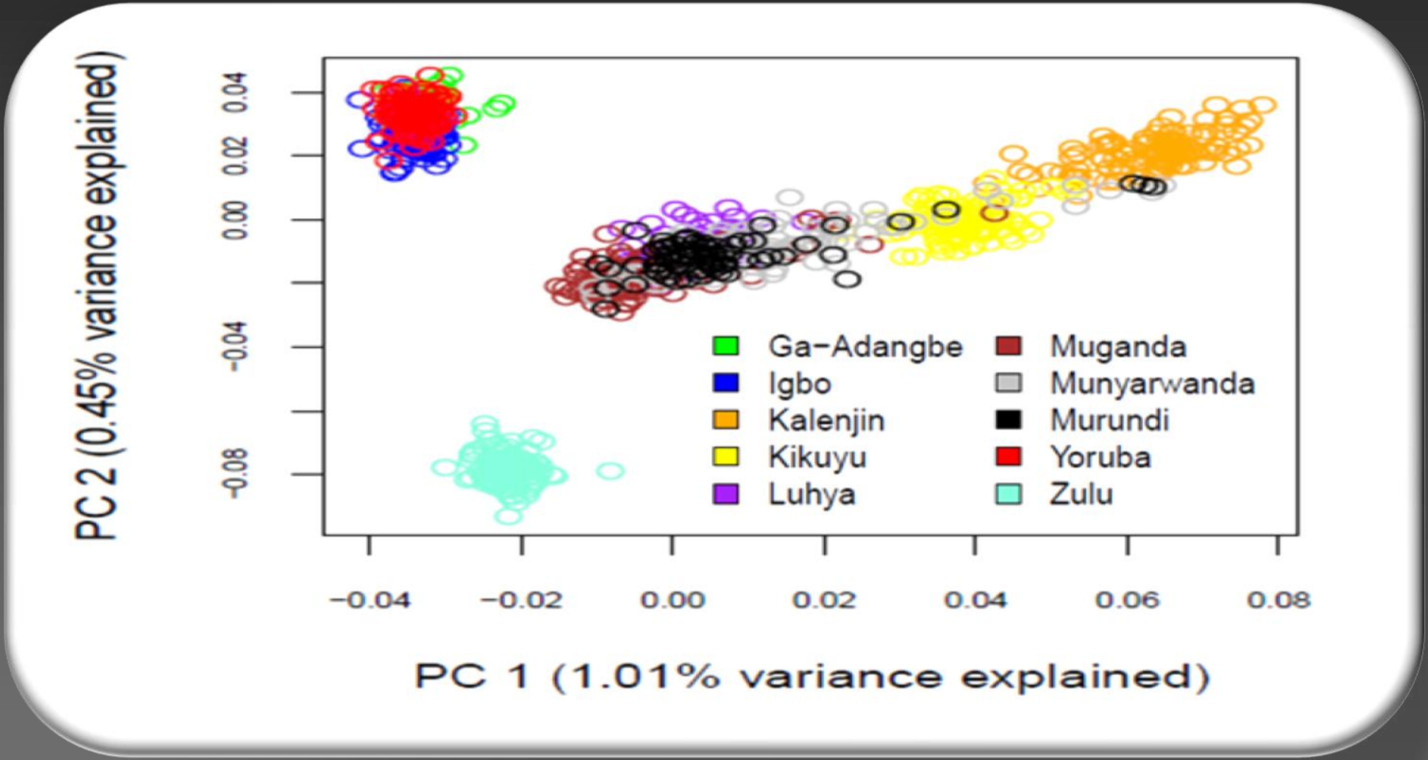
Sharing: The H3Africa Vision

- **Charles N. Rotimi, PhD**
- **Director: Center for Research on Genomics and Global Health**
- **Senior Investigator: Inherited Disease Research Branch, National Human Genome Research Institute, NIH**

