



March 2016

# NATIONAL INSTITUTES OF HEALTH

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

Accessible Version

# 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](mailto:kohnl@gao.gov).

March 2016

## NATIONAL INSTITUTES OF HEALTH

### 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.

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## Abbreviations

CTWG	Clinical Trials Working Group
HHS	Department of Health and Human Services
IC	institute and center
IOM	Institute of Medicine
NCI	National Cancer Institute
NIH	National Institutes of Health
OD	Office of the Director

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March 10, 2016

Congressional Committees

As part of its mission to improve the nation’s health, the National Institutes of Health (NIH), an agency within the Department of Health and Human Services (HHS), supports research on the effectiveness of various health care interventions, such as medications, therapies, or other clinical treatments. This research includes clinical trials, which are studies involving human subjects that test the effects of interventions on health-related outcomes.<sup>1</sup> In fiscal year 2014, NIH spent nearly \$3.2 billion on clinical trials, an amount representing about 11 percent of the agency’s overall budget, through 24 of NIH’s Institutes and Centers (IC).<sup>2</sup> According to NIH, clinical trials are a critically important component of NIH’s mission and among the most complex and challenging research activities the agency funds. In addition, because they involve human subjects, including some with life-threatening conditions, clinical trials inherently carry more risk than other types of research.

While NIH’s ICs are directly responsible for overseeing the clinical trials they fund, NIH’s Office of the Director (OD), the agency’s central policy office, is responsible for overseeing the operations of the ICs and for program coordination across the ICs, including ensuring that NIH’s research portfolio across the ICs is balanced, not unnecessarily duplicative, and utilizes cross-cutting research.<sup>3</sup> Because of the multi-billion dollar investment associated with clinical trials and the risk to patients who participate in them, NIH has stated that it has an obligation to exercise good

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<sup>1</sup>Specifically, NIH defines clinical trials as research studies in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions—including experimental drugs, treatments, and devices—on health-related biomedical or behavioral outcomes.

<sup>2</sup>According to NIH, in addition to clinical trials, this estimate includes some clinical trial training, fellowships, career awards, and awards for clinical trial infrastructure projects. NIH is composed of 27 ICs, each with its own mission. According to NIH, 24 of the 27 ICs fund clinical trials. NIH officials indicated that NIH’s Clinical Center, which does not fund clinical trials, provides support for clinical trials funded by other ICs.

<sup>3</sup>42 U.S.C. § 282(b)(2)-(3). These responsibilities apply to the NIH Director and therefore the OD, which is led by the NIH Director.

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stewardship over these studies, such as by reviewing data to help set agency-wide policies and priorities. According to NIH, the OD provides leadership to the ICs and helps coordinate research priority-setting activities across the ICs.

One of NIH's ICs, the National Cancer Institute (NCI), asked the Institute of Medicine (IOM) to review NCI's Cooperative Group Program, a component of a clinical trial network that comprised more than 3,100 institutions, 14,000 investigators, and enrolled more than 25,000 patients in clinical trials each year.<sup>4</sup> According to IOM, NCI requested this review to address several challenges faced by the Cooperative Group Program, such as redundancies and inefficiencies in its process for designing, reviewing, and initiating clinical trials. In 2010, IOM released its report detailing its review of the Cooperative Group Program and provided 12 recommendations—referred to in this report as the IOM recommendations—to improve the efficiency and effectiveness of clinical trials supported by the program.<sup>5</sup> For example, IOM recommended that NCI develop and evaluate novel clinical trial designs. NCI has efforts underway to implement each of the recommendations.

A provision in the Conference Report accompanying the Consolidated Appropriations Act, 2012, directed NIH to conduct a review of the applicability of the IOM recommendations to all of NIH's ICs that conduct clinical trials.<sup>6</sup> The Conference Report indicated that the review should examine ways to develop and strengthen NIH-wide policies, with a focus on identifying opportunities to incorporate innovative science, increasing the speed with which clinical trials are initiated and completed, improving the means of setting priorities, and developing better incentives to encourage participation in clinical trials. In March 2013, NIH provided a report to Congress on the findings of its review.

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<sup>4</sup>IOM is a division of the National Academies of Sciences, Engineering, and Medicine, which is a private, nonprofit institution. Clinical trial networks are a group of linked trial sites that may share resources to support clinical trials. In March 2014, the Cooperative Group Program became the National Clinical Trials Network.

<sup>5</sup>IOM. *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*. (Washington, D.C.: the National Academies Press, 2010).

<sup>6</sup>H.R. Conf. Rep. No. 112-331, at 1139 (2011).

