

# Diversity in clinical trials: It takes a village

Lorena Kuri, Cathy Florek, Jateh Major  
Bristol Myers Squibb, Summit, NJ, USA

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## Correspondence to:

Lorena Kuri  
Lorena.Kuri@bms.com

## Abstract

Clinical trials are becoming more complex and the efforts to optimise drug development are rapidly evolving. This Q&A gives a short overview of the strategies Bristol Myers Squibb implements to incorporate diversity into the clinical trial development process with the intent to enhance equity and inclusion for the diverse patient community that uses the treatments we develop.

### Q: Why is diversity in clinical trials important?

A: Diversity in clinical trials is a critical focus area in the pharmaceutical industry. The healthcare ecosystem around the world recognises the urgent need to address serious gaps in care among underserved communities to provide access to medicines to help patients prevail over serious diseases. As evidenced by the numerous webinars and presentations with FDA, diversity in clinical trials is both a social and a scientific imperative.

Recognising these challenges, Bristol Myers Squibb (BMS) aims to remodel multiple aspects of clinical trial design execution strategies, and the efforts to enrol patient participants through the company's diversity in clinical trials programme. The expectation is that doing so will positively impact a broader patient population, more reflective of the real world, and aligned with the epidemiology of the disease studied.

### Q: Patient voice is important in enabling clinical trial diversity. How does BMS incorporate patient voice into the clinical trial protocol development process?

A: The BMS Clinical Trial Engagement Strategy Team's work focuses on bringing the patient's unique experiences, perspectives, needs, and priorities into the design and execution of clinical trials. As experts in what it's like to live with their condition, patients are uniquely positioned to help in the drug development process. Each disease affects a person differently based on gender, race, ethnicity, etc. Through our Patient Voice programme, we are able to talk with patients about their lived disease experiences and understand the potential barriers to clinical trial participation. The insights we uncover help us to make recommendations to our protocol development teams that can reduce the burden of trial participation and improve the overall patient experience. We are also able to learn how best to target outreach and engagement at the most favourable inflection points along the patient journey to support clinical trial awareness and participation in diverse populations.

### Q: How do these insights obtained through Patient Voice impact the patient experience?

A: The insights from patients through the Patient Voice platform are used to drive change with the expectation of providing an improved experience for both patients and study sites.

Some of these are broadly applicable to a patient's overall clinical trial experience, and some are more specific to the clinical trial experience of a patient with a certain disease. BMS uses the research and learnings obtained from Patient Voice to make recommendations, build strategies, and implement actions to help make our clinical trials less burdensome to patients and sites. As an example, some Patient Advisory Board feedback has had an impact on reducing the site visit schedule and helping to create recruitment messages and materials that are culturally sensitive. Other protocol changes made based on patient feedback were around

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reduction of invasive biopsy procedures and changes to medication format to reduce the number of times per day patient needed to remember to take their pills.

### Q: What efforts have been made to build trust between underrepresented populations and BMS?

A: This is a multifactorial need, but to mention some strategies, we capture patient and caregiver insights through our diversity and inclusion framework. A disease may have varying severity and outcome based on patient characteristics such as gender, race, ethnicity, etc. BMS works with epidemiologists who serve as experts to help better understand the aggregate disease and patient outcomes.

In order to reduce barriers to enrolling diverse patients into BMS-sponsored studies, BMS is also committed to attracting diverse talent which will provide additional valuable perspective for diverse patient enrolment. In the case of clinical trials, we have created an internal People and Business Resource Groups (PBRG) Advisory Board that functions as an additional internal resource for feedback on patient facing materials and programmes. There are also sustainable relationships with community outreach groups and Patient Advocacy organisations. As we strengthen the





the company. Some of the key operational strategies include: assessing protocol language to identify ways to minimise barriers to enrolment; embedding study diversity plans as a natural step within the clinical development planning process; and engaging with diverse patient representative groups.

**Q: How is BMS engaging with regulatory agencies around diverse clinical trial enrolment?**

**A:** BMS is aligned with the FDA position that diversity in clinical trials is a necessary component of clinical trial execution. In order to ensure that BMS stays active in the conversation we are having study specific interactions with the FDA and engaging in non-asset specific conversations on this topic. Additionally, BMS is receiving feedback on regulatory documents that will further enhance our knowledge on the challenges to diverse enrolment so that we can implement strategies to address them.

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**Q: How has the position of health authorities evolved with respect to clinical trial diversity?**

**A:** The need for greater diversity in clinical trials has been a key message from health authorities around the world for several years with the release of new International Council for Harmonization (ICH) guidelines on multi-regional trials and ethnic factors considered when assessing foreign data. More recently, the FDA has announced project equity with the goal

of enhancing access to clinical trials for under-represented populations. Additionally, the FDA had released two guidances on enhancing clinical trial diversity populations (2020) and diversity plans (2022). Certainly, 2020 highlighted this imperative and ignited a more detailed assessment of an approach to enrolling diverse participants in clinical trials.

**Q: What specific actions are being taken across BMS to ensure diversity in clinical trials standards meet regulatory expectations?**

**A:** Diversity in clinical trials is a major focus for

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**Data availability statement**

For inquiries about data and other supplemental information, please contact the corresponding author.



**Author information**

**Lorena Kuri** has been leading the Diversity Strategy efforts for R&D at BMS since 2019. Before that, she spent several years in commercial roles in the pharmaceutical industry.



**Cathy Florek** has been with BMS for over 30 years, spending the majority of her time in R&D. She currently leads the Clinical Trial Engagement Strategy Team within Global Development Operations.



**Jateh Major** has been working in Regulatory Affairs Strategy for the past 6 years. He started his career at Merck, and joined BMS in 2020. Since then, he has been a key contributor and regulatory lead of the Diversity in Clinical Trials efforts for the company.