AGE GROUP ANALYSIS OF A RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY OF FEMPROX®, A TOPICAL ALPROSTADIL CREAM WITH A NOVEL TRANSDERMAL DELIVERY TECHNOLOGY (NEXACT®) FOR THE TREATMENT OF FEMALE SEXUAL AROUSAL DISORDER (FSAD)

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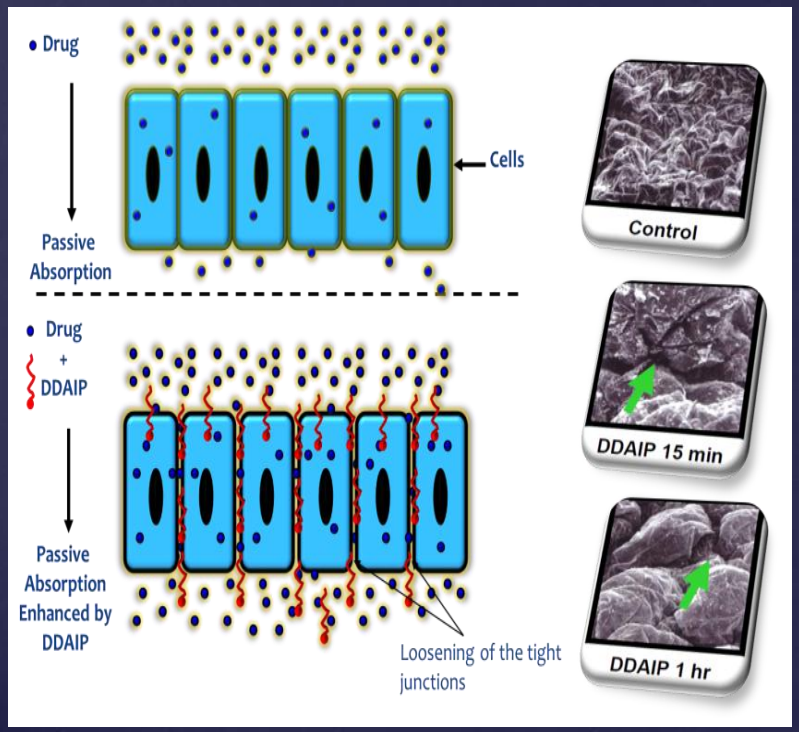
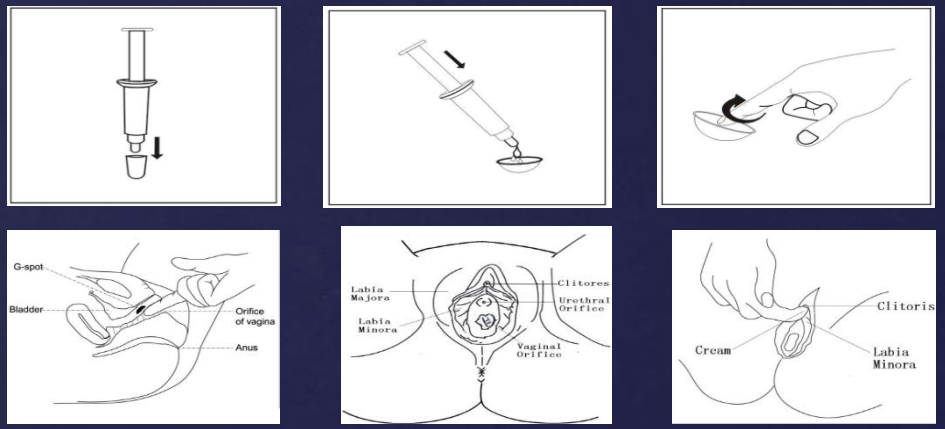
Convenient Delivery of Alprostadil Cream for FSAD
Alprostadil + DDAIP = Femprox™

DDAIP is a novel proprietary skin permeation enhancer
It acts by loosening the tight junctions of the skin



