



## 2004 Women and HIV Think Tank

October 14-17, 2004

The Sanctuary at Camelback Mountain, Scottsdale, Arizona

Funding for this meeting provided through unrestricted educational grants from:  
Abbott Virology, Boehringer Ingelheim, Bristol-Myers Squibb Virology, Gilead Sciences

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This report was written and distributed by The Well Project, Inc, a 501c3 Not for Profit Corporation committed to reducing the total human cost of the HIV/AIDS pandemic through a unique and comprehensive focus on women. For more information please contact The Well Project, Inc via email [admin@thewellproject.org](mailto:admin@thewellproject.org), telephone at 434-293-2955, or by mail, P.O. Box 8101, Charlottesville, VA 22906.

## Executive Summary

The 2004 Women and HIV Think Tank convened October 14-17, 2004 in Scottsdale, Arizona. This meeting surpassed our expectations by achieving all of its stated objectives as well as developing additional opportunities for collaboration and advocacy. This Think Tank meeting was the second annual gathering of the Women and HIV Think Tank Initiative, conceived by The Well Project in 2002. The Think Tank Initiative's mission is to promote and facilitate expedience and efficiency in research on HIV disease in women by producing a coordinated effort across disciplines and organizations. In support of this mission, the Think Tank has established a unique, ongoing collaborative process of dialogue, brainstorming, prioritization, and action by a multi-disciplinary group of scientists, clinicians, advocates, and researchers.

Building on the work of the 2003 Think Tank, the purpose of the 2004 meeting was to *design and launch an action plan* for coordinating a multi-disciplinary effort to develop, track, and enhance research on HIV disease in women. This year, participants evaluated three major areas of focus that were identified as critical by the 2003 Think Tank: generating and disseminating a research agenda that addresses women's issues, enhancing the participation of women in research, and tracking progress of research on HIV disease in women.

The 2004 Think Tank meeting included 30 individuals representing research institutions, clinics, government agencies, advocacy organizations, and pharmaceutical companies. By engaging this diverse group of thought-leaders in a rigorous brainstorming process in full group and breakout group formats, a strong consensus emerged on the need for coordinated action and specific plans to proceed. Although the Think Tank generated a list of some 30 potential initiatives, the group prioritized ten initiatives that were regarded as the most feasible and/or the most important issues to be addressed first. They are the following:

- Develop standards for clinical research and drug development which will ensure that sex-based questions are addressed prospectively
- Support the establishment of comprehensive women's health centers that integrate research and care
- Establish a broad coalition of professional and advocacy organizations to ensure the accuracy and integrity of public information, and to increase the visibility of HIV disease in women
- Identify effective models for community-academic partnerships to enhance research, care, and service provision to women living with HIV disease

- Establish requirements to design and implement a comprehensive, searchable online database to house current and future research on HIV disease in women
- Develop and publish an online directory of links to sources for current data that will facilitate more novel and effective research
- Enlist the Special Programs of National Significance (SPNS) to prioritize women and HIV disease
- Identify best practices to enhance participation of women in clinical trials (including site and investigator selection, protocol design, and novel outreach and retention strategies)
- Convene a multidisciplinary meeting to address novel clinical trials design models and viability
- Elevate the visibility of HIV disease in women (including research and policy implications) at the 2006 International AIDS Conference in Toronto

In addition, the Think Tank participants identified an essential, overarching need for the Think Tank Initiative to provide a leadership role in support of the working groups. This role would encompass several areas: guiding strategy for the work of the Think Tank Initiative, preparing 1-year and 5-year plans, facilitating and supporting working groups, and convening future Think Tank events and the annual Think Tank meeting. To fulfill this role, financial support will be required to fortify, resource, and staff the Think Tank Initiative. The Well Project team continues to be inspired by this initiative and is committed to finding the funding to provide this leadership and put this much-needed infrastructure in place.

Of the ten initiatives described above, four were adopted by individuals or organizations and the remaining six were each turned over to a volunteer working group. All of the working groups developed initial action plans and follow-up will begin with each group in November 2004.

We are grateful for the support of our sponsoring partners through unrestricted educational grants for the 2004 Women and HIV Think Tank: Abbott Virology, Boehringer Ingelheim, Bristol-Myers Squibb Virology, and Gilead Sciences; and for the initial support for follow-up work from Pfizer.

