What companies say

About their relations with patient groups 2023–2024

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PATIENT VIEW

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Introduction

Every year, PatientView is grateful to pharmaceutical companies that provide the annual 'Corporate Reputation of Pharma' series of publications with an overview of their own perspectives on patient-group relationships—based on their own experiences, and with their own case studies.

The 2024 publication has received company contributions from:

- → Bayer AG;
- → Boehringer Ingelheim;
- → Gilead;
- → Novartis;
- → Novo Nordisk (Obesity division);
- → Pfizer;
- → Pfizer (Immunology and Inflammation division); and
- → ViiV Healthcare.

These companies bring valuable context to the main 'Corporate Reputation' report, providing, as they do, a strong indication of how pharma's relationships with patient groups are developing over time (and will likely adapt in the future).

The 13 years during which the annual 'Corporate Reputation' survey has been running have seen the gradual evolution from the concept of patient centricity as a*'good thing for a company to be doing'* to today's reality where the patient viewpoint appears to be embedded in 2024 into many aspects of the work of companies—both as a vital activity, and as a competence-driving strategy. Many—perhaps even most—companies now employ patient experts on steering groups; patient-centric strategies are firmly underpinned by company structures and processes aimed at fostering an internal culture of authentic patient focus. Companies leading the move along this route hold a defined set of values that aspire to deliver trusted, transparent, and mutually-valued patient-group relations.

The detailed perspectives provided to 2024's main 'Corporate Reputation' report by the eight contributing companies show that most not only work with hundreds of patient groups worldwide. The company comments additionally make clear that the pharmaceutical industry as a whole has largely advanced beyond episodic, advocacy-focused activity with patients and patient groups. Today's industry commitment is to highly-structured, systematic collaborations.

The change is demonstrated by the presence of various co-created initiatives (whether global or local), health-outcome driven, and rigorously monitored—each ensuring a continuous and consistent flow of insights to support strategy and operations. Examples range from global

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patient-led summits that set high-level agendas, and which create impetus for local 'disease-agnostic' projects, to highly-specific disease-oriented programmes designed to demonstrate the value and impact of patient engagement itself—something which is important to healthcare providers, regulators, and payors, and which will continue to enhance the role of the patient movement, as it strives to improve patient care. Most of the examples seek to help patient groups make the case for change *within* current healthcare systems. Other examples, though, show that patient experiences are also being used to shape all future aspects of care provision.

Contributing companies stress that they seek patient engagement across the development life cycle (not just at late stage), and that patient groups can still benefit from more support to build the competencies needed to engage effectively.

Looking forward, the pharma industry, as represented by the companies contributing to this 'Corporate Reputation' Appendix, see patient engagement continuing to grow as a well-structured, mature function sitting at the heart of company organisation. However, feedback from the 2,518 patient groups responding to 2023-2024's 'Corporate Reputation' survey does suggest that companies still have some way to go. Indeed, the future stability and value of pharma's relations with patients and patient groups remains dependent on companies continuing to institute improvements to their corporate reputation—not only in the public eye, but with the patients they serve.

Mat Phillips,
Associate Director,
PatientView

What is the name of your company?
Bayer AG.

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
Global.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
441.

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?

- ➔ Funding (for example, grants or donations).
- ➔ Speaker engagements.
- ➔ Consultancy activities.
- ➔ Provision of information to patient groups.
- ➔ Supporting patient-group campaigns.
- ➔ Co-creating projects.
- ➔ Creating support tools for patients and carers.
- ➔ Helping patient groups to network.
- ➔ Training and capacity building.
- ➔ Involving patient groups in R&D.
- ➔ Support in building web or e-health resources for patient groups (such as apps).

Could you specify which are the most common of these relationships?

1. Co-creating projects.
2. Speaker engagements.
3. Consultancy activities.
4. Involving patient groups in R&D.
5. Funding (for example, grants or donations).

During which of the following corporate activities does your company seek PATIENT/PATIENT-GROUP INPUT OR ADVICE?

- ➔ **Strategic input**: Sometimes.
- ➔ **Finance**: Usually not.
- ➔ **Human resources**: Usually not.
- ➔ **Investor relations**: Sometimes.
- ➔ **Early-stage research**: Regularly.
- ➔ **Late-stage research**: Regularly.
- ➔ **Manufacturing (including packaging)**: Sometimes.
- ➔ **Pharmacovigilance**: Sometimes.
- ➔ **Supply chain and distribution**: Sometimes.
- ➔ **Marketing and sales**: Sometimes.
- ➔ **Market access**: Regularly.
- ➔ **Regulatory affairs**: Regularly.
- ➔ **Medical affairs**: Regularly.
- ➔ **Public affairs/corporate communications**: Regularly.

Bayer AG

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes?
(The projects can be at global, regional, or country level, or in specific therapy areas. If you wish, you may mention urls/online links, to provide further context to your reply.)

In our priority therapeutic areas, we have formulated **strategic plans for engaging with patients** and their care partners. These plans encompass the establishment and expansion of patient partnerships, integration of the patient and care-partner diverse voices in our clinical programs, including patient councils to inform our strategies and activities, and fostering patient-led innovation and publications.

We co-created an **Engagement and Diversity Initiative with the American Association of Kidney Patients** (AAKP). This co-created initiative was the first of its kind for both Bayer and AAKP. It went beyond the normal course of business to enable equitable awareness of, access to, and participation in, Bayer's Phase-III label extension clinical trial for people with Chronic Kidney Disease (CKD). Focusing on enhancing the diversity of people who are Black and African American, as well as those who are Latino and Hispanic, the co-created initiative allowed for creativity and breadth of concept. The approach was comprehensive, and included:

➔ developing and engaging a monthly, diverse Standing Patient Council (SPC) that supported issue/situational assessments, provided systematic feedback for a study microsite, study materials and outreach strategy, and held frequent ideation and input sessions, resulting in strategic review and revision of trial materials and ways of working;

➔ engaging and deploying grassroots AAKP Patient Ambassadors to spread awareness in their communities of the trial via a trusted fellow patient voice; and,

➔ developing an AAKP HealthLine Innovation Webinar on discussing Diversity in Clinical Trials, which provided information about the specific trial of interest directly to the patient population the trial aimed to recruit. The partnership consistently drove greater understanding towards a targeted audience which resulted in increased diverse enrolment of participants in the trial. (For more information, see: Webinar: Increasing Diversity in Clinical Trials: The FIND-CKD Study, an AAKP HealthLine Innovator webinar – YouTube)

Bayer and the **National Kidney Foundation** (NKF) co-created an educational session at the Congressional Black Caucus Events, "Kidney Equity for All: Saving Others From the Fire through Earlier Detection & Awareness." The event featured NKF President-Elect Kirk Campbell; Vicki Hall, Executive Director of Market Access Strategy, CVR, Bayer; and platinum recording artist Freeway, who shared his personal story about life as a transplant recipient. (For more information, see: Kidney Equity for All: NKF's Mission to End Racial Disparities in Kidney Care | National Kidney Foundation)

National Kidney Foundation's CKDintercept, a multi-sponsored initiative to improve CKD testing and recognition by primary-care physicians (for more information, see: CKDintercept | National Kidney Foundation, and KIDNEY EQUITY FOR ALL – National Kidney Foundation), a patient-focused, community-based initiative to ensure that all kidney patients have access to high-quality, patient-centered care.

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Additional key projects include **Stroke Diversity Standing Council**, to ensure that we are listening to, and co-creating with people who are representative of the stroke community in the US.

In 2023 and 2024, we also held a diverse global **patient council in Congestive Heart Failure** to discuss topics related to gene therapy.

The **Global Oncology** Unit has partnered with the European Association of Urology Patient Office to develop resources for patients on Shared decision making (for more information, see: EAU Patient Information on X: "Healthcare works best when patients and HCPs work together. Shared decision-making is a collaborative approach to making treatment choices that are right for patients. Learn more here: https://t.co/aeS9KxFYEB" / X (twitter.com)) because shared decision making is an important decision model for patients, and there is an increasing amount of data to demonstrate that value of shared decision making in prostate-cancer decision making.

We also have established an Oncology Patient Engagement Access Council with expert patient advocates to focus advocacy on inequalities and HTA reform in Europe.

We have supported the IASLC STARS Program and AACR Scientist Survivor Program to empower more people living with cancer to interact with researchers and get involved in research.

We are an active member of FT3 (From testing to targeted treatment) cross-stakeholder coalition to tackle barriers to biomarker testing.

We have co-created and launched a Global Patient Website to make it easier for patients and caregivers to find easy to understand resources (for more information, see: https://cancer-patients.bayer.com/).

To elevate Prostate Cancer Patient Voices, we have supported Prostate Cancer Foundation and UroToday to launch a one stop shop of tailored resources for people dealing with prostate cancer (for more information, see: Prostate Cancer Patient Voices).

b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

In addition to those key projects mentioned for 2023, we supported the following webinar, which debuted on April 17th 2024 for **World Hemophilia Day** (for more information, see: Healthcare While Black: How HTC's & Chapters Can Better Serve the African American Community - YouTube), as well as Hemophilia Federation of America's Health Equity initiative in 2024.

Also in 2024, we are focusing on mental health, and supporting **mental health initiatives** in the bleeding disorders and pulmonary hypertension space, including the following initiative, Supporters — Bleeding Disorders Substance Use & Mental Health Access Coalition (bdsumhac.org), and sponsoring Spanish support groups and webinars for the Pulmonary Hypertension Association (PHA) and Team PH.

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Moreover, in 2024, we extended the work with did with AAKP in **FIND-CKD** to bring this process to all of our kidney studies.

Another strategic Patient Engagement project – an innovative solution co-created with patients for patients, which was implemented in 2023 in a pilot for Germany as blueprint for other countries, is 'solike'. 'solike' is a **patient and care-partner matching platform** that was established to serve as a specialized offering from experienced individuals who have been affected by certain conditions. It was launched to provide anonymous search capabilities for individuals seeking others who have been similarly affected, to foster personal exchanges with diverse offerings, and to organize to meet and more. The platform is of particular importance for patients as it provides indication-specific support and background knowledge about diseases, and it is inclusive of other conditions as well. Additionally, 'solike' offers matching and special services for relatives of those affected by various conditions. The importance of 'solike' for patients lies in its ability to connect them with others who have similar experiences, to share knowledge and provide support, which is crucial for managing their conditions and improving their quality of life. It also emphasizes the value of having a community and resources that are tailored to specific indications, as well as the inclusion of a broader range of conditions, ensuring that a wide patient population can benefit from the platform's services.

In 2024, Bayer is reaching out to a number of Patient Organizations operating in various therapeutic areas, asking for feedback and collaboration, to optimize the platform, and make it even more user-friendly, and to raise the awareness of this existing service for patients and care partners. (For more information, see: Press release: Bayer and Observia launch the first matching system for patients and caregivers; Platform: https://space.bayer.de/solike).

At global level, we are continuing with our **Patient Friendly Language initiative**. In 2024, Bayer is committed to enhancing patient communication by implementing several initiatives focused on patient-friendly language to improve the patient experience. We plan to introduce new data extraction solutions and create a dedicated graphic library specifically designed for patient-friendly language. Supportive innovative tools will be optimized to ensure clarity and quality in patient communications. The use of clear and empathetic language, along with resources like generative AI solutions, the systematic use of an AI-based writing support, as well as the development of a Terminology Management Tool to establish a standardized term base for technical and lay terminology, contributes to enhancing general comprehension and medical literacy. This is designed to contribute towards patients feel more empowered and engaged when they can understand and take an active part in their healthcare journey. Additionally, Bayer intends to develop standardized templates for patient-facing documents and leverage tools like generative AI for crafting Patient Lay Summaries (such as plain language summaries of study results or plain language summaries of publications), which are part of Bayer's broader Patient Centricity strategy to foster consistency in technical and lay language and boost medical literacy.

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On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

Bayer has processes in place for early and consistent patient engagement from the beginning of R&D and throughout the lifecycle. In this process we have an increasing use of **Patient Advisory Boards and/or Standing Councils** to provide consistent feedback throughout the R&D process.

Bayer has instituted various initiatives aimed at engaging with and learning from patients, one of which is the establishment of a structured **Protocol Optimization process**. This process entails early involvement of patients (and sites) to glean insights for protocol refinement. By incorporating patients at this stage, we are positioning them at the core of our clinical trial planning efforts.

A **Global Oncology** Unit's Patient Engagement initiative connected to drug development was, for example, a Virtual Patient Summit, which was held to focus on how we can solve inequalities by partnering with communities to improve cancer care with the goal to increase understanding of the role of community engagement and leverage learnings from real-world case studies by patient advocacy experts. Furthermore, the Patient Engagement Research Council has been expanded to include more diverse representation. The council now actively engages and reviews our clinical trial diversity plans.

