Hogan Lovells

Just One More Day: Compliance Deadline for New ClinicalTrials.gov Regulations is Tuesday, 18 April 2017

17 April 2017

On 21 September 2016, the Department of Health and Human Services (HHS) published a final rule that clarified and expanded the requirements for clinical trial registration and results submission on the ClinicalTrials.gov website. The effective date of the final rule was 18 January 2017. We are issuing this alert to remind our clients that responsible parties must comply with the new ClinicalTrials.gov requirements by ***Tuesday, 18 April 2017.***

We previously outlined the contents of the final rule in another client alert[1] and related blog post[2]. The new regulation created, among other things, substantially revised results posting requirements, as well as new obligations to submit a separate expanded access record for any investigational drug or biological product for which expanded access is available. Those new requirements are briefly summarized below.

Expanded Results Posting Requirements

For applicable clinical trials completed on or after 18 January 2017, the final rule adds certain new requirements for the submission of results information. These new requirements include:

- The submission of race and ethnicity information for study participants, if collected under the study protocol.
- Descriptions of the metrics used to characterize the specific outcome measures used in the study.
- The submission of the protocol and statistical analysis plan.
- Adverse event information on all-cause mortality, with the number and frequency of deaths due to any cause by arm or comparison group.

New Requirements for Expanded Access Records

If the responsible party for an applicable clinical trial is both the study sponsor and the manufacturer of the investigational drug or biological product, and if the product is available for any type of expanded

[1]See https://www.hoganlovells.com/en/publications/it-s-final-expanded-registration-and-results-submission-requirements-for-clinicaltrials-gov.
[2]See http://www.hlregulation.com/2016/09/29/compliance-deadlines-for-new-clinicaltrials-gov-requirements-explained-what-results-to-post-and-when/

access, that party must submit a separate expanded access record which includes details about how to obtain expanded access to that investigational product. Only one expanded access record should be created for any given product.

When creating a separate expanded access record, under the Expanded Access Type element, the responsible party must set forth the type(s) of expanded access for which the product is available (*i.e.*, individual patient, intermediate, or treatment use) and, depending on the type of program, must submit different categories of information.

After the separate expanded access record is created for an investigational product, a National Clinical Trial (NCT) number will be assigned to the record. The responsible party must update all ClinicalTrials.gov entries involving the investigational product to include the expanded access record's NCT number. This NCT number should also be included in the registration information for any future clinical trials involving that product.

* * * * *

If you have any questions about the new ClinicalTrials.gov requirements, please do not hesitate to contact one of the authors of this client alert or other lawyers you work with at Hogan Lovells.

Contacts

Robert F. Church
Partner, Los Angeles
Tel +1 310 785 4646
robert.church@hoganlovells.com

Bert Lao
Senior Associate, Los Angeles
Tel +1 310 785 4712
bert.lao@hoganlovells.com

Justin Yu
Associate, Los Angeles
Tel +1 310 785 4642
justin.yu@hoganlovells.com