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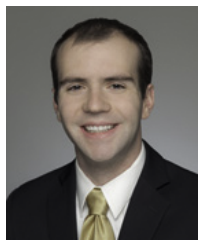
National Institutes of Health Issues a Notice of Proposed Rulemaking on Clinical Trials Registration and a Draft Policy on Registration and Reporting of Results for NIH-Funded Clinical Trials



By Mark Barnes, Tom Bulleit, Albert Cacozza and David Peloquin

On Nov. 19, 2014, the National Institutes of Health (''NIH'') published a long-awaited Notice of Proposed Rule Making setting forth draft regulations interpreting the provisions of the Food and Drug Administration Amendments Act of 2007 (''FDAAA'')[1] that govern clinical trial registration and summary results reporting on ClinicalTrials.gov (the ''Proposed Rule'').[2] That same day, the NIH published a draft policy (the ''Draft Policy'') that would require all NIH-funded clinical trials (including clinical studies that are not testing drugs or devices, and even phase I drug trials) to follow the registration and results-reporting requirements set forth in the FDAAA, even if such trials are not required to be registered under the FDAAA and its newly proposed regulations.[3] If finalized in their current form, these two sets of proposed requirements—one tied to FDAAA jurisdiction and the other to the NIH's authority to impose terms and conditions on its own research

[1] Pub. L. No. 110-85, § 801, *codified at* Section 402 of the Public Health Service Act, 42 U.S.C. § 282(j).

Mark Barnes and David Peloquin are attorneys in the Boston office of Ropes & Gray LLP, and Tom Bulleit and Albert Cacozza are attorneys in the firm's Washington, D.C., office.

[2] *See* National Institutes of Health, Department of Health and Human Services, *Clinical Trials Registration and Results Submission*, 79 Fed. Reg. 69,566 (Nov. 21, 2014).

[3] *See* National Institutes of Health, Request for Public Comments on the Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, NOT-OD-15-019 (Nov. 19, 2014).

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funding—will increase significantly the number of clinical trials for which registration and results reporting on ClinicalTrials.gov is required. We provide below an overview of the requirements of the Proposed Rule and the Draft Policy that are likely to have the most significant impacts on clinical trial sponsors and investigators.

I. Background

ClinicalTrials.gov was created in 2000 to fulfill the mandate of the Food and Drug Administration Modernization Act of 1997 (''FDAMA'') that the NIH create a database listing (i) clinical trials of drugs treating ''serious or life-threatening conditions,'' (ii) investigational new drug applications for expanded access protocols and (iii) experimental treatments available as Group C cancer drugs.[4] Registration of other trials was permitted on a voluntary basis. The primary purpose of the database was to provide a resource for patients suffering from serious diseases and their treating providers to find a clinical trial of an experimental treatment.

The clinical trials registration requirements of the FDAMA were greatly expanded in 2007 with the passage of the FDAAA, which broadened the ClinicalTrials.gov registration requirements to include trials of all drugs, biologics and devices (not just those treating serious or life-threatening conditions), and also introduced a requirement that summary results of registered trials of products approved, licensed or cleared by the Food and Drug Administration (''FDA'') be posted in the database.[5] While both the registration and results-reporting requirements of the FDAAA are self-executing, the act grants the secretary of health and human services (the ''Secretary'') authority to modify by regulation the ClinicalTrials.gov registration requirements, so long as he or she ''provides a rationale for why such a modification improves and does not reduce such clinical trial information.''[6] The FDAAA further directs the Secretary to promulgate regulations governing the ClinicalTrials.gov results submission requirements, including regulations addressing the question of whether summary results reporting should be required for drugs and devices that have not yet been approved, licensed or cleared by the FDA.[7]

Rather than await promulgation of regulations, in 2008 the NIH began requiring registration and results reporting of clinical trials consistent with the FDAAA's self-executing provisions for clinical trials initiated after Sept. 27, 2007, or initiated before that date and ongoing as of Dec. 26, 2007. The NIH made available its interpretation of the FDAAA's provisions governing clinical trial registration and results reporting in a guidance document posted on the ClinicalTrials.gov website, and has required registration and results submission consistent with this document.[8] The Proposed Rule fulfills the Secretary's rulemaking obligations under the FDAAA and expands upon the earlier guidance posted by the NIH on ClinicalTrials.gov regarding clinical trial registration and results reporting requirements.

