TRANSFORMING AFRICAN MEDTECH CONFERENCE

TAMC REPORT 2024

TRANSFORMING AFRICAN MEDTECH CONFERENCE

The second annual Transforming African MedTech Conference was held in Nairobi, Kenya from 28th-30th August 2024. With stakeholders from across the continent and beyond, delegates spent three days learning from experts, discussing relevant issues, hearing from MedTech entrepreneurs, and connecting with like minded professionals.

Letter from the Chair

Dear African Medtech community,

It means a great deal to me to be part of this thriving group of people who have a real sense of urgency around accelerating the MedTech industry on the African continent. I could tell at this year's conference that there was impatience to come together to affect changes to move the MedTech industry forward.

It is not news that the African MedTech industry faces challenges such as limited access to funding, inadequate infrastructure, regulatory hurdles, and limited collaboration among stakeholders. The working groups at the convening compellingly voiced the need for a dedicated association to address these challenges by providing resources, fostering networks, and advocating for supportive policies.

We are actively working on launching an Association for African MedTech Practitioners by TAMC 2025! This will help to streamline our collaborations and provide resources and information needed by stakeholders to get high quality MedTech into our hospitals.

I appreciate all the partners, sponsors, volunteers and delegates of TAMC 2024. It was powerful to extend the vision of a thriving African Medtech industry created at TAMC 2023. We have quite a journey ahead of us, but we have taken the all-important first steps.

As I hand over as chair of the organizing committee, I feel confident that what we have started has great momentum that will accelerate the African MedTech industry and have a huge impact on healthcare on the African continent, create high quality jobs and contribute to the African economy.

See you all at TAMC 2025 and I can't wait to hear what each of you achieves this year.

Wambui Gachienga Nyabero

CEO MEDevice Kenya

Executive Summary

The second annual Transforming African MedTech Conference was held in Nairobi, Kenya from 28th-30th August 2024. With almost 200 stakeholders from across the African continent (92%) and beyond (8%), delegates spent three days learning from experts, discussing relevant issues, hearing from MedTech entrepreneurs, and connecting with like minded professionals.

Addressing Africa's Healthcare Challenges

The conference opened with discussions about Africa's critical healthcare barriers, including access to medical oxygen, affordable healthcare technology, and the need for sustainable systems. Experts like Dr. Bernard Olayo (Hewatele) and Dr. Lucy Mazyanga (Africa CDC) emphasized local innovation and reducing reliance on imports to build stronger, self-reliant systems.

MedTech Innovation and Industry Growth

The MedTech industry's challenges—ranging from dependency on imported devices to regulatory complexities and funding gaps—dominated discussions. Solutions focused on:

- Local manufacturing and tailored innovations.
- Streamlined regulatory processes.
- Blended finance models and strategic partnerships.
- Building skilled workforces and fostering ecosystems for startups.

Policy and Regulatory Improvements

Fragmented regulations in Africa hinder MedTech growth. Experts advocated for harmonizing standards through initiatives like the African Medicines Agency (AMA) to ensure faster approvals, better compliance, and improved patient safety.

Spotlight on Startups

The startup pitching competition highlighted Africa's MedTech ingenuity, with innovators presenting solutions like AI-driven diagnostics and locally produced devices. This year's winning startups are all developing homegrown diagnostic solutions in maternal child health and non-communicable diseases. They received a total of $20,000 in grant funding and mentorship to develop and scale their impact.

Building a Local MedTech Industry

Africa imports over 90% of the health system's medical devices and equipment resulting in high costs and inefficiencies that are borne by patients. Experts noted the potential for locally developed and manufacturing health technologies and proposed strategies like establishing local assembly plants, creating innovation hubs, and supporting local talent. Sustainable funding and policy support are essential to foster growth.

Strategic Roadmap for Africa

The conference culminated in actionable recommendations:

1. **Investment:** Develop Africa-specific funding models and attract local and global investors.
2. **Product Development:** Promote scalable, locally driven innovations to address healthcare gaps.
3. **Regulation:** Harmonize standards continent-wide to streamline product approvals and enhance safety.

Looking Forward

TAMC 2024 showcased a shared vision of transforming Africa's MedTech landscape through collaboration, innovation, and sustainable practices, setting the stage for improved healthcare outcomes across the continent. Over the next year, in preparation for the next TAMC, working groups have been formed to continue to develop this sector on the African continent.

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DAY 1

Theme:

How a robust African medtech industry contributes to Improved Patient Care, Universal Health Coverage and Resilient Healthcare Systems

Fireside Chat

A conversation between Eng. Wambui Nyabero and Dr. Bernard Olayo

Access to medical oxygen is a key challenge facing the African health sector. Dr. Bernard Olayo, founder of Hewatele, highlighted this critical issue, stating that the lack of oxygen available was causing preventable deaths. Additionally, patients in certain regions in Africa were paying up to 10 times more for oxygen compared to North America and Europe. This disparity motivated him and his team to develop a solution that would make oxygen widely available without sacrificing quality.

The Hewatele initiative was born from the realisation that hospitals were not generally able to maintain Pressure Swing Adsorption (PSA) oxygen plants, leading to frequent equipment failures. To address this, Dr. Olayo and his team took over the responsibility of maintenance and also built large-scale PSA plants. Their oldest plant has been running for 10 years. Over the last two years, they have raised $20 million after proving they could produce and distribute medical oxygen efficiently.

Dr. Olayo shared that while dealing with government processes is challenging, it is possible and important to do business with them. The key is persistence. Starting a new initiative comes with many challenges, including failure and rejection. Dr. Olayo emphasised the importance of entrepreneurs surrounding themselves with supportive individuals who can cheer them on and share in their journey. He also reminded the audience that self-care is crucial, urging entrepreneurs not to sacrifice their well-being for the cause. Even in the face of failure, the message was clear: don't get discouraged—keep going.

Guest of Honour Remarks

***Speaker:** Dr. Lucy Mazyanga, Africa CDC*

Dr. Mazyanga has contributed extensively to the field of medical science, authoring 145 scientific papers and five books. She is currently the Regional Director for the Eastern Africa Regional Co-coordinating Centre of the Africa CDC. She shared that, though Africa is rich in natural resources, the continent faces significant challenges in responding to medical interventions, but they also represent numerous opportunities for improvement.

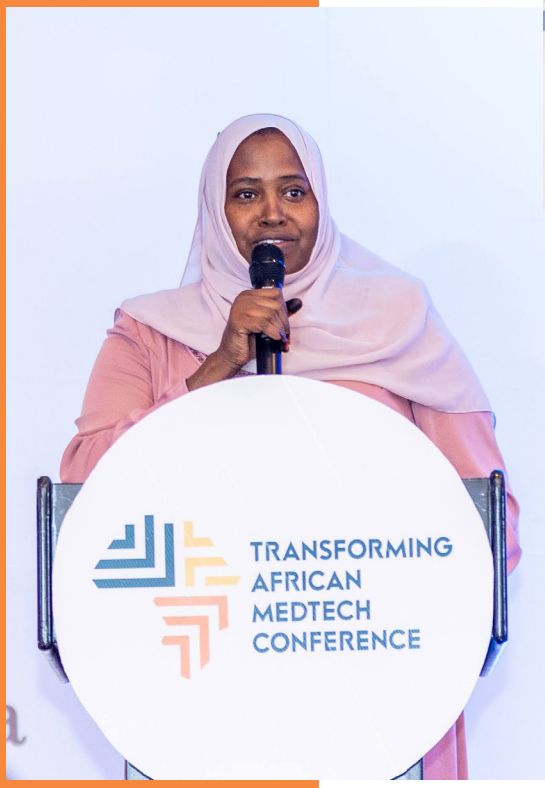
Dr. Mazyanga emphasised the critical role that medical technology plays in enhancing healthcare, particularly in underserved and rural areas. Digital health tools, such as AI-powered diagnostic tools and technologies for data collection and planning, can improve efficiency and healthcare access. She cited a pilot program in Ethiopia that uses air pressure technology for children as an example of innovation.

A robust MedTech industry is essential for fostering innovation, research, and positioning Africa as a global player in healthcare. By developing this industry, Africa can reduce its reliance on imported medical technologies and create cost-effective solutions. Partnerships with organisations like the Africa CDC are key to achieving these goals. Digital tools are transforming healthcare delivery, including vaccine production and point-of-care services. Dr. Mazyanga urged stakeholders to commit to supporting and nurturing the MedTech industry to ensure that healthcare becomes a right for all, not a privilege.

