Clinical Trials Community
United for Africa's Health

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Clinical Trial Community An Update

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1. Executive Summary

Only 2% of the clinical trials conducted globally occur on the African continent. There are many factors contributing to this low investment, but we would like to highlight 2 topics relevant to this update report: the dearth of knowledge on the location and capabilities of existing clinical trial sites, and the uncertainties associated with competency, expectations, and timelines of regulatory and ethical reviews across the 55 African countries. For these reasons, the process of site feasibility analysis can be onerous for the trial sites and time-consuming and expensive for the trial sponsors.

The African Academy of Sciences led an effort to identify gaps, elicit stakeholder interest via a pilot project, and eventually obtained funding to develop an open-access platform that will bring together key players in the clinical trials space to; increase their visibility, provide site feasibility intelligence important in decision making and encourage continuous engagement among stakeholders. Our initial pool of stakeholders include: local and international clinical researchers, biopharma representatives, product development partners, African regulatory representatives and clinical trial participants.

To this end, a series of stakeholder engagement meetings were held in 2019 to gather user requirements that will shape key elements of the platform. Using this data, the AAS will work with experts in software development and seek input from an advisory committee to prioritize identified elements and pave the way for the actual development of the system. This will be followed by a series of meetings with representatives from the various stakeholder groups. These meetings will allow participants to provide real-time feedback on the platform's functionality thus informing future iterations to meet user needs.

Clinical Trial Community An Update

1. Background

Africa accounts for 15% of the global population and 25% of the global disease burden – yet less than 2% of global clinical trials take place on the continent of Africa – those that do are mainly concentrated in 2 countries: South Africa and Egypt. As a result, during clinical drug development, most medicines are studied in clinical trials conducted outside Africa without considering implications of use in African patients or within African health systems.

The Coalition for African Research Initiative (CARI) is a nascent effort by the African Academy of Sciences (AAS) to build a highly coordinated, well-funded and African-led innovation enterprise for the African continent. In recognition of this, the AAS presented the Academy's vision for building Research and Development (R&D) capacities in Africa at a convening of global leaders of research organizations in 2016. The group then proposed to facilitate more engagement between the private sector (particularly with the biopharma industry) and the AAS. A subsequent panel discussion was organized at the World Economic Forum (WEF) in 2017 in Davos, this time engaging broader representation from global pharmaceutical companies to further discuss innovative and sustainable biomedical research in Africa.

Senior leaders from the public sector (US National Institutes of Health -NIH), the private sector (Johnson & Johnson -J&J) and philanthropy (Bill & Melinda Gates Foundation – BMGF) played an important leadership role at this convening. In order to impact on the quality and volume of the African R&D enterprise, stakeholders agreed that the first task was to pull together a single source of data on African clinical trial sites and their capabilities. Subsequently, the AAS engaged a consultancy firm to undertake a study to map the existing African clinical trial sites and their capabilities.

In October of 2018, as part of the Grand Challenges Annual Meeting (GCAM) in Berlin, Germany the AAS presented the pilot inventory mapping and also heard from various other teams and organizations that are carrying out clinical trials/capacity building in Africa. A key outcome of the GCAM Berlin meeting was a recommendation that AAS, working with partners in Africa and globally, move forward to build a versatile, comprehensive open-access database to provide real-time visibility of African clinical trials sites and their capabilities, to improve findability for potential collaborations across the product development ecosystem.

2. Key activities and Milestones

a. **Database Developer:** Following a rigorous evaluation process of 15 high quality and high-profile applicants, Interactive Pharma Services (IPS), a digital technology service provider won the tender to commence with the first phase of working with the AAS to gather in-depth user requirements and other preliminary work necessary to inform platform development decisions.