Dosing Instructions

Single Dose Dispenser

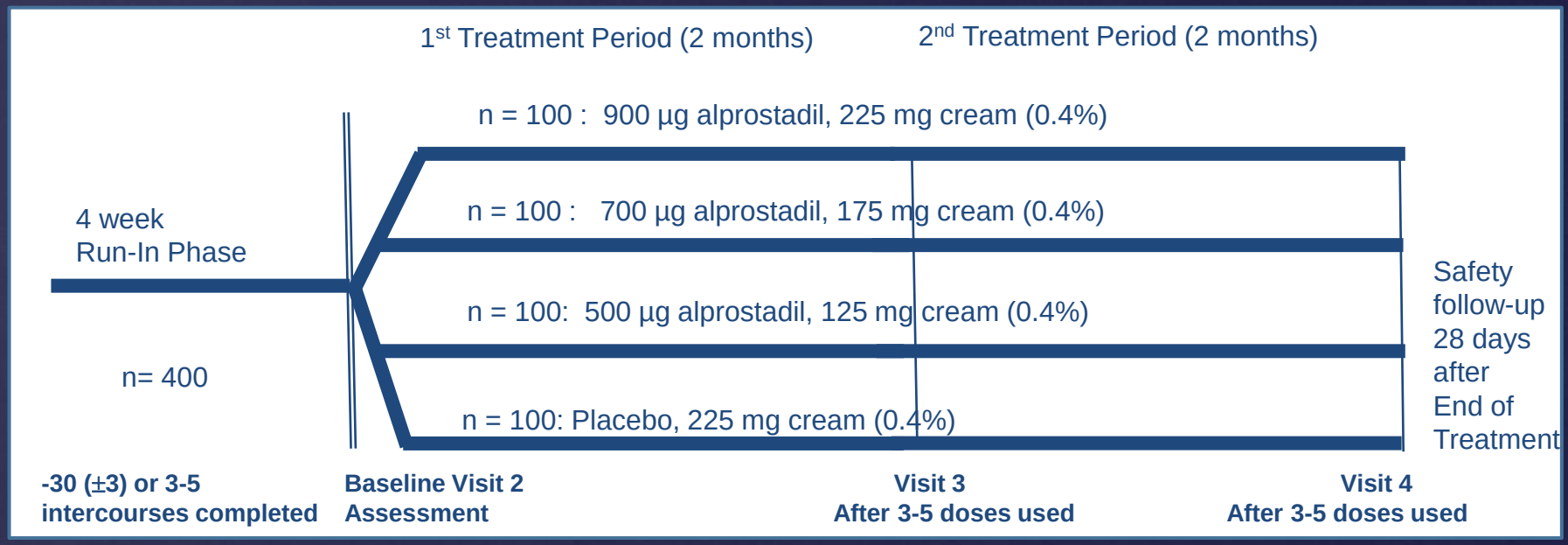


To be applied topically to clitoris and distal anterior vaginal wall (G-Spot)

Femprox: Phase 3 – Clinical Trial in Female Sexual Arousal Disorder (FSAD)

Overall population: **n= 400 women with FSAD, 22 to 65 years old, mean age: 60.7 years**

Population of this analysis: **Age group < 45, n= 168; age group 46 - 65 years, n= 206**



Primary Efficacy Endpoints

- **Satisfactory Sexual Events (SSE),** defined as the number of "Yes" responses to Question 3 of the Female Sexual Encounter Profile (FSEP) divided by number of the sexual encounters.

