From: OC GCP Questions
To:
Subject: 28 day mortality

Date: Wednesday, May 21, 2014 9:08:05 AM

Good morning --

My office only answers general good clinical practice questions. You might want to reach out to the Center for Drugs (CDER) at druginfo@fda.hhs.gov or the Center for Biologics (CBER) at ocod@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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-----Original Message-----

From: [redacted]

Sent: Wednesday, May 21, 2014 8:14 AM

To: OC GCP Questions Subject: 28 day mortality

Good morning, I write from Guatemala. I ask for your help. Where I can find the definition and use of the 28 day mortality? I work in PICU of the [redacted]

, my colleagues and I find this a point break used in your trials and I need to use as iindicator.

Thank you [redacted]