



# Public Health Laboratory Service

Public Health Laboratory  
Withington Hospital  
Manchester M20 8LR  
Telephone 061-445 2416

22nd March, 1983

Our ref JC/PH

Your ref

## DRAFT LETTER

Dear Director,

### TRIALS OF 'HEPATITIS REDUCED' FACTOR VIII

The Hepatitis Working Party has drawn up the enclosed protocol, as a result of discussions at the Haemophilia Reference Centre Directors meeting, for use in trials of this product to assess the efficacy of the different methods used for the removal of hepatitis viruses. You will see that the class of patients to be given these products are those who have had no previous treatment with factor VIII concentrate.

It is likely that there are only a limited number of these patients in the U.K. who will require factor VIII therapy in any one year. We will be grateful if you would notify Dr. J. Craske of any approaches from commercial firms with a proposal to evaluate their product.

From our calculations, it is possible that all products likely to come onto the market within the next year can be catered for if the trials are arranged on a collaborative multi-Centre basis. There is a danger that the firm whose product is first on the market will use up all suitable patients if a number of Centres evaluate the product without exchanging information. This would mean that a year or so may elapse without adequate trials being arranged for other products. It is also important to ensure that the firm concerned agrees to adhere to the protocol as outlined in the enclosed documents.

We hope that this will encourage you to identify suitable patients for inclusion in the trial so that these can be located before any products become available. Discussions can then proceed when the number of patients available and the number of products for evaluation is known.

Thank you for your co-operation.

Yours sincerely,

J. Craske  
Charles Rizza  
Arthur Bloom