Considering the letter that was submitted by the PI on 9/28/16 that he holds the full responsibilities (1-4 letter), the ministry has no objection for this trial to proceed.

10/5/2016

Date: August 2nd, 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 "A Phase 3B, Randomized, Double-Blind Clinical Trial to Evaluate the Efficacy and Safety of Abatacept SC in Combination with Methotrexate Compared to Methotrexate Monotherapy in Achieving Clinical Remission in Adults with Early Rheumatoid Arthritis who are Methotrexate Naive". We acknowledge receipt of your submission dated May 31, 2016.

The study is sponsored by Bristol-Myers Squibb Research and Development.

Research proposal	Reviewed Document
15452/15	1) 15452_ DiaryCard_Mal_V1_03Aug15_02Pages 2) 15452_ DiaryCard_Urd_03Aug15_02Pages 3) 15452_AbataceptInvestigatorBrochure_V18_13 Nov14_205Pages 4) 15452_AbataceptPacketSupplies_Ara_04Pages 5) 15452_AbataceptPacketSupplies_Eng_13Oct15_05Pages 6) 15452_AbataceptPacketSupplies_Hin_23Oct15_04Pages 7) 15452_AbataceptPacketSupplies_Mal_23Oct15_04Pages 8) 15452_AbataceptPacketSupplies_Urd_24Oct15_04Pages 9) 15452_BloodVolumeChart_01Page 10) 15452_CaseReportForm_27Aug15_840Pages 11) 15452_DiaryCard_Ara_01Apr15_02Pages 12) 15452_DiaryCard_Eng_01Apr15_02Pages 13) 15452_DiaryCard_Hin_V1_03Aug15_02Pages 14) 15452_FACITFatigueScale_ePRO_Ara_V4_13Jan15_01Page 15) 15452_FACITFatigueScale_ePRO_Eng_V4_16Nov07_01Page 16) 15452_HAQ-DIAU_SA_Ara_V1_15May06_02Pages 17) 15452_HAQSourceDoc_Eng_02Pages 18) 15452_InformedConsent_Ara_Site129_V1_06May16_17Pages 19) 15452_InformedConsent_Eng_Site129_V1_04May16_13Pages 20) 15452_InformedConsent_Hin_Site129_V1_09May16_15Pages 21) 15452_InformedConsent_Mal_Site129_V1_09May16_15Pages 22) 15452_InformedConsent_Urd_Site129_V1_09May16_14Pages 23) 15452_InstructionsForUseAbataceptPlaceboInjection_Ara_V4_10Pages 24) 15452_InstructionsForUseAbataceptPlaceboInjection_Eng_V4_08Pages 25) 15452_InstructionsForUseAbataceptPlaceboInjection_Hin_V4_08Aug15_08Pages 26) 15452_InstructionsForUseAbataceptPlaceboInjection_Mal_V4_11Aug15_08Pages 27) 15452_InstructionsForUseAbataceptPlaceboInjection_Urd_V4_11Aug15_08Pages 28) 15452_InvestigatorBrochure_Addendum01_V2_19Dec14_02Pages 29) 15452_InvestigatorBrochure_Addendum02_V2_29Jun15_06Page 30) 15452_ListOfParticipatingCountries_01Page

