[PF1-1] [04/19/2001 (Thr) 15:30 - 16:30 / Hall 4]

Standardization of Human recombinant Interferon alpha

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The specific activity of recombinant interferons made by different manufacturers can vary and bioassay systems which are utilized to determine the biological potency of interferon may be affected by a number of factors, such as cell lines, viruses and the statistical analysis of the assay. Therefore the bioassay of interferon, like as other biological products, is essentially comparative and thus requires a fixed reference standard and standardized assay conditions. A collaborative study was performed for standardization of interferon bioassay. Six laboratories of interferon manufacturers and KFDA were participated in this study. All laboratories measured the potency of 'the same interferon samples' by their own routine methods and the reference method which was offered by KFDA. The results were analysed by both ways using their own data analysis methods and the usual statistical methods for a parallel line assay. The relative sensitivities of each assay system and the potency of each working standard of the participants were compared by assessing the assay performance such as accuracy, precision and reproducibility. The results showed best precision and reproducibility when the potency was measured by the manufacturer's routine methods and calculated by parallel line analysis. The estimated potency was from 80 % to 125 % and the confidence limit was from 64 % to 156 % of the stated potency in most laboratories, which showed good accuracy. Differences in data analysis between the manufacturer's routine analytical method and the parallel line assay were not significant by 't-Test' and differences in all results from routine assay and reference assay also were not significant by 'analysis of variance'. Based on the results of the collaborative study, all participants were 'standardized' in the interferon bioassay and we may consider the change of the data analysis of interferon potency to the statistical method for a parallel line assay.

[PF1-2] [04/19/2001 (Thr) 15:30 - 16:30 / Hall 4]

Security Measure for Clinical Information Management System on Internet

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Clinical information needs to have high level of authetication and should be free of any kinds of unauthorized modication of data. Several different kinds of security measure should considered to ensure integratiry of clinical data. Security measure for clinical information management system on Internet has been studied in terms of data, user authentication and audit trail. For data encryption, DES(Data Encryption Standard, 64bit/128bit) and RSA(Rivest, Shamir, Adleman) algorithm were evaluated. For message authentication and user authentication, Kerberos algorithm was considered and for WWW security, IP address authentication, basic authentication with login id and password, and message digest authentication(MD5) were evaluated. In addition to these security measures, the use of secutiry protocol such as S-HTTP and SSL was considered. Some of the evaluated security measures or the combination of them will be incorporated in the clinical information management system under development called [ClinEva].