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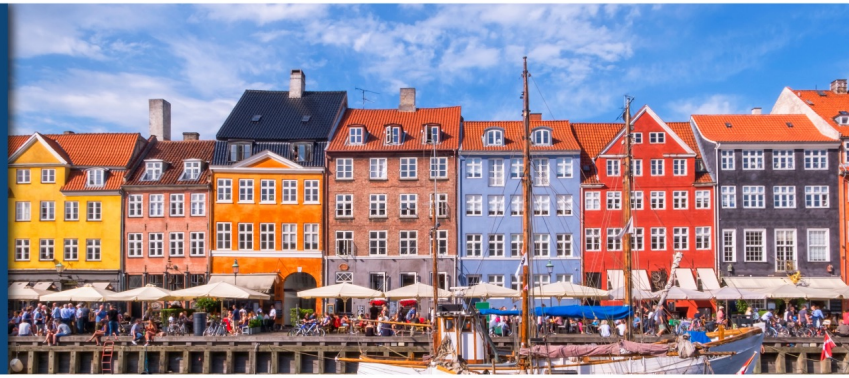

Leveraging Real World Evidence (RWE) to Address Pitfalls in the Design and Conduct of Clinical Trials in Africa: Strategies for Optimizing Patient Recruitment and Retention.

Presented by Dr. Obiageli Onwusaka; Director, Biostatistics; Biometrics Department, ClinFocus,

Meet the Speaker

Dr. Obiageli Onwusaka

Title: Director, Biostatistics

Organization: ClinFocus Inc.

Dr. Obiageli Onwusaka is a renowned biostatistician with extensive experience in Public health research. She received her master's degree in public health and a PhD in Biostatistics from the University of Ibadan, Nigeria.

Dr. Obiageli's expertise lies in the application of statistical methods to the analysis of health data, particularly in the areas of epidemiology and clinical trials.

Before joining ClinFocus Inc., Dr. Obiageli held faculty position for close to a decade at a prestigious academic institution in Africa. She has also served as a consultant for numerous healthcare organizations and government agencies, providing statistical expertise for research studies and clinical trials.

She is currently the director, Biostatistics at ClinFocus and is passionate about enhancing the scope of clinical trials particularly recruitment and retention among underserved populations. She has focused on providing best practices for success in clinical research, particularly emerging regions, and in areas targeted at providing context-fit and patient-centered solutions..

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. Background- The landscape of clinical trials in SSA
   - Windfalls and pitfalls of clinical research in SSA
2. The place of RWE in clinical research
3. Strategies for enhancing recruitment and retention (3Ds)

-Digitization, Decentralization, Discourse

4. The ClinFocus ACE Project

Background

The landscape of clinical trials in Sub-Saharan Africa

The state of Clinical trials in Contemporary Africa

- 50% of the global burden of disease, mostly due to infections, reside in sub-Saharan Africa
- Host to 17.5% of the global population, the African continent is dramatically underrepresented in clinical trials – only between 2.5–10% of clinical trials
- Majority of trials occur in South Africa or Egypt
- Focus on infectious diseases such as HIV and tuberculosis
- However public health focus expanding to noncommunicable diseases

Pitfalls

- Bureaucratic bottlenecks;
- Poor infrastructure leading to delayed timelines;
- Historically, lack of experienced personnel;
- Lack of standard operating procedures for clinical activities;
- Patient recruitment and retention challenges due to narrow inclusion criteria;
- Paucity of information on study participants, and;
- Historical malpractice causing mistrust

Windfalls

- Globalization of clinical research in the pharmaceutical industry
- Ensuring Diversity, Equity and inclusion in clinical trials
- Reduce global healthcare disparities
- Sub-Saharan Africa as an emerging market in the clinical research industry
- The need to access wider pools of study participants, reduce research timelines, and address the global burden of disease
- Africa is the most genetically diverse continent in the world
- Availability of highly skilled professionals in new research markets
- Lower costs of carrying out research

Windfalls

- Faster patient recruitment that allows for earlier drug application approvals
- Concentrations of huge populations for future drug sales
- Successes in conjugate meningitis and Ebola vaccine trials
- Short clinical trial approval benchmark required by the African Vaccine Regulatory Forum
- Valuable opportunities to progress where vaccines need to be tested for safety and efficacy on populations that suffer the diseases

The place of RWE in clinical research

RWE and RWD

- October 2021, the Food and Drug Administration (FDA) issued guidance on the expanded use of RWE an RWD, acknowledging their increasing role in health care decisions beyond post-approval safety and efficacy studies
- July 2022 , the EMA endorsed a joint statement calling for international collaboration to enable the generation and use of real-world evidence for regulatory decision-making
- RWE trials are crucial for further understanding newly approved medicinal products in the real-world setting.
- In this highly digital age, sources of RWD are varied and large.
- Challenges remain to be addressed- heterogeneous data sources across the globe and different levels of quality of the data

Strategies for enhancing recruitment and retention (3Ds)
-Digitization, Decentralization, Discourse

Digitization, Decentralization, Discourse

- Employing the Use of Digital Technologies (DHTs) for Effective and Efficient Recruitment of Patients
- full benefits of digital technologies to strengthen the health systems are yet to be fully harnessed due to critical challenges in the sector.
- Challenges include weak health systems governance, weak infrastructural investments, inadequate resources, weak human resource capacity, high cost of scaling-up and coordination issues, among others.
- Lack of systems thinking, and design have significant impact on coordination of efforts resulting in fragmentation and non-interoperability among various applications
- Electronic medical record (EMR) data, the use of big data technologies, the use of automated patient can be utilized to overcome the challenges of clinical trial recruitment.

Digitization, **Decentralization,** Discourse

- Decentralization in clinical research has partly been driven by the need to increase diversity and inclusion among trial patients
- They make it easier to find eligible patients, and they encourage those patients to participate by reducing the amount of time they spend traveling.
- harness local pharmacies, primary care providers and community health centers as extensions of major research centers
- widening eligibility criteria, tapping into community-based medical centers, and leveraging patient advocacy

Digitization, Decentralization, **Discourse**

- Clinical Research should demonstrate both social and scientific value to ensure effective stakeholder engagement
- trial sponsors must ensure that pre-trial activities must give room to accommodate a robust stakeholder engagement as this is also key to project buy-in

Conclusion

- Clinical research continues enlarge its confines to embrace innovative data sources as RWD and RWE,
- we must also ensure that the appropriate, adaptive analytical techniques are applied to better understand these ‘unconventional’ data sources and
- appraise efforts to standardize them particularly among underserved and excluded populations.
- After DDD, there is a need for data standardization, CDISC is at the center of all data standardization initiatives> improved data quality, >data interoperability, >data sharing, >data reuse>>>> evidence-based decision making

The ClinFocus ACE Project

Thank You!

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