From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: RE: CT.gov reporting requirements
Date: Wednesday, June 14, 2017 11:21:00 AM

Good morning,

Please see the FAQ page from the ClinicalTrials.gov website here https://clinicaltrials.gov/ct2/manage-recs/faq#42CFRPart11 . There is a question and answer at the bottom of the page regarding expanded access which directly addresses your question. The text is below.

"Who should submit an Expanded Access record?

The final rule clarifies that expanded access (EA) use of a drug, biological, or device product is not considered an "applicable clinical trial" (ACT) under the definition in 42 CFR 11.10 (81 FR 65009-10). Thus, the submission of clinical trial registration and results information for EA use would not be required by 42 CFR 11.22 and 42 CFR 11.42.

However, for "applicable drug clinical trials" that are required to submit the registration information specified in 42 CFR 11.28, and the responsible party is both the drug manufacturer and trial sponsor, information on the availability of investigational drug products for expanded access is required to be submitted as part of the registration information under 42 CFR 11.28(a)(2)(ii)(H). In addition, an expanded access record must be submitted as required under 42 CFR 11.28(c) to provide details about how to obtain access to the investigational drug (including biological) product. The regulations at 42 CFR 11.64(a)(1)(ii)(D) and (E) requires this availability of expanded access and expanded access record information to be updated. More information about the expanded access submission requirements is available in the final rule preamble. (81 FR 65059-62)"

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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Office of Good Clincial Practice
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Monday, June 12, 2017 1:53 PM
To: CDER DRUG INFO
Subject: CT.gov reporting requirements

Hello,

I was informed at last week's HCCA research compliance conference that expanded access INDs (single pt. INDs, expanded use protocols) need to be registered in CT.gov. This is compatible with information from the CT.gov website section "Registering Expanded Access Records": https://clinicaltrials.gov/ct2/manage-recs/how-register

FDA guidance from last week seems to indicate that expanded access INDs (single pt. INDs, expanded use protocols) do not need to be registered in CT.gov:

https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Do investigator-initiated (not pharma) expanded access INDs (single pt., expanded/compassionate use) need to be registered in CT.gov?

Thank you for your guidance.

[redacted]

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