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The Joint Explanatory Statement to Accompany the Consolidated and Further Continuing Appropriations Act, 2015, includes a provision for us to review how NIH applied the IOM recommendations across its ICs.<sup>7</sup> 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.

To identify the steps that NIH took, if any, to apply the IOM recommendations across its ICs other than NCI, we reviewed documentation from NIH's Clinical Trials Working Group (CTWG), NIH's Task Force on Clinical Trials Stewardship Reform—referred to in this report as the Task Force, and NIH's OD, such as a presentation on the applicability of the IOM recommendations.<sup>8</sup> We interviewed officials who were involved in determining the applicability of the IOM recommendations across NIH, including officials from the OD. To supplement our understanding of the steps NIH took to apply the IOM recommendations, we interviewed officials from a nongeneralizable selection of 4 of the 24 ICs that fund clinical trials.<sup>9</sup> Our selection included ICs with a range of low, medium, and high levels of funding for clinical trials in fiscal year 2014 and included two ICs with clinical trial networks and two ICs without

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<sup>7</sup>160 Cong. Rec. H9833 (daily ed. Dec. 11, 2014).

<sup>8</sup>The CTWG is a working group that NIH formed in September 2012 to make recommendations to enhance NIH's stewardship of clinical trials. The Task Force is a group that NIH formed in April 2015 to implement the CTWG's recommendations. We excluded efforts taken by NCI to apply the IOM recommendations because these efforts were documented by IOM through two workshop summaries in 2011 and 2013. See, IOM. *Implementing a National Cancer Clinical Trials System for the 21st Century: A Workshop Summary*. (Washington, D.C.: The National Academies Press, 2011) and IOM. *Implementing a National Cancer Clinical Trials System for the 21st Century: Second Workshop Summary*. (Washington, D.C.: The National Academies Press, 2013).

<sup>9</sup>Specifically, we interviewed officials from the National Institute of Child Health and Human Development, the National Heart, Lung, and Blood Institute, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of Biomedical Imaging and Bioengineering.

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clinical trial networks.<sup>10</sup> We interviewed officials from the selected ICs about the applicability of the IOM recommendations to clinical trials funded by their ICs and how NIH assessed the applicability of the IOM recommendations across the ICs. We also interviewed officials from IOM about the IOM recommendations. Finally, we interviewed stakeholders involved in clinical trial activity, such as groups representing pharmaceutical companies and clinical researchers, to obtain their perspectives on NIH's clinical trial activity.

To determine the extent to which NIH's OD uses data to oversee clinical trial activity across the ICs, we reviewed documentation of the data that the OD reviews related to clinical trial activity, such as documentation of the funding provided for each clinical trial supported by the ICs. We compared the types of data the OD reviews on clinical trial activity with the federal internal control standards described in *Standards for Internal Control in the Federal Government*, which specify that agencies should have operational and financial data to determine whether they are meeting their goals.<sup>11</sup> We interviewed OD officials about the process they use to review data on clinical trial activity, and we compared the OD's process with requirements for comparing actual performance to planned or expected results outlined in *Standards for Internal Control in the Federal Government*.<sup>12</sup> To supplement our understanding of how the OD reviews data from IC officials, we interviewed officials from the four selected ICs described above about the data that they provide to the OD and about how the OD uses that information. We also reviewed documentation from the selected ICs on the types of information the ICs collect on clinical trial activity, such as information collected through progress reports submitted to NIH by recipients of NIH clinical trial funding.

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<sup>10</sup>We ranked ICs by their funding for clinical trials in fiscal year 2014 and split them into three equal groups—low (the ICs with allocations in the lowest third), medium (the ICs with allocations in the middle third), and high (the ICs with allocations in the highest third). According to NIH, the allocations for clinical trials at each IC also include some clinical trial related training, fellowships, career awards, and awards for clinical trial infrastructure projects.

<sup>11</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

<sup>12</sup>[GAO/AIMD-00-21.3.1](#).



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We conducted this performance audit from July 2015 through March 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

NIH comprises 27 ICs and an OD and is headed by a presidentially appointed and Senate-confirmed director. NIH funds clinical trials through 24 of its 27 ICs. Each IC has its own mission and generally focuses on specific diseases, systems, organs, or stages in life (e.g., childhood). In addition, ICs each have their own director and staff, which help to support and oversee the IC's work. The OD includes various offices responsible for issues, programs, and activities that span NIH components, such as research initiatives involving multiple ICs. By law, the OD has several responsibilities, including coordinating and overseeing the operation of the ICs and ensuring, in consultation with the ICs, that NIH's research portfolio is balanced, not unnecessarily duplicative, and utilizes cross-cutting research.<sup>13</sup>

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## Clinical Trials Supported by NIH

NIH's ICs support clinical trials predominantly through extramural research—awarding funds to researchers at universities or other research entities through grants, contracts, and cooperative agreements.<sup>14</sup> These ICs use a standard peer review process to help determine which clinical trials and

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<sup>13</sup>42 U.S.C. § 282(b)(2)-(3).

