

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: FDA Form 1572 - for Multi-National Study Including USA - Question about Lab to List
Date: Monday, May 06, 2019 12:57:32 PM
Attachments: [REDACTED]
Importance: High

Good morning –

I would think you could list the different central labs on the US 1572 [REDACTED] and the Rest of World regions 1572 [REDACTED] separately. However, since it appears that you are conducting a study under IND, you should probably ask the FDA regulatory project manager of the IND for advice or the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov

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: Monday, May 06, 2019 12:08 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [REDACTED]
[REDACTED]
[REDACTED]
Subject: FDA Form 1572 - for Multi-National Study Including USA - Question about Lab to List
Importance: High

Dear FDA,

My study is using the FDA 1572 as we are conducting research in the USA. We are also conducting research in many other European countries, for which we are collecting the 1572.

In the USA, we are using a central lab [REDACTED] and in the Rest of World regions, we are using a lab called [REDACTED]

Our question is, for the 1572s completed by investigators in the Rest of World regions, do we need to list the USA central lab [REDACTED] in addition to the central lab they use [REDACTED]? **OR**, [REDACTED] sufficient to

list in the European 1572 as the only central lab as those countries do NOT use [REDACTED] as their central lab.

We have the same question for the USA 1572s, do we need to list the European lab on our USA 1572s?

Warm Regards,

