

MINNESOTA APPLIED RESEARCH CENTER

Data Quality Audit Certificate

This is to certify that

University of Minnesota General Clinical Research Center

passed the Data Quality Audit for data transfer of the primary objective data
from medical and research records into the clinical trial database

Protocol Title: The Lipid-Altering Effects of Barley Beta-Glucan

Sponsor: Cargill Health Foods Incorporated

Principal Investigator: Joseph M. Keinan, MD

Co-Investigator: Joel J. Pins, PhD

Date of Inspection: September 30, 2005

Certificate Number: 2005-MARC-008

Certifying Agency: Minnesota Applied Research Center

Certification Date: October 3, 2005

Auditor: Joy Frestedt, PhD, Executive Director of Research
Minnesota Applied Research Center

Signed: _____

Joy Frestedt

Date: _____

10-4-05

RECEIVED
9/23/05

UNIVERSITY OF MINNESOTA DATA AUDIT REPORT PLAN

Protocol Title (Sponsor): The Lipid-Altering Effects of Barley Beta-Glucan (Cargill)

Objective: To verify the accuracy of the Clinical Trial Data in order to substantiate and strengthen Cargill's FDA submission regarding barley beta glucan.
Information to be reviewed: Seven data points (primary outcome variables) will be reviewed at baseline and end of study: LDL, HDL, Tgl, diastolic BP, systolic BP, abdominal fat (g) (DEXA), body weight. Diastolic and systolic BP measurements will also be audited at study midpoint.
Percent of data to be reviewed: ~10% of subject charts. Specifically, to preserve balance among groups, 20 of 155 will be selected at random (4 from each group A-E; 2 with metabolic syndrome and two without).
Audit method: After review of the full protocol, IRB/ethics approved informed consent/s, and IRB communications about the trial, a print out from the final locked database will be compared to the source documents. All errors will be documented on the print out and the error rate calculated as defined below.
Acceptable error rate: Percentage of errors (# errors/total number of fields audited x 100) will be less than 0.3%.
Expected outcome: Pass with less than 0.3% error.

Audit plan approved:

Signature: [Signature] Date: 9/23/05
MARC Research Director

Signature: [Signature] Date: 1/25/05
MARC Medical Director

Signature: [Signature] Date: Sept. 9, 2005
Cargill Regulatory Affairs Manager

Signature: [Signature] Date: 22 Sept 2005
Principal Investigator



UNIVERSITY OF MINNESOTA DATA AUDIT REPORT

AUDIT DATES: 9/30/05

AUDIT OUTCOME: PASS FAIL*

Results: (Include a narrative description by variable for each subject affected, if applicable)

[Empty box for narrative description]

*If audit failed, refer to Corrective Action Document.

List failed outcomes:

[Empty box for failed outcomes]

Audit Report Complete? YES NO

Form completed by:
 Signature: *D. J. [Signature]* Date: 10-4-05

MARC Director:
 Signature: *D. J. [Signature]* Date: 10-4-05

By signing below, you are stating that all corrective actions are completed:

Signature: _____ Date: _____