



**Date:** January 04, 2016

Hamad Medical Corporation  
Medical Research Center  
Attention: Ms. Angela Ball

Dear Ms. Angela Ball,

This letter is in reference to the Hamad Medical Corporation's submission of the clinical trial study titled "*An Open-Label, Multicenter Study to Evaluate Long-Term Outcomes With ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With or Without Ribavirin (RBV) in Adults With Genotype 1 Chronic Hepatitis C Virus (HCV) Infection (TOPAZ-I)*". We acknowledge receipt of your submission dated December 14, 2015. We have completed our review of the below submitted documents, and have concluded 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.

Study Number	Reviewed Document
15165/15	<ol style="list-style-type: none"><li>15165_15_IRB_Signed_Approval Letter_13Dec2015</li><li>15165_15_eCRF_Archive_M14-423_Go_Live_v14Aug2014_116Pages</li><li>15165_15_Investigator_Brochure_267_ib-ed5_v13Jun2014_271Pages</li><li>15165_15_Investigator_Brochure_333_ib-ed7_13Jun2014_271Pages</li><li>15165_15_Investigator_Brochure_450_ib-ed7_13Jun2014_321Pages</li><li>15165_15_15_Labels_for_Qatar_03Pages</li><li>15165_15_M14-423_Dosing_Instruction_Card_AR_V6Aug2014_01Page</li><li>15165_15_M14-423_Dosing_Instruction_Card_Eng_V6Aug2014_01Page</li><li>15165_15_M14-423_ICF_AR_v19Jan2015_33Pages</li><li>15165_15_M14-423_ICF_Eng_19Jan2015_36Pages</li><li>15165_15_M14-423_PPD_SMMP_20Jul15_06Pages</li><li>15165_15_M14-423_Subject_Info_Card_V13Sep2014_AR_01Page</li><li>15165_15_M14-423_Subject_Info_Card_V13Sep2014_Eng_01Page</li><li>15165_15_M14-423_FACIT_FatigueScale_AR_v05Oct09_01Page</li><li>15165_15_M14-423_FACIT_FatigueScale_ENG_V16Nov2007_01Page</li><li>15165_15_M14-423_(SF-36V2®Health Survey Standard, UK (English))_06Pages</li><li>15165_15_Topaz_Protocol_Amendment_v19Jan2015_129Pages</li></ol>



We remind you that you must comply with the requirements set forth under SCH policies and regulations "The ethical conduct of clinical trials". If you have any questions, contact Mr. Nordin Fallouch, Clinical Research Specialist, at 974-4407-0981.

Sincerely yours,

Eman Sadoun, MD  
Manager, Biomedical Research Division  
Healthcare Quality Department  
Supreme Council of Health