As mentioned above, in our kidney-studies we partner with AAKP to have standing councils that provide ongoing, bidirectional input into our kidney studies. They also utilize their grassroots ambassadors to help with clinical trial awareness, meeting people where they are in the community. Bayer won a **Driving Health Equity Award at the Reuters Events Pharma Awards USA 2024** for its project improving patient diversity solutions in clinical trials related to chronic kidney disease. The awarded project which we worked closely on together with a partnering patient advocacy group, the American Association of Kidney Patients (AAKP), creates a new blueprint for clinical trial development that can be replicated in other studies. Focusing on enhancing the diversity of people who are Black and African American, as well as those who are Latino and Hispanic, the co-created initiative allowed for creativity and breadth of concept. The significance of patient-centered approaches and collaborative partnerships between industry and patient advocacy groups is underscored, playing a pivotal role in advancing health equity. (For more information, see: LinkedIn posts: https://www.linkedin.com/posts/reuterseventspharma_repharmausa-activity-7178460106920005633-IkOv/?utm_source=share&utm_medium=member_desktop; https://www.linkedin.com/feed/update/urn:li:share:7179144841249894400/)

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For another relevant Patient Engagement initiative—Advancing access to clinical trials and innovative treatments for babies born prematurely—we were shortlisted for the **Reuters Europe Driving Health Equity Award**, which is a great recognition, given the hundreds of nominations. Pre-term birth occurs in approximately 10 percent of live births each year in the US and EU (and considerably more frequently in certain other countries). Preterm infants are a therapeutically-neglected population with marked health disparities, as only a handful of medications have been thoroughly vetted and approved for use in this population. This project sought to understand a specific, previously unmet patient need for premature babies, a highly vulnerable population due to their underdeveloped organ systems, often facing multiple, severe medical complications simultaneously.

Recognizing the challenges and disparities faced by this group, Bayer initiated a global clinical trial to evaluate the utility of its medicine in development to treat Retinopathy of Prematurity (ROP), a rare and serious disease leading to childhood blindness in premature infants. Bayer engaged with key patient-advocacy groups, and conducted face-to-face interviews with parents and healthcare professionals to understand safety concerns, cultural diversity, and communication preferences, integrating these insights into study recruitment and retention processes and patient-facing materials.

This comprehensive approach led to timely trial completions and multiple Health Authority approvals across the globe in 2022 and 2023. Recognized for its commitment to patient-centricity, the program aimed to provide an additional therapeutic option for families with premature babies, ultimately improving access to treatments for a rare and serious disease affecting vulnerable communities.

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b.) What equivalent plans in partnering does your company have for early- and late-stage R&D during 2024?

One of the primary initiatives within the **Clinical Customer Centricity** function for 2024 is the development of a comprehensive strategy for gathering, analyzing, and leveraging feedback from study participants across all our clinical trials. This underscores our commitment to continuously understanding the patient journey, enabling timely adjustments where feasible, and informing the design and solutions of future trials.

In 2024, we have been increasing our work with our early-stage R&D colleagues to have early and consistent patient engagement.

At **Global Oncology** we are proactively incorporating Patient-Reported Outcomes (PROs) and digital tools to enhance the patient experience.

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On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?

Trust and authenticity are the cornerstones of our partnerships. We have internal process and practices that we consider when forming partnerships.

Formal processes exist in R&D to guide us as we co-create early, meaningfully, and systematically during R&D and throughout the lifecycle. These processes address a number of items, including patient engagement and representation. We have **guiding principles** which we use as we develop our patient engagement strategic plan, conduct stakeholder mappings, and begin relationships or continue to build existing relationships.

Every year, the global Patient Partnerships team leads an internal **Patient Engagement Awards** program, which aims to recognize the remarkable accomplishments of our colleagues in prioritizing people with lived experience in their work. The Patient Engagement Awards program is an **important internal instrument** because it acknowledges and encourages efforts that lead to enhanced communication between patients and healthcare providers, which is crucial for improving patient outcomes and reducing the frequency of hospitalization. The program underscores the significant role of storytelling in capturing patient experiences, which can greatly inform and improve medical guidelines. Additionally, it addresses critical issues, such as gender and diversity in patient engagement across various disease areas. The program's significance is also reflected in its potential for long-term impact on patient care and the healthcare system.

Within the Patient Engagement Awards program, the role of the patient judge is to bring a unique and essential perspective to the evaluation process. The patient judge is someone with personal experience of the healthcare system, and can assess the entries through the lens of a patient, ensuring that the initiatives are genuinely centered around patient needs. This perspective is vital in evaluating the relevance, impact, and authenticity of projects aiming to enhance patient engagement.

Patients or people with lived experiences play a pivotal role in the award program as they are the primary beneficiaries of the initiatives being recognized. Their involvement is not limited to the role of a judge; they also contribute to the development of the award criteria, ensuring that the standards for evaluation reflect real-world patient concerns and aspirations.

The engagement of patients and people with lived experiences is a cornerstone of the program, as it aligns with the overarching objective of the awards: to celebrate and promote the integration of the patient's voice in healthcare. This approach ensures that the awarded projects are not only innovative, but also empathetic and responsive to the needs of those they are designed to serve. The awards ceremony for this program usually takes place in January. (For more information, see: LinkedIn post: https://www.linkedin.com/feed/update/urn:li:share:7158740144563322881/)

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Bayer is advancing **sustainability** worldwide. Including Patient Engagement as a sustainability aspect is crucial because it leads to better health outcomes and improved patient satisfaction, which are key indicators of a sustainable healthcare system. In line with our mission #HealthForAll #HungerForNone, we strive to engage with individuals representing diverse and underserved patient populations, including across clinical trials, to advance more equitable access to healthcare for everyone, which leads to societal well-being. (For more information, see: LinkedIn post: https://www.linkedin.com/feed/update/urn:li:ugcPost:7178734987347693568/; Bayer's Annual Sustainability Report: https://www.bayer.com/en/sustainability/sustainability-reports)

We continue to collaborate externally with **key patient organizations**, such as the Patient Engagement Open Forum (PEOF), EUPATI, TransCelerate, and various consortia with academia, industry, and patient groups.

For the past three years Bayer has been a contributor to the Patient Engagement Open Forum (PEOF), bringing together multi-cultural and multidisciplinary patient advocates, industry experts, regulatory influencers, and academia to co-create innovative solutions for the future of patient engagement. A pivotal initiative of this forum is the Patient Engagement Metrics Selector, a web-based tool facilitating the tracking and measuring of patient engagement impact. In 2023, Bayer piloted and co-led a multi-stakeholder session, during the PEOF face-to-face event, to advance the implementation of the selector. This tool originates from our active participation in the PARADIGM program, a public-private partnership co-led by the European Patients' Forum and the European Federation of Pharmaceutical Industries and Associations (EFPIA), underscoring our commitment to developing comprehensive tools and practices for integrating patient perspectives into medicine development effectively. Furthermore, Bayer engages in broad partnerships with organizations to co-develop solutions based on the lived experiences of individuals facing health-related challenges. In 2023, we collaborated with Women Political Leaders (WPL) to unveil an extensive policy toolkit on World Menopause Day. This toolkit aims to aid policymakers in recognizing and effectively addressing the stigma surrounding menopause. Serving as a resource, it provides evidence-based information and practical recommendations to empower policymakers in supporting women through this phase across various settings, including the workplace and healthcare. In Oncology, we have in place a research council that routinely reviews and guides our development programs. In social media, we offer a novel Instagram channel that focuses on patient-friendly education. We host two key events annually: the Global Oncology Patient Partnership Summit, and the Global Precision Oncology Patient Innovation Awards Program (POPIA). The POPIA program fosters innovation and collaboration to improve access to precision oncology care and tackles inequalities for people with cancer around the world. In 2023, the summit brought together diverse patient groups virtually to collaboratively address inequalities in cancer care through community engagement. (For more information, see: https://www.bayer.com/sites/default/files/2024-03/bayer-sustainability-report-2023.pdf)

Bayer AG

At Bayer we highly appreciate the collaboration with your partner Patient Organizations (PO's). As their feedback and insights play a crucial role in helping us to improve our work and better understand their needs, we invited all Patient Organizations Bayer worked with in 2023 to complete a **feedback survey** at the end of last year. By introducing this feedback instrument, we have set up a feedback process that will help us to improve how we partner and co-create with patient communities. We aim for continuous improvement cycles, as we will take up the feedback and include it in our decision-making processes. We plan to repeat the feedback survey in 2024.

Looking to THE FUTURE

How do you expect your company's RELATIONS with patient groups to change over the next five years (2024 to, say, the end of the decade)?

Given the evolving landscape, we anticipate a significant transformation in our company's relations with patient groups over the next five years, extending to the end of the decade. By 2030, we foresee the patient voice becoming even more pivotal in both our internal decision-making processes, and our external engagements. As a result, we are committed to forging partnerships with a clear intent and conviction, aiming to collectively advance patient care. This era represents a period of profound change, where disruptive innovation is reshaping treatment paradigms. Collaborating with our patient partners, leveraging digital technologies, and exploring new modalities, our goal is to halt disease progression, reverse diseases, and work towards developing cures that address the unmet needs defined by patients, enabling empowered individual healthcare decisions. Together with our patient partners, we seek to enhance our capabilities to drive efficiencies in healthcare delivery. Patient insights and evidence will be integral in guiding our strategies and operations, integrated across geographies, methodologies, and the value chain. We recognize the importance of all stakeholders, including payers, policy makers, pharmaceutical companies, prescribers, and, most importantly, the patients themselves.

What is the name of your company?
Boehringer Ingelheim.

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
Global.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
> 500.

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?

- ➔ Funding (for example, grants or donations).
- ➔ Speaker engagements.
- ➔ Consultancy activities.
- ➔ Provision of information to patient groups.
- ➔ Supporting patient-group campaigns.
- ➔ Co-creating projects.
- ➔ Creating support tools for patients and carers.
- ➔ Helping patient groups to network.
- ➔ Supporting patient-groups' publicity.
- ➔ Training and capacity building.
- ➔ Involving patient groups in R&D.
- ➔ Support in building web or e-health resources for patient groups (such as apps).

Could you specify which are the most common of these relationships?
Co-creating projects, consultancy activities, training and capacity building.

During which of the following corporate activities does your company seek PATIENT/PATIENT-GROUP INPUT OR ADVICE?

- ➔ **Strategic input**: Regularly.
- ➔ **Finance**: Sometimes.
- ➔ **Human resources**: Sometimes.
- ➔ **Early-stage research**: Sometimes.
- ➔ **Late-stage research**: Regularly.
- ➔ **Manufacturing (including packaging)**: Regularly.
- ➔ **Pharmacovigilance**: Regularly.
- ➔ **Supply chain and distribution**: Sometimes.
- ➔ **Marketing and sales**: Regularly.
- ➔ **Operations**: Sometimes.
- ➔ **Market access**: Regularly.
- ➔ **Regulatory affairs**: Sometimes.
- ➔ **Medical affairs**: Regularly.
- ➔ **Public affairs/corporate communications**: Sometimes.

Boehringer Ingelheim

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes?
(The projects can be at global, regional, or country level, or in specific therapy areas. If you wish, you may mention urls/online links, to provide further context to your reply.)

At Boehringer Ingelheim, we have set ourselves a clear ambition to integrate patient perspectives into everything we do—from early research, to market entry, and beyond. We embrace patients and patient organizations as critical stakeholders across the development lifecycle of our treatments and services, because we believe that the needs of patients, caregivers, and disease communities should inform our most-critical strategic decisions.

As we work towards this ambition, our focus is threefold. Firstly, we work hard to develop strong, long-term relationships with patient partners and patient organizations, by collaborating with them as equal partners, with trust and transparency. Secondly, we strive to systematically integrate patient insights, early and throughout the entire development process. And, thirdly, we seek to foster a company-wide culture of patient centricity, so that every colleague at Boehringer understands their responsibility to innovate in partnership with, and for the benefit of, people who have lived experience of disease.

The depth and breadth of our relationships with the patients and patient organizations that we partner with is critical to how we co-create solutions with them, to deliver more value for patients.

The following examples are a small selection that testify to the emphasis we place on the quality of our patient/patient organization relationships—and the power of these in delivering better outcomes for patients.

➔ Global Patient Partnership Summit (GPPS)

Our Global Patient Partnership Summit (GPPS) is a biennial flagship initiative. Its purpose is to take collaboration between Boehringer and patients, patient advocates, and patient organizations to new heights, by bringing all groups together to co-create solutions to global, disease-agnostic, systemic challenges in the healthcare ecosystem.

GPPS is led by a Steering Committee of patient leaders, who work in partnership with the Boehringer Global Patient Engagement team. They jointly identify the global challenges each summit seeks to address; they shape the agenda; co-chair working groups; co-host the event, and lead initiatives that emerge from the summit.

GPPS was launched as a virtual event in 2021, during the Covid-19 pandemic. In May 2023, it was hosted as an in-person global event in three geographic hubs: Miami, Singapore, and Vienna. Over three days, more than 270 participants came together to foster cross-disease relationships, share, learn, and co-develop initiatives that will positively impact outcomes for patients.

Boehringer Ingelheim

➔ GPPS Community Calls

At the request of, and in partnership with patients and patient organizations from the GPPS Community, we host monthly community calls, to maintain a regular touchpoint (beyond a biennial moment in time). These sessions, co-hosted by Boehringer and patient partners, allow time and space for the GPPS community to discuss topics of relevance to them and their patient communities—such as the 'role of the caregiver', and 'patient-doctor communications'—and to be kept informed and updated about the numerous projects that have evolved out of the most recent summit.

➔ Patient Experience Data (PED) Capability Training

Along with a wide selection of regional projects that are now being developed through partnerships between patient oranizations, and with local Boehringer offices, GPPS23 also identified a global PED project which is now being co-created with patient partners from the summit. Patient organizations have the potential, and increasing opportunities, to generate and submit PED as input into healthcare decision-making. GPPS23 identified a need for better training, to enable patient organizations to generate structured PED, and submit this data to regulators and payors, according to their standards.

Accordingly, this initiative has assessed the current PED capability-training landscape, and conducted research across organizations represented at GPPS, to determine their needs to develop trusted resources, tools, and training programs, to build and upskill patient organizations' PED capabilities.

