

Breaking News on Outsourcing Pharma

Previous page : [INC Research launches women-focused unit](#)

INC Research launches women-focused unit

By Kirsty Barnes

02/06/2008- **INC research has announced the launch of its new Women's Health division that will focus on drug development issues that are "unique" in women.**

The US contract research organisation (CRO) has recruited Cynthia Madden to lead the new division, which will combine clinical expertise in the diseases that most affect women, with an understanding of the challenges faced in developing drugs for this population, allowing for gender and age nuances.

Commenting on the appointment, John Potthoff, chief operating officer of INC said that Dr Madden has 19 years of direct clinical care experience, focusing on women's health issues and has developed a "*distinctive acumen for the complex underlying medical, recruitment and retention issues which so dramatically impact the success of clinical trials in women.*"

Her previous posts include working for the US Food and Drug Administration (FDA) in the Division of Investigational New Drugs, and received additional training at the National Institutes of Health.

The firm said it established the new division in order to further enhance its global service offering in response to customer demand.

"*Dr Madden and her experienced team are now organised to develop solutions and deploy best practices to manage programs addressing women's unique health needs. Their specialised expertise is a huge value-add for our customers,*" said Potthoff.

The number of clinical trials that are female-focused is almost double that of those that are male-focused, according to new research, which showed that out of 400 clinical studies, containing 546,824 participants, published in journals between 1 January 2003 and 31 May 2006, 36 were male-only and 78 were female-only. In 62 per cent of these studies, segregation by sex was deemed to be "*biologically necessary*".

However, the study, recently published by researchers from the School of Medicine at Flinders University in Adelaide, Australia, also concluded that women are too often "*under-represented*" in research focusing on important health issues unrelated to the biological aspects of reproduction.

"*Research on women's health continues to focus predominantly on their reproductive capacity and function, whereas research with men continues to investigate conditions that are not specific to one sex,*" wrote the study authors.

This is despite the presence of mounting evidence that gender differences exist in the incidence of certain diseases, responses to treatment and long-term outcomes.

According to the study, published in the May issue of Mayo Clinic Proceedings, gender-specific reporting of trial results is "*sorely lacking*", with only 28 per cent of the studies reviewed including a covariate adjustment or subgroup analysis by sex, and only 7 per cent including sex-specific reporting of results.

The authors concluded that men or women were commonly being excluded from clinical trials for "*apparently arbitrary reasons*" and recommended that clinical trial registries should routinely gather data pertaining to the gender of trial subjects, along with the development of standard mechanisms for sex-specific reporting and analysis of trial results in publications.

Copyright - Unless otherwise stated all contents of this web site are © 2000/2008 – Decision News Media SAS – All Rights Reserved. For permission to reproduce any contents of this web site, please email our Syndication department: [contact our Syndication department](#). Full details for the use of materials on this site can be found in the [Terms & Conditions](#).