



VIA E-MAIL

Oklahoma Medical Research Foundation
Attn: Tim Mather, Ph.D., Director of Educational Services/Compliance Officer
825 NE 13th Street
Oklahoma City, Oklahoma 73104
Tim-Mather@omrf.org

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2020-122
NCT02270957 and NCT01781611

Dear Dr. Mather:

Based on an initial review of Food and Drug Administration (FDA) records, information from the ClinicalTrials.gov data bank operated by the National Library of Medicine (a part of the National Institutes of Health), and any available public information, it appears that Oklahoma Medical Research Foundation is the “responsible party”¹ for the above-identified clinical trials, which appear to be “applicable clinical trials”² subject to the requirements of section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date of the applicable clinical trial, unless the responsible party has submitted a certification of delay.³

FDA has identified potential noncompliance related to the above-identified clinical trials:

¹ See section 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of *responsible party*.

² See section 402(j)(1)(A)(i) and (iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i) and (iii)) and 42 CFR 11.10 for the definition of *applicable clinical trial*.

³ See section 402(j)(3)(E) of the PHS Act (42 U.S.C. 282(j)(3)(E)) and 42 CFR 11, subpart C for results information submission requirements.

- “Clarification of Abatacept Effects in Systemic Lupus Erythematosus (SLE) With Integrated Biologic and Clinical Approaches (The ABC Study),” evaluating the efficacy of abatacept in subjects with lupus arthritis and other manifestations of lupus
- “Dipyridamole Assessment for Flare Reduction in Systemic Lupus Erythematosus (SLE) (DARE),” evaluating the efficacy of dipyridamole with aspirin in subjects with systemic lupus erythematosus (SLE)

It appears that results information for the referenced applicable clinical trials has not been submitted to the ClinicalTrials.gov data bank. Your organization should review its records of these clinical trials and determine whether your organization submitted all required results information. If your organization determines that results information is required and due for these clinical trials, please submit the results information promptly.

Failure to submit clinical trial information required under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), including information required under the regulations found in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(jj)(2)). FDA intends to further review and assess the above-identified clinical trials beginning 30 calendar days after you receive this letter. If FDA determines that your organization is not in compliance with all applicable requirements of section 402(j) of the PHS Act (42 U.S.C. 282(j)) and 42 CFR part 11, your organization may receive from FDA a Notice of Noncompliance,⁴ and FDA may thereafter initiate an administrative action seeking a civil monetary penalty.⁵ In addition to civil monetary penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution.

As requested, please review your organization’s clinical trial records and submit any required results information to the ClinicalTrials.gov data bank. You can access the ClinicalTrials.gov

⁴ See section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

⁵ Under section 303(f)(3)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 333(f)(3)(A)), “[a]ny person who violates section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] shall be subject to a civil monetary penalty of not more than \$10,000 for all violations adjudicated in a single proceeding.” Moreover, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)) provides that “[i]f a violation of section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than \$10,000 for each day of the violation after such period until the violation is corrected.” The civil monetary penalty amounts listed in this letter reflect the amounts listed in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461, note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

website at <https://register.clinicaltrials.gov>. If you have any questions about this letter, you may call Mark S. Miller, Pharm.D., at (301) 796-2798. Please have the FDA reference number provided at the top of this letter available when you call. Alternatively, you may e-mail him at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions you have taken in response to this letter. If you believe that your organization has complied with applicable requirements, please provide us with your reasoning and include any supporting information for our consideration. Please direct your response to the address below and include the FDA reference number in all correspondence relating to this matter.

Mark S. Miller, Pharm.D., BCPS, RAC
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Sincerely yours,

**David
Burrow -S**

 Digitally signed by David Burrow -S
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ou=FDA, ou=People, cn=David Burrow -S,
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