➔ Inflammation Knowledge-Sharing Symposium

In October 2023, in partnership with patients, we established a knowledge-sharing symposium for Rheumatology and Pulmonology, because of the many commonalities across these two disease areas. By connecting rare-disease patient communities from different geographies, we facilitated the exchange of ideas between patient organizations, to help them grow their networks, share learnings, and build new capabilities, for the benefit of the patients and families that they serve.

➔ A Blueprint for Patient Involvement in Medical Device Development

Patient participants of GPPS21 gave voice to an industry-wide problem: the lack of patient involvement in medical device development. In response to this, we brought together a cross-stakeholder group of patients and Boehringer's medical device developers to create a blueprint for the early, and systemic, integration of patient insights into medical device development.

Boehringer Ingelheim

Together, we co-created detailed, holistic guidance covering what patient insights should be captured—and when—as well as packaging needs, and plain language user-education requirements. The guidance serves to bring patient preferences to the forefront, so that developers factor in what patients want and need in terms of device size/discretion, portability, connectivity, accessibility, etc., from the outset of the design process, and throughout the development process.

This blueprint is now being used across Boehringer as standard practice in the design and development of medical devices for new indications. To foster greater patient involvement in medical device development across the pharmaceutical and med tech industries, we have also made a version of the blueprint publicly available. This guidance was published on the Patient Focused Medicines Development (PFMD) open-source Synapse platform. Now, any organization can apply this framework to their own device development process.

➔ GPP Coalition in Italy

Generalized pustular psoriasis (GPP) is a rare, lifelong skin disease, which in some cases, can be life threatening if left untreated. Back in 2022, Boehringer convened a multi-stakeholder forum to co-create a GPP Charter. The purpose of the community-led tool is to equip the patient community to effectively engage with the healthcare system to receive treatment; access decision makers; and give strength and credibility to core ‘asks’ for GPP patients. The International Federation of Psoriasis Associations’ Executive Director described the forum, and creation of the charter, as “the day we committed to put specific targets towards reaching all people living with GPP, to ensure good health and wellbeing.”

This statement was proven true in 2023, when Boehringer colleagues in Italy—where GPP is a relatively neglected disease—formed a multi-stakeholder coalition with members of the scientific community, patient organizations, and national policy makers. Together, we used the GPP Charter to:

- connect with inter-parliamentary groups
- gain government support to increase awareness
- secure a formal commitment to help people living with GPP
- facilitate a wider community discussion on the disease.

This intervention will transform the lives of GPP patients in Italy, who will soon have access to life-changing treatment for their condition.

Boehringer Ingelheim

b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

This year, Boehringer's patient engagement activities will reach a new level of maturity. We will launch ambitious educational projects, innovate with new engagement formats, and enhance efforts to empower people living with disease. This is reflected in plans we are developing for GPPS25 and ongoing GPPS community calls—all of which we curate in partnership with patients. The continued and sustained momentum behind GPPS—an evergreen patient engagement initiative—enables Boehringer to continue evolving our patient partnerships, and culture of patient centricity, from a strong foundation.

➔ Disease-Simulation Experiences

This momentum requires input from the entire Boehringer workforce. Each one of us is called to understand and address the actual, rather than the assumed needs of patients—but many roles do not encompass direct contact with patients. We are working with A Life in a Day to close a knowledge gap between what people think they know about the lived experience of disease, and the holistic realities of debilitating disease. These 24-hour simulations, created with the input of patients, provide our people with a new appreciation of the patient experience. With greater understanding, our employees are seeking out patient insights in their daily work and championing the patient cause.

In 2023, over 300 employees participated in a Chronic Kidney Disease (CKD) simulation experience. The CKD experience is being repeated in 2024 with another 300-400 participants, and we are commissioning six other disease simulation experiences—three of which we are creating from scratch, in partnership with patients. In the interests of advocating for patient needs, industry-wide, these newly created simulation experiences (once tested and piloted) will be available for use in healthcare organizations around the world on a non-proprietary basis. This initiative addresses the critical challenge of how to enable many thousands of industry professionals (at Boehringer and beyond) who do not have one-to-one interactions with patients, to gain a broader understanding of the lived experience of disease, and a renewed recognition of the value that patient perspectives bring to the strategic development of treatments and services.

➔ Patient Integration in Publications and Lay Language Summaries

To make scientific information available to the general audience, Boehringer has established a lay-language publication strategy. Boehringer is also exploring different lay language summary formats (including a patient podcast), to accompany published scientific research and clinical study results, to reach the patient population, and to bring R&D information to them in a digestible fashion.

The lay language publication strategy is also committed to elevating the patient voice in published research. The publications team already offers patients who have the relevant skills and insights an option to co-author published content. Boehringer is looking at extending the invitation, and building on existing patient-centric resources—i.e., we already provide open access to research publications.

Boehringer Ingelheim

On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

We anchor our drug development in patient insights and feedback, striving to integrate learnings early, and systematically, across the entire development process. We are continually evolving and improving how we involve patients, and we respond to their feedback across the R&D development lifecycle. Some examples of areas we placed particular focus on in 2023 include:

➔ Patient-Experience Assessments (PEAs)

We use Patient Experience Assessments (PEAs) to guide asset development and inform strategic decisions. PEAs summarize what is known and unknown about the patient experience in a specific disease area. They are created six to nine months before the start of asset development for a new indication. At every research milestone, the PEA is updated with new patient insights, and with feedback from patients and patient organizations—which then informs the next phase of development. This early understanding of the experiences, needs, and priorities of patients informs the strategic decision making and processes of all the cross-functional colleagues who contribute to the drug development process, and leads to better medications and services for patients.

➔ Patient-Centric Clinical Trials

At Boehringer, we are designing and conducting our clinical trials in partnership with patients and their caregivers to minimize participation burden, and to accelerate the delivery of new treatments to patients in need. We are incredibly proud of the progress we have made in this area. While only done sporadically in the past, our trials are now systematically designed with input from patients and caregivers. For example: to understand barriers to trial participation, we conduct simulations of planned trials with patients and caregivers. These role-plays allow us to understand the main pain points that patients and caregivers experience in their trial journey. We then use these insights to remove from the trial design barriers to participation.

Boehringer Ingelheim

During the trial conduct, we continue to engage with patients and caregivers to create a positive trial experience for them. We have implemented trial experience surveys in all our trials, allowing us to obtain feedback from trial participants about how the trial experience can be further improved. We are now also engaging early with communities that are at risk of being underrepresented in clinical trials, to understand their specific needs, and their barriers to participation. This enables us to co-create solutions that address their needs, so that our clinical trials become more inclusive.

In fact, diversity in clinical trials is a company-wide focus for 2024 and we are currently building a holistic end-to-end global strategy for this with frameworks and processes, benchmarking metrics and an ambitious change management approach. As an example, in support of this, we are establishing a global diversity advisory board and have embedded diversity targets in our Clinical Development & Operations (CD&O) priorities and performance expectations.

Our future initiatives will align with Boehringer's goal to expand access to health, as part of our sustainable development for generations strategy, and will lead to better and more robust data to improve patient treatment for everyone (leaving no one behind).

➔ Early Research Patient-Steering Committees

Boehringer seeks to integrate patient insights from the early stages of research. By creating Early Research Patient-Steering Committees, containing diverse groups of patients living with a specific disease, our R&D teams can consult with patient stakeholders early in the therapeutic lifecycle, and have regular touchpoints with a committed team of patient partners. They help us to ask the right questions, and gather insight and feedback with sufficient runway to enable us to pivot, optimize trial protocols, and—ultimately—better meet patient needs.

b.) What equivalent plans in partnering does your company have for early- and late-stage R&D during 2024?

In 2024, we continue to evolve our practices and partnerships with patient organizations, to ensure on-going improvement in the systematic integration of patient insights, and to work towards ever-greater diversity of patient representation in the insights and feedback we gather.

➔ Patient-Experience Data (PED)

In response to an industry-wide push to systematically leverage PED to direct drug development, Boehringer is collaborating with patient experts to craft a training curriculum for different levels and roles within the patient community, which will be delivered regionally, with links to already existing training resources. This will offer coaching and upskilling opportunities, and will systematically assess existing training materials to look for gaps. The discovery phase is underway. This GPPS23 global project is also exploring how PED can be best generated and used by patient organizations in Health Technology Assessment (HTA) submissions. It has reviewed recent HTA submissions from patient stakeholders, and identified best practices to incorporate PED in these submissions, to inform decision making.

Boehringer Ingelheim

➔ Oncology Council

Boehringer stands up numerous Patient Advisory Boards to gather patient insights on specific disease areas. We also invest in creating patient councils as a format for patient partners to participate in longer-term collaboration and sustained goals. To date, we have successfully implemented multiple disease-specific, and cross-disease, patient councils—at both global and regional levels. In 2024, we are focused on establishing a global Oncology Council with cross-cancer patient representatives, in partnership with patient organizations, to help us advance early patient intervention, and strategic engagement in this therapeutic area.

➔ Patient Contracting and Payment

Pharmaceutical companies operate in a heavily-regulated environment. There are many rules, industry codes, and regulations to follow, to engage compliantly with patients and patient organizations. Within this framework, we are constantly striving to make it easier for patients and patient organizations to work with Boehringer. This includes simplification of procedures—such as timely payments of expenses, and reduction of time to contract, as well as the simplification of contract templates. We have a particular focus in 2024 on advancing these efforts to simplify processes that enable partnership in early- and late-stage R&D. For example, we have recently established and implemented lay-language contracts for our patient collaborations, which significantly remove barriers to trustful and transparent partnerships.

On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?

At Boehringer, the strength of our patient organization partnerships rests on our commitment to build genuine relationships. As with any relationship, this can only be achieved with two-way dialogue and personalized interactions, conducted on an equal footing. For this reason, we do not subscribe to a standardized process of engagement. Rather, we empower our colleagues to establish direct, individualized relationships with patient organizations, based on trust, transparency, and mutual respect.

These values are embedded from the outset, through our process of discovery. Patient organizations often tell us about the long, and sometimes challenging journeys they've been on to achieve visibility in the healthcare sector. We recognize that this effort often requires a voluntary, honorary commitment. Part of Boehringer's process, therefore, involves our understanding the patient organization's history, focus, and vision.

Transparency underpins our approach. We ask patient organizations to state their expectations of Boehringer. In the spirit of coming to the table as equal partners, we seek mutual understanding, agreement on what a win/win situation looks like, and how we can achieve our common goals, hand in hand.

Boehringer Ingelheim

Acknowledging that a one-size-fits-all process won't address individualized needs, Boehringer colleagues operate within the parameters of the following values-based framework, guiding how we interact (and build trusted and collaborative partnerships) with patient organizations.

➔ **Open dialogue**: Initiate open and honest dialogue, share authentically, and actively listen.

➔ **Joint planning**: Identify synergies, and collective opportunities for collaboration.

➔ **Build trust**: Invest time, effort, and energy in the success of a partnership, demonstrating consistency, reliability, and transparency.

➔ **Flexibility in approach**: Be willing to adapt to the evolving needs and circumstances of patient organizations, and the varying health systems in which they operate.

➔ **Empowering engagement**: Empower patients and patient organizations by providing tailored support.

➔ **Shared benefits**: Set clear objectives, and deliver tangible benefits for both Boehringer and the patient organization.

➔ **Accountability and ownership**: Foster a sense of ownership and equal accountability for agreed commitments and responsibilities.

➔ **Long-term relationships**: Nurture, and value, long-term relationships—prioritizing sustainability and longevity over short-term gains.

➔ **Continuous Improvement**: Invite regular feedback, and evaluate progress. Learn and grow together.

Looking to THE FUTURE

How do you expect your company's RELATIONS with patient groups to change over the next five years (2024 to, say, the end of the decade)?

Patients are already a highly-valued stakeholder for Boehringer—we work hard to understand the needs of, and collaborate in equal partnership with patients, patient organizations, and the patient communities we serve. Building genuine, authentic, and meaningful partnerships with patients and patient organizations will remain the cornerstone of our work at Boehringer over the next five years and beyond.

Our focus in the next five years will therefore be on:

➔ Increasing the number and diversity of patient partners with which we collaborate, as we standardize consistent, systematic integration of patient insights and perspectives across the whole development lifecycle—from preclinical (informing our research pipeline), to market entry, and beyond.

➔ Pioneering new forms of engagement, as we continue to find new ways to equip, empower, and enable patients, carers, and patient organizations to participate as equal partners in the development of treatments, services, and systems.

Boehringer Ingelheim

➔ Breaking down barriers and hurdles to patient/carer/patient-organization partnerships, making compliant collaboration simpler and easier for us all.

Beyond Boehringer, we recognize the role and responsibility we have in positively impacting the lives of patients, by coordinating and/or entering multi-stakeholder partnerships and coalitions. Our aim is to extend the partnerships we have with patients and patient organizations, to include HCPs, payors, regulators, and policy makers—so that, together, we can collectively work to bridge the gap between what patients expect and deserve, and what the pharmaceutical industry and healthcare ecosystem is presently structured to provide.

As part of our commitment to facilitate and support non-competitive collaboration for the benefit of all patients, Bronwyn Lewis, our Global Head of Patient Engagement sits on the Board of Patient Focused Medicine Development (PFMD), a global coalition of experts and organizations which co-designs the future of healthcare with patients.

What is the name of your company?
Gilead Sciences.

