Bringing the Patient Voice to Clinical Development an Industry Sponsor Perspective

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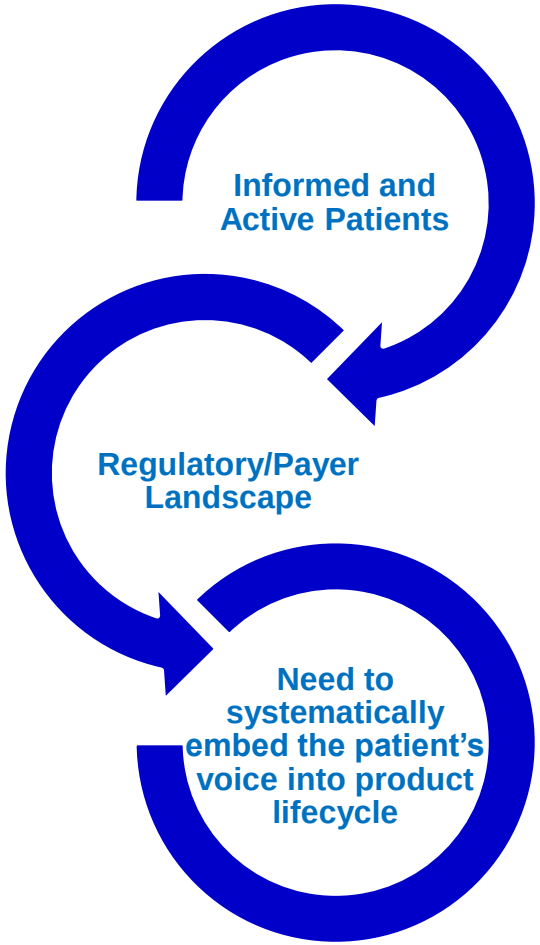
The Importance of Partnership

Patients are influencing the Regulatory and Payer landscape

- FDA, EMA, MHRA are establishing expectations for integrating patient centricity into the development process
- Marketing approvals are at risk if we don't integrate the patient's insights Regulators are considering
- Patients are advising payers about which PROs are most important to them and should be included in their assessments
- Payer decisions are at risk if we don't integrate the patient's insights Payers are considering
- Patients are advocating for public policies (pricing, reimbursement and drug supply issues) to ensure access and we need to be part of the conversation



Patients are more informed and active than ever before

- Savvy Consumers who are impatient and aren't waiting for us to invite them
- "Nothing about us without us"…Activism not limited to Rare Diseases and Oncology
- See themselves as "payers" who should have a say in development of medicines and policies

Need to systematically embed the patient's voice in our products' lifecycle to maximize the value of our products and limit asset attrition

- Satisfy changing Regulatory, Payer and Patient requirements
- Reduce protocol amendments and improve protocol feasibility
- Increase Clinical trial enrollment and retention
- Improve adherence
- Design product enhancements

Patient Insights Across the Clinical Research Continuum

CLINICAL TRIALS TRANSFORMATION INITIATIVE

PLOS ONE

Published: October 14, 2015

Patient Engagement Practices in Clinical Research among Patient Groups, Industry, and Academia in the United States: A Survey

Sophia K. Smith[1]*, Wendy Selig[2], Matthew Harker[3], Jamie N. Roberts[3], Sharon Hesterlee[4], David Leventhal[5], Richard Klein[6], Bray Patrick-Lake[3], Amy P. Abernethy[7]

- Financial support for research
- Natural history data
- Input on relevance of research to patients
- Access to translational tools
- Help defining eligibility criteria
- Input on meaningful endpoints & PROs
- Advocacy for policy & funding issues†
- Education to patient community†

- Support to sponsors around key regulatory meetings
- Support preparing submissions for newborn screening for rare diseases Informing regulators on benefit-risk†
- Public testimony at regulatory meetings†

Discovery & Preclinical‡ → **Phase 1–3** → **Regulatory Review** → **Postapproval**

