Saint Louis University
Center for Vaccine Development
Focus Group Report
January 2003

Linking People Strategies With Business Strategies
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Introduction

Focus group sessions were held at the Center for Vaccine Development (the Center) in St. Louis, Missouri from November 21 through December 16, 2002. Judy Gruender and Kara Erker of Aon Consulting conducted each focus group session. Sharon Irby-Moore, RN, MPH, CPNP, CCRC, recruiter and community educator of the Center, welcomed focus group participants and provided an overview of the Center and clinical vaccine trials. She then left each session. Jonathan (Jon) Taulbee, marketing research assistant of the Center, remained in each session to answer technical questions about clinical vaccine trials as well as about the genital herpes vaccine trial.

These focus group sessions were designed to bring individuals (women) together to share and discuss new ideas about where the Center might find participants for clinical vaccine trials that it conducts throughout the year and, specifically, female participants for the upcoming trial it is conducting for a genital herpes vaccine.

A total of 83 women between the ages of 18 and 30 participated in eight focus group sessions that were conducted over nearly four weeks. The women represented different backgrounds including college students, former clinical vaccine trial participants, parents of former clinical vaccine trial participants, and professionals from the St. Louis metropolitan area. Each session lasted approximately 90 minutes. Focus group session dates, times and number of participants were as follows.

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<tr>
<th>Date</th>
<th>Time</th>
<th>Number of Participants</th>
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<tbody>
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<tr>
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A structured focus group guide was used with all groups. Questions asked of all participants are included in the Summary of Findings section of this report.

The focus group results presented in the following pages use the words most, many and some as follows:

- Most means that almost all participants made the statement or agreed with it
- Many means that a majority of participants made the statement or agreed with it
- Some means that a significant number, but not a majority of participants, made the statement or agreed with it.
Executive Summary

In recent focus groups conducted with 83 women between the ages of 18 and 30, we found that these women would be most interested in participating in a clinical vaccine trial for the financial reward (assuming, of course, that the risks are minimal). In fact, the primary reason participants signed up for the focus groups was to obtain a $25 Westfield Shoppingtown gift card. Participants do, however, understand that there is a limit as to how much of a financial reward can be offered to trial participants.

Because many participants were unaware of the existence of the Center and its constant need for vaccine trial participants, they feel that the Center must direct some of its efforts to better market its mission and goals with the public and, especially, with the Saint Louis University community. One of the best ways to do this may be to identify a national or local spokesperson who could bring credibility and attention to clinical trials in general and, specifically, to the Center (examples are included in this report). Clearly, the St. Louis University student population provides a huge resource for clinical trial participants.

Regarding its current need for participants for the genital herpes vaccine trial, many believe a spokesperson could work for that as well, especially if the spokesperson is someone who has been touched by the disease (e.g., knows someone who has it or has seen the devastating effects on childbirth). Other ideas for educating the public about the Center are included in this report. However, direct contact in the way of small or large group clinical vaccine trial education presentations was recommended as a better approach to promoting the Center than flyers or general advertisements. In addition, building relationships with community organizations (such as Planned Parenthood) and businesses (such as bars, restaurants and shopping malls) was highly recommended.

Once awareness has been raised of the Center and it is able to recruit an adequate number of clinical vaccine trial participants, most focus group participants stressed that maintaining relationships with trial participants is critical to the continued success of the Center. Focus group participants offered many ways to ensure a positive experience, starting with a clinical vaccine trial participant’s first exposure to the Center (i.e., provide respectful, courteous service), to extra incentives during the trial (e.g., award gift certificates, coupons to local stores and restaurants; provide food to take home), to keeping participants aware of trial progress (e.g., distribute frequent communications to current and former clinical vaccine trial participants).
Summary of Findings

1. First of all, does everyone understand the concept of a clinical vaccine trial?

Most participants feel they understand the concept of a clinical vaccine trial.

To ensure focus group participants from each session completely understood the concept of a clinical vaccine trial, Sharon Irby-Moore provided an overview. She explained that vaccine trials are the final stages of developing vaccines and that a clinical vaccine trial is defined as an experiment in human subjects. She described four phases of clinical trials, which are as follows.

- **Phase 1** consists of a small group of participants (usually fewer than 100) and is the first time the vaccine is given to humans. Participants are monitored closely. At this stage, researchers are looking for side effects and are paying close attention to safety issues.
- **Phase 2** consists of a larger group of participants (usually a few hundred). At this stage, dosages are determined. Researchers continue looking for side effects and safety issues.
- **Phase 3** consists of a much larger group of participants (usually thousands). Generally, there are multiple Phase 3s. Researchers continue looking for side effects and safety issues. This phase precedes marketing of the vaccine.
- **Phase 4** occurs after the product (i.e., vaccine or medicine) is in the marketplace. Sometimes the product is recalled during this phase when a problem is found.

