From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: FDA Regulations - Laboratory Testing
Date: Monday, September 24, 2018 10:49:00 AM

In general, if there is an FDA cleared or approved test available, that would be preferable. There may be circumstances in which a cleared/approved test is not available. I recommend that the use of a specific LDT be discussed with your submission review team prior to initiating the study; the quality and validity of these tests varies significantly. Also see the link for LDTs, which can be found on the left column of the IVD website link sent below, or you can access it directly at https://www fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/default htm

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst

Office of Special Medical Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration
Tel: 301-796-6563
sheila.brown@fda hhs.gov

-----Original Message-----
From: [redacted]
Sent: Monday, September 24, 2018 10:36 AM
To: Brown, Sheila (OGCP) <Sheila.Brown@fda hhs.gov>
Subject: Re: FDA Regulations - Laboratory Testing

Sheila,

Thank you kindly for the response. This is immensely helpful. One additional question, are laboratory developed tests suitable for measurements in support of clinical trials submissions?

Best,

[redacted]

[redacted]

> On Sep 24, 2018, at 6:19 AM, Brown, Sheila (OGCP) <Sheila.Brown@fda hhs.gov> wrote:
>
>
> Dear[redacted],
> We recommend using laboratory tests that are cleared or approved by FDA, when available. More information about in vitro diagnostic testing can be found on FDA's website at https://www fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm . If you have questions about specific testing for a study, we recommend that you contact the review team for your submission.

>
> I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda hhs.gov .
>
> Best regards,
>
> Sheila
>
> Sheila Brown, RN, MS
> Policy Analyst
>
> Office of Special Medical Programs
> Office of Good Clinical Practice (OGCP)
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> Tel: 301-796-6563
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> This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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.
>
>
> -----Original Message-----
> From: [redacted]
> Sent: Thursday, September 20, 2018 2:40 PM
> To: OC GCP Questions <gcpquestions@fda.hhs.gov>
> Subject: FDA Regulations - Laboratory Testing
>
> I have a question with regards to the regulations that pertain to a CLIA laboratory participating in clinical trials. I understand the FDA recognizes CLIA, as overseen by CMS. More specifically, are there any additional requirements for the following types of laboratory testing in support of a clinical trial?
>
> -primary and secondary endpoint/efficacy
> -safety
> -patient inclusion/stratification
> -pharmacodynamic (PD)
> -exploratory
>
> Thank you for your time and clarity on this matter.
>
> Best,
>
[redacted]