## Think Tank 2004 Summary Findings

The 2004 Women and HIV Think Tank convened October 14-17, 2004 in Scottsdale, Arizona. This meeting surpassed our expectations by achieving all of its stated objectives as well as developing additional opportunities for collaboration and advocacy. This Think Tank meeting was the second annual gathering of the Women and HIV Think Tank Initiative, conceived by The Well Project in 2002. The Think Tank Initiative's mission is to promote and facilitate expedience and efficiency in research about HIV disease in women by producing a coordinated effort across disciplines and organizations. In support of this mission, the Think Tank has established a unique, ongoing collaborative process of dialogue, brainstorming, prioritization, and action by a multi-disciplinary group of scientists, clinicians, advocates, and researchers.

Building on the work of the 2003 Think Tank, the intent of the 2004 meeting was to *design and launch an action plan* for coordinating a multi-disciplinary effort to develop, track, and enhance research on HIV disease in women. This year, the meeting participants included 30 individuals representing research institutions, clinics, government agencies, advocacy organizations, and pharmaceutical companies. By engaging this diverse group of thought-leaders in a rigorous process of brainstorming in both full group and breakout group formats, a strong consensus emerged on the need for coordinated action and specific plans to proceed. The participants evaluated three major areas of focus which were identified as critical by the 2003 Think Tank: developing and disseminating a research agenda that addresses women's issues, enhancing the participation of women in research, and tracking progress of research on HIV disease in women.

This report outlines the case for coordination, the problems and priorities identified by the Think Tank body, and the key elements of the action and resource plan the group developed.

### The Case for Coordination

The case for coordination of research efforts on HIV disease in women is strong. Dr. Judith Auerbach's editorial (*The Washington Post*, October 14, 2004) captured the sentiments and frustrations of the Think Tank, which began just over a week after the vice presidential debates. During the debate, when asked about the disproportionate impact of HIV/AIDS on African American women, "both candidates displayed an alarming ignorance of the reality of the crisis." The AIDS epidemic now disproportionately impacts women (representing more than half of new infections globally) and is the leading cause of death among African American women ages 25 to 34.

Unfortunately, a keen awareness of the true scope of the epidemic, and of its impact on women, is lacking among top policymakers. As a result, funding for research, treatment, and care are not sufficient to address the full scope of the crisis among women. In the face of these realities, the Think Tank body believes that the research community must take the lead in coordinating efforts to ensure the most efficient and expedient use of available resources.

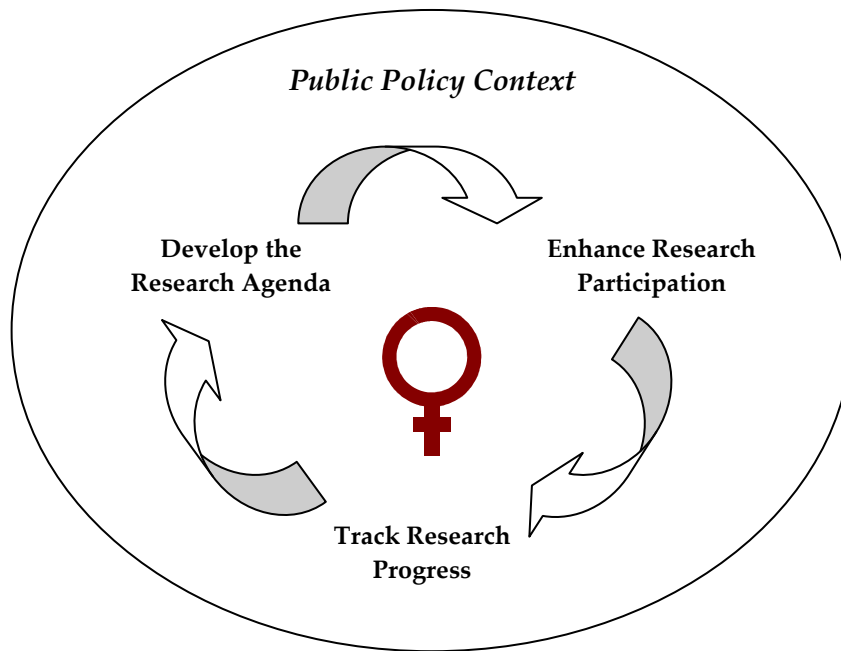
This need to coordinate efforts emerged from the work of the 2003 Think Tank. The body convened to explore the gaps and controversies in research on HIV disease in women. As the group identified gaps in knowledge, they also identified a significant lack of coordination and infrastructure needed to address these gaps in knowledge. For example, one of the research gaps identified in 2003 relates to differences in biology of antiretroviral treatment in women. How do sex-based differences impact the efficacy, toxicity, dosage and effects on quality of life of various treatment regimens? How do these differences impact the initial regimen, adherence, virologic response, and emergence of virologic resistance?