II. Key Provisions of the Proposed Rule

a. Clarification of Applicability of Registration Requirements

The FDAAA requires registration of a class of clinical trials referred to as ''applicable clinical trials,'' a term which is defined to include both ''applicable drug clinical trials'' and ''applicable device clinical trials.''[9] As explained below, the preamble to the Proposed Rule (the ''Preamble'') clarifies the definition of both of these terms.

Following from the statutory definition, the Proposed Rule indicates that an ''applicable drug clinical trial'' includes a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to Section 505 of the Federal Food, Drug, and Cosmetic Act (''FDCA''), or to Section 351 of the Public Health Service Act.[10]

The Preamble explains that a clinical investigation ''includes any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects'' and will be considered ''controlled'' if the investigation is designed to permit a comparison of a test intervention with a control, regardless of whether the control is ''concurrent,'' *e.g.*, a multiple-arm clinical trial, or ''non-concurrent,'' *e.g.*, a single-arm trial in which baseline data of the participants themselves or existing patient records provide the control, also referred to as ''historical control.''[11] The Preamble further elaborates that a drug is subject to Section 505 of the FDCA or to Section 351 of the Public Health Service Act if it is the subject of an approved New Drug Application (''NDA'') or licensed biologics license application (''BLA''), or an approved NDA or licensed BLA would be required in order for the drug or biologic to be legally marketed, such as an investigational drug for which an investigational new drug application (''IND'') is required prior to shipment of the drug to a clinical trial site.[12] The Preamble clarifies that even clinical trials having no sites within the U.S. may become subject to the FDAAA's registration requirements if the drug under investigation is manufactured in the U.S. and an IND is required for export of the drug.[13]

The Proposed Rule defines ''applicable device clinical trial'' consistent with the statutory language of the FDAAA as:

> (I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the [FDCA] against a control in human

[4] *See* Pub. L. No. 105-115, § 113. Expanded access protocols allow for an investigational drug or investigational device treating an immediately life-threatening condition to be made available for treatment purposes. *See* 21 U.S.C. § 360bb(c). Group C cancer drugs are investigational study drugs showing ''evidence of relative and reproducible efficacy in a specific tumor type'' that are distributed by the NIH under National Cancer Institute protocols for treatment, as opposed to research, purposes. *See* FDA, Treatment Use of Investigational Drugs, Guidance for Institutional Review Boards and Clinical Investigators, *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126495.htm.

[5] *See* 42 U.S.C. § 282(j)(3)(A).

[6] *See* 42 U.S.C. § 282(j)(2)(A)(iii).

[7] *See* 42 U.S.C. § 282(j)(3)(D)(ii)(II).

[8] *See* FDAAA 801 Requirements, https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhenDoINeedToRegister.

[9] *See* 42 U.S.C. § 282(j)(1)(A)(i).

[10] *See* Proposed 42 C.F.R. § 11.10, 79 Fed. Reg. at 69,667.

[11] *See* 79 Fed. Reg. at 69,574.

[12] *See id.* at 69,601-602.

[13] *See id.*

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subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure is related to feasibility and not to health outcomes); and (II) a pediatric postmarket surveillance as required under section 522 of the [FDCA].[14]

In expanding upon this definition, the Preamble explains that the term ''clinical study'' means an ''investigation in which a device is used in one or more human subjects,'' with the term ''human subject'' including human subjects on whom or on whose specimen a device is used, except that de-identified human specimens will be excluded from the definition of ''human subjects.''[15] Consistent with the definition of ''applicable drug clinical trial,'' the Preamble explains that a device is considered to be compared against a control both in studies using concurrent controls and those using non-concurrent controls. The Preamble also clarifies that the phrase ''[a] device subject to section 510(k), 515, or 520(m) of the [FDCA]'' includes devices requiring (1) a finding of substantial equivalence under Section 510(k), (2) an order approving a pre-market approval application under Section 515 of the FDCA, or (3) a humanitarian device exemption under Section 520(m) of the FDCA before they may be legally marketed in the U.S.[16] The Preamble further explains that the second part of the definition, *i.e.*, ''pediatric postmarket surveillance,'' encompasses *any* pediatric postmarket surveillance required under Section 522 of the FDCA, and thus may include surveillance taking a variety of forms, ranging from literature reviews to controlled clinical trials.[17] As with drug trials, the Preamble clarifies that a device trial taking place entirely outside of the U.S. may be an ''applicable device clinical trial'' subject to the FDAAA's registration requirements if the device under study is manufactured in the U.S.[18]

