Innovative Recruitment Methods for Oncology Clinical Trials

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Presentation Overview

I. Background: Clinical Trials
II. Clinical Trials: The Good, The Bad and The Ugly
III. Participants Recruitment: Barriers & Facilitators
IV. Innovative Models for Clinical Trials Recruitment
“Using African DNA in genome research offers many benefits. One of the most important is that Africans’ genomes are some of the most diverse on the planet because modern *Homo sapiens* originated in Africa 200,000 years ago. …”

“Given the vast genetic variation that exists in African genomes, it is likely that we can find genetic variants that are important to cancer that may not be discovered from other human populations.”

*Quote from*
Charles Rotimi, PhD
NIH Distinguished Investigator
Metabolic, Cardiovascular and Inflammatory Disease Genomics Branch
https://www.cancerhealth.com/article/african-dna-hold-key-cure-cancer
I. Background: Clinical Trials

• Clinical Trials: The Good, The Bad and The Ugly
• Innovative Models for Clinical Trials Recruitment
Clinical Trials (NIH)

“A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”

**Mechanistic:** designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention.

**Exploratory:** performed early in Phase I, prior to dose escalation and safety and tolerability trials.

**Feasibility:** the product is used in a small number of human patients who are carefully monitored.

**Interventional:** participants are assigned to receive one or more interventions (or a placebo or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes.

**Behavioral:** focused on evaluating changes to participants' behavior.
Oncology Clinical Trials

“any research study that prospectively assigns human participants to one or more health-related interventions [anywhere in the cancer care continuum] to evaluate the effects on health outcomes’
Why focus on OCT in Africa?

- Africa is 2\textsuperscript{nd} largest population in the world
  - 16.36\% in 2016 (1.216 billion)
  - By 2050
    - 25\% of the world population will live in Africa by 2050

Cancer in Africa ... a running train!
Estimated age-standardized incidence rates (World) in 2018, all cancers, both sexes, ages 0-74
Estimated number of prevalent cases (5-year) as a proportion in 2018, all cancers, both sexes, ages 0-74

Proportions per 100 000

- ≥ 232.7
- 186.3-232.7
- 166.0-186.3
- 135.7-166.0
- < 135.7
- Not applicable
- No data

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Data source: GLOBOCAN 2018
Graph production: IARC (http://gco.iarc.fr/today)
World Health Organization
### Demographic Change for Cancer Incidence

**2018 to 2040**

All cancers, Gender, Ages

<table>
<thead>
<tr>
<th>Region</th>
<th>% Change 2018-2040</th>
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<tbody>
<tr>
<td>World</td>
<td>63.4</td>
</tr>
<tr>
<td>North America</td>
<td>46.3</td>
</tr>
<tr>
<td>Eastern Africa</td>
<td>115.5</td>
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<tr>
<td>Middle Africa</td>
<td>115.3</td>
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<tr>
<td>Northern Africa</td>
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<td>Southern Africa</td>
<td>67.6</td>
</tr>
<tr>
<td>Western Africa</td>
<td>101.1</td>
</tr>
</tbody>
</table>
% Demographic Change for Cancer Mortality

2018 to 2040

All cancers, Gender, Ages
URGENT Need for Clinical Trials in Africans

Health & Biomedical Innovations are increasing the Disparities in Africans!
• Genome-Wide Association Studies (GWAS)
• Precision/Personalized Medicine (PM)
• Pharmacogenomics!
II. Clinical Trials: The Good, The Bad and The Ugly

• Innovative Models for Clinical Trials Recruitment
• Large pool of patients/participants for recruitment
• Faster patient recruitment
  – Short timeline
• Low operational cost
• Reduced regulatory barrier
• Unique opportunities for brand exposure of therapies.
The Bad Challenges

- Lengthy approval process to start a clinical trial
- Recruitment issues, especially for participants in rural areas
- Patient adherence issues
- Challenges with follow-up
- Challenges with ethical review and approval
- Political instability
  - Including at academic settings

- Standard of care issues
- Limited access to health care
- Limited access to skilled clinical trials workforce
- Availability of treatment/therapies
- Cultural challenges
- Conflict of interests
  - Clinical trials key personnel
• Although it is the “Gold standard” to develop therapeutic interventions, clinical trials is not required to introduce new therapies to most African countries.

What does this mean for Africa?
Without sufficient representation of Africans in clinical trials, **optimal prevention, diagnosis and treatment decisions cannot be made for them.**

So, what are we doing about this?
Africa is Ready!
CaPTC-Led
AGCPN Recommendations

• Develop BEST PRACTICES for patient recruitment, enrollment, and retention for Africa.

• Develop a Community Cancer Research Engagement & Support (CCaRES) Network that will facilitate linkages between researchers and CT participants.

