CHAPTER 2

ESTABLISHING ECO-SYSTEMS IN SUPPORT OF MEDICAL DEVICES INDUSTRIALISATION

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ABSTRACT

Africa is set to become the most populous continent in the decades to come. In contrast to this – and with minor exceptions – only a small fraction of the Medical Devices deployed here are sourced from Africa. This anomaly is not sustainable in the medium term and begs several questions:

i. *How does one create an eco-system that is conducive to localisation in South Africa and other African countries?*
ii. *What are the specific challenges that often lead to the non-conversion of ideas to viable products – and how can wasteful industrialisation be avoided?*
iii. *Looking into the future, what is the nature of Systems Thinking solutions required to support optimal collaborative industrialisation in a 4th Industrial Revolution (4IR) environment?*

The purpose of this write-up is to offer a high-level glimpse into these three issues with a view to defining the requirements for sustainable and future-orientated Medical Devices industrialisation in Africa.

ESTABLISHMENT OF MEDICAL DEVICES ECO-SYSTEMS FOR EFFECTIVE INDUSTRIALISATION

How does a country in Africa establish an eco-system, which supports the establishment of a vibrant and sustainable Medical Devices industry? Building on Michael Porter's "Porter Diamond" (Porter, 1998), competitive advantage can be derived and improved by the optimal alignment of various aspects related to value creation, such as technology industry, skilled labour, and government support for a country's economy.

2.1 Establishment of an overarching Industrialisation Eco-system Framework

Applying competitiveness enablement principles at a very practical level means dealing with two dimensions:

i. Definition and establishment of a Medical Devices Value Chain, to outline the respective stages that play a critical role in end-to-end and successful product industrialisation and deployment; and

ii. Focus areas for the effective enablement of the respective stages in the Value Chain.

The proposed solution model sees the application of three primary industrialisation enablement focus areas overlayed with eight customized Medical Devices Value Chain stages:

i. Policy, intelligence, regulations and investment planning / funding;
ii. Market demand / orders, tariffs, designation and partnering;
iii. Ideation, Research and Product Development;
iv. Prototyping, base product testing, 1st level regulatory solution and venture funding;
v. Regulatory compliance preparations incl. manufacturing site certification;
vi. Sourcing, sub-assemblies, final assembly and regulatory compliance;
vii. Distribution / market segment penetration: Local and international; and Business Development, sales, device deployment and post-sales.

In combination, this leads to the so-called "Medical Devices Industrialisation Eco-system establishment Matrix", Figure 1, where the shaded areas indicate which industrialisation enablement area applies to which stage in the Medical Devices Value Chain:

Medical Devices Industrialization Eco-system establishment Matrix			Value Chain stages							
			a	b	c	d	e	f	g	h
			Policy, intelligence, regulations and investment planning / funding	Market demand / orders, tariffs, designation and partnering	Ideation, Research and Product Development	Prototyping, base product testing, 1st level regulatory solution and venture funding	Regulatory compliance preparations incl. manufacturing site certification	Sourcing, sub-assemblies, final assembly and regulatory compliance	Distribution / market segment penetration: Local and international	Business Development, sales, device deployment and Post-sales
Eco-system enablement focus areas	1	Policy, legislative, local socio-economic imperatives, procurement et al								
	2	Research & Development, product industrialization, regulatory compliance and industrialization skills								
	3	Sourcing, manufacturing, in-country operational challenges and satisfaction of market needs								

Figure 1: Medical Devices Industrialisation Eco-system establishment Matrix

2.2 Enablement focus area: Research & Development, Skills Development, industrialisation, regulatory compliance and similar