Secondary Efficacy Endpoint

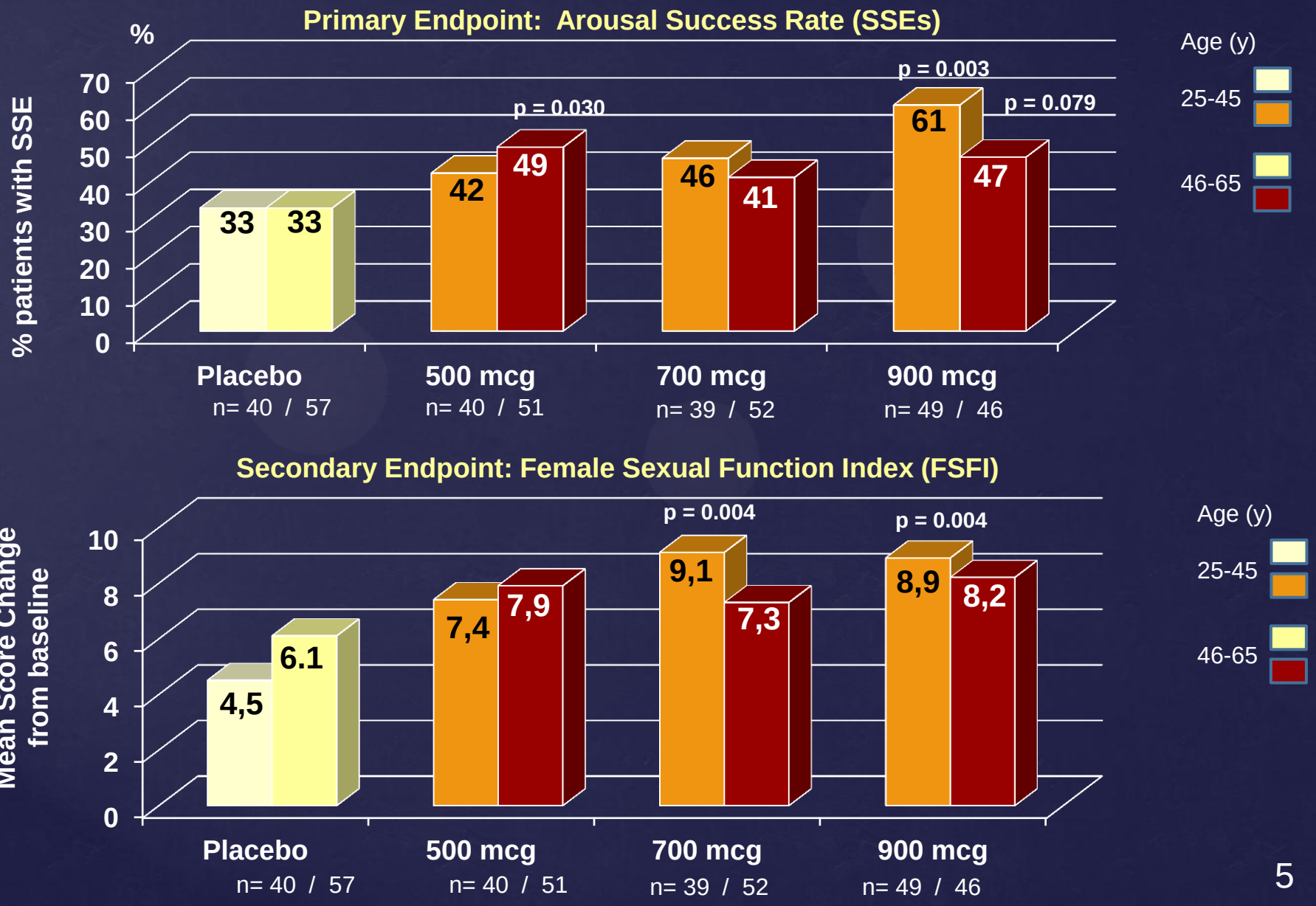
- **Female Sexual Function Index (FSFI), Female Sexual Distress Score (FSDS)**
- **Global Assessment Question (GAQ)**

Key Overall Efficacy Results (Intent-To-Treat Population)

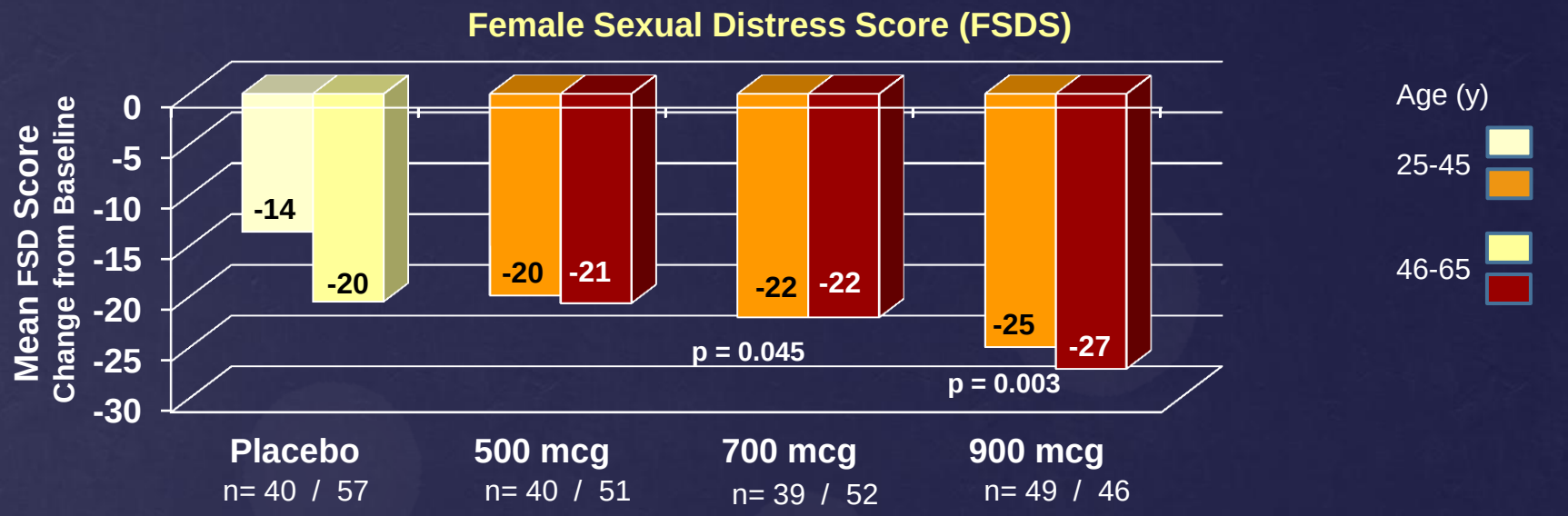
- The overall analysis of the primary endpoint showed **statistically significant superiority of the 900 mcg dose over placebo** (54% vs. 33 %, p=0.0002)
- The mean changes in the **total FSFI score, relative to baseline were 5.4 for placebo and 8.6 for the 900 mcg alprostadil treatment** group (p = 0.0017)
- The 900 mcg alprostadil treatment demonstrated **statistically significant superiority over placebo for all FSFI domains (see Table)**

