Introduction

In recent years, the FDA has made what many clinical trial sponsors have seen as an about-face in regulatory guidance, calling on sponsors to move away from the traditional system of 100 percent on-site monitoring of clinical trials and toward a centralized, risk-based approach.

Under this new approach, monitors collect and analyze study data remotely, looking for trends or irregularities that could prompt follow-up, in-person visits to particular sites. The idea, the agency says, is not to eliminate on-site monitoring, but to make use of improvements in technology to make monitoring more efficient and site visits better targeted. Using a risk-based approach, sponsors could focus their monitoring attention on the riskiest elements of a given study — in terms of both study integrity and patient safety — and on the study sites where the most problems are occurring.

The key, experts say, is to take full advantage of the statistical analysis available in a system of centralized monitoring while ensuring that the remaining site visits are as focused and productive as possible.

This report will walk you through the FDA guidelines, share expert advice on how to get the most from both remote and on-site monitoring, and show how to develop a comprehensive data and document management plan . The report will offer a blueprint of what to expect during an FDA inspection of a clinical trial, whether that inspection is focused on a particular study site, the study sponsor, or even the independent review board, each of which will face a different set of questions and document requests when FDA investigators come to call.

Finally, the report will present the results of a recent survey of clinical trial sponsors that shows how the industry is reacting to the risk-based monitoring approach.