Dr. Mazyanga concluded by encouraging continued efforts in fostering medical innovation and creating sustainable healthcare systems in Africa.

Chief Guest Opening Remarks Summary

***Speaker:** Dr. Zainab Gura, Deputy Director General, Kenya Ministry of Health (MOH)*



Dr. Gura emphasised the Kenyan Ministry of Health's commitment to strengthening health systems, while acknowledging the challenges that hinder progress. The ministry is focusing on universal health coverage (UHC) to ensure a robust healthcare environment, one that encourages innovation and comprehensive reforms.

A significant milestone will be the digitization of healthcare systems across Kenya. This comprehensive digitization is a cornerstone of the UHC reforms. Dr. Gura also highlighted the upcoming launch of Social Health Technology, part of Kenya's efforts to improve healthcare services and access. Additionally, over 10,000 health workers have been hired as part of the government's commitment to strengthening healthcare delivery.

Expanding the use of technology is critical, especially given that 70% of medical products used in Kenya are imported. Dr. Gura called for innovative solutions that can simplify the national procurement process and emphasised the ongoing review of regulations to encourage innovation.

A key message was the need to foster self-sustainability within Kenya's healthcare system, reducing reliance on imports and promoting local solutions. Dr. Gura encouraged stakeholders to support these initiatives and work towards a more sustainable and technology-driven healthcare system in Kenya.

Panel Discussion 1 Summary: MedTech Industry 360 View

Moderator: *Moses Waweru*

Panellists: *Karl Heinz Tundo (TU Delft), Dr. Lisa Ochola (Medical Director, Malaica), Abdel Nasser Daoud Kinefour (Senior Program Officer, MSMEs, AUDA-NEPAD), Christine Were (Hatch Technologies)*

Challenges Discussed:

1. **Lack of Access to Healthcare in Remote Areas:**
   The absence of healthcare services, such as ultrasounds and CT scans, coupled with the shortage of skilled professionals like sonographers, leads to high maternal and child health complications.

2. **Limited Local Production of Medical Devices:**
   Only 5% of medical devices are manufactured locally, with the rest being expensive imports. This dependency delays delivery and inflates costs, hindering timely care.

3. **Infrastructure and Logistical Barriers:**
   Unreliable electricity, poor internet access, and logistical complexities in rural areas affect the use of advanced medical devices.

4. **Regulatory Hurdles:**
   Lengthy regulatory approval processes (up to six years in some cases) slow down the introduction of innovative solutions to African markets.

5. **Lack of Skilled Workforce:**
   A shortage of biomedical engineers and technicians further complicates local innovation and maintenance of medical technologies.

6. **Insufficient Funding:**
   The high cost of manufacturing and lack of investment make scaling healthcare innovation difficult. Local funding and support are needed to sustain the industry.

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Proposed Solutions:

- **Local Manufacturing and Innovation:**
  Dr. Lisa emphasised the need for locally made devices designed for the African context, such as those that can handle limited electricity and infrastructure. Local capacity-building and partnerships with universities were also highlighted as crucial.

- **Funding Mechanisms:**
  Karl Heinz stressed the importance of local investments, suggesting that Africa adopt models like the Netherlands, where 50% of R&D is funded by private industries and 30% by government, to boost innovation.

- **Regulatory and Market Access Support:**
  Abdel Nasser shared AUDA-NEPAD's efforts to streamline regulatory processes and assist startups through capacity-building and technical support, fostering faster market entry.

- **Comprehensive Distribution Systems:**
  Christine from Hatch Technologies shared their model of aggregating demand and providing working capital to local distributors in six African countries, ensuring affordable and accessible medical devices.

Key Decisions:

Encouraging Local Manufacturing:
The panel agreed on the need for local manufacturing to reduce logistics costs and increase accessibility of medical devices across Africa. Supportive policies and collaboration with government, academia, and industry are essential to driving this forward.

Investment in Innovation:
Private sector funding and government support were highlighted as critical to the growth of Africa's MedTech industry, reducing reliance on imports and enabling local solutions.

Lessons Learned:

- Building strong distribution networks, like Hatch Technologies, is key to ensuring affordable access to medical devices in remote areas.
- Africa can benefit from European models of investment in R&D, and collaboration between stakeholders is necessary to build local capacity.
- MedTech solutions must be designed with local challenges, such as unreliable electricity, in mind.
- Participants were urged to explore ways to develop local manufacturing capabilities, which would reduce costs and enhance the availability of medical devices in Africa.

Primary Session Takeaway:

The discussion underscored the importance of fostering local manufacturing in the African MedTech sector to address healthcare challenges. By developing affordable, contextually relevant solutions, supported by robust policy, infrastructure, and funding, Africa can reduce dependency on imports and improve healthcare access across the continent.

Breakout Sessions

Innovation & Investment Track (Part 1)

Medtech Industry Barriers

Moderator: *Dr. Bahaa Eddine Sarroukh (Phillips Foundation)*

Panellists: *Sona Shah (Neopenda), Masoud Mnonji (Ifakara), Prof. Ndirangu Kioni (Dedan Kimathi University), Grace Baloyi (Global Health Innovation Accelerator)*

Challenges/Concerns:

1. **Reliance on Imported Devices:**
   Dr. Bahaa Eddine Sarroukh emphasised Africa's dependence on expensive, imported medical devices that are often not tailored to local needs. This leads to inefficiencies and limits investments.

2. **Regulatory Barriers:**
   Sona Shah highlighted the regulatory burden of meeting local and international standards, including the challenge of navigating approvals for clinical trials and the cost of establishing a quality management system.

3. **Weak Manufacturing Ecosystem:**
   Prof. Kioni noted that Africa's manufacturing sector is underdeveloped, making it difficult for innovators to find facilities to produce medical devices, compounded by a lack of skilled workforce and base technologies.

4. **Regulatory Hurdles and Knowledge Gaps:**
   Grace Baloyi discussed the lack of clarity around the steps for registering MedTech products and the prioritisation of pharmaceuticals by regulatory bodies over medical devices.

5. **Physical Workspaces and Mentorship Issues:**
   Participants pointed out that government labs often lack resources, and African-made products are perceived as lower quality. Finding mentors and understanding investment jargon are additional challenges for MedTech entrepreneurs.

Proposed Solutions:

- **Strengthen the MedTech Industry Focus:**
  Prof. Kioni advocated for dedicated spaces and initiatives focused on MedTech, including partnerships with universities to develop technical capacity and relevant curriculums.

- **Collaborate for Technical and Regulatory Support:**
  Masoud Mnonji emphasised collaboration with hubs and ecosystem players to bridge gaps in technical skills and testing facilities, particularly through partnerships like Ifakara Hub's collaborations with Villgro Africa and other industry players.

- **Leverage Existing Resources for Standards Compliance:**
  Sona Shah suggested contracting technical experts and partnering with organisations that already have access to necessary standards and resources to save costs and navigate regulatory processes.

- **Regulatory Engagement:**
  Grace Baloyi recommended engaging regulatory authorities and ecosystem partners to support clinical trials and ease the path to product approval.

- **Improving Manufacturing Standards:**
  Prof. Ndirangu Kioni stressed the need to enhance local manufacturing capabilities to ensure high-quality production and meet industry standards.

Lessons Learned:

- **Collaboration and Patience in Fundraising:**
  Sona Shah shared that fundraising is a lengthy process requiring patience, collaboration with hubs, and participation in accelerator programs.

- **Understanding Key Industry Players:**
  Masoud Mnonji emphasised identifying gaps within the ecosystem and collaborating with others to fill them, especially in technical skills and facilities.

Action Points & Next Steps:

- ISO Certification Course:
  Grace Baloyi to connect with a university working on an ISO certification course to help standardise MedTech production processes in Africa.

The African MedTech sector faces significant barriers, including regulatory challenges, limited access to manufacturing and technical skills, and underdeveloped ecosystems. However, collaboration across universities, innovators, and hubs, alongside investments in manufacturing and regulatory frameworks, can help overcome these hurdles and drive growth in the industry.

Innovation & Investment Track (Part 2)

What Would Crowd in More Funding for African Medtech Startups?