<sup>14</sup>According to NIH, about 95 percent of clinical trials funded by NIH in fiscal year 2014 were extramural research, and about 5 percent were intramural research, which is performed by NIH scientists in NIH facilities.

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other extramural research projects to fund.<sup>15</sup> The size and composition of the ICs' clinical trial portfolios vary substantially, depending on factors such as the IC's budget and mission.

Officials at each IC oversee clinical trial activity within their IC through the review of various reports, correspondence, site visits, and other available information. For example, NIH requires that all grant recipients, including those conducting clinical trials, submit progress reports annually to ICs that describe the major goals of the trial and what activities have been accomplished and that provide financial information. According to NIH officials, IC staff generally use this information to identify potential problems and areas where assistance might be necessary for individual trials, and to help determine whether the IC will continue funding the trial.

While ICs are responsible for determining which clinical trials to fund and for overseeing the progress of individual clinical trials, officials from the OD are responsible for overseeing the operations of the ICs and, in consultation with the ICs, ensuring that NIH's research portfolio across the ICs is balanced, not unnecessarily duplicative, and utilizes cross-cutting research. For example, the OD has indicated that it aims for a balance of short- and long-term research activities across the agency, among other things.

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## Overview of IOM Recommendations

The 2010 IOM report to NCI made 12 recommendations across 4 goals to reduce redundancy and improve the effectiveness and efficiency of the clinical trials supported by the Cooperative Group Program. (See Table 1.)

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<sup>15</sup>When reviewing grant applications for extramural research studies, NIH follows a process of peer review, established by law. This peer review system has two sequential levels of peer review. The first involves panels of experts to assess the scientific merit of the proposed science. The second level, also referred to as Advisory Council review, involves panels of scientists and public representatives who, in addition to scientific merit, also consider the IC's mission and strategic plan goals, public health needs, scientific opportunities, and the portfolio balance of the IC funding the research. After NIH's peer review process is concluded, IC directors make final extramural funding decisions. For more information, see GAO, *National Institutes of Health: Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research*, [GAO-16-13](#) (Washington, D.C.; 2015).

**Table 1: Summary of the Institute of Medicine’s Goals and Recommendations to the National Cancer Institute**

Goals	Recommendation
Consolidation and efficiency: Improve the speed and efficiency of the design, launch, and conduct of clinical trials	Review and consolidate some front office operations of the cooperative groups on the basis of peer review <sup>a</sup> Consolidate back office operations of the cooperative groups and improve processes <sup>b</sup> Streamline and harmonize government oversight Improve collaboration among stakeholders
Science: Incorporate innovative science and trial design into cancer clinical trials	Support and use biorepositories <sup>c</sup> Develop and evaluate novel trial designs Develop standards for new technologies
Funding and support: Improve the means of prioritization, selection, support, and completion of cancer clinical trials	Reevaluate the role of the National Cancer Institute in the clinical trials system Increase the accrual volume, diversity, and speed of clinical trials <sup>d</sup> Increase funding for the Cooperative Group Program
Participation: Incentivize the participation of patients and physicians in clinical trials	Support clinical investigators through training and mentoring, paid protected research time, sufficient resources, and recognition Cover the cost of patient care in clinical trials

Source: IOM. | GAO-16-304

<sup>a</sup>Front office operations refer primarily to the cooperative group scientific committees and statistical offices, which are responsible for activities such as trial design, prioritization, and data analysis. When the 2010 Institute of Medicine report was published, the National Cancer Institute supported a clinical trials system called the Cooperative Group Program, which comprised cooperative groups, such as cancer centers that develop cancer clinical trials and help enroll patients in trials. In March 2014, the Cooperative Group Program became the National Clinical Trials Network.

<sup>b</sup>Back office operations refer to administrative structures and activities that include such things as data collection and management, data queries and reviews, patient registration, and audit functions.

<sup>c</sup>Biorepositories are infrastructures within which biological specimens, such as cells, tissue, or blood, are identified, collected, and stored. Biorepositories allow biological specimens to be used for additional research beyond the original clinical trial for which the specimens were collected.

<sup>d</sup>Accrual refers to the number of patients enrolled in a research study, such as a clinical trial.

