From: OC GCP Questions
To: [redacted]
Subject: not collecting DOB in trials of children
Date: Wednesday, June 13, 2018 8:14:00 AM
Attachments: [redacted]

Good morning –

Thank you for your patience. Below is the response from the Center for Drugs (CDER), Office of Medical Policy (OMP). The Office of Pediatric Therapeutics (OPT) and the Division of Pediatric and Maternal Health (DPMH) have provided input into the response.

Response:

Current FDA regulations do not require the collection of age or date of birth (DOB), nor do they prohibit collection of this information. Certain FDA regulations pertaining to adverse event reporting do require the reporting of either patient age at the time of the adverse drug experience or DOB, but do not specify one over the other (see, e.g., 21 CFR 310.305(d), 314.80(f), and 329.100(b)).

From a scientific perspective, there are age-related differences in pharmacokinetics, vital signs, and other physiologic characteristics, such that knowing exact age (i.e., DOB) would be preferable to simply knowing the study subject's age in years. In addition, collecting DOB may be preferable over age in years to avoid confusion regarding the age of the study subject at the time of data collection versus other time points during the study.

With respect to pediatric study subjects, developmental changes occur so rapidly that knowing a subject's DOB can be integral to the interpretation of study data. Collecting age in years is not sufficient for characterizing developmental changes that occur over months. For infants and toddlers, in particular, DOB is important to accurately track developmental milestones (e.g., physical, cognitive, and psychosocial) across narrow age ranges. Collection of DOB in these patients is needed to accurately interpret the study data in its proper context. Similarly, for children and adolescents, collection of DOB allows study data to be interpreted within the context of developmental changes, including puberty. At the least collection of age in months, rather than years, would be necessary for most pediatric trials.

In the neonatal population, maturational changes occur over days to weeks, and DOB is necessary for the evaluation of pharmacokinetic data and for dose determination. As an example, pharmacokinetic studies in neonates need to collect DOB, gestational age at birth, and post-natal age for evaluation of drug exposure and safety in this population.

The information provided in response to this inquiry does not address any specific product or trial. For specific trial questions, Janssen pediatric trials staff may be able to provide guidance. Follow-up questions regarding specific products or trials should be directed to the appropriate FDA review division by the sponsor.

I hope this information is helpful.

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, May 09, 2018 12:00 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Re: not collecting DOB in trials of children

hi

[redacted]

[redacted]

i guess to be precise EU has not explicitly directed pharma to stop collecting DOB. But the regulation requires data minimization, strict necessity, and has penalties and DOB is one of the sensitive pieces of info. So at least my big pharma co has chosen to stop collecting DOB globally and only collect age in years, even for pediatrics. Seems to me the requirements of GCP and safety of children was not adequately considered here. for meds age should be in at least years + months.

i cam up with this list of potential problems...

1. Imprecise lab, ecg and vital normal ranges
2. Imprecise PK
3. Introducing error into any efficacy or safety analyses where age is an important factor
4. Harming ability to assess growth, development, milestones, puberty
5. Harming ability to score psychometric/cognitive instruments
6. Decreasing ability to centrally monitor/confirm signing of ICF when child turns 18
7. precise age wont be available when needed for analyses that can't be foreseen but the need for which might arise at any point in a drugs development

> On May 9, 2018, at 10:47 AM, OC GCP Questions <gcpquestions@fda.hhs.gov> wrote:
>
> Good morning –
>
> In order to adequately answer this question, cay you provide the source that the EU has directed pharma companies to stop collecting DOB on subjects?
>
> Kind regards,
>
> The OGCP Group
>
> ---
>
> **From:** [redacted]

Sent: Tuesday, May 08, 2018 1:55 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: not collecting DOB in trials of children

HI

The EU has directed that pharma companies stop collecting DOB and only collect age in years even in children in drug trials.

Does the FDA agree that it is GCP to only have children's ages in years and not even in years/months, considering all the impacts that might have on lab/ecg/vital sign normal ranges; growth/development/puberty/milestone assessment; safety and efficacy measures where age is an important covariate? All these are important even in adolescents.

Thanks

_____
[redacted]