Development of a Patient-Centric Exit Study to Contextualize and Assess Meaningfulness of a Potential Treatment for Hypoactive Sexual Desire Disorder (HSDD)

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**I-152**

**Objective**: To conduct a mixed-method study to inform the development of an exit study to contextualize the clinical and survey data from a randomized clinical trial for a novel treatment for HSDD in premenopausal women.

**Methods**: Women who completed the Exit Study were paid a small stipend. The Exit Study was developed using a mixed-method design with three components: Clinical Study Data (Table 1), Qualitative Interviews, and Quantitative Survey.

**Survey Design**
- The RECONNECT Exit Study Objectives were developed in collaboration with the study team to ensure: (1) clinical and survey data are assessed for meaningful benefit, (2) the qualitative data are meaningful, and (3) the exit study is acceptable to patients.
- The Exit Study was designed to include primary and secondary objectives and measures.

**Survey Components**
- **Clinical Study Data** (Table 1) included patient demographic and clinical characteristics.
- **Qualitative Interviews** included a semi-structured interview guide, interviewers were blinded to treatment assignment, and recordings were transcribed for analysis.
- **Quantitative Survey** was developed using a mixed-method design.

**Data Analysis**
- The survey was formatted for optical character-recognition (OCR).
- Data were analyzed using SAS (V9.4; SAS, Cary, NC).
- Multiple imputation was used to handle missing data.

**Conclusions**
- This study provides a mixed-methods approach to understand patient experiences and contextualize clinical and survey data.
- Mixed-methods analysis can be used to assess the clinical and survey data from randomized clinical trials.

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**Table 1. Patient Demographic and Clinical Characteristics by Study Population**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Survey + Interview N = 160</th>
<th>Survey Only N = 193</th>
<th>Overall Study N = 353</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean 27.8 (SD 4.8)</td>
<td>Mean 27.9 (SD 5.0)</td>
<td>Mean 27.8 (SD 4.9)</td>
</tr>
<tr>
<td>Reproductive Status</td>
<td>Mean 2.3 months (SD 6.7)</td>
<td>Mean 2.4 months (SD 8.7)</td>
<td>Mean 2.3 months (SD 6.7)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Multiple 128 (36.4%)</td>
<td>Single 109 (27.1%)</td>
<td>Overall 237 (67.1%)</td>
</tr>
<tr>
<td>Baseline SSEs</td>
<td>Mean 6.8 (SD 3.1)</td>
<td>Mean 6.8 (SD 3.1)</td>
<td>Mean 6.8 (SD 3.1)</td>
</tr>
<tr>
<td>Baseline FSFI</td>
<td>Mean 23.8 (SD 5.7)</td>
<td>Mean 24.3 (SD 5.5)</td>
<td>Mean 24.0 (SD 5.6)</td>
</tr>
</tbody>
</table>

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**Key Results**
- **Survey Results**
  - **Study Population (Table 1)**
    - Survey respondents were 248 women, 6 of whom were excluded due to incomplete data. Women were predominantly recruited from clinical centers in the United States.
    - **Data Analysis**
      - The data was analyzed using multiple imputation (Table 1).

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**References**
- Shifren JL, et al. 
- PFEK Operations GmbH, Berlin; V7.1 or higher) 
- DataFax (DF/Net Research, Inc, Seattle, WA) was used for data collection.