PROJECT AGREEMENT

NUMBER 33

To: Craig Steele
MDS Pharma Services (US) Inc.
The Triad
2200 Renaissance Blvd., Suite 400
King of Prussia, Pennsylvania 19406-2755

From: Hans Roethig, M.D., Ph.D.
Director, Clinical Evaluation
Philip Morris Incorporated
615 Maury Street
Richmond, Virginia 23224

This project agreement, dated as of September 1, 2002 (the "Project Agreement"), is entered into pursuant to the Master Services Agreement, dated as of December 21, 2001 (the "Agreement"), by and between MDS Pharma Services (US) Inc., a Nebraska corporation ("Contractor") and Philip Morris Incorporated (d.b.a. as Philip Morris U.S.A.), a Virginia corporation ("Company"). In accordance with the terms and conditions of the Agreement, which terms and conditions are incorporated herein by reference, Contractor shall provide the Services set forth herein.

1. Contractor shall provide the Services specified in Attachment A hereto including, without limitation, the following:

a) Provide data management services for the clinical study titled "A Multi-Center Study to Determine the Exposure of Adult U.S. Smokers to Cigarette Smoke" (Philip Morris USA Clinical Evaluation Study No. TESMC/01/02, MDSPS No. PHILO2001, Protocol PM-1337).

b) Perform statistical analysis of the results of the above study.

c) Provide an integrated study report of the above study.

Notwithstanding anything to the contrary in the study protocol attached hereto as Attachment C ("Study Protocol"), all services outlined above shall be provided by Contractor through its employees and nothing in the Study Protocol shall be interpreted as granting Contractor permission to provide Services through independent contractors.

2. In full and complete compensation for the Services rendered throughout the specified term of the Project Agreement, the Company will pay Contractor, in accordance with Article 3 of the Agreement and as specified in Attachment A of this Project Agreement, a fee of Trade Secret Information Redacted Company shall not pay any amounts in excess of a cumulative total of Trade Secret Information Redacted Trade Secret Information Redacted for Services pursuant to this Project Agreement, unless a higher amount is authorized in advance in writing by the Company.

Pass-through expenses payable under this Project Agreement of approximately Trade Secret Trade Secret Information Redacted include travel expenses for meeting attendance.

3. The term of this Project Agreement will commence as of the date of this Project Agreement and will continue through the later of April 30, 2004, or the completion of the Services to be provided pursuant to this Project Agreement to the reasonable satisfaction of the Company.

4. If Company proposes to change the scope of the Services, Company shall so advise Contractor and shall submit specifications to Contractor. After receipt of specifications, Contractor shall provide Company with a cost estimate for performing the changed or additional Services. All changes must be approved in writing by an authorized representative of each party in accordance with Section 18.02 of the Agreement. ~~Without limiting the foregoing, any changes to the Study Protocol that are approved in accordance with Section 15.3 of the Study Protocol also must be approved in writing by an authorized representative of each party in accordance with Section 18.02 of the Agreement.~~ *(Current protocol does not have a section 15.3. As MDS is not writing the protocol, is this sentence relevant to current project?)*

5. This Project Agreement is subject to the terms and conditions of the Agreement. In the event of conflict between the provisions of the Agreement and this Project Agreement, the provisions of the Agreement will control. In the event of conflict between the provisions of the Agreement or this Project Agreement and any attachment hereto, the provisions of this Project Agreement will control over any attachment hereto and the provisions of this Agreement will control over this Project Agreement and any such attachment. ~~Without limiting the generality of the foregoing, the parties hereby acknowledge and agree that the terms and conditions of the Agreement shall prevail over any inconsistent terms of Section 15.2 and Section 15.5 of the Study Protocol.~~ *(Same comment as above with respect to 15.2 and 15.5 of protocol)*

6. Contractor Project Manager: Steven Zwieg
Company Project Manager: Hans J. Roethig, M.D., Ph.D.

7. Archiving Requirements: As specified in Section 7.05 of the Agreement.

~~10. Notwithstanding Section 13 of the Study Protocol or anything else to the contrary in the Study Protocol, (a) Company's right to audit and inspect the Services shall be as specified in the Agreement including, without limitation, Section 1.04 of the Agreement and (b) any such audits and inspections shall not relieve Contractor of its obligation to provide Services in accordance with the terms and conditions of the Agreement, this Project Agreement, and the attachments to this Project Agreement. Contractor shall correct, at its own expense, any deficiencies identified by any audit or inspection.~~ *(No section 13 in study protocol – the rest is already agreed upon in the Master Agreement)*

11. ~~The parties hereby acknowledge and agree that, as of the date of this Project Agreement, the Study Protocol has been approved by the appropriate Institutional Review Board.~~ *(IRB approval is beyond the scope of MDS' responsibilities in this study.)*

IN WITNESS WHEREOF, the parties have caused this Project Agreement to be executed by their respective duly authorized officers.