b. Expansion of Registration Information

The FDAAA requires that the ''responsible party''[19] provide four categories of information when registering an ''applicable clinical trial'' on ClinicalTrials.gov: (i) *descriptive information*, such as a brief summary, the expected start date and the primary disease being studied; (ii) *recruitment information*, including eligibility criteria, overall recruitment status and individual study sites and their status; (iii) *location and contact information*, such as the name of the sponsor and the responsible party; and (iv) *administrative data*, including the FDA IND/IDE numbers and the unique protocol identification number.

The Proposed Rule largely parrots the statute with respect to the information required upon registration, but introduces four modifications.[20] The first modification involves requesting additional details regarding certain data elements required by statute, such as requiring the IND/IDE element to include the name of the FDA center issuing the IND or IDE, the IND or IDE number and any serial number that has been assigned to the filing. The second modification requires the responsible party to indicate whether the product under study is manufactured in the U.S., because as discussed in section II.a *supra,* such information may help to determine whether a trial carried out entirely outside of the U.S. is an ''applicable clinical trial.'' The third modification introduces new data elements designed to help users more easily search the database, such as by requiring the submission of other current and former names of the studied intervention(s). A final modification involves the addition of a data field titled ''ethical and scientific review status'' in which the responsible party must indicate whether the trial has undergone review by an institutional review board or whether the trial is exempt from such a requirement under applicable law.[21]

c. Expansion of Results Reporting Requirements

The most significant change contained in the Proposed Rule concerns the requirement that summary results from trials involving drugs and devices that have not yet been approved, licensed or cleared by the FDA be submitted to ClinicalTrials.gov. This is a departure from current practice, which requires summary results reporting only for trials involving products approved, licensed or cleared by the FDA. The Preamble explains that the NIH is pursuing this change because it believes that the public availability of results from trials involving unapproved, unlicensed and uncleared products may:

(1) mitigate the bias that results if sponsors or investigators choose to publicize, through journal publication or other means, only those trials that show beneficial effects of drugs or devices;

(2) protect human subjects by preventing repetitive clinical trials that are unnecessary or that are potentially harmful, as demonstrated by previously released results of similar clinical trials;

(3) assist patients and their care providers in deciding whether to participate in a clinical trial of an unapproved product by providing them with information about the results of trials studying similar products;

(4) provide a basis for comparison of the unapproved version of a product with the version that ultimately receives approval, or with products from the same class that already have received approval; and

(5) satisfy an ethical obligation to clinical trial participants by permitting knowledge gained in the clinical trial to be available for use in advancing biomedical science.[22]

The NIH's stated rationale for expansion of the summary results reporting requirement demonstrates that while ClinicalTrials.gov remains a tool to assist patients

[14] *See* Proposed 42 C.F.R. § 11.10, 79 Fed. Reg. at 69,667.
[15] *See* 79 Fed. Reg. at 69,599.
[16] *See id*. at 69,600.
[17] *See id.* at 69,601.
[18] *See id*. at 69,600.
[19] The term ''responsible party'' is defined in the FDAAA as ''(i) the sponsor of the clinical trial . . ., or (ii) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.'' 42 U.S.C. § 282(j)(1)(A)(ix). The Proposed Rule defines the term in substantially similar fashion. *See* Proposed 42 C.F.R. § 11.10, 79 Fed. Reg. at 69,667.
[20] *See* Proposed 42 C.F.R. § 11.28, 79 Fed. Reg. at 69,671.
[21] *See* 79 Fed. Reg. at 69,575.
[22] *See id*. at 69,577.

in finding trials studying their disease, it increasingly is focused on transparency for the sake of advancing science.