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
Global.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
More than 500.

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?

- ➔ Advancing patient and person centric approaches
- ➔ Co-creation opportunities
- ➔ Sponsorships and grants
- ➔ Addressing health disparities
- ➔ Efforts increasing access to screening, testing, and improving overall quality of life for patients
- ➔ Advancing efforts which increase equitable access to innovative treatments and medicines
- ➔ Efforts increasing patient voice and representation in strategic planning
- ➔ Inclusion of patient experiences in clinical development

Could you specify which are the most common of these relationships?
Gilead collaborates with communities around the world to expand access, improve health equity and fulfill our responsibilities as a corporate citizen.

During which of the following corporate activities does your company seek PATIENT/PATIENT-GROUP INPUT OR ADVICE?

- ➔ **Strategic input**: Yes.
- ➔ **Finance**: No.
- ➔ **Human resources**: No.
- ➔ **Early-stage research**: Yes.
- ➔ **Late-stage research**: Yes.
- ➔ **Manufacturing (including packaging)**: Yes.
- ➔ **Pharmacovigilance**: Yes.
- ➔ **Supply chain and distribution**: No.
- ➔ **Marketing and sales**: Yes.
- ➔ **Operations**: Unknown.
- ➔ **Market access**: Yes.
- ➔ **Regulatory affairs**: Yes.
- ➔ **Medical affairs**: Yes.
- ➔ **Public affairs/corporate communications**: Yes.

Gilead Sciences

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes?
(The projects can be at global, regional, or country level, or in specific therapy areas. If you wish, you may mention urls/online links, to provide further context to your reply.)

Gilead's key philanthropic initiatives are incepted and designed in close collaboration with the people and communities they are intended to serve. In 2023, Gilead's grant programs provided more than $100 million in funding to support over 500 community-based organizations across 40 countries, focusing on HIV, viral hepatitis, and oncology.

Programs such as The COMPASS Initiative® and HepConnect® address geographical disparities in HIV and HCV, respectively. These programs increase awareness and education, expand screening and prevention services, improve access to treatment, and address stigma. Since its launch in 2017, The COMPASS Initiative® has provided more than $100 million in grant funding across nearly 400 Community Based Organizations in 16 US States, primarily serving Black, Indigenous, and other people of color (BIPOC) communities and Priority Populations.

Additionally, Gilead supports organizations working to improve the overall health and wellness of communities most impacted by HIV through grant programs like Zeroing In® and HIV Age Positively®. Vitally, these partnerships help to bolster support services that are critical to combatting stigma, improving adherence to treatment and preventative medications, and empowering informed decision-making around health and quality of life. In 2023, and as in years prior, Gilead supported patient and advocate groups with sustained partnership, funding, and resources to drive advances toward WHO public-health targets, and to promote global community health for key populations, especially those disproportionately facing barriers to care.

Gilead recognizes, and adapts to, the needs of communities and patients. With HIV Age Positively, Gilead's aim is to improve the quality of life and health for individuals living and aging with HIV. With nearly 50% of people living with HIV in the US now over the age of 50, and an expected increase to 70% by 2030, the program recognizes the unique challenges faced by this population. As such, since 2018, Gilead has awarded over $35 million in grants to 42 organizations focused on improving care coordination through education, training, and innovative models of care; enhancing well-being by connecting individuals to additional resources, like health hotlines; and advocating for policy change to benefit people aging with HIV.

Gilead Sciences

b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

Black cisgender women and Transgender women and girls are currently disproportionately impacted by the HIV epidemic. For instance, transgender women and girls experience the highest rates of new HIV diagnoses among Transgender people [reference 1]. In response, in 2023, Gilead announced, and in early 2024 Gilead launched, Setting the P.A.C.E. (Prevention, Arts and Advocacy, Community, Education) initiative. Setting the P.A.C.E. is a three-year, $12.6 million commitment toward increasing HIV prevention, anti-stigma, and health-equity efforts by supporting 19 organizations dedicated to tackling these disparities. Through this initiative, Gilead helps organizations implement projects that enhance health outcomes for Black women and girls, including expanding culturally-responsive care training programs, and utilizing arts and media to engage local communities, and to address stigma.

To achieve the World Health Organization's global target of ending viral hepatitis by 2030, Gilead has also developed the Viral Hepatitis Relink program in the United States, allocating $8 million in funding to relink people living with HCV and HBV back to necessary care and treatment. Gilead has partnered with the CDA Foundation, which will lead implementation and fund distribution for this grant, given their dedication to developing successful disease-elimination strategies. This initiative will prioritize programmatic partnerships around evidence-based solutions, intervention modeling, and collaborative knowledge sharing to address barriers to viral-hepatitis treatment by connecting people who have been lost in the healthcare system.

Furthermore, for 2024, Gilead committed $5 million in grant funding to support health-equity programs globally through our Toward Health Equity Oncology Grant™. This initiative is targeted at driving organizational capacity building around person-centered care and caregiver support. The goals of this program include: increasing access to clinical trials and participation rates within communities of color, to ensure equitable access to treatment, and the availability of comprehensive data, and enhancing the diagnosis rates of metastatic breast cancer (mBC) by facilitating access to screening, and promoting the availability of support resources.

Ref 1: Centers of Disease Control and Prevention, 'HIV and Transgender People', 2024.

Gilead Sciences

On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

At Gilead, our commitment is to lead person-centered innovations in research, with a primary focus on addressing unmet needs within communities. Sustained success requires a comprehensive care approach that fosters community empowerment, enabling individuals to become active participants in decisions shaping their long-term health and well-being. By adopting a person-centered research approach, Gilead has gained insights into the unmet needs of communities.

Across a range of therapeutic areas and indications, patient feedback from community engagements has informed every aspect of Gilead's clinical-trial design—from protocol development, to inclusion criteria, to recruitment techniques.

b.) What equivalent plans in partnering does your company have for early- and late-stage R&D during 2024?

Gilead has developed comprehensive community-engagement models across its HIV portfolio spanning HIV prevention studies have been designed to help ensure that those who may benefit most from HIV prevention are represented, and their experiences can center how we improve patient outcomes in the present and future. Gilead is actively engaging underrepresented groups globally, and aims to assess the safety and efficacy of new options for PrEP across diverse communities through these trials, including women and adolescent girls in Sub-Saharan Africa, Black and transgender men who have sex with male partners, cisgender women, and people who inject drugs.

Additionally, to address deeply-rooted health disparities in Triple-Negative Breast Cancer (TNBC), Gilead proactively works with patient communities and advocate organizations to seek their input into how Gilead can better design real-world evidence studies to assess meaningful quality-of-life measures to inform targeted future clinical development.

Gilead Sciences

On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?

The process of forming partnerships with patient groups generally involves a 5-step approach:

➔ **Understand patient experiences**: We actively engage with patient communities through various approaches, including but not limited to advisory boards and market research, to understand their experiences, challenges, and priorities in receiving care. By listening to their voices, we ensure their needs remain central to any collaborative effort.

➔ **Advocate and prioritize**: We advocate for advancing identified patient priorities and for overcoming key challenges. We empower patients to influence decisions that impact their care and ensure patient-centered solutions are developed.

➔ **Build relationships**: We establish strong relationships with patient community organizations with the goal of fostering continuous collaboration through meaningful initiatives. For instance, we have patient and community-group advisory boards for patient groups to provide thought partnership, and directly impact Gilead's ways of working with the community.

➔ **Develop tailored solutions through collaborative initiatives**: Our collaborative initiatives aim for long-term improvements in care. By collaborating with these patient-advocacy groups, we address barriers, education gaps, and disparities in health delivery.

➔ **Launch programs to address prioritized challenges**: Based on insights gained and collaborative efforts, we launch targeted programs designed to address prioritized challenges and contribute to better health outcomes.

Looking to THE FUTURE

How do you expect your company's RELATIONS with patient groups to change over the next five years (2024 to, say, the end of the decade)?

Gilead is continuously exploring new opportunities that further our goal of improving patient outcomes, with patient groups valued and treated as partners and innovative leaders throughout the process. We expect to continue to engage patients, caregivers and advocates as we plan and design clinical trials and other initiatives across government policy, access and reimbursement, navigating the AI landscape, workforce/care shortages, and broader advocacy for community-organization needs.

In the HIV landscape, we will expand our partnership with organizations representing the underserved communities most in need of improved access to and quality of care. Our efforts will continue to focus on initiatives aimed at enhancing access, addressing stigma, and advancing research for long-acting prevention and treatment options globally.

What is the name of your company?
Novartis.

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
Global, across all therapy areas.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
339 patient organizations in 62 disease areas, from 40 countries, engaged in global initiatives to inform decision-making.

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?

- ➔ Funding (for example, grants or donations).
- ➔ Speaker engagements.
- ➔ Consultancy activities.
- ➔ Provision of information to patient groups.
- ➔ Supporting patient-group campaigns.
- ➔ Co-creating projects.
- ➔ Creating support tools for patients and carers.
- ➔ Helping patient groups to network.
- ➔ Training and capacity building.
- ➔ Involving patient groups in R&D.
- ➔ Support in building web or e-health resources for patient groups (such as apps).

Novartis

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes?
(The projects can be at global, regional, or country level, or in specific therapy areas. If you wish, you may mention URLs/online links, to provide further context to your reply.)

Yes—we would like to share our Global project on Patient Engagement Impact Measurement (PEIM). With an ambition to consistently and systematically elevate the patient voice in the decision-making and actions of our company across the medicines lifecycle, we wanted to create a framework to measure and improve the impact of this work—for patients, health systems, and business.

It is well recognized that meaningful patient engagement is needed for the authentic patient voice to inform research and regulatory decisions. However, for this to happen systematically and consistently across the pharmaceutical industry, there is still a need to measure, demonstrate, and communicate the value of patient engagement to all stakeholders.

Over the past two years, a collaborative team of external consultants, patient advisors and a cross-functional working group from Novartis has co-created a framework to measure and demonstrate the impact of patient engagement across the medicines lifecycle. The aim is to clearly demonstrate and elevate the value of the work that we are doing with patients, by using pre-defined metrics. It is our ambition to use this framework to elevate the industry standard for the involvement of patients as stakeholders and partners through drug development and beyond, in order to improve patient outcomes, and deliver value to health systems and business.

To do this, we identified an internal cross-functional working group, and external partners, to co-create the framework and support the project: Dot I/O Health consultancy, and a council of patient advisors (including current and former patient-group representatives, academic experts in measurement and patient-experience data collection, and expert patients)—selected by Novartis' Patient Engagement Center of Excellence, as being individuals who are familiar with the medicines lifecycle, and how patient-engagement and patient-experience data collection is done, and who understand how patient advocacy can add value across stakeholder interactions, including healthcare systems, clinical, health technology assessments, regulatory processes, and policy development.

Dot I/O Health conducted an environmental analysis of patient engagement and its measurement (across peer-reviewed literature, pharma company ESG and corporate reporting, publicly available news, and web content), as well as an internal review of Novartis' patient-engagement systems and practices.

Novartis

The environmental analysis showed that, despite initial work by IMI-PARADIGM and PFMD, there is no current best practice for the measurement of the impact of patient engagement across all stages of medicines development that includes robust tools, metrics, and methodologies. A draft framework based on behavior-change-model principles was proposed by Dot I/O Health, and reviewed by a cross-functional internal working group, as well as the patient council. The internal group suggested edits to meet internal capabilities and priorities. The patient council advised to adapt the Donabedian model for health-systems continual quality improvement [https://en.wikipedia.org/wiki/Donabedian_model], and to ensure the framework was cyclical, with patient collaboration at the center, to reflect how sequential **patient engagements** across the medicines lifecycle (**inputs**) can build via **learnings** and **actions** taken (**outputs**) to deliver **value** via direct short- and long-term **outcomes**, and contribution to the **impact** that our company has at a societal level.

With help from the patient council and the internal working group, the framework was populated with priority metrics of relevance to patients and decision-making stakeholders, as well as our business, and designed to work across varied global and local patient-engagement and advocacy activities at all stages of a medicine's lifecycle—with internal team capability, the collection and use of patient-experience data (PED), and collaboration with the community consistently tracked and evaluated across priority patient-engagement activities of:

➔ understanding Patient Life Experience (PLE—our core approach to gathering PED);

➔ input into Target Product Profile (TPP);

➔ Patient-Focused Drug Development (PFDD—including patient preference studies (PPS), and patient input into clinical trials);

➔ input into strategic plans and dossiers;

➔ co-creation of patient-directed materials and programs; and

➔ local advocacy and launch excellence.

A simple illustration of the framework was included in page 21 of our Novartis in Society Report [https://www.novartis.com/sites/novartis_com/files/novartis-integrated-report-2023.pdf], with an example patient-engagement project used to demonstrate how it works [see box on next page for this example].

To our knowledge, this is the first framework to measure the value of patients' voices across all stages of a medicine's lifecycle. We aim to publish our full framework, and the results of its use, to enable the community to build off our initial work to create industry best practice.

In 2023, we conducted a retrospective analysis of patient input into Patient Support Program (PSP) design, to practically apply the framework, and understand any barriers to its use, while at the same time revealing the value of patient engagement in PSP design.

Novartis

Novartis case study: Listening to the CML patient community

Patient insights helped us remove a potential barrier to participation in Phase III clinical trials for *Scemblix* as a potential first-line treatment for chronic myeloid leukemia (CML), a type of cancer that develops in the blood-forming cells of the bone marrow.