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31) 15452_ListOfParticipatingEU_NCA_02Pages
32) 15452_MatrexMethotrexate_Jun14_10Pages
33) 15452_PatientRecruitment_Ara_04Pages
34) 15452_PatientRecruitment_Eng_02Pages
35) 15452_PatientTransportPaymentAcknowledegment_Ara_02Oct15_01Page
36) 15452_PatientTransportPaymentAcknowledegment_Eng_02Oct15_01Page
37) 15452_PregnancyTestPackhCGUrinePI_Ara_24Jun05_09Pages
38) 15452_PregnancyTestPackhCGUrinePI_Eng_24Jun05_09Pages
39) 15452_Protocol_V2_29Sep2015_118Pages
40) 15452_SF36_Standard_Ara_v2_06Pages
41) 15452_SF36_StandardScreenShotSample_Ara_V2_12Aug15_11Pages
42) 15452_SF36_StandardScreenShotSample_Eng_V2_11Pages
43) 15452_SF36_StandardSingleItem_Ara_V2_12Aug15_03Pages
44) 15452_SF36StandardSingleItem_Eng_V2_04Pages
45) 15452_SITEproDTA_FACITF_arQA_V1_27Nov13_18Pages
46) 15452_SITEproDTA_FACITF_enUS_V1_27Nov13_18Pages
47) 15452_SITEproDTA_FACITF_hiQA_V1_27Nov13_18Pages
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50) 15452_SITEproDTACustomSubject_arQA_V1_27Nov13_17Pages
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54) 15452_SITEproDTACustomSubject_urQA_V3_27Nov13_17Pages
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56) 15452_SITEproDTAHAQ_enGB_V2_27Nov13_31Pages
57) 15452_SITEproDTAHAQ_hiQA_V2_31Pages_31Pages
58) 15452_SITEproDTAHAQ_mlQA_V2_27Nov13_31Pages
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60) 15452_SITEproDTASADA_arQA_V1_14Sep15_04Pages
61) 15452_SITEproDTASADA_enGB_V1_14Sep15_04Pages
62) 15452_SITEproDTASADA_hiQA_V1_18Sep15_04Pages
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64) 15452_SITEproDTASADA_urQA_V2_04Pages
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70) 15452_SITEproDTAWPAI_arQA_V1_27Nov13_12Pages
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72) 15452_SITEproDTAWPAI_hiQA_V1_27Nov13_12Pages
73) 15452_SITEproDTAWPAI_mlQA_V2_27Nov13_12Pages
74) 15452_SITEproDTAWPAI_urQA_V3_27Nov13_12Pages
75) 15452_StudyFlowChart_V01_26Aug15_30Pages
76) 15452_SubjectAlertCard_Ara_V1_13Oct15_01Page
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Upon review of the submitted documents, the Ministry of Public Health (MoPH) supports the conduct of this clinical trial. This support is conditioned by governing the following responsibilities:

- **It is HMC-Medical Research Center to:**

1. Govern the MoPH-HMC assurance's terms of function.
2. Provide sufficient staff to support the IRB's review, recordkeeping, and trial monitoring.

- **It is HMC-IRB's responsibility to:**

1. Protect the safety and wellbeing of research participants.
2. Protect the privacy and confidentiality of participants.
3. Provide one to one training to involved research staff.
4. Ensure that informed consents are in place.
5. Conduct periodic reviews throughout the trial's duration.
6. Conduct continuous monitoring during the conduct of the trials
7. Report all unanticipated problems including adverse events to the MoPH and Bristol-Myers Squibb Research and Development.
8. Keep IRB meeting minutes, trial recordkeeping, etc. for inspection purposes.
9. Monitor the work conducted by the Data and Safety Monitoring Board.

- **It is the DSMB coordinated by Clinserv CRO's responsibility to:**

1. Periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy.
2. Make recommendations concerning the continuation, modification, or termination of the trial.
3. Ensure that the timeliness, completeness, and accuracy of the data submitted to them for review are sufficient for evaluation of the safety and welfare of study participants.
4. Report adverse events to the IRB, Bristol-Myers Squibb Research and Development, and MoPH.

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- **It is the HMC's Principal Investigator (PI), Dr. Muhammad Hammoudeh's responsibility,** to ensure that this Clinical Trial is conducted in compliance with MoPH regulations and the principles of International Conference of Harmonization (ICH) - Good Clinical Practice (GCP).

It is the PI's responsibility to:

1. Protect the safety and wellbeing of participants.
2. Obtain informed consent from subjects or their legally authorized representative prior to initiation of research procedures.
3. Report all unanticipated problems, including adverse event(s) in accordance with the HMC-IRB's policy on reporting unanticipated problems including adverse events.
4. Conduct the research in accordance with the trial's protocols and the principles of research ethics.
5. Submit the protocol's amendments (e.g., protocol, recruitment materials, consent form, status of the study, etc.) to HMC-IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the HMC-IRB as unanticipated problem.
6. Record and maintain all drug logistic.
7. Inform all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.

For any enquiries, please contact the Research Department via: irb@moph.gov.qa

Sincerely yours,

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