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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Ref: Docket No. 02D-0018, CDER 200272. Draft Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products.

Abbott Laboratories commends the Agency on their efforts to provide guidance to industry on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products, published in the Federal Register on January 30, 2003.

We are very pleased to have the opportunity to comment on this draft guidance and thank the Agency for your consideration of our attached comments. Should you have any questions, please contact Ivone Takenaka, Ph.D. at (847)-935-9011 or by FAX at (847) 938-3106.

Sincerely,

for:
Douglas L. Sporn
Divisional Vice President
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Abbott

March 26, 2003

Comments on the
Draft Guidance for Industry on the
Collection of Race and Ethnicity Data in Clinical Trials for
FDA Regulated Products

DOCKET No. 02D-0018

The following comments are submitted on behalf of Abbott Laboratories.

GENERAL COMMENTS

We commend the Agency on their endorsement of the collection of demographic data sometimes difficult to obtain. In general, it is well recognized among the stakeholders that there are compelling medical reasons for collecting race and ethnicity data in clinical trials. Therefore, we believe it is not necessary for the guidance to provide the rationale for this collection multiple times throughout the document.

We appreciate the intent of the guidance to standardize categories in data collection for racial and ethnic groups for the purposes of assessing, in a meaningful way, potential safety and efficacy subgroup differences. However, we believe stratifying clinical research subjects into 5 races and 2 ethnic groups seems oversimplified. As a general practice, we suggest the clinical protocol design should determine what demographic information is important for the particular study.

SPECIFIC COMMENTS

I. INTRODUCTION

Lines 29-36. "...FDA encourages sponsors to collect the data...." for medical devices.

Comment

Unlike pharmaceuticals, there is not a medical device regulation requiring the collection of race and ethnicity data, which could lead to inconsistent application of the guidance document to similar devices and/or studies.

We question the need for including medical devices in this document. Removing the reference to medical devices in this document does not prevent the collection of race and ethnicity data when relevant to determining the safety and effectiveness of a device. However, including the reference could lead to broad interpretation and inconsistent application.

A. Relevance of Population Subgroup Studies

Line 69. 'The OMB stated that its race and ethnicity categories were nonanthropologic (in other words, not scientifically based) designations..."

Comment

The designation of race/ethnicity categories as socio cultural rather than anthropologic, while politically correct, weakens the utility of genetically-influenced differences between populations. We suggest that the Agency carefully re-evaluate the objective of this data collection and the proposed categories.

III. COLLECTING RACE AND ETHNICITY DATA IN CLINICAL TRIALS

Line 151. # 2. "We recommend that study participants self-report race and ethnicity information..."

Comment

Subject self-selection of category may weaken the ability to develop medical associations with those categories, in the same way that self-assigned census data can be defective. For the purpose of the clinical research, the clinical investigator should have the ability to correct any inaccuracies from self-selection.

Lines 157-167. #3. "For ethnicity, we recommend the following choices...."
#4. "When race and ethnicity information is collected..."

Comment

The two-question collection process (determination of Latino or non-Latino ethnicity first, followed by race) will ultimately make it difficult to perform meaningful statistical subgroup analyses of clinical efficacy and safety data. Please clarify what is the rationale for separating out Latino ethnicity from race for purposes of clinical trial data analysis and the reason for having ethnicity limited to two options only. We would like the Agency to recommend an alternate terminology and a more objective set of categories meaningful to the purposes of these data collection.

APPENDIX 2 - REVISITED DIRECTIVE 15

Line 407 - Categories & Definitions.

Comment

Although the guidance attempts to define race and ethnicity, some of the terminology is difficult to understand. As one further reads, "the original peoples of ...", or a person "having origins in ...", or "culture" is vague. These terms need to be defined. In addition, some decisions appear to be made by geographic/country boundaries that may not necessarily apply, i.e., White. Therefore, we suggest that the Agency recommend a better definition of race and ethnicity that can be understood by a subject in a study and can be consistent across the board.