

Access to investigational medicines

Expanding Patient Access to MSD Investigational Medicines

When results from clinical trials suggest that one of our investigational medicines may offer benefits for patients facing life-threatening conditions, MSD is committed to bringing that medicine to those patients as quickly and equitably as possible. Participation in clinical trials should be the primary route by which patients get access to investigational medicines and contribute to the collection of safety and efficacy data needed to support regulatory approval worldwide. These clinical studies are needed to demonstrate that the medicine meets the standards for safety and efficacy that government regulatory agencies have established for granting approval. Gaining regulatory approval for a medicine is the best way to bring rapid access to the greatest number of patients who may benefit.

For patients with a serious or life-threatening disease who are ineligible or unable to participate in a clinical trial, use of an expanded access program *may be* an option. Depending on country regulations and the program criteria, access to investigational medicines may be provided through Expanded Access Programs (EAP) (known as compassionate use programs in certain jurisdictions), or Country-Specific Authorization to Use cohorts.

Decision criteria for considering an EAP

The following criteria must be met before MSD will consider establishing an EAP for a MSD investigational product:

- There is an unmet medical need that cannot be met by existing products
- The benefit-risk profile of the drug in the indication and the patient population is positive
- There is a good understanding of the likely indication to be approved
- There are definite plans to file and commercialize the drug in the region
- The program will be fairly and equitably available to the population of the region in question
- The program is compliant with local rules and laws
- There are adequate supplies of investigational product to meet the needs of the EAP without impairing the clinical trials program
- The program must be discontinued as soon as feasible when approval of the drug is achieved in the country

Process for seeking access

Patients should consult with their healthcare provider about their eligibility to enroll in any of MSD's clinical trials and expanded access programs.

If the physician feels that the patient is not able to participate in an available clinical trial and that an expanded access program may be suitable for the patient, the physician should contact MSD to make the request on behalf of the patient. This will enable the physician to work with experts within the company to determine the appropriate course of action.