*Note: The genital herpes clinical vaccine trial will be a Phase 3 trial that comprises nearly 7,000 women across the United States. Saint Louis University is the lead site.*

The following questions were asked to clarify participants’ experience with focus groups, the recruitment process for this focus group as well as clinical vaccine trials in general.

**Have you ever been involved in a focus group before?** Most participants have not been involved in a focus group before.

**How did we find you to participate in this focus group session?** Most participants heard about the focus group session as a result of Jon Taulbee visiting their classes. Many also saw the flyer. Some were in the Center’s database.

**What inspired you to participate in this focus group?** Most participants were inspired to participate in the focus group because of the $25 Westfield Shoppingtown gift card. Some participants were interested in learning more about genital herpes because they know people who have the disease.

**If you have been involved in a clinical vaccine trial, what inspired you to participate?** Of the nearly 20 focus group participants who have been involved in a clinical vaccine trial, most were inspired to participate in the trial because of the money and the opportunity for a free vaccine. Others wanted to participate out of good will.
2. When you think of a clinical vaccine trial, is your perception positive or negative? Why? What do you think the perception of a clinical vaccine trial is for the public-at-large?

Most focus group participants perceive a clinical vaccine trial as positive because it can advance efforts to protect society from certain diseases. Some perceive a trial as negative because of the risks associated with participating in a trial.

Some participants agree that while trials are necessary because society needs vaccines, they would rather not participate in trials themselves. And, most agree that the public-at-large is more interested in trial results than in participating in trials.

Most participants feel that the perception of a clinical vaccine trial for the public-at-large is negative because of the following reasons:

- Lack of education
- Fear of side effects
- Fear of contracting a disease
- Aversion to shots.

3. Have you heard or seen advertisements to recruit participants for clinical vaccine trials in the past? Where have you heard/seen these advertisements? What institution was advertising the need for participants?

Most focus group participants have heard or seen advertisements to recruit participants for clinical vaccine trials in the past. Following is a list of places where participants have heard or seen these advertisements.

- Newspapers (e.g., *St. Louis Post-Dispatch*, *Riverfront Times*, *St. Louis American*, *U News*, etc.)
- Television (e.g., Channels 2, 4 and 5, Al Wyman, the Weather Channel, cable television’s general information channel, etc.)
- Radio stations (e.g., KTRS, KMOX, Z107.7, 101 The River, etc.)
- Flyers on billboards, at bus stops, in student mailboxes on college campuses and in the occupational therapy building at the School of Allied Health Professions at Saint Louis University
- Barnes-Jewish Hospital’s intensive care unit
- Clinics and OB/GYN offices
- *Time and Temperature* telephone number
- The Internet.

For most participants, Gateway Medical Research Inc. stands out as the most advertised clinical research trial center, followed by Saint Louis University and Washington University.
4. For those of you who have heard/seen these advertisements, how effective do you think they have been? Can you remember anything specific about them? Can you remember your reaction when you heard/saw these advertisements for the first time?

Many participants feel that the advertisements they have heard/seen have been somewhat effective. Following is a list of specific things that participants remember about the advertisements.

- Amount of money offered
- Duration of the trial
- Side effects.

In addition, most participants said they pay more attention to flyers that have tear-off telephone numbers than flyers that only list a telephone number that they must write down.

Some participants had the following reactions when they heard/saw clinical vaccine trial advertisements for the first time.

- I can do that!
- If the money is right, I’ll consider doing it. I trust that if the study or drug made it this far, it probably can’t hurt me. I look at the positive results of my participating.
- What’s in it for me.

5. One of the next clinical vaccine trials being conducted by the Center involves a vaccine for the possible prevention of genital herpes, a sexually transmitted disease for which there currently is no known cure. [May wish to explain the disease and how it is spread.] Where do you think we should be advertising for healthy candidates for a study that involves such a sensitive subject?

[Jon reviewed the criteria for the genital herpes trial. He explained that eligible female candidates must be healthy, which is defined as noninfected with the herpes virus and having no immune system deficiencies. They must be between the ages of 18 and 30 and available to participate in the trial for up to 20 months. They must anticipate being involved in more than one sexual relationship (i.e., having anal, oral or vaginal sex) during the next 12 months. He explained that eligible candidates cannot be in a monogamous relationship unless the candidate’s partner already has herpes. Participants cannot become pregnant during the trial nor can they be exposed to immunocompromised people while participating in the trial.]

