EMD Serono's Commitment to Health Equity and Inclusion in Clinical Study Participation

At EMD Serono, we are dedicated to developing treatments that meet the needs of patients with various hard-to-treat diseases. We recognize the importance of adequately representing diverse participants in our clinical studies to ensure assessment of safety and efficacy of our drugs across different patient populations. The need to do so has been acknowledged across the pharmaceutical industry, by its trade organizations, and health authorities.[1-6] Our research approach aims to achieve this by equitably enrolling diverse study participants in terms of age, sex, race, ethnicity, religion, socioeconomic background, and disability, among others.

To this end, we have a strategy built on four key pillars:

1. Broadening and enhancing our clinical trial site selection process to focus on healthcare providers who serve communities with underserved populations affected by the disease.
2. Designing inclusive clinical studies that adhere to all applicable laws and guidelines.
3. Ensuring that study participants represent populations affected by the disease.
4. Investing in community outreach and building trust within communities and patient organizations to enhance clinical study awareness and participation.

To support these efforts, we have worked with patients and research staff to co-develop a comprehensive toolkit to address population-specific challenges and increase outreach to support clinical trial participation.

We track the execution of our measures against these four pillars and also include our position and efforts within public reports, including our annual Corporate Sustainability Report[7]. In 2023, we published our first report as a testament of our efforts to enhance the inclusion of representative populations affected by different diseases.

Looking ahead, we will continue our pursuit of health equity, working towards a future where every individual has equal access to medical innovations wherever possible. Developing drugs that improve the outcomes of patients is integral to everything we do.

The Healthcare business of Merck KGaA, Darmstadt, Germany operates as EMD Serono in the U.S. and Canada.
Effective date: September 16, 2025 Version 2.0

References

1) PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results. October 2020. Available on: https://phrma.org/resource-center/Topics/Cost-and-Value/PhRMA-Principles-on- Conduct-of-Clinical-Trials. Last accessed: 16 September 2025
2) IFPMA. Diversity and Inclusion in Clinical Trials: Bioethical Perspective and Principles. May 2022. Available on: https://www.ifpma.org/publications/diversity-and-inclusion-in-clinical-trials-bioethical-perspective-and-principles/. Last accessed: 16 September 2025
3) Momoh O, et al. Inclusion & Diversity in Clinical Trials. EUPATI. November 2020. Available on: https://toolbox.eupati.eu/wp-content/uploads/sites/4/2020/11/EUPATI_Inclusion-and-Diversity-in-Clinical-Trials.pdf. Last accessed: 16 September 2025
4) FDA. Collection of Race and Ethnicity Data in Clinical Trials. Final Guidance, October 2016. Available on: https://www.fda.gov/media/75453/download. Last accessed: 16 September 2025
5) FDA. Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products. Draft Guidance, January 2024. Available on: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials-and-clinical-studies-fda-regulated-medical. Last accessed: 16 September 2025
6) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, repealed Directive 2001/20/EC on 31 January 2022. Available on https://eur-lex.europa.eu/eli/reg/2014/536/2022-12-05. Last accessed: 16 September 2025
7) Merck KGaA, Darmstadt, Germany's Corporate Sustainability Report. 2023. Available on: https://www.emdgroup.com/company/sustainability/us/Sust-Report-2023-US.pdf. Last accessed: 16 September 2025

The Healthcare business of Merck KGaA, Darmstadt, Germany operates as EMD Serono in the U.S. and Canada.