

EMD Serono's Commitment on Diversity, Equity, and Inclusion in Clinical Study Participation

At EMD Serono, we are dedicated to developing treatments that meet the needs of diverse patients. 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 pharmaceutical industry and by its trade organizations, with health authorities establishing requirements for diverse representation in clinical trials¹⁻⁶. Our research approach aims to achieve this by equitably enrolling diverse study participants in terms of age, sex and gender identification, 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 cater for underserved populations.
- 2. Designing inclusive clinical studies that adhere to guidelines on patient diversity.
- 3. Ensuring that study participants represent populations affected by the disease.
- 4. Investing in community education, outreach, and building trust within diverse communities and patient organizations to enhance clinical study awareness and participation.

To support these efforts, our Diversity, Equity and Inclusion (DE&I) Advisors, Champions, and External Advisory Committee provide strategic guidance, and we have worked with patients and research staff to co-develop a comprehensive toolkit to address population-specific challenges, overcome social barriers, and increase community outreach.

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 Report⁷. In 2023, we published our first DE&I report⁸ as a testament of our support for all dimensions of diversity and our commitment to non-discrimination, which is also reflected in our Human Rights Charter⁹. We publish our efforts regularly in various outlets, e.g. including in the UN Global Goals Yearbook 2023¹⁰.

Looking ahead, we will continue our pursuit of health equity, working towards a future where every individual, regardless of their background, has equal access to medical innovations wherever possible. Developing drugs that improve the outcomes of all patients is integral to everything we do, and we are committed to responsibly developing drugs for all patients.



1 of 2



References

- 1) PhRMA Principles on Conduct of Clinical Trials. October 2020. Available on: https://phrma.org/resource-center/Topics/Cost-and-Value/PhRMA-Principles-on-Conduct-of-Clinical-Trials. Last accessed: 06 September 2024
- 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: 06 September 2024
- 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: 06 September 2024
- 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: 06 September 2024
- 5) FDA. Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies Guidance for Industry. Draft Guidance, June 2024. Available on: https://www.fda.gov/media/179593/download. Last accessed: 06 September 2024
- 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: 06 September 2024
- 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: 06 September 2024
- 8) Merck KGaA, Darmstadt, Germany's first DE&I Report. 2023. Available on: <u>EMDGroup First DEI Report | Merck KGaA, Darmstadt, Germany</u>. Last accessed: 06 September 2024
- 9) Merck KGaA, Darmstadt, Germany's Human Human Rights Charter. Available on: https://www.emdgroup.com/company/responsibility/us/Human-Rights-Charter.pdf. Last accessed 06 September 2024
- 10) United Nations Global Goals Yearbook. 2023. Available on: <u>Global Goals Yearbook</u> 2023 makes SDG impact measurable (yumpu.com). Last accessed: 06 September 2024



Effective date: 1st October 2024