Focus group participants suggest the Center advertise for healthy candidates at the following places.
Suggested Places to Advertise for Healthy Candidates

- **Community organizations, agencies and clubs**
  - Girl Scouts
  - Women’s shelters
  - Feminist groups such as Una at Saint Louis University
  - Temporary agencies
  - Unemployment office
  - Libraries
  - Health clubs and gyms (New Lady Fitness, YWCA, etc.)

- **Health clinics, medical centers and donor organizations**
  - John C. Murphy Health Center
  - Grace Hill
  - Planned Parenthood
  - Doctors’ offices (e.g., OB/GYN, general practitioners, etc.)
  - College clinics
  - People’s Health Centers
  - County health department
  - American Red Cross
  - Plasma centers and bone marrow donor organizations

- **Schools**
  - High schools
  - Local colleges, universities and community colleges (at dorm and sorority house meetings)
  - Beauty colleges

- **Stores, bars and restaurants**
  - Discount stores such as Target and Wal-Mart
  - Bookstores
  - Grocery stores
  - Nail, hair and tanning salons
  - Restrooms in theatres, malls and bars (in private places – like the stalls)
  - Coffee shops (e.g., Aesop’s, Borders, Coffee Cartel, Kaldi’s, etc.)
  - St. Louis Bread Company

- **Other**
  - Internet
  - Word of mouth
  - Direct mailings
  - Movie screen advertisements
  - Rental property/large leasing agency newsletters
  - Laundromats
  - Appoint a genital herpes personality/spokesperson.

- **Media**
  - Newspapers (e.g., *St. Louis Post-Dispatch, Riverfront Times, St. Louis American, Ladue News, U News, Stall Street Journal*, etc.)
  - Women’s magazines (e.g., *Women’s Health, Glamour, Cosmopolitan, O, The Oprah Magazine, etc.*)
  - Television (e.g., Eye on St. Louis, Channel 5’s Window on St. Louis, Channels 10 and 12, the Billiken channel, etc.)
  - Radio programs
If the Center develops a flyer to help advertise the genital herpes clinical vaccine trial, participants suggest the following information be included on the flyer.

- The amount of money participants will receive
- A description of the study and the time commitment (include the Center’s flexibility with its hours of operation)
- A positive message
- Prevalence of the disease
- Factors that would prohibit participation (having the Hepatitis A vaccine, the vaccine many food service workers receive)
- That it is a Phase 3 trial (and what that means)
- A description of potential candidates (i.e., healthy, single, sexually-active individuals)
- The name of a main contact at the Center (e.g., Sharon Irby-Moore).

Most participants agree that using an interactive approach, such as conducting an informational meeting where people would hear a presentation and then ask questions of a Center representative, will be the most effective approach to recruiting candidates to participate in the clinical vaccine trial for genital herpes.

**6. What do you think is fair compensation for a commitment to participate in a clinical vaccine trial? Do you think different clinical vaccine trials should offer different levels of compensation depending on the nature of the trial?**

Most participants feel that the level of compensation for clinical vaccine trials should depend on the nature of the trial.

Overall, most felt that $40 isn’t enough to recruit participants for the clinical vaccine trial for genital herpes, unless other compensation such as gift certificates, free food and/or transportation reimbursement would be offered in conjunction with the money.

Many agreed that $100 per visit would be fair compensation for a commitment to participate in a clinical vaccine trial for genital herpes. Some said $50 per session would be fair compensation.

Many focus group participants feel the Center must ensure trials are handled in a professional manner, facilities are clean and trial participants know they are appreciated. In addition, many participants suggested that personal contact with Center staff would go a long way toward making participants feel appreciated and accountable for their ongoing participation in the trial.

Most participants feel the Center should ensure trial participants are paid in a timely manner and consider offering other rewards in conjunction with direct compensation. Some ideas are as follows.

- Hold a drawing at certain intervals or at the end of the trial for a special gift/reward
- Give something in addition to money at each visit (e.g., discount coupons, free food)
- Increase the compensation as time goes on to encourage participants to complete the trial
- Offer day care for the children of participants.
7. Can you think of any other relationships that the Center could form to help provide a steady stream of clinical vaccine trial participants, especially for the clinical vaccine trial involving a vaccine for the prevention of genital herpes?

Most participants feel that the Center needs to build alliances with organizations that have integrity, credibility and that people trust already. Most think that establishing a Web site for the genital herpes vaccine trial may help in this effort. Examples of relationships that could help provide a steady stream of clinical vaccine trial participants are as follows.

