Interoffice correspondence

TRAVENOL

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to:	David Galliford	date:	16th September, 1987
from:	Ivan Bryant	copies:	Gillian Traynor Dierdre Tait - Egham John Brooks - Egham
subject:	HEMOFIL M CTX APPLICATIONS		

Notes on meeting of 9/9/87 at St. Thomas's Hospital

Present:	TRAVENOL	Ivan Bryant (IJB) Dierdre Tate (DT)
	ST. THOMAS	Dr. Geoffrey Savidge (GS) Gill Harrington (GH)

1. GS/DT discussed at length the politics and anticipated problems that would be encountered in our introduction of a non-heat-treated FVIII preparation, especially now that heat-treatment is the universally accepted viral inactivation process. (Method M utilises treatment with TNBP/Triton X-100 and purification by FVIII-specific mAb immunoaffinity chromatography). Ironically, GS foresees politically motivated inertia ("delaying tactics"), on the part of the D.H.S.S., similar to that displayed when heat-treated products were introduced. Recent problems with Armour and Elstree FVIII preparations make this a highly sensitive area within the D.H.S.S. and medical fraternity.

2. GS was very eager to obtain 'indemnity' for himself in case any of the patients seroconverted (to HIV Antibody positive) during the trial. This was of particular importance with respect to the 'virgin patients' trial, but was also an issue in the 'previously treated patients' trial as approximately half of the patients will be HIV Antibody negative. DT to contact legal advisors in U.S.A. and Europ but the company does not normally do this.

3. During subsequent discussions it was agreed that the best course of action was to:

   a) Submit and obtain CTX for 'previously treated patients' trial protocol, using T4/T8 ratio improvement seen in preliminary U.S.A. trial data (see 4c) as a justification for the inclusion of HIV Antibody-negative patients in the trial.

   b) Obtain 6 months data for 'previously treated patients' trial to prove efficacy and (non-viral) safety of HEMOFIL M before applying for CTX for the 'virgin patients' trial.

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Continuation: HEMOFIL M CTX APPLICATIONS

4. Draft CTX applications presented by IJB and scanned by GS/DT/GH. GS/DT to review CTX applications and comment. To achieve the objectives agreed in Point 3 the following changes/additional information are required:

   a) Develop, at this stage, only the 'previously treated patients' CTX application, removing references to the 'virgin patients' trial - IJB.

   b) Include Immunoblot data on HEMOFIL M, as suggested by GS, to provide complete characterisation data - IJB.

   c) Include preliminary T4/T8 ratio evidence from U.S.A. trials - DT to provide.

   d) Include revised trial protocol - IJB.

   e) Include details of additional investigator - DT to provide.

   f) Update nomenclature used for Factor VIII parameters as indicated by GS - IJB.

5. IJB/DT to maintain contact and arrange a further meeting with GS/GH when second draft of the CTX application is available.

Regards

GRO-C

I.J. Bryant