

From: OC GCP Questions
To: [REDACTED]
Subject: RE: Searching for FDA clinical trial information
Date: Wednesday, April 12, 2017 8:35:00 AM
Attachments: [REDACTED]

Good morning,

Since the trial you are referring to was completed in 2002, there is not a requirement for registration of the trial on ClinicalTrials.gov.

It is unclear from your message exactly what information you are looking for. In addition, there may be different Centers at FDA which may be in a better position to address your question. If you are interested in the use of acyclovir via iontophoresis, you may wish to contact FDA's Center for Drug Evaluation and Research at the following:

Division of Drug Information
Phone: 855-542-3784
E-Mail: druginfo@fda.hhs.gov

If you are interested in the iontophoresis device described in the article, you may wish to contact FDA's Center for Devices and Radiologic Health at:

Division of Industry and Consumer Education
Phone: 800-638-2041
E-Mail: DICE@fda.hhs.gov

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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Senior Health Policy Analyst

Office of Good Clinical Practice
U.S. Food and Drug Administration



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: Tuesday, April 11, 2017 3:30 PM
To: OC GCP Questions
Subject: RE: Searching for FDA clinical trial information

Dear FDA:

I discover the publication of a FDA Phase 2b clinical trial (PMID 16838235, doi: 10.1086/505872 Paper-attached), and was unable to locate any additional FDA information.

I searched through "ClinicalTrial.gov" data base but failed to find the FDA DCT... identification number or any information on this Trial. I also contacted NIH/NLM/NCBI and they were unable to locate the Trial ID or any info on this dated clinical trial.

Would you please help me identify the FDA data base that I can perform a search? The clinical trial was conducted in USA between April 2001 and Feb 2002.

Thanks so much,

[REDACTED]