

FemPulse Pre-Screening Tool

This worksheet is a supplemental screening aid and is not a substitute for the site's formal Inclusion/Exclusion Criteria assessment. All formal eligibility must be assessed and documented per site standard procedures and the study protocol.

GUIDANCE NOTE

YES = favorable / NO = concern

Basic Eligibility

Item	YES	NO	Comments
Age \geq 21 years	<input type="checkbox"/>	<input type="checkbox"/>	_____
Diagnosis of OAB, with symptoms for \geq 6 months	<input type="checkbox"/>	<input type="checkbox"/>	_____
No contraindication to anticholinergic medications	<input type="checkbox"/>	<input type="checkbox"/>	_____
Willing / able to complete 7-day bladder diary (phone App, e-diary)	<input type="checkbox"/>	<input type="checkbox"/>	_____
No current UTI symptoms or history of frequent UTI	<input type="checkbox"/>	<input type="checkbox"/>	_____
No active pelvic inflammatory disease	<input type="checkbox"/>	<input type="checkbox"/>	_____
No active vaginitis or vulvar inflammatory issues	<input type="checkbox"/>	<input type="checkbox"/>	_____
No chronic bladder/pelvic pain (IC, vulvodynia, vaginismus, neuralgia)	<input type="checkbox"/>	<input type="checkbox"/>	_____
No pain with pelvic exams / tampons / penetration / intercourse	<input type="checkbox"/>	<input type="checkbox"/>	_____
No prior pelvic radiation or major pelvic surgery affecting anatomy	<input type="checkbox"/>	<input type="checkbox"/>	_____
Has uterus (has not had a hysterectomy)	<input type="checkbox"/>	<input type="checkbox"/>	_____
Never treated with Botox or tibial or sacral neuromodulation for OAB	<input type="checkbox"/>	<input type="checkbox"/>	_____
Does not have a cardiac arrhythmia	<input type="checkbox"/>	<input type="checkbox"/>	_____
No vaginal prolapse \geq Stage II	<input type="checkbox"/>	<input type="checkbox"/>	_____

Comfort & Prior Use

Item	YES	NO	Never Tried*	Comments
Patient has had good experiences inserting / removing vaginal products (examples - tampons, menstrual cup, vaginal ring, diaphragm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Patient is physically comfortable placing / removing vaginal products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Patient is psychologically comfortable placing / removing vaginal products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

*Ok / Open to learning and may require extra teaching

Mobility & Dexterity

Item	YES	NO	Comments
Adequate hand dexterity (no major stiffness or limitation)	<input type="checkbox"/>	<input type="checkbox"/>	_____
Able to maintain position(s) needed for insertion/removal	<input type="checkbox"/>	<input type="checkbox"/>	_____
Able to manually reach vaginal opening comfortably	<input type="checkbox"/>	<input type="checkbox"/>	_____

Menopause & Vaginal Tissue History

Item	YES	NO	N/A	Comments
Menopausal Status (circle): Pre- / Peri- / Post-				
Vaginal atrophy severity (circle): None / Mild / Moderate / Severe / Unknown				_____
Using local vaginal female hormones: Estrogen / progesterone / testosterone (circle)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Using systemic hormones: Estrogen / progesterone / testosterone (circle)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
No unexplained abnormal vaginal bleeding or spotting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
No symptoms of vaginal dryness / itching / burning / discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Pre-screening red flags**Examples of findings that suggest subject is **not suitable**:**

- Moderate or severe vaginal atrophy / other vaginitis symptoms
- Vaginal stenosis / short genital tract (if known)
- Prolapse Stage II or higher
- Hypertonic or tender pelvic floor / pelvic, bladder and / or vulvar pain issues
- Difficulty with vaginal wearables / hesitancy about vaginal wearable
- Not good candidate for anti-cholinergic medication
- Pregnant / desires pregnancy in next year / refusing contraception if at risk of pregnancy
- Not able or willing to download and maintain 7-day bladder diary

OUTCOME:

- NO CONCERNS** identified on worksheet. Site may continue with protocol required I/E eligibility assessment
- BORDERLINE FINDINGS** — consider discussion with Sponsor prior to moving forward.
- NOT SUITABLE** candidate for device wear. Site should review protocol I/E criteria before proceeding.
Discuss with Sponsor if any questions

Comments: _____

Completed By (Name/Role): _____

Signature: _____ Date: _____

Supplemental worksheet. Not a protocol document. Refer to study protocol for full eligibility requirements.