From: OC GCP Questions
To: [redacted]
Subject: Race/ ethnicity and clinical trials in Europe
Date: Thursday, June 11, 2015 12:33:40 PM

Good morning –

I checked with colleagues in my office and generally the underlying reason for collecting demographic data such as ethnicity is to be able to conduct subset analysis. (Post hoc or otherwise). It is recommended that you discuss your questions with the review division that is overseeing the IND.

Kind regards,

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

From: [redacted]
Sent: Thursday, June 11, 2015 8:16 AM
To: OC GCP Questions
Subject: RE: Race/ ethnicity and clinical trials in Europe

Thank you very much for your prompt answer. I have the 2 additional questions below

- I read in the FDA guidance that the rationale for collecting race/ethnicity is to know efficacy/ safety within the different groups of patients, due to intrinsic factors, extrinsic factors, or interactions between these factors. Obviously, it makes sense.

  But, if in the protocol, we don't plan stratification for **pre**-identified subgroups, analyses will be considered as post hoc and no robust/valid conclusion could be draw. So the protocol should specify what kind of analysis are scheduled linked to race/ethnicity with a scientific rationale. That's exactly what requests European Union regulations. I do not find such expectations in the FDA guidance which accept routine collection of race without any criteria.

  Post hoc analyses are not, in my opinion, a sufficient relevant reason to collect race/ethnicity if they are no part of protocol objectives.

So, does FDA require, in the protocol, specific justifications for collecting race/ethnicity and relevant methods to address them through sub-group analyses ?

- In 1993, FDA also published *New Drug Evaluation Guidance Document: Refusal to File*, on the Agency's use of the refusal-to-file (RTF) option if certain analyses were not performed.

Do you think FDA would accept sponsor doesn't collect race/ethnicity if justification for not collecting them is mentioned in the protocol ?

Best regards.

[redacted]

De : OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Envoyé : mercredi 10 juin 2015 20:27
[redacted]
Objet : Race/ ethnicity and clinical trials in Europe

Good afternoon –

Please see the FDA guidance (link below) on race and ethnicity data in clinical trials, especially Section III.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf

Kind regards,

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

From: [redacted]
Sent: Wednesday, June 10, 2015 3:26 AM
To: OC GCP Questions
Subject: Race/ ethnicity and clinical trials in Europe

Dear Sir,

As you know, Subject Race/ ethnicity are considered as sensitive data as per European regulations.

So they can be collected in the framework of a clinical research **only** if they fit with a clear study objective, i.e. described in the study protocol. But most of the protocols currently describe **no** objectives linked to race/ethnicity. So in theory, these data could not be collected.

I am often told (with no clear justification) that FDA required, in routine, collection in the CRF of race/ethnicity even if there is no protocol objective directly linked them. What is really the current position of the FDA on that topics with your rationale to match with the European requirements ?

Thank you in advance for your clarifications.

Best regards.
[redacted]