

Expanded Access Programs

Administer a compliant and successful Expanded Access program

Expanded Access Programs (including Named Patient, Early Access, Compassionate Use and Temporary Authorisation for Use (ATU) programs), are being designed to provide patient and physician access to investigational drugs outside of clinical trials and prior to marketing approval and launch. These programs are improving access to drugs for the fulfillment of unmet patient needs in an ethical way.

The rapidly evolving legislative environment (“Right to Try Act”- USA, “21st Century Cures Act”- USA, “Early Access to Medicines Scheme (EAMS)”- UK, etc.), will eventually force all drug manufacturers to publicly disclose their policies and procedures for making such drugs available to patients who are in need. ideaPoint software helps companies manage compliant and successful, local and global Expanded Access Programs so that companies are providing the ability to grant access to the drug(s) while approvals are sought in various countries. Some additional benefits to a well-run and compliant Expanded Access Program supported by ideaPoint web-based software include:



Access to documentation for HCP's and Patients



Access and screen physicians, and develop a network of physicians who have early experience with the drug



Track and report on all decision points and program-related activities, milestones and contract obligations



Comply with evolving country-specific regulatory guidelines & reporting requirements



Consistency but with flexible approach as program scope will constantly change



Maintain a high-level of information security

With ideaPoint, our customers have a guided approach to support their specific selection and management processes and a unified system that provides complete transparency and historic views into evaluations and physician/patient engagements.

ideaPoint software is also entirely configurable, and so able to support our customers' existing processes and evolve with changing requirements and regulatory guidelines.

Our customers tell us that the system is one that their teams actually want to use because they see it add value to their work, without it being a burden, particularly as it automates key workflows that significantly accelerate program management and requires a fraction of the time of ad hoc approaches for record keeping and reporting.

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