

The CAMUS Study Data Archive

The Complementary and Alternative Medicine for Urological Symptoms (CAMUS) Archive contains the Protocol, Manual of Operations, Forms, Study data, and Dataset Integrity Check. The files are organized into the following directories:

- Documentation
- Forms
- Data
- Dataset Integrity Check (DSIC)

CAMUS Documents

The CAMUS Documentation directory contains:

- CAMUS Protocol Version 2.0 REVISED 11 19 08.pdf — updated study Protocol
- CAMUS - Manual of Operations.pdf – CAMUS Operations Manual
- CAMUS Form Instruction 06 02 08.pdf— Question by question instruction on how to fill out data forms
- CAMUS Lab Manual Version 1.pdf— project manual provided by the Core Laboratory for Clinical Studies (CLCS) of Washington University Medical School that served as the central laboratory for the PSA analysis for CAMUS. The manual contains information for collection, processing and shipping of PSA specimens to the lab for analysis.
- CAMUS - Schedule of Evaluations (Version 2.0 REVISED 111908).pdf—table displaying study visits and related study tasks.

CAMUS Forms

This subdirectory contains the following file:

- ALL (07062007).pdf

Contents of this file are summarized in the table below. 45 forms represent 37 study data forms. Nine forms are self-administered and available in English and Spanish (shaded in table). All forms are annotated to serve as codebooks.

	Form #	Form Name	Completed by
1	CAM01	Eligibility and Randomization Form	SC
2	CAM 102	Screening Log Form (SV1/SV2)	SC
3	CAM 21	Demographic Data and Medical History Form	SC
4	CAM 22	History Update Form	SC
5	CAM 23	Concomitant Medication Form	SC
6	CAM 24	Urology Medication Tracking Form	SC
7	CAM 31	Vital Signs Form	SC
8	CAM 32	Physical and Digital Rectal Exam Form	SC
9	CAM 41	PSA Sample Collection and EKG Form	SC
10	CAM 42	Uroflow Measurement Form	SC
11	CAM 45	CBC, Serum Chemistries, Prothrombin Time and EKG Form	SC
12	CAM 46	Urinalysis Form	SC
13	CAM 47	Serum for Banking Form	SC
14	CAM 51	Study Drug Administration and Compliance Form	SC
15	CAM 52	Permanent Discontinuation of Study Medication Form	SC
16	CAM 61	BPH Outcome Events Form	SC
17	CAM 62	Permanent Discontinuation of Study Form	SC
18	CAM 71	Jenkins Sleep Dysfunction Scale Form	Subject
19	CAM 71S	Formulario de Escala de Disfunción del Sueño Jenkins	Spanish Speaking Subject
20	CAM 72	Erectile Function Form	Subject
21	CAM 72S	Formulario de Función Eréctil	Spanish Speaking Subject
22	CAM 73	Ejaculatory Function Form	Subject
23	CAM 73S	Formulario de Función Eyaculatoria	Spanish Speaking Subject
24	CAM 74	Bladder Function Form	Subject
25	CAM 74S	Formulario de Función de la Vejiga	Spanish Speaking Subject
26	CAM 75	International Prostate Symptom Score (IPSS)	Subject
27	CAM 75S	Formulario IPSS de Calificación Internacional de Síntomas de Próstata	Spanish Speaking Subject
28	CAM 76	BPH Impact Index Form	Subject
29	CAM 76S	Formulario de Índice de Impacto BPH	Spanish Speaking Subject
30	CAM 77	Subjective Global Assessment Form	Subject
31	CAM 77S	Formulario de Evaluación Global Subjetiva	Spanish Speaking Subject
32	CAM 78	NIH-Chronic Prostatitis Symptom Index (NIH-CPSI)	Subject
33	CAM 78S	Índice de Síntomas de Prostatitis Crónica de NIH (NIH-CPSI)	Spanish Speaking Subject
34	CAM 79	Participant Treatment Perception Form	Subject
35	CAM 79S	Formulario de percepciones del participante sobre el tratamiento	Spanish Speaking Subject
36	CAM 81	Adverse Event Form	SC
37	CAM 82	Serious Adverse Event Form	SC
38	CAM 91	Death Form	SC
39	CAM 92	Missed Visits Form	SC
40	CAM 93	Comments Form	SC
41	CAM 94	Interim Visit Checklist Form	SC
42	CAM 95	Protocol Exemption Form	SC
43	CAM 96	Participant Relocation Tracking Information Form	SC
44	CAM 97	Post Week 72 Follow-up Form	SC
45	CAM 104	Individual Patient's Drug Accountability Form	SC

CAMUS Data

The CAMUS data directory contains:

- aesae.sas7bat – This dataset contains adverse events for subjects enrolled in CAMUS.
- all.sas7bdat – This dataset contains all variables from all forms used on CAMUS for each enrolled subject.
- all_derived.sas7bdat – This is the primary analysis file for the study.
- camu23.sas7bdat- dataset of Form CAM23 (Concomitant Medication Form) which was completed at each clinic visit
- camu24.sas7bdat- dataset of Form CAM24 (Urology Medication Tracking Form) which was completed at each clinic visit
- SAS program_Effect of Increasing Doses of Saw Palmetto Extract on Lower Urinary Tract Symptoms.sas- publication related analysis program
- SAS program_Performance of the American Urological.sas- publication related analysis program
- SAS program_Recruitment of Participants to a Clinical Trial of Botanical Therapy for Benign Prostatic Hyperplasia.sas- publication related analysis program
- SAS program_The Relationship Between Lower Urinary Tract Symptom.sas- publication related analysis program
- **CAMUS Data\Contents**
 - CAMUS CONTENTS.rtf- Contents procedure for primary analysis dataset (all_derived.sas7bdat).
 - Comments.xls-excel file containing 4 worksheets that are data dictionaries for forms: CAM23; CAM24; CAM82/83 and the primary analysis dataset which is called “CAMUS MAIN” in this file.
 - format for CAMUS Main.sas-variable listing for CAMUS MAIN
 - label for CAMUS Main.sas-label listing for CAMUS MAIN
 - JAMA CAMUS discrepancies.docx- a description of differences between the data and an article published in Journal Of The American Medical Association

CAMUS DSIC

Analyses described in the Dataset Integrity Check were performed to duplicate results for the data published in Michael J. Barry, MD, et al for the Complementary and Alternative Medicine for Urological Symptoms (CAMUS) Study Group; **Effect of Increasing Doses of Saw Palmetto Extract on Lower Urinary Tract Symptoms**; The Journal of the American Medical Association; September 2011; Vol 306, No. 12, 1344-1350. The results of the replication are similar to published results.