Moderator:*Steve Sewu (Jaza Rift)*

Panellists: *SEric Osiakwan (Chanzo Capital), Christophe DiMantio (Beyond Capital Ventures), Rahel Musyoki (Unique Global), Hiroki Ishida (Director of ARC Kenya), Wilfred Njagi (Villgro Africa)*

Challenges/Concerns:

1. **Healthcare Accessibility:** Rahel highlighted that most Africans struggle with affordable access to healthcare.
2. **Investment Gaps:** Christophe emphasised that many MedTech startups fail to meet investment criteria, as they lack necessary licences or are not post-revenue.
3. **Equity-based Funding:** Dr. Watu pointed out that 98-99% of funding for African MedTech startups comes from equity-based investments, which are difficult to secure.
4. **Regulatory Hurdles:** Obtaining regulatory approvals, such as FDA or CE Marks, is costly and time-consuming, hindering early-stage companies.
5. **Knowledge Gaps:** Innovators often lack business expertise and financial networks, which limits their ability to secure funding and scale up.

Proposed Solutions:

- **Deregulation:** Christophe suggested lowering standards for medical devices and reducing risks for startups through targeted funds for early-stage innovators.
- **Blended Finance:** Wilfred proposed combining grants, technical support, and equity to de-risk the sector.
- **Commercial Partnerships:** Entrepreneurs should seek strategic commercial relationships for growth before seeking significant funding.

Lessons Learned:

- **Skillset Development:** Rahel advised innovators to focus on building complementary skill sets within their teams.
- **Validation:** Wilfred highlighted the importance of validating solutions in the market to attract investment.
- **Investor Networks:** Hiroki emphasised creating a network of early-stage investors to support financial scaling.

Action Points & Next Steps:

- Explore establishing an African-level regulatory body to streamline processes.
- Form a consortium of investors to share due diligence and support startups through various stages.

The panel discussed the African MedTech sector's growth potential and challenges, including market size, regulatory approvals, and investment criteria. They emphasised the need for a blended finance model, commercial partnerships, and building a strong pipeline of investment-ready startups. The session also called for increased collaboration among investors and ecosystem support to de-risk early-stage ventures and encourage more funding into African MedTech.

Market Shaping & Regulatory Track (Part 1)

Market Shaping Efforts in the African MedTech Sector

Moderator: *Khatuchi*

Panellists: *Dr. Muthoni (Philips East Africa), Dr. Madiko Riro (Clinton Health Access Initiative (CHAI), Ali Khalid (Hatch Technologies)*

Sinapi Biomedical Case Study

Founded in the early 2000s by Chris de Villiers, Sinapi Biomedical specialises in developing innovative medical devices, particularly disposables used in hospitals. One of its most impactful products is the Elavi Uterine Balloon Tamponade, designed to address postpartum haemorrhage—a leading cause of maternal death in Africa. This device was developed in response to a request from PATH to create a regulated, pre-assembled alternative to the makeshift condom catheter method. The device has proven highly successful, particularly in a South African district where maternal deaths from postpartum haemorrhage dropped dramatically from 270 to 47 over five years, with no recorded cases since 2021.

Despite its success, Sinapi Biomedical faced challenges in scaling the Elavi Uterine Balloon Tamponade across Africa. While initial efforts focused on training healthcare providers, a shift to a top-down strategy, involving ministries of health, became necessary. The company also discovered that partnering with NGOs and global funders was more effective in distributing the product in regions with low healthcare budgets. Sinapi Biomedical's growth was rooted in organic expansion within South Africa, without external funding, allowing it to be agile and responsive to market needs.

Looking ahead, Sinapi Biomedical aims to grow both its commercial and impact product lines. The company is committed to continuing its work in saving mothers' lives through innovative devices while expanding its commercial operations in first-world countries. Founder Chris de Villiers emphasises the need for strong business skills in the African medical device industry, alongside technical expertise, to ensure sustainable success and greater health outcomes across the continent.

Challenges/Concerns:

1. **Regulatory Complexity:** Companies must register products in each African country individually, creating a regulatory burden. Harmonising regulatory frameworks across countries is crucial.
2. **Supply Chain & Distribution:** Local distributors often lack the funding needed to meet demand in their countries.
3. **Awareness Gaps:** There is a lack of awareness, particularly in the public sector, which impedes connections with key stakeholders.
4. **Sustainability Issues:** Disposal of used medical devices is a growing concern, contributing to 4% of healthcare's carbon emissions. Public procurement only allows for new equipment, complicating efforts to refurbish or reuse devices.
5. **Public Procurement Restrictions:** Public procurement practices prevent the refurbishment of medical devices, adding to environmental concerns and costs.

Proposed Solutions:

- Research & Innovation Hub: Establish a hub to focus on the specific needs of African MedTech, including innovative solutions and collaboration opportunities.
- Private Partnerships: Leveraging private-to-private partnerships to finance and distribute MedTech products.
- AI Integration: Integrating artificial intelligence to enhance existing solutions.
- Sustainability Initiatives: Prolonging the lifecycle of medical devices through remanufacturing, software updates, and buy-back programs to reduce environmental impact and cost.
- Local Distributor Support: Engage with local distributors by providing discounts for bulk purchases and ensuring that these savings reach the end users.

Decisions Made:

- **Policy Advocacy:** A consensus was reached to collaborate and influence MedTech policy-making to benefit the industry, with a focus on environmental sustainability and efficient procurement practices.

Lessons Learned:

- **Procurement Strategy:** Monitoring procurement patterns can help aggregate demand, offering stronger negotiating power and lowering costs.
- **Sustainability:** Sustainable procurement practices can reduce costs and promote environmental responsibility in healthcare.

Action Points & Next Steps:

- **New Procurement Standards:** Develop guidelines promoting sustainability in healthcare procurement, with a focus on the environmental impact.
- **Government Collaboration:** Work with governments to shape policies that support MedTech growth.
- **Financing & Innovation:** Explore creative financing options and engage with donors and funders to support the MedTech community.
- **Telehealth & Public Awareness:** Implement telehealth solutions and create public documents to enhance awareness and guide discussions on key MedTech issues.

The session addressed the regulatory and sustainability challenges in the African MedTech sector. Solutions centred on creating an innovation hub, leveraging private partnerships, and promoting sustainable procurement practices. The panel emphasised the importance of regulatory harmonisation, local distributor support, and creative financing to stimulate sector growth.

Market Shaping & Regulatory Track (Part 2)

During this session, attendees were divided into groups to collaboratively design a comprehensive roadmap aimed at addressing the unique challenges and opportunities within the sector.

Facilitated by Dahlberg, this interactive session fostered in-depth discussions and brainstorming, enabling participants to leverage their diverse expertise and perspectives. Each group focused on identifying critical barriers, proposing solutions, and outlining actionable steps for advancing market access across the continent.

The following section presents the key insights and recommendations generated during these collaborative efforts, which are intended to guide stakeholders toward more inclusive and sustainable medtech growth in Africa.

KEN- M&E			
PHASES	**NEAR TERM**	**MID TERM**	**LONG TERM**
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Current state of M&E • Identification of gaps in M&E • Existing of policies and regulations	• Creation of Framework for M&E • Education and Training • Infrastructure	• Scaled Unified M&E • Feedback

PHASES	NEAR TERM	MID TERM	LONG TERM
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Interview and services • Government guidelines • Questionnaire and survey • Engaging stakeholders	• Documentation • Standard operation procedure • Developing Infrastructure/ Platforms	• Analysis of Data • Modify according to feedback • Create awareness
Deliverables: Are the tangible outputs or results that ore expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Needs assessment documents • Technical Know-how	• Systems and platforms	• Full network of M&E
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Government Engagement • Lack of Infrastructure • Lack of funding • Lack of expertise	• Government • Adoption of solutions • Regulatory constraints	• Government • Lack of funding
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Expertise • Business Developer • Human resources	• Infrastructure	• Finance • Organisational Structure

MARKET LANDSCAPING			
PHASES	**NEAR TERM**	**MID TERM**	**LONG TERM**
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Build a directory for all market players. Launch next year at TAMC • Demand - Supply - Structural factors	• Data analytics for decision making	AI based predictive platform for MEDTECH Industry
PHASES	**NEAR TERM**	**MID TERM**	**LONG TERM**
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Collect primary data using Interviews and surveys • Find where data sits • Visualization (Interface)		
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Champion/ Funder • Host • Collector • Visualizer • Directory		
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Unresponsive stakeholders • Bias info by region • Non-Mapped areas • Pick wrong champion • Language barrier • Data security		
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Financial • Human		

