median

Case study:

FDA Inspection

Leveraging an FDA inspection to demonstrate company-wide commitment, quality, and expertise

Background

The US Food and Drug Administration (FDA) occasionally inspects the operations of clinical investigators to determine if they are running their studies in compliance with all statutory and regulatory requirements. The FDA typically performs this oversight function through on-site inspections.

In 2019, Median learned that it would be subject to an FDA inspection of three studies then in progress — one Phase II study in advanced non-small cell lung cancer begun in 2015 and run from the US, and 2 solid tumors Phase I studies begun in 2016 and run from Canada. The lung cancer study involved 200 sites, more than 336 patients, and more than 3,000 time points. The solid tumors studies involved 10 sites, more than 40 patients, and more than 200 time points.

For all studies, the primary outcome was the objective response rate as assessed by the blinded independent review committee (BICR). Criteria for assessment were RECIST 1.1, RANO, and RANO-BM.

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The Situation:

An FDA inspection is a serious matter that can have significant consequences for any company and place strain on its personnel and operations for weeks.

Because the projects to be audited in this case had been underway for several years, this inspection would be especially challenging as there was more history to review. As required, the FDA notified Median of the upcoming inspection 2 months in advance. The inspection itself would take one week.

The Challenge

The requirements of this inspection were complex. The inspection would cover about 5 years of activity across 210 sites in total. An additional aspect of the challenge was the fact that the 3 trials that would be subject to the inspection were in the process of "fast-tracked" approval, an opportunity to expedite drug review and get to market faster if all goes well during clinical trials — and a reason for heightened stress and anxiety in pharmaceutical companies. (In each of the past 5 years, the FDA has granted fast-tracked approval to at least 60% of new drugs approved.) Finally, a merger and acquisition at the sponsor level had disrupted the sponsor's teams.

All in all, the FDA inspection represented a huge opportunity for Median to demonstrate its ability to work under FDA guidelines and provide a high level of quality for clinical trials.

The Solution

As an imaging contract research organization (iCRO), Median is always prepared for an FDA inspection. However, knowing about this inspection 2 months in advance inspired the team at Median to do everything possible to ensure the FDA would be thoroughly impressed. They resolved to prepare intensively, in the same way that world class athletes, although confident in their abilities, take every opportunity to train and improve.

Preparation for the inspection would be taken on as a project, a vast project every detail of which would be micromanaged. There would be 2 main phases: the preparation and the inspection itself.

Early preparations included:

— Identification of a Median core team

— Evaluation of Median experts' need for external support

— Training of core personnel to fulfill roles and meet challenges specific to the inspection

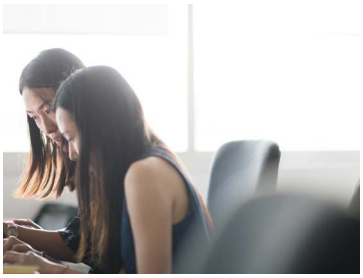
— Creation of a companywide communications plan surrounding the inspection

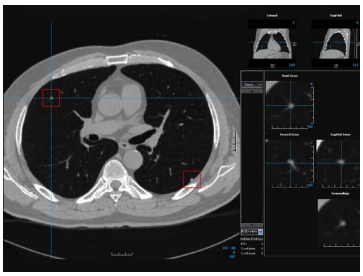
— Evaluation of impacted people at Median (internal stakeholders)

Communications about achievements, main events, follow-up on current actions, issues, requests, warnings, and risk analysis were structured to include weekly reporting, weekly meetings of 30 minutes each, and flash meetings with the core team.

Actions included verification and identification of all sites on the study (documents, training records), essential documents of the study, data, computerized systems and first use of these systems, Median team adequation to QA, SOPs, and study documents. Verification of all locations was also done. Preparations for the onsite audit included preparing rooms and back rooms, logistics, communications during the audit, and the training of people who would be interviewed.

During the actual inspection, the Median team provided daily updates to executive management and to the sponsor's quality assurance team.





The Results

Thanks to the dedication and focus of its multi-discipline team, and an organization-wide commitment to high performance, Median was well prepared for the FDA inspection and passed successfully: Firstly, Median received no 483 letter, the dreaded communication stating that the FDA inspection revealed violations of the US Food, Drug, and Cosmetic At or related Acts. Secondly, the FDA inspectors complimented Median on its exceptional preparedness.

In other results, success with the inspection served to strengthen Median's partnership with the trial sponsor. And finally, internal Median processes that received attention in preparation for the FDA inspection were strengthened moving forward. In short, Median fully realized the daunting challenge of an FDA inspection as an opportunity to demonstrate excellence.

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About Median Technologies

At Median, we transform medical images into meaningful, actionable insights to help better diagnose, treat, and monitor patients. We harness the power of medical images by using the most advanced Artificial Intelligence technologies, to increase the accuracy of diagnosis and treatment of many cancers and other metabolic diseases at their earliest stages and provide insights into novel therapies for patients. Median's Imaging CRO business provides leading oncology clinical trial imaging services, empowering our life sciences partners to accelerate the development and delivery of life-saving cancer treatments with unmatched operational excellence and reliability. And we don't stop there. We are forging the way when it comes to innovative imaging technology, leveraging the latest in AI-powered imaging intelligence to develop actionable insights for sponsors worldwide.

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