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**From:** Stiens, Angela [Angela.Stiens@mdsinc.com]  
**Sent:** Monday, November 06, 2006 9:49 AM  
**To:** Schulz, Diane M.  
**Cc:** Zedler, Barbara; Sarkar, Mohamadi  
**Subject:** RE: RESPK\_03\_06 Study

**Confidential**

Diane,

Thank you.

Angela

Angela Stiens  
Clinical Study Manager II  
MDS Pharma Services  
621 Rose Street  
Lincoln, NE 68502  
Tel: (402) 437-4779  
Fax: (402) 476-7598  
[Angela.Stiens@mdsinc.com](mailto:Angela.Stiens@mdsinc.com)

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**From:** Diane.M.Schulz@pmusa.com [mailto:Diane.M.Schulz@pmusa.com]  
**Sent:** Monday, November 06, 2006 7:25 AM  
**To:** Stiens, Angela  
**Cc:** Barbara.K.Zedler@pmusa.com; Mohamadi.Sarkar@pmusa.com  
**Subject:** RE: RESPK\_03\_06 Study

Angela,

Upon my conversation with Barb, she did not have any safety comments on Friday with the CCSR. Please proceed.

Thanks for your patience.

Regards,

*Diane M. Schulz*

Diane M. Schulz  
Asst. Clinical Study Manager  
Clinical Evaluation  
Philip Morris USA  
Tel: 804.274.2613  
Cell: 804.239.4279  
Fax: 804.274.2891

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

**From:** Stiens, Angela [mailto:Angela.Stiens@mdsinc.com]  
**Sent:** Tuesday, October 31, 2006 9:47 AM

**To:** Diane.M.Schulz@pmusa.com  
**Cc:** Mohamadi.Sarkar@pmusa.com; Prchal, Kimberly; Mowitz, Jacqueline  
**Subject:** RE: RESPK\_03\_06 Study

Diane,

That's fine. Just get it back to me when you can and we'll go from there.

Regards,  
Angela

Angela Stiens  
Clinical Study Manager II  
MDS Pharma Services  
621 Rose Street  
Lincoln, NE 68502  
Tel: (402) 437-4779  
Fax: (402) 476-7598  
[Angela.Stiens@mdsinc.com](mailto:Angela.Stiens@mdsinc.com)

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**From:** Diane.M.Schulz@pmusa.com [mailto:Diane.M.Schulz@pmusa.com]  
**Sent:** Tuesday, October 31, 2006 7:52 AM  
**To:** Stiens, Angela  
**Cc:** Mohamadi.Sarkar@pmusa.com; Prchal, Kimberly; Mowitz, Jacqueline  
**Subject:** RE: RESPK\_03\_06 Study

Angela,

I apologize for the delay but I have sent the report to Barb for her review and am waiting on her comments. As soon as I receive her feedback I will get back to you.

Regards,

*Diane M. Schulz*

Diane M. Schulz  
Asst. Clinical Study Manager  
Clinical Evaluation  
Philip Morris USA  
Tel: 804.274.2613  
Cell: 804.239.4279  
Fax: 804.274.2891

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

**From:** Stiens, Angela [mailto:Angela.Stiens@mdsinc.com]  
**Sent:** Friday, October 27, 2006 4:26 PM  
**To:** Diane.M.Schulz@pmusa.com  
**Subject:** RE: RESPK\_03\_06 Study

Diane,

You should have received the CCSR in an e-mail I sent the other day. All I need is any comments you might have on the report, so that I can make any necessary changes.

Thanks,  
Angela

Angela Stiens  
Clinical Study Manager II  
MDS Pharma Services  
621 Rose Street  
Lincoln, NE 68502  
Tel: (402) 437-4779  
Fax: (402) 476-7598  
[Angela.Stiens@mdsinc.com](mailto:Angela.Stiens@mdsinc.com)

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**From:** Diane.M.Schulz@pmusa.com [mailto:Diane.M.Schulz@pmusa.com]  
**Sent:** Wednesday, October 25, 2006 11:39 AM  
**To:** Stiens, Angela  
**Subject:** RE: RESPK\_03\_06 Study

Opps I thought your prior email had clinical report attached. Could you email me and let me know if there is something pending?

Regards,

*Diane M. Schulz*

Diane M. Schulz  
Asst. Clinical Study Manager  
Clinical Evaluation  
Philip Morris USA  
Tel: 804.274.2613  
Cell: 804.239.4279  
Fax: 804.274.2891

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

**From:** Stiens, Angela [mailto:Angela.Stiens@mdsinc.com]  
**Sent:** Wednesday, October 25, 2006 12:29 PM  
**To:** Diane.M.Schulz@pmusa.com  
**Cc:** Mowitz, Jacqueline  
**Subject:** RE: RESPK\_03\_06 Study

Diane,

I apologize for the lateness in sending this out. Attached is the metrics for the RESPK study. Please let me know if you have any questions.

