

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** FDA\_Lab address QUESTION  
**Date:** Monday, March 02, 2015 11:16:07 AM  
**Importance:** High

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Good morning ---

I think question #28 and #29 in the guidance answers your question.

**V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY**

**28. What qualifies as a clinical laboratory facility for Section #4?**

*Section #4 is intended to 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 IND.*

**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.*

The primary (central) lab should be listed on the 1572 form.

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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**From:** [REDACTED]  
**Sent:** Monday, March 02, 2015 8:37 AM  
**To:** CDER DRUG INFO  
**Cc:** OC GCP Questions  
**Subject:** FDA\_Lab address QUESTION  
**Importance:** High

Dear All,

I have reviewed the guide but I have not got answer to my question.

Please advise in case in my study we will use **3 laboratories.**

- 1.Laboratory in Italy when blood samples will be analyzed
- 2.Laboratory in Germany when swab samples will be analyzed

3.The PPD central lab will be involved in the process, samples will be sent to sites and collect from sites then in one transport at the end of the study these samples will be sent to mentioned above laboratory to get results.

Please advise if it necessary to add the PPD central lab address to FDA 1572 in this case.

Thank you in advance.

Kind Regards

[REDACTED]

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