National Black Church Initiative’s NBCI Clinical Trials

NBCI HED
Outline

• Introductions

• Partnership Overview

• NBCI Background

• Bridge Clinical Background

• Next Steps
Partnership Overview

Our Sense of a Partnership’s Goals

• Increased Clinical Trial Awareness/Education

• Recruitment into BMS Clinical Trials

• Benchmark Awareness of BMS Brand in Black Church Community

• Post Approval Market Assessment/Engagement
  1) Surveillance (Adverse events/ New Indications)
  2) Phase IV Studies
  3) Consumer Behavior
  4) New Study Design
Partnership Overview cont.

Potential Long Term Outcomes

• Positive/Enhanced BMS Brand Awareness
• Community Engagement
• Optimized Study Recruitment
• Reduction in Health Disparities
The National Black Church Initiative (NBCI)

The National Black Church Initiative is a coalition of 34,000 African American churches that is committed to eliminating health disparities through health information seminars and health promotion activities.
BRIIDGE Clinical Research

**Who We Are:** The premier full service clinical research organization dedicated to providing all your diversity research needs.

**Our Expertise:**
- Our team specializes in clinical research support including but not limited to, minority patient recruitment, investigator training and site referral and analytics.
- We utilize a vendor management system to bring clinical trial solutions to clients in North America, Latin America and Europe.
- Through our computerized database, investigator sites, community groups and associated patients can be quickly identified and screened against protocol inclusion and exclusion criteria.

**Network Comprised Of:** Practicing physicians with varied levels of clinical trials experience. Most investigators have been trained in Good Clinical Practice and prescreened by BRIIDGE.
Senior Operations Team

- **Owen Garrick, MD, MBA - President & COO**
  - MD - Yale School of Medicine; MBA - Wharton School of Business
  - Member, Secretary’s Advisory Committee on Human Research Protections
  - Former Director Corporate Strategy McKesson
  - Former Global Head M&A Negotiations Novartis
  - Board Member - AMA Foundation (Past President), New York Blood Center, Sutter Health

- **Sheila Thorne - Senior VP, Multicultural Marketing & Community Outreach**
  - B.A., Hunter College, City University of New York
  - Former President of the Multicultural Healthcare Marketing Group at McCann Ericson Healthcare
  - Former Vice President of Healthcare International at Edelman Public Relations
  - Published in Pharmaceutical Executive, Medical Marketing & Media, HealthLeaders.com, PharmaVoice, and the American Journal of Multicultural Medicine
  - Co-chair of the Cultural and Linguistic Competency Committee of the Federal Office of Minority Health Region II

- **Susan Night - Vice President, Targeted Recruitment**
  - LLM University of Houston, Health Law; PhD University of Texas Medical Branch at Galveston
  - Former Policy Fellow Baylor College of Medicine - Eliminating Disparities in Clinical Trials
  - Former University of Texas Medical Branch, Human Subject Research Advocate
  - Former Texas Medical Association, Director - Managed Care

- **Marshall Lindsey, PhD - Director, Research & Data Analytics**
  - PhD - Chemical & Biological Engineering, Northwestern University, MBA Carnegie Mellon
  - Expertise in modeling consumer and patient behavior
  - Former Research Analyst British Petroleum
Senior Scientific Directors

- **Maria Alexander-Bridges, MD PHD - Medical Director, Endocrinology**
  - MD/PHD - Harvard Medical School
  - Residency/Fellowship - Johns Hopkins University/Massachusetts General Hospital
  - Former Clinical Research Director Amgen
  - Former Associate Professor of Medicine - Harvard Medical School
  - Head - Endocrine Society Task Force on Increasing Minority Participation in Clinical Trials

- **Andrea Edwards, MD - Oncology**
  - MD - Yale University School of Medicine
  - Hematology/oncology fellowship training - Yale University School of Medicine
  - Special interest in breast cancer
  - 15 years of experience in Clinical Oncology and Research

- **David Smith, MD - Cardiovascular Disease**
  - MD - University of Medicine and Dentistry of New Jersey
  - Residency/Fellowship - Yale University School of Medicine
  - Co-Chair, Research Committee - Association of Black Cardiologists
  - Special expertise in cardiovascular disease, cardiac CT, echocardiography and nuclear cardiology

- **Lashonda Spencer, MD - Infectious Disease**
  - MD - University of Southern California
  - Residency/Fellowship - University of Utah/University of Southern California
  - 15 years of experience in Clinical and Basic Research
  - Assistant Professor of Pediatrics, Division of Infectious Diseases - Keck School of Medicine/USC

- **Brenda Spriggs, MD MPH FACP - Medical Director, Rheumatology/Autoimmune**
  - MD - Meharry Medical College, MPH - UCLA
  - Clinical Professor Emeritus at University of California San Francisco
  - Fellowship - University of California San Francisco
  - Board member and lecturer Northern California Arthritis Foundation
  - 25 years of experience in practicing and teaching rheumatology/immunology
NBCI HED Clinical Trials Approach

NBCI understands the importance of clinical trials for African-Americans. It is important that African-Americans are proportionately represented in clinical trials for common diseases such as Diabetes, AIDS, cancer and heart disease that affect African Americans disproportionately.

