

Patient Voice/Patient-Focused Drug Development (PFDD)

Working Group Leader	BMS Champion	GRYT Health Leader
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Participants' Affiliate Organizations



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The group began by thinking about the purpose of the 'Patient Voice' and why it is important

Attributes of the 'Patient Voice'

- **Ensures the needs and expectations of patients are understood by others**
 - Expresses, qualifies and quantifies the experiences of patients
 - Is unique amongst stakeholders – *only patients have these insights*
 - Is both backward and forward looking (capturing experiences and expectations)
 - Is (ideally) diverse, capturing the insights from a wide spectrum of affected patients

Who do we need to listen and take action?

- **Everyone else involved that is making decisions that affect patients, including:**
 - *Academic researchers*
 - *Industry / drug developers*
 - *Regulators*
 - *HTAs*
 - *Healthcare systems*

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Specifically, what did the group consider important topics for the Patient Voice in medicine development?

Opportunity to input

At the moment, input into research and clinical trial design is limited to input from those that are 'invited' to give input - need to make it more open and seamless (break down the barriers to getting involved)

Lack of diversity

Danger that researchers and drug developers are getting input from a very narrow demographic that does not represent the diverse patient population (the group discussed gender imbalances, racial imbalances, rural versus city imbalances and many more). *There may be some crossover with the Healthcare Disparities working group.*

Collaboration not validation

Suspicion that sometimes the patient voice is used to seek validation of already decided approaches and not a true collaboration to help shape approaches together. (It was highlighted that the BMS PEER project involves patients very early to avoid this).

Clear purpose and feedback

There is an opportunity to really define what is the goal of patient voice in drug development - from each stakeholder perspective. Also, need more clarity from the researchers / drug developers on why they are seeking input and what they plan to do with this (with feedback to patients involved on what happened with their collaboration/inputs)

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Key insights generated during the discussions

Purpose: Sometimes patients can get lost in the data. They become lab numbers. Their perspectives, needs and expectations are lost.

This connects to the insight from Sheila's group: "Statistics are people with the tears rubbed off."

Purpose:
What is the fundamental purpose of the patient voice in medicine development?

- *To deliver better outcomes*
- *To support development of better medicines focused on our needs*
- *To improve the wellbeing of people*
- *To get the patient more involved*
- *To allow patients to have more of a say in their own treatment, care plans and processes*

Opportunity: *We don't know where the channels are for patient voice input. Where and to whom can our voice be communicated?*

Opportunity / Diversity:
Seems like you have to be the right person in the right place in order to lend your voice

Diversity: *Across all dimensions, races, gender, economic status, geographic location, age, ... **Need to ensure diverse input, not the same input from the same people all the time***

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Two main gaps identified as areas to focus on for second session (expanded from the discussions)



Open and diverse channels
for patient voice



Ensuring impact



How can we make the channels more open and diverse? How can we promote the opportunities more widely and to a diverse audience?

- Potential content as food for thought: Lessons from other areas, e.g.:
 - How do HTA bodies do this?
 - What do regulators do?
 - What do academic researchers do?
 - What do some healthcare systems do?

How do we build trust in patients who have been ignored and have lost trust with the system and the healthcare stakeholders?

How is the patient voice listened to, acted upon and the impact fed back to those involved?

- What are the principles of good involvement that leads to impact?
- Where can we already see impacts?
- What can we learn from other areas?

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External resources discussed during session 1:

EUPATI EUPATI (European Patients' Academy on Therapeutic Innovation) - <https://eupati.eu/> - university level research and education about drug development so patients can learn and build on their knowledge.

PFMD (Patient Focused Medicines Development) - <https://patientfocusedmedicine.org> - Lots of collaboration here around a focus on tools, resources, and education (other stakeholders including industry) around patients, advocates, and drug development.

PARADIGM (Patients Active in Research and Dialogues for an Improved Generation of Medicines) - <https://imi-paradigm.eu> - lots of guidance around how to better involve patients in decision making

National Health Council (USA) - <https://nationalhealthcouncil.org/issue/patient-engagement/> - What frameworks work in the US context but is translatable across other countries.

Hypertrophic Cardiomyopathy Association Voice of the Patient report (6/26/20): <https://www.4hcm.org/content.asp?contentid=417>

Join Us for the Next Working Group Session

Thursday, March 11, 2021

12:00 – 1:30pm ET