THE CREATIVES			
PHASES	**NEAR TERM**	**MID TERM**	**LONG TERM**
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Creating a collaborative platform to discuss the end goal. • Co Creation, Gov't, NGO	• Increased open source MedTech Innovations as a result	90% open Innovations high quality products greater reach Industry standard
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Buy in Lobbying • Develop protocols, procedures (Documentation)	• Piloting • Continuous Lobbying	• Impact assessment • Winning a nobel peace prize

PHASES	NEAR TERM	MID TERM	LONG TERM
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Agreements • Creatives platform • Defined roles • Projections	• Market Assessment report • Product • Projections (redefined)	• Optimized service offering • Return on Investments • Make it a policy
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• The whole thing falls apart	• Pilot Fails • Government objections	• No returns on investment
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Secretariat • Funding	• Champions FUNDING	• Nobel peace price • Some self reliance

CROSS BORDER VC			
PHASES	**NEAR TERM**	**MID TERM**	**LONG TERM**
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Developing tools [Pilot]	• Deploy in first Market	Scale
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective.These activities are often broken down into actionable steps and include who is responsible for each task.	• Needs Identification • Validate the needs • Double up concept • Partner to pilot • Learning & Adaptation	• Market segmentation • Build a business Model • Policy/ regulatory requirement • Implementation partners • Entry into first Market • Learning/ Iteration & adaptation	• Scale Blueprint {Go to Market strategy for scale up}

Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Data collection tools • Training tools • TOTs • Reports • Ethical Clearance	• Business Model • Financial Model. • M&E Framework • Regulation and regulatory compliance	• Blueprint/ Strategy • Adaptation tools to local context
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Ethical Clearance • Access to talent/ skills • Access to money • Licence to operate • Political environment	• Access to skills/ talent • Access to money • Political Environment • Policy	• Access to money • Political Environment
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Money • Expert in qualitative and quantitative research • User experience design • Software developers • Context experts	• Sales (Business Developers) • Finance • Hr • IT	• Hr • Translators • Finance • IT

Opportunity Areas

1. Establish knowledge management + knowledge generation mechanisms. Product Visibility
2. Continuous market landscaping and insights
3. Take a community- centred approach to demand generation
4. Leverage tech for data for decision making and market intelligence
5. Designing for the circular economy
6. Catalyse local manufacturing across the Value Chain
7. Innovation in service delivery
8. Pooling of resources.
9. Aggregation of demand
10. M&E
11. Policy contextualization e.g Public Procurement policy reform
12. Innovation technology - telehealth
13. Private - Private cOllaboration

14. Strengthening logistics & distribution channels
15. Understanding the End-User
16. Working with the donor - taking of localization approach
17. Long term impact of the donor marKet
18. Training and capacity development.
19. Cross cutting regulation across borders
20. Unified Information sharing across markets
21. Market entry blueprint for new innovations. Unified specs
22. Unified African body for regulations

Startup Pitching Competition

MariTest
A non-invasive, AI-powered, portable device for accurate, early detection of malaria, minimising waste and adapting to Plasmodium mutations.

Stainsmart Innovations
A low-cost, automated slide stainer in order to reduce misdiagnosis caused by poor slide staining in medical labs.

ThetaMed
Their insulin pump prototype features a micro-controlled syringe infusion mechanism delivering insulin in two formats: bolus doses for meals and glucose corrections and continuous basal doses for between meals.

Che Innovations
Their NeoNest device is a low-cost baby warmer that can be used in transport.

Neosave Technologies
A wearable bracelet that continuously monitors the vital signs of newborn babies.

UP ELEC SARL
A warming table for newborns and premature babies that features a sensor, a digital screen to display the temperature, a safety alarm, and automatic operation for ease of use and enhanced safety.

SaFHAM
A wearable device for people with epilepsy, providing real-time updates and alerts to users and caregivers for seizure management.

GAT & Associate Engineering Ltd.
Their Digital Video Integrated System (DVIS) is the aggregation of different components which enables its users to transmit audio-visual information within an operating theatre to a choice location at real time.

21st Biotech Solutions Limited
A vein-finding device that helps to locate veins that are not visible to the attending doctor's eye.

Kunamandla Health Solutions Pty. Ltd.
A point-of-care test device for simultaneous testing of TB and HIV.

PlusLife Company Ltd.
An easy-to-operate Bubble Continuous Positive Air Pressure (bCPAP) device to help babies with respiratory distress syndrome (RDS).

Ifakara Biotech
A simple and affordable point-of-care testing device for preeclampsia.

LabX Technologies
Offering 3D-printed dental implants that are up to 80% cheaper and have a faster production time.

DAY 2

Theme:

How a robust African medtech industry contributes to the economy

The Economic Case for a Local MedTech Industry

Speaker: *Dr. Stanley Aruyaru, Chief Medical Officer & Secretary General, Surgical Society of Kenya*

Challenges/Concerns:

1. **Frequent Machine Shutdowns:** Medical machines, such as image intensifiers, frequently shut down due to a lack of maintenance, causing disruptions in healthcare delivery.
2. **Costly Spare Parts:** Spare parts for biomedical gadgets are expensive and often need to be shipped, leading to delays in repairs and extended machine downtime.
3. **Skill Gaps:** The biomedical team often lacks the updated skills required to keep up with rapid technological changes in MedTech.
4. **Impact on Hospital Operations:** Breakdowns in medical equipment disrupt hospital services, as these machines are integral to various hospital operations.
5. **Shifting Focus in Healthcare:** As healthcare becomes more mechanised, attention shifts from staff performance to machine performance, with challenges in managing server downtime and technical issues.
6. **Effect on Quality of Care:** When machines fail to provide accurate information, the quality of healthcare delivery is compromised.

Solutions Proposed:

- **Local Assemblies:** Establishing local manufacturing and assembly plants for medical equipment could reduce dependency on imported spare parts, lower costs, and improve machine availability.
- **Absorbing Trainees:** Encouraging local training programs for biomedical teams would ensure that hospitals have skilled professionals able to maintain and repair equipment.
- **Planned Maintenance:** Implementing regular maintenance schedules would help prevent equipment breakdowns and minimise machine downtime.

Additional Notes:

- Machine downtime not only reduces productivity but also frustrates healthcare workers, affecting overall hospital morale.
- Tracking machine performance and reporting downtime can help measure effectiveness and identify areas for improvement.

Session Takeaway:

The need for a local MedTech industry in Africa is critical to reducing costs, improving machine uptime, and ensuring the quality of healthcare delivery. By investing in local manufacturing and training, the sector can overcome key operational challenges and improve healthcare outcomes.

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How the Private Sector Can Contribute to the Innovative MedTech Industry in Africa

Speaker: *Dr. Watu Wamae (Africa Oxford Initiative)*

Key Discussion Points:

1. **People as a Resource:** The primary asset for developing the MedTech industry in Africa is its people, particularly those with a robust understanding of science. However, universities often produce graduates with only basic technical skills, which are insufficient for fostering a truly innovative MedTech sector.

2. **Current MedTech Landscape:**
   - **Non-Existent Industry:** There is no established innovative MedTech industry in Africa. The speaker questioned whether the current environment even qualifies as a "MedTech industry" given the lack of structured manufacturing and innovation capabilities.
   - **Manufacturing Needs:** To build an industry, there is a need to start with low-level manufacturing and progressively move upstream by developing deliberate plans and technical capabilities within companies.

3. **Role of Private Sector:**
   - The private sector is critical to developing the MedTech industry but often lacks structured support. Innovators need access to specialised technical skills and complementary expertise to develop innovative solutions.
   - The sector requires a strategy to ensure these skills are accessible and to provide structured support for companies developing MedTech solutions.

4. **Role of Government in Regulation:**
   - There is a need for the government to play an active role in establishing regulations that encourage industry growth, innovation, and private sector involvement.
   - A shift in thinking around regulations and a coherent, wider policy are essential to create a favourable environment for MedTech development.

5 Funding Environment:

- The North American model for funding MedTech innovations does not necessarily suit the African context. There is a need to develop funding models tailored to African challenges and opportunities.
- Dr. Watu emphasised the importance of creating funding models that incentivize and shape the growth of the MedTech sector in Africa.

