CASE STUDY:
Medical Device

IMPLANTABLE MEDICAL DEVICE

Global Medical Device Maker Turns to Trialbee's Honey™ Platform to Avoid Post-Approval FDA Penalties

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Challenge:

A leading global medical device company received a warning letter from the United States Food and Drug Administration (FDA), citing a failure to comply with post-approval ePRO (electronic patient-reported outcome assessments) requirements related to a cleared implantable medical device. The FDA letter gave the device maker eight weeks to make corrective measures, namely following up and engaging with the 3,400 patients that participated in the clinical study.

Complicating the issue was the patient population itself; throughout the clinical trial, this group had proven difficult to keep on track. They often missed follow-up visits and procedures or, if they did make these appointments, they were inconsistent in effectively completing their ePROs. Similarly, patients struggled with compliance related to getting required annual follow-up MRIs.

The device maker needed a solution for engaging with these patients in order to improve post-approval ePRO compliance. At risk were costly fines and further punitive action by the FDA, which could include revoking clearance for the device.

Solution:

With a need to act quickly, the medical device leader sought a partner with deep patient engagement experience that could help them get where they needed to be quickly in terms of post-approval ePRO compliance. Trialbee was chosen based on its reputation for excellence in recruitment and engagement. Trialbee worked with the sponsor to identify a strategy for keeping

Study Overview:

- FDA-cleared implantable medical device suffered poor post-approval ePRO and imaging compliance
- Sponsor served with FDA warning letter and given 8 weeks to take corrective measures
- Follow-up with 3,400 patients with record of poor compliance was necessary
- Severe fines from the FDA were possible, along with risk of further actions including revocation of FDA clearance

Outcome:

- Honey™ Platform deployed in just 4 weeks
- Use of the technology focused on keeping patients engaged without undue burden
- Rate of patient compliance went from <50% to >90% in 8 weeks
- The sponsor avoided FDA penalties
- The Honey solution was set up to keep compliance high through patient engagement for the next 10 years

patients engaged in a way that minimizes their burden.

Trialbee deployed its technology solution through its proven recruitment and engagement platform, Honey, in just four weeks. Features of Trialbee's solution included:

- Setting up reminders and easy-to-follow guidance for patients to complete their ePRO assessments and take part in the necessary MRIs
- Configuration of a dedicated web portal to manage multi-touchpoint follow-up for each individual patient's schedule
- The creation of a dashboard where the medical device company can see at-a-glance, granular reporting on each patient's compliance activity, set up for 10 years of data collection

trialbee honey™

For more information or to schedule a demo, email us at solutions@trialbee.com or visit us at trialbee.com

Outcomes:

Despite the short, eight-week deadline, Trialbee was able to help the sponsor deploy the necessary corrective measures in half the time (four weeks).

Prior to Trialbee's involvement, less than 50% of the patient population was compliant with ePRO and MRI requirements. Within eight weeks of deployment, Trialbee's Honey technology increased patient compliance to over 90%.

The sponsor was able to avoid severe FDA penalties and the potential for further punitive actions. Additionally, they were able to demonstrate to regulators that the system Trialbee helped to put in place was set up to assist patients in maintaining high rates of compliance for the next 10 years.

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