



July 3, 2023

Robert M. Califf M.D., MACC  
Commissioner  
United States Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Methodological Challenges Related to Patient Experience Data; Request for Information and Comments

Dear Commissioner Califf:

The National Health Council (NHC) thanks the Food and Drug Administration (FDA) for the opportunity to respond to the Food and Drug Administration's (FDA) request for information (RFI) and comments on barriers to collection of patient experience data.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of more than 155 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

The NHC appreciates the FDA's questions and the focus on identifying and overcoming barriers to collecting patient experience data. The results of this RFI will help the FDA create consistency, while creating opportunities for patient input, support, and education.

We applaud the FDA for this effort to increase the use of patient experience data. We hear consistently from patient groups and product sponsors that one of the primary barriers to collecting quality patient experience data is the lack of tools, resources, and training for patients, sponsors, and other stakeholders on how to achieve quality patient experience data. The resources and comments below primarily address two questions raised in the RFI.

1. Describe any challenges and limitations experienced when selecting, modifying, or developing fit-for-purpose Clinical Outcome Assessment measures.
2. Describe any challenges and limitations experienced when developing and conducting patient preference studies to support regulatory submissions.

## **Tools and Resources to Address Challenges Raised in the RFI**

The NHC has worked with both the patient and sponsor communities to develop tangible tools to achieve this shared goal. We encourage the FDA to incorporate and amplify some of the lessons we have learned.

The NHC urges the FDA to consider the following six domains of patient-centered engagement and methodological practices as included in the NHC [Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem](#). The rubric was designed in a multi-stakeholder effort to elevate meaningful patient engagement and ensure patient voice inclusion is seen in studies and that engagement includes:

- Patient Partnership;
- Transparency;
- Representativeness;
- Diversity;
- Outcomes Patients Care About;
- Patient-Centered Data Sources and Methods; and
- Timeliness.

In addition to the rubric mentioned above, the NHC has several tools that can help identify and infuse the collection of quality patient experience data like the Patient Experience Mapping Toolbox, which was developed to help researchers capture patient experience data more holistically and in a standardized manner across chronic diseases. The toolbox<sup>1</sup> We have also created a blueprint for the development of , which address inconsistencies between what is important to patients and the information that is typically collected in research and care. A PC-CIS is a standardized, patient-derived, and patient-prioritized list of the most important impacts (both clinical and non-clinical) a disease and/or its treatments have on a patient's health and daily life, and that of their family and caregivers. [Patient-Centered Core Impact Sets \(PC-CIS\)](#), which address inconsistencies between what is important to patients and the information that is typically collected in research and care. PC-CIS are standardized, patient-derived, and patient-prioritized lists of important impacts (both clinical and non-clinical) a disease and/or its treatments have on a patient's health and daily life and that of their family and caregivers.

## **Additional Topic for Workshops**

Finally, in addition to the questions posed in the RFI, the NHC urges the FDA to consider the opportunities and barriers that patient experience data present to increasing diversity and inclusion. While patient experience data can be an important tool for collecting information about different priorities and experiences of diverse communities, it can also be skewed by bias and the self-selecting nature of the

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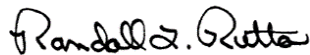
<sup>1</sup> All patient-facing tools in the Toolbox were reviewed externally by health literacy experts and refined through patient interviews. To encourage uptake, the Toolbox is made available free for public use.

practice.<sup>2</sup> Like our shared concern about diversifying clinical trial populations, the NHC believes patient experience data is most useful when a diverse and representative population has been engaged to collect the data. The NHC produced [Tackling Representativeness: A Roadmap and Rubric](#) as a resource to entities conducting patient engagement to help ensure representativeness in their data. We urge the FDA to explore how patient experience data can drive diversity and inclusion, as well as barriers of diversity and inclusion, in patient engagement with the workshops this RFI is supporting.

### Conclusion

The NHC thanks CMS for the opportunity to provide input on these important questions. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these comments in greater detail. He is reachable via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,



Randall L. Rutta  
Chief Executive Officer

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<sup>2</sup> [Patient-Experience Data and Bias — What Ratings Don't Tell Us | NEJM](#)