WEP

With Every Patient.

COLLECTING REAL WORLD DATA (DATA) IN EXPANDED ACCESS PROGRAMS

Overview

The traditional clinical trial setting is rigid and controlled and the stringent inclusion/exclusion criteria used for these studies produce a homogenous patient population.

Expanded Access Programs (EAPs), on the other hand, allow sponsors to collect RWD that can provide a broader and more diverse representation of the patient population that will use the drug in the real-world setting, once it is approved and commercially available.

When compiled and analyzed, RWD becomes Real World Evidence (RWE) which can be used by companies and key stakeholders to derive scientific conclusions.

The Benefits

Support Clinical Trial Data

- Collect safety and efficacy data that supports what is being collected in the Clinical Trial (CT)
- This data can be submitted to regulators alongside CT data to support product approval
- Especially significant in rare diseases where every dataset is important due to the small patient numbers

Inform Future Clinical Study Efforts

- Gain insight into new patient populations and indications that you are unlikely to get from the CT population
- Understand new outcomes and evaluate whether these are significant and warrant additional clinical studies

Increase Understanding of Study Drug

- Gain further insight into patient compliance and tolerability

- Understand possibility for off-label uses
- Determine value-effectiveness for future drug reimbursement

Increase Awareness Among Stakeholders

- Provide early experience for HCPs and advocacy groups who could be future advocates and users of the approved product
- Raise awareness of your product among patients who could be future clinical trial participants and/or users of your drug

As the need and desire for RWD grows, WEP has built out a team that can service all RWD collection and management needs.

WEP's EDC Capabilities

WEP's preferred EDC system for EAPs is an affordable, 21 CFR Part 11 compliant, intuitive web-based platform that makes data collection compliant and efficient. It has the robustness of commonly used clinical trial EDCs (such as InForm and Rave, etc) but at a reduced cost and set-up time. The capabilities of this system are outlined below:

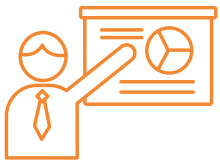
- **Fully Validated 21 CFR Part-11 Compliant**
- **Annex 11 Compliant**
- **HIPAA Compliant**
- **GDPR Compliant**

- **Data Accuracy Assurances**
- **Field functionality and logic checks**
- **MedDRA & WHODrug Certified**

Utilize via Multiple Platforms including Desktop, laptop, tablet, Apple and Android

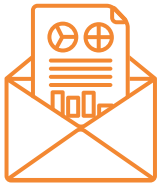
Integration Options with other Site Databases CTMS, eDocs, Scheduling, etc.

Custom Reporting Allows collection from patients



Data Extraction Into .CSV Format for Easy Conversion to Excel or SAS

Intuitive Design for Easy Use by Patients



Text or Email Reminders to Patients or Site Staff When Visits or Data Collection is Due

For companies looking to learn more, we would be happy to provide a demo of this platform and discuss its capabilities in greater detail.