



Draft

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Guiding Principles to Support Medical Device Health Equity

AUTHORING GROUP

IMDRF Management Committee

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Preface

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Andrzej Rys, IMDRF Chair

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1. Background

Health equity refers to the absence of unfair and avoidable or remediable differences in health among population groups. Evidence demonstrates that biological, economic and social differences among diverse groups of people can contribute to differences in health outcomes. The consideration of these differences as part of International Medical Device Regulators Forum (IMDRF) working group discussions could help to promote health equity.

In some circumstances, regulators may consider population differences when assessing the safety and performance of a medical device. Numerous factors can contribute to such population differences. Some of the key factors are defined as follows:

- **Sex** refers to a person's biological and physiological characteristics. A person's sex is most often designated by a medical assessment at birth.
- **Gender** refers to roles, identities, expressions, and behaviours that a given society may construct or consider appropriate for the categories of "men" and "women". It can result in stereotyping and can set expectations about what people should or can do.
- **Gender identity** refers to how people may experience gender. This could be congruent with their birth-assigned sex, or the person may identify with the other gender ("man/boy" or "woman/girl"), or neither of the genders.
- **Race** refers to a social construct. It is not grounded in biology but can influence how people access programs and services. The impacts of racialization and racism on various race groups (e.g., Black, White, Asian, etc.) should be measured and assessed along with other identity factors as determinants of health.
- **Ethnicity** refers to categorizations of groups of people according to their cultural expression and identification. Commonalities such as racial, national, tribal, religious, linguistic, or cultural origin may be used to describe someone's ethnicity.

2. Guiding Principles to Support Health Equity

Guiding principles have been developed for use by the IMDRF, a voluntary group of medical device regulators from around the world, to advance health equity discussions for underrepresented populations in the development and regulation of medical devices. This document is intended to assist IMDRF working groups in considering health equity principles, where relevant, in the development of IMDRF technical documents.

Recognize potential health equity considerations for medical devices: Where relevant in IMDRF working group discussions, members should broadly consider health equity, as well as aspects related to its implementation. For example, when drafting technical documents, where feasible, consider implementing approaches that are inclusive of population related factors or differences.

Identify any differential impacts of a device on subpopulations: It may be helpful to identify and take into consideration differential impacts of a device on various subpopulations, such as sex, gender, age, race, or other characteristics. For example, where practical, device designs should take into account unique anatomical or physiological characteristics, or differential rates of use, of people impacted by the device.

Consider the relevance of disaggregated data: Disaggregated data are broken down into subcategories or target groups. For some medical devices, in certain scenarios, the use of quantitative (e.g. sex, gender, race) and/or qualitative disaggregated data can allow for a better understanding of medical device safety and performance in the different populations expected to use the device. For example, the use of disaggregated data could detect different levels of device performance in relation to different subpopulations.



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