Attempting to address these research gaps immediately triggers a more fundamental question: What will it take *to even begin to study* these gaps? This fundamental question leads to a series of other sub-questions: What research has already been done? What will it take to get these questions to the top of the research agenda? What will it take to enroll and retain women in studies to answer these questions? What will it take to track the progress of this research?

These questions were the starting point for the work of the 2004 Women and HIV Think Tank. Over a three-day period we explored the critical challenges, identified solutions, and established priorities for ongoing working groups to address these needs.

### **Critical Challenges**

Breakout groups were formed to discuss three important areas of focus: developing and disseminating a research agenda that addresses women's issues, enhancing participation of women in research, and tracking the progress of research. As the breakout groups began to explore these focus areas, the Think Tank participants quickly determined that the challenges in coordination must be set in a broader public policy context. A brief discussion of these policy issues occurred at a plenary session, and is provided below as an overall context to frame the findings in the three focus areas.



### **Public Policy Context**

The U.S. healthcare system, along with the changing nature of HIV/AIDS, creates several challenges for addressing the women and HIV crisis:

- The nature of the U.S. system “divides the pie,” as advocates must pursue funding to support specific diseases rather than a comprehensive health focus
- Current policies do not appreciate that HIV, particularly in the U.S., is increasingly becoming a chronic disease that is largely preventable
- Research and care are viewed as separate efforts, rather than integrated

The Think Tank recognized the need to explore multiple strategies and methods to raise awareness through top-down and bottom-up initiatives to drive policy shifts through both legislative and regulatory advocacy.

Within the HIV arena, specific public policy challenges were identified:

- No mandate exists to coordinate research efforts
- Lack of or limited involvement of professional societies (ACOG, HIVMA, IDSA, IAS, AMA, IAS-USA) on women’s policy
- Lack of sex- and gender-specific analysis in clinical research and drug development trials
- Research networks often do not have sufficient representation of affected groups
- Lack/shortage of scientists in the advocacy community
- Lack of public policy awareness of domestic HIV issues

Several strategies were identified:

- Create a coalition to pursue an advocacy agenda
- Establish policy fellowships & training for scientists and community
- Pursue legislation and/or incentives to encourage coordination of research efforts
- Pursue incentives and regulations to ensure analysis of sex- and gender-based data

### **Developing the Research Agenda**

Think Tank 2003 identified and prioritized the gaps and controversies in research on HIV disease in women. For Think Tank 2004, the focus shifted to strategy and implementation: How do we ensure that the research gaps and controversies are continually evaluated and such information is disseminated to drive the agenda of the research community in the most thoughtful way?

A number of specific problems were identified with regard to *developing the research agenda*:

- Lack of coordination among government, industry, and academia
- Lack of patient-focused research
- Lack of dissemination of study results and best practices
- Insufficient cohort studies
- Insufficient numbers of women in studies to power statistically meaningful results specific to women

To overcome these problems possible solutions were identified:

- Explore appropriate and effective mechanisms to encourage coordination of research
- Explore opportunities to establish a congressional mandate on coordination of research
- Explore appropriate and effective mechanisms to ensure sufficient numbers of women in trials
- Create partnerships between key players in industry, government, and clinical settings
- Encourage multidisciplinary research teams
- Pursue community-academic partnerships
- Create a comprehensive database of research
- Initiate more women-focused cohort studies



## **Enhancing Research Participation**

As previously noted, ensuring sufficient participation of women in research is critical to advancing knowledge of how to prevent and manage HIV disease in women.

