disconnect between patients and physicians in terms of expectations for dSSc treatment, we worked with one leading patient advocacy group (Scleroderma Foundation) to conduct direct patient interviews; the feedback we received is now being used to refine our patient-centric study protocols and create more effective educational materials.¹³

MEDICAL AFFAIRS: The Medical Affairs team established a medical education steering committee (MESC) to guide the scientific and educational needs in non-metastatic castration resistant prostate cancer. This committee is typically composed of prostate cancer experts such as expert physicians and investigators. The team decided to expand the MESC by including a patient advocate and nurses, thereby bring the patient perspective into a conversation that has been historically dominated by physicians. One of the discussion topics was on the importance of adverse event identification and education in this patient population. As a result of the patient voice, the group was not only able to address the physician needs, but was also able to consider tools to improve the patient-physician dialogue. They were also able to identify gaps in educational resources for patients and family caregivers, allowing for a more productive and holistic approach to adverse events.

COMMERCIALIZATION: Macular degeneration is the leading cause of vision loss in people over the age of 55. The current gold standard of care requires intensive regular treatment over long periods of time that has a significant impact on the life of patients and their families and also incurs a corresponding financial commitment. As such, patients are prone to non-adherence and poor persistence to treatment which translates to sub-optimal outcomes. What has become evident through our in-depth consultations with patients is that their thoughts, concerns and needs are often not taken into account when considering medical applications in daily life. Bayer's ophthalmology team worked with a leading advocacy organization to create the SmartSight Patient Support Program, an evidence-based initiative to maximize adherence to Bayer's marketed treatment for neovascular age-related macular degeneration. A comparison of persistence rates of patients enrolled in the SmartSight program compared to those who are not revealed an improved persistence rate over two years.

DIGITALIZATION: Bayer's Grants4Apps or G4A program is a global effort dedicated to helping innovative healthcare start-up companies grow, and to enabling positive disruption and progress within the digital healthcare universe. Our G4A Accelerator programs help strike deals with leading innovators, and offer places to work and network. In collaboration with PIE teams, the Accelerator held the first-ever G4A Patient Jury Workshop to include patient perspectives in the official selection of 2018 G4A finalists. Joan Jordan, a blogger for EUPATI and member of the 2018 G4A patient judging panel, said: "The jury was just as passionate and as innovative as the solutions being considered. Not surprising when you consider nobody has more skin in the game. This is patient involvement as it should be!"

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Bridge2Bayer is a platform where you can register to be a patient or caregiver partner with us. Make your voice heard: Share your experiences. Test solutions. Provide your feedback and be compensated for your cooperation. Register now at <https://www.bridge2.bayer.com>

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