IMDRF International Medical Device Regulators Forum

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Guiding Principles to Support Medical Device Health Equity

AUTHORING GROUP

IMDRF Management Committee

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Preface

Jeffrey Shuren, IMDRF Chair

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1. Background

Health equity is the absence of unfair and avoidable or remediable differences in health among population groups, including the absence of unfair systems and policies that cause health inequalities, allowing everyone to attain their full potential for health and well-being. 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, effectiveness and performance of a medical device. Numerous factors can contribute to such population differences. Some of the key factors are defined as follows:

- **Age**: refers to the amount of time during which a person has lived. Different age groups experience health differently.
- **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, expressions, and behaviours that a society constructs and uses to categorize individuals, for example as "men" and "women". Gender identity refers to how people experience their gender and biological sex and it may or may not be congruent with their birth-assigned sex.
- **Ethnicity** refers to the categorization of groups of people according to their cultural expression and identification. It is related to socio-demographic characteristics, including language, religion, geographic origin, nationality, cultural traditions, ancestry and migration history, among others.
- **Race** refers to the social construct used to categorize people based on perceived differences in physical appearance. There is no scientifically-supported biological basis behind this construct.
- **Socio-economic status** refers to an individual's experience of social and financial factors such as income, education, housing, and community.

2. Guiding Principles to Support Health Equity

Guiding principles have been developed for use by the IMDRF to advance health equity discussions for underrepresented populations in the development, evaluation 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. These principles should be considered throughout the total product lifecycle. Each working group will determine how best to use this document in their discussions and deliverables.

Recognize and address potential health equity considerations for medical devices: Where relevant in IMDRF working group discussions, members should broadly consider implementing aspects that support health equity. For example, when drafting technical documents and, where feasible, considering approaches that are inclusive of subgroup related factors or differences.

Consider the relevance of disaggregated data: Disaggregated data are broken down into subcategories. Looking at data within and across specific categories (e.g. age, sex, gender, ethnicity, race, socioeconomic status) 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 inequitable levels of device use or performance in relation to different subgroups. This principle hinges on data collection processes that lead to sufficient information across different categories to enable meaningful analysis and assessment between populations, both for pre-market and post-market data collection.

Identify any differential impacts of a device on subgroups: It may be helpful to identify and take into consideration differential impacts of a device on various subgroups, such as age, sex, gender, ethnicity, race, socio-economic status, or other characteristics. For example, where practical, device designs should consider sex- and gender-related factors, unique anatomical or physiological characteristics, or differential rates of access to or use among people impacted by the device. Differential impacts can be assessed with data from clinical trials and from post-market surveillance.

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