Acknowledging the social value of the project, some of the RFP (the original **R**equest **F**or **P**roposals is available on request) applicants have expressed interest in collaborating with the AAS to ensure the successful development of the African platform as the AAS progressed into the subsequent phases of building and maintaining the platform. To this end, we are in conversation with IQVIA, Clarivate, TGHN and NuvoteQ.

b. Stakeholder Engagement and Needs Assessment

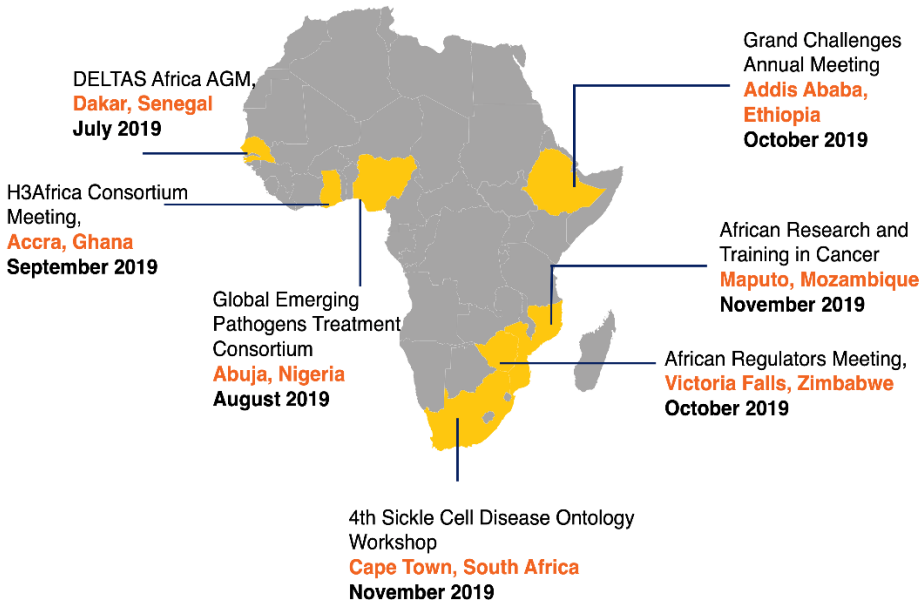
Stakeholder engagement has been a key activity in the past several months of the user-requirements gathering phase of the project. The goal has been to get buy-in from key stakeholders, by making sure we fully understand their needs to inform platform features. In addition, this was important because we recognize that there are existing initiatives that cover some aspects of our proposal and hence there is a need to avoid duplication of existing work and instead promote synergistic and complementary efforts.

We adopted an open approach to communication. Key stakeholders including local and international clinical researchers, biopharma representatives, product development partners (PDPs), and African regulatory representatives have been contacted via face-to-face and/or teleconference meetings. At these meetings, we have raised awareness of the proposed initiative and listened to both endorsements and concerns from various groups.

c. Stakeholder Engagement Activities

i. Clinical Trial Principal Investigators/Researchers

Our approach has involved attending and presenting our work at various meetings across the continent. In 2019, together with our partners, we created awareness at 8 major meetings as shown in the map below:



In addition, the AAS organized a stand-alone stakeholder engagement workshop that was hosted at Ifakara Health Institute, October 1st-2nd, Dar Es Salaam, Tanzania.

A detailed report on these engagements is available upon on request.

Above: Photos from the AAS organized workshop at Ifakara Health Institute, Tanzania

ii. Funders and Sponsors - The conversations that led to this initiative started within the CARI Pharma Working Group which included representatives from AUDA-NEPAD, Pharma, the NIH, the World Economic Forum, Wellcome Trust and the Bill and Melinda Gates Foundation. The initial activities were commissioned and supported by senior leaders from several multinational pharmaceutical companies including; JnJ, GSK, Sanofi, Merck, Pfizer, and Novartis. JnJ provided seed funding to the AAS to undertake a mapping exercise of African clinical trials sites. Upon completion of the clinical trial landscape mapping exercise, the AAS presented the findings to this group in April 2018.

