



February 12, 2004

Maria Gogova  
Study Manager  
Clinical Evaluation  
615 Maury Street  
Richmond, VA 23224

Dear Maria,

Please find the enclosed draft proposal for the May Study, in Lincoln.

Since we didn't have a chance to discuss the new study in detail, I based my assumptions on our learnings from the Phoenix study. This proposal suggests much stronger training and communications elements for subjects and site personnel. You may consider providing coordinated communications materials on all aspects of the study requirements for subjects. When we get to that point, I would like to review a few ideas with you.

If you have questions, please contact me anytime.

Sincerely,

Charles Borg  
CEO

**WatchPC**™

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## Philip Morris USA Study MAY 2004 – Scope of Work (SOW)

Interfusion Partners Inc. (IPI) is pleased to submit the following estimate for our electronic patient diary and data collection program, utilizing the WatchPC hardware platform, for a Philip Morris USA Study in May 2004, at the MDS site in Lincoln, NE.

### REQUIREMENTS

Based on information provided to IPI, it is understood that PMUSA has the following requirements:

IPI is to supply 130 WatchPC units for electronic patient diaries for subjects participating in a three-month clinical study.

It is understood that, for the delivery of the WatchPC units, IPI will meet the following requirements:

1. Program WatchPC units to register and deliver information about the following criteria, which are identical to the MARL/02/03 study:
  - Facilitate the user entering when a study cigarette is smoked, and time- and date-stamp the entry. By the same means, allow the user to identify as accurately as possible the brand of a non-study cig smoked, as this occurs.
  - Provide set reminders/alarms if the subject doesn't register smoking by the end of designated periods throughout the day. These reminders are set at 12:00 for the period of 7:00-12:00; at 17:00 for 12:00-17:00; at 21:00 for 17:00-21:00; and, a reminder until 7:00 next day if no cigarettes are entered in the period of 21:00-7:00.
  - Allow the smoker to register the missed entries for any or all missed periods, identifying study and non-study cigarettes smoked, from memory, for a period of up to 24 hours.
  - Just prior to the scheduled monthly clinic visit, the WatchPC is to provide a two-day and one-day reminder for urine collection, and to record when the subject collected the urine.
  - Register daily when grilled food is consumed.
2. Install software for uploading data from the WatchPC to dedicated computer(s) at the clinical trial site, meeting the technical specifications provided by MDS.
3. Install a patient compliance-monitoring program for use by site coordinator(s). This program is to identify the subject's level of adherence to the protocol while outside of the clinic, which then can be analyzed in correlation with the results of clinical testing.
4. Provide a data export program, as per specifications by MDS, to transfer subject data from the dedicated computer to MDS' database.
5. Write, test and produce instructions for subjects and trial personnel.
6. Provide on-line and telephone support to site personnel during work hours (CST).

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**DELIVERABLES AND COST (US\$)**

<b>1.) Project management</b>	<b>\$6,500-\$7,800</b>
Meetings/correspondence and documentation Re-examine how to improve training of subjects and site personnel for improved compliance; restructure training materials Supervision and coordination	
<b>2.) WatchPC device software licensing</b>	<b>N/C</b>
<b>3.) Set up WPC device software for new study</b>	<b>\$3,800</b>
Set up for new watch ID and serial number generation Install watch software for in-house testing	
<b>4.) New site license for WPC data upload and validation software</b>	<b>\$10,000</b>
<b>5.) Set up data upload software for new site</b>	<b>\$4,200</b>
Set up screen IDs for new site Configure security and networking Issue access permissions Data upload from watch to database; test Tech support during testing Provide CD and instructions for installation of programs	
<b>6.) Database maintenance (\$45 per subject x 110)</b>	<b>\$4,950</b>
<b>7.) WatchPC units (\$100 per WPC x 130)</b>	<b>\$13,000</b>
<b>8.) Site preparation and implementation</b>	<b>\$13,000-\$15,800</b>
Revise Coordinator Manual and crib sheets System Administrator training; account access and admin procedures Site Coordinator training Subject instruction materials Subject instructions presentation Online and telephone support for coordinators Installation of software at study site Travel re training	
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<b>TOTAL</b>	<b>\$55,450-\$59,550</b>
<b>Optional: Software changes in WatchPC</b>	<b>\$4,500</b>
Adjustments to software programming to accommodate "recently missed" entries. Preparation of 3 test watches for client Re-write instructions and adjust artwork for printed materials	

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**Out-of-pocket expenses will be charged at cost**

Air fare, car rental, hotel and meal charges; deliveries, Webex communications, etc.

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**Warranties**

**Product replacement:** The WatchPC is warranted to be free from defects in material and workmanship under normal use for a period of one year. During the warranty period IPI will replace malfunctioning WatchPC units free of charge except for damage to case, band and lens and for depleted battery. Delivery charges will be billed at cost.

**Site support/Troubleshooting:** IPI will provide assistance within 24 hours from Monday to Friday in response to telephone or e-mail requests, at no additional charge. Requests received over weekends will be responded to on the following Monday.

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**Licensing terms**

**WatchPC-based programs:** The license for the software installed in the WatchPC device is for specified clinical trial parameters only, but is granted for unlimited use in the specific trial. Should trial specifications change, IPI will submit a new quote for the new application.

**Data upload and data transfer software:** As these programs have been developed to client's specific technical requirements, the development fees cover the rights to unlimited use of the specific program. A new site license fee will apply for the proprietary data upload and transfer platform developed by IPI, when the platform is installed at a different site. Should other trial specifications change, IPI will submit a new quote for the new application.

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**Delivery**

IPI intends to implement and/or deliver the finished products/programs for Study of "May 2004, Lincoln, NE", by April 15, 2004.

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**Client responsibilities - approvals**

IPI will document the project development via progress reports and may send requests for timely approvals or decisions. If a delay in receiving such an approval or decision results in additional costs to IPI, IPI will send a written description of the delay and the additional costs to PMUSA. Also, if IPI is required to perform additional services outside of the scope of this proposal, it will advise PMUSA of the same, and request payment for the additional time required to provide those additional services at IPI's standard hourly rates.

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**Schedule and terms for interim billings:**

— On approval of SOW	30%
— Approval of subject and coordinator training materials	30%
— Completion of installation and training at study site	40%

Payments due on receipt of invoice

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