

## INC Research Creates New Division for Women's Health Research

Raleigh, N.C.-based contract research organization (CRO) INC Research launched its women's health division to address the diverse challenges associated with female-related health issues, and to meet the escalating need to increase the enrollment of women in trials across all therapeutic areas.

The company is taking its existing experience in women's health and consolidating into one unit.

"INC Research has already developed a solid reputation for the successful conduct of clinical trials in women's health such as breast cancer trials in our Oncology Division and fibromyalgia trials in our CNS Division. Their specialized expertise is a huge value-add for our customers," said John Potthoff, chief operating officer at INC Research.

INC has completed more than 120 women's health studies involving more than 170 sites and 17,000 patients. The company stated that it made sense to bring all of that experience under one banner, giving that capability more visibility

to its clients and improving on how drugs are developed.

"We've done a lot of women's health-related studies and have wonderful expertise and understanding of this type of work. That expertise is permeating from the RA, CRA level all the way up to the leadership ranks; it is just going to provide a deeper focus, a different understanding to the trial. Now we've reorganized and concentrated that expertise in a way that we can provide more visibility to it and offer a very robust value-add to our customers," said Cynthia Madden, M.D., who will head the group as its senior director of clinical operations. Madden was formerly a senior director of medical affairs at INC.

Madden is a physician who has worked in public health, trained in clinical epidemiology and was a former staff member at the U.S. Food and Drug Administration (FDA) Division of Investigational New Drugs.

She stated that the unit will focus on issues that disproportionately affect women, but she also stressed that lack of minority participation in clinical trials results in safety

and efficacy data that may not fully represent the treatment population.

Industry attention has been building around gender differences in metabolism, disease symptoms and treatment response, which are all typically under-scrutinized in female populations.

"So there is a burgeoning need, but also a recognition, that more trials need to be done that include women and, for some trials, performed exclusively on women," said Madden.

There are also nuances in conducting trials with women subjects—depending on their age, lifestyle or the type of study—that sites may not anticipate. Many studies, such as for osteoporosis, often call for older, post-menopausal women subjects who may not drive. Studies investigating the effectiveness of an investigational contraceptive often seek younger women of child bearing age. Addressing these patient recruitment and retention issues in women's health studies will be a big part of the work at INC's new division.

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