Input: An advisory board of patient advocates reviewed the participation and screening criteria for two Phase III clinical trials in adults and children. To help reduce the burden on patients and caregivers, they recommended removing the need for a bone marrow aspiration test as a requirement to enter the trial.

A bone marrow aspiration test is a painful and invasive procedure for patients. It is also an emotional burden for caregivers to see loved ones, especially children, undergo the procedure. Requiring a confirmatory test during trial screening was recognized as an unnecessary barrier for participation in the trial, since people living with CML typically already have the results of such a test on file.

Output: Based on the input from CML patient advocates, and following a discussion with regulatory authorities, we removed the requirement for a bone marrow aspiration test from the trial screening process, and logged the results of patients' previous tests instead.

Value: In addition to an improved experience for patients and caregivers, qualitative feedback from investigators suggested a relatively easier patient recruitment experience. Enrolment for both trials was completed 10 months ahead of schedule.

b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

Yes—the Patient Engagement Impact Measurement project continues with retrospective analyses and prospective pilots of the use of the framework and metrics, helping us to create improved and connected measurement systems. We are piloting across medicines development for PLE, TPP, PPS, clinical trials, and UK and US advocacy and launch excellence. We will report on, and publish, our findings.

Novartis

On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

Patients and caregivers know better than anyone what it means to live with a disease every day. We must prioritize the outcomes that matter most to them, to bring forward innovative medicines that create value for patients, health systems, and our business.

By working with patient organizations, we build patients' perspectives into key decisions throughout a medicine's lifecycle—from initial research, through to development and commercialization. By reflecting lived experience, our medicines are more likely to address outcomes that matter most to people living with a disease.

This systematic, integrated approach supports our strategy. It allows us to set clearer priorities for R&D, supports enrollment, retention, and protocol adherence in our clinical trials, and enables us to bring our medicines to patients faster.

From involving the perspective of those living with a condition at an early stage, through to co-creating clinical endpoints, trial protocols, and patient support programs, we are applying this approach to more than 100 investigational medicines at different stages of the lifecycle. These include potential treatments for chronic myeloid leukemia (CML), psoriasis, hidradenitis suppurativa, and Sjögren's syndrome.

In addition, we measure the impact of our approach to improve the quality of our engagement over time and ensure we generate effective outcomes that create value for patients, health systems, and Novartis.

On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?

Within our PEIM framework, **Inputs** are, like the Donabedian approach, divided into **Structures** and **Processes**.

A key **Structure** used in our patient organization collaborations is the Engagement Follow-up Questionnaire (EFQ). A short version is issued after each engagement, and a long version once a year, or at the end/key milestone of a project. This allows us to track and quantify the satisfaction with the relationship in terms of experience rating, potential improvements, what was liked (short EFQ), and topic suitability, timeliness of inclusion, information and remuneration, task and contract clarity, being listened to attentively (long EFQ)—as well as outcomes (long EFQ, being informed of how input was incorporated, likelihood to participate in future), and impact (long EFQ, whether the project was meaningful for the patient community).

Novartis

Other **Structures** that help ensure quality patient engagement include guidance documents and a Patient Engagement Navigator that details the different methodologies and best practices to choose from; and our Patient Organization Mapping system, which helps ensure governance, while supporting the right choice of the right organization to partner with for specific tasks (e.g., with respect to mission and capabilities). We also have a Patient Engagement Academy Learning Management System available for colleagues across all functions.

Our PEIM framework not only measures the efficacy and uptake of these **Structures**, and tracks their use within our **Processes**, but it also instils priority **Output** metrics of sharing back to the patient organizations draft **Learnings** for them to verify; as well as updates of what **Actions** were (or were not) taken across our company based on the learnings, and why.

We are committed to sharing back our **Outcomes** and **Impact** results to the patient community too, so that we can jointly demonstrate the **Value** to patients, health systems, and business of consistent, systematic patient engagement across the medicines lifecycle.

"Patients like to feel they've been heard. It's not a pick-up and drop, it's how can we get you to the next stage … This is where I think measurement comes in—what are the steps on the way, acknowledgment of patients in that journey, and deeper involvement that goes continually over time."

—Patient advisor

"We are moving to mature relationships and dialogues with the patient community … Stakeholders don't want transactional relationships, [they] want ongoing, continuous engagements, and that requires feedback at each stage—what insights were taken on board, and what impact are they having?"

—Zack Pemberton-Whiteley, Executive Director,
Patient Engagement Center of Excellence, Novartis

What is the name of your company?
Novo Nordisk (Obesity Division)

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
➔ Global.
➔ Obesity.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
At global level, probably around 25.
At national level, the number is much higher, as we operate in 80 countries, and partner with one-to-five patient groups in most countries (more, in some countries).

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?
➔ Funding (for example, grants or donations).
➔ Speaker engagements.
➔ Consultancy activities.
➔ Supporting patient-group campaigns.
➔ Co-creating projects.
➔ Helping organise events.
➔ Creating support tools for patients and carers.
➔ Involving patient groups in R&D.
➔ Support in building web or e-health resources for patient groups (such as apps).

Could you specify which are the most common of these relationships?
➔ At global level, the most-important one is to ensure that our efforts to shape patient-centric healthcare policies are based on real needs—as seen from the patient-and-carer perspective.

During which of the following corporate activities does your company seek PATIENT/PATIENT-GROUP INPUT OR ADVICE?
➔ **Strategic input**: Regularly.
➔ **Finance**: Never.
➔ **Investor relations**: Never.
➔ **Early-stage research**: Sometimes.
➔ **Late-stage research**: Sometimes.
➔ **Manufacturing (including packaging)**: Sometimes.
➔ **Pharmacovigilance**: Usually not.
➔ **Supply chain and distribution**: Never.
➔ **Marketing and sales**: Never.
➔ **Operations**: Never.
➔ **Market access**: Sometimes.
➔ **Regulatory affairs**: Sometimes.
➔ **Medical affairs**: Sometimes.
➔ **Public affairs/corporate communications**: Regularly.

Novo Nordisk (Obesity Division)

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes?
(The projects can be at global, regional, or country level, or in specific therapy areas. If you wish, you may mention urls/online links, to provide further context to your reply.)

We are keen to break down silos between chronic diseases which are—from a scientific and societal view—closely related. This could be diabetes, cardiovascular diseases, liver disease, obesity, and osteoarthritis. Since medical societies work somewhat disconnectedly in these areas, the same tends to happen with patient organisations (obviously, also, since fundraising is an issue across the patient community), and it might seem easier to prioritise 'disease exclusivity'. We believe that coalitions will be more impactful going forwards, as healthcare systems struggle, and staff are critically in demand everywhere.

We have led a program in five countries, in which we invited national patient groups (which might not usually engage much) to co-develop anthropological patient research, and take part in discussion thereof in a shared event.

b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

We hope to put more focus on health inequality in our dialogue and partnerships with patient organisations this year.

On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

We have put tremendous efforts into this for a couple of years, but it is an extremely-difficult requirement to meet, these days, as any collaboration and contact between pharma and patient organisations is scrutinized, and often leads to discredit of both patient organisations and the pharmaceutical company in question. Another inherent dilemma is the remuneration of patients when providing input. While pharma are obliged—and should be obliged—to compensate the time spent, and the valuable input provided, the transactional nature of a collaboration is often cast in the media, and in public perception, as suspicious, undue influence, etc. We are working on identifying the best models for structured and meaningful involvement of patients and patient organisations, while balancing the above challenges.

Novo Nordisk (Obesity Division)

A final comment on this point is the issue in a large number of patient organisations of low capacity, and expertise in how to provide meaningful input of use in R&D. While some patient organisations in some therapy areas have been fortunate (and skilful) in fundraising, and have managed to build this expertise—having teams and leadership with knowledge in R&D from a patient perspective (this is often the case with patient groups specialising in cancer, rare diseases, or neurological diseases)—many of the others are mostly used to manage peer-to-peer support, disease-awareness campaigns, and things like that. The idea of pharma 'educating' patient groups of this is, in itself, an invitation to criticism, and poor judgement, as the power imbalance is obvious. It might be more appropriate for regulators to take on this task, and put some more effort into the process necessary to fulfil their ask for patient evidence.

On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?

We have worked intensely to clarify the dynamics, opportunities, AND challenges of partnerships. The principles of mutual benefit, complete transparency, and—if possible—independence of patient organisations in partnerships have been key for us. We have developed a corporate-partnership guide which provides direction and guidance, but does not specify tactics in any way—as partnerships will only be of value if they are shaped by, and tailored to, the specific cultural/national context, government structure, language, etc.

It has also been key for us to stress that partnerships can be short-term endeavours, and should—again, if possible—also include public stakeholders, to ensure the perspective and interest of a public healthcare system is always part of it (thus coming back to our focus on health inequities).

Looking to THE FUTURE

How do you expect your company's RELATIONS with patient groups to change over the next five years (2024 to, say, the end of the decade)?

We expect to move even further away from the strictly transactional, towards a more-balanced collaboration. We also expect to move beyond the patient groups that have traditionally been perceived as the 'patient representatives', towards other organisations—such as senior-citizen groups, children's-rights groups, vulnerable-communities' NGOs, etc. People living with chronic diseases might not think of themselves as patients, but because they still experience barriers in healthcare, it is important that organisations outside of the classic patient associations sphere also raise the voice for them.

What is the name of your company?
Pfizer Inc.

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
Global.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
1200.

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?

- ➔ Funding (for example, grants or donations).
- ➔ Speaker engagements.
- ➔ Consultancy activities.
- ➔ Provision of information to patient groups.
- ➔ Supporting patient-group campaigns.
- ➔ Co-creating projects.
- ➔ Helping organise events.
- ➔ Creating support tools for patients and carers.
- ➔ Helping patient groups to network.
- ➔ Supporting patient-groups' publicity.
- ➔ Training and capacity building.
- ➔ Involving patient groups in R&D.

During which of the following corporate activities does your company seek PATIENT/PATIENT-GROUP INPUT OR ADVICE?

- ➔ **Strategic input**: Regularly.
- ➔ **Finance**: Regularly.
- ➔ **Human resources**: Regularly.
- ➔ **Investor relations**: Sometimes.
- ➔ **Early-stage research**: Regularly.
- ➔ **Late-stage research**: Regularly.
- ➔ **Manufacturing (including packaging)**: Sometimes.
- ➔ **Pharmacovigilance**: Sometimes.
- ➔ **Supply chain and distribution**: Regularly.
- ➔ **Marketing and sales**: Regularly.
- ➔ **Operations**: Sometimes.
- ➔ **Market access**: Regularly.
- ➔ **Regulatory affairs**: Regularly.
- ➔ **Medical affairs**: Regularly.
- ➔ **Public affairs/corporate communications**: Regularly.

Pfizer Inc.

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes?

The Patient Advocacy Leadership Collective (PALC), co-created by Pfizer in partnership with a Global Advisory Board of patient advocates, was launched in 2023 to support patient advocacy organizations around the world by empowering advocates with knowledge and skills. Advocacy skills are essential for patient organizations, enabling patients and advocates to actively engage in their healthcare, improve communication with healthcare providers, access information, and contribute to positive changes in the healthcare system. Patient Advocacy Leadership Collective, provides connectivity, community resources, and tools focused on sustainable capacity building for patient advocates globally.

The PALC includes key three programs:

1. NexGen Leadership Program: a flexible, self-guided learning resource designed to support the growth and development of current and future leaders in patient advocacy. Registered learners can access course content for free via Coursera.

2. Mentor Match: Helping to connect patient advocacy professionals to support one another in their growth and development.

3. Global Health Fellows Program: Places Pfizer colleagues on skills-sharing assignments with global health organizations to help strengthen local health systems.

The program also offers eligible advocates access to the Clear-A Health Literacy Tool - an evidence-based, health literacy tool designed to meet different patient needs. It helps individuals communicate in a clear and understandable way, through incorporating health literacy best practices. Clear-AI improves written text by checking readability, understandability, and actionability, the core principles of health literacy.

Learn more at: www.patientadvocacy.com

b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

In 2024, we look forward to convening for our third annual Global Patient Advocacy Forum which will bring together senior advocacy leaders from around the world to discuss how to continue to best partner with and serve patients. Attendees will include Pfizer's Global Pan-Therapeutic Patient Centricity Advisors council. This external council, including advocates from Latin America, Europe, Asia, Canada, Africa and the United States, has been assembled to educate Pfizer colleagues on trends and issues patient groups face, provide candid input on key patient-focused programs and resources, and to collaborate with Pfizer colleagues and senior leadership to co-develop meaningful approaches to measure progress on behalf of patients.

Finally, we look forward to hosting our annual enterprise-wide Patients in Focus week in October. In 2023 Patients in Focus, Pfizer's weeklong celebration of our commitment to Patient Centricity, engaged 40,000+ colleagues and 350 patient advocacy groups across 35 countries in town halls, patient panels and community service opportunities.

Pfizer Inc.

On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

Pfizer aims to embed the patient perspective across everything we do, from the earliest stages of research to the final approval and use of our medicines and vaccines. Throughout early and late stage Research and Development, we strive to set the foundation for trusted, enduring connections with patients and advocates and work to better understand patients' experiences with their conditions, unmet needs, disease burden and side effects impacting quality of life, and meaningful benefit from potential treatments.

These insights guide our work throughout the entire drug development continuum as they can help inform therapeutic development, clinical trial design, evidence for regulatory submissions, as well as our support programs and services.