Consistent with the timeline currently in place for submission of summary results from trials of approved, licensed and cleared products, the Proposed Rule provides that results from trials of unapproved, unlicensed and uncleared products must be made not later than one year after the completion date of the clinical trial, with ''completion date'' defined as the ''the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome.''[23] Importantly, the Preamble recognizes that submission of results for unapproved, unlicensed and uncleared products may result in a competitive disadvantage to clinical trial sponsors and product manufacturers by requiring the release of information regarding product development that could be of commercial use to competitors. The Proposed Rule thus permits the responsible party to seek a delay of the summary results reporting requirement in instances in which the sponsor or manufacturer intends to seek initial approval, licensure or clearance for (i) the product studied in the trial, or (ii) a new use, studied in the trial, of a product that already has been approved, licensed or cleared for another use.[24] If the product currently is not approved, licensed or cleared for *any* use, the responsible party seeking a delay in the results reporting timeline must submit to ClinicalTrials.gov a certification that the sponsor is either seeking, or intends to seek, FDA approval, licensure or clearance of the product under study.[25] In such a case, the results submission requirement will be delayed until 30 calendar days from *the earlier of* the date on which (1) FDA approves, licenses or clears the drug or device for any indication studied in the applicable clinical trial, or (2) the marketing application or premarket notification is withdrawn without resubmission for 210 calendar days. Substantially similar requirements exist for certifications seeking delay in instances in which approval is sought for a new use of an already approved product, except that in such cases the responsible party must certify that the sponsor has submitted or intends to submit an application to the FDA seeking approval, licensure or clearance of the use being studied *within one year* of filing the certification.[26]

Under either of the two pathways for delay discussed above, the certification must be submitted before result submission would be required for the trial in the absence of certification, *i.e.*, one year from the trial's ''completion date.'' The Proposed Rule further provides that the maximum delay in results submission due to a certification is two years from the date on which the certification is submitted.[27] Accordingly, a responsible party may have at most three years from an applicable clinical trial's completion date to submit summary results, assuming that the party waits until shortly before the one-year anniversary of the completion date to submit the certification. The Preamble notes that this three-year time frame ''reflects a balance between the need to protect competitive advantage and the desire for public access to clinical trial results,'' and further explains that ''[w]ithin this time frame a sponsor or manufacturer would often make a decision about whether to initiate another clinical trial or submit a marketing application or premarket notification to FDA.''[28] The Preamble explains that competitive concerns are lessened where a sponsor decides to initiate another clinical trial of a product, since such clinical trial generally would be an ''applicable clinical trial'' for which registration on ClinicalTrials.gov is required, thereby alerting competitors of the sponsor's product development plans.[29]

The FDAAA also permits the NIH director to grant an extension of the clinical trial summary results reporting deadline in circumstances in which the responsible party submits a written request demonstrating ''good cause'' for the extension and provides an estimate of the date on which the information will be submitted.[30] Neither the FDAAA nor the Proposed Rule define ''good cause,'' however, the Preamble indicates that the NIH periodically will update ClinicalTrials.gov with a list of reasons the agency generally considers to be ''good cause'' and ''not good cause'' for granting extensions, noting that the list of reasons qualifying as ''good cause'' is likely to be extremely limited.[31] The Preamble further explains that to date, the NIH has identified only two situations that would constitute ''good cause'' for an extension of the results reporting deadline:

(1) the need to preserve the scientific integrity of an applicable clinical trial for which data collection is ongoing, *e.g.*, where release of results information for the primary outcome would bias ongoing collection of data on the secondary outcome; and

(2) emergencies that prevent timely submission of clinical trial results information, *e.g.*, where a clinical trial site is affected by a natural disaster.[32]

The Preamble also lists two examples of situations that generally would *not* constitute good cause: (1) pending publication, because the International Committee of Medical Journal Editors has clarified that submission of results to ClinicalTrials.gov will not be considered ''prior publication,'' and (2) delay in data analysis for unspecified reasons.[33] If the request for a good

[23] *See* Proposed 42 C.F.R. § 11.44, 79 Fed. Reg. at 69,674. The Proposed Rule differentiates between the ''primary outcome'' (or ''primary outcome measure'') which is defined as ''the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation,'' and ''secondary outcome measure,'' which is defined as ''an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified plan for evaluating the effects of the intervention or interventions under investigation in a clinical trial.'' *See* Proposed 42 C.F.R. § 11.10, 79 Fed. Reg. at 69,668-69. The Proposed Rule recognizes that data for secondary outcomes may be collected following the trial ''completion date'' and thus provides that data on ''secondary outcome measures'' are required to be submitted not later than one year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for a given secondary outcome measure. *See* Proposed 42 C.F.R. § 11.44(d), 79 Fed. Reg. at 69,635, 69,674.

[24] *See* Proposed 42 C.F.R. § 11.44(b)-(c), 79 Fed. Reg. at 69,674.

