

-----Original Message-----

From: Walk, Roger A.

Sent: 18 juillet 2000 00:56

To: Reininghaus, Wolf; Tricker, Anthony; Sanders, Edward; Kinser, Robin D.

Cc: Solana, Rick P.; islesail@rivnet.net; walnutgrove@dellnet.com

Subject: Validation of analytical measurements -

Dear All,

Let me suggest to consider to ask the future CRO we will select for the pilot study to share (some) samples with

- * INBIFO;
- * Richter, Muenchen; or
- * other 'reference' labs (?)

to verify analytical results?

This would require to

- * agree on assay methodologies;
- * define the transport conditions;
- * have or establish SOPs;
- * define the number of samples we want to determine (as you know we have planned 120 adult participants in 3 groups, 3 sample collections per participant on subsequent days (=360 samples of blood, 360 24-h urine samples (in divided aliquots!));

- * check whether transport of exhalate across the Atlantic makes any sense; and
- * many other things I cannot think of at this moment.

Could Hans-Juergen and Tony look into the feasibility of such an approach?

The big 'plus' I see in this is our continuous involvement in the scientific aspect of the project without being directly involved in generating the study data. It also gives these European labs an opportunity to prepare for the case that they actually have to perform some of these assays in the study itself in case none of the CROs can provide such services in the study.

What do you think?

By the way, the Request for Proposal was today sent to Quintiles, Covance and Parexel and we ask them to respond until August 2, 2000.

Regards,
Roger