

Who We Are Matters: Inclusive Demographic Data Collection in Patient-Centered Outcomes Research

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Objectives

> **Inclusivity in research** focuses on ensuring individuals across various identity groups are represented

> Demographic data collection has the potential to **perpetuate harmful bias** or **promote inclusivity and equity**

> Traditional demographic data collection in outcomes research has not always considered inclusive data collection methods, which can result in study populations that are **inadequately described or under-researched**, and can potentially be harmful to participants

> Inclusive research methods are critical to promoting diversity in patient-centered research, **aligning with regulatory guidance, and scientific and societal expectations**

>The goal of this work was to review current questions and response options used to collect demographic data, to determine revisions needed in order to **generate more inclusive data overall**

Methods

Figure 1. Methods overview

Discussion and review:
Review of questions and response options to ensure clarity and comprehensiveness

Organize into standard form and item bank:
Added item bank to generate options to adapt based on relevance to individual study designs

Revisions of questions and response options:
Revised to develop more representative questions and response options by expanding language and selections available to participants

Evaluation of existing demographics form:
Identified exclusionary questions and binary, mutually exclusive, or bucketed response options for revision

Targeted literature review:
Targeted literature review of regulatory guidance, peer-reviewed journals, and sources reflective of lived experience

Methods: An iterative process

Conclusion

> This poster provides recommendations based on the core findings of a targeted review of literature and best practices, and **identifies key areas of focus** for inclusive demographic data collection (see Figure 2)

> Demographic data collection forms should be tailored to suit the needs of the study and population based on the **condition, age, and location** of participants; an item bank can be developed as needed

> **Trainings on administration** of revised demographic questions and response options can help ensure study participants comprehend and are comfortable completing the form, and that **data collection is uniform** across administrators

> A well-created demographic data collection form is **easy to clean for quantitative analysis** without negative consequences; programmers can align categories and collapse if needed, while still being inclusive for participants

Results

> From the activities conducted (Figure 1), **key areas of focus** for inclusive demographic data collection and **recommendations** were identified (presented in Figure 2 and Table 1, respectively)