• Collect data on and continuously address individual-level barriers that influence participation in Clinical Trials.
III. Participants Recruitment: Barriers & Facilitators
Participant-focused Barriers

- Social and economic difficulties including lack of access to care and poor quality of care.
- Cultural beliefs or myths about specific diseases or illnesses.
- Fear and Mistrust.
- Time commitments
- Past experience with health care and research studies.
- Belief in conspiracy theories

- Lack of information as barriers to participation in research.
- Family obligations
- Lack of valid and culturally appropriate sampling tools or questionnaires.
- Lack of understanding and trust of informed consent procedures.
- Stereotyping (by researchers and physicians)

We need research on this in Africa!
- Doctor’s influence / recommendation.
- Therapeutic benefit.
- Altruism or to advance medicine/science.
- Refusal to give up/no other medical option available.
- Trial provides meaningful cadence to day-to-day living.
- Ability to gain access to leading specialists in a particular type of cancer.
- Ability to get cutting edge care and the latest treatment discoveries.

- Knowledge of Institutional Review Boards (IRB) assures patients that their well-being is as important as the scientific research.
- In order to earn extra money.
- To obtain education about treatment / improving health.
- To obtain free medication.
- Curiosity about study/medical practice.

We need research on this in Africa!
IV. Innovative Models for Clinical Trials Recruitment

Avoid Common Mistakes
Avoid Common Mistakes

Ripple Science

- Lack of familiarity with sources of participants.
- Develop your strategies without understanding sources of participants.
- No effort placed on building relationship with relevant stakeholders and targeted community.
- Lack of recurrent, testable and measurable recruitment processes.
- Not testing multiple versions of recruitment ads to select most appropriate.

- Lack of analytics to assess your recruitment efforts.
- Lack of structured process to guide recruitment.
- Lack of understanding of barriers, facilitators and motivation for participation.
- Underutilization of clinical registries.
- Not having your own registry.

Reference: https://ripplescience.com/
IV. Innovative Models for Clinical Trials Recruitment

Research Principle for Success

CaPTC
Prostate Cancer Transatlantic Consortium
Community-Based Participatory Research (CBPR)

• **Definition**: CBPR is “[a] collaborative approach to research that equitably involves, for example, community members, organizational representatives, and researchers in all aspects of the research process. The partners contribute unique strengths and shared responsibilities . . .”

• **Aim**: “. . . to enhance understanding of a given phenomenon and the social and cultural dynamics of the community, and integrate the knowledge gained with action to improve the health and well-being of community members” (Israel et al. 1998, 2003).
“A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community and has the aim of combining knowledge with action and achieving social change...”

~ Community Health Scholars Program. A WK Kellogg Foundation-funded post-doctoral fellowship program in CBPR

**Key Words** - “collaborative,” “equitably,” “partners,” “combining knowledge with action” and “achieving social change.”
Key Principles of CBPR

- Recognizes community as an unit of identity
- Builds on strengths and resources within the community
- Facilitates collaborative, equitable involvement of all partners in all phases of the research
- Integrates knowledge and intervention for mutual benefit of all partners
- Promotes a co-learning and empowering process that attends to social inequalities
- Involves a cyclical and iterative process
- Addresses health from both positive and ecological perspectives
- Disseminates findings and knowledge gained to all partners
- Involves long-term commitment by all partners.

(Israel et al., 1998)
IV. Innovative Models for Clinical Trials Recruitment

Ambulant Care Services

CaPTC
Prostate Cancer Transatlantic Consortium
Ambulant Care Services

• Blood draws
  – safety labs, pharmacokinetics, genomics
• Other biologic sampling
  – pharyngeal and oral mucosal swabs, urine
• Clinical assessments
  – vital signs, ECGs, concomitant medications, adverse events

• Patient training and education
• Patient chaperoning services to sites
• Study compliance checks
• Patient questionnaires
• Visit documentation

Global care clinical trials: www.globalcarect.com
Chaperone Services

• Assisting patients to travel to investigator sites for protocol visits when they are not able to travel on their own
• Travel from patient’s home by plane, train or automobile
• Assistance with lodging and meals
• Escort from department to department within hospital

Site Support Services

• Assistance with patient screening/scheduling for study candidates
• On-site study activities
• Staff training on devices or procedures
Central and Local Pharmacy Services

- Storage and distribution of study drug
- Compounding and dispensing
- Ancillary supplies
- Cold chain logistics
- Sourcing of commercial products and devices (infusion pumps)
• Background: Clinical Trials
• Clinical Trials: The Good, The Bad and The Ugly

Innovative Models for Clinical Trials
Recruitment

Model: CCaRES Network

CaPTC
Prostate Cancer Transatlantic Consortium
Develop a Community Cancer Research Engagement & Support (CCaRES) Network that will facilitate linkages between researchers and CT participants.
• Core service to improve participation in clinical trials and bio-specimen research
  
  – **Identify** patients who may be eligible for participation in **future** research studies
  – **Match** participants to clinical trial screening criteria based on their medical history
  – Facilitate the **access** to eligible clinical trials.
A database of participants who consent to be contacted for biomedical research including clinical trials and bio-specimen research.

Database serves as sampling frames for selecting healthy individuals/controls and patients who fulfill specific study eligibility criteria.

Recruitments Sites
- Clinics
- Education & Outreach events including health forums, churches, mosques, barbershops etc.
- Community pharmacies
- Neighborhoods
- Homes
- Social events
- Web
- Social Media
• Funding
  – NIH/National Cancer Institute
  – Prostate Cancer Transatlantic Consortium (CaPTC)
  – University of Florida
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Website: [http://epi.grants.cancer.gov/captc](http://epi.grants.cancer.gov/captc)

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QUESTIONS