	Placebo	500 mcg	700 mcg	900 mcg
Number of patients	97	91	91	95
Desire factor	0.70 (1.36)	0.87 (1.22)	1.11 (1.36)	1.20 (1.25)
p-Value		0.189	0.076	0.002
Arousal factor	0.720 (1.26)	1.21 (1.20)	1.31 (1.24)	1.48 (1.32)
p-Value		0.017	0.009	<0.001
Lubrication factor	1.19 (1.60)	1.50 (1.44)	1.52 (1.30)	1.64 (1.48)
p-Value		0.263	0.25	0.0001
Orgasm factor	0.73 (1.41)	1.25 (1.33)	1.27 (1.22)	1.56 (1.44)
p-Value		0.020	0.033	0.0001
Satisfaction factor	0.72 (1.53)	1.25 (1.24)	1.37 (1.19)	1.31 (1.23)
p-Value		0.008	0.001	0.0005
Pain factor	1.24 (1.77)	1.64 (1.48)	1.67 (1.65)	1.62 (1.76)
p-Value		0.335	0.149	0.045

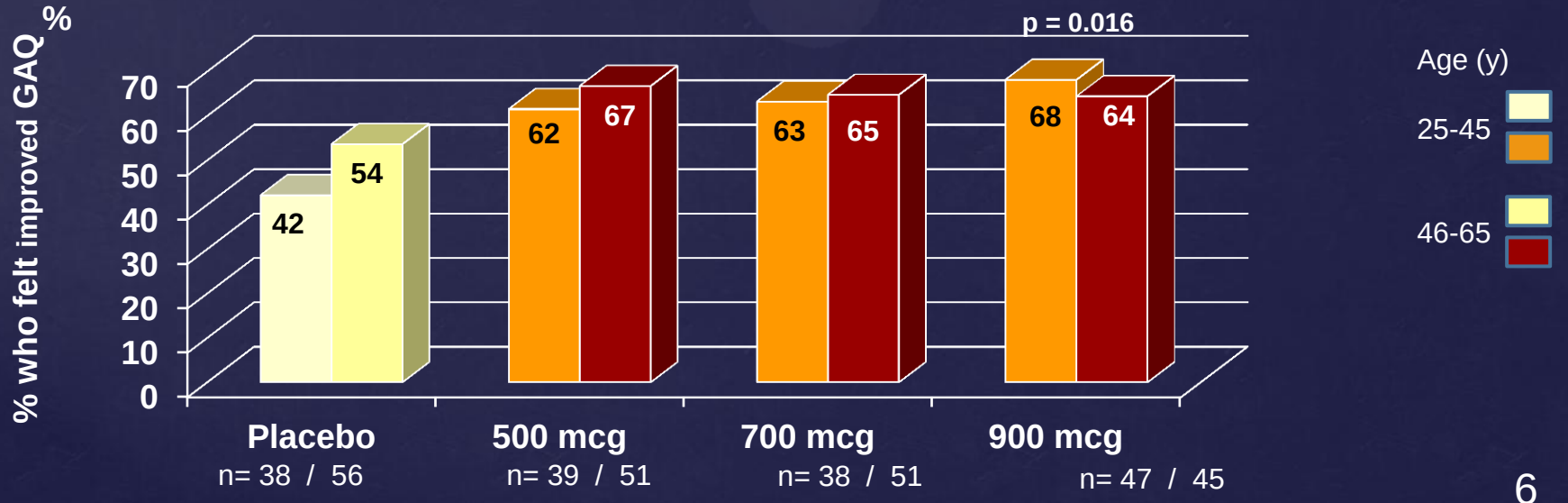
Age Group Analysis for Primary and Secondary Efficacy Endpoints



