

# Patient Voice Patient-Focused Drug Development - Update

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8 April 2021

# Patient Voice / Patient-Focused Drug Development

## Background on the focus of this group – summary

Multiple stakeholders around the world, including medicine developers, regulators, Health Technology Assessment bodies (HTA), are increasingly engaging with the patient community to:

- Understand the experiences and unmet needs in specific disease areas
- Aid in decision making so that medicines are more closely meeting patient needs and expectations
- Create more patient-focused clinical trials and research

This group of patient advocates explores the value and purpose of ‘patient voice’ in the development of medicines and the gaps that need to be bridged to increase the opportunities of a diverse range of patient advocates and patient experts inputting into medicine development programs

# The Patient Voice in Drug Development

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## Defining the patient voice

The group began by defining the attributes of the 'patient voice' that makes it unique:

### Attributes of the 'Patient Voice'

- Expresses, qualifies and quantifies the experiences and expectations of patients
- Is unique amongst stakeholders – *only patients have these insights*
- Is both backward and forward looking
  - Capturing experiences (backward looking)
  - Capturing expectations (forward looking)
- Contains **advice and clear recommendations** on how to meet the needs and expectations of patients
- **Should be diverse**, capturing the insights from a wide spectrum of affected patients

Ensures the needs and expectations of patients are understood by others

# Patient Voice / Patient-Focused Drug Development

Who is the 'patient voice' directed to?

**Who should listen  
to the patient  
voice?**

- Academic researchers
- Industry / drug developers
- Regulators
- HTAs
- Healthcare systems
- Caregivers
- Doctors
- Program managers
- Healthcare providers
- Authorities + companies

**And many more  
stakeholders**

Everyone that is making decisions that affect patients should be listening  
**and acting on** the patient voice

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## Challenges in providing the 'patient voice' in drug development

The group highlighted four key areas where improvements are needed



### Opportunity to input:

Ensuring a wider and more open process for input into drug development programs and activities



### Diversity of inputs:

Creating processes that recognise and include inputs from a diverse range of patients, not the privileged few



### Collaboration:

Ensuring that engagements are not a validation step too late in the process to have an impact, but true collaboration



### Clarity of purpose:

Stakeholders need to be clear on the purpose of engagements and need to provide feedback on the results

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'Opportunities to input' highlighted as a priority need

Key questions emerged from the discussions



## Opportunity to input:

Ensuring a wider and more open process for input into drug development programs and activities

**Building open and  
diverse channels  
for the patient  
voice**

- How can we make the channels more open and diverse?
  - What methods exist already?
- How can we promote the opportunities more widely and to a diverse audience?
  - How are these opportunities currently promoted?
- How do we build trust in patients who have been ignored and have lost trust with the system and the healthcare stakeholders?

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Ensuring impact by having a clear purpose and feedback to those who contributed

Key questions emerged from the discussions



## Clarity of purpose:

Stakeholders need to be clear on the purpose of engagements and need to provide feedback on the results

The principles of engagement that lead to a clear impact

- How is the patient voice listened to and acted upon?
  - What are the principles of good involvement practices?
- How are impacts and actions fed back to those who contributed?
  - So that we can all learn what works well and what needs improvement
- What can we learn from other stakeholder groups?
  - Regulators and HTA bodies – how do they include the patient voice?

# Patient Voice / Patient-Focused Drug Development

## Approaches emerging from the working group

Ideas to improve the openness and diversity of patient engagement in PFDD



### Opportunity to input:

Ensuring a wider and more open process for input into drug development programs and activities



### Diversity of inputs:

Creating processes that recognise and include inputs from a diverse range of patients, not the privileged few

Better and wider promotion of patient input opportunities by medicine developers

Mixed methods to gain inputs from a wide patient expert and patient advocate community

Learn from others who have made great progress, for example, HIV. “What does good look like?”

**PROJECT IDEA:** Build a set of guiding principles that will guide the development of more inclusive approaches