Figure 2. Key areas of focus for inclusive demographic data collection

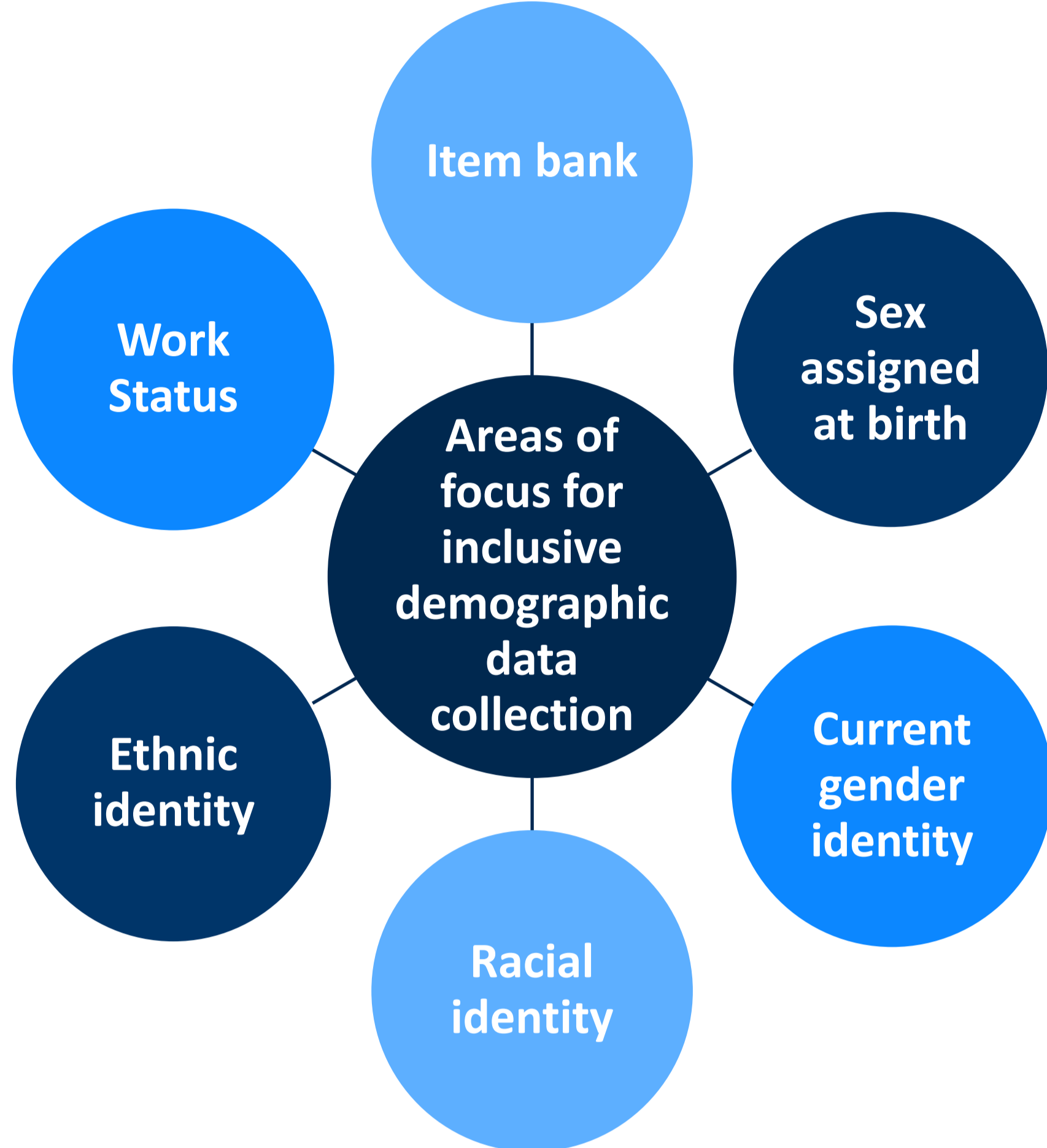


Table 1. Recommendations for inclusive demographic data collection and example questions

Recommendation	Example typical US demographic question	Example inclusive US demographic question
Use several non-mutually exclusive response options that provide options for respondents who may fall within multiple categories ^{1, 2}	What is your gender? • Female • Male	What is your current gender identity? (Please choose all that apply) • Woman • Man • Transgender • Non-binary • Another gender identity; please specify: ____ • Prefer not to say
Provide examples to help respondents understand which response option(s) are most fitting for them ^{3, 4}	What is your race? • Asian • Etc...	Which of the following best describes your race? (Please choose all that apply) • Asian (for example, Chinese, Filipino, Asian Indian, Vietnamese, Korean, Japanese, Pakistani, Cambodian, Hmong, etc.) • Etc...
Use language that can be understood and applicable to all respondents by offering different terminology as needed ^{4, 5}	Are you Spanish/Hispanic/Latino? • No, not Spanish/Hispanic/Latino • Yes, Mexican/Mexican American, Chicano • Yes, Puerto Rican • Yes, Cuban • Yes, other; please specify: ____	Are you Hispanic, Latino/a/x, or Spanish origin? • Yes, Mexican, Mexican American, Chicano/a/x • Yes, Puerto Rican • Yes, Cuban • Yes, Another Hispanic, Latino/a/x, or Spanish origin, please specify: ____ • No, not of Hispanic, Latino/a/x, or Spanish origin • Prefer not to say
Create multiple questions to best represent respondents' identities and lived experiences ^{6, 7}	What is your gender?	What is your current gender identity? (Please choose all that apply) What was your sex assigned at birth?

Abbreviations: FDA=Food and Drug Administration; US=United States

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