National Patient Safety Agency

National Research Ethics Service

ANNUAL PROGRESS REPORT TO MAIN RESEARCH ETHICS COMMITTEE
(For all studies except clinical trials of investigational medicinal products)

To be completed in typescript and submitted to the main REC by the Chief Investigator. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

Name:	Professor Kamlesh Khunti
Address:	Department of Health Sciences University of Leicester 22-28 Princess Road West Leicester LE1 6TP
Telephone:	+44 (0) 116 2525445
E-mail:	kk22@leicester.ac.uk
Fax:	+44 (0) 116 2525413

2. Details of study

Full title of study:	A multicentre, open-label, non-randomised, non-interventional study to evaluate the safety of self-titration in insulin-naïve people with Type 2 diabetes treated with insulin detemir and oral antidiabetic agents. The SOLVE Study: 'Self-titration of Once-daily LeVemir Evaluation'. Observational, non-interventional study.
Name of main REC:	Oxfordshire
REC reference number:	~~HTGG/NN3573~~ 08/H0606/63
Date of favourable ethical opinion:	24-Jul-2008
Sponsor:	Novo Nordisk

3. Commencement and termination dates

Has the study started?	***Yes*** */ No*
If yes, what was the actual start date?	15-Sep-2008
If no, what are the reasons for the study not commencing? What is the expected start date?	
Has the study finished?	*Yes /* ***No***

If yes, complete and submit "Declaration of end of study" form, available at http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endofstudy/	

If no, what is the expected completion date? *If you expect the study to overrun the planned completion date this should be notified to the main REC for information.*	Last Patient Last Visit = 15-Feb-2010
If you do not expect the study to be completed, give reason(s)	

4. Site information

Do you plan to increase the total number of sites proposed for the study? If yes, how many sites do you plan to recruit?	*Yes / **No***

5. Recruitment of participants

In this section, "participants" includes those who will not be approached but whose samples/data will be studied.

Number of participants recruited:	*Proposed in original application: 2000* *Actual number recruited to date:772*
Number of participants completing trial:	*Actual number completed to date:293*
Number of withdrawals from study to date due to: (a) withdrawal of consent : N/A (b) loss to follow-up: 18 (c) death (where not the primary outcome): 0 Total study withdrawals:124	
*Number of treatment failures to date (prior to reaching primary outcome) due to: (a) adverse events: 13 (b) lack of efficacy: N/A Total treatment failures: * *Applies to studies involving clinical treatment only*	
Have there been any serious difficulties in recruiting participants?	***Yes** / No*
If Yes, give details:	Feasibility of study was completed before GLP1's were on the market. The use of GLP1s has reduced the amount of patients starting on once daily Levemir. Patient

	recruitment was also affected by the swine-flu pandemic and the adverse weather conditions at the beginning of 2010.
Do you plan to increase the planned recruitment of participants into the study? *Any increase in planned recruitment should be notified to the main REC as a substantial amendment for ethical review.*	*Yes / **No***

6. Safety of participants

Have there been any related and unexpected serious adverse events (SAEs) in this study?	***Yes** / No*
Have these SAEs been notified to the Committee? *If no, please submit details with this report and give reasons for late notification.*	***Yes** / No /Not applicable*
Have any concerns arisen about the safety of participants in this study? *If yes, give details and say how the concerns have been addressed.*	*Yes / **No***

7. Amendments

Have any substantial amendments been made to the trial during the year?	***Yes** / No*
If yes, please give the date and amendment number for each substantial amendment made.	Amendment 1.0 approved 21-Jun-2010

8. Serious breaches of the protocol

Have any serious breaches of the protocol occurred during the year? *If Yes, please enclose a report of any serious breaches not already notified to the REC.*	*Yes / **No*** *Yes / No*

9. Other issues

Are there any other developments in the study that you wish to report to the Committee? Are there any ethical issues on which further advice is required? *If yes to either, please attach separate statement with details.*	*Yes / **No*** *Yes / **No***

9. Declaration

Signature of Chief Investigator:	
Print name:	KAMLESH KHUNTI
Date of submission:	19th July 2010