The development of a MedTech industry in Africa requires a multi-faceted approach, including skill development, low-level manufacturing, regulatory reform, and a shift in funding models. It is time for a strategic and deliberate effort to create a structured MedTech ecosystem in Africa, driven by private sector innovation and coherent government policies.

Regulatory Landscape for MedTech in Africa

Moderator: Susan Chia-Lin (PATH)

Panellists: Daniel Atwine (SC Research Foundation), Dr. Esther Anyango (PATH), Dr. Ken Iloka (Kenyatta University)

Key Discussion Points:

1. **Lack of Regulatory Harmonisation:**
   - Africa's fragmented regulatory landscape complicates market access. Each country has different requirements, making it difficult for manufacturers to navigate multiple markets efficiently.
   - Dr. Esther Anyango highlighted how fragmentation delays product access, impacting safety, quality, and affordability of medical devices.
2. **Limited Regulatory Capacity:**
   - Many countries lack the necessary resources, expertise, and infrastructure to regulate medical devices effectively, leading to delays in product approvals and market entry.
3. **Political Influence:**
   - Political cycles and elections can disrupt the regulatory environment, creating delays and uncertainties in regulatory processes.

Proposed Solutions:

1. **African Medicines Agency (AMA):**
   - AMA is a critical initiative to harmonise regulatory practices across Africa. It aims to streamline regulations across regional economic communities rather than individual countries, improving access to essential medical products and responding to health emergencies (e.g., Mpox, COVID-19).
   - Dr. Anyango emphasised AMA's role in supporting national regulatory authorities and providing guidance on complex medical products. Currently, 28 countries have ratified AMA.

2. **Regulatory Reliance and Convergence:**
   - Encouraging collaboration and information-sharing among countries will shorten regulatory processes and facilitate market entry for innovators.
3. **Supporting Policies and Incentives:**
   - Governments should implement policies that streamline compliance systems, foster innovation, and support the growth of the diagnostics industry. Both public and private sectors need to incentivize regulatory improvements.
4. **Academic Collaboration:**
   - Daniel Atwine stressed the importance of academic institutions collaborating on research, which would accelerate innovation and regulatory approvals.

Key Decisions:

- Harmonising Regulatory Practices: The panellists agreed on prioritising AMA's operationalization to harmonise regulations across Africa, ensuring timely access to safe medical products.
- Partnerships between government, academia, and the private sector were identified as crucial to achieving these goals.

Lessons Learned:

- **Misinformation About AMA:** Some countries have not ratified AMA due to misconceptions about its role. It was clarified that AMA does not replace national regulatory bodies but supports them in complex product approvals.
- **AMA's Benefits:** Timely product approval, improved access to safe medical products, and more efficient regulatory processes were highlighted as benefits of AMA.

Action Points & Next Steps:

- Innovators from countries that haven't ratified AMA were encouraged to advocate for its ratification to participate in the regulatory decision-making process.
- Stakeholders should continue working toward regulatory harmonisation to improve access and innovation in Africa's MedTech industry.

The panel underscored the importance of regulatory harmonisation in Africa's MedTech sector to enhance product safety, quality, and access. Collaborative efforts between governments, private sectors, and academia are essential to overcoming regulatory barriers and building capacity. The session emphasised AMA's role as a unifying force for improving regulation across the continent.

Breakout Sessions

Innovation & Investment Track (Part 1)

End-to-End Product Development Strategy

Moderator: *Wilfred Njagi (Co-founder and CEO, Villgro Africa)*

Panellists: *Williams Baah (Rice University), Dr. Kamau Gachigi (Gearbox), Kara Palamountain (Northwestern University), Karlheinz Samenjo (Delft University)*

Key Challenges:

1. **Sustainability of MedTech Programs:**
   - Most rely heavily on grants, which threaten long-term viability if funding stops.
   - **Example:** Gearbox used a grant for rent, but Dr. Kamau suggested an alternative where funders invest directly, gaining shared benefit.
2. **Government Procurement:**
   - Governments, the largest buyers of medical equipment, often don't purchase locally made devices, limiting revenues for African innovators.
3. **Regulatory Barriers:**
   - Poor communication from regulatory bodies hinders progress in product approvals.

Proposed Solutions:

Dr. Kamau Gachigi:

- **Frugal Innovation:** Focus on building practical solutions for local use, prioritising basic functions to reduce production costs.
- **Rapid Prototyping Equipment:** CNC machines, 3D printers, and other tools are available to support local manufacturing.
- **Strategic Partnerships:** Gearbox is collaborating with UNDP and launching Unipods to enhance prototyping capabilities across Africa.
- Innovators need to understand regulatory requirements early and align their designs with manufacturing capabilities and market needs.

Williams Baah:

- Emphasised quantity over quality during ideation to generate more viable solutions.
- Start small during prototyping (e.g., using cardboard models) to iterate cheaply before scaling.
- Innovators must create market awareness to build local trust in African-made solutions.

Kara Palamountain:

- Prioritising collaboration with students and professors can drive affordable innovation.
- Encouraged removing silos in the ecosystem to enhance collaboration across disciplines (innovators, doctors, businesspeople).

Karlheinz Samenjo:

- Governments should be incentivized to buy local products and collaborate with innovators to drive demand for local solutions.

Key Decisions:

- The panellists agreed on the need to embrace frugal innovation and focus on local production to reduce costs.
- There is a clear need for collaborative innovation between academia, industry, and government to overcome resource limitations.

Lessons Learned:

- Innovators need to design solutions tailored to the local market, avoiding unnecessary features.
- African talent is abundant, but a shift in mindset is needed to retain and develop this talent locally.
- Regulatory considerations must be integrated early in the product development process to avoid costly rework.

Action Points & Next Steps:

- Michelle (CEO of Kunamandla) aims to collaborate with Gearbox for low-cost manufacturing.
- Investors should explore new funding models that are not reliant on external funding to better support African MedTech startups.

Main Takeaways:

- Frugal innovation and focusing on the essentials in product development are crucial for cost-effective local solutions.
- Greater collaboration between different stakeholders (government, academia, industry) is essential to foster innovation and market success.
- There is a need for African governments to prioritise local procurement of MedTech solutions to create a sustainable ecosystem.
- An open-source platform connecting stakeholders in the MedTech space could facilitate collaboration across the production process.

Innovation & Investment (Part 2)

Practical Strategies for Medtech Startups Masterclass

Moderator: *Winnie Kibiru (Villgro Africa)*

Panellists: *Eric M. J. Gona (CKN Advocates LLP), Hellen Gitonga (Philips Health Systems)*

Key Challenges:

1. **Regulatory Complexity (Hellen Gitonga):**
   - Regulatory bodies often comprise pharmacists, medical practitioners, and clinicians, leading to sector-specific challenges.
   - Requirements for clinical trials and approvals vary across countries, such as needing a pharmacist in Cameroon for trials.
2. **Lack of Intellectual Property (IP) Awareness (Eric M. J. Gona):**
   - Innovators often lack a clear strategy for IP registration, which is territorial and can be expensive. Many avoid registering due to the cost and complexity.

Proposed Solutions:

1. **Regulatory Navigation (Hellen Gitonga):**
   - Startups should read the guidelines thoroughly and negotiate with regulators to navigate the system.
   - Forming an association of startups can help lobby for more favourable regulatory conditions.
2. **IP Strategy (Eric M. J. Gona's Session):**
   - Innovators should focus on registering IP in key markets to reduce unnecessary costs and annuities.
   - Utility Models: A more accessible alternative to patents, especially for frugal innovations.
   - Innovators can leverage trade secrets and licences, which offer protection without the need for patents.

Lessons Learned:

1. **Regulatory Harmonization is Possible:**
   - Examples like Tanzania show that proactive engagement with regulators can lead to a more supportive environment for innovation.
   - In some cases, like Uganda, certain regulatory requirements (e.g., clean rooms) were unnecessary, highlighting the need for localised understanding of regulations.

2. **Leveraging IP Flexibility:**
   - Not all innovations require patents; frugal innovations can rely on alternative protections such as trade secrets or utility models.
   - Evergreening, improving on an original patent, can extend the patent period beyond 20 years.

Action Points & Next Steps:

- IP Audits and Strategy
  - Innovators should conduct IP audits to streamline and optimise their IP portfolios.
  - Awareness campaigns are needed to educate startups on IP registration and protection strategies.

