And

Creating a New Path Toward Clinical Trials In the African American Community Utilizing a Faith-Based Scientific Approach

NBCI Southern Clinical Strategy
Who is NBCI?

The National Black Church Initiative (NBCI) is a coalition of 34,000 African-American and Latino churches working to eradicate racial disparities in healthcare, technology, education, housing, and the environment. NBCI's mission is to provide critical wellness information to all of its members, congregants, churches and the public. The National Black Church Initiative's methodology is utilizing faith and sound health science.

The aim is to offer our member congregants and the public helpful and healthy science-based tips on how to develop and maintain a healthy lifestyle. The website also offers the latest information on housing, education, technology and environmental issues.

The National Black Church Initiative's purpose is to partner with major organizations and officials whose main mission is to reduce racial disparities in the variety of areas cited above. NBCI offers faith-based, out-of-the-box and cutting-edge solutions to stubborn economic and social issues. NBCI's programs are governed by credible statistical analysis, science-based strategies and techniques, and methods that w
What is the NBCI Health Emergency Declaration?

The National Black Church Initiative declared a national health emergency in the Black Church highlighting the health crisis in the African American community. This paper explains why we are taking such dramatic actions and the proven, scientific methods we will be using to solve the crisis.
How is NBCI 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 Churches Zip Codes  Appendix 2
Breakdown of NBCI Churches by States  Appendix 3
What Is NBCI COMMUNICATION AND DISTRIBUTION NETWORK?

We will activate both NBCI’s Communication and Distribution Network and NBCI Technology Distribution Network.

NBCI has 34,000 African American churches and 116,000 sister churches. Because of our enormous size, we are able to conduct targeted distribution of health literature and other materials. This makes us one of the largest distribution networks in the country. We can quickly increase our distribution network to all NBCI churches, and our sister churches (116,000 Black churches who are not members of NBCI but is a part of our overall Black Church network), or other churches outside our distribution network.

With this enormous distribution network, we can touch every metropolitan and rural area in the country where African Americans and Latinos reside. We also can create literature both in Spanish and in English. Having this reach gives us a unique service to reach into metropolitan areas and deliver literature to zip codes, wards of cities (city election boundaries), as well as to specific neighborhoods. Over the years, we have been able to perfect this particular distribution network.

This is one of NBCI’s strong suits, and we are developing new technologies and strategies to improve the accuracy and speed of delivery of critical health information and other materials that will strategically affect the African American and Latino communities.
Who are our Scientific Partners?

Bridge Clinical
www.bridgeclinical.com
We focus on five therapeutical areas: Oncology, Immunology, Anti-infectives, Cardiovascular, and Endocrinology. Our work is a scientific protocol development, drug logistics, data collection, and patient recruitment.

RokketMed
www.RokketMed.com
Making certain that every American wakes knowing they have access to basic healthcare in their community. Making basic healthcare simple to find. Making basic healthcare affordable to purchase. In other words, making what many believe impossible… Possible!

Westat
www.westat.com
We see the world through data
Westat began as a visionary startup in 1963. Now, 50+ years later with 1,900 employees, we continue to pioneer new ways to support the changing needs of clients. Our unique collaborative culture enables us to create dynamic multifaceted teams with broad experience across wide range of topics.

Elligo Health Research
www.elligohealthresearch.com
We bring clinical research direct to clinical health care.
At Elligo, we are redefining conventional patient recruitment to bridge the gap between clinical research and clinical health care. Our Goes Direct® approach helps solve patient access challenges by enabling clinical research as a care option in physician practices that do not currently have the infrastructure to conduct trials.
The National Black Church Initiative Clinical Trials Education Awareness and Participation Program (CTEAPP) Southern Strategy

CLINICAL TRIALS EDUCATION AWARENESS AND PARTICIPATION PROGRAM (CTEAPP)

Appendix 5
The National Black Church Initiative Clinical Trials Education Awareness and Participation Program (CTEAPP)

Education Success Story

53,564

How do we educate?

Who conduct the session?

What is the Curriculum-Project Power?

