Q on non-english-speaking subjectsFrom: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 07, 2006 4:23 PM
To: 'Mathieu, Mark'
Subject: RE: Question

Hi Mark,

David asked me to respond to your email below. David meant that we are re-looking at our BIMO program at present and as we move forward in this process, additional guidance will be developed as appropriate and will be posted on FDA's GCP website. At this point I think that it's too early to speculate where this will all lead.

I'm sorry I can't provide more information.

My best,

Bonnie
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-----Original Message-----
From: Mathieu, Mark [mailto:Mark.Mathieu@parexel.com]
Sent: Monday, March 27, 2006 10:49 AM
To: OC GCP Questions
Subject: Question

I would appreciate your insights on the following question:
Q. In a September 2005 speech, David Lepay, director of GCP programs, said that, as part of the agency's emerging GCP risk-based approach, FDA hopes to "query the [clinical research] process beyond documentation, including the process of subject protection."Can you specify what is meant by this, whether this has begun, and what specific implications this might have for FDA GCP inspections, and how the nature of such inspections might change in

light of this?

Thanks and best regards,

Mark