

CLARINESS

# Patient recruitment for women's health conditions

Discover how Clariness supports women's  
participation and representation in clinical trials



# Women's participation in clinical trials

**Women make up half the global population, and yet clinical trials have historically underserved women and treated men as the default.**

Even today, clinical studies focused on women-specific conditions or outcomes are chronically underfunded. Across the industry, there is significant work to be done in planning and funding trials aimed at improving women's health outcomes.

We are supporting sponsors to change the record. Using our expertise in patient recruitment, we are committed to increasing the participation in and representation of women in clinical trials.





# Women in clinical trials

A statistical overview highlighting gender disparities in medical research

**37%** A study of 86 clinical trials across 9 journals found women's representation to be only 37%

**38%** Cardiovascular disease is the leading cause of death of women globally, yet women made up only 38% of cardiovascular trials between 2010-17

**3%** Only 3.2% of women enrolled in global cardiovascular drug trials, were Black or African American

**5%** 5% of patients with breast cancer (99% of whom are female) have participated in a clinical trial, despite a woman being diagnosed with breast cancer every 14 seconds globally

**76%** 76% of female global novel drug clinical trial participants between 2015 and 2019 were white

**16** For 16 years, from 1977 to 1993, women of child-bearing potential were generally excluded from early phase clinical trials, due to an FDA policy

1. US Food and Drug Administration Drug Trials Snapshots. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials>
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3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9043984/>
4. American Heart Association. Women still underrepresented in clinical research, science and medicine that could save them from their No. 1 killer. Accessed 9 July 2024. <https://newsroom.heart.org/news/women-still-underrepresented-in-clinical-research-science-and-medicine-that-could-save-them-from-their-no-1-killer>
5. Liu KA, Mager NA. Women's involvement in clinical trials: historical perspective and future implications. Pharm Pract (Granada). 2016;14(1):708. doi:10.1854
6. Clariness. Breast cancer patient recruitment for clinical trials. Accessed 9 July 2024. [Breast Cancer - Clariness](#)

# How do you turn women's enthusiasm into consented patients?

70% of women are willing to participate in clinical trials



## Patient focus

- Our Patient Insights team identify barriers to participation women face through interviews and surveys
- Women's health conditions are often underdiagnosed, while trials have complex I/E criteria. Women may also face higher financial barriers



## Intersectional focus

- Identify site locations with more diverse patient populations
- Tailor strategies and patient friendly materials to local cultures to increase recruitment of minority women and address disparate health outcomes for white and minority women



## Topic focus

- Design a study that boosts representation of minority women
- Learn how hybrid and DCT can reduce drop-out rates
- Create new study evaluation processes



## Protocol focus

- Take a patient-centric approach by seeking women's feedback on your I/E criteria
- For example, PMDD trial pre-screening questionnaires can face high fail rates due to complex menstrual cycle questions, symptoms and subjective factors

# How can we help?

As experts in patient recruitment, we have experience supporting over ten trials specializing in women's health, including:

- Bacterial vaginosis
- Breast cancer
- Endometriosis
- LSIL
- Menstrual discomfort
- Ovarian cancer
- PCOS
- PMDD
- Tubal ligation
- Vulvodynia



## EXPERIENCE OVERVIEW

### Our efforts in recruiting women over the past year

**67%**

of the individuals who registered for our studies were women

**65%**

of referrals we received were women

**70%**

of those who reached our phone screening stage were women

**62%**

of participants who were randomized into studies were women

# Our recent experience in women's health

## Case studies include:

- Endometriosis
- Premenstrual dysphoric disorder
- Vulvodynia
- Breast cancer



# Our campaign generated >760k ClinLife® website visits

## Overview:

- > Online patient recruitment for a Phase IIb study on women with symptomatic endometriosis
- > Study enrollment planned for 51 sites in 10 countries, with a target of 318 randomized patients
- > Strict I/E criteria on time since diagnosis and co-requiring participants to have received a surgical diagnosis of endometriosis in the past 10 years, more than 70% of pre-qualified referrals failed initial screening