The next level of industrialisation eco-system development relates to the detailing of the three focus areas as outlined in section 2.1. For obvious reasons, the

focus area to be detailed relates to “Research & Development, product industrialisation, regulatory compliance and industrialisation skills”. The following enablers are believed to be critical for enablement:

i. Use of academia and publicly funded institutions as extended R&D workbench of industry;
ii. Use of public funded IP development and alignment with industry;
iii. Testing and prototyping facilities incl. Technology stations;
iv. Regulatory measures - Local and export focused ("Extensive" such as FDA and CE Mark) and Local-only ("Lite" such as SAHPRA as regional body);
v. Securing and channeling various sources of funding and investments in capacity building and eco-system enablement;
vi. Use of public and private sector resources (funding, support, facilities etc.) for optimal eco-system enablement;
vii. Inspection authorities- and enablement support;
viii. Support programs to curb illegal or illicit activities;
ix. Critical number of ISO 13485 companies and optimal use of multi-national registration for activities in-country and overseas; and
x. Skills Development and on-going industrialisation training.

When the critical enablers of this focus area are aligned with a Value Chain perspective, this leads to the so-called “Medical Devices focus area 2 Enablement Matrix”, Figure 2, where the shaded areas indicate which industrialisation enabler applies to which stage in the Medical Devices Value Chain:

Medical Devices focus area 2 Enablement matrix: Research & Development, Skills Development, industrialization, regulatory compliance and similar			Value Chain stages							
			a	b	c	d	e	f	g	g
			Policy, intelligence, regulations and investment planning / funding	Market demand / orders, tariffs, designation and partnering	Ideation, Research and Product Development	Prototyping, base product testing, 1st level regulatory solution and venture funding	Regulatory compliance preparations incl. manufacturing	Sourcing, sub-assemblies, final assembly and regulatory compliance	Distribution / market segments: Local and international	Business Development, sales, device deployment and Post-sales
Critical enablers	1	Use of academia and publically funded institutions as extended R&D work-bench of industry								
	2	Use of public funded IP development and alignment with industry								
	3	Testing and prototyping facilities incl. Technology stations								
	4	Regulatory measures - Local and export focused ("Extensive") and Local-only ("Lite")								
	5	Securing and channelling various sources of funding and investments in capacity building and eco-system enablement								
	6	Use of public and private sector resources (funding, support, facilities etc.) for optimal eco-system enablement								
	7	Inspection authorities- and enablement support								
	8	Support programs to curb illegal or illicit activities								
	9	Critical number of ISO 13485 companies and optimal use of multi-national registration for activities in-country and overseas								
	10	Skills Development and on-going industrialization training								

Figure 2: Medical Devices focus area 2 Enablement Matrix

The establishment of a localisation-friendly Medical Devices eco-system is not a haphazard and laissez-faire occurrence, but instead requires multi-party buy-in, value chain thinking and the alignment of various measures for success.

INDUSTRIALISATION CHALLENGES RELATED TO THE "VALLEY OF DEATH"

One could be tempted to assume that industrialisation is largely a technocratic and mechanistic process, where an optimal "sausage machine" assures a constantly pipeline of successful Medical Devices. This is not the case! Instead, a variety of factors are at work and involving people – with their inherent strengths and weaknesses. Outcomes are much more difficult to predict, than one would imagine. Also, not all stages of the value chain are equally prone to failure with certain specific hand-over stages being particularly susceptible to ineffectiveness and problems. Welcome to the phenomenon called the "Valley of Death".

3.1 The "Valley of Death" phenomenon plaguing Product Development

There is an extensive body of knowledge dealing with the so-called "Valley of Death", as the gap between invention and (implemented) innovation or the challenge of accelerating an innovation after proof of concept has been given.

The Valley of Death, as described in Markham, Ward, Aiman-Smith, & Kingon (2010) is defined as the space between opportunity discovery and product development as shown in Figure 3. It occurs between the Product life-cycle stages of pre-New Product Development (pre-NPD) and completed Development:

