# POSTER 161

# ESTeeM study design: assessing the burden, treatment patterns, and unmet needs of women experiencing sleep disturbances and menopause

**Fiona C. Baker**[1], Claudio N. Soares[2], Lisa Larkin[3], Ruth D. Holzmann[4], Senka Djordjevic[5], Ann-Kathrin Frenz[6], Julie Dorey[7], Huda Shalhoub[4], Pauline M. Maki[8]

[1]SRI International, Menlo Park, CA, USA; [2]Queen's University, Kingston, Ontario, Canada; [3]Ms.Medicine Cincinnati, OH, USA; [4]Bayer AG, Berlin, Germany; [5]Bayer Consumer Care, Basel, Switzerland; [6]Bayer AG, Wuppertal, Germany; [7]Bayer Healthcare SAS, La Garenne-Colombes, France; [8]University of Illinois, Chicago, IL, USA

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## INTRODUCTION

Sleep disturbances are one of the most common and debilitating symptoms experienced by women during and after the menopause transition,[1,2] affecting **up to 69%** of women in this life stage.[1] Sleep disturbances are often driven by **hormonal changes** (e.g., estradiol decline), which disrupt the sleep-wake cycle and contribute to frequent **night-time awakenings** and increased **wake after sleep onset.**[1] **Vasomotor symptoms** (VMS), such as daytime and night-time hot flashes, further compound sleep difficulties,[1] though not all awakenings are attributed to VMS,[3,4] underscoring the complex and multifaceted nature of menopausal sleep disturbances.

Sleep disturbances not only impair **quality of life** but also strain **personal relationships**, disrupt **daily functioning**, and elevate risks for **metabolic, cardiovascular, cognitive,** and **mental health** issues.[1,5,6] Despite these widespread impacts, the burden of sleep disturbances and the effectiveness of treatment options remain underexplored. Hormone therapy helps with VMS-related sleep issues, but its benefits for women without VMS are unclear.[7,8] Furthermore, antidepressants, hypnotics, and non-prescription therapies are not standard recommendations for postmenopausal sleep disturbances due to concerns about tolerability, adverse events, or lack of evidence for effectiveness.[1]

The **ESTeeM study** aims to better understand these gaps by assessing the **real-world burden** and **treatment patterns** of sleep disturbances in postmenopausal women experiencing menopause through the collection of **subjective** and **objective** data.

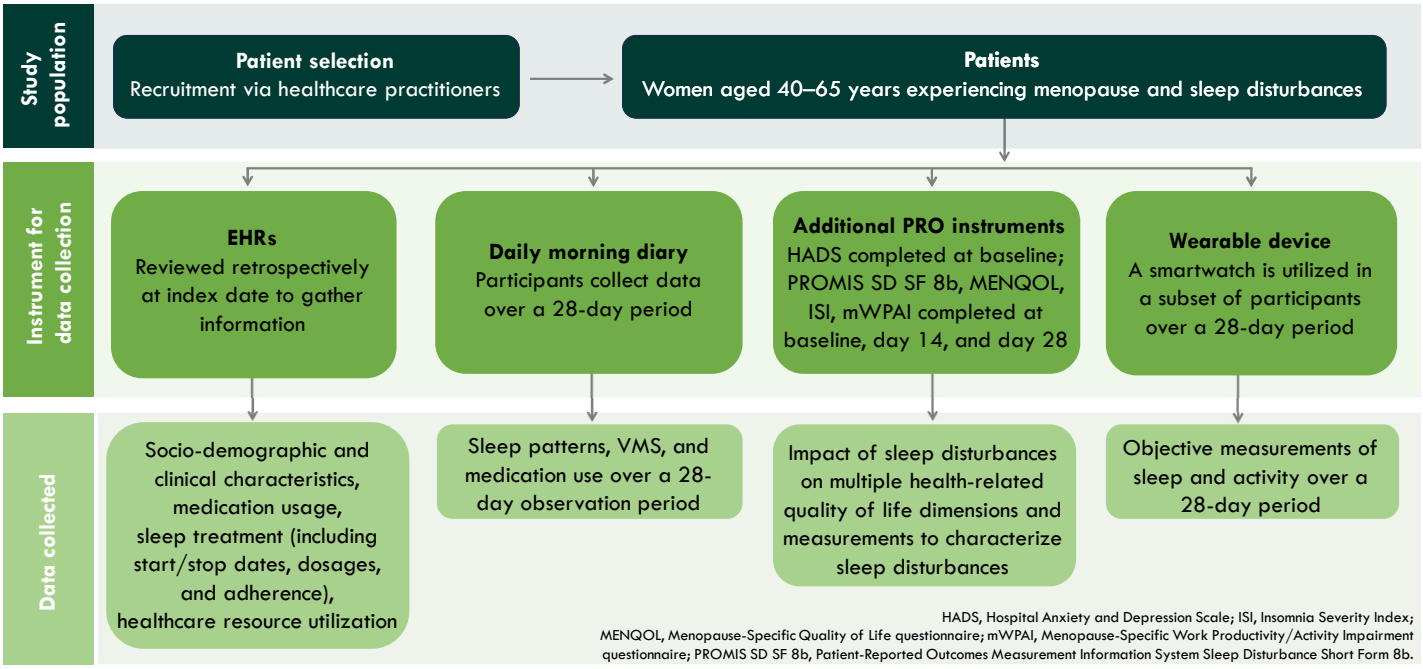
## DESIGN

ESTeeM is a real-world, observational study conducted in the **United States,** utilizing electronic health records (EHRs) and patient-reported outcomes (PROs), including a daily morning diary and a wearable device. The study aims to enroll between **500–1000** women aged 40–65 years who are experiencing natural or surgical menopause and reporting sleep disturbances (**Table 1**). Recruitment will be via **healthcare professionals** in primary care, sleep medicine, and gynecology clinics. The study flow chart and data collection methods can be found in **Figure 1**.

### Table 1. Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|---|---|
| Naturally/surgical post-menopausal women aged **40–65 years** | Menopause induced chemically or from radiation therapy (e.g. chemotherapy). |
| Self-reported **sleep disturbances** associated with menopause | Medical conditions that can impact sleep, (e.g. diagnosed chronic insomnia, sleep apnea, restless leg syndrome, circadian rhythm sleep disorder) |
| | Recent use of prescription treatments for menopausal symptoms |

### Figure 1. Study flow chart and data collection methods




HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; MENQOL, Menopause-Specific Quality of Life questionnaire; mWPAI, Menopause-Specific Work Productivity/Activity Impairment questionnaire; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b.

## RESULTS

Key metrics to be evaluated include the prevalence of sleep disturbances, usage and satisfaction with sleep medications, and the impact of sleep disturbances on work productivity and quality of life.

The primary objectives of ESTeeM are to assess the **burden of sleep disturbances** in women experiencing menopause, focusing on their impact on **quality of life** and evaluating the **unmet need** for effective treatments

The secondary objectives are to explore the **current treatment landscape,** including **treatment usage, adherence,** and **satisfaction,** as well as reasons for **treatment discontinuation**

## CONCLUSIONS

**The ESTeeM study aims to address knowledge gaps on sleep disturbances in women experiencing menopause, particularly the burden on quality of life and current treatment patterns. By identifying unmet needs, the study will inform future treatment strategies to improve women's health outcomes, productivity, and quality of life**

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## DISCLOSURES

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