From: OC GCP Questions
To: [redacted]
Cc: [redacted] Less, Joanne; Kezer, Doreen M
Subject: FW: Question Regarding Patient Registry of Study Participants
Date: Monday, July 09, 2018 9:50:00 AM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. Dr. Less forwarded your question to me, and I also understand that you sent the same question to our OGCP mailbox and received a response from my colleague, Doreen Kezer.

As Ms. Kezer indicated, and as addressed in FDA's Draft guidance titled, "Informed Consent Information Sheet, Guidance for IRBs, Clinical Investigators, and Sponsors" – see https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm#morethanone), FDA acknowledges your concern and strongly discourages enrollment of a subject in more than one study (see section V, Additional Considerations, subsection G of the guidance, also copied here for your reference):

> **G. Subject Participation in More Than One Clinical Investigation**
>
> Some subjects may wish to participate simultaneously in more than one clinical trial or enroll in a single clinical investigation multiple times. FDA strongly discourages these practices as enrollment in more than one clinical investigation could increase risks to subjects, particularly because they may be exposed to more than one investigational product for which the safety profile may not be well understood. In addition, the subjects may find it difficult to understand all the risks and proposed benefits, much less meet the demands, of multiple protocols. Moreover, there may be potential drug or device interactions, and the simultaneous use of more than one investigational product may confound the results of the clinical investigations.
>
> Sponsors generally include prohibitions related to the use of concomitant medications in the protocol or restrict (via exclusion criteria) inclusion of subjects who have participated in another clinical investigation within a specified period of time (for example, the washout period before a subject can enroll in a new clinical investigation). Implied in the prohibitions on concomitant medications is the idea that subjects should not participate in more than one clinical investigation at a time. Investigators should inquire about multiple enrollments and discourage this practice in the consent form and during any informed consent discussions.

By raising our concerns in guidance with study sponsors, researchers and IRBs, we hope to discourage this practice in FDA-regulated trials. In addition, in FDA's educational outreach activities, we reiterate the Agency's concerns with this practice.

As Ms. Kezer indicated, FDA does not have a nationwide patient registry, nor are we aware of a single nationwide registry. However, we are aware that there have been efforts by various commercial companies to develop database registry(ies)/tools to assist in addressing the issue of subjects enrolling in multiple trials. You can likely find more information about these efforts in the literature and by doing a Google search on the internet. I am not aware that FDA has resources to assist you in your efforts, however, I think you may find a literature and internet search helpful should your organization decide to develop a pilot program.

Simply for your consideration as you think through this issue, although there may be advantages to a national registry, there may be some potentially significant hurdles to developing a national registry of clinical trial participants. Such hurdles would include, among others, logistical, patient privacy, and sponsor confidentiality issues. For example, patients may legitimately enroll in both a device and drug study if the studies are for different indications and confounding effects are not a concern. Similarly, a patient may appropriately choose to sequentially enroll in more than one trial after the required wash-out period. A clinical trial participant registry would need to account for a variety of such circumstances. Patient privacy and confidentiality issues related to sharing identifiable information would need also to be addressed, as well as commercial confidential information for study sponsors.

Thanks again for your question. I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
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: OC GCP Questions
Sent: Friday, July 06, 2018 9:08 AM
To: [redacted]
Subject: FW: Question Regarding Patient Registry of Study Participants

Dear [redacted] -

The Office of Good Clinical Practice has received your question sent to Dr. Less and is working on a response. We will respond as soon as possible. Many thanks.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

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

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From: [redacted]
Sent: Thursday, June 28, 2018 1:30 PM
To: Less, Joanne <Joanne.Less@fda.hhs.gov>
Cc: [redacted]
Subject: Question Regarding Patient Registry of Study Participants

Good morning Ms. Less:

I am a study coordinator at [redacted]. Our research center has been conducting GI clinical trials (e.g. Crohn's, Ulcerative Colitis, EoE, IBS, etc.) for 30+ years. At times, we become concerned that a patient may be participating in another clinical trial at the same time he or she is participating in one of our clinical trials. As you know, this could be very

detrimental to the patients' health and provide erroneous data to the Sponsor along with other negative possibilities.

I am writing to inquire whether there is a nationwide patient registry listing all study participants including which trial they are participating in and on what dates (especially a date of completion). If there is not, our research center would like to look into this situation further. We may also be interested in setting up a pilot program to develop and test a local patient registry with intent to develop a national registry. We are looking for information and guidance to get this endeavor started, and we are hoping you could get us pointed in the right direction; perhaps the FDA has a specialized department for projects such as this or other guidance to get us started.

Any assistance you can offer would be greatly appreciated. My contact information is listed below; [redacted] I look forward to hearing back from you.

Thank you for your consideration,

[redacted]

[redacted]

[redacted]