In addition, these conversations progressed at The Hever Group meeting in April 2019 - an informal gathering of the heads of research and development of the large pharmaceutical companies including the NIH and BMGF

Pharma is eager to be part of this initiative and continue to provide tangible and vocal support e.g. senior technical and operational experts joined our interview panel to select the platform vendor, we had good representation at the closed-door update meeting during the Grand Challenges Annual Meeting (GCAM) in Addis Ababa, Ethiopia from JnJ, Roche, Genentech, and Novartis. We discussed possible long-term engagement activities between the industry and the AAS such as collaborative capacity building. The AAS will expand the Pharma Working Group to continue to gather inputs from this key sponsor of global clinical trials.

d. Global Health Clinical Consortium (GHCC)

This is a consortium of 11 Product Development Partners (PDPs) initiated in 2009. Members include; International AIDS Vaccine Initiative, PATH, Medicines for Malaria Ventures, Drugs for Neglected Diseases initiative, Foundation for New Drugs, Global Alliance for TB Drug Development, Infectious Disease Research Institute, International Partnerships for Microbicides, International Vaccine Institute, Aeras and Sabin Vaccine Institute. Their goal is to combat diseases that affect the poorest globally. They are an important stakeholder because Pharma relies on them to deliver their global health project work which includes conducting clinical trials for vaccines, therapeutics, preventives and diagnostic products.

Members of GHCC agree that the proposed platform would be beneficial to the clinical trials community operating in Africa and have shared their lists of trial sites and will facilitate the process of obtaining site feasibility information from their partner sites.

The AAS continues to engage GHCC representatives through updates and they will participate in testing the platform as it develops.

e. Regulatory and Ethics

Throughout our conversations, Regulatory and Ethics approval processes appear to be a major bottleneck as reported by the clinical trial principal investigators (PIs), PDPs and the pharma representatives. There is a keen interest to have up-to-date information on country-specific clinical trial regulatory guidelines and ethics committee approval processes.

Together with the African Vaccine Regulatory Forum (AVAREF) which has been involved with regulatory strengthening activities since 2006, we have developed a checklist excel tool that captures Regulatory/Ethics information. The tool was approved by the AVAREF steering committee in August 2019. The tool was subsequently presented to the member states and was pilot-tested by 9 early adopter countries (both regulatory agencies and ethics boards) including; Nigeria, Burkina Faso, Ghana, Cameroon, Gabon, Zimbabwe, Malawi, Kenya, and Uganda.

Early feedback on this tool was presented to stakeholders at the GCAM in Addis Ababa, in October 2019. Overall, the tool has been well received in the countries that participated in the piloting. Some feedback to improve on the tool was given as below.

- To regularly inform countries on the reasons behind collecting this information
- Reporting period to be adjusted to applications received per financial year as opposed to the calendar year
- Provide the tool in an online version

3. Key Learnings from Engagements

Below is a summary of the key messages from these convenings and conversations.

1. Bring all the clinical trial stakeholders into one virtual network or community.
2. Map disease burden to the location of clinical trial sites
3. Increase the visibility of trial sites, their capacity, and capabilities and provide a platform for them to engage with each other and with stakeholders to fulfill future interests
4. Increase the efficiency of regulatory and ethics requirements across different countries or ethical review boards by improving their visibility and capabilities.
5. Ensure the inclusion of information on trial sites for non-communicable diseases (NCDs) with special mention of Cancer and Sickle Cell Disease
6. Provide access to site feasibility intelligence
7. Promote sustainability of sites
8. Promote practical training on how the top tier clinical trial sites achieved their success
9. Link proposed tool with other existing platforms with similar and/or complementary information to add value and contribute to a better understanding of the data.

4. Key Requests to Stakeholders

Preliminary consultations with key partners and existing platforms to share data or allow for application program interface (API) links are ongoing. Below are examples of key potential partners that we have had initial consultations with. Please note that no contracts have been signed yet.

