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Date: 1993.04.16
Ref. No.: K 113.01
Total page(s): 3

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Dear Satya,

I hereby fax you the paper I sent to the *49th Session of the International Statistical Institute.*

As I told you yesterday, I have not been able to really make the paper I wanted to, because the EC statistical guidelines have not been released for comments by the CPMP. Therefore, my paper expresses my intentions for what to present only. I might be forced to even do otherwise than intended if the CPMP delays the release of the guidelines. However, right now I expect the guidelines to be released after the next CPMP meeting in May.

If you have any idea of the date at which the session on harmonization takes place, please let me know.

I shall keep in touch with you and look forward to meeting you again in Florence.

Best regards,

Karsten Schmidt

AN APPRAISAL OF THE PROPOSED STATISTICAL GUIDELINES FOR DRUG LICENSE APPLICATION IN THE EC

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The European Community Good Clinical Practice (GCP) Guidelines came into force in July 1991. These guidelines emphasize the necessity of experienced and appropriately qualified statisticians being involved in clinical trials in order to assure high quality allowing for an efficient and fast new drug approval process. However, the GCP guidelines do not give details as regards statistical methodology, and therefore preparation of a supplementary statistical guideline was initiated at the beginning of 1992. A proposal: "Guideline on Biostatistical Methodology in Clinical Trial in Drug License Applications" is now available for discussions, only awaiting the formal release by the CPMP, which will hopefully happen in May 1993. Although experienced statisticians could have given valuable input during the long process of developing the proposal, it has been classified as confidential, and therefore specific comments must wait for the formal release.

For the experienced statistician, who knows generally accepted appropriate statistical practice it may be important that a guideline expresses what the regulatory agencies prefer in complex and/or controversial areas, where an established appropriate practice is not agreed upon, without thereby excluding innovations and reasonable alternatives. To promote harmonization contradictions to other guidelines and international standards should be avoided.

The European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) is an umbrella organization for 7 national European biostatistical organizations, having a total membership of more than 1000 biostatisticians with particular interest in the new statistical guidelines that are hopefully directed towards an audience of experienced biostatisticians in industry and regulatory agencies. Each member organization will discuss the new proposal, and at a full day meeting of the EFSPI Council Members the various views will be coordinated. This paper will summarize the views with special emphasis on the potential impact of the proposal on the global harmonization process. In addition, the paper will address other key issues important for the harmonization of statistical practice such as e.g. the need of having statistical expertise within the European regulatory agencies for providing statistical review, dialogue with and feedback to industry statisticians, a need that will pertain regardless of any guidelines as currently debated in the ISCB Working Party on Statisticians in European Drug Regulation (SEDREG).

Other potential problems regarding harmonization from the industry statisticians' perspective will be identified and discussed.

Résumé

Cette présentation résumera le point de vue de la Fédération Européenne des Statisticiens de l'Industrie Pharmaceutique (EFSPI) sur un projet de texte intitulé "Recommendations sur la méthodologie statistique des essais cliniques réalisés pour les demandes d'enregistrement des médicaments". Il s'agira tout particulièrement d'évaluer l'impact potentiel de ce texte sur le processus d'harmonisation des pratiques dans le domaine des essais cliniques, processus actuellement en cours. D'autre art, des points considérés comme très importants, relativement à l'harmonisation des pratiques proprement statistiques, scront également discutés.