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Expanded Access Program Considerations beyond Clinical Trials

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Introduction

An immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. An Expanded Access Program (EAP) is a program that provides access to investigational products to treat patients with serious or immediately life-threatening conditions who have no satisfactory alternative treatment options [1-5].

Program selection considerations

Expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrolment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

Food and Drug Administration (FDA) has not yet approved or cleared any investigational medications, biologics, or medical devices, and FDA has not determined that these items are secure and efficient for the intended uses. Additionally, the investigational medicinal product might or might not be successful in treating the illness, and using it could have unanticipated, serious side effects.

Whenever possible, an investigational medical product should be used as part of a clinical trial. However, there are times when it is not possible for a patient to be a part of a clinical trial (e.g., that there are no ongoing trials, a patient may not have access to a clinical trial or may not be eligible for the clinical trials, distance to get to a trial prevents access). In those circumstances, expanded access may be the only way for a patient to receive an investigational medical product.

EA for individual patients depends on the cooperation and expertise of many. The physician (who applies on behalf of the patient and will oversee the treatment use), the drug company (that is developing the treatment), the institutional review board (which reviews the EA request and informed consent document), and the FDA or regulatory agency (which reviews the application to determine if the treatment may proceed) all have important roles and must collaborate for the EA process to work.

Sponsor considerations

Companies must be upfront with the treating physician about the therapy's administration procedures as well as any unique handling requirements or maintenance issues. If refrigeration is necessary, for instance, would the company transport it at the proper temperature, and can the patient and doctor ensure those requirements through to the actual administration at the prescribed dosing.

Patient considerations

Every patient is different. Age, gender, diagnosis, awareness of any co-existing diseases, prior therapies, or prior involvement in clinical trials is all possible factors that could affect a patient's eligibility for EA.

Companies and providers must work together to fully assess what is known about the patient and the proposed therapy prior to proceeding with treatment to ensure that no undue harm comes to the patient.

Bioethical considerations

Ensuring patient safety should be a top priority for biopharmaceutical companies and the FDA along with fairness and equality. When formulating EA policies, biopharmaceutical companies should take into account a number of bioethical considerations

Reporting requirements

There are reporting requirements on ClinicalTrials.gov regarding availability of EA that apply to the industry sponsor of an applicable clinical trial who is also the manufacturer of the drug. As with any IND, the sponsor, whether company or physician, is responsible for submitting to FDA an IND safety report and annual reports when the IND or protocol continues for one year or longer. For single-patient IND, regulations specify that after treatment the physician must provide to FDA a written summary of the results of the expanded access use, including adverse effects. While FDA considers adverse event information from expanded access in the safety assessment of a drug, it is very rare for this information to negatively impact regulatory decision-making.

Conclusion

While not a requirement for regulatory submission, expanded access presents an opportunity to gather real-world data that can improve knowledge and help modernize drug development processes. The additional safety and real-world data that helps in understanding how the drug will be used in clinical practice. Expanded access provides physicians with experience using the new medicine, creating advocates for the drug prior to its launch.

Conflict of Interest

The author shows no conflict of interest towards this manuscript.

References

1. Investigational New Drug Application, Subpart I–Expanded Access to Investigational Drugs for Treatment Use. *Food and Drugs* 320 (2009): 300-312.

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2. Expanded Access to Investigational Drugs for Treatment Use (2017).
3. https://www.wepclinical.com/expanded-access-programs/
4. https://navigator.reaganudall.org/companies-and-sponsors
5. http://edocket.access.gpo.gov/2009/pdf/E9-19005.pdf.

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