MDS PHARMA SERVICES (US) INC.	PHILIP MORRIS INCORPORATED
By:_____	By:_____
Printed Name:_____	Printed Name:_____
Title:_____	Title:_____

ATTACHMENT A

MDS Pharma Services
WORK PRODUCT
Philip Morris Clinical Evaluation Study No. TESMC/01/02

Work Product for services in support of Clinical Study entitled: "A Multi-Center Study to Determine the Exposure of Adult U.S. Smokers to Cigarette Smoke" (Philip Morris USA Project No. TESMC/01/02, MDSPS No. PHIL02001, Protocol PM-1337).

Services:

Contractor has provided and shall provide data management, statistical analysis, and report writing services ("Services") as described in the attached Budget Summary and Assumptions (Attachment B).

Services will be performed in accordance with the Study Protocol and standards of performance outlined in Section 7.02 of the Agreement.

Payment Terms:
Company agrees to Trade Secret Information Redacted for the Services provided pursuant to the Project Agreement, in accordance with the terms of Article 3 of the Agreement. Contractor shall invoice Company in accordance with the following payment schedule:

20% Initial Payment;

14% Ongoing Project Management (14 units of Trade Secret invoiced monthly from March 2003 through April 2004);

10 % Database setup;

10 % Monthly data imports (11 units of Trade Secret invoiced monthly from March 2003 through January 2004);

10 % Approval of Statistical Analysis plan;

12 % Completion of draft tables and listings;

10 % Completion of final tables and listings;

7 % Completion of draft clinical study report;

7 % Completion of final clinical study report

Pass-through expenses, if incurred, will be invoiced at actual.

ATTACHMENT B

MDS Pharma Services

BUDGET SUMMARY AND ASSUMPTIONS

Philip Morris Clinical Evaluation Study No. TESMC/01/02

Philip Morris's specifications for the Total Exposure Study are as follows:

Protocol Number:	PM-1337
Indication:	Exposure to cigarette smoke
Number of Investigators:	40
Number of Subjects to Enroll:	5000
Enrollment Period:	8 months
Enrollment Rate:	625 subjects/month
Treatment Period:	1 week
Estimated No. of Case Report Form (CRF) Pages:	10
Estimated No. of Unique CRF Pages:	7

Time Line Specifications:

Philip Morris's timeline for this project is as follows:

Duration in Months	
Project Implementation	1.0 months
Subject Enrollment	8.0 months
Subject Involvement	0.25 months
Study Site Close-out	2.0 months
Data Management	1.0 months
Statistical Analysis*	1.5 months
Medical Writing*	1.5 months
TOTAL DURATION	**15.25 months**

* This is an estimate, the exploratory nature of this analysis makes the timeline estimate subject to possible delays.

ATTACHMENT B

MDS Pharma Services
BUDGET SUMMARY AND ASSUMPTIONS
Philip Morris Clinical Evaluation Study No. TESMC/01/02

Philip Morris has requested that Contractor undertake the following services with regard to the proposed study:

DIVISION OF RESPONSIBILITIES	Philip Morris	Contractor
A. Investigators' Meeting / Implementation Meeting		
Plan and handle logistics	X	
Participate in meeting conduct	X	X
Attend meeting	X	X
B. Data Management		
Design and develop database		X
Test and validate database		X
Receive/upload vendor data (5 sources)		X
Merge data		X
Perform Q.C. audit of merged database		X
Test merged data transfer		X
Final merged data transfer		X
C. Statistical Services		
Prepare statistical analysis plan		X
Provide review and input	X	
Program and validate tables and listings		X
Perform interim statistical analysis	N/A	N/A
Perform final statistical analysis		X
D. Final Clinical Report		
Provide report template (if available)	X	
Provide Philip Morris SOPs	X	
Provide draft study report		X
Provide review and comments	X	
Provide final study report		X

ATTACHMENT B

MDS Pharma Services
BUDGET SUMMARY AND ASSUMPTIONS
Philip Morris Clinical Evaluation Study No. TESMC/01/02

Trade Secret Information Redacted

I. CLINICAL DATA MANAGEMENT

- Investigators' Meeting (exclusive of travel)
- Implementation Meeting (exclusive of travel)
- Internal Project Team Meetings
- Database Setup
- Archival Activities
- Database Transfers
- eCRF data
- Questionairre Data
- Lab #1
- Lab #2
- Lab #3
- Administrative Overhead

II. STATISTICAL ANALYSIS

- Investigators' Meeting (exclusive of travel)
- Implementation Meeting (exclusive of travel)
- Client Interface/Project Management
- Statistical Analysis Plan
- Statistical Support
- Final Analysis Programming
- Documentation and Archival
- Administrative Overhead

III. INTEGRATED STUDY REPORT

- Investigators' Meeting (exclusive of travel)
- Implementation Meeting (exclusive of travel)
- Client Interface
- Background/Preparation
- Review Statistical Section/Analysis Plan
- Review Tables/Listings/CRF Tabulations
- First Draft
- Report Revisions
- Document Processing
- QC
- Documentation and Archival
- Report Audit
- Administrative Overhead