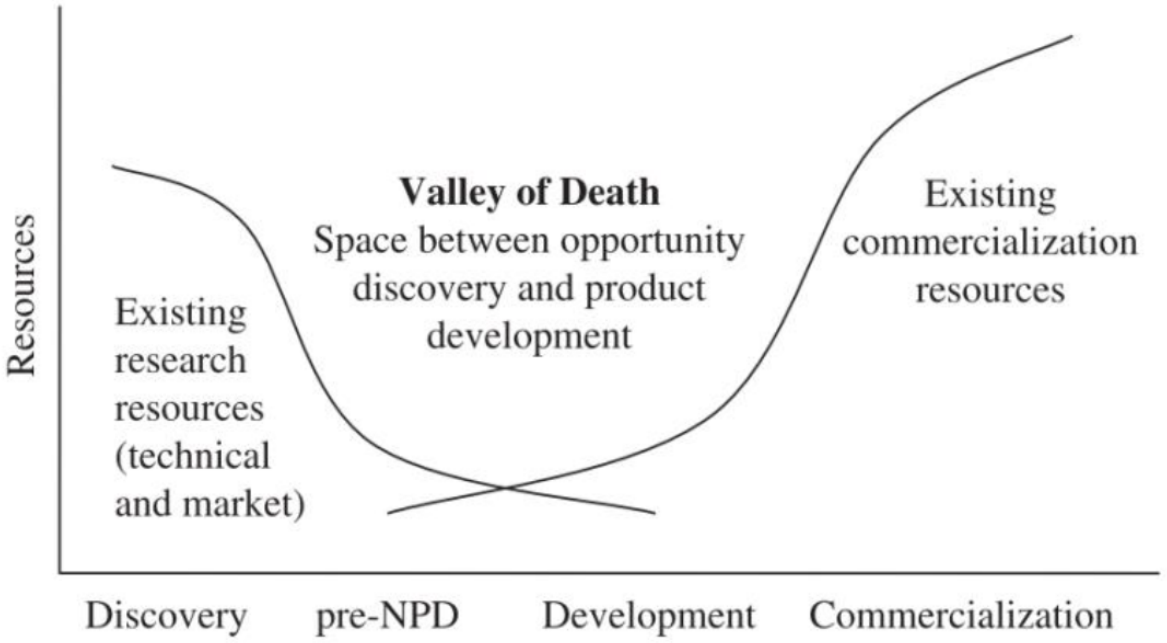

Figure 3: Valley of Death (Klitsie, Price & de Lille, 2018)

Sandberg & Aarikka-Stenroos (2014) further assert that the Valley of Death phenomenon is most likely to occur in the following Technical Readiness Levels (TRLs):

- TRL 4: Technology validation in lab;
- TRL 5: Technology validation in operation;
- TRL 6: Technology demonstration in operation; and
- TRL 7: System demonstration in real world.

This, in turn, leads to affected parties being confronted by the following type of challenges inhibiting successful industrialisation:

- Product challenges (Quality, performance, sustainability etc.);
- Business challenges (Costs, production efficiency, profitability etc.);
- Innovation challenges (Commercial success, market attractiveness, customer feedback etc.); and
- Process challenges (Expertise, relationships, diverse goals etc.).

3.2 Understanding contributors to the Valley of Death phenomenon

To illustrate the challenges of industrialisation, it is apt to create an analogy between Product Development and rugby with a multitude of "passes" between parties being necessary to achieve winning results. Simplistically put, the current game is characterized by undefined teams, poor passes and the ball often being dropped.

After extensive exposure to the phenomenon during Covid 19 and the personal involvement in a number of Medical Devices industrialisation projects, a list of the most prominent Valley of Death contributors has been created, Table 1:

Table 1: Most Prominent Valley of Death contributors

Nr	**Valley of Death contributor**	**Description**
1	Parties operating in silos	• The parties along the value chain (e.g. academia, manufacturers, funders etc.) mostly only understand their siloed perspective - and not the other stages and perspectives required for success. • *Silo-based perspectives pose challenges for collaborative multi-stage product development.*
2	Long learning cycles to gain necessary expertise	• Industries like Medical Devices are very complex and require a long learning period for parties to get their own and extended domain knowledge to function optimally. • All people in the value chain (e.g. innovator, manufacturer, patent lawyer etc.) constantly need to upskill given the pace of change - with learning only being topical when the issue actually occurs and relative to the role played in the industrialisation eco-system. • There is a shortage of “integrative” skills development solutions, that allow for accelerated- and multi-