- Follow-Up on Regulatory Discussions
  - Continued lobbying for regulatory reform, including fast-tracking processes and harmonising standards across African countries.

Main Takeaways:

- IP Flexibility: Not all innovations require patents; utility models and trade secrets offer viable alternatives for protecting intellectual property.
- Regulatory Advocacy: Forming associations and working with government agencies can help startups navigate complex regulatory landscapes.
- Frugal Innovation: Entrepreneurs should assess whether IP protection is necessary, especially in cases of cost-effective innovations.

Market Shaping Track (Part 1)

A Focus on Tanzania

Panellists: *Praygod Japhet (Tanzania Startup Association), Amina Nyuri (Ifakara Biotech)*

Key Challenges:

1. **Lack of Public Sector Understanding of Tech Startups:**
   - Limited knowledge within government on tech startup dynamics, particularly in MedTech and HealthTech.
2. **Regulatory Barriers:**
   - Regulators tend to adopt a policing role rather than collaborating with innovators.
   - Slow regulatory processes hamper innovation and market entry.
3. **Financing Gap:**
   - Foreign Direct Investment (FDI) is decreasing, while Domestic Direct Investment (DDI) is on the rise, but local funding for startups is still insufficient.
4. **Poor Infrastructure:**
   - Inadequate infrastructure along the innovation value chain limits scalability and implementation of MedTech solutions.

Proposed Solutions:

- **Regulatory Sandboxes:**
  - Tanzania is co-creating regulatory sandboxes to support innovators from ideation to market access.
  - TMDA: Sandbox for medical device innovations.
  - TIRA: Insurance regulatory sandbox.

- **Policy and Collaboration with Government:**
  - The government is working on a Digital Economy Framework (2024 launch) with key performance indicators specific to sectors like MedTech.
  - A Startup Act has been in development for four years, focusing on creating a more supportive ecosystem.

- **Financing Initiatives:**
  - Domestic investors are becoming more involved, with local institutional investors aiming to fill early to mid-stage funding gaps.
  - Ticket sizes for local investments have grown from $20k to over $250k. A local Fund of Funds (FoF) is being established to increase investment in the startup ecosystem.

- **Regulatory Mindset Shift:**
  - Advocated for regulators to move from a "policing" mindset to becoming collaborators and partners in innovation.
  - Ecosystem players should focus on sensitising regulatory bodies about the benefits of collaborating with startups.

Q&A Insights:

1. **How to Engage with Government:**
   - Focus on targeting strategic-level staff within government agencies who have decision-making power, rather than technical-level staff who primarily enforce policies without influence.

2. **Key Government Agencies for MedTech Innovators in TZ:**
   - **COSTECH:** For letters of recommendation for innovations.
   - **TMDA:** To access the regulatory sandbox for pitching ideas.
   - **COPTECH:** For research institutes and clinical trials.
   - **TZ Bureau of Standards:** For certification and market entry approval.

3. **Investment Models in TZ:**
   - Blended financing (equity, debt, etc.) is ideal, with mutual funds pooling resources from public and private investors.

Next Steps & Learnings:

- **Mindset Shift:**
  - Regulatory authorities need to move from being gatekeepers to collaborators, fostering an environment where innovation can thrive.
- **Public-Private Partnerships (PPP):**
  - Co-creating regulatory sandboxes across various sectors to support innovation and streamline market entry.
- **Key Government Partnerships:**
  - Innovators should identify and collaborate with key government officials who are open to risk-taking and supporting innovation.
- **Fast-Tracking Regulations:**
  - Establish fast-track mechanisms for MedTech devices by waiving unnecessary regulatory barriers to expedite the approval and importation process.
- **Infrastructure Development:**
  - Innovators and the government should work together to promote infrastructure improvements in both public and private institutions (e.g., hospitals).

Main Takeaways:

This session highlighted the importance of regulatory reform, local investment, and infrastructure development in fostering MedTech innovation in Tanzania. Collaboration between government, private sector, and innovators is essential for overcoming current barriers.

Market Shaping Track (Part 2)

Best Practices in Regulation for Medical Devices

Keynote Speaker: *Eng. Maryanne Muriuki (Kenyatta University)*

Key Challenges:

The ideal pathway to medtech regulation in Africa involves two key steps: regulatory approval and quality compliance. The regulatory landscape can be understood through case studies from different regions, such as the U.S. and Europe, offering insights into the processes for obtaining market approval for medical devices.

Case Study 1: U.S. Regulation (FDA)
In the U.S., FDA regulatory processes are mandatory for products targeting more than 4,000 people. However, exemptions exist for humanitarian devices and life-or-death situations if the product targets fewer than 4,000 individuals. A significant part of the regulatory process is compliance with 21CFR Part 820, which indicates that a device has achieved quality compliance.

Risk Classification:
- **Class I:** Low risk
- **Class II:** Moderate risk
- **Class III:** High risk (clinical risk not well known)

Devices are further classified by their interaction with the body, including implantable invasive devices, transient devices (less than 30 minutes), and long-term devices (more than 30 days). This classification impacts the regulatory pathway, including the need for clinical trials.

Device Approval by Class:
- **Class I Devices:** No clinical trials needed due to existing data on similar devices.
- **Class II Devices:** Pre-market notification (510k) required, with historical data or competitor case studies to demonstrate safety. If approved, no clinical trials are necessary.
  - **Examples:** Prosthetics, knee replacements.

- **Class III Devices:** Pre-market notification required, and clinical trials may be necessary if insufficient historical data is available. The R&D stage can take 12 years and cost $2-5 billion.
    - Examples: Pacemakers, family planning devices.

Case Study 2: European Regulation (CE Mark)
The CE Mark process, common in Europe, Asia, and Africa, is less stringent compared to the FDA. It ensures conformity and quality compliance, with ISO 13485 as the primary indicator of quality compliance. A certified auditor is required to mediate between the company and the regulatory authority, and the regulatory framework is harmonised across the European Union.

Device Classification:
- **MDR:** Medical Devices
- **IVDR:** In Vitro Devices

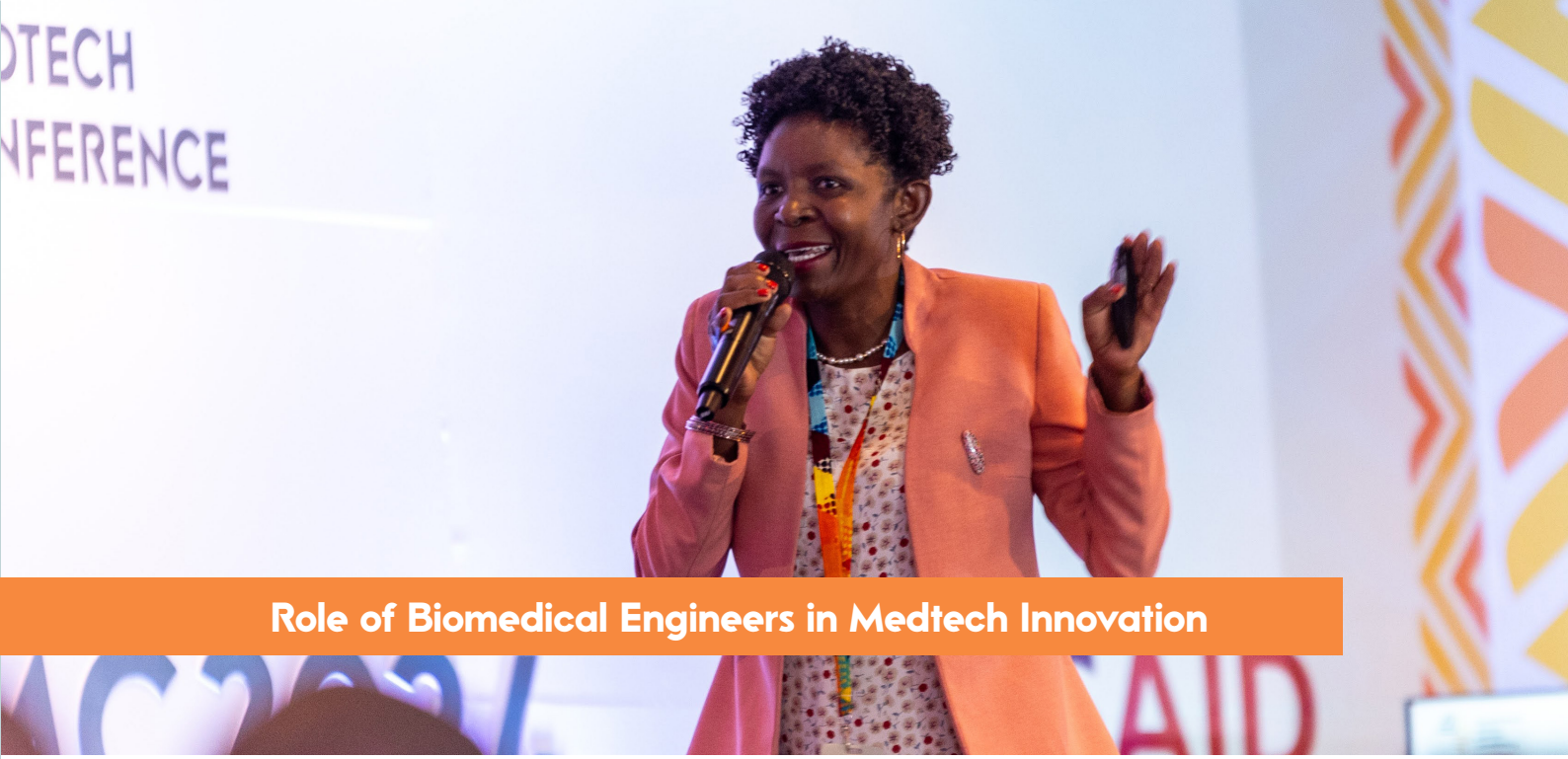
Devices are categorised into Class I, II (A), III (B), and Class III, covering sterile devices to active implantable devices.

