



White paper

Strategies to enhance the provider and patient EAP experience



Expanded access programs (EAPs) play a multifaceted role in the drug development life cycle, serving as a critical bridge between clinical trials and commercial availability.

These programs offer a lifeline to patients who may have exhausted other treatment options and can also offer pharmaceutical companies valuable real-world data, paving the way for smoother commercial transitions.

The stakeholders involved in EAPs have diverse needs and concerns. Healthcare professionals (HCPs) require clear, accessible information and straightforward processes. Patients and their families need assurance about treatment continuity and support throughout their journey. Sponsors must navigate complex regulatory landscapes while ensuring alignment with broader clinical and commercial strategies. Balancing these considerations requires an approach that centers around the clarity and availability of information.

BRIDGING THE AWARENESS GAP

The fundamental purpose of an EAP is for treatment of patients with an unmet medical need. For this to occur, their HCP needs to take the necessary steps to enroll them; this means they need to know that the product exists, that it has the potential to be useful for their patient, and how to access it.

The foundation of an EAP's success is awareness, but all requests for access must be unsolicited.^{1,2,3} Given that the unlicensed therapies included in EAPs cannot be marketed, sponsors need to consider other strategies to ensure physicians have the information they need.

Building Medical Community Awareness

HCPs who have been involved in clinical trials for the product are a natural starting point for raising awareness. These investigators already have firsthand experience with the therapy and can serve as valuable sources of information for their peers. Similarly, members of scientific advisory committees who have worked with the sponsor are well-positioned to understand the potential benefits of the investigational product.

Medical congresses present another opportunity for awareness-building. HCPs attending these events can gain insights into the potential of new therapies. This exposure can spark interest and lead to inquiries about expanded access options.

The general medical press can also play a role in broadening awareness. As publications discuss new therapies and ongoing research, HCPs may become aware of potential treatment options for their patients with unmet medical needs. When an EAP goes live, the sponsor can also issue a press release through business-related newswires. This information is often picked up by patient advocacy groups and other interested parties, facilitating broader dissemination within relevant communities.

Additionally, HCPs and patients can find information about EAPs on various external websites and databases. In the U.S., these include the Reagan-Udall Foundation Expanded Access Navigator as well as ClinicalTrials.gov.^{4,5} In the EU, resources can be found on a variety of competent authority websites, including the Federal Agency for Medicines and Health Products in Belgium and the National Agency for the Safety of Medicines and Health Products in France.^{6,7}

Ensuring Transparency & Clarity of Information

Once the medical community is aware of an EAP, they need to be able to easily find information on how to take the next steps. Implementing a clear policy on company websites allows them to do so effectively. Per guidance from the 21st Century Cures Act, the policy should be easy to find and outline the sponsor's approach, including eligibility criteria and the process for requesting access.⁸

Medical affairs teams also play a pivotal role in facilitating access to EAP information while maintaining compliance. Through scientific communications aligned with regulatory guidelines, these teams can respond to unsolicited requests with detailed information about the availability of EAPs and how to access them.

Transparency is equally important when an EAP is not yet available. Sponsors should have an internal policy for responding to inquiries in these situations. Rather than simply declining, it may be beneficial to indicate whether access might be considered in the future. Keeping HCP's details on file and committing to update them can maintain positive relationships and ensure that potential participants aren't lost due to communication gaps.

Leveraging Digital Tools

Digital tools can help enhance the EAP experience. A well-designed website with clear, accessible information about policies serves as a central hub for information, as can physician-facing microsites. Digital strategy should also include a dedicated contact email address for inquiries. This ensures that questions and requests are directed to the appropriate team members who can provide timely and accurate responses.

FACILITATING SEAMLESS EAP PLACEMENT

While raising awareness within the medical community is crucial, ensuring a smooth transition from awareness to patient enrollment is equally important. HCPs who are ready to enroll patients often need ongoing support as they navigate the complexities of the EAP process.

Some steps to enable this include:

- A dedicated support team or liaison
- A simplified application process, using user-friendly digital platforms where possible
- Providing realistic timelines for product availability and sharing updates in case of delays
- Sharing step-by-step guidance with HCPs, including checklists, flowcharts, or interactive online guides
- Supporting regulatory applications by offering expertise and resources
- Assisting with local approvals (e.g., addition to hospital formularies)
- Offering training on the product and EAP procedures

ENHANCING PATIENT EXPERIENCE DURING EAP EXECUTION

In addition to continuing strategies to keep HCPs informed, approaches that center the core principles around clear communication and readily available information can improve the patient experience.



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Addressing Patients’ Needs and Concerns

For patients with serious or life-threatening conditions, EAPs can offer access to potentially life-changing therapies when other options have been exhausted. However, this often comes hand in hand with anxiety about the process.