H3Africa Consortia meeting – Addis Ababa - Oct 2012

Wellcome Trust Genetic Epidemiology course
in the Uganda MRC
Sept 2013

AFRICAN GENOME VARIATION PROJECT

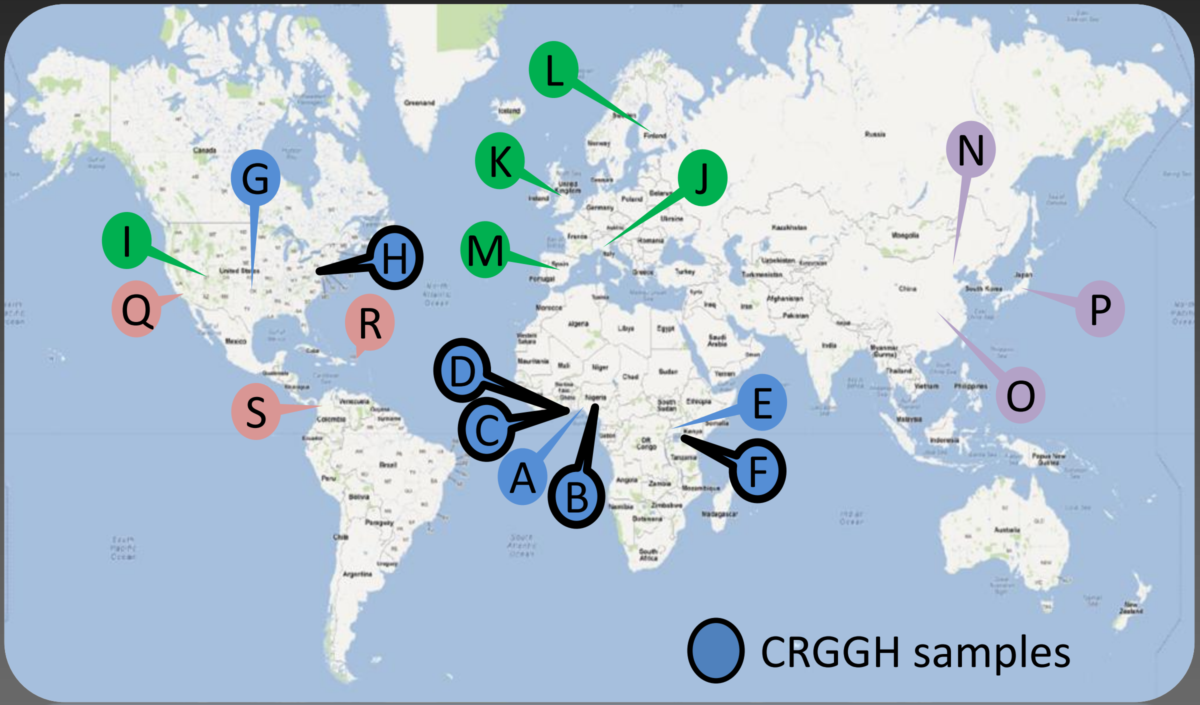


African Genome Variation Project

-100 individuals from 18 sub-Saharan ethnic groups

Database of Pharmacogenomic Variants in 19 Global Populations

- GOALs:
- Examine PGx variation across global populations and its influence on clinical decision making.



A = YRI
B = IGBO
C = GAA
D = AKAN
E = LWK

F = MKK
G = ASW
H = HUFS

I = CEU
J = TSI

K = GBR
L = FIN
M = IBS

N = CHB
O = CHS

P = JPT

Q = MEX
R = PUR
S = CLM

Sharing: The H3Africa Vision

High-Level Principles on Ethics, Governance and Resource Sharing

- NIH and the WT expect all funded researchers to maximize access to their research data with as few restrictions as possible.

- Ensure that adequate safeguards are in place to protect participants, while maximizing the ability of investigators to advance research.

