

## Epilobium Study for BPH on Geriatric Patients

Study Start Date: 11-1-2012

Principal Investigator: Dr. Daniel L. Johnson MD

Summary Date 7-26-13

### SIGNATURE PAGE

Principal Investigator or Clinical Site Investigator:

Signed: \_\_\_\_\_



Date: \_\_\_\_\_

7-31-13

Name: Dr. Daniel L. Johnson MD

Title: Principle Investigator

### SUMMARY

**Title:** Epilobium Study of BPH on Geriatric Patients

**Objectives:** Observe the efficacy of epilobium based product with the active ingredient brand known as 12DayEpilobium™, under the brand names of Proselene™ and 12dayProstate™

Primary: The objective was to observe a small sample size of men with an average age over 80 with BPH, The common malady of frequent trips to the bathroom.

Secondary: Urine flow, urgency to urinate

**Population:** After withdrawal's and those with serious health issues:  
9 Males ages 60-90-moderate health taking into consideration for age, the majority of participants are on some medication(s)

**Number of Sites:** One site - Longevity Institute Palm Desert, Ca.

**Study Duration:** Four months

**Subject Participation Duration:** One Month

**Time to Complete Enrollment:** Two months

**1 KEY ROLES AND CONTACT INFORMATION**

**Principal Investigator:** Dr. Daniel L. Johnson MD  
**Monitor:** Registered Nurse

**2 STUDY SCHEDULE**

**2.1 Screening**

Doctor visit, answer questionnaire, medical exam including blood workup

**2.2 Enrollment/Baseline**

Doctor visit, review questionnaire, medical exam an blood workup an

**2.3 Final Study Visit**

Doctor visit, answer current BPH status questionnaire

**3 STATISTICAL CONSIDERATIONS**

**3.1 Study Hypotheses**

Validate the positive antidotal observations of epilobium users and the effectiveness on BPH

**3.2 Sample Size Considerations:** A study within a known demographic i.e. Dr. Daniel L. Johnson MD and the Longevity Institute current patients

**3.3 Final Analysis**

750ml of Epilobium Pavarflorium extracted with sugarcane alcohol and purified water with the active ingredient Brand Name 12DayEpilobium™ and product Brand Names Proselene™ and 12DayProstate™

<u>Age</u>	<u>Before Date</u>	<u>Before Score</u>	<u>After Date</u>	<u>After Score</u>	<u>Difference</u>	<u>Percentage Change</u>	<u>Quality of Life Before</u>
81	12/6/2012	21	4/15/2013	10	11.0	52%	4
84	11/20/2012	25	13-Mar	16	9.0	36%	4
82	12/6/2012	13	3/21/2013	16	-3.0	-23%	5
80	11/1/2012	10	4/2/2013	13	-3.0	-30%	3
87	10/13/2012	28	4/18/2013	14	14.0	50%	3
86	12/3/2012	8.5	4/6/2013	9	-0.5	-6%	3
60	11/9/2012	7	4/1/2013	7	0.0	0%	3
85	12/6/2012	9	4/12/2013	7	2.0	22%	4
76	11/20/2012	11	4/5/2013	2	9.0	82%	2
<b>81</b>		<b>132.5</b>		<b>94</b>	<b>38.5</b>	<b>29%</b>	<b>31</b>

I-PSS Score Table

- 1-7 Mild
- 8-19 Moderate
- 20-35 Severe

**Quality of Life**

- 0 Delighted
- 1 Pleased
- 2 Mostly Satisfied
- 3 Mixed
- 4 Mostly Dissatisfied
- 5 Unhappy
- 6 Terrible

## **Summary:**

**From Dr. Daniel L. Johnson MD**

**This study was done on a difficult elderly population in generally poor health mostly with multiple prescription medications, ( Average age 80.1years.If we eliminate the 60 year old, then the average is 82.6 years)**

**In spite of this , the results were rather remarkable in that 55.6% (5 out of 9) improved significantly, with an average improvement of 48%.**

**11.1 % (1 out of 9) showed no change.**

**33.3 % (3 out of 9) worsened with an average worsening of only 19.7%. It seems likely in this difficult population, that these would have worsened anyway, with or without intervention.**

### **QUALITY CONTROL AND QUALITY ASSURANCE**

Desert Longevity Institute Palm Desert, California.

### **4 DATA HANDLING AND RECORD KEEPING**

#### **4.1 Data Management Responsibilities**

Desert Longevity Institute, Pam Desert, California.

### **5 RESEARCH REFERENCES**

Vitalone 2002, 2003 – Durcey 97