To help physicians more effectively ease patient concerns, sponsors should consider providing clear, comprehensive information. This includes explaining what patients can expect during treatment, potential side effects, and the experimental nature of the therapy. By demystifying the process, patients and their families can make informed decisions and feel more in control of their healthcare journey.

A primary concern for many patients is treatment continuity. Addressing this in EAP documentation can help give treating physicians the necessary information to guide these discussions, including any plans for transitioning patients to the commercial product once it becomes available. Additionally, plans should consider options for treatment continuity if the product fails clinical trials or local launch.

The Role of Medical Affairs for Patients

While the medical affairs team plays a crucial role in HCP engagement, their involvement in patient care takes on a different dimension. Here, the focus is on developing patient-friendly educational materials that explain complex medical concepts in an accessible language. These resources should be available in local languages to ensure all patients can fully understand their treatment.

Medical affairs teams also support HCPs in their patient communication and care. This might involve providing additional context about the therapy that HCPs can use in patient discussions or offering guidance on managing potential side effects specific to the investigational product.

Managing the Logistics of Patient Care

Coordinating treatment initiation is a critical step in the patient journey, requiring careful planning to ensure product availability at the treatment site. Ongoing support for treating physicians, including regular check-ins, adverse event management, and real-world data collection, can help promote both patient safety and program success. Digital tools can play a significant role in streamlining these logistical aspects, enhancing both efficiency and the patient experience.

For example:

- **Patient portals** provide centralized access to treatment information, appointments, and FAQs, which can be particularly valuable for patients with rare diseases
- **Treatment scheduling and reminders** help patients adhere to their therapy regimen, especially crucial for treatments with complex schedules
- **Platforms for ongoing support** facilitate real-time communication between patients and their care team, enabling quick responses to concerns and enhancing safety

THE IMPORTANCE OF CONTINUITY

Each stage of the EAP process builds upon the previous one, creating a complex, interconnected ecosystem of care. This underscores the importance of continuity in EAP management. When a single provider manages the entire process, it creates a unified channel of communication, ensuring all stakeholders receive coherent, up-to-date information.

For pharmaceutical companies, working with a single EAP provider simplifies program management and reporting. It provides a clear, comprehensive view of the EAP's progress and outcomes, facilitating more informed decision-making. Additionally, a well-managed, cohesive EAP can enhance a sponsor's reputation within the medical community and among patients, potentially easing the transition to commercial launch.

Healthcare providers also benefit from having a single point of contact throughout the EAP process. This reduces administrative burden, allowing HCPs to focus more on patient care.

For patients, the benefits of continuity are perhaps most profound. A single provider approach with a patient support program means that patients and their families have consistent support throughout their treatment journey. This can significantly reduce anxiety and confusion, as patients know exactly who to turn to with questions or concerns. Additionally, it ensures that all aspects of their care are coordinated, from treatment scheduling to ongoing monitoring.

Beyond operational coordination, continuity also enables a more holistic, patient-centric support model. Integrated nurse-led services, home-care coordination, and digital support tools provide patients with practical and emotional guidance alongside their treatment, helping them navigate both clinical and everyday challenges. Engagement with patient advocacy groups further strengthens this ecosystem, ensuring that patient voices and unmet needs are recognized throughout the program. When delivered through a single, connected provider, these support elements work in concert to enhance adherence, confidence, and overall experience during what is often an uncertain period for patients and their families.

APPLYING KEY PRINCIPLES TO EMERGING TRENDS

The evolving landscape of EAPs presents new challenges, but the core principles of clear communication and seamless coordination remain essential. This is particularly true in areas where scientific innovation and commercial considerations add additional layers of complexity to program design and execution. Two emerging trends illustrate how these pressures can intensify the demands placed on EAPs:

- **Charging for products in rare disease EAPs:** If a sponsor chooses to charge for a product in an EAP, they should have clear messaging strategies that explain their rationale and provide detailed cost breakdowns; additionally, navigating reimbursement pathways requires close coordination between sponsors, HCPs, and payers



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SUPPORT YOUR EAP WITH END-TO-END SOLUTIONS

Success in EAPs hinges on clear communication, seamless coordination, and a patient-centric approach. By focusing on raising awareness among healthcare professionals, ensuring transparency of information, and providing continuous support throughout the patient journey, sponsors can create EAPs that truly serve all stakeholders involved.

Uniphar's end-to-end solutions cover the entire spectrum of EAP needs, from clinical development strategy to commercialization. With a team of experienced professionals who understand the perspectives of all parties involved, Uniphar can help you design and implement successful EAPs. From medical communications and site training to nurse-led patient support services, we offer tailored solutions to meet your specific needs.



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