

Capricor Expanded Access Policy Statement

As a healthcare company, Capricor's role is first and foremost to discover and develop innovative products with the potential to save and improve lives. We conduct and support clinical trials to evaluate the safety and efficacy of our products. These trials are fundamental to the development of novel medicines that can potentially treat illness. The enrollment criteria for these trials are necessarily designed to evaluate the investigational product (investigative drug or biologic) in a defined population. Expanded access (also called compassionate use) is the use outside of a clinical trial of an investigational drug or biologic that has not yet been approved by the FDA. Capricor has an ethical responsibility to subjects enrolled in its clinical trials and will evaluate the opportunity to provide broader access to its investigational therapies once the clinical trials have been completed. For this reason, Capricor will not have an expanded access program, nor will preferential enrollment considerations for siblings of trial subjects be provided, at this time.