

THE RHEUMATOID DISEASE FOUNDATION

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JOHN R. A. SIMOONS, Ph.D.
President

May 22, 1985

H. Bradley Wells, Ph.D.
Professor of Biostatistics
Bowman Gray School of Medicine
Winston-Salem, N.C. 27103

Dear Dr. Wells:

Re: Clotrimazole Study R-1120-A

I would like to keep you informed of the status of our double-blind study after the March 4, 1985 meeting with Dr. Turner which you also attended. We are concerned about the very slow rate of admissions into the study and the extremely high drop-out rate. In your "Feasibility" projection of the Protocol you expected that an average of 4 patients per month could be entered and that 90% are expected to complete the 12-week study. We should then have admitted about 20 patients to date with 2 drop-outs. I enclose copies of our correspondence with Dr. Turner of May 20 and 21 and his letter dated May 9 and a report from Ms. Crater of March 25, 1985 for your information.

We hope that Dr. Turner will try to accelerate the admission of patients and encourage them to stay on the study unless, of course, they encounter very serious side-effects. In our experience, most patients will develop a Herxheimer reaction when treated with anti-amoebic compounds such as Clotrimazole but these symptoms are transient and in most cases disappear within six weeks.

We will keep you informed of further developments.

Yours sincerely,


John R.A. Simoons, Ph.D.

Encl/

cc: Mr. Perry A. Chapdelaine, Sr.

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THE ROGER WYBURN-MASON & JACK M. BLOUNT FOUNDATION
FOR THE ERADICATION OF RHEUMATOID DISEASE

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