- Benefit-risk & patient-preference studies
- Protocol design & study feasibility input
- Study recruitment & retention strategy input
- Increased awareness about trials
- Participant feedback on trial experience
- Input on informed consent content & processes
- Peer advocates for participants†
- Clinical trial networks†
- Data and Safety Monitoring Board members†

Phase 1-3 activities and…

- Support interpreting & disseminating study results
- Collaboration on post-marketing studies & surveillance initiatives
- Support developing access strategy & preparing for value or health technology review

Pfizer

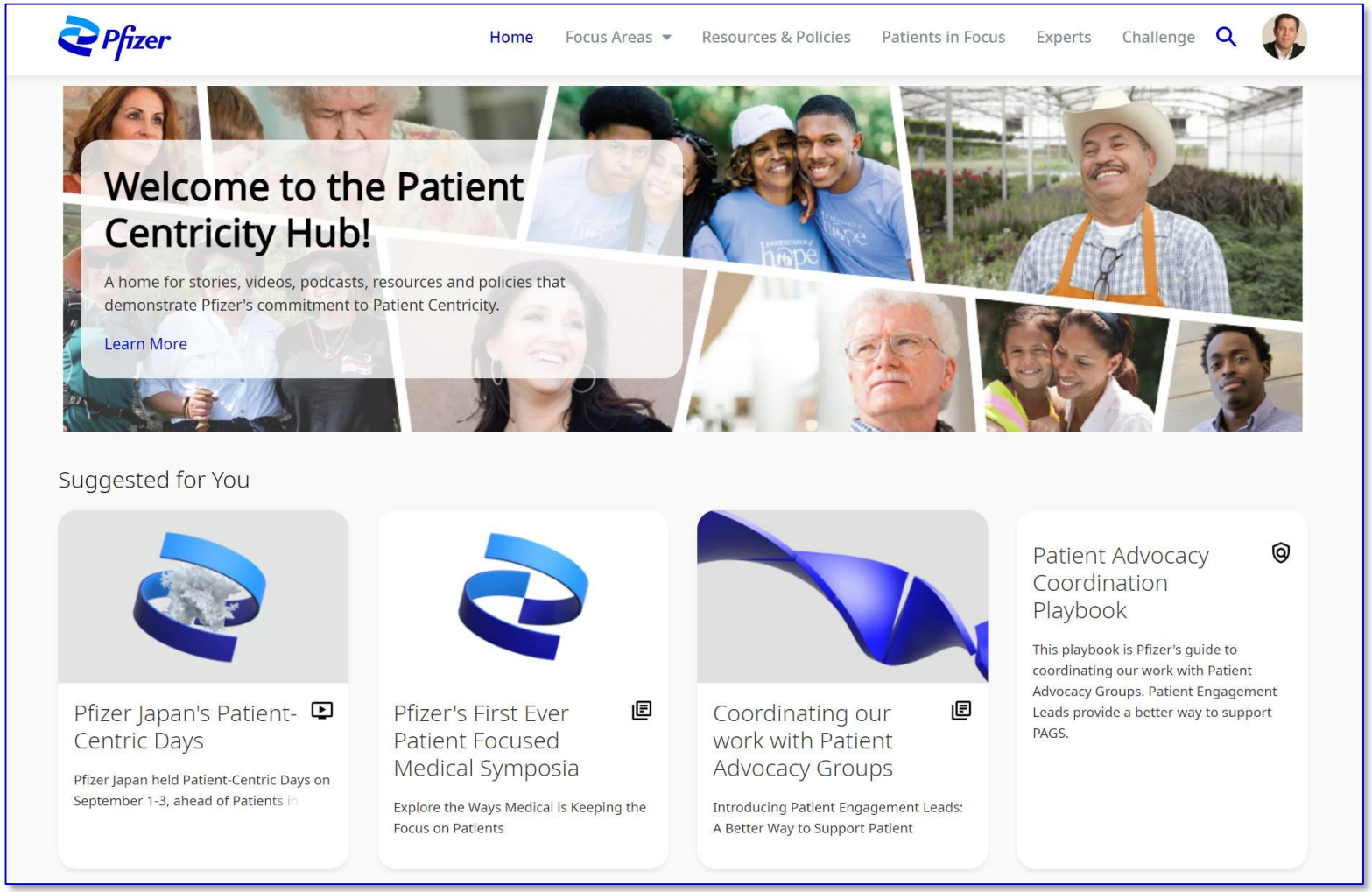
https://ctti-clinicaltrials.org/our-work/patient-engagement/patients-groups-clinical-trials/