Several specific problems were identified in *recruiting and retaining women in research*:

- Traditional research sites are not conducive to participation by women; little investment occurs in non-traditional and non-HIV specific sites
- Disconnect between investigator interests and participant interests
- Stigma
- Lack of understanding by women about clinical research
- Gaps between qualitative and quantitative research
- Women often are an afterthought, not a primary focus of research
- Lack of racial concordance between patient and investigator
- Failure to invest in best practices and skills
- Failure to develop investigator skills

To overcome these problems, several possible solutions were identified:

- Establish women's centers for care and research
- Conduct outreach and education to raise visibility of women's issues and increase women's empowerment
- Pursue funding of women's initiatives by Special Programs of National Significance (SPNS) from HRSA
- Establish community-academic partnerships
- Determine best practices for research building upon prior work and documentation
- Coordinate with pharmaceutical companies and the FDA to develop standards of participation and data collection across gender and race subsets
- Develop novel clinical trial designs

## **Tracking Research Progress**

The central problem in tracking research progress on women and HIV is that no single, practical mechanism exists to easily and reliably track current and ongoing research.

To overcome this problem, several possible solutions were identified *to track research progress*:

- Create and maintain an online directory of existing research sources (the "Link Project")
- Define, design and develop a "supersite" that provides easy and reliable online access to past and present research efforts
  - Conduct stakeholder workshops to assess needs and requirements

- Convene a working group to identify funding mechanisms
- Establish a phased approach to implementation
- Pursue a National Library of Medicine conference grant for stakeholder kick-off conference
- Establish a fellows program to work on health information systems
- Identify and prioritize content sources (e.g. build emerging literature abstract database on HIV to merge with Pubmed)

### **Plan for Action**

After completing intensive brainstorming about problems and solutions, the Think Tank participants worked together to prioritize ideas generated during the breakout sessions and to create action plans for the highest priority initiatives.

Although the Think Tank generated a list of over 30 potential action items and initiatives, the group prioritized ten initiatives as the most feasible and/or most important issues to be addressed.

| <b>Initiative</b>  | <b>Description</b>  |
|--|---|
| Improving standards for clinical research and drug development | <ul style="list-style-type: none"> <li>○ Identify standards needed to ensure adequate enrollment of women and adequate data collection to support research efforts</li> <li>○ Ensure that drug development and clinical research adequately reflect the population affected by HIV, in particular women, and that such specific issues as safety and efficacy in women are investigated; ensure that women-specific issues are explored (e.g. women and contraceptives)</li> <li>○ Identify incentives or policies needed to establish these standards of care in pharmaceutical industry research</li> </ul> |
| Women’s Center for Research and Care                           | <ul style="list-style-type: none"> <li>○ Support the establishment of comprehensive women’s health centers that integrate research and care</li> <li>○ Identify innovative models for linking research and care, to support the establishment of women’s centers that integrate the two</li> </ul>  |
| Coalition  | <ul style="list-style-type: none"> <li>○ Establish a coalition of professional and advocacy organizations to ensure the accuracy and integrity of public information and to increase the visibility of HIV disease in women</li> </ul>  |
| Community-Academic Partnerships                                | <ul style="list-style-type: none"> <li>○ Identify effective models for community-academic partnerships to enhance research, care and service provision to women living with HIV disease</li> </ul>  |

|                                     |  |
|-------------------------------------|--|
| Research Database                   | <ul style="list-style-type: none"> <li>○ Establish requirements for the design and creation of a comprehensive, searchable online database to house past and present research on HIV disease in women</li> </ul>   |
| Links Project                       | <ul style="list-style-type: none"> <li>○ Develop and publish an online directory (list of links) to sources for current data to facilitate more novel and effective research</li> </ul>  |
| SPNS                                | <ul style="list-style-type: none"> <li>○ Secure support from the Special Programs of National Significance (SPNS) to focus on women and HIV disease</li> </ul>   |
| Best Practices in Clinical Research | <ul style="list-style-type: none"> <li>○ Identify best practices and tools to enhance participation (enrollment and retention) of women in clinical trials and research (including site and investigator selection, protocol design, and novel outreach and retention strategies)</li> </ul> |
| Novel Clinical Trial Design         | <ul style="list-style-type: none"> <li>○ Convene a multi-disciplinary meeting to address novel clinical trials design models and viability</li> </ul>  |
| International AIDS Conference       | <ul style="list-style-type: none"> <li>○ Elevate the visibility of HIV disease in women (including research and policy tracks) at the 2006 International AIDS Conference in Toronto</li> </ul>   |

Of the ten initiative areas described above, four (Links Project, SPNS, Novel CT Design, and the Toronto AIDS conference) were adopted by individuals or organizations to pursue. The remaining six were each turned over to a volunteer working group based on the interest and leadership of Think Tank participants. All of the working groups developed initial action plans and follow-up will begin with each group in November 2004.