- **Informed Consent -** The consent needs to be broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health.

http://www.h3africa.org/ethics_governance_resourcesharing.cfm

H3Africa Resources -Types of Data and Samples

Samples

1. Blood (DNA, cell lines, RNA, Plasma, Serum)
2. Urine
3. Biopsy (e.g., adipose or muscle -- RNA)
4. Saliva
5. Stem cell
6. Others

Data

1. Demography
2. Epidemiological
3. Clinical
4. Genomic
5. Others

H3Africa Resources - Sharing

Generation of high quality data and samples

Storage and distribution of generated data and samples

- Avoiding contamination
- role of the data centers and biorepositories

H3Africa Resources - Sharing

Different data types raise unique issues & challenges.

A. No phenotype

1. With identifiers (personal, etc)
2. Without personal identifiers (HapMap, 1000 Genome, encode type data). Data users may freely download and analyze data without restrictions

B. With phenotype

1. With personal identifiers
2. Without personal identifiers

H3Africa Resources

Exclusive vs Public use of collected data and samples

Will any of the H3Africa data be Exclusive?

Stakeholders

1. Primary investigators/institutions
2. Nations
3. Funding agencies
4. Others

Sovereignty of physical samples and clinical data

1. Need for permission of the contributing investigator?

2. Need for legal and ethical approval by the country of origin and by the country where proposed experiment will take place

Genomic sovereignty is the capacity of a people, a country or nation to own, to control both access to and use of, samples, data and knowledge concerning or emanating from genomic material (1). This definition pertains to genetic material of human, animal and plant origin.

National Biotechnology Advisory Committee (NBAC) Position statement on Genomic Sovereignty in South Africa

Sovereignty of physical samples and clinical data

3. Can the contributing investigator(s) recall the physical samples at any time?

4. Use of samples outside of the primary reason for collecting the data – e.g., diabetes and then for mental health research or population history

Conditions for Timely Data Sharing

1. After acceptance for publication of the main findings from the final dataset.

2. Define period of time – e.g., 24 months "moratorium" after data collection - to allow the data producers the opportunity to publish first if they wish

3. Should these options be influenced by the nature of collected data?
    1. Small vs large studies;
    2. Prospective vs cross-sectional projects;
    3. Easily identifiable groups

Biological sample sharing

1. When?

2. How do we prevent depletion of biological specimens?

3. When shared, should unused samples be returned to the H3Africa repository if not used up? (Contamination problems)

4. Does the H3Africa network require a standard material transfer agreements (MTA). How should this be influenced by national requirements?

Populating the H3Africa Database

Require users of shared samples to return the related research data and information to the H3Africa network.

Who will manage this resource?

IP protection

Wellcome Trust and NIH policies - intellectual property should be developed and used in a way that maximizes global health benefit.

Research Networks and programs should seek to manage intellectual property, and develop appropriate licensing terms, in ways that help to ensure equitable access to resulting health products and technologies for low and middle-income countries.

http://www.h3africa.org/ethics_governance_resourcesharing.cfm

IP protection

1. When should IP be sought?

2. What are the potential impacts of IP on global access?

3. Royalties from IP licenses– how should this be administered (investigators, institutions and communities)?

4. Data release policy – any need for IP protection?

Nightmare Situation

Data release policy leading to majority of H3Africa publications being led by non-African investigators

What are the responsibilities of African scientists, their collaborators and funding agencies to ensure that this nightmare does not come true

Avoiding the Nightmare Situation

1. Protect the interests of African Scientists

2. Capacity building – training, training and training of young investigators in rigorous labs locally and internationally

3. Exposing young investigators to existing genomic and genetic epidemiology datasets

4. It takes time (1 to 3 years) to train. Thus, training of promising investigators should begin now.

Role of African Investigators - Who really “own” the data?

The role of the funders

Foster an environment that enables H3Africa researchers to maximize the value of research data by

1. Requiring and ensuring the generation of high quality data and samples
2. Providing support for data management centers
3. Supporting the development of H3Africa best practice guidelines for data sharing
4. Recognizing and protecting the interests of researchers who generated and shared datasets

Thank you