

GAO Highlights

Highlights of [GAO-16-304](#), a report to congressional committees

Why GAO Did This Study

In fiscal year 2014, NIH spent nearly \$3.2 billion on clinical trials as part of its research activities. NIH's OD oversees the operations of 27 ICs to ensure that NIH's research portfolio is balanced, not unnecessarily duplicative, and utilizes cross-cutting research. In 2010, IOM made recommendations for clinical trials supported by NCI, one of NIH's ICs. In 2012, NIH was directed to conduct a review of the applicability of IOM's recommendations across all NIH ICs that conduct clinical trials.

A Joint Explanatory Statement accompanying a 2015 appropriations act included a provision for GAO to review how NIH applied the IOM recommendations. This report examines (1) the steps that NIH took, if any, to apply the IOM recommendations across its ICs other than the NCI, and (2) the extent to which NIH's OD uses data to oversee clinical trial activity across the ICs. GAO reviewed NIH documentation on the applicability of the IOM recommendations, data the OD uses to oversee clinical trial activity, and its process for using such data. GAO compared these to federal standards for internal control. GAO also interviewed NIH and IC officials, IOM officials, and stakeholders, such as a group representing researchers.

What GAO Recommends

GAO recommends that the NIH OD (1) finalize data on clinical trial activity that the OD needs to collect from ICs, and (2) establish and implement a process for using those data. HHS concurred with the recommendations.

View [GAO-16-304](#). For more information, contact Linda Kohn at (202) 512-7114 or kohnl@gao.gov.

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Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency

What GAO Found

Although the National Institutes of Health (NIH) assessed the applicability of recommendations made by the Institute of Medicine (IOM) in 2010 to improve clinical trials—studies involving human subjects that test the effects of interventions on health-related outcomes—within one of its Institutes and Centers (IC), NIH did not apply the recommendations across its ICs. In response to a conference report provision that it review the applicability of the IOM recommendations across its ICs, NIH administered a survey to all 24 of the ICs that fund clinical trials and presented the findings at a leadership forum and in a report to Congress. These findings showed that over half of the ICs surveyed indicated that the majority of the recommendations were applicable. NIH decided not to apply the recommendations across its ICs because more analysis was needed before proposing any NIH-wide recommendations, given the variation across ICs. Officials explained that the IOM recommendations were designed for one program within the National Cancer Institute (NCI) and that most ICs do not support clinical trial networks that operate with the size and volume of the program, thus making the recommendations more pertinent to NCI. Leaders from NIH and the ICs indicated that more analysis was needed to account for the ICs' portfolios and management activities. As a result, NIH developed its own recommendations that aimed to enhance its stewardship of clinical trials, including several to improve data collection across the ICs. For example, its recommendation to improve monitoring systems, tools, and processes could assist NIH in identifying additional data that could be collected across the ICs.

NIH's Office of the Director (OD) reviews some data on clinical trial activity across NIH but has not finalized what additional data it needs or established a process for using these data to enhance its stewardship of clinical trials, as intended by NIH's own recommendations. The OD only reviews two types of data related to clinical trial activity on a regular basis: financial data and data on the inclusion of minorities and women. Beyond these data, OD officials review other data from the ICs on clinical trial activity if there is a specific inquiry. Officials from the OD acknowledged that they do not regularly review much data specifically related to clinical trial activity, but they are considering reviewing additional data collected from the ICs to inform the OD's stewardship of clinical trial activity across NIH. However, the OD has not finalized what data it needs from the ICs. In addition, the OD has not established a process that specifies how and when the OD will use the additional data it decides to review. As a result, it is unclear how often the OD will review the data, for what purpose, and what the product of its analysis will be. *Federal Standards for Internal Control* state that agencies need operational and financial data to determine whether they are meeting their goals for effective and efficient use of resources. Given that ICs oversee specific clinical trials, the OD may not need the same data or level of detail collected by ICs. However, until the OD determines which additional data it will review and the process it will use to review these data, NIH is limited in its ability to make data-driven decisions regarding the use of its roughly \$3 billion annual investment in clinical trials.