## Our approach:

- > Online awareness campaign, including search engine marketing, banner advertising on relevant websites and social media
- > Cooperation with patient organizations and other advocates
- > Patient engagement and educational content was created for the target group, as well as specific landing pages
- > Active site support to contact, process, and enroll referred patients. 7k+ patients pre-screened online

## Our results:

✓ **1k+**  
patients  
referred

✓ **32%**  
of referred  
patients passed  
screening visit

✓ **20%**  
of consented  
patients  
contributed  
by Clariness





**CASE STUDY**  
PREMENSTRUAL DYSPHORIC DISORDER

**Online pre-screening completions 407% above target**



**Overview:**

- > Direct-to-patient digital outreach campaign targeted to women aged 18-45 with severe PMS symptoms or diagnosed with severe PMS/PMDD
- > Active campaign in Germany, Poland, Sweden and the United Kingdom

**Our approach:**

- > Dynamic targeting of patients based on geographic location close to active sites, demographic and behavioral targeting, use of lookalike audiences
- > 87.46% of referrals were generated via online advertisements
- > Ongoing review and adjustment of pre-screener questionnaire based on complexity in answering questions on menstrual cycle timing, symptoms and subjective factors, leading to fail rates

**Our results:**

✔ **2k+**  
referrals

✔ **88k+**  
online pre-screenings completed

✔ **€2.53**  
cost per completed online pre-screening



# Completed survey target exceeded by 427% in only 3 weeks

## Overview:

- > Our Patient Insights team conducted a survey for patients suffering from Vulvodynia to understand the patient population and their interest in clinical trials
- > Survey was conducted in 7 countries: Austria, France, Germany, Italy, Spain, UK, and the US
- > 70% of respondents were 40-60 years of age

## Our approach:

- > Ads were placed on Facebook and other websites based on patient population demographics
- > Link to specific online questionnaire included in newsletters and online ads
- > Local language ads and ClinLife® survey were customized for all participating countries

## Our results:

✔ **40%**  
of respondents gave  
contact details to  
receive more  
information  
on vulvodynia

✔ **52%**  
of patients  
with vulvodynia  
showed interest in  
participating in  
clinical trials

✔ **3k+**  
completed  
surveys



# Fear of side effects and lack of understanding of study phases main barrier to apply



## Overview:

- > Our Patient Insights Team ran a qualitative focus group to understand the patient journey of women with breast cancer from diagnosis to study registration and find out what motivates them to apply for a clinical trial
- > Participants were between 35 and 55 years old from Germany
- > We conducted 5 1:1 online interviews with women who applied for a breast cancer study via ClinLife® in the last 2 years

## Our findings:

- > Studies that focus on post-treatment care or treatment side effects may have a recruitment advantage over first-line-treatments
- > All participants are members of online patient groups and showed interest in seeing more information on clinical trials in these groups
- > All participants were unaware of the “absence” of a placebo group in breast cancer clinical trials

## Our findings:



**5/5**

primary interest is in additional benefit on top of current treatment



**4/5**

now see their diagnosis as a manageable condition with hope for the future



**2/5**

interested in studies on whether additional medication can improve efficacy of current drug



# Get in touch

Learn how we can support your women's health studies

[CONTACT US](#)

## About Clariness

At Clariness, we accelerate patient recruitment for clinical trials, to bring new medicines and treatments to patients faster. With 18 years of experience in digital recruitment, we know how to connect you to the right patients, under budget and ahead of schedule.

**We have supported 1,200+ clinical trials across all major indications.**

Our extensive experience and medical knowledge in a multitude of therapeutic areas has proven to significantly improve patient enrollment and retention rates, which is why we have been entrusted with patient recruitment studies for 13/15 leading pharmaceutical companies, across 7,000+ research centers worldwide.



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