In addition, the Think Tank body identified an essential, overarching need for the Think Tank Initiative to be fortified and become a facilitator to support the ongoing working groups. The Well Project team continues to be inspired by this initiative and has committed to seek the funding to put this much needed infrastructure in place.

### **Next Steps**

The Think Tank 2004 recognizes that while much has been accomplished in our collective efforts to combat the AIDS epidemic, much work remains to be done.

The Well Project is committed to providing leadership and support for the ongoing work of the Think Tank. We are actively and aggressively seeking additional financial support for this role, which would encompass: guiding strategy for the work of the Think Tank, preparing 1-year and 5-year plans, facilitating and supporting working groups, and convening future Think Tank events as well as the annual Think Tank meeting.

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through unrestricted educational grants for the  
2004 Women and HIV Think Tank:  
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and for the initial support for follow-up work from **Pfizer.***



\*This report was written and distributed by The Well Project, Inc, a 501c3 Not for Profit Corporation committed to reducing the total human cost of the HIV/AIDS pandemic through a unique and comprehensive focus on women. The Well Project is pursuing three key areas where our expertise will have the greatest possible impact on the HIV/AIDS pandemic:

- Treatment and Care information provided via the web portal [www.thewellproject.org](http://www.thewellproject.org)
- Thought and Action Leadership through key stakeholder meetings and the Think Tank initiative
- Advocacy, Education and Awareness to generate better public understanding of HIV and AIDS

For more information please contact The Well Project, Inc via,

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## Women and HIV Think Tank 2004 Meeting Design

### The Well Project Mission

The Well Project is committed to reducing the total human cost of the HIV/AIDS pandemic through a unique and comprehensive focus on women.

### Think Tank Program Mission

The Women and HIV Think Tank, first convened in 2003, is committed to encouraging expedience and efficiency in research about HIV disease in women by producing a coordinated effort across disciplines and organizations.

### Think Tank 2004 Meeting Intent

The intent of the 2004 Think Tank is to *design and launch an action plan* for coordinating a multi-disciplinary effort to develop, track, and enhance research on HIV disease in women.

### Desired Results

By 12:00 noon on Sunday, October 17, 2004, we will have:

- **Established and begun** the process of developing relationships among all participants
- **Mobilized** the group to develop effective ways to coordinate the research effort on HIV disease in women
- **Developed** a strategy to integrate priority research questions into current and planned research efforts on women and HIV
- **Identified** effective approaches to enhance participation of HIV+ women in research
- **Identified** one or more specific initiatives to track progress of research on women and HIV
- **Established** work groups to develop and pursue action plans in support of identified initiatives
- **Identified appropriate direction and role** for the Think Tank program
- **Agreed on next steps, including the dates for our next meeting**
- **Shared our reflections on our meeting**

## Summary Agenda

### *Thursday, October 14, 2004*

- 12:00 pm – 7:00 pm ..... Optional pre-meeting activities (hike, swim, spa, massage, etc)
- 7:00 pm – 9:00 pm ..... Welcome Reception and Dinner (also optional)

### *Friday, October 15, 2004*

- 7:00 am – 8:00 am ..... Breakfast (buffet style, in meeting room)
- 8:00 am – 9:15 am ..... Welcome, Introductions, and Meeting Overview
- 9:15 am – 9:30 am ..... Break
- 9:30 am – 10:00 am ..... Call to Action: Coordinating Research Efforts
- 10:00 am – 12:00 pm ..... Integrating Identified Research Gaps into Current and Future Research
- 12:00 pm – 1:15 pm ..... Lunch & Break
- 1:15 pm – 3:00 pm ..... Enhancing research participation
- 3:00 pm – 3:20 pm ..... Break
- 3:20 pm – 4:30 pm ..... Enhancing research participation (cont' d)
- 4:30 pm – 5:00 pm ..... Reflections on the day
- 5:45 pm ..... Bus 1 departs to Scottsdale for shopping & walking
- 6:45 pm ..... Bus 2 departs for restaurant
- 7:00 pm – 9:00 pm ..... Dinner