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## NIH Assessed the Applicability of the IOM Recommendations and Determined Not to Apply Them across ICs, but Developed Its Own Recommendations

To assess the applicability of the IOM recommendations from a 2010 review of NCI's Cooperative Group Program across the agency, NIH administered a survey to its ICs that fund clinical trials. While NIH decided not to apply the IOM recommendations across its ICs, NIH developed its own recommendations with an aim to enhance NIH's stewardship of its clinical trials, including several recommendations to improve data collection across the ICs.

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## NIH Surveyed ICs to Assess the Applicability of the IOM Recommendations and Determined Not to Apply the Recommendations across ICs

In response to a conference report provision to review the applicability of the IOM recommendations, NIH administered a survey to all 24 of the ICs that fund clinical trials and then aggregated the results.<sup>16</sup> NIH presented these results at an annual leadership forum in September 2012 and reported these results to Congress in March 2013. The survey results showed that over half of the ICs surveyed indicated that 7 of the 12 IOM recommendations were applicable to their IC.<sup>17</sup> For example, 75 percent of the ICs surveyed indicated that the recommendation to increase the volume, diversity, and speed of accrual was applicable.<sup>18</sup>

Similarly, stakeholders we spoke with also indicated that some of the recommendations, such as the ones relating to patient accrual and the development and evaluation of novel trial designs, may be relevant

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<sup>16</sup>Through a provision in the Conference Report accompanying the Consolidated Appropriations Act, 2012, NIH was directed to conduct a review of the applicability of the IOM recommendations from its 2010 report to all of NIH's ICs that conduct clinical trials. H.R. Conf. Rep. No. 112-331, at 1139 (2011).

<sup>17</sup>The seven recommendations that over half of the ICs surveyed indicated were applicable are as follows: (1) streamline and harmonize government oversight; (2) improve collaboration among stakeholders; (3) develop and evaluate novel trial designs; (4) develop standards for new technologies; (5) reevaluate the role of NCI in the clinical trials system; (6) increase the accrual volume, diversity, and speed of clinical trials; and (7) support clinical investigators through training and mentoring, paid protected research time, sufficient resources, and recognition.

<sup>18</sup>Accrual refers to the number of patients enrolled in a research study, such as a clinical trial.

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across NIH's ICs, in addition to NCI. For example, one stakeholder we spoke with said that the recommendation to develop and evaluate novel trial designs is important because it could ultimately lead to trials that are not as costly or lengthy without compromising the information obtained from the trial.

OD officials told us that NIH decided not to apply the IOM recommendations across all of its ICs that fund clinical trials 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 NCI—the Cooperative Group Program—and most ICs do not support clinical trial networks that operate with the size and volume of NCI's Cooperative Group 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.

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**NIH Developed Its Own Recommendations That Aim to Enhance its Stewardship of Clinical Trials, Including Several to Improve Data Collection across its ICs**

Through its CTWG, NIH developed recommendations that aim to enhance its stewardship of clinical trials, including several recommendations to improve NIH's ability to collect data on clinical trial activity across its ICs. According to officials, the CTWG—a working group which included officials from NIH's OD and the ICs—began in February 2013 in response to discussions among NIH officials at the agency's annual leadership forum, where officials presented the results of NIH's survey on the applicability of the IOM recommendations. Although it decided not to apply the IOM recommendations across ICs, NIH officials recognized that they could enhance aspects of NIH's stewardship of clinical trials, and so they developed the CTWG to provide recommendations on how NIH could do so. In August 2013, the CTWG issued eight recommendations intended to enhance NIH's stewardship of clinical trials. (See Table 2.)

**Table 2: National Institutes of Health (NIH) Clinical Trials Working Group Recommendations to Enhance NIH’s Stewardship of Clinical Trials**

