

Enhancing Local Manufacturing and Supply Chain Management for Health Commodities and Supplies in Nigeria

Updates: June 26, 2025



Outline



Key achievements in last reporting period



Workplan tracking



Challenges and corresponding mitigation strategies



Next Steps

Key Achievements for Reporting Period (1/2)



Workstreams	Key Achievements
Administrative	<ul style="list-style-type: none"> ▪ All selected consulting firms have fully executed their contracts. The consultants include: <ol style="list-style-type: none"> 1. API –USP 2. ACT and RDT Oversight – CHAI 3. ACT Assessment--MedRealm Pharmaceuticals and Consulting Limited 4. LLIN – Access-Centric and Sustainability Foundation (ASF) 5. RDT Assessment – Sages Synergy Integrated Systems 6. Vaccine Production – NSIL 7. NAFDAC Institutional Capacity – Empower School of Health 8. Other Regulatory Capacity - Capacity Connect Limited 9. Harmonization of Manufacturing Regulatory Standards – New Vale Nigeria Limited 10. Harmonization of Regulatory Standards for Clinical Research – Green Fountain Medical Services 11. Digital support for NAFDAC – Infinity Health Africa ▪ Four (4) consulting firms have confirmed receipt of their first tranche payment.
Stakeholder Engagement	<ul style="list-style-type: none"> ▪ Introductory letters addressed to the identified organizations—including relevant agencies and manufacturers—have been developed and duly signed by the PVAC National Coordinator. ▪ The Project Management Team facilitated the physical delivery of these letters to organizations based in the FCT, while the remaining letters are to be handled by individual consultants.
Capacity for ACTs	<ul style="list-style-type: none"> ▪ The draft workstream workplan and inception report for the assessment component have been developed and are currently under review by CHAI and InSiGHt. ▪ The assessment tools are also currently undergoing review.
Capacity for LLINs	<ul style="list-style-type: none"> ▪ The workstream workplan has been finalized. ▪ The consultant (ASF) published an Expression of Interest (EOI) for local manufacturers interested in strengthening their capacity to produce LLINs and has received 6 responses to date. ▪ The assessment tools are also currently undergoing review.

Key Achievements for Reporting Period (2/2)



Workstreams	Key Achievements
Capacity for RAs	<ul style="list-style-type: none"> ▪ The workstream workplan has been developed and will be finalized this week. ▪ The assessment tools are also currently undergoing review. ▪ Consultants have begun initiating contact with NAFDAC and other relevant regulatory agencies. The recent engagement with NAFDAC revealed the following: <ul style="list-style-type: none"> ○ The team engaged multiple global regulatory information management system providers to ensure alignment with industry standards. ○ Dossier submission portal opens July 1st, with three windows (300 dossiers per window). NAFDAC trained stakeholders on how to navigate it. ○ Some privacy issues were identified around data privacy when AI-driven tools like the dossier portal are used; the tool will be piloted using non-proprietary molecules as a workaround. ○ Efforts to secure a meeting with the NAFDAC DG remain unsuccessful. PVAC is currently planning to formally introduce the project consultants to NAFDAC.
Capacity for RDTs	<ul style="list-style-type: none"> ▪ The draft inception report, workplan, and assessment tools are currently undergoing review.
Capacity for Vaccines and Clinical Research	<ul style="list-style-type: none"> ▪ The draft inception report, workplan, and assessment tools are currently undergoing review.
Capacity for APIs	<ul style="list-style-type: none"> ▪ The draft inception report, workplan, and assessment tools are currently undergoing review.
Pooled procurement	<ul style="list-style-type: none"> ▪ The workstream workplan has been finalized. ▪ A meeting was held with Medipool on Monday (June 23, 2025) to discuss their approach to essential medicines, including malaria commodities, and their strategy for bulk purchasing and supply planning.
Project Management and M&E	<ul style="list-style-type: none"> ▪ The team has successfully conducted onboarding meetings with all consultants across the various workstreams. ▪ Workstream-specific weekly meetings have been scheduled to ensure continuous coordination and progress tracking. ▪ Dedicated Google Drive folders have been created for each workstream to facilitate collaborative document review prior to finalization. ▪ The development of the June progress report is currently underway.