In the United States, Pfizer's Oncology Patient Centricity Ecosystem (POPCE) is an example of this commitment to end-to-end advocacy. POPCE continuously engages more than 65 patient advocacy leaders representing national organizations across the cancer landscape who have provided input and feedback to help enhance Pfizer's patient centricity agenda for oncology, through a holistic understanding of community in the areas of, health equity health literacy and patient engagement in clinical trials.

In 2023 we also made impactful changes in abstract plain language summaries, clinical trial diversity websites & brochures, medicine administration, internal policies for health literacy best practices and dissemination of resources to reach historically disregarded patient populations.

b.) What equivalent plans in partnering does your company have for early- and late-stage R&D during 2024?

At Pfizer, we recognize that involving patients as co-leaders and co-creators in research is key to reflecting the patient's voice in decision-making. However, co-creation of patient-centered data to inform decisions is rare, especially in early drug development where patient input is critical to prioritizing patient-relevant outcomes and endpoints for use in clinical trials. Despite the industry's growing commitment to patient centricity, most patients are excluded from sharing their expertise in research; more inclusive methods of engaging patients as research partners are needed.

Pfizer Inc.

For example, Pfizer partnered with Sick Cells, a patient advocacy group, in developing, conducting, and disseminating the results of a patient preference evidence-generation program in the United States. This program is being leveraged to understand priorities of patients and caregivers for treatment features and outcomes in sickle cell disease to inform endpoint selection in clinical development. The results of this program will be used as a basis for continued interaction between patients and the sponsor and to inform ongoing clinical development and evidence-generation activities. This case study demonstrates an approach to meaningful collaborations between patient organizations and pharmaceutical companies aimed at including the patient's voice early in the medical product lifecycle.

On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?

As an effort to help improve the ease of working with Pfizer, the Global Patient Advocacy team has launched a new Corporate Global Policy that outlines the requirements and principles that guide all interactions with patients and Patient Advocacy groups at Pfizer. The policy delineates the proper internal coordination colleagues must adhere to when interacting with Patients and Patient Advocacy Group partners. To ensure a mutually beneficial, transparent, respectful, and streamlined engagement, the policy outlines key roles and responsibilities, including the Patient Engagement Lead or specified lead point of contact at Pfizer for each Patient or Patient Advocacy Group.

Looking to THE FUTURE

How do you expect your company's RELATIONS with patient groups to change over the next five years (2024 to, say, the end of the decade)?

In 2023, approximately 618 million patients around the world were treated with Pfizer medicines and vaccines. Additionally, Pfizer received a record number of FDA approvals for new molecular entities; and we completed our acquisition of Seagen, a critical step in our ambition to end cancer as we know it. This newly combined expertise and resources hold great promise for our oncology organization. Over the next five years, we are excited about what we can do help the millions of patients worldwide living with cancer and other conditions. We aim to continue building innovative ways to listen and learn from patients and co-creating solutions that will help deliver breakthroughs to all patients, advocates and caregivers – everywhere.

Pfizer Inc.

Additionally, digital capabilities and AI are transforming healthcare, accelerating our ability to bring new breakthroughs to patients everywhere. For years, Pfizer has been harnessing Digital and AI across the entire company to drive innovation and productivity on a global scale. For example, supercomputing, AI, and virtual in silico screening accelerate our scientific research by reducing computational times by 80-90%, and our industry-first Digital Operations Center and AI-powered manufacturing processes are increasing throughput by 20%, enabling us to deliver more medicines to patients faster.

In 2023, we introduced our internal generative AI platform that accelerates our work and is estimated to have the potential to deliver $750 million to $1 billion in value in the near term. For example, AI is helping to create more customized content 75% faster, so patients and doctors receive the most relevant information when they need it. In manufacturing, Pfizer is identifying the optimal process parameters for manufacturing a given product (which we refer to as a “Golden Batch”), and then using AI to detect anomalies and recommend real-time actions to our operators – aiming to improve product yield by 10% and cycle time by 25%.

Looking ahead at the next five years, as we accelerate our battle against cancer with the acquisition of Seagen, we are applying Digital and AI across the entire oncology business, including identifying novel drug targets and accelerating clinical trials, manufacturing, and regulatory submissions to transform the future of cancer care. We hope to have a similar level of impact for cancer as we were able to achieve with COVID-19 because we know that for patients and their loved ones, time is life.

What is the name of your company?
Pfizer Inc. (Immunology and Inflammation Division).

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
- ➔ Global.
- ➔ Inflammatory bowel disease.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
14 at global level.

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?
- ➔ Funding (for example, grants or donations).
- ➔ Speaker engagements.
- ➔ Consultancy activities.
- ➔ Supporting patient-group campaigns.
- ➔ Co-creating projects.
- ➔ Helping organise events.
- ➔ Creating support tools for patients and carers.
- ➔ Supporting patient-groups' publicity.
- ➔ Involving patient groups in R&D.

Could you specify which are the most common of these relationships?
Co-creating projects.

During which of the following corporate activities does your company seek PATIENT/PATIENT-GROUP INPUT OR ADVICE?
- ➔ **Strategic input**: Regularly.
- ➔ **Finance**: Sometimes.
- ➔ **Human resources**: Sometimes.
- ➔ **Investor relations**: Sometimes.
- ➔ **Early-stage research**: Sometimes.
- ➔ **Late-stage research**: Regularly.
- ➔ **Manufacturing (including packaging)**: Regularly.
- ➔ **Pharmacovigilance**: Sometimes.
- ➔ **Supply chain and distribution**: Sometimes.
- ➔ **Marketing and sales**: Regularly.
- ➔ **Operations**: Sometimes.
- ➔ **Market access**: Regularly.
- ➔ **Regulatory affairs**: Regularly.
- ➔ **Medical affairs**: Regularly.
- ➔ **Public affairs/corporate communications**: Regularly.

Pfizer Inc. (Immunology and Inflammation Division)

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes?
(The projects can be at global, regional, or country level, or in specific therapy areas. If you wish, you may mention urls/online links, to provide further context to your reply.)

➔ **Global IBD Patient Council**

A group of patient/caregivers' leaders, represented by national, regional, global patient organizations, was set up at the start of clinical development of the molecule, all the way until communication)—ongoing.

➔ Improving patient experience and outcome through utility of IUS (intestinal ultrasound) in IBD (inflammatory bowel disease)—ongoing.

b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

In addition, we are coalescing external multi-stakeholders to surface solutions to support disease management.

On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

Through our global IBD Patient Council, we have co-defined clinical protocol, and communication to patients, to support recruitment, and are also communicating the publications from the studies in accessible and relatable language.

Pfizer Inc. (Immunology and Inflammation Division)

b.) What equivalent plans in partnering does your company have for early- and late-stage R&D during 2024?	Similar as before, and the intent is to engage with patients/community as early as possible in the drug development.

On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?	Using the EFPIA principles—and always with good intention.

Looking to THE FUTURE

How do you expect your company's RELATIONS with patient groups to change over the next five years (2024 to, say, the end of the decade)?	Specific for IBD—it has gone better, due to a dedicated function, leading the continued integration of the patient voice into the company's focus area.

What is the name of your company?
ViiV Healthcare.

Which views are you expressing in this questionnaire on your company's patient-related activities in 2023 (and forthcoming for 2024)?
Global.

Approximately how many patient groups (PAGs) did your company PARTNER with in 2023?
200+.

What MAIN TYPES OF RELATIONSHIPS did your company have with your patient-group partners in 2023?

- ➔ Funding (for example, grants or donations).
- ➔ Speaker engagements.
- ➔ Consultancy activities.
- ➔ Provision of information to patient groups.
- ➔ Supporting patient-group campaigns.
- ➔ Co-creating projects.
- ➔ Helping organise events.
- ➔ Creating support tools for patients and carers.
- ➔ Helping patient groups to network.
- ➔ Supporting patient-groups' publicity.
- ➔ Training and capacity building.
- ➔ Involving patient groups in R&D.

During which of the following corporate activities does your company seek PATIENT/PATIENT-GROUP INPUT OR ADVICE?

- ➔ **Strategic input**: Regularly.
- ➔ **Finance**: Usually not.
- ➔ **Human resources**: Usually not.
- ➔ **Investor relations**: Usually not.
- ➔ **Early-stage research**: Regularly.
- ➔ **Late-stage research**: Regularly.
- ➔ **Manufacturing (including packaging)**: Sometimes.
- ➔ **Pharmacovigilance**: Sometimes.
- ➔ **Supply chain and distribution**: Sometimes.
- ➔ **Marketing and sales**: Sometimes.
- ➔ **Operations**: Sometimes.
- ➔ **Market access**: Sometimes.
- ➔ **Regulatory affairs**: Sometimes.
- ➔ **Medical affairs**: Regularly.
- ➔ **Public affairs/corporate communications**: Regularly.

ViiV Healthcare

On CO-CREATION and PATIENT OUTCOMES

a.) Would you like to showcase any KEY PROJECTS during 2023 in which your company worked in partnership with patient groups—projects that have the aim of improving patient outcomes? (The projects can be at global, regional, or country level, or in specific therapy areas. If you wish, you may mention urls/online links, to provide further context to your reply.)

ViiV Healthcare is the only biopharmaceutical company 100% dedicated to researching and delivering innovative HIV prevent and treatment options. We seek to improve health outcomes and quality of life for people living with HIV, and those who could benefit from greater choice in HIV prevention. We also invest in research to address HIV remission and cure.

Throughout 2023, ViiV Healthcare collaborated with patient and community organisations and networks to improve our understanding of the evolving needs and challenges faced by a diverse population of people living with HIV, as well as people who could benefit from HIV prevention. We have delivered and supported numerous community-driven national and regional programmes, which broadly align to three areas of focus:

1. Improving health outcomes, and addressing health inequalities.
2. Improving health-related quality of life (HRQoL), and ending HIV-related stigma.
3. Enhancing community-led advocacy and public-policy engagement.

1. Improving health outcomes, and addressing health inequalities

At ViiV Healthcare, we recognise that resourcing public, private, and community-led initiatives to reduce health inequalities is essential to remove barriers hindering access to HIV prevention, treatment, and care.

Expanding access and choice to innovative HIV testing, prevention and care

In 2023, and renewed in 2024, ViiV funded the first and second LGBT community-led healthcare conference, which brought together Checkpoints (community-based HIV and STI testing centres across European cities), policy advocates, and LGBT health activists to establish best-practices in queer and trans healthcare. This partnership also led to the creation of a series of videos which highlighted issues in LGBT access to healthcare, to emphasize why community-led care is so important to enhance accessibility.

ViiV Healthcare

ViiV Healthcare and PENTA (Paediatric European Network for Treatment of AIDS) collaborated with groups of adolescents living with HIV across Argentina, South Africa, Thailand, Uganda, and the UK to deliver the Long Acting Injectables Advisory Group Project. The objective of this project was to gather comprehensive insights on long-acting injectable (LAI) HIV therapy for adolescents living with HIV. Workshops took place in the aforementioned countries, using a youth-participation approach. This included adolescents living with HIV being provided with access to data and technology (including interpreters when required) to ensure active participation. The workshops uncovered unmet needs and barriers to care. Participants also suggested solutions to overcome the challenges identified. Subsequently, national representatives from each country attended a global advisory-group meeting to discuss the people-centred solutions. This included highlighting the importance of meaningfully involving patients to shape healthcare decisions and strategies, to optimise health outcomes and healthcare experiences.

Partnerships and multi-year funding to support sustainability

In 2023, ViiV Healthcare, GSK, and the Global Fund announced a 3-year partnership and £6 million Gender Equality Fund. The Gender Equality Fund works alongside women, girls, and gender-diverse communities and their organisations to design, deliver, influence, and advocate for gender-transformative and gender-affirmative approaches to health. It will support community-based and community-led organisations working to deliver lasting changes that tackle gender inequalities in health policies and programmes, transform gender norms, and eliminate discrimination, to improve health outcomes, and integrate HIV, tuberculosis, malaria, sexual/reproductive health and rights-programming services. The Fund will benefit from matched funding from the Bill & Melinda Gates Foundation, and will contribute towards the Global Fund's mission more broadly.

The **HER Voice Fund** is dedicated to supporting adolescent girls and young women to have a meaningful voice in decisions that affect their lives, and is funded by ViiV and the Global Fund. Y+ Global, a youth-led organisation seeking to empower young people living with HIV globally, continued to implement the HER Voice Fund in 13 high HIV-burden sub-Saharan African countries in 2023. Furthermore, an additional £2 million in funding was announced for the Fund for 2024-2026.

ViiV Healthcare

The **Paediatric Breakthrough Partnership** is an international coalition of organisations committed to ending paediatric AIDS by 2025. This innovative partnership is driven by Aidsfonds, Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), United Nations Children's Fund (UNICEF), Paediatric-Adolescent Treatment Africa (PATA), and is supported through a strategic partnership, including multi-year grants provided by ViiV Healthcare. In 2023, given the impact of the intervention in Mozambique, Nigeria, and Uganda, the Paediatric Breakthrough partnership was extended into a second phase (2023-2026). The collaboration continues to harness the combined expertise of partners to support interventions which have increased access to testing, treatment, and retention in care for children and adolescents living with HIV more than standard of care. Informed by the UNICEF Paediatric Service Delivery Framework, the partnership seeks to maximise health impact by identifying and support family-centred and community-led health services seeking to end paediatric AIDS. Due to the impact in Phase I, the Partnership has also been expanded to include Cameroon and Tanzania. Cameroon and Tanzania were prioritised due to the high number of children aged 0-14 living with HIV, high vertical transmission rates, existing partner footprint and relationships in-country, and investment gaps in national funding.

