

From: OC GCP Questions
To: [REDACTED]
Subject: Question on SAE definition-classification
Date: Friday, September 30, 2016 3:06:00 PM
[REDACTED] [REDACTED]

Good afternoon –

FDA does not clearly define the difference between medical and surgical interventions. Perhaps doing a web search would be a better way to determine the difference between the two. I also think the protocol should define the specifics that you might be looking for.

Since you mention “device investigational site” you might want to consult FDA’s Center for Devices (CDRH) at DICE@fda.hhs.gov

Kind regards,

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From: [REDACTED]
Sent: Thursday, September 29, 2016 1:13 PM
To: OC GCP Questions
Subject: Question on SAE definition-classification

Other than the vague definitions in the FDA regulations, what are some examples of “resulted in medical intervention” versus “resulted in surgical intervention”. Of course, an event meeting one of these definitions is more than likely an SAE. My device investigational sites are always trying to define medical versus surgical intervention. Sometimes the clinical experience of the study coordinator determines how they want to classify the SAE (incision of skin versus puncture, surgeon versus non-surgeon, etc).

Can you provide examples of surgical intervention???

Thank you in advance.

[REDACTED]