SUBTOTAL EXCLUDING TRAVEL AND PASS-THROUGH EXPENSES

IV. INVESTIGATORS' MEETING

Estimated @ Trade Secr per participant
3 MDS Pharma Services personnel

V. SPONSOR MEETING TRAVEL

Implementation Meeting
3 attendees estimated @ Trade Secr per attendee

SUBTOTAL TRAVEL AND ESTIMATED PASS-THROUGH EXPENSES

TOTAL ESTIMATED PROJECT

ATTACHMENT B

MDS Pharma Services
BUDGET SUMMARY AND ASSUMPTIONS
Philip Morris Clinical Evaluation Study No. TESMC/01/02

General

1. Services to be provided by Contractor and the assumptions upon which associated costs were determined are based on Protocol PM-1337 dated July 19, 2002 and our discussions with Philip Morris since August, 2002. It should be noted, however, that the costs presented in this budget for these services are estimated pending review of the final specifications and CRF.

Project Implementation

2. Costs presented in the budget are based upon Philip Morris' estimated timeline. Contractor will make every effort to reach the targeted timeline in the most efficient manner possible. Should the timeline be extended, additional project management costs may be incurred. Contractor will notify Philip Morris in a timely manner of these additional costs.
3. Labor for one (1) implementation meeting with Philip Morris and Contractor's Manager of Biometrics, Database Administrator, and Medical Writer has been included in the budget.
4. Labor for the attendance of Contractor's Statistician, Database Administrator and Medical Writer at one (1) Investigators' meeting has been included in the budget.

Ongoing Sponsor Meetings

5. Costs for preparation and attendance at Project Team meetings with Philip Morris are not included in this proposal.

Clinical Data Management

6. Per Philip Morris, Contractor has assumed the receipt of five (5) data resources (eCRFs, questionnaires, and 3 lab sources) and that these resources will be received monthly in electronic form.
7. No interim analyses will be performed.
8. Costs in the budget assume that Contractor receives clean data from each source and any data anomalies that may appear during the analysis process will be forwarded by Contractor to applicable source for correction.

ATTACHMENT B

MDS Pharma Services
BUDGET SUMMARY AND ASSUMPTIONS
Philip Morris Clinical Evaluation Study No. TESMC/01/02

Statistical Analysis

9. Contractor will prepare the statistical analysis plan with review and input by Philip Morris.

10. Contractor will perform the programming of tables and listings, as well as the statistical analysis. Contractor assumes that twelve (12) primary tables and forty-five (45) subset tables will need to be programmed. In addition, Contractor assumes eleven (11) listings will be generated. Due to the exploratory nature of this study, it is anticipated that the initial analysis will generate questions that will lead to additional analyses. Costs for additional tables and listings that may be requested by Company upon its review of the initial analysis are not included in the appended budget. Additional tables and listings will be billed at Trade Secret per listings, Trade Secret per unique table or unique graph, and Trade Secr per subset table. Associated additional time for exploratory analysis performed by the senior statistician will be billed at Trade Secr per hour.

11. Costs for tables and listings include one (1) major and one (1) minor revision.

12. Costs for the analysis plan and table shells include one (1) revision.

13. SAS programs and datasets will be provided to Philip Morris at the completion of the study.

Medical Writing

14. The cost for narrative preparation has not been included in the present budget. No narratives are expected.

15. Costs are based on the assumption that Philip Morris will provide a sample of a Clinical Study Report for this product, and that Philip Morris will provide the style/format template (SOP) for the report. If Philip Morris chooses not to provide a template or sample report, Contractor will use our standard report format (ICH-compliant).

16. Contractor anticipates that the Medical Writer will be included in the early discussions of table development and timelines with Philip Morris.

17. Contractor assumes it will receive the following necessary documents and information from Philip Morris eight (8) weeks before data are available: electronic copy of the Protocol and a sample of the Clinical Study Report for this product and/or the style/format template (SOP).

18. Contractor will first prepare a shell report, which includes the method sections of the Clinical Study Report and shell tables, if available. Because of the exploratory nature of some analyses, (i.e. data analyses may change based on exploratory results), it is understood that certain sections of the shell report may not be completed before the first draft. Once the shell is approved by Philip Morris and tables and listings are available, Contractor will prepare a complete first draft of the Clinical Study Report. Feedback on that draft will be used to create the second draft. The Clinical Study Report will then be QC'd and a final report prepared.

19. Contractor will deliver report, tables and listings to Philip Morris as Word/SAS documents. Appendices will be delivered as paper copies. If the client wishes to receive the report and appendices as a complete PDF document (including scanning, cleaning, and bookmarking), Contractor will provide that service for an additional charge.

Pass-Through Expenses

20. Costs associated with miscellaneous postage and project supplies have not been estimated or included in the present budget. Actual costs will be invoiced to Philip Morris on a pass-through basis.

ATTACHMENT C

STUDY PROTOCOL

Philip Morris Clinical Evaluation Study No. TESMC/01/02 dated July 2002