- Pharma, Product Development Partners (GHCC) and research sites to share their own lists of sites and site-level intelligence with the AAS. We continue to receive site feasibility data from sites asscosited with some of the PDPs.
- Invite existing platforms to partner with us and allow mutual access to data.
    - Institute of Health Metrics (IHME) – Epidemiological data
    - NIH ClinRegs- Regulatory intelligence data
    - IQIVIA - Access to know-how related to their DrugDev tool
    - BVGH - Access cancer clinical trial intelligence data
    - WHO-ICTPR – Access clinical trial registry information
    - SACRA - provide South African clinical research data and connections
    - PACTR - Access African clinical trial registry information
    - Clarivate - Access clinical trial registry and site intelligence data
    - CEPI - Share West Africa Lassa fever site intelligence data
    - Swiss TPH- Share African clinical trial site information

    - Gates MRI and the TB Pharma consortium - Share global TB site intelligence data.
- Pharma companies to help fill skills and infrastructure gaps by collaborating in clinical trial capacity building programs
- Private-sector and public funders to partner with the AAS to ensure the sustainability of the platform
- Ministry of Health/Regional regulators: to improve the efficiency of clinical trial application (CTA) processes e.g. via within-country harmonization and parallel processing of IRB/EC and regulatory applications and cross-country mutual recognition of CTA's where feasible.
- Support to translate the content of the database to other African Union recognized languages such as French, Portuguese and Arabic

5. Program Branding

After a series of consultations both internally and externally, including an externally administered survey, it was agreed that the new name of the project will be **Clinical Trials Community (CTC)** with the tagline- **United for Africa's Health.**

6. CTC Advisory Committee

An advisory committee comprising of reputable experts active in the clinical trial space on the African continent has been set up to advise the AAS on all matters related to the project.

	Name	Expertise /Region
1	David Ishola	PI, Guinea
2	Issaka Sagara	PI, Mali
3	Thomas Nyirenda	EDCTP, South Africa
4	Sameh Trabelsi	PI, Tunisia
5	Priscilla Nyambayo	Regulatory, Zimbabwe
6	Jerome Singh	Bioethics, South Africa
7	Margareth Ndomondo-Sigonda	NEPAD-AUDA, South Africa
8	Skhumbuzo Ngozwana	CRO, South Africa
9	MAIGA, Diadié	WHO-Afro, Congo Brazzaville
10	Jeanine Condo	Researcher, Rwanda
11	Trudie Lang	The Global Health Network (TGHN)

Some members of the steering committee were present at the Grand Challenges CARI Pharma closed door meeting in Addis and provided their support for the progress made thus far.

In the meantime, the AAS will organize a virtual meeting to discuss this update, any matters arising and to seek input on any emerging issues prior to commencing the platform development phase.

7. CTC Visibility

The CTC communications plan was structured in a way to best meet our goal of creating the highest levels of awareness about the project in addition to providing a platform upon which we can interact effectively with our stakeholders. Our target audience includes scientific communities on the continent, government officials and local communities where clinical trials are conducted, biopharma industry, PDPs and international global health funders. We expect that these engagement efforts will translate to increased usage of the service, and ultimately to more, high quality, ethical and relevant clinical trials across the continent.

Currently, we are in the process of putting together a video highlighting the importance of building this platform for the African continent. This video will include interviews with some key stakeholders and footage from some model clinical trial units from across the continent.

8. Looking into the Future

- The next phase is to build the beta version of the platform, a so-called “minimum viable product”. The AAS has synthesised all the user requirement data obtained thus far and will consult with the advisory committee as it prioritizes elements that will go into the beta version.

- The AAS will then work with a software developer to start the actual platform building using what is known as “agile methodology” that will allow rapid incorporation of user feedback..
  This phase will include workshops during which real-time feedback will be collected.
  - In collaboration with AVAREF and WHO-AFRO, the AAS will hold a face-to-face meeting with representatives from regulatory agencies to collect their input and feedback to the beta version. The meeting will be held in Nairobi, Kenya May 12th and 13th, 2020.
  - Another meeting will be organized by the AAS and hosted by CAPRISA in Durban, South Africa, in July 28th and 29th, to seek further user feedback.
  - We also plan to conduct multiple community and regional targeted workshops across the continent once the platform goes live to build user capacity and develop resources for future system improvement and feedback channels. The dates for this activity and venues are yet to be determined.

With guidance from the advisory committee, AAS intends to develop a roll-out plan focused on creating streams of users utilizing the platform and continuous system improvements based on feedback and experience. A sustainability plan to ensure a long term existence of the system with improved features will also be developed.