Workplan Tracking



Work Plan Tracking (1/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
PM and M&E	Develop a comprehensive Monitoring and Evaluation (M&E) framework	May	<ul style="list-style-type: none"> Finalized M&E framework 		Approved by NMEP
PM and M&E	Support the implementation of the M&E framework	Ongoing	<ul style="list-style-type: none"> M&E updates 		
PM and M&E	Organize bi-weekly update meetings with NMEP	Ongoing	<ul style="list-style-type: none"> Meeting notes detailing the discussions and next steps 		1 st meeting Apr 3, 2025
PM and M&E	Develop and submit monthly program reports by the 10th of the following month	Ongoing	<ul style="list-style-type: none"> Monthly project reports 		To commence July 10, 2025
Stakeholder engagement	Organize engagement meetings with all key stakeholders & assign focal persons responsible for communicating and coordinating project activities	May	<ul style="list-style-type: none"> Workshop report Database of focal persons Stakeholder engagement and communication protocol document. 		Onboarding meetings have been successfully conducted with all consultants across the various workstreams.
Stakeholder engagement	Develop and sign Memorandums of Understanding (MOUs) or formal agreements with each organization	May	<ul style="list-style-type: none"> MOUs or institutional agreements signed. 		All contracts have been fully executed by all organizations/consultants.

Completed
 Ongoing
 Not due
 Not Started

Work Plan Tracking (2/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
Stakeholder Engagement	Coordinate policy dialogues with key stakeholders to develop an implementation framework for priority recommendations	August	<ul style="list-style-type: none"> Priority recommendations for all project components. 		Pending assessments yet to be conducted
PM and M&E	Synthesize policy and regulatory landscape into a white paper.	August	<ul style="list-style-type: none"> Finalized white-paper 		PM Consultant engaged.
RDTs	Develop recommendations for critical policy and regulatory reforms required for the local manufacturing of RDTs.	August	<ul style="list-style-type: none"> Finalized recommendations 		Pending assessment – not yet commenced
RDTs	Develop a status update on capacity for RDT production through stakeholder engagement, facility visits & assessments	August	<ul style="list-style-type: none"> Assessment report with recommendations 		<ul style="list-style-type: none"> Contracts signed. Assessment tools are being developed.
ACTs	Develop recommendations for critical policy and regulatory reforms required for the local manufacturing of malaria ACTs	August	<ul style="list-style-type: none"> Finalized recommendations 		Pending assessment – not yet commenced
APIs	Develop recommendations for critical policy and regulatory reforms required for the local manufacturing of malaria APIs	August	<ul style="list-style-type: none"> Finalized recommendations 		Pending assessment – not yet commenced

Completed
 Ongoing
 Not due
 Not Started

Work Plan Tracking (3/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
ACTs	Develop a status update on the capacity for malaria production through stakeholder engagement, facility visits, and assessment.	August	<ul style="list-style-type: none"> Assessment report with recommendations 		<ul style="list-style-type: none"> Assessment tools are being developed. Contracts signed Workplan and inception report under review.
LLINs	Develop recommendations for critical policy and regulatory reforms required for the local manufacturing of LLINs	August	<ul style="list-style-type: none"> Finalized recommendations 		Pending assessment – not yet commenced
LLINs	Develop a status update on the capacity for LLINs production through stakeholder engagement, facility visits, and assessment	August	<ul style="list-style-type: none"> Assessment report with recommendations 		<ul style="list-style-type: none"> Assessment tools are being developed. Contract signed Workplan finalized
PM and M&E	Develop quarterly financial reports	Ongoing	<ul style="list-style-type: none"> Finalized quarterly financial reports 		PM Consultant selected to liaise with HSCL
Stakeholder Engagement	Organize workshops to validate findings and co-develop a strategic roadmap for vaccine, RDT, LLINs and ACT production with stakeholders.	August	<ul style="list-style-type: none"> Stakeholder Workshop Reports 		Pending until all assessments are conducted
RDTs	Validate findings and co-develop a strategic roadmap for malaria product (RDT) production.	August	<ul style="list-style-type: none"> Finalized strategic roadmap 		

Completed
 Ongoing
 Not due
 Not Started

Work Plan Tracking (4/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
RDTs	Finalize the selection of manufacturers for technical assistance for institutional and manufacturing capacity development	August	<ul style="list-style-type: none"> Finalized list of RDT manufacturers 		
ACTs	Explore local sourcing of inputs for producing malaria ACTs from other local sectors (e.g., the petrochemical industry)	August	<ul style="list-style-type: none"> List of priority local available inputs and potential engagement framework. 		
ACTs	Validate findings and co-develop a strategic roadmap for malaria ACTs production.	August	<ul style="list-style-type: none"> Finalized strategic roadmap 		
APIs	Validate findings and co-develop a strategic roadmap for malaria APIs production.	August	<ul style="list-style-type: none"> Finalized strategic roadmap 		
ACTs	Finalize the selection of manufacturers for technical assistance for institutional and manufacturing capacity development	August	<ul style="list-style-type: none"> Finalized list of ACT manufacturers 		
APIs	Finalize the selection of manufacturers for technical assistance for institutional and manufacturing capacity development	August	<ul style="list-style-type: none"> Finalized list of API manufacturers 		