Clinical Trials Working Group recommendation	Description of recommendation
1. Improve application, acceptance, and award processes for clinical trials	<ul style="list-style-type: none"> <li>• Institutes and Centers (IC) should establish and apply research priorities when reviewing and awarding clinical trial applications.</li> <li>• ICs could use alternative award mechanisms to manage trial cost and risk.</li> <li>• Applications should be submitted under trial-specific funding announcements which could enhance tracking and analysis across NIH.</li> <li>• Criteria for applications should be redesigned to more adequately assess the scientific merit and potential of applications.</li> </ul>
2. Improve peer review and Advisory Council review <sup>a</sup>	<ul style="list-style-type: none"> <li>• Peer review should be made more rigorous and conducted by appropriate experts such as biostatisticians.</li> <li>• Advisory Council review should address IC clinical research priorities.</li> </ul>
3. Incorporate trial-specific language into Notice of Award <sup>b</sup>	<ul style="list-style-type: none"> <li>• ICs should be strongly encouraged to incorporate language specific to the trial into Notices of Awards, such as language to establish a timeline for start-up.</li> </ul>
4. Improve monitoring systems, tools, and processes	<ul style="list-style-type: none"> <li>• ICs need monitoring systems and tools to ensure accountability of public funds.</li> <li>• Definitions of core elements should be standardized to allow for interoperability across different IC systems.</li> <li>• Data collection should be more frequent than once a year and extend beyond the annual grant progress report.</li> </ul>
5. Train and empower program officers <sup>c</sup>	<ul style="list-style-type: none"> <li>• Program officers need appropriate training in order to properly evaluate clinical trial progress.</li> <li>• Program officers should also have enough administrative authority to implement and enforce warranted action.</li> </ul>
6. Streamline Institutional Review Board review of multi-site studies <sup>d</sup>	<ul style="list-style-type: none"> <li>• Finalize changes to 45 C.F.R. Part 46 Protection of Human Subjects<sup>e</sup></li> <li>• Develop standard language for ICs to use when mandating the use of a single Institutional Review Board.</li> <li>• Create and post a toolbox with information on establishing agreements between research institutions.</li> </ul>
7. Disseminate clinical trial results	<ul style="list-style-type: none"> <li>• Dissemination of results should be a requirement for successful completion of clinical trial funding.</li> <li>• Expand the range of NIH’s ClinicalTrials.gov website to include clinical trial results.</li> <li>• As a term of award, require publication by some specific deadline.</li> <li>• Withhold funding on applications from the grantee institution until sharing requirement is met.</li> </ul>
8. Good Clinical Practice <sup>f</sup> training for investigators and staff	<ul style="list-style-type: none"> <li>• All personnel involved in clinical trials should receive documented Good Clinical Practice training.</li> <li>• Refresher courses should be completed every three years.</li> </ul>

Source: GAO analysis of NIH documents. | GAO-16-304

<sup>a</sup>Advisory Council review is NIH’s second level of peer review that involves panels of experts and leaders of non-science fields, including patient advocates who, in addition to scientific merit, also consider the IC’s mission and strategic plan goals, public health needs, scientific opportunities, and the portfolio balance of the IC funding the research.

<sup>b</sup>A Notice of Award is a document issued to notify a recipient that an award has been made and that funds may be requested from NIH.

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<sup>c</sup>Program officers are officials who monitor the progress of grant awards, such as clinical trials.

<sup>d</sup>An Institutional Review Board is an entity formally designated to review and monitor clinical trials with the intended purpose of protecting the rights and welfare of the research subjects. Institutional Review Boards are generally affiliated with the site of the research, such as a university or medical center.

<sup>e</sup>These changes would require that all domestic clinical trial sites in a multi-site study rely on a single Institutional Review Board review.

<sup>f</sup>Good Clinical Practice, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, is defined as a standard for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials or studies.

Several of the CTWG recommendations aim to improve the data NIH collects from across the ICs. For example, in developing the fourth recommendation to improve monitoring systems, tools, and processes, the CTWG concluded that there is a need for standardized data collected across NIH's ICs that would help NIH identify the factors or characteristics that contribute to a successful clinical trial. The CTWG indicated that one type of additional data that could be collected across the ICs is accrual data—that is, information on the number of patients enrolled in a research study, such as a clinical trial. According to the CTWG, some ICs have their own systems for monitoring clinical trials, which could be used to collect accrual data, while other ICs do not have these systems and instead rely on communication with awardees and grant reports to monitor their clinical trials. The CTWG explained that these different monitoring practices result in variation in the types of clinical trial data currently collected at the IC level.

To implement the recommendations of the CTWG, NIH formed the Task Force in April 2015. Officials on the Task Force told us that they are taking steps to address the CTWG recommendations by developing policies and procedures. For example, officials stated that the Task Force is currently working on identifying a standard set of data on clinical trials that each IC would collect to respond to the CTWG's fourth recommendation to improve monitoring systems, tools, and processes. NIH said that this could improve monitoring systems by ensuring that all ICs collect similar data on clinical trials, which could facilitate analysis of such data across ICs. NIH could not provide an expected date for when the Task Force would complete its work; however, officials expect that the Task Force will continue its efforts at least through July 2016.

