cisiv

Pregnancy Registries

Empowering a CRO with data capture and eConsent tools for a suite of pregnancy registry studies

Synopsis:

Pregnancy registries gather health information from women who take prescription medicines or vaccines when pregnant and compare it with data from women who have not taken medicine during pregnancy. These registries play a vital role in improving safety information for medicines used during pregnancy and informing drug labelling.

Cisiv works closely with a leading global CRO providing the technology to underpin their portfolio of real-world evidence and late-phase studies. The CRO planned a post-marketing observational pregnancy registry study to support the mid-size pharmaceutical sponsor's product in a pain indication.

The single country study aimed to enrol 800 patients and compare the maternal, foetal, and infant outcomes of women exposed to the sponsor's drug during pregnancy with outcomes in an unexposed comparator population. The CRO needed to implement a data capture and eConsent solution that could support the requirements of this study while establishing a streamlined process adaptable for future projects with similar parameters. They turned to Cisiv for support as experts in real world evidence and late phase data capture technology.

Challenge

One of the challenges of pregnancy registry studies of this nature is achieving an adequate sample size. To meet the study's enrolment targets within a relatively limited target population, the CRO needed to employ a range of recruitment tactics to reach the pregnant women and ensure a consent process was available to meet each individual's needs. Their strategy included traditional enrolment through physician referrals and directly targeting patients through a digital and offline advertising campaign.

Therefore, providing the technology to support a range of consent options depending on the enrolment route was vital for the client.

Another characteristic of the study was its use of a Registry Coordinating Centre (RCC) to oversee registry operations, including data entry, data management, analysis, and reporting.

Solution

Cisiv's Baseline Plus delivers a complete suite of tools and workflows within a single platform combining data capture with eConsent and ePro solutions.

Reflecting the integral role of the Registry Coordinating Centre (RCC), the data capture workflows and user roles were designed to allow the RCC professionals to both create records and review the data. Cisiv designed data entry forms to reflect the study objectives and incorporate participant registration information, pregnancy Information, pregnancy and infant outcome information, and Adverse and Serious Adverse Events. All these key parameters could be entered by the RCC at anytime, multiple times.

The most crucial part of the implementation of this study was to accommodate the full range of consent options required to support the overall recruitment strategy.

The Cisiv team successfully implemented a full suite of consent options within the study design including:

- Consent of the patient over the phone through the RCC.
- Consenting the patient through a paper form to be subsequently uploaded into Baseline Plus
- Consent following an invitation from a referring physician.
- Consent when the patient self-enrols after seeing the study advertised.

The flexibility of the Baseline Plus platform was ideally suited to accommodate this hybrid consent approach.

Outcome

This project resulted in positive and close collaboration with the client to tailor the established Baseline Plus data capture and eConsent technology.

We successfully established a standardized, yet configurable approach for the CRO's pregnancy registry studies to account for the full range of consent options and support their recruitment strategy. With a robust overall structure in place, the CRO is now well equipped with the technology to roll out similar studies efficiently and quickly.

About **cisiv**

Cisiv has worked closely with leading pharmaceutical companies for over 15 years developing collaborative web platforms for use in post approval activities. Baseline Plus was developed to meet the need to capture essential real world data in an international setting. The Baseline Plus platform provides a flexible, cost effective, quick to implement and easy EDC system for non-expert users.

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