PRECISION for medicine

CASE STUDY

Securing FDA approval for a new diagnostic when compared to the "gold standard"

Study synopsis

In diagnostic trials, it is common and often expected to compare performance of a new diagnostic to the "gold standard" based on current standard of care. After planning a study to assess typical measures of sensitivity and specificity, our sponsor was asked by the FDA to modify the primary endpoint used to interpret whether the new diagnostic was sufficiently comparable to the existing gold standard. The sponsor turned to Precision for Medicine to navigate the request.

Challenges

Several issues stood in the way of FDA review of the new diagnostic:

- The study was designed to look at specificity and sensitivity, but in reviewing the data—after the trial was concluded—the FDA requested a different primary endpoint be shown
- The study was not powered to demonstrate efficacy using the revised primary endpoint
- Several divisions of the FDA were involved, each requesting slightly different information

When the FDA receives data they don't understand, requests often go back and forth. Those requests need to be turned around very quickly so as not to extend review times

Solutions

We played a dual role: ensuring that the sponsor had the facts necessary to satisfy the FDA's request and that the data was presented in a way that met FDA standards. To those ends, we:

- Conducted multiple new biostatistical analyses of the study data to derive the estimated standard deviation and confidence interval around the new FDA-requested endpoint
- Worked with the FDA to ensure we provided the level of detail necessary to support the trial as conducted
- Managed communications between the sponsor and FDA and attended multiple FDA meetings

Results

The FDA was able to review the data we provided, verify it and trust it, which allowed it to focus on the interpretative value of the data. Their additional questions were limited to interpretation, not verification, facilitating and streamlining the timeline by several months, and ultimately resulting in FDA approval for the new diagnostic.

We typically provide FDA reviewers with a level of documentation and clarity that they can understand, allowing them to focus on the results rather than on follow-up questions

Rarefied Thinking

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