- **Celebrities**
  - National (e.g., Tori Amos, Madonna, Ani DiFranco, Brad Pitt, Sheryl Crow, Tina Turner, Jackie Joyner-Kersey, etc.)
  - Local (e.g., Julius Hunter, Al Wyman, Kathryn Jamboretz, Karen Foss, etc.)

- **Media**
  - Radio
  - Newspapers including the *Riverfront Times*
  - Women’s magazines (e.g., *Marie Claire, Cosmopolitan*, etc.)

- **Medical centers**
  - Hospitals, urgent care centers, community health centers and clinics (e.g., BJC Healthcare, Grace Hill, John C. Murphy Health Center, etc.)
  - Doctor offices (provide incentive to OB/GYNs for referrals)
  - Medical schools

- **Organizations, agencies and businesses**
  - Local women’s shelters, crisis centers and organizations
  - Social workers; the Missouri Department of Social Services Division of Family Services
  - Discount stores such as Target and Wal-Mart
  - Public transportation (Bi-State Development Agency buses, MetroLink)
  - Night clubs and bars
  - Soulard area merchants/restaurants/bars
  - Gyms (e.g., New Lady Fitness, Wellbridge, YWCA, etc.)
  - Beauty parlors (especially African American salons), barbershops and beauty colleges

- **Schools**
  - High schools (sexual education classes)
  - Local colleges (e.g., Washington University, Webster University, Fontbonne College, University of Missouri-St. Louis, Maryville University, SIU-Edwardsville, Lindenwood College, Harris-Stowe, etc.)
  - Student organizations (e.g., sororities, student government, drama club, etc.)
  - College professors

- **Other**
  - Quality Control (a company that maintains a database and screens candidates for groups)
  - Playbill of the Vagina Monologues
  - Informational meetings on college campuses (Community 101)
  - Link to the Center’s Web site from the Saint Louis University home page.
8. **Do you think it will be more difficult to recruit participants for the clinical vaccine trial involving a vaccine for the prevention of genital herpes? If so, why?**

Most participants agreed that it will be more difficult to recruit participants for a clinical vaccine trial involving a vaccine for the prevention of genital herpes.

On a difficulty scale of 1 to 10 (with 10 being the most difficult), most participants rated the job of recruiting participants for this clinical vaccine trial a seven. This rating is due in part to the fact that it’s a sensitive topic and potential participants may be afraid that they will be infected with the virus and/or that they will be treated disrespectfully.

Most participants agreed that certain things might help make the recruitment process easier. Several examples are as follows.

- Referral fees
- High compensation
- Innocuous advertising
- Assurance that there is no chance of contracting genital herpes through the vaccine
- Privacy assurances
- Respectful treatment of participants.

Other comments associated with this question are as follows.

- The word *herpes* will stop people; the stigma of herpes may keep people from participating
- People will be concerned that they will get it, or they may think the Center is looking for participants who have herpes
- Put as much information as possible in the advertisements to help educate people
- Hearing a presentation about the genital herpes clinical vaccine trial would be beneficial
- Because blood tests are required, some people may not want to participate because they might find they have the disease already (and are happier not knowing)
- Advertising for sexually active participants may discourage people from participating (may not be willing to make this public).
9. **What are the barriers to recruiting individuals to participate in the clinical vaccine trial involving a vaccine for the prevention of genital herpes?**

According to focus group participants, the following are barriers to recruiting individuals to participate in the genital herpes vaccine trial.

- Fear of being judged by others
- Fear of participating in a clinical trial
- Fear of contracting genital herpes
- The stigma attached to genital herpes
- Embarrassment
- Adequate compensation
- Time commitment [Note: For trials that are longer than 12 months in duration, targeting freshmen and sophomores would be better since they likely will be in St. Louis longer than juniors and/or seniors.]
- No compensation for referring potential participants
- Having to stay in St. Louis for an extended period of time
- Not knowing all the facts about the trial and trials in general
- Eligibility requirements to participate in the trial, especially the requirement that trial participants be involved with more than one partner in a 12-month period of time
- Educating participants about the risks; convincing them that it’s risk-free for the short term (but may not be for the long term)
- For many people who work, it may be difficult to fit appointments into their work schedules.

10. **What potential benefit do you see to participating in a clinical vaccine trial?**

Most participants said that the number one benefit to participating in a clinical vaccine trial is being paid.

Some participants said that, if the vaccine works, they liked having free access to it before it was made available to the public at large.