[25] *See* Proposed 42 C.F.R. § 11.44(c), 79 Fed. Reg. at 69,674.

[26] *See* Proposed 42 C.F.R. § 11.44(b), 79 Fed. Reg. at 69,674.

[27] *See* Proposed 42 C.F.R. § 11.44(b)(2), (c)(2).

[28] *See* 79 Fed. Reg. at 69,580.

[29] *See id.*

[30] *See* 42 U.S.C. § 482(j)(3)(E)(vi).

[31] *See* 79 Fed. Reg .at 69,636.

[32] *See id.* at 69,636-37.

[33] *See* 79 Fed. Reg. at 69,637.

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cause extension is denied, the responsible party may appeal such denial by writing an appeal letter to the NIH director. Notably, unlike the certifications discussed in the previous paragraph which limit delays in results submission to two years from the date of certification, there is no explicit limit on the length of a good-cause extension, and a responsible party may request more than one good-cause extension for the same applicable clinical trial.[34]

The NIH recognizes in the Preamble that announcements of the delay of results could themselves reveal confidential information of the sponsor. For example, announcement that results are delayed due to a certification under proposed Section 11.44(b) could inform competitors that the sponsor intends to seek FDA approval for the use of a drug or device analyzed in the applicable clinical trial. In response to this concern, the Preamble provides that where results are delayed due to a certification or a good-cause extension, ClinicalTrials.gov will indicate merely that the results have been delayed, but it will not provide the reason for such delay.[35]

Also of note with regard to results reporting, the Preamble observes that results reporting requirements for clinical trials are spreading globally. Accordingly, the Preamble indicates that the NIH has worked with the European Medicines Agency (''EMA'') to harmonize to the greatest extent possible the summary results information required for submission to ClinicalTrials.gov with the information the EMA requires to be reported to the EU Clinical Trials Register (''EudraCT'').

d. Voluntary Registration

In addition to the changes to mandatory registration and results submission of applicable clinical trials discussed in sections II.b and II.c, *supra*, the Proposed Rule also contains provisions governing the ability of sponsors voluntarily to register and/or submit results from clinical trials for which such actions are not obligatory. Specifically, the Proposed Rule requires that if a responsible party voluntarily registers a clinical trial, it must submit the complete set of registration information that would be required if registration of the trial were mandatory.[36] The Proposed Rule also contemplates that a responsible party may choose voluntarily to submit results for a clinical trial that had not been registered previously on ClinicalTrials.gov. In such an instance, the Proposed Rule requires that the responsible party submit a list of basic registration information along with the results.[37]

The Preamble indicates a concern on the part of the NIH that manufacturers of products may use voluntary results submission as a means to register and report results for trials showing positive benefits of their products, while avoiding reporting results of trials with results unfavorable for their products.[38] To prevent such a practice, the Proposed Rule requires that when a manufacturer (but not other types of responsible parties) voluntarily submits results information of a clinical trial to ClinicalTrials.gov, the manufacturer also must submit results information for any clinical trials that are required to be submitted to the FDA under the Public Health Service Act or the FDCA in an application or report for licensure, approval or clearance of the product for the use studied in the voluntarily submitted trial.[39] The Preamble notes that this requirement is likely to impact primarily clinical trials that are exempt from mandatory reporting because of their age (*i.e.*, trials initiated on or before Sept. 27, 2007, and reaching completion prior to Dec. 26, 2007), since most newer trials submitted to the FDA in support of an application for licensure, approval or clearance would be subject to the FDAAA's mandatory reporting requirements.[40]

III. Draft Policy

On the same day as it made available for public inspection the Proposed Rule, the NIH published for public comment a draft ''Policy for Registration and Reporting of Results for NIH-Funded Clinical Trials.''[41] The Draft Policy states that it is ''intended to complement the statutory mandate under Title VIII of [FDAAA] that requires registration and submission of summary results for certain clinical trials, whether funded by NIH or other entities, to ClinicalTrials.gov.''[42] Under the policy, all NIH-funded awardees and investigators conducting clinical trials that are funded in whole or in part by the NIH will be required to register such trials on ClinicalTrials.gov and to report summary results therefrom on ClinicalTrials.gov as if the trials were subject to the FDAAA.[43] The Draft Policy does not specify an effective date, instead noting that a separate effective date will be established for grant applications, contracts and intramural research projects.

