

Ref: STH16542

30 June 2021

European Medicines Agency

PO Box 71010

1008 BA Amsterdam

The Netherlands

Dear Sir/Madam

EudraCT Report Publication

STH ref:	STH16542
EUDRACT ref:	2012-004165-41
CTA ref:	34237/0001/001 (previously 21304/0248/001)
CTA date:	04 November 2013
Study title:	Hematopoietic Stem Cell Therapy for Patients with Inflammatory Multiple Sclerosis Failing Alternate Approved Therapy: A Randomized Study
CI:	Professor Richard Burt
UK CI:	Professor Basil Sharrack
Sponsor:	Northwestern University, USA
UK Legal Representative:	Sheffield Teaching Hospitals NHS Foundation Trust

Enclosed is the publication of the results of the above referenced trial. Sheffield Teaching Hospitals NHS FT is the UK Legal representative and Northwestern University USA is the Trial Sponsor.

Collaboration with the Sponsor on this trial is no longer ongoing. The Sponsor provided confirmation on the 18th of October 2019 that the trial had ended, all the sites, including the UK site, have been closed after the required number of participants have been recruited and follow up to create sufficient data to progress to analysis and publication. The FDA had been informed and the ClinicalTrials.gov (NCT00273364 <https://clinicaltrials.gov/ct2/show/NCT00273364>) has been updated. All global information available to the UK Legal Representative is found in the attached publication, and no further data has been or will be provided by the Sponsor.

We request that this publication is accepted as the final results available to the UK Legal Representative.

Update 02/07/2021: As per advice provided by Francesca Scotti on EMA Service Desk, the pdf is posted as a summary attachment by answering "yes" to the question "has this trial prematurely ended" as a workaround to report final results.

Yours faithfully



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