

EMD Serono Position Statement on Post-Study Access to Experimental Medicine

For External Use

Why It Matters?

Patients facing life-threatening, chronic or seriously disabling illnesses or diseases live with the hope that tomorrow will bring a new medicine to extend and improve their lives. EMD Serono is committed to developing new medicines for patients with such illnesses and diseases. EMD Serono believes the best way to fulfill this commitment is to conduct clinical studies to assess the safety and effectiveness of experimental medicines which, if proven, will allow us to obtain drug approval from regulatory authorities and provide patients with broad access to these new medicines. EMD Serono believes that patients who desire access to experimental medicines should be encouraged to participate in clinical studies, the goal of which is to secure approval of new, safe and effective medicines for the broadest number of patients.

EMD Serono also understands that in the conduct of clinical studies, access to experimental medicines following clinical studies is often necessary for the continued health and well-being of patients participating in the studies. EMD Serono also recognizes that continued access to experimental medicine post-studies may be a legal, regulatory and/or ethical obligation under some circumstances.

EMD Serono encourages patients to consult their physicians to determine the best course of action depending on their individual needs.

EMD Serono Position Statement

1. Principles Governing Post-Study Access to Experimental Medicines

EMD Serono is committed to high quality clinical research, following all legal, ethical and scientific standards. As part of this commitment and in accordance with the Declaration of Helsinki, EMD Serono offers patients who participate in EMD Serono-sponsored clinical studies continued access to the experimental medicine that they received during the study after completing the study, when appropriate, as described below.

EMD Serono will use the following principles to govern when a patient who participates in a EMD Serono-sponsored clinical study of an experimental medicine shall have continued access to that medicine after completion of the clinical study, free of charge:

- a) The patient should have a life-threatening, chronic or seriously disabling illness or disease, as defined by the local laws and regulations applicable to the particular patient, and the benefits outweigh the risks for this patient to continue to receive the investigational medicine;
- b) There are no appropriate alternative treatments or clinical studies available to the patient; and

- c) The patient and his/her own treating physician comply with and satisfy any legal or regulatory requirements applicable to them.

2. Exceptions

EMD Serono will not provide post-study access to experimental medicine as described above if:

- a) The experimental medicine is commercially marketed in the patient's country and is reasonably accessible to the patient (e.g., is covered by the patient's insurance or would not otherwise create a financial hardship for the patient);
- b) EMD Serono has discontinued development of the experimental medicine or data suggest that the experimental medicine is not effective for the relevant indication;
- c) EMD Serono has reasonable safety concerns regarding the experimental medicine for the relevant indication; or
- d) Provision of the experimental medicine would not be permitted under the laws and regulations of the patient's country.

3. Mechanisms for Providing Post-Study Access

All EMD Serono-sponsored protocols and informed consent forms should include a general plan for post-study access. When post-study access is not appropriate under the above principles, this should be made clear in the protocol and informed consent forms.

Several mechanisms are utilized for providing post-study access to study participants. These include:

- a) **Open-label clinical studies**, including open-label extension studies and rollover studies: a continuation of a study or a new study for patients who have completed a clinical trial. In these types of studies, all patients receive investigational medicines. For rollover studies, patients may be grouped from several clinical studies into one trial or from different cohorts within a single clinical study. This is done in situations when data collected from such studies continues to be useful for understanding safety or efficacy of the medicine being studied.
- b) **Single patient post-study access**: implemented when further research data on efficacy is not needed. Under this mechanism, individual patients who completed a study may be provided with experimental medicine outside of the clinical study. Data on safety events continue to be collected per a safety reporting agreement with the patient's treating physician.
- c) **Patient support or access programs**: used in some countries when the medicine is approved and available in the country's health care system for the same indication but might not be accessible to some patients (e.g., because of lack of affordability or health plan coverage).

4. Regional Variations in Post-Study Access

Various regulatory mechanisms exist in different countries to govern post-study access to experimental medicine and as a result, regional variations in post-study access may occur. Any post-study access to experimental medicine must always comply with the applicable country-specific laws and regulations, including medicine importation requirements for approved and investigational drugs.