Although NIH officials said that the CTWG and the IOM recommendations are not related, we identified similarities between two of the CTWG recommendations and the IOM recommendations. Specifically, the CTWG recommendation to streamline Institutional Review Board review of multi-site studies aligns with the IOM recommendation to streamline

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and harmonize government oversight.<sup>19</sup> Additionally, the CTWG recommendation to provide Good Clinical Practice training for investigators and staff is similar to the IOM recommendation to support clinical investigators through training and mentoring, paid protected research time, sufficient resources, and recognition.<sup>20</sup>

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## NIH's OD Reviews Some Data on Clinical Trial Activity across ICs, but Has Not Finalized What Additional Data it Needs or Established a Process for Using These Data

NIH's OD reviews some data on clinical trial activity across the agency, but has not finalized what other data it needs to enhance its stewardship of clinical trials, as intended by the CTWG recommendations, or established a process for using these data. Specifically, the OD only reviews two types of data related to clinical trial activity on a regular basis: financial data and inclusion data. The OD collects financial data from its ICs to determine how much funding is allocated across all of NIH's clinical research—which include clinical trials as well as other types of research. The OD reviews this information as part of the agency's efforts to develop its annual budget. The OD also reviews inclusion data it collects from the ICs on the enrollment of minorities and women in clinical trials—information which NIH provides to the Congress in a biennial report required by law.<sup>21</sup> However, as we have previously reported, the inclusion data the OD reviews is limited because the data only provide information on aggregate-level enrollment across NIH and for each IC, which may inadvertently mask low enrollment in clinical trials related to specific diseases or research areas.<sup>22</sup>

Beyond financial and inclusion data, OD and IC officials said that the OD does not routinely review additional data on clinical trial activity. Rather, OD officials review data from the ICs on clinical trial activity in response to specific inquiries. For example, OD officials reviewed information from the

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<sup>19</sup>An Institutional Review Board is an entity formally designated to review and monitor clinical trials with the intended purpose of protecting the rights and welfare of the research subjects. Institutional Review Boards are generally affiliated with the institution responsible for the research, such as a university or medical center.

<sup>20</sup>Good Clinical Practice, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, is defined as a standard for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials or studies.

<sup>21</sup>42 U.S.C. § 289a-2.

<sup>22</sup>[GAO-16-13](#).



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ICs on their clinical trial activities in India after regulatory requirements in India changed during the past two years and the officials received an inquiry about it. According to OD officials, ICs are responsible for overseeing the clinical trials they fund and for collecting data for this purpose. Officials from the four ICs we spoke with provided various examples of data on clinical trial activity reviewed at the IC level, such as data on the number of clinical trials funded by the ICs and the amount allocated for each clinical trial per year. While the frequency of these reviews varies, IC officials review these data at least once a year.

While officials from the OD acknowledged that they do not regularly review much data specifically related to clinical trial activity, they are also considering changing this practice and reviewing additional data collected from the ICs to inform the OD's stewardship of clinical trial activity across NIH. According to OD officials, the additional data that they could review may include the standardized data that NIH's Task Force is responsible for identifying. As we previously mentioned, NIH's Task Force is developing a set of standard data that the ICs would collect on the clinical trials they support. Some or all of these data could potentially be used by officials from the OD to review NIH's clinical trial portfolio. For example, OD officials told us that one example of standard data could be accrual data, which could be used by the OD to determine whether or not clinical trials across NIH are enrolling patients according to proposed timelines.

While OD officials have speculated about what additional data from the ICs they may review, the OD has not finalized which of these data the office needs. According to OD officials, they are waiting for the Task Force to complete its efforts to identify a standardized set of data to be collected across 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.<sup>23</sup> Given that ICs oversee the clinical trials they award, the OD may not need the same data or level of detail collected by ICs, or need to review the data with the same

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<sup>23</sup>[GAO/AIMD-00-21.3.1](#).

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frequency. 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 about the use of its roughly \$3 billion annual investment in clinical trials. Furthermore, reviewing operational and financial data could help NIH reach its strategic plan goal of ensuring a continued high return on the public investment in research.<sup>24</sup> Finally, reviewing standard data on clinical trials could help OD officials ensure that NIH meets its responsibility to ensure that its research portfolio is balanced, not unnecessarily duplicative, and utilizes cross-cutting research.

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## Conclusions

As part of its mission, NIH is responsible for exercising good stewardship of its multi-billion dollar public investment in clinical trials. The outcomes of these trials are vital for improving public health and advancing science, as they are used to identify the effects of medications and other health care interventions on people, some with life-threatening illnesses and conditions. Although NIH's ICs are responsible for the clinical trials they fund, federal law requires NIH's OD, in consultation with the heads of the ICs, to coordinate NIH's research portfolio to ensure that it is balanced, not unnecessarily duplicative, and utilizes cross-cutting research. NIH decided not to apply the IOM recommendations across its ICs; however, it does acknowledge the need for enhanced stewardship of its clinical trials and developed its own recommendations for this purpose. Consistent with our finding that NIH's OD only uses some data to oversee clinical trial activity across the ICs, some of NIH's own recommendations recognize the need for additional data. However, NIH's OD has not determined which data it needs or how it will use the data to strengthen its stewardship of NIH's clinical trials and research portfolio. Until the OD identifies what data to review, and how the data will be used and when, NIH is missing an opportunity to maximize the public investment in clinical trials.