Regards,  
Angela

Angela Stiens  
Clinical Study Manager II  
MDS Pharma Services  
621 Rose Street  
Lincoln, NE 68502  
Tel: (402) 437-4779  
Fax: (402) 476-7598  
[Angela.Stiens@mdsinc.com](mailto:Angela.Stiens@mdsinc.com)

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**From:** Diane.M.Schulz@pmusa.com [mailto:Diane.M.Schulz@pmusa.com]  
**Sent:** Tuesday, October 03, 2006 8:50 AM  
**To:** Stiens, Angela  
**Cc:** Mowitz, Jacqueline  
**Subject:** RE: RESPK\_03\_06 Study

Angie/Jackie,

Could I please have a Metrics Tracking log for this study similar to what you provided for the RESLS\_1\_001\_06 study.  
(Study Event/Total Opportunity/Opportunities Completed/ # Errors/Error Rate/Reason for Error/missed opportunities/% missed)

Please include the following:

**Study Events**

**Disposition of Study Cigarettes:** Cigarette Dispensing  
Cigarette Butt Collection

**Urine Collection:**

Deviation windows ( 1-10min/ 11-20min/ 21-30min/ >31min) for each collection window time point

4 HR

6 HR

24 HR

Urine Pooling

Urine Weights

**Aliquoting**

# required

# taken

# missed

**Blood Collections**

Deviation Windows ( 0-5 min/ 6-10 min >11 min) for each collection window

4 HR

6 HR

24 HR

# protocol violations

# protocol deviations

**Subject Participation metrics**

# recruited

# subjects screened

# subjects checked in (Smokers vs. non smokers)

# subjects Completed

**# Smokers vs. Non-Smokers**

# Male/ female of each

Age of, Non-smoker +/- 5yrs of at least 1 smoker of same gender

BMI of each Nonsmoker +/- of at least 1 smoker of same gender

Age and BMI match of the NON-smokers cover the entire range of Smokers

**Quit Assist Log**

#Offered brochure vs. Accepted at start of study and at end of study

Regards,

*Diane M. Schulz*

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Asst. Clinical Study Manager  
Clinical Evaluation  
Philip Morris USA  
Tel: 804.274.2613  
Cell: 804.239.4279  
Fax: 804.274.2891

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

**From:** Stiens, Angela [mailto:Angela.Stiens@mdsinc.com]  
**Sent:** Monday, September 25, 2006 2:06 PM  
**To:** Diane.M.Schulz@pmusa.com; Mowitz, Jacqueline  
**Subject:** RE: RESPK\_03\_06 Study

Diane,

I have attached the revised protocol deviations to include the blood and urine deviations outside of the designated windows. You will notice that most of the urine deviations occurred during the Day -1 (09 August 2006) 1900 through Day -1 (09 August 2006) 2300 collection interval. I spoke with the associate that started this collection interval they inadvertently started the collection late in error causing the duration of the collection interval to be less than 4 hours. The most anyone was off was 45 minutes, however, most were off somewhere between 21 and 30 minutes.

Also, you will notice that most of the blood deviations occurred during the Day -1 (09 August 2006) 0700 collection. The phlebotomist for this draw had some difficulty early on causing a majority of the subjects to be drawn late for the event. The most anyone was off was approximately 21 minutes, however, most were off somewhere between just over 2 minutes and 5 minutes.

Please let me know if you have any questions regarding the deviations. Also, I will send you the updated medical licenses as soon as we receive all of them. We are still waiting to receive a couple of them.

Regards,  
Angela

Angela Stiens  
Clinical Study Manager II  
MDS Pharma Services  
621 Rose Street  
Lincoln, NE 68502  
Tel: (402) 437-4779  
Fax: (402) 476-7598  
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**From:** Diane.M.Schulz@pmusa.com [mailto:Diane.M.Schulz@pmusa.com]  
**Sent:** Friday, September 22, 2006 3:15 PM  
**To:** Stiens, Angela; Mowitz, Jacqueline  
**Subject:** RESPK\_03\_06 Study

Angela and Jackie,

Based upon our phone conversation on Fri, could you provide me with the following items. My understanding is that you will try to get them to me on Monday.

- Copies of Faxes from ABF verifying receipt of two shipments.
- Copy of Cigarette Accountability Log from Pharmacy
- Updated Protocol Deviation Table
- Copies of updated renewal of Medical licenses of Investigator and sub-Investigators (Expected to expire Oct 2006)
- Confirm the name of the CRF specialist I met- Sheron Bradnet?

Thank you sooo much!

Have a great weekend.

Regards,

*Diane M. Schulz*

Diane M. Schulz  
Asst. Clinical Study Manager  
Clinical Evaluation  
Philip Morris USA  
Tel: 804.274.2613  
Cell: 804.239.4279  
Fax: 804.274.2891

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