For the past four years NBCI has conducted seminars in its faith communities to encourage more African Americans to participate in clinical trials.
NBCI believes it has finally reached a point where it can begin to encourage African Americans to participate in clinical trials in larger numbers.
Activities for 2015

There will be 5 aspects to our clinical trial program.

1. A comprehensive social medial campaign targeting African American church goers, allowing people to communicate concerns and interest with clinical trials.

2. We will organize 3 live educational sessions in Atlanta, Chicago and Washington, DC (suggested). NBCI would coordinate with Bristol-Meyers Squibb to select locations/speakers.
Activities for 2015 (continued)

3. We plan to distribute 50,000 pieces of literature and a broader number of electronic impressions.

4. We will administer a survey to 35,000 parishioners throughout the country concerning their views on targeted BMS clinical trials or therapeutic areas.

5. We will produce a social media campaign including a YouTube video concerning BMS clinical trials and blast it to our membership 10 times over the next three months.
More information on the following clinical trials can be found in the document at

NBCI / ConnectMe Autism Clinical Trials Program

- This was an awareness and clinical trial program in five cities, Washington, DC, New York, NY, Cleveland, OH, Charleston, SC and Raleigh/Durham, NC
- 27,552 people received information and literature, over 700 children screened for the research study and 164 children enrolled in the research study.
“You’ve Got the Power”
Clinical Trials Fact Sheet

WHAT IS A CLINICAL TRIAL?
A clinical trial is the scientific term for the step-by-step process that studies or tests in humans a new procedure, drug, vaccine or device for prevention, treatment, screening or quality of life. The majority of clinical trials conducted in the United States test new drugs.

- Prevention trials look at drugs, vaccines or lifestyle changes that may help prevent disease.
- Diagnostic trials test at ways of detecting or finding out more about a disease.
- Treatment trials may monitor new drugs or evaluate new combinations of established treatments.
- Screening trials may be conducted to find out if a screening test (such as for prostate cancer) is useful in detecting the disease at an early stage and, as a result, reduce the number of deaths from the disease.
- Quality of Life trials may study the psychological impact of the disease and ways to improve a person’s comfort and quality of life.

WHY SHOULD MINORITIES PARTICIPATE?
In the past, most drugs were tested on white men. Groups such as African Americans, Hispanic Americans, Native Indians, Asian Americans, and women, had generally not been a part of drug clinical trials. Studies have shown that sometimes drugs work differently in people in these groups. It is important to make sure we understand how to use drugs to get the best results in all people.

BENEFITS
- Opportunity to get a new drug before it’s available to the general population.
- Possibility of being among the first to benefit from a new treatment or new information about a current treatment.
- Special care and close care by trial doctors.
- Possibility of free health screenings and exams.
- Opportunity to contribute to medical and scientific knowledge, possibly for your good and/or the good of future generations.

PARTICIPANT PROTECTIONS
- Participants own understanding of the process.
- Informed Consent Process (where you learn about all the expected risks and benefits of a clinical trial).
- Institutional Review Boards (a group of scientists, doctors, clergy and consumers that review and approves the active plan for every clinical trial).
- Your Physician.
- The Food and Drug Administration.
- The National Institutes of Health.
NBCI Program Experience in Clinical Trials

Johns Hopkins

- NBCI was recruited to work as a third party agent for a Johns Hopkins study on hypertension in African-Americans.
- There were five educational sessions over a four month period, 962 people participated in the sessions.
- 6554 people received literature concerning the clinical trials.
NBCI Program Experience in Clinical Trials

COPD (Johns Hopkins study)

- The twelve-week demonstration project was applied to 52 additional African-American churches to create a substantial sampling that would illustrate the need in the African-American community for COPD education.
- Over 100,000 NBCI members were impacted.
- Health screenings were conducted at over 50 churches, impacting over 30,000 congregants.
NBCI Program Experience in Clinical Trials

Hypertension/ Blood Pressure (Project I.M.P.A.C.T.)

• NBCI, working with Project I.M.P.A.C.T. and the National Medical Association participated in a clinical trials program to measure the rates of African-Americans and the role of stress in their lives.