2. Improving health-related quality of life (HRQoL), and ending HIV-related stigma

The evolution of HIV health technologies has significantly improved choice, as well as the quality and efficacy of HIV prevention and treatment options and seeks to prioritise what matters most to people and communities living with, and affected by, HIV.

HIV awareness and education campaigns

In 2023, we expanded ViiV's US Risk to Reasons initiative, designed to increase awareness and action to prioritise HIV prevention for Black women who could benefit from greater choice. Guided by the Black Women's Working Group and informed by 'From Risk to Reasons: A Guide to Communicating and Connecting with Black Women about HIV', this initiative works to create new messages and methods of communicating and connecting with Black women about HIV across the USA. The initiative supports 17 community-led organisations with more than $8 million USD in grant funds over 3 years, and capacity building support to engage women, train healthcare providers, and to change the narrative around HIV and sexual and reproductive health by connecting more women to prevention care. In 2023, the initiative launched the 'Activity Book' series, which includes a collection of interventions seeking to help women engage in conversations with their partners and healthcare providers around sexual health and intimacy as entry points for discussion about HIV prevention. More than 7,000 copies of the Activity Books have been distributed, and over 5,600 people participated in more than 89 Risk to Reasons events across the US. In 2024, Risk to Reasons will continue supporting community-led awareness by expanding its focus to fully engage healthcare professionals to meet the HIV prevention needs of diverse Black women.

ViiV Healthcare

In an innovative collaboration with the National Association of People with HIV Australia, ViiV Healthcare provided significant support, including a grant, for the **HIV Science as Art exhibition** at the International AIDS Society 2023 conference in Brisbane, Australia.[1] The exhibition was designed to stimulate conversations about living with HIV, and discuss recent scientific advancements through the eyes of 12 artists living with HIV. The project uses art as a medium to educate, inspire, and highlight contemporary issues around quality of life for people living with HIV, and to increase visibility and help to reduce stigma. The exhibition was free and open to the public, and was seen by over 3,000 visitors over two weeks. It was received positively by media, with 118 stories being published across Australian and international media outlets, generating over 165+ million opportunities to see messages relating to HIV and using art to translate key scientific advancements.

The **'Young Reporters'** project was a collaboration with PENTA and young people living with HIV, with the aim of making scientific knowledge from HIV conferences accessible through social media to children and teenagers living with HIV. Three adolescents living with HIV were recruited, and underwent online training on how to use social media to report and disseminate scientific information, and build health campaigns. These young reporters attended global conferences, interviewed researchers, and implemented their skills under the mentorship from a third-party communications specialist. The project successfully engaged over 25 million people through various social-media platforms during 2023.

ViiV Healthcare has leveraged the world of sport to combat misinformation and stigma about HIV. The **Tackle HIV campaign** is a public awareness and education initiative led by former rugby international Gareth Thomas CBE, in partnership with ViiV Healthcare, and with charity partner, the Terrence Higgins Trust (a UK HIV and sexual-health charity).[2] The campaign was established in 2020 to address HIV-related stigma through public-education campaigns, and by creating dialogue about HIV and normalising HIV testing. In 2023, Tackle HIV had a strong presence at the Rugby World Cup in France, with a dual-language campaign bus visiting rugby fan villages across the country. Working in partnership with World Rugby, the French government and city mayors, and AIDES (a major French patient-advocacy group), we hosted stakeholder events, and engaged with rugby fans and members of the public over the three-week major sports tournament. Following the success of the Tackle HIV bus in France, we travelled to Nottingham University, working with the Terrence Higgins Trust to engage and educate students on HIV.

ViiV Healthcare also sponsored the EuroGames and Bern Pride Festival in Switzerland in July 2023, a celebration of inclusivity, diversity, and unity.

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Using digital platforms to understand the impact of stigma on people's lives and healthcare experiences

ViiV Healthcare recognises the power of amplifying the voices, visibility, experiences, and agency of people living with HIV to eliminate stigma. Throughout 2023, we have partnered with people living with HIV and community-led organisations through several innovative digital initiatives, including the 'Chapters of Stigma' virtual-reality experience, 'Me in You, You in Me' HIV-prevention campaign, Positive Life Films Festival-Switzerland, and the 'HIV in View' photographic gallery [see below, for further details on these four initiatives].

ViiV Healthcare invested in developing the above-mentioned innovative virtual-reality (VR) experience entitled **'Chapters of Stigma'**. ViiV collaborated with individual patients and representatives of patient organisations to write stories that portrayed lived experiences of people living with HIV. Through vibrant scenes and emotionally-charged portrayals, this ground-breaking VR journey invites participants to step into the shoes of people living with HIV, and experience the daily struggles they face. The objective seeks to improve public understanding about the micro-traumas and societal pressures people living with HIV frequently endure. Showcased at the 12th International AIDS Society conference on HIV Science in Brisbane, Australia, at the Tackle HIV Rugby World Cup tour in France, and then also at EACS in Warsaw, Poland, and finally at ICASA in Harare, Zimbabwe, 'Chapters of Stigma' has had a significant emotional impact on viewers, and is a powerful tool which ignites conversations, dismantle barriers, and strives to create a more empathetic and supportive environment for those living with, or affected by, HIV. ViiV is committed to building on this success by evolving the narrative to encompass even more diverse populations, and to broaden use and awareness in communities across 2024.

In 2023, ViiV Healthcare expanded the above-mentioned US campaign **'Me in You, You in Me'**, which raises awareness of HIV prevention by promoting conversations (both online, and across communities). 'Me in You, You in Me' prioritises reaching Black and Latino men who have sex with men, Black women, and trans women. In 2023, the campaign reached more than 24 million people through social media, with more than 700 million impressions from organic media coverage. It mobilised more than 7,000 people to participate in local events, where they connected with vital community resources.

To end stigma in the general public, ViiV has supported two initiatives that share people's stories about the rich and rewarding lives of people living with HIV. The **Positive Life Festival** in Switzerland uses culture as a tool to make scientific research and lived experiences accessible to the general population, HIV communities, and clinicians. The Festival was developed by people living with HIV, and in December 2023, ViiV created a series of six short films for the event, which conveyed what it is like to live with HIV in Switzerland.

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Additionally, ViiV continued its collaboration with Shutterstock Studios on the **'HIV in View'** gallery, allowing people to access and use high-quality, royalty-free images of people living with HIV, to showcase their diversity. This approach aims to change outdated and inaccurate perceptions about the realities of living with HIV, and is the largest online photo library dedicated to this. The 'HIV in View' gallery was launched on World AIDS Day 2020, and in 2023, has been expanded to include images of people living with HIV in Canada, Germany, Kenya, Portugal, Russia, Taiwan, the UK, the US, and Uruguay.[3]

Prioritising Patient Reported Outcome Indicators

We welcomed the revised EACS guidelines in October 2023 that were updated to "recommend utilization of PROM [patient reported outcome measures] tools annually in every individual to facilitate the dialogue between care providers and the patient, improve patient and physicians' awareness of their own health, introduce patient-centred care, and to empower patients in this conversation".[4] We have continued our work on PROMs with a breadth of stakeholders, including patients, to evidence and report the benefit of PROMs in routine care, and develop solutions with clear implementation pathways to promote uptake.

In 2023, ViiV Healthcare continued to disseminate our multi-clinic North American implementation study **(The PROgress Study)** evidencing the value of PROs to support clinics seeking to adopt PRO practice in routine care. Community involvement in dissemination and collaboration included a plenary presentation and panel debate at the AIDS Impact Conference in Stockholm, entitled 'Living Well with HIV–Quality of Life for Communities Matters'. We recorded and disseminated a 'Science on the Sofa' video *"Seeing More Than HIV Through Patient Reported Outcomes (PROs)"*. This discussed the value of PROs in routine care with patients; and PROs were also showcased in a live 'Deliberate Discussions' panel debate with patients at the International AIDS Society conference in Brisbane. We also continued work with community groups in Australia to disseminate the implementation experiences of PRO uptake identified through our research. This includes a community co-authored manuscript that is currently still under review.

In 2023, ViiV Healthcare developed and initiated a **PRO digital solution (MyPRO)** to enable simpler adoption of PROs by clinics. This was designed and built with continuous patient involvement as part of the core steering group. By the end of 2023, a pilot study in Canada was established, to assess the implementation success.

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3. Enhancing community-led advocacy and public policy engagement

ViiV Healthcare understands that prioritising people-centred innovative prevention, treatment and care is critical to focus on what matters most for people and communities. We collaborate with community partners to advocate for policy change which creates a more enabling environment for people living with, and affected by, HIV. This includes prioritising health-related quality of life, protecting public health, addressing HIV-related stigma, reducing discrimination, as well as criminalisation, and advocating for continued investment in innovative prevention, treatment, care, and service delivery to end an infectious and chronic disease which remains a public-health threat.

In 2023, we developed a **joint advocacy partnership** with the International Association of Providers of AIDS Care (IAPAC), which led to the development of a multistakeholder letter addressed to the European Commission, asking for a new **HIV Action Plan** in the next EU Mandate following the 2024 European parliamentary elections. The letter was endorsed by prominent European HIV community and civil-society organisations representing some of the most-underserved populations (foe instance, sex workers, transgender individuals, and migrants). The European Commission responded in January 2024, encouraging civil society to pursue its HIV advocacy for further action at a European level, stating that: “People with HIV can today live long, healthy lives. We need to continue to join forces, as we strive to end HIV/AIDS in Europe and beyond.” ViiV aims to continue supporting civil society elevating its voice in the EU policy arena.

In March 2023, ViiV Healthcare also developed a **strategic partnership** with the **African Women’s HIV Prevention Accountability Board** seeking to advance progress in HIV-prevention innovation across the continent. The Accountability Board developed the HIV Prevention Choice Manifesto—a collection of voices from African women and girls across Southern and Eastern Africa who unite in their call for continued political and financial support for expanding choices in HIV prevention.[5] This manifesto underscores the unprecedented opportunity to build a choice-based prevention programme that offers people a range of options, with information in plain language about risks and benefits, as well as supportive counselling promoting choice that meets people’s needs. The HIV Prevention Choice Manifesto was developed for, and by, communities, centring around choice in HIV-prevention options, and differentiated prevention programming for women and girls as they navigate various stages of life. The manifesto focuses, invests, and prioritises adolescent girls and young women in Africa, and of African descent globally. Critically, the manifesto puts African women and girls at the forefront of prevention responses, including in research, and in access to products that are shown to be safe and effective. The manifesto was fully endorsed by UNAIDS and other external stakeholders, and launched with the support of the UNAIDS Executive Director in Uganda in September 2023.

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In 2023, ViiV Healthcare hosted its annual **US national advocacy roundtable** meeting with approximately 30 patient advocates from across the US, who sought to examine current Medicaid HIV healthcare provision for people and communities on low incomes. This focused on how to advocate for the Centers for Medicare and Medicaid Services (CMS) to contribute to the National US HIV/AIDS Strategy and Ending the HIV Epidemic Initiative, as well as make a compelling case for Medicaid to ensure long-term security for HIV treatment, care, and prevention.

Working closely with the civil society organisation GATE (Global Alliance for Trans Equality), and public health researchers, ViiV Healthcare provided a grant to the **International Working Group on Transmasculine People and HIV** in 2023. The working group developed policy tools to help governments, NGOs, and national HIV strategies include transgender men in their guidelines, alongside the development of a roadmap to enable a more coordinated response to support transmasculine health.[6] The best-practice guides developed have been recognised by UNAIDS and the World Health Organisation. In 2024, ViiV Healthcare will continue to support the transmasculine working group, to ensure adoption of the transmasculine best-practice guides by governments and decisionmakers.

In 2023, Uganda introduced the Anti-Homosexuality Act, which criminalises same-sex sexual relations (including an offence of 'aggravated' homosexuality that carries the death penalty). The Act has stoked a climate of fear and violence towards LGBTQIA+ communities across Uganda, and escalated issues of human rights impacting LGBTQIA+ communities globally. ViiV and GSK were invited to join the **Human Rights Awareness and Promotion Forum**, the Council for Global Equity, and Open for Business, to support legal proceedings to challenge this Act. These proceedings were brought by local activists and lawyers, to challenge the constitutionality of this discriminatory law, through the filing of an amicus brief. ViiV and GSK took the decision to lend their support, inspiring other private-sector companies to follow. ViiV and GSK prepared evidence to demonstrate that anti-LGBTQIA+ laws have a regressive impact on the fundamental human right to access healthcare, and will adversely impact public health, which ultimately only acts to increase HIV transmission, and compound the HIV epidemic. While ViiV and GSK's amicus brief was not ultimately accepted by the Court because it took the view that as a company that publicly supports LGBTQIA+ rights, ViiV Healthcare could not be impartial, similar evidence filed by UNAIDS was permitted. The decision of Uganda's Supreme Court is still awaited, but, in the meantime, ViiV has taken the public position to speak out against this law, which will set back the great work Uganda has undertaken in recent years to reduce HIV transmissions and AIDS-related deaths.

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b.) Would you like to mention any equivalent KEY PROJECTS that your company has planned for 2024?

Many of ViiV Healthcare's people-centred and community-focused engagements and partnerships in 2023 will continue to evolve across 2024.

