

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Questions related to FDA1572 section #4
Date: Wednesday, November 29, 2017 11:20:00 AM
Attachments: [REDACTED]

Good morning –

It appears from the limited information in your email and following the 1572 guidance that Covance US is the main laboratory and Covance Singapore is a satellite lab. However the samples traced to the satellite lab must be clear and well documented.

Kind regards,

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



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From: [REDACTED]
Sent: Wednesday, November 29, 2017 10:30 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Questions related to FDA1572 section #4

Dear Sir/Madam,

I'm working at [REDACTED] and I have one question related to FDA1572 section #4.

In FDA1572 guideline, it is written as below,

29. If a laboratory is sending samples to satellite or other contract labs for additional testing, should these labs be identified in Section #4?

It is only necessary to list the primary laboratory, provided that laboratory can trace the samples to each of the satellite and/or contract labs where the tests were performed.

Now we are going to use Covance US for blood lab test, and also going to use Covance Singapore for tumor sample test.

So in my opinion, this 2 lab information should be listed in section #4 as primary laboratory.

But now one of sponsor is saying that they regards only headquarter of Covance Inc. is primary

laboratory, so even though tumor sample test is done at [REDACTED] it doesn't need to be listed in section 4.

Would you please provide the guidance on this?

Kind Regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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