A few participants said they liked the idea of participating in and being associated with a study that would benefit society and would be part of medical history.
11. In what ways could the Center keep the interest of clinical vaccine trial participants to continue to participate, especially if the clinical vaccine trial is for an extended period of time? [NOTE: Trials may last anywhere from one year to five years, with an average of about 1½ years.]

Most participants feel that the Center will keep the interest of clinical vaccine trial participants by treating them with respect and in a professional manner. This includes how candidates are treated at the time they are recruited to participate in a trial, during the trial and once the trial has been completed. Here’s a list of other ideas.

- Send incentives (e.g., thermometers, magnets, etc.) in the mail to candidates, former participants and current participants
- Compensate participants and/or consider increasing the compensation depending on how often they sign up to participate in a trial
- Offer resources (e.g., access and information about other Web sites that offer clinical trials, etc.) so participants can stay involved with trials in general even if they aren’t involved in a trial at the Center
- Provide free food to eat at the Center or take home; distribute gift certificates to the mall, movie theatres, etc.
- Hire competent, polite people
- Keep participants informed about how the trial is going so they feel part of the team
- Reach out so participants know they are valued and respected
- Ensure confidentiality
- Deliver prompt, courteous service
- Provide a comment box in the reception area at the Center so participants can give candid feedback about their experiences
- Write thank you notes to participants
- Sponsor a monthly dinner (attendance would be optional)
- Consider approaching trials from a case management perspective by assigning to each participant a case manager. This case manager would be responsible for fostering participant relationships, reminding participants of upcoming appointments, checking in with participants after an appointment, etc. Reward case managers for the success of their participant relationships.

Most focus group participants feel that trial participants would have more privacy if, when they arrive for appointments, they were required to provide the Center receptionist their names only rather than also announcing which trial they are participating in.
12. What else, if anything, would you like to add?

- One participant is curious as to whether people will be less careful in the future with sexual activities if they know there is a vaccine for genital herpes.
- Some participants feel that it will be difficult to find college students who have not had the Hepatitis A shot, which is required to work in restaurants and with children (two types of jobs many college students have).
- Some participants asked how safe the genital herpes vaccine trial was and whether they would contract the disease if they participate in the trial (since there’s not a cure for genital herpes, many focus group participants would be afraid to participate in the trial because they don’t want to contract the disease).
- One participant suggests that the Center show what genital herpes does to infected women and what it can do to their babies.
- Many participants suggest the Center reinforce to clinical vaccine trial participants that they are making an important difference in society.
- Most focus group participants feel that, in addition to printing and posting flyers, face-to-face interaction would help the Center recruit more candidates.
- Many participants suggest the Center build awareness of its mission, activities and trials (e.g., participate in the general information sessions that are held each fall and spring at Saint Louis University, distribute free T-shirts, etc.).

Most participants feel it is a good idea to have a national spokesperson for genital herpes and the vaccine trials. Ideally, this spokesperson should not be associated with another cause and should be someone young, credible and personally touched by the disease (either someone who has herpes or knows someone who does). A list of names and groups of people to consider is as follows.

- Actors from Dawson’s Creek
- Cedric the Entertainer
- Ben Affleck
- Bono
- Brad Pitt
- Brenda Warner (who is a nurse)
- Britney Spears (some said not her)
- Chelsea Clinton
- Debra Messing
- Doctors
- *Friends* stars
- Jackie Joyner-Kersey
- Jennifer Lopez
- Julia Roberts
- Katie Holmes
- Kay Quinn (Channel 5)
- LaToiya
- Mia Hamm
- Michael J. Fox-type person who could participate in public service announcements (PSAs)
- Nelly
- Oprah Winfrey
- Susan Sarandon
- Trish Gazelle (101.1 The River)
- *The Bachelor*

Other ideas related to building national awareness include developing a 7th *Heaven* episode about genital herpes followed by a PSA for the clinical vaccine trial. An idea for building local awareness includes developing an advisory board of students that could help the Center recruit for clinical vaccine trials, especially the genital herpes vaccine trial.
Focus group participants suggested several key messages that they feel the Center should communicate during the genital herpes clinical vaccine trial recruitment process. These messages are as follows.

- You will not be at risk for contracting the disease
- It’s OK if you are sexually active; you’re not a bad person
- We’ll treat you professionally and with kindness and compassion
- The environment at the Center is professional
- You may be asked questions, but you don’t have to answer any questions that you are uncomfortable answering
- The Center will be very sensitive and will limit the kind of questions asked to that which is germane to what is being studied.