CASE STUDY

Intensive Bioresearch Monitoring (BIMO) preparation is key to successful inspection results for sponsors and sites

A medical device manufacturer conducted a successful randomized Investigational Device Exemption (IDE) clinical trial, but at the time of study closure they decided not to file the Premarket Approval (PMA) application for business reasons. However, five years later, the business climate had improved and the company proceeded with its PMA application. The sponsor knew this unique situation would present significant challenges readying the long-closed study sites for the expected FDA BIMO inspections.

The client's challenge

Many of the 30+ clinical study sites had study team turnover, archived study documents, or in some cases, actually ceased to exist. Additionally, Fortrea had also archived the sponsor documents. The sponsor needed to ensure all study documents at all locations were accessible to the FDA and in excellent order and that study sites were well prepared to participate in successful BIMO inspections.

The Fortrea integrated approach

Senior clinical staff at Fortrea worked with the sponsor to develop a multi-tiered plan to prepare both sites and Fortrea for the BIMO inspections.

- First, Fortrea contacted all the sites, updated their contact information and documented the location of the study files and the process required to retrieve them from archives. A list of all sites and the status of their documents was provided to the FDA as part of the PMA application to help the FDA with its BIMO plans

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- Next, Fortrea retrieved its archived study documents, which included most sponsor-required files and the paper case report forms and subject questionnaires, and meticulously cataloged and filed them. Fortrea developed detailed electronic tracking documents to record all items and to allow for rapid retrieval during the inspection. At the time of the PMA submission, Fortrea spoke with all of the sites to notify them of the submission and pending BIMO inspections. Each site was offered customized, proactive training via webinar to ensure that current site personnel were refreshed on the specifics of the study and the site's participation in it. Training also included proper inspection conduct, how to interact collaboratively and effectively with the FDA, and to ensure personnel were comfortable with the inspection process and could answer the FDA's questions honestly and confidently
- Finally, Fortrea trained the principal investigator (PI) specifically on what to expect during the inspection and refreshed his memory about the study and his site's results, adverse events and protocol deviations. Fortrea also offered to come to the site in advance of an announced inspection to facilitate document organization and to be present during the inspection as support to the PI and site staff

The outcome

As expected, the FDA conducted intensive BIMO inspections at Fortrea and two study sites. All inspections went very smoothly with no issuance of a Form 483 for any entity, and the inspectors were highly complimentary to all involved. The FDA noted the level of organization of the documents, quick responses to their questions and document requests, and the professionalism and collaborativeness of the inspections. One of the two sites requested the presence of Fortrea before and during the inspection and the FDA inspector expressed her sincere appreciation for the support Fortrea provided. She acknowledged the challenges for a site to be inspected by the FDA under more typical circumstances, such as during a study or immediately after closure, but also commented on the unique burden placed upon the site during the inspection of a long-closed study. She stated that the FDA recognized that sponsor/CRO support is very helpful to both the site and the FDA in reducing that burden. Well-planned and well-executed preparation for any BIMO inspection is key to a successful outcome for sponsors and sites, and the on-site support of the sponsor or CRO can ensure a successful result especially under unique circumstances, such as this long-closed trial.

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