CTEAP_FINAL-3(1).pdf
The Importance of NBCI Lecture 15 cities on Clinical Tails

NBCI/CTEAPP Lecture Series

The National Black Church Initiative is initiating a ten-part nationwide lecture series that will highlight noted African American clinicians and to further NBCI Clinical Trials Education Awareness and Participation Program (CTEAPP). The lecture series is another important building block of creating an expansive clinical trials initiative to increase minority participation. The goal of NBCI/CTEAPP is to assure 15 percent or more black participation in clinical trials.

There are three goals of the lecture series

1. Highlight the extraordinary partnership forged between Bridge Clinical and the National Black Church Initiative --- combining science and faith.

2. Identify expert African American Clinicians who can serve as primary investigators in major clinical trial programs.

3. Build a list of 100,000 key African American stakeholders who are supportive of African American participation in clinical trials along with NBCI/HED Volunteer Health Corp.

We hope to galvanize and identify 2,500 key community stakeholders in each city of NBCI Churches who are in the health space and understand the historic importance of this movement by NBCI Clinical Trials Education Awareness Participation Program. We plan to turn these individuals into clinical trial advocates. We will provide them with the training, education, and information they need. They will our frontline advocates when we need to identify potential participants in a particular clinical trial. We plan to provide online training through a new website called www.blackchurchandclinicaltrials.com. This online educational portal for African American church members and their families will allow them to search for clinical trials of their choosing.

1. Lupus/Black Women’s Health
2. Rare Diseases/Infectious Diseases (HIV)
3. Diabetes
4. Eye Care and Blindness
5. Oncology/Cancer
6. Heart Disease
7. Hypertension
8. Multiple Myeloma/Blood Diseases
9. Nutrition and Obesity
10. Autism

Appendix 7
Appendix

Appendix 1


Appendix 2

NBCI Churches Zip Codes (Attachment in the email)
CTEAP_FINAL-3(1).pdf

Appendix 3

Breakdown of NBCI Churches by States-It is the back of the CTEAPP booklet
CTEAP_FINAL-3(1).pdf

Appendix 4

NBCI COMMUNICATION AND DISTRIBUTION NETWORK (see attach in the email)
Appendix 5


Appendix 6


CTEAP_FINAL-3(1).pdf

Appendix 7

NBCI Global Health Fund
NBCI Southern Clinical Strategy

Primary Objectives for this Global Health Fund in the Black Church

- The chief goal is to advocate for sound health policies for African Americans.
- The mission is to educate our congregants on the importance of a healthy lifestyle.
- The Fund will be used to advocate sound health policies by working with other Black Health Organizations.
- Our priority is to financially assist our members in the area of medication, rehabilitation, housing, food and other related health matters.
NBCI Southern Clinical Strategy: Trust Experience Access Reach Success
THE WHY

Racial Disparities in Clinical Trials
Black Patients Miss Out On Promising Cancer Drugs

- A ProPublica analysis found that black people and Native Americans are under-represented in clinical trials of new drugs, even when the treatment is aimed at a type of cancer that disproportionately affects them.

- One out of five people diagnosed with multiple myeloma in the U.S. is black, and African Americans are more than twice as likely as white Americans to be diagnosed with the blood cancer.

- Out of the 722 participants in the Nilarno trial, only 13 — or 1.8 percent — were black.

- A ProPublica analysis of data recently made public by the FDA found that in trials for 24 of the 31 cancer drugs approved since 2015, fewer than 5 percent of the patients were black. African-Americans make up 13.4 percent of the U.S. population.
Black Americans Face the Highest Risk of Multiple Myeloma but Are Underrepresented in Trials Treating the Cancer

New Cases of Multiple Myeloma, Per 100,000 People

- White: 6 cases
- Black: 14 cases
- Asian: 4 cases
- Native American: 6 cases

Representation in Clinical Trials

<table>
<thead>
<tr>
<th></th>
<th>Darzalex</th>
<th>Farydak</th>
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</thead>
<tbody>
<tr>
<td>White</td>
<td>76%</td>
<td>63%</td>
</tr>
<tr>
<td>Black</td>
<td>10%</td>
<td>3%</td>
</tr>
<tr>
<td>Asian</td>
<td>6%</td>
<td>33%</td>
</tr>
<tr>
<td>Native American</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
</tbody>
</table>
Empliciti

- White: 84%
- Black: 4%
- Asian: 10%
- Native American: <1%

Ninlaro

- White: 85%
- Black: 2%
- Asian: 9%
- Native American: Not reported

**Notes:** Race was not reported for 8 percent of Darzalex's clinical trial participants, and 4.7 percent of Ninlaro's clinical trial participants.