Group Activity

During the session, participants were divided into groups and tasked with classifying a hypothetical device according to risk level and aligning it with the ideal regulatory pathway in their respective countries, with Kenya as the primary market. Photos of the group's thought processes are attached for further reference.

DAY 3

Strategy & Action Planning Day



Role of Biomedical Engineers in Medtech Innovation

Speaker: *Eng. Millicent Alooh - Biomedical Engineer, NEST360*

Key Points:

1. **Importance of Biomedical Engineers in Innovation:**
   - Biomedical engineers play a critical role in the service, maintenance, and calibration of medical devices throughout their lifecycle. They ensure equipment is safe for both users and patients and handle health technology management (HTM), which includes planning, purchase, operation, and decommissioning.

2. **Lifecycle Management:**
   - Innovators must collaborate closely with biomedical engineers to ensure that devices can be maintained effectively over their lifespan. They should clearly describe their innovations to aid in seamless maintenance and consider end-of-life disposal to avoid excessive repairs.

Challenges:

1. **Skills and Knowledge Gaps:**
   - Continuous training is needed for biomedical engineers to keep up with advancing technology. Open access to equipment manuals is essential for effective service.

2. **Interdisciplinary Collaboration:**
   - Communication gaps between biomedical engineers, innovators, and clinical staff hinder smooth collaboration. Early involvement of biomedical engineers in device design is crucial.

3. **Equipment Maintenance:**
   - Budget constraints limit the ability to perform preventative maintenance and repairs. There are also delays in acquiring spare parts and challenges in maintaining ageing equipment.

4. **Regulatory and Compliance Issues:**
   - There is a weak regulatory framework for both pre-service and in-service HTM training and operations.

Opportunities:

1. **Capacity Building & Awareness:**
   - Hospital-based biomedical engineers need capacity building to improve patient safety and reduce equipment downtime.
2. **Collaboration & Partnerships:**
   - Partnerships between innovators and biomedical engineers, especially in the early stages of design and testing, can enhance device effectiveness and safety. Collaborations with professional associations are also crucial.
3. **Advocacy:**
   - Promoting best practices, setting standards, and investing in co-innovation projects with hospital-based biomedical engineers can improve equipment management and innovation outcomes.

Call to Action:

- **Bridging the Gap:**
  - There is a need to close the gap between local innovators and hospital-based biomedical engineers to ensure effective equipment management and innovation.
  - Reducing medical "junkyards" in hospitals is essential through proper equipment lifecycle management.

Key Takeaway:

Collaboration between innovators and biomedical engineers is crucial for ensuring medical devices are not only innovative but also maintainable, safe, and sustainable throughout their lifecycle.

Workshops

Product Development Group

Group 1

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• To make the necessary information readily available to the entrepreneur. - Collect data on current hurdles regarding taxabon to build a case. - Proper HR Training	• Less Bureaucracy when dealing with government institutions. • Reducing time for procurement of spare parts. • Change policy on import tariffs on components for medical devices using innovators association.	• Optimising policy guidelines based on lessons learned over time. • Expanding to regional blocks

PHASES	NEAR TERM	MID TERM	LONG TERM
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective.These activities are often broken down into actionable steps and include who is responsible for each task.	• Clear, complete and easily accessible guidelines on requirements needed by regulatory bodies. This is on digital platforms. • Regulator contacts • Reduced Tax/ Tax Incentives. • Reduced fee for regulatory approval. • National Regulatory Authority should train their staff on approval of regulatory requirements.	• AI powered platform for FAQs. • Government-Innovator collaboration to create a local market for products. Digitization of the procurement process. • Develop a case study demonstrating how imported components affect local manufacturing companies	• Complete harmonisation of requirements set by regulatory bodies.
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Digitised platform with regulatory information.	• Digitised platform with regulatory information. • Having competent regulatory officers. • Accredited/ Approved MOUs between Government and Innovators	• Actualizing acquired skills. • An automated system for the procurement process. • Signed MOUs between the Government and innovators
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.			• System Downtime. • Cyber attacks. • - Non - Compliance between parties in MOUs.
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Finances. • Trained experts • Trained data collectors. • Cooperation and collaboration between regulators.	• Investments in digital systems. • Trained Data analysts.	• Continued cash flow. • Trained experts. • Data visualisation tools.

Group 2

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Formation/ Establishment of Medtech community	• Establish Association	• Sustainability and Key Driver for MedTech Industry
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Formation of government body • Benchmarking in existing networks/ Association / landscaping efforts. • Planning sessions/ Meetings (Online). • Identifying stakeholders.	• MedTech expos. • Registration. • Structuring association • Fundraising. • Building repository.	• Manufacturing companies Established. • Advocating for MedTech Innovation in Investment and regulatory. • Supporting Startups.
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Governing body • Stakeholder engagement. • MedTech Community	• Visibility for MedTech. • Structured Association. • Funds for MedTech products and Association. • Association.	• MedTech companies. • Policy Briefs/ Reports
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Language barrier. - Conflicts. - Political barriers. • Untimely response/ Slow response	• Bureaucracy • Continental fragmentation. • Resources needed. • Demotivation. • Politics.	• Conflicts and Disagreements
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Money. • HR • Experts/ Champions	• Money. • Platforms. • Government's suppor	• Money

Group 3

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Playbook for MedTech Innovation. • Founder Wellness program. • Building Networks and Mentorship	• Less Bureaucracy when dealing with government institutions. • Reducing time for procurement of spare parts. • Change policy on import tariffs on components for medical devices using innovators association.	• Optimising policy guidelines based on lessons learned over time. • Expanding to regional blocks
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Curriculum. • Team Forming. • Finding founders. • Forming online support group. • Sharing founders story. • Find mentors, mentees and areas in need of mentoring. • Anonymous surveys.	• Map out amounts entrepreneurs need. • Identify donors and investors who can invest 10k per idea. • Picking priority areas for an exchange program. • Augmented reality development for a Virtual knowledge exchange program. • Shark Tanks	• Operationalize ; Website, Location, Coursework, Leadership. • Having Pre-fellows enter next phase. • Measure Impact, Funding and outcomes of systems.
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Anonymous surveys • Whatsapp Group. • Draft for playbook. • Document for M-Combination Vision. • Putting together a Network.	• 2 exchange programs. • Partnerships. • Documented founders journey. • Database • Complete playbook and Curriculum testing.	• Exchange of lecturers. • Impact portfolio. - Number of patents filed and followup, funding, commercialization.
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Team Commitment. • Geographical Distance. • Lack of Resources and Incentives.	• Financing exchange, Visa. • Returning those sent out.	• Lack of commitment (Innovators and Team)