Completed
 Ongoing
 Not due
 Not Started

Work Plan Tracking (5/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
LLINs	Validate findings and co-develop a strategic roadmap for LLINs production.	August	<ul style="list-style-type: none"> Finalized strategic roadmap 		
LLINs	Finalize the selection of manufacturers for technical assistance for institutional and manufacturing capacity development	August	<ul style="list-style-type: none"> Finalized list of LLINs manufacturers 		
Regulatory	Identify respective regulatory agencies' (e.g. NAFDAC, PCN and others TBD from mapping) support needs	August	<ul style="list-style-type: none"> Finalized report 		Empower's rapid assessment to inform in-depth assessment.
Regulatory	Co-develop (with regulatory agencies) a short and mid-term capacity development plan	August	<ul style="list-style-type: none"> Finalized costed capacity development plan 		
Regulatory	Facilitate the establishment of a NAFDAC-led quality assurance task force.	August	<ul style="list-style-type: none"> Established NAFDAC-led QA task force 		
Vaccine and CR	Establish partnerships to expand innovative clinical research to local sites and strengthen the capacity and quality of clinical research.	August	<ul style="list-style-type: none"> Map of potential partnerships to strengthen in-country capacity for vaccine and other research 		

Completed
 Ongoing
 Not due
 Not Started

Work Plan Tracking (6/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
Stakeholder Engagement	Ensure all raw materials needed for producing malaria vaccines, RDTs, LLINs and ACTs are included in the presidential executive order.	August	<ul style="list-style-type: none"> Raw materials for ACTs and other products included in executive order list 		Executive order communicated to customs with raw materials included (Mar 2025)
RDTs	Provide technical support to implement the strategic roadmap for local manufacturers of RDTs	August – December	<ul style="list-style-type: none"> Reports on technical assistance provided 		
ACTs	Provide technical support to implement the strategic roadmap for local manufacturers of malaria ACTs.	August – December	<ul style="list-style-type: none"> Reports on technical assistance provided 		
APIs	Provide technical support to implement the strategic roadmap for local manufacturers of malaria APIs	August – December	<ul style="list-style-type: none"> Reports on technical assistance provided 		
LLINs	Provide technical support to implement the strategic roadmap for local manufacturers of LLINs	August – December	<ul style="list-style-type: none"> Reports on technical assistance provided 		
Regulatory	Regulatory harmonization for manufacturing standards.	August	<ul style="list-style-type: none"> A comprehensive framework or set of guidelines 		<ul style="list-style-type: none"> Consultant selected. Contract signed
Regulatory	Provide technical assistance to NAFDAC	August – December	<ul style="list-style-type: none"> Reports on technical assistance provided 		

Completed
 Ongoing
 Not due
 Not Started

Work Plan Tracking (7/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
Pooled Procurement	Conduct a comprehensive assessment of the current capacities for pooled procurement at state and national levels	August	<ul style="list-style-type: none"> Finalized assessment report 		<ul style="list-style-type: none"> Consultant selected Contract signed
Pooled Procurement	Co-develop a phased intervention plan with stakeholders	August	<ul style="list-style-type: none"> Finalized costed capacity development plan 		
Pooled Procurement	Establish a committee for pooled procurement of malaria commodities	August	<ul style="list-style-type: none"> State level pooled procurement committees 		
Vaccine and CR	Develop a status update on in-country capacity for vaccine production by different vaccine types – LAV, mRNA, etc., including malaria vaccines.	August	<ul style="list-style-type: none"> Finalized status update report 		<ul style="list-style-type: none"> Assessment tools are being developed Contract signed
Vaccine and CR	Develop recommendations for critical policy and regulatory reforms required for the local manufacturing of vaccines.	August	<ul style="list-style-type: none"> Finalized recommendations for local manufacturing of vaccines 		
Vaccine and CR	Identify collaboration opportunities with regional initiatives such as RVSC, etc. (emphasizing malaria vaccines) and key participation steps.	August			

Completed
 Ongoing
 Not due
 Not Started

Work Plan Tracking (8/8)



Workstream	Activities	Completion Timeline	Deliverables	Status	Comments
Vaccine and CR	Regulatory harmonization of standards for clinical research and trials.	August	<ul style="list-style-type: none"> A comprehensive framework or set of guidelines 		<ul style="list-style-type: none"> Consultant selected Contract signed
Regulatory	Enhance market surveillance and quality control.	September	<ul style="list-style-type: none"> Market surveillance and quality control framework 		
Pooled Procurement	Provide technical support for pooled procurement at state and national levels	September	<ul style="list-style-type: none"> Centralized procurement guidelines. Report on technical assistance provided 		
Vaccine and CR	Collaborate with stakeholders to identify potential clinical trial locations/sites that can participate in clinical research into new therapeutics and other interventions.	September	<ul style="list-style-type: none"> Database of local site for vaccine trials 		
Pooled Procurement	Strengthen inventory management and visibility	December	<ul style="list-style-type: none"> Implemented digital tools for inventory management 		
PM and M&E	Develop end-of-project report with lessons learned for future programming	December	<ul style="list-style-type: none"> Finalized end-of-project report 		

Completed
 Ongoing
 Not due
 Not Started

(1) Finalization of workplans

Finalize all workplans across the respective workstreams.

