Development Cycle-Time Metrics (We’re Pretty Good at This)

**Study level**
- Protocol Synopsis developed
- Protocol approved internally
- Planned first patient enrolled
- First patient enrolled
- Last patient enrolled
- Planned last patient enrolled
- First dose to first patient
- Last patient last visit
- Database lock
- Key statistical analysis
- Final integrated report

**Country level**
- Core package from head office
- First ever Submission to local Authority
- Clinical Trial Application submitted
- All local approvals secured
- Clinical Trial Application approved
- First patient enrolled
- Last patient enrolled

**Site level**
- Site Ethics committee or IRB submission
- Site Ethics committee or IRB approval
- Site initiation
- First patient enrolled
- Last patient enrolled
- First dose to first patient
- Last patient last visit

**Metrics**
Planned milestones
Actual milestones
Current State:

- There is no universally accepted standard for “how” and “when” patient involvement should take place in medicine development and life cycle management. Current patient involvement is inconsistent and organizationally fragmented.

Patient Engagement Strategic Intent

- By driving patient-centricity at Pfizer, we will systematically integrate the patient’s voice across the medicine development lifecycle. In doing so, our medicines will deliver more relevant and impactful patient outcomes by addressing unmet patient needs. As a result, medicine development will be faster, more efficient, and more productive.
Clinical Innovation Patient Engagement Framework

Pre-study Planning & Recruitment
- Pfizer.com TrialFinder
- Study Pages
- Patient to Trial API
- PfizerLink PRO Data
- Patient Recruitment KM Wiki
- Referral+
- ePharmasolutions
- ePatient Finder
- & Stimulating Referrals
- Pharmacy Outreach
- Live Protocol Simulations
- Patient Insights - PGCT

Conduct
- BYOD ePRO
- Drug intake diary
- Sensor
- eConsent
- Education materials (trial, drug, disease, etc.)
- Scheduler, reminders and alerts (basic)
- Participant dashboard
- eVisit/video conferencing & Home visits
- EHR integration eSource

Post Trial
- PfizerLink
- BlueButton
- Patient Lay Summaries

Patient Engagement Playbook / Toolkit / Policy Dependencies
The primary objective of the **Rare Disease Patient Engagement Best Practices Survey** was to support the Rare Disease Patient Engagement Working Group in setting a agenda for a workshop. The workshop planned to discuss challenges and opportunities in patient engagement and communications for Pfizer Rare Disease. The feedback from representatives was sought on the following issues:

- **Challenges** representatives experience in trying to **execute** on patient engagement activities?
- **Policies** that representatives feel that **need to be changed** in order to better engage with rare disease patient communities?
- **Engagement opportunities** are **important** for the representatives but are currently **not easy to do at Pfizer**?
- **Background materials** do the representatives need before the workshop?

To gain insight into the key questions of the study, an online survey was fielded to **62 stakeholders**:

- The response rate was ~38%

- For **closed-end** questions in the survey, the **frequency analysis** was conducted and presented in the form of **stack charts**

- For **open-end** questions, the **responses** of colleagues were **analyzed** and **categorized** into common **themes**
Patient Group Engagement: Not Easy to Do (or Measure) at Pfizer

Potential Opportunities

- Involving Patients / Advocates in the Clinical Development Process
- Providing Adequate Resource Allocation to have a Deeper and Wider Coverage
- Finding New Avenues for Deeper Engagement with Patient / Advocacy Groups
- Engaging Patients and Advocacy Groups to Share their Experience
- Developing Relationship with Patients and Advocacy Groups by Engaging them through Seminars / Meetings
- Allowing Sharing of Information with Patient Advocacy Groups
- Ensuring Senior Management Trusts Subordinates and Understands the Importance of Patient / Advocate Engagement

Perceived Challenges

Source: Provide examples of patient/advocate engagement opportunities/activities you believe are important, but are currently not easy to do at Pfizer
Best Practices to Strive For

- Including Patient Voice / Representative in Development and Planning
- Engaging through a Single Point of Contact
- Having a Patient Advocacy Resource For Improved and Transparent Coordination within Teams
- Employing Holistic Communication to Show Pfizer’s Commitment to People
- Ensuring Meaningful Engagement / Discussion with Patients / Advocacy Groups
- Leveraging Engagements with Advocates for Right Diagnosis and Treatment of Patients

Source: As it relates to patient/advocate engagement, what is a Pfizer “Best Practice” you would like to strive for?
Policy / Practices that Need to be Modernized

Modernization of Policy / Practices

- Communication Policies, especially Confidentiality on the Pipeline / Asset in Development
- Policies That Inhibit Interaction with Patients and Community at Personal Level
- SOP / Policies Related to Interactions with Patients / Advocacy Groups
- Legal Operating Practice Related to Interaction with Patient Advocates / Patient Engagement
- Financial Resource Allocation

Source: What Pfizer policy/practices need to be changed/improved/re-evaluated in order to better engage with rare disease patient communities/advocacy groups?
Patient Group Engagement: Establishing New Measurements

Key Challenges
- Inadequate funding and other funding related issues
- Unclear guidelines on patient engagement activities
- No / Low involvement of patients in clinical development process
- Legal constraints
- Lack of clarity on the ownership of patients engagement programs

Opportunities That are Not Easy to Do at Pfizer
- Allocating adequate resources to increase coverage of patient engagement activities
- Involving patients in clinical development process
- Identifying new channels for patient engagement, and developing relationship with patients
- Allowing colleagues to share appropriate information with patient groups

Policy / Practices That Need to be Changed
- Confidentiality policy related to product pipeline
- Policies that inhibit interaction with patients / advocacy groups
  - Legal operating practice
  - Regulatory and compliance policies

Best Practices
- Including patient voice / representative in development and planning
- Use single point of contact to engage patients
- Communicate Pfizer’s commitment to patients
- Ensure meaningful dialogue with patient and advocacy groups
  - Leverage discussions to arrive at right diagnosis and treatment for patient

We are Building a New Framework for Measuring our Effectiveness