Operationalizing Patient/Advocacy Partnering at Pfizer

- **What Goals Did We Set?**
  - Communicate Existing Resources for Global Product Development (GPD) Teams
    - Key colleagues, tools & platforms
  - Build New Capabilities and Legal Framework to Enable Easier Engagement
  - Demonstrate Impact of Patient Engagement/Advocacy
    - Pilot tools & methodology in 2-3 clinical programs with required GPD patient engagement to measure study impact
  - Identify Gaps & Make Recommendations for the Best-in-Class Capability to Engage Patients in Development

- **What was the Result?**
    - Teams know when & how to engage patients in development
    - GPD colleagues lead teams in consistently engaging patients [codified]
    - Teams know how to incorporate feedback to realize value
    - Fewer protocol revisions, improved recruitment, retention and compliance
    - Improved patient experience

Pfizer Patient Centricity Hub: Making Patient Insights Accessible



- **The Patient Centricity Hub enables study teams to engage patients to demonstrate impact. Includes capabilities to help Identify existing resources available for Pfizer study teams**

- **We've deployed these tools for study teams to make partnerships easy and patient insights accessible**

In Pfizer Global Product Development, all clinical teams consider key, patient centric questions as they develop new protocols

- **Have you discussed protocol with patients and/or their representatives? Does protocol have relevant patient-centric viewpoints?**

- **How do the complexity and timing of treatments or clinical assessments, or duration of participation, affect the patient?**

Industry Collaboration – TransCelerate Patient Experience Team

Patient Experience

Helping design clinical trials which are fit for patients. The Patient Experience Initiative develops tools to provide more effective ways to engage with patients in the design and execution of clinical studies.

Project Life Cycle Phase:

Last Update: March 2021

Benefits:

- Increased engagement for patients through better communication and feedback processes
- Increased patient understanding of the value in participating in clinical trials
- Expected decrease in the patient burden of participating in clinical trials and anticipated improvement in patient experience
- Potential improvement in patient recruitment and retention
- Potential improvement in adherence (e.g., less protocol deviations) within clinical trials and less need for protocol amendments since the study was designed "right" the first time
- Potential increase in efficiencies, including possible reduction in long term costs and time, through more effective and upfront patient engagement

Solutions:

***Patient Protocol Engagement Toolkit (2019):** Infographic that details purpose of toolkits. The Patient Protocol Engagement Toolkit (P-PET) is a comprehensive set of materials that sponsors and other stakeholders can use to engage patients during protocol development. The goal of the P-PET to improve patient experience and reduce patient burden as a study participant

***Study Feedback Participant Questionnaire Toolkit (2019):** The Study Participant Feedback Questionnaire (SPFQ) is a survey provided to study participants at the beginning, middle and end of a clinical study. Use of the SPFQ is intended to improve the patient experience in current and future clinical studies and programs

***Amplifying the Voice of the Patient in Clinical Research* Paper (2020):** This paper provides insight into the P-PET and SPFQ toolkits, patient and site feedback, and sponsor-simulated pilots that led to the launch of the two toolkits.