### *Saturday, October 16, 2004*

- 7:00 am – 8:00 am ..... Breakfast
- 8:00 am – 8:30 am ..... Day 2 Kickoff Session
- 8:30 am – 10:00 am ..... Tracking research progress
- 10:00 am – 10:20 am ..... Break
- 10:20 am – 12:00 am ..... Tracking research progress (cont' d)
- 12:00 pm – 1:00 pm ..... Lunch
- 1:00 pm – 3:00 pm ..... Summary
- 3:00 pm – 7:30 pm ..... Relax, reflect, & re-energize
- 7:30 pm ..... Dinner onsite

### *Sunday, October 17, 2004*

- 8:00 am – 9:00 am ..... Breakfast
- 9:00 am – 11:00 am ..... Action Planning
- 11:00 am – 12:00 pm ..... Meeting Close

## Women and HIV Think Tank 2004 Attendees

### Attendees

**Judith Auerbach, PhD**

Vice President, Public Policy  
American Foundation for AIDS Research

**Dawn Averitt Bridge**

Founder  
The Well Project

**Arlene Bardeguet, MD, MPH, FACOG**

Associate Professor, Director HIV  
New Jersey Medical School, Department of OB-GYN

**Julie Barroso, PhD, ANP, CS**

Assistant Professor  
Duke University School of Nursing

**Karen Beckerman, MD**

Chair, Department of OB-GYN  
Newark Beth Israel Medical Center

**Carol Brosgart, MD**

Vice President, Clinical Research  
Gilead Sciences

**Gina Brown, MD**

Cicatelli Associates

**Victoria Cargill, MD, MSCE**

Director of Minority Research  
National Institutes of Health

**Rebecca Clark, MD**

Associate Professor of Medicine  
Louisiana State University Health Sciences Center

**Susan Cohn, MD, MPH**

Associate Professor of Medicine  
University of Rochester Medical Center

**Elaine M. Daniels, MD, PhD**

Senior Medical Director  
Therapeutic Group Leader for HIV & Women's Health  
Pfizer, Inc.

**Jane Hitti, MD**

Associate Director, Department of OB-GYN  
University of Washington

**Tina Kanmaz, PharmD**

Clinical Scientist  
Abbott Virology

**Ben Kozub**

Associate Product Manager, Viramune  
Boehringer Ingelheim

**Sharon Lee, MD**

Southwest Boulevard Family Health Care Services

**Martin Lewis, M.Ed., MSN, RNCS, ANP, ACRN**

Associate Director, Community Relations  
Gilead Sciences

**Veronica Miller, PhD**

Director  
Forum for Collaborative HIV Research

**Donne Newbury, PhD**

Bristol-Myers Squibb

**Karin Nielsen, MD, MPH**

Associate Clinical Professor, Pediatric Infectious Diseases  
UCLA Department of Pediatrics

**Nancy Norman, MD, MPH**

Director of Women's Health  
Fenway Community Health

**Keri Oberg**

National Manager, HIV Community Relations  
Boehringer Ingelheim

**Andrew Pavia, MD**

Professor of Pediatrics and Medicine  
University of Utah

**Tonia Poteat, PA-C**

Grady Health System

**Patricia Reichelderfer, PhD**

Microbiologist  
National Institutes of Health / NICHD

**Stephen Storfer, MD**

Associate Director, Virology  
Boehringer Ingelheim

**Melanie Thompson, MD**

Principal Investigator  
AIDS Research Consortium of Atlanta

**Jennifer VanHorn, MD**

Department of OB-GYN  
University of Utah

**Fulvia Veronese, PhD**

Chair, Etiology and Pathogenesis and Microbicides Research  
National Institutes of Health

## Meeting Staff

### The Well Project

**Richard Averitt**  
Chief Operating Officer  
The Well Project

**Megan Raspa, MPH**  
Project Manager  
The Well Project

### Facilitators

**Rachel Conerly**  
**Ron Wilder**  
Aligned Action, Inc.

### Meeting Planners

**Debbie Cooke**  
VP, Chief Operations Officer  
Meeting Masters, Inc.

**Tina DeRenzis**  
President  
Meeting Masters, Inc.