For consistency across data sources, percentages have been rounded to the nearest integer, so numbers may not add up to 100. For some drugs, a percentage of clinical trial participants is unreported. New cases are calculated per 100,000 people by race and per year. Native American figures include both American Indians and Alaska Natives.

Source: U.S. Food and Drug Administration; National Cancer Institute (Riley Wong for ProPublica)
Southern Clinical Strategy Solution

Trust

• An initial and vital important step regarding recruitment of African Americans is the establishment of trust and credibility

• Mistrust of medical research is an extremely important barrier hindering recruitment in African American (AA) communities

• Mistrust concerns regarding previous researchers
Southern Clinical Strategy

Experience

NBCI and its SCS has enrolled thousands of patients for studies, programs and projects. We have developed a highly successful congregate recruitment formula since we began offering these services.

Enrollment

Patient referrals are necessary to initiate the recruitment but, it is patient enrollment that equates to success.

Typical /traditional method
• volume referrals

NBCI SCS
• highly qualified referrals
  • more likely to be converted into randomized patients resulting in increased enrollment at participating sites
Southern Clinical Strategy

Access: rapid launch

Our SCS “trust factor” and expertise facilitates our ability to rapidly initiate recruitment of the desired patient population
  • Direct patient access
  • Survey data
Improved ROI

NBCI SCS

• Efficient and effective patient recruitment
• More economical and strategic approach
• Maximizing your company’s investment
• The earlier the engagement of the SCS, the better your ROI
# Overview of Data Collection Techniques

<table>
<thead>
<tr>
<th>Technique</th>
<th>Key Facts</th>
<th>Example</th>
</tr>
</thead>
</table>
| Interviews              | • Interviews can be conducted in person or over the telephone  
                          • Interviews can be done formally (structured), semi-structured, or informally  
                          • Questions should be focused, clear, and encourage open-ended responses  
                          • Interviews are mainly qualitative in nature                                                                                       | One-on-one conversation with parent of at-risk youth who can help you understand the issue  
                                                                                                    | Click here to see a sample key informant interview.                                                                                     |
| Questionnaires and Surveys | • Responses can be analyzed with quantitative methods by assigning numerical values to Likert-type scales  
                              • Results are generally easier (than qualitative techniques) to analyze  
                              • Pretest/Posttest can be compared and analyzed                                                                                   | Results of a satisfaction survey or opinion survey  
                                                                                                    | Click here to see an example of a survey created using the CYFERnetSEARCH Interactive Survey Builder feature.  
                                                                                                    | Click here to see a sample survey on middle school youth risk behavior.                                                                 |
# Overview of Data Collection Techniques

<table>
<thead>
<tr>
<th>Observations</th>
<th>Focus Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Allows for the study of the dynamics of a situation, frequency counts of target behaviors, or other behaviors as indicated by needs of the evaluation</td>
<td></td>
</tr>
<tr>
<td>• Good source for providing additional information about a particular group, can use video to provide documentation</td>
<td>• A facilitated group interview with individuals that have something in common</td>
</tr>
<tr>
<td>• Can produce qualitative (e.g., narrative data) and quantitative data (e.g., frequency counts, mean length of interactions, and instructional time)</td>
<td>• Gathers information about combined perspectives and opinions</td>
</tr>
<tr>
<td></td>
<td>• Responses are often coded into categories and analyzed thematically</td>
</tr>
<tr>
<td></td>
<td>• A group of parents of teenagers in an after-school program are invited to informally discuss programs that might benefit and help their children succeed</td>
</tr>
</tbody>
</table>
## Overview of Data Collection Techniques