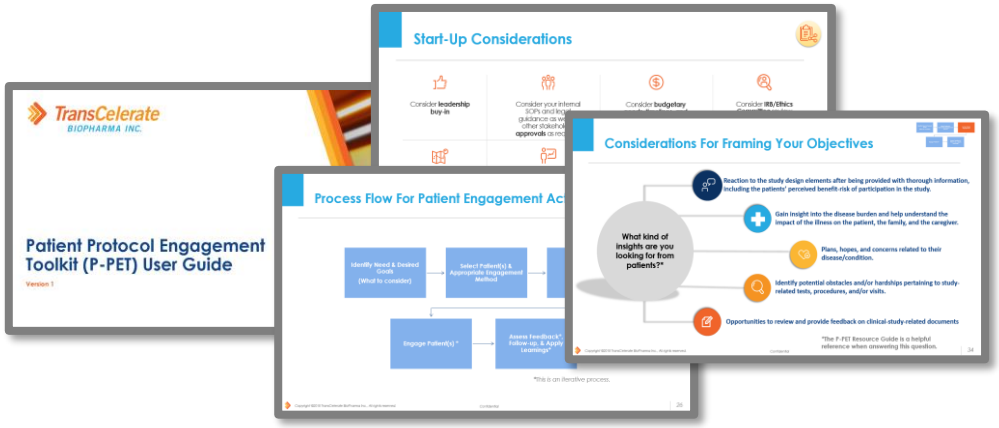
***Content Validity & Cross-Cultural Validity of the SPFQ* Paper (2020):** This manuscript describes the qualitative interviews that were conducted with 80 clinical study participants.

SPFQ Translations (2021): Translations of the SPFQ in 15+ languages.

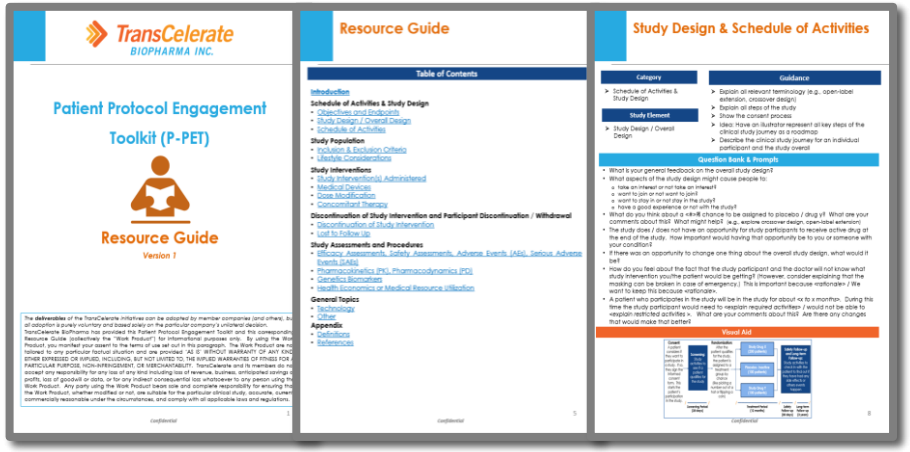
*Solutions with an asterisk are receiving updates for re-release in 2021
**Please refer to the Patient Experience Assets page for a compete repository of key resources and tools

Patient Protocol Engagement Toolkit (P-PET)

