

From: OC GCP Questions
To: [REDACTED]
Subject: sNDA require inspections of clinical investigators
Date: Tuesday, July 10, 2018 11:57:00 AM
Attachments: [REDACTED]

Good afternoon –

Generally, some of the clinical investigator sites are inspected when an NDA is filed. There is a clinical investigator inspection list (see below) but you would have to populate the fields to get a search result.

[Clinical Investigator Inspection Search](#)

Kind regards,

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From: [REDACTED]
Sent: Tuesday, July 10, 2018 11:30 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: sNDA require inspections of clinical investigators

To whom it may concern,

When filing sNDAs does the FDA inspect clinical investigator sites as part of the approval process? If yes, where can I find the summary of these clinical investigations. Thank you in advance