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## Recommendations for Executive Action

To enhance its stewardship of clinical trials across the ICs, we recommend that the Secretary of HHS direct the NIH OD to take the following two actions:

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<sup>24</sup>For more information, see the Department of Health and Human Services, National Institutes of Health, *NIH-Wide Strategic Plan: Fiscal Years 2016-2020*, (Dec. 16, 2015).

- 
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.

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## Agency Comments

We provided a draft of this report to HHS for comment. HHS provided written comments, which are reprinted in appendix I. HHS concurred with our recommendations and stated that the agency plans to complete its efforts to identify additional data that will be collected from the ICs on a regular basis. HHS indicated that these data will provide the OD with readily available information on the number, type, and progress of clinical trials funded across the ICs. Although HHS did not specify plans to establish and implement a process for using the data, it said its goal is to complete its current efforts during 2016 and to implement other strategies to enhance the quality and transparency of HHS-funded clinical trials.

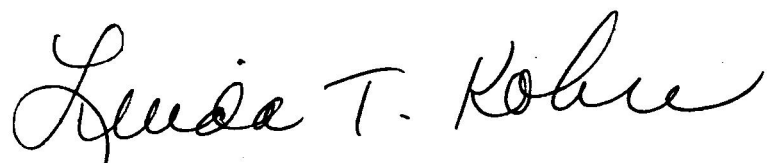
In its comments, NIH also stated that the report over-emphasized NIH's decision to not apply the IOM recommendations across the ICs and under-emphasized the role and scientific expertise of the ICs in managing and overseeing clinical trials. We maintain that the report appropriately describes the steps taken by NIH to assess the applicability of IOM's recommendations and to enhance its stewardship of clinical trials. Further, the report notes that the ICs and the OD both play a critical, but different, role in ensuring the stewardship of clinical trials across the agency. In addition, HHS provided technical comments, which we incorporated as appropriate.

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We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

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If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at [kohnl@gao.gov](mailto:kohnl@gao.gov). Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix II.

A handwritten signature in black ink that reads "Linda T. Kohn". The signature is written in a cursive style with a large initial "L" and a distinct "T" and "K".

Linda T. Kohn  
Director, Health Care

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Committee on Appropriations

United States Senate

The Honorable Tom Cole

Chairman

The Honorable Rosa DeLauro

Ranking Member

Subcommittee on Labor, Health and Human Services, Education,  
and Related Agencies

Committee on Appropriations

House of Representatives

# Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

FEB 25 2018

Linda T. Kohn  
Director, Healthcare  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Ms. Kohn:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*National Institutes of Health: Additional Data Would Enhance the Stewardship of Clinical Trials Across the Agency*" (GAO-16-304).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT "NATIONAL INSTITUTES OF HEALTH: ADDITIONAL DATA WOULD ENHANCE THE STEWARDSHIP OF CLINICAL TRIALS ACROSS THE AGENCY" (GAO-16-304)**

The Department of Health and Human Services appreciates the review conducted by the Government Accountability Office (GAO) on stewardship of clinical trials and the opportunity to provide comments on its draft report.

The GAO report responds to a provision of the Joint Explanatory Statement accompanying the Consolidated and Further Continuing Appropriations Act of 2015 directing GAO to review the steps the National Institutes of Health (NIH) took, if any, to apply the recommendations made by the Institute of Medicine (IOM) in 2010 to the National Cancer Institute (NCI), one of the 27 NIH Institutes and Centers (IC), regarding a specific clinical trials network program, and the extent to which NIH Office of the Director (OD) uses data to oversee clinical trial activity across the ICs. In 2012, NIH was directed in Congressional report language (House Report 112-331 of the Consolidated Appropriations Act of 2012, Public Law 112-74) to undertake an analysis of the relevance and applicability of those IOM recommendations to the other NIH ICs and examine the ways in which we could improve our stewardship of clinical trials in order to ensure that the most appropriate proposals were selected for funding and, once funded, they were carried out in the most efficient way possible.

