From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 Question
Date: Monday, June 17, 2019 10:48:17 AM
Attachments: [redacted]

Good morning –

Based on the limited information in your email, it appears that the global imaging vendor does not have to be listed on the 1572 form.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Monday, June 17, 2019 10:19 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA 1572 Question

Dear FDA,

I was wondering if you could provide guidance on the following;

In Field 4; if there is global imaging vendor for the study however a particular site is not participating in this element therefore will not be submitting images, is it necessary for this vendor to be listed in Field 4/continuation page?

Field 4: NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY

Identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an Investigational New Drug Application (IND).

Many thanks,

[redacted]