The Draft Policy defines the term ''clinical trial'' as ''a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.''[44] Accordingly, the Draft Policy's definition of ''clinical trial'' is broader than that of the FDAAA and thus potentially will require registration and summary results reporting from trials of surgical techniques and other intervention types that fall squarely outside of the FDAAA's registration requirements. Also of note, the Draft Policy indicates that the ClinicalTrials.gov reporting requirements will apply ''regardless of study phase,'' and thus it appears that phase I drug trials will be included in the reporting requirements, unlike clinical trials that are subject to the FDAAA's registration and reporting requirements independent of the Draft Policy.[45] The NIH provides no express justification for this distinction from the FDAAA's requirements, although presumably the NIH is simply

[34] *See* Proposed 42 C.F.R. § 11.44(e), 79 Fed. Reg. at 69,674.
[35] *See* 79 Fed. Reg. at 69,638.
[36] *See* Proposed 42 C.F.R. § 11.60(a)(2)(i)(A), 79 Fed. Reg. at 69,677-78.
[37] *See* Proposed 42 C.F.R. § 11.60(a)(2)(i)(B), 79 Fed. Reg. at 69,678.
[38] *See* 79 Fed. Reg. at 69,648.
[39] *See* Proposed 42 C.F.R. § 11.60(a)(2)(ii), 79 Fed. Reg. at 69,678.
[40] *See* 79 Fed. Reg. at 69,649.
[41] *See* National Institutes of Health, Request for Public Comments on the Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, NOT-OD-15-019 (Nov. 19, 2014) [hereinafter ''Draft Policy''].
[42] *See* Draft Policy at 2-3.
[43] *See* Draft Policy at 3.
[44] *See* Draft Policy at 3.
[45] *See id*.

seeking here to impose more rigorous transparency requirements for clinical trials funded by taxpayer dollars. The Draft Policy recognizes that a clinical trial funded by the NIH also may be an ''applicable clinical trial'' subject to the FDAAA's registration and reporting requirements, noting that in such situations only one entry on ClinicalTrials.gov will be required.[46]

In discussing the rationale for the new policy, the Draft Policy discusses the ability of shared clinical trial information to drive scientific progress, optimize the return on the nation's investment in clinical trials, fulfill clinical trial subjects' expectation that the risk they undergo through trial participation will contribute to generalizable knowledge of human health and increase public trust in research. This is quite different than the initial justification for ClinicalTrials.gov of providing a tool for patients to locate a clinical trial studying their disease or condition, and demonstrates the extent to which clinical trials transparency rather than the needs of particular patients increasingly has become the primary rationale for ClinicalTrials.gov. Moreover, the Draft Policy appears to be part of a broader movement on the part of the NIH to increase data sharing from all NIH-funded research.[47]

IV. Conclusion

Seven years following the passage of the FDAAA, the Proposed Rule represents the first rulemaking by the NIH to codify in regulation the registration and results reporting requirements for ClinicalTrials.gov. While the Proposed Rule largely repeats the statutory text and the NIH's current guidance governing ClinicalTrials.gov registration and summary results reporting requirements, it introduces significant new requirements for trials of unapproved products and thereby will increase the number of trials for which results must be reported. The NIH has indicated, by allowing a certification process for delay of the results submission deadline, that it is sensitive to the possibility that reporting of results for such trials may have anti-competitive effects; however, it remains to be seen the extent to which such efforts will effectively allay fears of clinical trial sponsors that the new results reporting requirements will make valuable, strategic information available to competitors.

The Draft Policy represents a continuation of the NIH's efforts to increase data sharing requirements for all research funded by the NIH and also provides further evidence of the transformation of ClinicalTrials.gov from a database of clinical trials available for patient enrollment to a vehicle for clinical trials and scientific data transparency. Because the Draft Policy requires registration of, and results submission from, phase I clinical trials and trials of interventions not subject to FDA jurisdiction, the Draft Policy, if finalized, will expand significantly the number of trials for which information is included on ClinicalTrials.gov, while also creating a disparity regarding registration requirements depending on funding source.

We close by noting that those wishing to submit comments on the Proposed Rule and the Draft Policy must do so by Feb. 19, 2015.

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[46] *See id.*

[47] *See, e.g.*, NIH Genomic Data Sharing Policy (Aug. 27, 2014) (requiring that the results of all NIH-funded research that generates large-scale human or non-human genomic data be contributed to an NIH-designated repository from which it may be made available to other researchers).

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