

3 STEPS TO A SUCCESSFUL EXPANDED ACCESS PROGRAM

Conducting an Expanded or Managed Access Program (EAP/MAP), whether under a Treatment IND, Emergency Use Protocol, Compassionate Use or Named Patient Basis program, requires specialized strategies, skills and resources that are different to a conventional clinical trial. There are three key critical considerations to embarking on an EAP:

1

WHEN TO START AN EAP

Timing is driven by when sufficient data exist to assess the risk-to-benefit ratio for patients

- As soon as Phase II data become available
- Or, as late as during the review period for the marketing authorization application

2

WHO IS ELIGIBLE FOR AN EAP

- Patients with life-threatening or severely debilitating disease who are not eligible for, or have no access to clinical trials
- Patients for whom there is no effective marketed treatment
- Patients who have failed marketed treatment or non-drug procedures

3

HOW TO DEVELOP AN EAP

Clearly define scope upfront and ensure the patient population is classified beyond the primary diagnosis and “unmet need”

- Determine any local regulations, processes and requirements
- Consider patient needs e.g., medical history, patient condition
- Identify any limitations on drug supplies, countries and clinicians



MANAGING & INFORMING MULTIPLE STAKEHOLDERS

Consider internal and external stakeholders such as sales teams and patient advocacy groups



LOCAL REGULATORY INTELLIGENCE

Access to local regulatory knowledge / Access to local regulatory intelligence



DRUG DISTRIBUTION

Labelling, importation / exportation requirements

CONSIDERATIONS FOR BUILDING AN EAP OPERATIONAL PLAN:

A nimble operational plan is required to respond to the unique and variable nature of expanded access programs.



RESOURCES

Amount of drug to be supplied, budget, staff required to support and execute program



PROCESSES

Ensure appropriate EAP SOPs are in place to enable efficiency



TECHNOLOGY

A robust platform becomes a worthwhile investment as size of program or portfolio increases

Conducting expanded access programs requires highly efficient, cost-effective systems and procedures to maximize investment return. Moreover, participating physicians tend to not be professional investigators, efficiently supporting their diverse needs, while achieving the study objectives, is a key measure of EAP success.

Through an integrated operational approach, specifically designed for EAPs, PAREXEL provides the experience and critical strategies for the effective management of Expanded Access Programs.

For more information about developing a successful EAP, get in touch today or download our white paper entitled, *Expanded Access Programs: Navigating the When, Who and How to Deliver a Successful Program.*

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