		perspective learning and Systems Thinking enablement.
3	Lacking Product Life-cycle Management expertise	• The parties don't have a common industrialisation process or understanding of milestones (from different role-player perspectives) to work off and have a problem of communicating what they need from each other - and why this is important for the achievement of goals. • *Effective collaboration is hampered by parties first needing to agree on "basics", which should form part of their sector "general knowledge" portfolio.*
4	Challenges with inter-party communica-tion in terms of information needs	• The sectors are highly data-intensive (e.g. Data on markets, trends, products, competitors etc.) with parties not knowing where to find the right information or what information is required to satisfy the requirements of other value chain role-players (e.g. market size, feasibility etc.) • *Communication between parties is often in-effective with the needs of the other party not being clearly understood and the messages being conveyed, not satisfying the needs of the receiving party.*
5	Use of common reference framework between eco-system role-players	• Parties don't have a common "language" or reference framework to optimally govern the handovers between each other and uniquely describe the basis of their interaction. • *The use of different and potentially confusing terms by different parties as synonyms (e.g. "Ventilator", "Non-invasive ventilator, "BPAP" etc.) when interacting, contributes to significant confusion but also limits the effective deployment of digitalisation technologies for value addition.*
6	Alignment between innovation and demand-side triggers and role-players	• Value chains typically require sound and timeous inter-linkages between "demand" and "supply" in order for innovation activities to be off take orientated and fundable. • *There is a need to establish better connections between the major role-players along the value chain such as innovators, manufacturers, and Medical Devices buyers – and use "push" or "pull" triggers to initiate collaborative interactions between parties.*

3.3 Active avoidance and countering of the Valley of Death phenomenon

Equal emphasis should be given to both Valleys of Death, which are arguably equal in their negative effect on successful product industrialisation:

- Valley of Death 1: Space between opportunity discovery and product development, i.e. between “idea” and “product”; and
- Valley of Death 2: Space between successful product development and commercial success, i.e. “product” and “market”.

The following checklist, Figure 4, has been created to avoid the Valley of Death phenomenon from negatively affecting Product Industrialisation outcomes of Medical Devices:

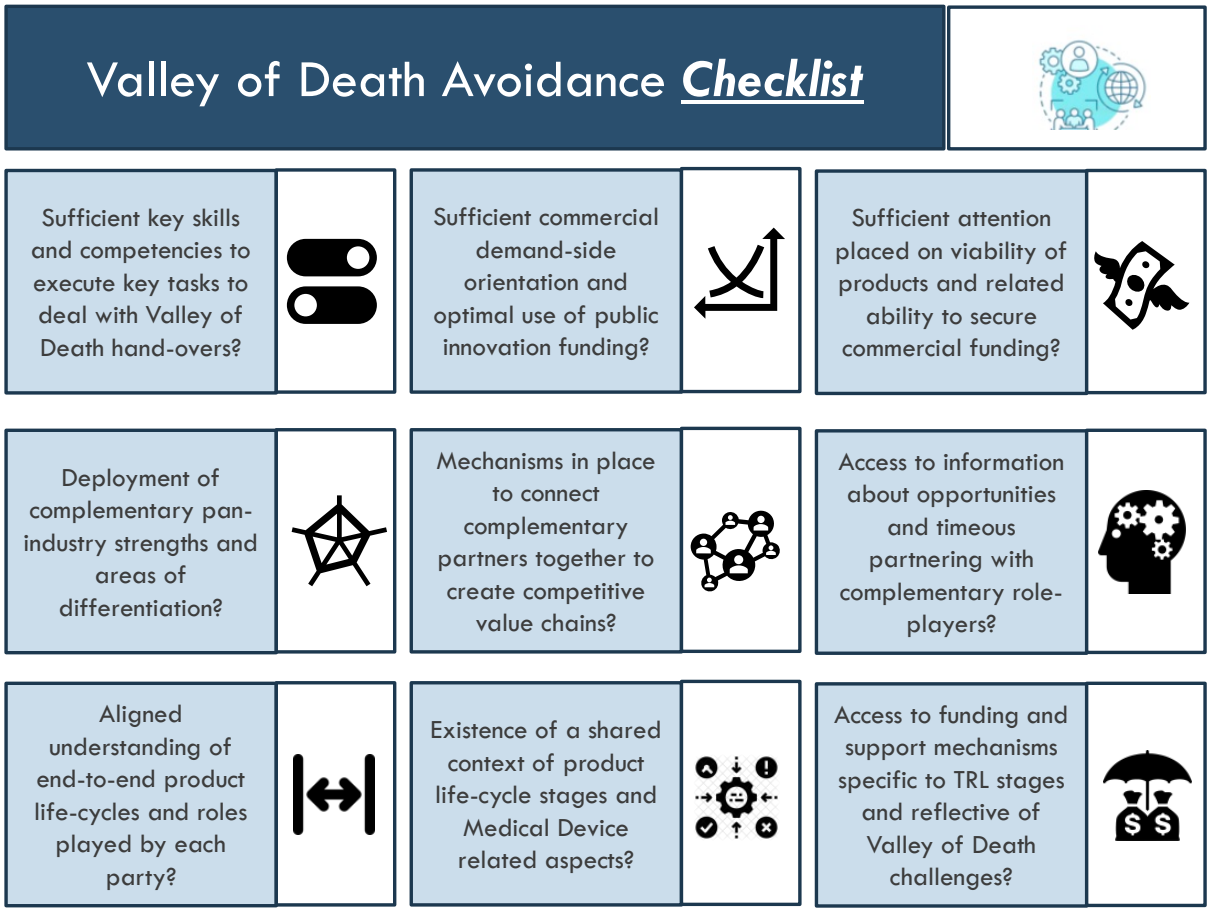

Figure 4: Valley of Death Avoidance Checklist

Similar to the establishment of localisation-friendly eco-systems being strategic and deliberate, so too is there a need for concerted Systems Thinking solutions to effectively counter-act and avoid the Valley of Death phenomenon from negatively inhibiting national and regional Medical Devices industrialisation.

INDUSTRIALISATION IN A DIGITALLY ENABLED COLLABORATIVE 4IR ENVIRONMENT

Is it possible to deal with the significant challenges of industrialisation, as outlined in the previous chapters, without significantly altering the make-up of the industrialisation “system”? The author believes that product industrialisation value chains will increasingly experience seismic change through 4th Industrial Revolution (4IR) factors. This will necessitate a fundamental re-invention as to how parties

collaborate to create value around new products. Current outcomes are simply not good enough – and "tweaking" existing industrialisation systems will not lead to the desired results.

4.1 Imagining a new industrialisation paradigm for Medical Devices

As the world becomes increasingly globalized and competitive, people and organisations are challenged in the following areas, as shown in Figure 5:

i. Dramatic increase in the amount of data and information needing to be processed;
ii. Dramatic increase in competitive pressures and client expectations;
iii. Dramatic increase in the reach and spread of localized competition; and
iv. Dramatic increase in the number of relationships and networks to be maintained.

In contrast to this, however, the there is a reduction in the available resources to deal with these increases, as shown in Figure 5, namely:

i. A reduction in the time available to perform tasks;
ii. A reduction in resources and an expectation for costs to be reduced; and
iii. A change in people, who are increasingly impatient to do perform activities deemed to be time-wasting in nature; and
iv. A reduction in the time-scale that learned knowledge is relevant and topical:

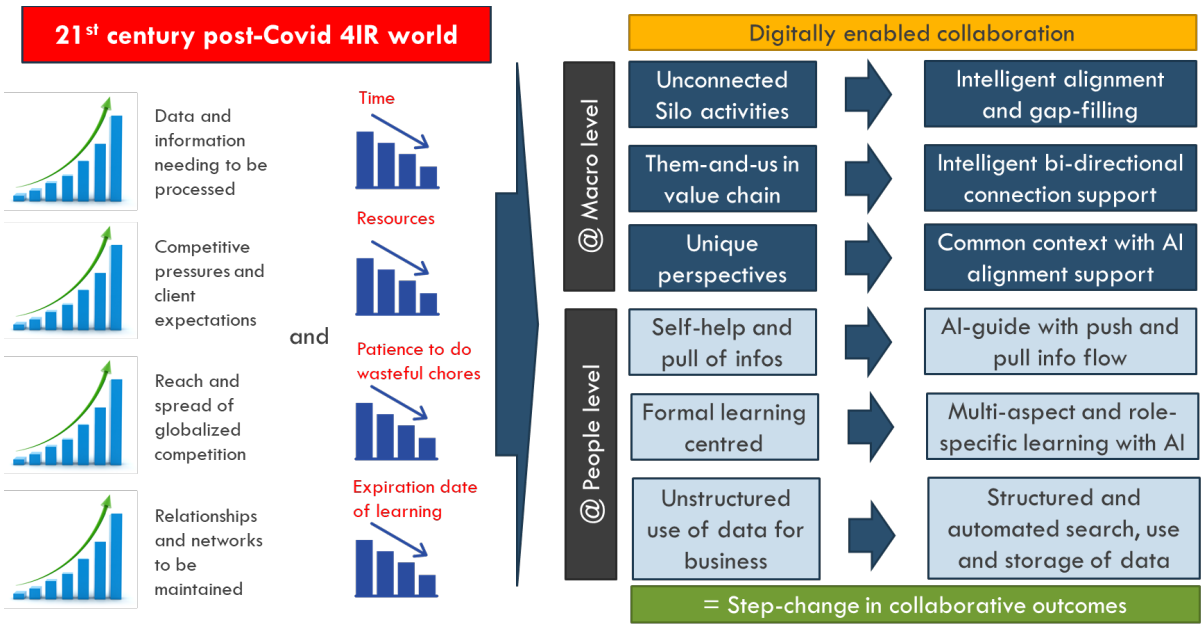

Figure 5: Industrialisation paradigm for Medical Devices

It is argued that the ever-increasing "imbalance" created will drive new forms of collaboration, both at a macro- as well as people level. This will herald a fundamental shift to digitally enabled collaboration, as the only way for the increased demands to be accommodated, as shown in Table 2:

Table 2: Implications and benefits of digitally enabled collaboration

Nr	Future state collaboration base-line	Implications and benefits:
1	Intelligent alignment and gap-filling	• Definition of role-specific partnering profile • Selection of best partners on the basis of dynamic data, various decision aspects and Machine Learning • *Benefit: Support for best role-player specific value chain for optimal competitiveness*
2	Intelligent bi-directional connection support	• Intelligent identification and notification of cooperation opportunities along value chain • Support for better fit of partnering activities (e.g. cooperation of academia and manufacturer around R&D project) with use of common nomenclature • *Benefit: Dynamic, ongoing and "push-driven" notification to all parties of parties as soon as opportunities are identified*
3	Common context with AI alignment support	• Use of common product life-cycle management processes and templates for referencing and mapping of stakeholder activities • *Benefit: Use of digital tools including AI to intelligently monitor collaborative processes, identify gaps and support remediating actions – with massive benefits for users*
4	AI-guide with push and pull info flow	• Support for the industrialisation eco-system participants in the form of a personalized and role-specific "AI-guide" to assist • Intelligent AI-enabled identification of aspects of importance and actions required – and notification of the user to act or take a decision (referred to as "push" process) • *Benefit: Significant saving of time and effectiveness improvements for the user through the "filtering" out of irrelevant information and notifying the user to act*
5	Multi-aspect and role-specific learning	• Definition of competency requirements for different roles performed in the industrialisation eco-system • Ability of technology to identify learning aspects based on defined profiles and dynamically adjust skill level requirements • Intelligent AI-enabled identification of aspects to be