Patient-centred research

At ViiV Healthcare, we work to meaningfully involve patients, and we are guided by patient insights to advance the development of our clinical studies which support medicines development. In addition, ViiV also focusses on patient-centred research as a way to understand the needs (as well as amplify the voice, visibility, and agency) of people living with, and affected by, HIV. Our **Positive Perspectives** studies exemplify this priority. These are some of the largest global, cross-sectional surveys of people living with HIV which are co-designed by community advocates, people living with HIV, healthcare providers, and industry representatives. A previous waves of the study, Positive Perspectives 2 (2020) surveyed 2,389 people across 25 countries, and contributed to the literature on unmet needs, improving retention and engagement in care, identifying critical gaps in communication between patients and healthcare providers, and understanding the need for increasing knowledge and awareness of U=U (undetectable equals untransmittable—which means that HIV cannot be passed on to sexual partners from individuals on effective treatment who are virally suppressed). ViiV is planning a third wave of research, to be conducted in 2024. **Positive Perspectives 3** will expand on previous research by broadening the population surveyed, to include adolescents with better representation of trans and gender-diverse people, and older populations. The survey's geographical coverage will expand in scope, to include 29 countries. The study has been co-created with community representatives, and aims to gather data on patient experiences, unmet needs, and future aspirations in relation to HIV treatment and care. The aspiration for data and insights from this research is to inform development of initiatives to improve HIV care.

Expanding access and choice to innovative HIV prevention options

Expanding access to health technologies for prevention, including for pre-exposure prophylaxis (PrEP), could significantly contribute to reducing HIV transmission by providing people with greater choice in prevention options. 2023 enabled the consolidation of progress following the 2022 signing of a voluntary licencing agreement which allows selected manufacturers to develop, manufacture, and supply generic versions of ViiV's PrEP option. This agreement between ViiV Healthcare and the Medicines Patent Pool (MPP—a global health agency) aims to enable access to ViiV's PrEP option in least-developed, low-income, lower-middle-income, and sub-Saharan African countries.[1, 2] In 2023, the Medicines Patent Pool signed sublicensing agreements with three generics manufacturers, which will enable 90 countries to access this generic PrEP option, subject to required regulatory approvals.

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Enhancing community-led advocacy in public policy engagement

As a company 100% focused on HIV, ViiV Healthcare prioritises elevating the voice, visibility, and agency of people and communities, to focus on what matter most with respect to health outcomes and healthcare experiences. In 2024, this focus will foster more integrated joint-advocacy efforts to identify partnership opportunities, and drive platforms for discussion. This includes planned collaboration with European Parliamentarians and public-health and policy stakeholders. Together, we seek to advocate that the new European Parliament issues a refreshed EU mandate to develop an EU Action Plan to ensure that it delivers on its commitment to end AIDS as a public-health threat by 2030.

In Spain, a **national policy initiative** was established to focus on national and regional implementation of innovative and people-centred models, to optimise long-term care for chronic diseases. This project will continue to evolve in 2024 with the aim of ensuring government investment in innovation, health-related quality of life, and promote PROs, to better understand unmet needs and optimise care.

HIV Awareness and public-education campaigns

As a key focus for 2024, we will work collaboratively with community-led organisations, as well as with patient-advocacy groups, to improve health literacy for people living with HIV and those who could benefit from PrEP. We aim to support, inform, and enable people and communities to more proactively engage in their own care, and advocate for what matters most for their health outcomes and healthcare experiences. Our public-disease awareness and education campaigns will also continue to focus on addressing HIV-related stigma, discrimination, and criminalisation. Following the success of 2023, the **Tackle HIV campaign**[3] will continue to evolve throughout 2024 with an expansion of an educational bus tour of universities and colleges across the UK. This outreach aims to educate students about HIV, and promote HIV testing among young people.

In Japan, ViiV Healthcare is planning to develop **seminars** and web content in 2024 to improve health literacy, and encourage patients to become proactively involved in their HIV care, to improve treatment outcomes. In Spain, the **'#YoNoMeOlvido'** HIV-related stigma and discrimination awareness campaign will continue in 2024, collaborating with Cesida España (Coordinadora estatal de VIH y sida/State Coordinator for HIV and AIDS). In the US, **community advisory boards** have been planned, to seek advice to identify the gaps in education and health information, to ensure tailored people-centred resources are co-created to reach diverse communities.

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On DRUG DEVELOPMENT

Today, healthcare regulators, policymakers, payors, and providers are increasingly asking for evidence of PATIENT INVOLVEMENT AND FEEDBACK in drug development.

a.) In 2023, how did your company accommodate these new demands when partnering with patient groups in both early- and late-stage R&D?
(Again, the activities can be for a global, regional, or country level, or for specific therapy areas.)

ViiV Healthcare has long-standing relationships with patient organisations, and has engaged people and communities in drug development. We use these patient insights to inform the development of our innovative **options to prevent and treat HIV, to deliver quality and people-centred care**.

In 2023, ViiV built on its strong track record of engaging patients in drug development by evolving its **Patient Engagement strategy** and vision to elevate our commitment to improve the health and quality of life of people living with HIV, and those who could benefit from PrEP by even-more meaningfully engaging people and communities. To translate this strategy evolution into action, we sought to systematize the process by which patients are engaged, and insights are used, to inform and shape the lifecycle of drug development. This offers a significant opportunity to embed a people-centred focus in innovation—from drug discovery, to clinical development, and after medicines are launched. The objective of establishing a formal, enterprise-wide patient-engagement framework is to equip teams with the necessary guidance, tools, and resources to engage with patients, and embed patient insights to support their decision making. Our implementation focuses on ensuring that the organisation has the capabilities to independently engage, and effectively use, the patient insights shared. 2024 will focus on implementation and rollout of this patient-centred framework across the organisation.

ViiV's drug-development trials are designed and overseen by **ViiV physicians** in the R&D team—all of whom are infectious-disease specialists who have trained, practised, conducted research, and taught in academic clinical settings. Upon joining ViiV Healthcare, many retained their clinical responsibilities as volunteers in a variety of settings, including outpatient HIV clinics, and inpatient infectious-disease consultation services. By volunteering in the community across a wide range of geographies, the R&D physicians can integrate real clinical experience and insights into their research and clinical-trial designs, which ensures that expertise remains relevant and current, to address diverse needs in patient care.

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Requirements from diverse stakeholder including regulators, policy makers, healthcare practitioners, and communities for diverse and representative clinical-trial data, has led to the formation of ViiV Healthcare's **Clinical Trials Diversity Task Force**, established in 2020. This aims to optimize the demographic diversity of our clinical-trial participants (including with regard to age, sex, race, ethnicity, and gender identity). Understanding how any individual drug works in these diverse populations is important, as data and evidence increases our knowledge about the impact of our medicines, and heightens the confidence of diverse populations in the safety and efficacy of the medicines. Initially, the Task Force identified barriers towards diversity in clinical trials, and then developed detailed tactics for individual drug-development programs, and study teams, to use to address these barriers, as they design and conduct clinical trials. Insights from, and collaborations with, patient groups have helped to inform these tactics to achieve diversity targets. Critically, optimizing diversity in clinical trials is not a one-off process, and we continue to focus on education, broad study design, recruitment planning, community collaboration, and continuous communication.

For many years, women who are (or wished to become) pregnant were specifically excluded from participation in clinical trials. As a result, when a drug was approved for broad global use, no safety or efficacy data during pregnancy were available, and many years would pass before sponsors provided the critical data needed to make innovations in medicines available to this underserved population. Based on advocacy from patient groups, and this key data gap, we explored the possibility of opening clinical trials to women who are, or who may become, pregnant—collecting data, and encouraging investigators to retain women in clinical trials if they became pregnant. In 2022, we adopted a new **internal policy to accelerate the availability of data in pregnancy**, with this work continuing into 2023. All ViiV Healthcare early-development programs now require a pregnancy data-acceleration plan, to conduct the required preclinical and early-clinical testing, to perform pharmacokinetic (PK) modelling, and early PK testing in women, as well as to gradually expand clinical-trial access to women, prior to drug approval. As such, we are enabling early data generation in these underserved populations, protecting pregnant women through research—rather than protecting them from research.

In 2023, we delivered the 27th edition of our annual Spanish **National NGOs Training meeting**, working with key opinion leaders, and patient-advisory groups, to discuss the unfair exclusion of people living with HIV from non-HIV clinical trials. Advisors also took part in our PrEP steering committee, advisory boards, and were involved in the review of patient-information leaflets and informed-consent forms for Phase-II and -III clinical trials.

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b.) What equivalent plans in partnering does your company have for early- and late-stage R&D during 2024?

ViiV Healthcare recognises the need to address the disparities, inequalities, and vulnerabilities driving the epidemic. Mitigating these inequality drivers with responsive health innovations could include shaping the next generation of HIV prevention and treatment options, informed by those for whom these interventions matter most.

Throughout 2024, we will continue engagements and partnerships, and build new relationships, to ensure that we are informed about, and able to address, patient needs. In 2024, ViiV Healthcare is collaborating with individuals and patient groups, to establish a new Global Patient Panel to inform its approach to values-based and people-centred innovative care critical to treat and prevent HIV. Our shared approach with common purpose seeks to meaningfully focus on the health outcomes, and healthcare experiences, of patients, as well as engage understudied populations in clinical research. Working collaboratively, the partnership will develop insights, advice, information, and recommendations focused on issues which include drug discovery, research and development—driving change to transform care quality, as well as identify how best to eliminate HIV-related stigma (among other priorities). An emphasis will be placed on integrating regular input and collaboration throughout the entire product lifecycle—including in early- and late-stage drug development.

Supporting implementation research, to target access to underserved people and communities, will also be critical. This approach includes recognising the knowledge and expertise found in innovative, integrated, community-led care delivery. In addition, HIV remission and cure remains a priority for ViiV Healthcare, and our focus on people and communities will be critical to evolve this area of research.

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On FORMING patient-group partnerships

Could you describe the PROCESSES your company typically undertakes when forming partnerships with patient groups—processes to ensure that the relationship is mutually beneficial, trustworthy, and flexible?

Trust, collaborative planning, open communication, and continual feedback loops lie at the heart of our partnerships with patient groups, helping to foster mutually-beneficial relationships focused on improving patient outcomes. Patient groups are often key stakeholders, involved from project conception to completion, with ViiV Healthcare following the GIPA/MIPA (Greater and Meaningful Involvement of People Living with, or Affected by, HIV/AIDS) principle of "nothing about us, without us".[1]

Typically, new partnerships are formed, having reached out to, been referred to, or connected with patient groups that support, or advocate for, people living with HIV, and patient groups with a focus on HIV testing/prevention. Initial contact can involve informal discussion with a representative of the organisation, to understand their vision, mission, and objectives, to ensure alignment on common goals. This allows for the identification of potential areas for collaborative work. Further discussion allows for more-detailed planning of the parameters of collaboration. A defined, co-developed, and mutually-agreed framework allows for clear expectations of the terms and objectives for collaboration to be agreed on both sides. Transparency of intentions, resources, and limitations builds trust. While collaborations on specific projects may be short term, ViiV aims to build long-lasting relationships over the long term, through continuous open lines of communication and feedback, combined with strategic shared goals based on an understanding that improving health outcomes require enduring partnerships from all stakeholders across the healthcare ecosystem.

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Looking to THE FUTURE

How do you expect your company's RELATIONS with patient groups to change over the next five years (2024 to, say, the end of the decade)?

ViiV Healthcare will deepen relationships with patient groups, focusing on engaging patient organisations in even more collaborative initiatives that prioritise patient-centred outcomes, engagement, and empowerment in every aspect of our operations and decision-making processes. We will work with the community groups and individuals, to ensure that medicines development at ViiV Healthcare remains informed, diverse, and inclusive. Beyond medicines development, we will continue to engage with communities, and amplify patients' voices, in our work with other stakeholders in the healthcare ecosystem, to drive advancements in treatment and person-centric and community-led care.

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As the 2030 UN Sustainable Development target approaches, it will remain critical to focus our people-centred health innovation, and ambitious multi-sector partnerships, on what matters most to people and communities affected by HIV. We acknowledge that the global public-health threat has yet to be successfully addressed. Therefore, maintaining HIV as a public-policy priority will require more ambitious joint mobilisation and advocacy, to ensure that political responsibility and accountability (in terms of targeted investment, and a focusing on people and communities) is prioritised.

Shared public policy and advocacy mobilisation will also continue to intensify regarding eliminating HIV-related marginalisation, stigma, discrimination, and criminalisation. This is fuelled by a growing, and well-funded, anti-gender and anti-rights movements. Solidarity with people disproportionately impacted by these movements (including people of racial and ethnic diversity, LGBTQIA+ communities, as well as women and girls, among others) is becoming a growing imperative. ViiV Healthcare regards this engagement as essential to address growing threats which undermine public health and health equity, and could reverse progress made in the global HIV response.

ViiV Healthcare also recognises that, for the people and communities we serve, health-related quality of life, health outcomes, healthcare experiences, and public health more broadly will be impacted by several factors—including enablers, such as digital technology, and artificial intelligence (AI). The potential for AI to transform patient care in HIV is rising. This includes innovations, such as machine learning, natural-language processing, and other algorithms. AI's impact on the HIV response, and our relationship with patient groups, could include the role it plays in:

- supporting drug discovery, development, and implementation;
- how health data is analysed;
- improving clinical-trial participation;
- helping to ease administrative and communication tasks for healthcare providers; and
- increasing transparency in healthcare (among other functions).

However, important questions to explore include how these new enablers can ensure that health systems do not compound existing disparities—and how policymakers, legislators, and regulators can best manage risks and opportunities ushered in by AI.

PATIENT VIEW