Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Global Expansion: Activation of a Multicenter Phase II Immunotherapy Clinical Trial in Nigeria

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1. Background

Memorial Sloan Kettering's (MSK's) Multicenter Clinical Research Core (MCRC) is a centralized team dedicated to MSK-sponsored multicenter investigator-initiated trials (IIT). MCRC functions like a CRO and is responsible for managing activation, regulatory, protocol compliance, and data quality using risk-based monitoring with a focus on therapeutic clinical trials.

Global Cancer Research and Training Program (GCRT) is an MSK-led initiative by Dr. Kingham, to address cancer burden globally. MSK partnered with Professor Alatise at Obafemi Awolowo University Teaching Hospital (OAU) in Nigeria to create the African Research Group for Oncology (ARGO) to facilitate research and training initiatives in Nigeria. Since 2013, GCRT and ARGO have run several non-therapeutic and retrospective studies spanning 26 ARGO member sites and other Low-Middle Income Country sites.

MSK convened MCRC and GCRT to launch our first therapeutic multicenter clinical trial in Nigeria, to address the rising burden of colorectal cancer. This leveraged MCRC's therapeutic oversight and GCRT's relationships with the centers, OAU and Lagos University Teaching Hospital (LUTH).

2. Goals

Activate a therapeutic IIT in Nigeria to treat patients with mismatch repair deficient colorectal cancer using Tislelizumab. In the process, building capacity for a therapeutic clinical trial program in the region.

3. Solutions and Methods

Activation at MSK

- Protocol review through required committees
- Negotiation of contract with drug supporter, BeOne
- Identify drug distribution vendor with capabilities in the West African region

Obtain ethical approvals

- Rely on OAU to facilitate submission to National Health Research Ethics Committee (NHREC)
- Consent form review, ensuring content meets MSK standards while aligning with NHREC templates and recommendations
- Obtain local approval from OAU and LUTH Health Research Ethics Committees

Obtain regulatory approval

- Submission of clinical trial application to National Agency for Food and Drug Administration and Control (NAFDAC)
- Submission of import permit

Negotiate budgets and contracts with sites

- Include cost for all trial related assessments that would be considered standard of care or available in the US, i.e. hospitalization, supportive medications, technology, and local insurance
- Include contract terms for hospital strike contingency plans and local privacy regulations

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Site training

- A series of remote site initiation visits were scheduled covering topics; scientific background and protocol overview, safety, response assessments, investigational product (IP), Good Clinical Practice, NHREC and NAFDAC requirements, MCRC requirements, eligibility and registration, risk-based monitoring, data entry and timelines, regulatory documentation, specimen management, and platform trainings
- GCRT collaborated with Society Immunotherapy of Cancer (SITC) to provide training related to immunotherapy management to clinicians.

Drug distribution

- Work with drug distribution vendor to store and distribute IP in the region

4. Outcomes

NHREC approval was obtained Feb 20, 2025 and NAFDAC approval on October 24, 2025.

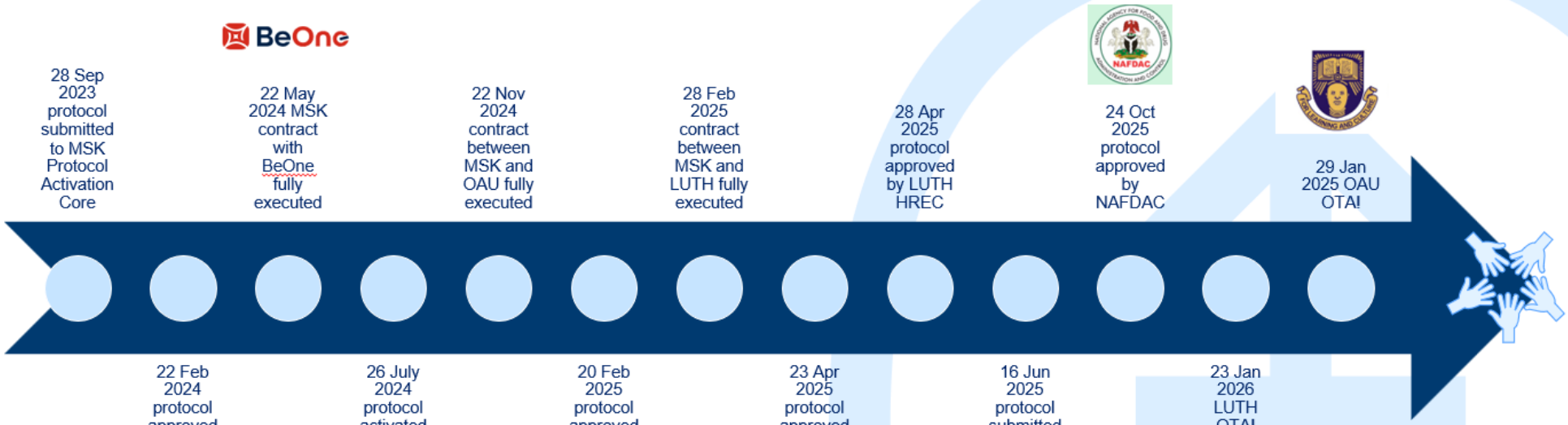
LUTH and OAU were opened to accrual on January 23 and January 29, 2026 respectively, within the NAFDAC required timeline for activation.

5. Lessons Learned and Future Directions

Local support and knowledge were vital for success. Prior GCRT experience and relationships provided a sound understanding of the local regulatory review and approval process.

Prior review of the NHREC and NAFDAC guidelines was critical to ensuring milestones were met and minimize unforeseen challenges.

This would not have been possible without the partnership and support of BeOne providing Tislelizumab


28 Sep 2023 protocol submitted to MSK Protocol Activation Core
22 Feb 2024 protocol approved by MSK IRB
22 May 2024 MSK contract with BeOne fully executed
26 July 2024 protocol activated at MSK
22 Nov 2024 contract between MSK and OAU fully executed
20 Feb 2025 protocol approved by NHREC
28 Feb 2025 contract between MSK and LUTH fully executed
23 Apr 2025 protocol approved by OAU HREC
28 Apr 2025 protocol approved by LUTH HREC
16 Jun 2025 protocol submitted to NAFDAC – 26 Jun 2025 payment / review timeline starts
24 Oct 2025 protocol approved by NAFDAC
23 Jan 2026 LUTH OTA!
29 Jan 2025 OAU OTA!