

To: 'Feldman@api.org' <Feldman@api.org>
From: Cagen, Stuart Z SHLOIL-SHOIL-SHS
</O=SHELL/OU=MSXSCC/CN=RECIPIENTS/CN=SC724012>
Cc: whiter@api.org <whiter@api.org>; Clegg, Patsy M SCC-DCS/22
<patsy.clegg@shell.com>; 'Hargettb@api.org' <Hargettb@api.org>; 'Ng@api.org' <Ng@api.org>;
'Greco@api.org' <Greco@api.org>
Bcc:
Received Date: 2007-05-27 02:50:46 GMT
Subject: RE: latest version of deliverables

All:

Is it too late to do something about this ? If Otto is concerned, we also should be concerned. It is unfortunate we did not have a chance to consult with him earlier.

Stuart

Stuart Cagen, Ph.D.

Senior Toxicologist
Shell Health Services
One Shell Plaza
910 Louisiana Street
Houston, Texas 77002

Telephone: 1-713-241-1407
Fax: 1-713-241-1596
Mobile: 1-832-646-3987

email: stuart.cagen@shell.com

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

From: ottowong@aol.com [mailto:ottowong@aol.com]
Sent: Friday, May 25, 2007 6:55 PM
To: Cagen, Stuart Z SHLOIL-SHOIL-SHS
Cc: whiter@api.org; Clegg, Patsy M SCC-DCS/22; Jmricewas@aol.com
Subject: latest version of deliverables

Dear Stuart:

I am glad that we got a chance to talk on the phone last night and you asked Russ White to send me the latest version of the deliverables of Cinpathogen. Russ sent me an earlier version of the deliverables some 3 or 4 weeks ago before I left for Shanghai and asked me to comment on them in connection with the CC study. I did and sent him my comments. I also talked to Rob Schnatter and Richard Irons on the phone about 2 weeks ago. Unfortunately many of my comments and our requirements are not in the latest version of the deliverables. Furthermore, it's unfortunately that I did not get a copy of the latest version of deliverables until this morning Shanghai time (Saturday).

The latest version of deliverables for the CC study lacks details and specificity. AHS is not specified as one of the recipients of the test dataset or the final dataset. The general items, quality or status of the datasets is not specified. This means that there is no guarantee that the datasets will be ready for analysis or "user friendly." This may become a major issue later on. In terms of data validation, we need to have some assessment of the completeness or representativeness of the patients (cases and controls) included in the study. We discussed this before, but it is not included in the deliverables.

The latest deliverables are not consistent with previous comments or discussion and they do not satisfy the needs of the CC study.

Regards,

Otto

Otto Wong, Sc.D., F.A.C.E.
Fellow, American College of Epidemiology
Chief Epidemiologist, Applied Health Sciences, San Mateo, California, USA
Adjunct Professor of Epidemiology, University of North Texas, Fort Worth, Texas, USA
Adjunct Professor of Community Medicine, Chinese University of Hong Kong
Honorary Professor of Community Medicine, University of Hong Kong
Visiting Professor of Occupational Epidemiology, Fudan University, Shanghai
Associate Editor, Annals of Epidemiology
Editorial Board, Regulatory Toxicology and Pharmacology

Tel: 1 (650) 347-7898
Fax: 1 (650) 344-6887
Email: OttoWong@aol.com

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Attachments:

Cagen, Stuart Z SHLOIL-SHOIL-SHS.vcf