900 mcg dose shows significant improvement in all primary and secondary endpoints

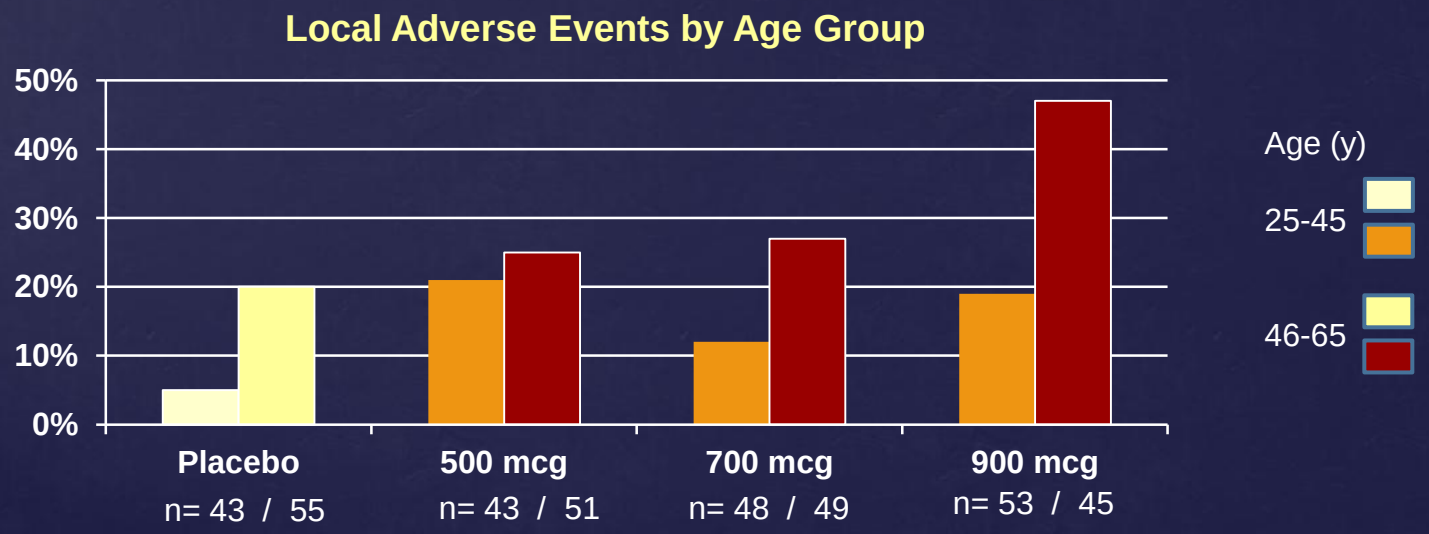


GAQ: When using study medication, did you feel your level of sexual arousal (excitement) improved?



Femprox Phase 3 Trial: Safety

	Placebo	Femprox® (500 mcg)	Femprox® (700 mcg)	Femprox® (900 mcg)
Number of Patients	98	94	97	98
Number (%) of patients with at least one related AE	15 (15%)	23 (24%)	19 (20%)	32 (33%)
Number (%) of patients withdrawn due to AEs	0	0 (0%)	2(2%)	3 (3%)
Number of severe AEs	0	2	1	2
Severe local burning	0	2	0	0
Severe vulvar stinging	0	0	1	1
Severe vulvar swelling and ache	0	0	1	1
Serious AEs (SAEs)	0	0	0	0



Conclusions

- In the Phase 3 trial (400 patients) **Femprox® (topical alprostadil cream 0.4 %) at a dose of 900 mcg showed clinically significant improvement over placebo in all primary and secondary endpoints**.

- The prevalence of local adverse events is similar in patients ≤ 45 years of age between all active treatment doses. Patients > 46 years of age reported **mild to moderate local adverse events** with the 900 mcg dose.

- Results demonstrate the **potential of Femprox® (topical alprostadil cream 0.4 %) to become a safe and effective drug for the treatment of FSAD.**