➢ User Guide



➢ Resource Guide



➢ Templates

View & download toolkit at: Transceleratebiopharmainc.com/patientexperience/

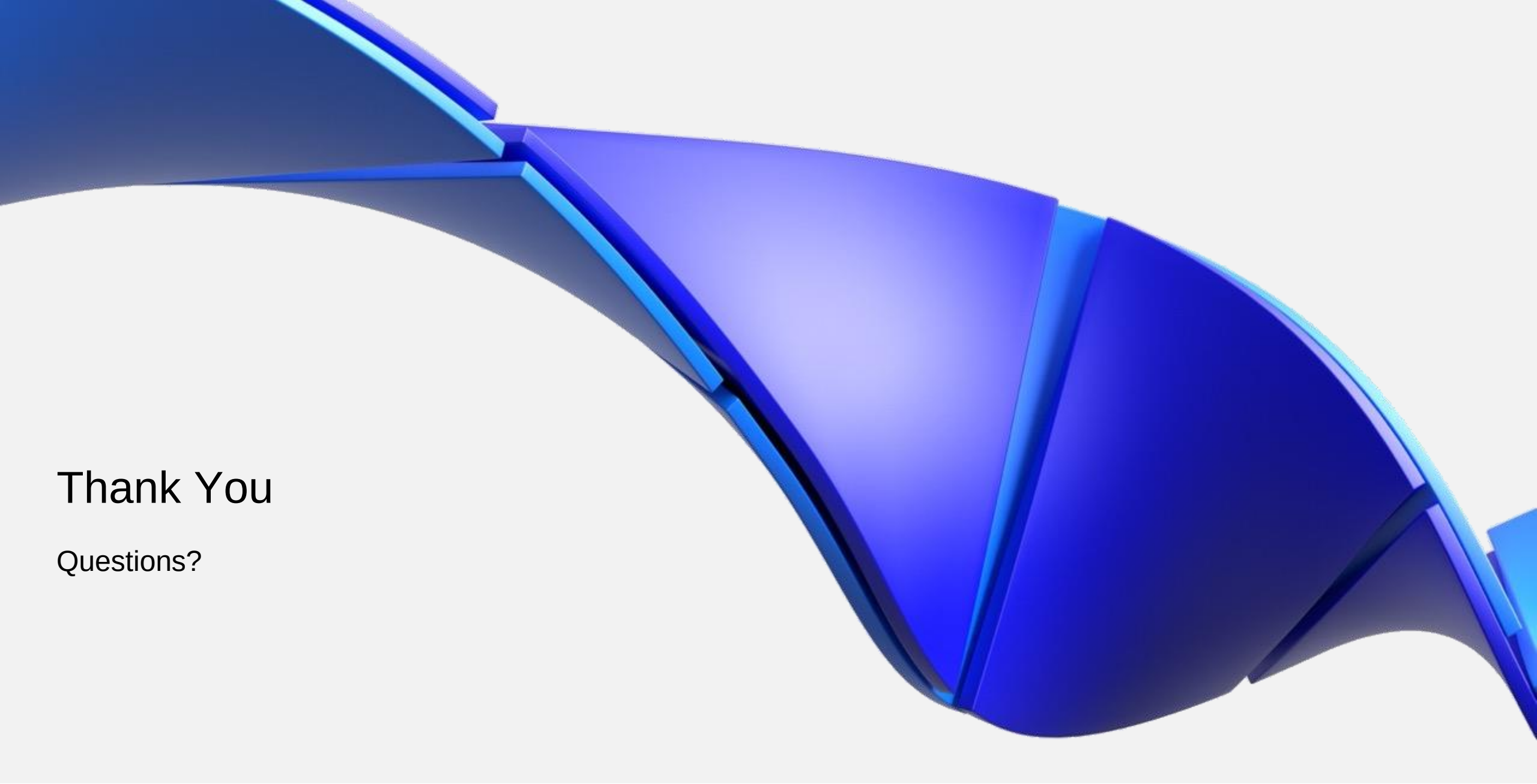
Pfizer's Commitment to Patient Engagement has never been stronger

COVID-19 must catalyse changes to clinical development

Rod MacKenzie✉, Peter Honig, Judy Sewards, Robert Goodwin and Marie-Pierre Hellio

NATURE REVIEWS | DRUG DISCOVERY

1. We commit that the **participants in our clinical trials will reflect the racial demographics** of the countries and communities in which we conduct our studies
2. We commit to **expand awareness and access to our clinical trials** and to improve the experience of our participants
3. We commit **to share our knowledge** more broadly
4. We commit to fully **embrace digital tools for speed and quality**



Thank You

Questions?