PHASES	NEAR TERM	MID TERM	LONG TERM
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Money. • Mentorship. • Domain Experts	• Money (50k- Fast Fund, 10K Student Exchange)	• Funding. • Team. • Time. • Commitment

Formation of Regulations in MedTech

Group 1

FORMATION OF A NATIONAL MEDTECH ASSOCIATION			
PHASES	**NEAR TERM**	**MID TERM**	**LONG TERM**
Timeframe: Indicate how long each phase will take to complete.	1 Year	3 Years	8 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• To mobilise and build support for the association • To create a platform for advocacy.	• To become a registered established association. • To build capacity. • To realise our objectives.	• To create a supportive regulation framework for a robust Medtech Industry.
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective.These activities are often broken down into actionable steps and include who is responsible for each task.	• Create a team/ Committee • Do a Needs assessment • Meeting Cadence • Define GOAL. • Physical address • Agree on Names	• Hold first Meeting. - Draft Constitution. • Prepare for application • Make an application • Lobbying	• Grow the Membership • Advocacy Begins *Create awareness *Flagship Activities • Identify Partners
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Needs assessment report. • Interim Directors	• Minutes of meeting. • Constitution. • Application	• Registration in Place. • Membership Growth. • Strategies plan. • Regulatory Changes

PHASES	NEAR TERM	MID TERM	LONG TERM
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Conflict with excisting sister associations. • Lack of Champions. - Bureaucracy in group	• Lack of funds. • Application Rejected	• Failure to grow Membership
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Technical Expertise - Funds. • Infrastructure • Time	• Time • Funds	• Understand Regulations. • Time. • Funds. • Infrastructure

Group 2

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	1-2 Years	1-2 Years	5+ Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Identify the Problem	• Building Advocacy Networks	• Mainstreaming and Maintaining our voice
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Stakeholder Mapping • Process Mapping	• Identify the champion. • Identify the champion needs • Identify what we want the champion to achieve.	• Policies and Innovations. • Registering a peak body of innovators.
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Accurate understanding of the problems and gaps	• Committed champions with clear understanding of needs and goals	• Policies and regulations. • A blueprint for continental replication.

PHASES	NEAR TERM	MID TERM	LONG TERM
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Biases towards the urban setting and underrepresentation. • Antagonising regulatory bodies. • Time taken may cause political implications.	• Turnover. • Outcasting of our champions.	• Turnover. • Underrepresentation of other countries' needs.
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• People (Human Resource) • Finances	• Human Resource • Finances	• Human Resource • Finances

Group 3

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	6-12 Months	1-5 Years	5+ Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Formulate a task force	• Understand Government laws with respect to MedTech regulation. • Create networks to enable Biomedical Engineers to achieve their objectives.	• Create a regulatory friendly environment for MedTech Innovators.
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective.These activities are often broken down into actionable steps and include who is responsible for each task.	• Identify the respective government and regulatory bodies and contact persons. • Documentation reviews. • Policy reviews.	• Focus group discussions. • Formulate MedTech recommendations and regulations. • Identify key stakeholders to support implementation.	• Advocate for implementation
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• A list of MedTech regulatory bodies and contact person. • A reviewed documentation report. - Policy review report.	• Qualitative data on regulatory gaps and recommendations in MedTech. • Analysed data and reports (Analysis report on gaps and recommendations) • List of stakeholders to support implementation.	• New MedTech Policies Implemented.

PHASES	NEAR TERM	MID TERM	LONG TERM
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Limited availability of required experts • Limited availability of existing documentation	• Bureaucratic processes • Limited Willingness to disclose relevant information	• Lack of cooperation from the relevant regulatory bodies. • Unpredictable Timeframes (Taking longer than 5 years)
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Human Resource - Financial resources • Networks • Time	• Human Resource • Financial resources • Networks • Time	• Human Resource and Networks • Media (Print, Digital)

Sand Boxes

Group 1

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Create awareness of how to use digital platforms • Create platforms with detailed information of innovations to increase awareness. • Use existing platforms (Free media like social media) and credible media (LinkedIn, Known Website) • Networking skills and Professionalism	• Branding • Increase number of innovators and stakeholders(Investors, Government, Policy people) to be invested *Create platform for that. • Product/Service advocate • Making it Digitally available.	• Increase demand and influence policy decisions. • Database for Innovations. • Data for Regulation (Push) • CPD Training and Academics.
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Look into target audience. • Creative storytelling. • Conferences and exhibitions.	• Marketing of the platform. • Product marketing. • Follow-up marketing. • Involve Influencers. • Follow-up Marketing.	• Data for collection of revenue • CPD Training programs and skill building

PHASES	NEAR TERM	MID TERM	LONG TERM
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Mentorship programs • Every startup must have a website and socials as well as SEO done. • Maintaining online presence on social media.	• Build them websites, association and credibility. • Newsletter/ booklets for creating awareness of ecosystem on socials.	• Partnerships. • Policy recommendation. • Revenue from database for decisions. • Scaling
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• CyberSecurity. • Scammers. • IP Infringement • Bad publicity and engagement. underrepresentation. • Antagonising regulatory bodies. • Time taken may cause political implications.	• IP • Regulatory Consensus	• Data privacy • Improvement in compliance. • Funding Constriction. • IP • Underrepresentation of other countries' needs.
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Money to pay for verification • - Human Resource ie Developers. • - Search Engine Optimization payments. • - Technical support for documents	• Human Resource • Finances	• Human Resource • Finances

Group 2

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	1 Year	2 Years	5 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Be accepted to the Sandbox social media visibility.	• Collect real life data, analyse it then report it. - Have some investors reach out.	• Social Media Marketing. • Investment. • Validated data.

PHASES	NEAR TERM	MID TERM	LONG TERM
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective.These activities are often broken down into actionable steps and include who is responsible for each task.	• Documentation. • Social Media Hype.	• Expert feedback. • Tentative reports. • Social Media Hype.	• Final analysis of data. • Media Presence. • Proposals
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Certificate of clearance. • Social Media Presence	• Timeline reports. • Brand reports. • Data collected.	• Present data analysis reports. • Get investors. • Publish scientific papers (Peer reviews)
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Not gaining enough visibility. • Not being accepted.	• Data does not fir in the design criteria. • Harmful to patients. • Sabotage the brand	• No Investors. • Competitive products. • Low demand for products
Resources needed: These are the financial or human resources needed to successfully carry out this phase.	• Biostarticians • Laboratories for testing. • Media experts. • Research assistants	• Data analysts • Media experts. • Test Laboratories. • Clinical experts.	• Risk analysts. • Field experts. • Media Experts. • Data analysts

Group 3

PHASES	NEAR TERM	MID TERM	LONG TERM
Timeframe: Indicate how long each phase will take to complete.	1 Year	5 Years	10 Years
Objective: This is a clear and concise statement of the specific goal or outcome that each phase of the roadmap aims to achieve. It sets the direction for the activities and ensures that all efforts are aligned with the overall strategy.	• Innovative mapping. • Gap identification within market. • Crowd sourcing/ Alumni	• Capacity building/ Sandboxes. • Product awareness/ promotion. • Application for funding. • Product review. • Strategic plan/ review. • Regulatory.	• Product regulatory. • Scaleup.

PHASES	NEAR TERM	MID TERM	LONG TERM
Key Activities: Are the specific tasks or actions that need to be carried out to achieve the objective. These activities are often broken down into actionable steps and include who is responsible for each task.	• Strategic development. • University mapping. • Resource mapping • Policy mapping. • Identify Industry expert	• Toolkit. • Monitoring and evaluation. • Digital Marketing and setting up conference. • Unity funding model. • Engaging in Partnerships.	• Monitoring and evaluation. • Join Programmes
Deliverables: Are the tangible outputs or results that are expected from completing the key activities. These can be reports, frameworks,plans, or any other concrete outcomes that serve as milestones to measure progress.	• Mapping reports. • Strategic plans. • M&E Frameworks.	• Toolkit • M&E Report. • Strategic documents. • Consolidated list of funders.	• Toolkit Implementation. • Product entry/ Scaling up. *Unified funds model • Review report • Joint work plans
Potential risks: That could impact the success of the roadmap and developing strategies to mitigate these risks. This component helps ensure that challenges are anticipated and addressed proactively.	• Human Resources • Personnel • Skills	• Sustainable partnership • Credible suppliers. • Government	• Finance. • Technical experts. • Unified funding model

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