Female sexual dysfunction (FSD) is a significant unmet medical need for a large population and thus a substantial opportunity for drug developers – provided development challenges can be addressed.

Female sexual dysfunction (FSD) is common, with 43% of women reporting sexual concerns and 12% reporting related distress, and yet has only a single FDA-approved treatment.\(^1\) Thus, FSD presents drug developers with a substantial opportunity based on the unmet medical needs of a large population. But if FSD represents a large target for developers, it is not a simple one. FSD encompasses disorders of desire, arousal, orgasm and pain and may involve biologic, social, psychological, environmental and hormonal factors. Treatments for FSD are limited, and experts encourage psychological and behavioral options as well as pharmacological.

A variety of other factors complicate development of FSD therapeutics:

- The terminology for female sexual disorders is evolving, with DSM-5 preserving female orgasmic disorder as a separate indication but merging female hypoactive sexual desire disorder (HSDD) and female arousal dysfunction into “female sexual interest/arousal disorder (FSI/AD)” and dyspareunia and vaginismus into “genitopelvic pain/penetration disorder.”\(^2\)

- DSM-5 diagnostic criteria for FSD and inclusion criteria for clinical trials are complex; e.g. a DSM-5 diagnosis of FSI/AD requires the presence of at least three of six criteria for six months with a frequency of 75-100%. In addition, eligibility for clinical trials often requires demonstration of significant sexual distress.

- Comorbidities are common but are often listed as exclusion criteria in clinical trials, resulting in significant challenges in screening and recruitment.

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Healthcare professionals treating FSD are diverse, with patients seeking care from OB/GYNs, psychologists, psychiatrists, sex therapists and pelvic physical therapists, and the number of sites experienced in FSD trials is limited, presenting challenges in site selection.

Expert opinion about assessments and endpoints appropriate for FSD trials varies, with possibilities including an increase in desire, an increase in satisfying sexual events and a decrease in stress, and yet evidence is lacking for a correlation among changes in Satisfying Sexual Events, desire as assessed with the Female Sexual Function Index and desire when assessed with an eDiary.3

Key Risks and Mitigations in FSD Studies

Risk 1: A high screen failure rate

Because inclusion/exclusion criteria are extensive and comorbidities are common, screen failure rates in FSD trials may be as high as 75 percent.

Mitigations

- Develop a robust pre-screening questionnaire for sites to use before scheduling a screening visit.
- Consider allowing patients to be re-screened if they previously failed because of a transient event such as a yeast or urinary infection but have signed an Informed Consent Form.
- Reimburse sites not only for enrolled patients but also for screening costs to prevent “study fatigue” and maintain site engagement with the study.

Risk 2: Subject failure to complete the eDiary within 24 hours of sexual activity

Subject failure to complete the eDiary in an FSD study could affect primary or secondary endpoints.

Mitigations

- Provide site staff with reference guides to assist in explaining to subjects the rationale for the use of eDiaries and their importance in the study.
- Select an eDiary vendor with extensive clinical trial experience and a simple, non-intrusive and efficient solution.
- Ensure the patient stipend is sufficient to compensate the patient for the time and burden associated with regular use of an eDiary.

For Assistance With Your FSD Program

As a CRO committed to improving healthcare outcomes for women, Health Decisions is committed to assisting developers in expanding the range of treatment options for women with FSD indications. The Health Decisions clinical team understands the key issues and risks in FSD trials and how to mitigate them. Our relationships with KOLs aid sponsors in areas including study planning and protocol development and our understanding of the therapeutic landscape enables us to identify appropriate sites and enroll subjects efficiently. Please contact us to explore how Health Decisions can assist with efficient, timely development of your investigational treatment for an indication in FSD.