Author's response to reviews

Title: Rationale and design of the Multinational Observational Study Assessing Insulin use: the MOSAIc study

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Author's response to reviews:

May 9, 2012
Timothy Shipley, Executive Editor
BMC Endocrine Disorders
Dear Mr. Shipley:
On behalf of my coauthors, I am pleased to submit revisions to the study protocol manuscript
“Rationale and design of the Multinational Observational Study Assessing Insulin use: the MOSAIc study” for consideration by the journal BMC Endocrine Disorders.
Below, please find a point-by-point response to the editors’ queries.
Editors’ queries

1) In your manuscript, you state that 175 practice sites across 18 countries will be invited to participate in your study. Before we can proceed further with your manuscript, we require you to clarify whether ethical approval has already been obtained from each of the countries participating in your study.

Yes, ethics approval has been sought and obtained from each of the 18 countries participating in the study. We have revised the text to convey this information. On page 7, paragraph 2, the text now reads:

“The study has received ethics approval in all 18 countries. All patients will complete informed consent forms approved by their country-specific institutional review boards.

The study’s analytic plan has been approved by the Brigham and Women’s Hospital Institutional Review Board.”

2) We also require you to clarify whether the practice sites have already been invited to participate and the total number which have agreed.

On page 6, paragraph 1 and page 7 paragraph 1, we clarify the current state of our practice site recruitment rates, and the most common reasons for refusal. The text now reads:

“At present, practice sites are being actively recruited in 13 of 18 countries, with recruitment efforts planned in the remaining 5 countries in summer 2012. The practice site recruitment rate varies between 25% (Japan and China) and 40% (e.g., U.S.,
Mexico, Saudi Arabia) at present, with the primary reasons for non-participation being conduct of competing studies, lack of interest in observational research, lack of personnel, perception that remuneration for observational research is too low, and concerns regarding the number of questionnaires. A total of 225 sites are recruiting patients at this time.