• 4,558 people participated in the educational series, 3,700 were screened for the research study and 558 enrolled in the research study.
Heart Disease (Project I.M.P.A.C.T.)

- The purpose of the project was to see if African-American heart disease patients experienced lifestyle change as a result of their heart disease.
- 15,726 people participated in the educational series, 400 people were screened for the research study, and 72 people enrolled in the research study.
NBCI Program Experience in Clinical Trials

Multiple Myeloma (Novartis)

- PR company Ruder Finn, on behalf of Novartis Pharmaceutical Company, worked closely with NBCI to support development of a multiple myeloma disease awareness microsite, To Stay in the Game, Maintain Your Frame (www.MaintainYourFrame.com), housed on the NBCI’s website.
Multiple Myeloma (Novartis)

- Over 1 million participated in the nationwide comprehensive online/web-based educational health awareness campaign.
- There was an 18.0% increase in screening among African-American men over 60.
- Five Myeloma associations experienced a 20% increase concerning drug therapy and other related information.
Data collection

The National Black Church Initiative's **Black Church Health Consumer Index Survey (BCHCIS)** - http://www.naltblackchurch.com/health/bchcis.html is an innovative tool to track and analyze up-to-date data covering our membership's interactions with the health care system.
How NBCI Is Organized?

NBCI is organized by dividing the country into five geographic areas.

1. South East Faith-Based Command Center located in Atlanta, GA
2. North East Faith-Based Command Center located in New York, NY
3. Mid-West Faith-Based Command Center located in Chicago, IL
4. Western Faith-Based Command Center located in Oakland, CA
5. South West Faith-Based Command Center located in Dallas, TX

**Key Churches**

- We divide every metropolitan city and rural area into key churches. These churches are placed strategically to cover all geographic areas.
- The number of key churches that we designate for any given area depends upon the size of the population of the state or the city.
NBCI Faith Communities
Demographics and Statistical Composition

NBCI has created a statistical analysis of its churches, locations and demographics.

The South East Faith Command - 16,830 Churches
The West Faith Command - 8,502 Churches
The Mid-West Faith Command - 3,047 Churches
South West Faith Command - 3,265 Churches
Western Faith Command - 2,356 Churches
## Site/Market Analysis

A look at MB130-002/
A Study to Evaluate BMS-986036 in Obese Adults With Type-2 Diabetes

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<th>Black Church Presence</th>
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Source: BMS Study Connect/Clinicaltrials.gov/US Census
Phased Approach to Recruitment Efforts

1. Identify Target Geographies
2. Locate Respected Individuals and Active Churches in Community
3. Focus on Distribution Channels that Increase Patient Awareness of Study
4. Deliver Content to Drive Patients to Sites
5. Ensure Smooth Handoff to Site and Warm Welcome
How we recruit

We employ our HED (Health Emergency Declaration) model approach.

We activate our congregational volunteers, aka “Health Navigators”

We activate our volunteer health corps.
How we recruit (continued)

1. We use members of our congregations who have the disease state and qualify for the clinical trials to encourage others to sign up for the trials themselves.
2. Distribute our “Health Alert” publications and additional flyers.
3. Make Church announcements.
4. Instruct Pastors to give a “Pastoral Announcement” during service.
5. e-mail blasts
6. We contact 50 times the amount of people needed for the clinical trials.

If you need 150, we contact 50 times 150 = 7500 people.

We do this per city, per zip code.
How we recruit (continued)

7. Notify congregants through church bulletins about the clinical trials
8. Black radio, television, newspapers and social media/bloggers
Ready to Deploy Partners

The Links, Incorporated

National Hispanic Medical Association

ABC Association of Black Cardiologists, Inc.

Saving the Hearts & Minds of a Diverse America

NCAPIP
NATIONAL COUNCIL OF ASIAN PACIFIC ISLANDER PHYSICIANS

EthosExcel
Recruitment Possibilities

Tap Bloggers Within A Disease Community
Leverage all their social media tools
Example: Renee Brown, co-founder of The Fibroids Project
What is HED?

The black church will utilize its moral authority and vast network of churches and create a science-based health prevention program that deals with every major chronic disease that directly impacts the state of black health.

We plan to utilize innovative health techniques and strategies within the existing structure of the black church thus turning the black church into a health educator.
Concluding Remarks

• The African American community and clinical trials have the same problem – they both need the other in order to be successful.

• NBCI’s and Bridge Clinical’s proven programming will help increase minority representation in quality clinical trials across the board.

• We plan to utilize innovative health techniques and strategies within the existing structure of the black church thus turning the black church into a health educator.
Questions/Next Steps
National Black Church Initiative’s NBCI Clinical Trials

NBCI HED