(2) Tools Finalization

Finalize assessment tools across all workstreams.

(3) Concurrent Assessments

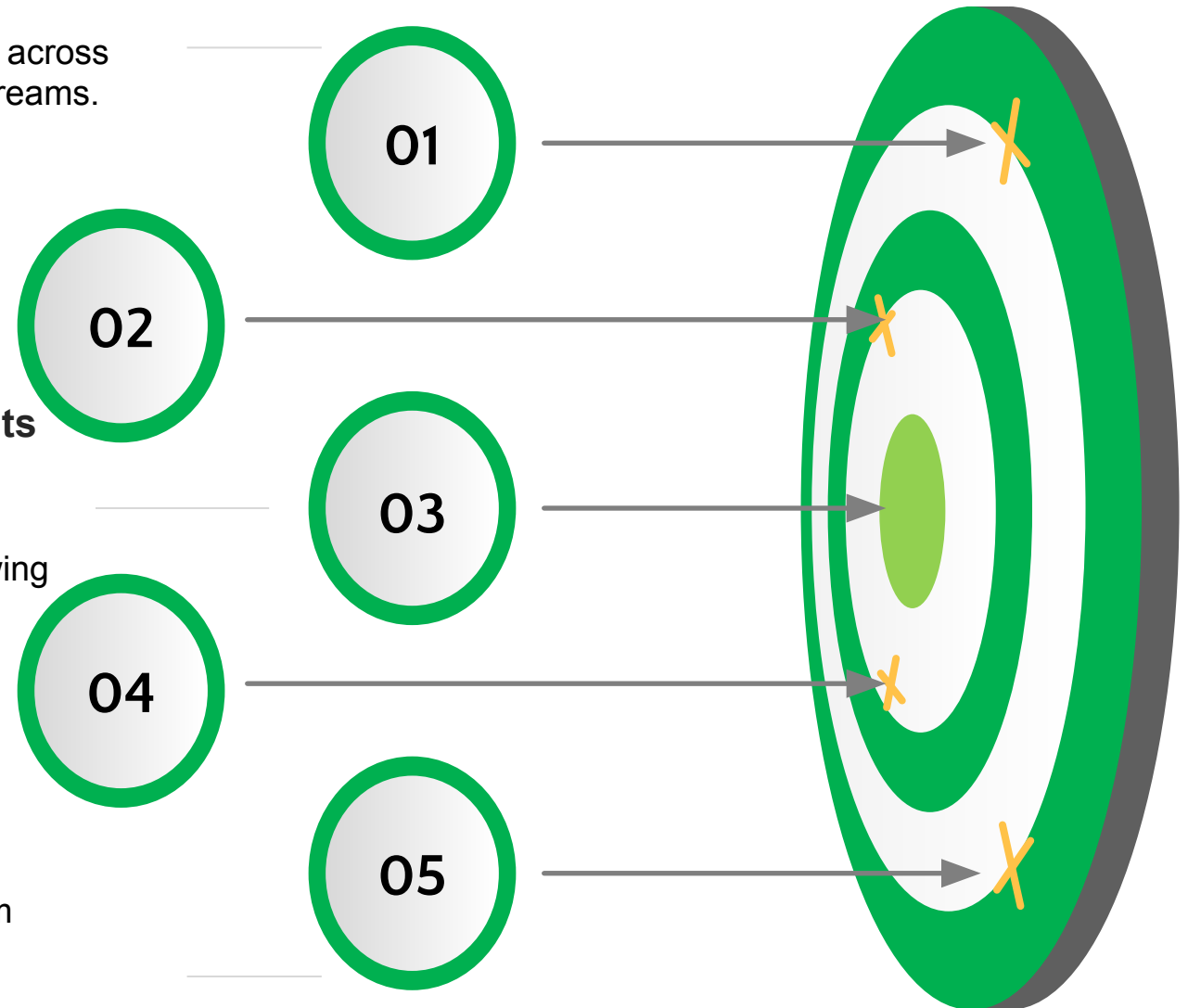
Finalize tools and run assessments for workstreams concurrently to inform the following activities.

(4) Stakeholder Engagement

Continue stakeholder engagement (including representatives from NAFDAC, NPSCMP, Association of Local Manufacturers, etc.).

(5) Progress Tracking

Continue with the workstream weekly meetings.



Thank You!