		learned and insights to be acquired – and notification of the user to be trained and monitor learning progress • <u>Benefit</u>*: Dramatic shortening of customary periods to gain the necessary knowledge combined, ongoing dynamic skills development as well as the ongoing customisation of learning content around the value chain role fulfilled and personal learner preferences*
6	Structured and automated search, use and storage of data	• Use of sector-related nomenclature (e.g. General Medical Devices Nomenclature or GMDN) for the systematic identification, sourcing, notification, storage of relevant data • Deployment of value chain context (Refer to number 3) to create a link between the information and relevant operational implications and deployment areas • Intelligent AI-enabled identification of data / information to be collected and leveraged for differentiation and value-add, with the notification of the user to take cognizance • <u>Benefit</u>*: Dramatic reduction in time to stay abreast of relevant developments, satisfy key information requirements and support differentiation through insights.*

It is envisaged that the future state collaboration baseline, as described in the table above, will become an indispensable enabler to achieve the necessary level of competitiveness required for success in a 4IR environment.

4.2 The need for digital platforms to enable future state eco-system collaboration in the Medical Devices sector

Can future state industrialisation be achieved without technology? The author is of the belief that this is not possible, and that the improvement potential of existing multi-party industrialisation activities is limited.

Inherently, the limitation is human in nature and the ability of people to deal with the enormous and ever-growing challenges associated with industrialisation. Effectively the work requirements of people operating along the industrialisation value chain are so complex, specialized, time intensive and silo-specialized that a dramatic improvement is ONLY possible through the effective deployment of technology to support value creation of the individual parties - as well as their collaborative efforts.

People need support from technology for industrialisation outcomes to be dramatically improved!

It is not possible to train every party along the value chain up to be a Systems Engineer, who understands all interactions. Neither is it possible nor feasible to try and upskill an innovator to also be an expert on patent law - and vice versa.

It is argued that substantial improvements to industrialisation outcomes are only possible through the application of digital platforms or eco-systems, which allow parties to work together in a cloud environment and where is technology is systematically deployed to support people. The envisaged platform solution:

i. Supports each of the parties in better performing the role that they play (e.g. innovator, testing laboratory, manufacturer etc.) - while supporting with the best "interface" or "translation" when dealing with other parties;
ii. Creates a common "game-plan" or reference framework for industrialisation for all parties to alleviate current communication and position themselves in terms of TRLs and other parameters;
iii. Uses sector-specific "language" to facilitate communication and process flow along the industrialisation value chain and between parties;
iv. Builds on standard human phenomena, which is one of making acquaintances, establishing relationships / trust and seeing a track-record when partnering; and
v. Leverages the "system framework" created by the measures above to enable digitalisation as the critical instrument to enable improvements for people, organisations, collaborating partners and sector eco-systems.

Industrialisation in the future is likely to be very different to today's relatively ineffective and hit-and-mis practices. Continuous improvement of current industrialisation systems is unlikely to lead to breakthrough results. It is argued that dramatic improvements in industrialisation outcomes are only possible through the intelligent application of technology to deal with current systematic shortcomings and play a key enabling role in maximizing the ability of people to add value.

Implications for Medical Devices Industrialisation in Africa

Africa needs to industrialize more Medical Devices and reduce its dependency on import. This process will not be easy – nor will it happen overnight. However, there are certain guidelines that the continent can draw from in charting its Medical Devices Industrialisation Roadmap:

i. Medical Devices Eco-systems can be established for sustainability, provided that these are well designed and based on Systems Thinking design principles;

ii. Universal phenomena such as the Industrialisation "Valleys of Death" are reasonably well understood, and measures can be undertaken to counteract their debilitating impact – provided that this is done systematically;
iii. Industrialisation is set to change in an emerging 4IR world and Africa would be well advised not to emulate current ineffective practices and systems – which are set for a fundamental overhaul in the years to come. Instead, platform solutions offer significant potential to leapfrog African Medical Devices industrialisation to global levels of competitiveness.

It is hoped that the consideration of the pointers provided will in some way contribute to the development of a sustainable and future-orientated Medical Devices industrialisation in Africa.

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