<table>
<thead>
<tr>
<th>Ethnographies, Oral History, and Case Studies</th>
<th>Shadowing a family while recording extensive field notes to study the experience and issues associated with youth who have a parent or guardian that has been deployed</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Involves studying a single phenomenon</td>
<td>Click here for an example of an oral history.</td>
</tr>
<tr>
<td>* Examines people in their natural settings</td>
<td>Click here for an additional example of an oral history.</td>
</tr>
<tr>
<td>* Uses a combination of techniques such as observation, interviews, and surveys</td>
<td></td>
</tr>
<tr>
<td>* Ethnography is a more holistic approach to evaluation</td>
<td></td>
</tr>
<tr>
<td>* Researcher can become a confounding variable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documents and Records</th>
<th>To understand the primary reasons students miss school, records on student absences are collected and analyzed</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Consists of examining existing data in the form of databases, meeting minutes, reports, attendance logs, financial records, newsletters, etc.</td>
<td>Click here for an example of a searchable database of aggregate data on youth risk behavior.</td>
</tr>
<tr>
<td>* This can be an inexpensive way to gather information but may be an incomplete data source</td>
<td></td>
</tr>
</tbody>
</table>
## Types of Data

<table>
<thead>
<tr>
<th>Quantitative Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Requires use of statistical analysis</td>
</tr>
<tr>
<td>- Variables can be identified and relationships measured</td>
</tr>
<tr>
<td>- Counted or expressed numerically</td>
</tr>
<tr>
<td>- Often perceived as a more objective method of data analysis</td>
</tr>
<tr>
<td>- Typically collected with surveys or questionnaires</td>
</tr>
<tr>
<td>- Often represented visually using graphs or charts</td>
</tr>
</tbody>
</table>
| Qualitative Data | • Examines non-numerical data for patterns and meanings  
| | • Often described as being more “rich” than quantitative data  
| | • Is gathered and analyzed by an individual, it can be more subjective  
| | • Can be collected through methods such as observation techniques, focus groups, interviews, and case studies |
| Mixed Methods Data | May increase the validity of your evaluation  
|                   | May explain unexpected results obtained using only one approach (quantitative or qualitative)  
|                   | Help you capture both process and outcome results  
|                   | May strengthen your analysis |
Social networking sites can include forums in which users can dialogue with one another. Data could be collected through sampling random sites for trends, soliciting information from specific users and creating a profile for data collection that attracts certain users for discussions (such as online focus groups).

## Social Networking Sites

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Able to reach a young demographic using a popular medium</td>
<td>• No verification of information available on public profiles</td>
</tr>
<tr>
<td>• Option to create a profile to target specific community</td>
<td>• Privacy settings on profiles may impede data collection</td>
</tr>
<tr>
<td>• Ability to engage participants at remote locations in real time</td>
<td>• Social networking caters to very specific demographic of users, with</td>
</tr>
<tr>
<td>• Can be a rich source of quantitative and qualitative data, some of which</td>
<td>an average age range of 14-35 years</td>
</tr>
<tr>
<td>is publicly available</td>
<td>• Consent issues involved working with underage youth (if soliciting</td>
</tr>
<tr>
<td></td>
<td>information not publicly available on profile)</td>
</tr>
</tbody>
</table>
## Technology and Data Collection Integration

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Simpler and quicker way of collecting both quantitative and qualitative data</td>
<td>• Limited to respondents who have access to the internet</td>
</tr>
<tr>
<td>• Easy to access a large group of respondents in geographically diverse locations</td>
<td>• Some may find on-line interface off-putting</td>
</tr>
<tr>
<td>• More cost effective than manually administering surveys</td>
<td>• Does not guarantee the quality (reliability and validity) of actual survey design</td>
</tr>
<tr>
<td>• Data can typically be exported, eliminating manual data entry</td>
<td>• Potential lack of security</td>
</tr>
<tr>
<td>• Improves accuracy of data entry (e.g., reduces omissions, duplicate entries)</td>
<td></td>
</tr>
</tbody>
</table>

Types of technology that can be used to collect data traditionally captured with surveys include:

- Online or web-based surveys
- Hand-held devices such as clickers and PDAs
- Text messages
- Social networking sites such as Twitter, MySpace, and Facebook to engage participants in a virtual focus group or conduct observations of interactions on that site

The United States Department of Agriculture’s National Institute of Food and Agriculture and the University of Minnesota