From: OC GCP Questions
To: [redacted]
Subject: Clinical trials in preterm infants
Date: Friday, November 06, 2015 5:51:52 AM

Good morning –

I am sorry this office does not have the expertise to answer your questions. It is best that you contact FDA's Office of Pediatric Therapeutics. Please see the websites below.

http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/default.htm

Office of Special Medical Programs > Office of Pediatric Therapeutics

Phone -- 301-796-8659

Email -- OPT@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, November 05, 2015 2:53 PM
To: OC GCP Questions
Subject: Clinical trials in preterm infants

Dear FDA,

I am working on a clinical trial to be conducted in preterm infants and am seeking advice concerning the appropriate interpretation presentation of clinical chemistry and hematology lab values when no universal standard of normal ranges is available for this specific population of subjects. Normal range values for full term infants are published and available to the central laboratory that we are using. Preterm infants, due to their stage of development have normal lab values that change over time as they mature and age and become more similar to full term infants.

We have discussed this non-availability of standard preterm normal lab range values with a member of the FDA Neonatal subcommittee who is also a member of the International Neonatal Consortium. They know this is an area they need to address to make available to all investigators in the future. Unfortunately, this information is not available in the current time frame for which we need it.

How have other sponsors dealt with the interpretation and presentation of lab results for their studies in preterm infants. Our listings for lab results will have numerous values which will be flagged as being outside the normal range (the normal range in use being that of full term infants).

Is it appropriate and acceptable to have a Sponsor-generated list of normal range values? A single table will not suffice however, because what is considered normal is a moving target as the premature infants mature and age.

Help!!!!!

[redacted]