**Recommendation**

To enhance its stewardship of clinical trials across the ICs, we recommend that the Secretary of HHS direct NIH OD to take the following two actions: (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 Response**

HHS concurs with the two recommendations made in the GAO report. We intend to complete the effort currently underway to identify additional data that will be collected from the ICs on a regular basis in order to provide the OD with readily available information on the number, type, and progress of the clinical trials being funded across the ICs. We will also implement a number of other strategies to enhance the quality and transparency of HHS funded clinical trials. Our goal is to bring these efforts to fruition over the course of the current year.

While we concur with the recommendations, we also want to address several statements that are made in the draft report that warrant comment and clarification. First, it is important to take note of the incongruity between the 2012 report language directed to NIH and the 2015 report language directed to GAO. HHS did not interpret the 2012 report language as assuming the outcome of the analysis would be the adoption of specific approaches IOM thought would work for a unique program of the NCI. Rather, we took the 2012 report language to mean that we should take stock of clinical trial stewardship activities across all the other ICs and, if needed, make improvements that are workable and appropriate across NIH. We responded to the 2012 directive by launching an extensive and multi-faceted effort to review clinical trial stewardship across the ICs, work that resulted in a set of enhancement proposals that take into consideration the diversity of clinical trial portfolios at the different ICs.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT "NATIONAL INSTITUTES OF HEALTH: ADDITIONAL DATA WOULD ENHANCE THE STEWARDSHIP OF CLINICAL TRIALS ACROSS THE AGENCY" (GAO-16-304)**

With regard to GAO's assessment of what steps we took to apply the IOM recommendations, the report makes too much of the fact that NIH decided that the IOM recommendations were not sufficiently relevant or applicable to warrant implementing them across the ICs. While the issues and concerns that the IOM identified about NCI's clinical trial network program had conceptual relevance to a number of the ICs that fund clinical trials, the recommendations themselves were not applicable or workable for all ICs. For example, the IOM recommended that NCI consolidate "front office operations by reviewing and ranking the Groups with defined metrics on a similar timetable and by linking funding to review scores." No other IC organizes its clinical trial networks like the NCI does, and some ICs do not have clinical trial networks. An across-the-board approach based on the IOM recommendations would not be appropriate given the unique nature of NCI's clinical trial network and the fact that the other ICs that support networks do so with a different organizational structure and, again, some support no clinical trial networks. ICs that fund networks also found the IOM proposals for structural and procedural changes to the NCI program to be of limited applicability, given differences in the way their networks are structured and function. The ICs also have systems in place to minimize redundancy and overlap in the generation and review of clinical trial concepts. Additionally, the issues raised by the IOM were less relevant to other types of clinical trials, such as those testing prevention strategies and behavioral approaches, and other clinical trial settings, such as community-based trials.

Given the second part of its charge, the GAO report understandably focuses on the activities and responsibilities of the OD. In so doing, however, the report understates the critical role and scientific expertise of the individual ICs in the management and oversight of clinical trials and overstates the OD's operational role. A more accurate and complete picture of HHS's stewardship activities would reflect the overarching structure and function of the ICs and OD and give greater weight to the responsibilities of the ICs and their activities to monitor, manage, and oversee clinical trials they fund. It would also recognize the breadth and diversity of science as well as how differences in IC missions and budget levels require individualized, IC-based approaches for oversight and management of trials. It would be clear that the OD's focus is to develop and foster overarching initiatives that complement and support the efforts of the ICs. It would acknowledge that while HHS intends to collect a standard set of data elements about NIH-funded clinical trials across NIH portfolio, the ICs will retain primary stewardship responsibilities over their clinical trial portfolios, for setting priorities, and for making decisions consonant with their individual missions.

HHS is committed to completing the efforts underway to enhance our stewardship of this critical component of the scientific enterprise. These enhancements will strengthen our ability to ensure that we are funding clinical trials that have the highest likelihood of improving health, informing clinical practice, or advancing future scientific investigations.



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# Appendix II: GAO Contact and Staff Acknowledgments

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## GAO Contact

Linda T. Kohn, (202) 512-7114 or [kohnl@gao.gov](mailto:kohnl@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Tom Conahan, Assistant Director; Krister Friday; Q. Akbar Husain; Morgan Jones; Rebecca Rust Williamson; and Emily Wilson made key contributions to this report.

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# Appendix III: Accessible Data

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## Agency Comment Letter

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Text of Appendix I:  
Comments from the  
Department of Health and  
Human Services

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Page 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation

Washington, DC 20201

FEB 25 2016

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Director, Healthcare

U.S. Government Accountability Office

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Washington, DC 20548

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Jim R. Esquea

Assistant Secretary for Legislation

Attachment

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Page 2

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