



Date: May 23, 2016

Prof. Ibrahim Al Janahi
Executive Director of Research
Medical Research Center
Hamad Medical Corporation

Dear Prof. Al Janahi,

This letter is in reference to the HMC's submission of the clinical trial titled "*Multicenter randomised, open label, non-inferiority active-controlled trial to evaluate the efficacy and safety of deferipone compared to deferasirox in pediatric patients aged from 1 month to less than 18 years affected by transfusion dependent haemoglobinopathies*" / DEEP-2 study. We acknowledge receipt of your submission dated April 18, 2016. We have completed our review of the below submitted documents.

Research proposal	Reviewed Document
15424/15	<ol style="list-style-type: none"> 1. 15424_3rdCountryForm_18June2015_pgs20 2. 15424_3rdCountryFormValidationReport_18June2015_pgs1 3. 15424_AssentForm6-10_AR_V2_30Sep2012_pgs2 4. 15424_AssentForm6-10_En_V2_30Sep2012_pgs2 5. 15424_AssentForm11-17_AR_V2_30Sep2012_pgs2 6. 15424_AssentForm11-17_En_V2_30Sep2012_pgs2 7. 15424_Booklet_0-6_AR_V2_30Sep2012_pgs3 8. 15424_Booklet_0-6_En_V2_30Sep2012_pgs3 9. 15424_Booklet_6-10_AR_V2_30Sep2012_pgs3 10. 15424_Booklet_6-10_En_V2_30Sep2012_pgs3 11. 15424_Booklet_11-17_AR_V2_24Feb2014_pgs13 12. 15424_Booklet_11-17_En_V2_30Sep2012_pgs13 13. 15424_CaseReportForm_En_V2_10Feb2014_pgs159 14. 15424_CenterList_V5_12Aug2015_pgs3 15. 15424_CHQ_PF28_Ar_2012_pgs4 16. 15424_CHQ_PF28_En_2006_pgs3 17. 15424_ClarificationToIRB_8Apr2016 18. 15424_ClinicalTrialLabel_2012_pgs1 19. 15424_CoverLetterIMPDP_En_29Oct2014_pgs1 20. 15424_Delegationlog_23Nov2015_pgs5 21. 15424_DFPLabelLog_pgs1 22. 15424_DFXLabelLog_pgs1 23. 15424_DrugLabel_En-Ar_5Aug2014_pgs1 24. 15424_IMPDP_En_29Oct2014_pgs362 25. 15424_InformativeLetterForDrs_Ar_V3_10Feb2015_pgs4



Research proposal	Reviewed Document
15424/15	<ul style="list-style-type: none">26. 15424_InformativeLetterForDrs_En_V3_10Feb2015_pgs427. 15424_InformedConsentform_18y_Ar_V1_10Feb2015_pgs1128. 15424_InformedConsentform_18y_En_V1_10Feb2015_pgs1129. 15424_InformedConsentform_parents_Ar_V3_10Feb2015_pgs830. 15424_InformedConsentform_parents_En_V3_10Feb2015_pgs831. 15424_InitialApplication_3Nov2015_pgs632. 15424_Insurance_En_29Oct2015_pgs133. 15424_InvestigatorBrochure_En_V10_20Jan2015_pgs10734. 15424_ManufacturesAuthorization_27Oct2009_pgs2935. 15424_Protocol-WP4_En_V3_10Feb2015_pgs6636. 15424_SmPCEjade_En_6Nov2014_pgs5237. 15424_StudySynopsis_Ar_V3_10Feb2015_pgs1538. 15424_StudySynopsis_En_V3_10Feb2015_pgs5

Along with HMC-IRB's approval of the study, we conclude that adequate information has been presented to protect the safety and wellbeing of participated subjects. Accordingly, this application is approved effective on the date of this letter

Sincerely yours,

Dr. Eman Sadoun
Manager, Human Research
Ministry of Public Health