EMERGING TECHNOLOGIES: COMMERCIAL READINESS INDEX (CRI) FOR MEDICAL ADDITIVE MANUFACTURING (AM)

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ABSTRACT

Technology Readiness Level (TRL) is widely used as a measure of technology maturity. However, TRL is not necessarily a good indicator of commercial readiness. In the renewable energy sector a Commercial Readiness Index (CRI) is used where only a technology with a high TRL qualifies for commercial readiness. Similarly TRL is used to measure the maturity of Additive Manufacturing (AM) technologies. This research proposes a Commercial Readiness Index (CRI) for Additive Manufacturing. A case-study on maxillofacial Ti6Al4V implants manufactured with AM is referred to.

1. INTRODUCTION

Previous research [1] on a step-by-step risk assessment of the process of manufacturing a successful maxillofacial implant showed to be theoretically unfeasible due to the risks being too high. In order to move from theoretical feasibility to real feasibility a mechanism to analyse the high risks needs to be developed.

The following case study is used; a maxillofacial implant manufacturing process. The Centre of Rapid Prototyping and Manufacturing (CRPM) [2] has been accredited to manufacture implants according to ISO13485. The commercialisation of this manufacturing process is currently in the ramp-up phase. The commercial sustainability of the manufacturing process still needs to be verified. This research uses as a base the Commercial Readiness Index (CRI) assessment, created by the Australian Renewable Energy Agency (ARENA) [3] [4]. The ARENA CRI is modified to apply to AM by using analysis and synthesis approach. The CRI is divided into several independent indicators assessing various commercial aspects and then combined into a single commercial index.

Therefore the CRI is compiled from commercial indicators including; Regulatory Environment, Stakeholder Acceptance, Clinical Performance, Technical Performance, Financial Performance - Cost, Financial Proposition -Revenue, Industry Supply Chain and Skills, Market Opportunities and Company Maturity. A diverse group of 15 experts assisted in defining maturity in each of the commercial indicators. The compiled results are presented. The value of this research lies in the ability for investors to now assess the commercial viability of AM. AM is considered a disruptive and emerging technology designated to replace conventional manufacturing processes.

2. METHODOLOGY

The research has started by interviewing seventeen experts on their view and opinion on commercial readiness. These experts were chosen based on their knowledge within specific industries. The professional environments of these experts include: Associate Professors from different South-African Universities, investment managers, senior directors of innovative companies, venture capitalists, executive managers and mechanical engineers. These experts are versed in: strategic decision making; experience in standards development for materials; paediatric applications; managing product-to-market endeavours; maxillofacial reconstruction; venture capitalism; commercial incubator activities; innovation processes ; aerospace product development ; enterprise engineering; regulatory and conformance quality; logistics and supply chain and systems integration.
Their opinions contributed to defining the CRI indicators for AM. Using the TRL, introduced by NASA in 1970[5], each of the technologies are evaluated in terms of their maturity. The individual TRL's will be added in the value chain in order to calculate the CRI

2.1 Objectives

1. Define CRI for AM based on CRI for renewable energy by process of expert opinion
2. To define a framework against which the commercial maturity of processes using AM technology can be measured
3. To use a case study to confirm the framework

3. LITERATURE ANALYSIS REVIEW

3.1 Additive Manufacturing technologies within medicine

At the start of this research, a better understanding of AM in general was needed. Additive Manufacturing products within the medical industry are of high value and small physical

volume, custom-designed within the AM technology. These products continue to deliver innovative solutions for customer needs [6].
AM medical devices can improve the manufacturing of the product and the physical fit to the patient, supporting the medical device industry which focuses on enhanced customisation. The alignment between medical device and AM is strong due to the demand for low-volume, high-customised products with life dependent outcomes. This is exactly the case for the maxillofacial implant.

3.1.1 Maxillofacial implant

Figure 1: Maxillofacial implant [2]

The CRPM has been successful in manufacturing and implanting this implant, shown in Figure 1. The CRPM is an institute of the Central University of Technology (CUT).

3.1.2 AM research funding

The development of AM technologies in South Africa has been through provisional and upfront grants [7]. Grants from the government can be useful in assisting companies with funding for their projects. The introduction of new technologies into existing markets face difficulties in the commercialisation process [3].

3.2 Defining key terms

3.2.1 The manufacturing process chain

The manufacturing process chain is the specific part within the production we are interested in to calculate the TRL. First we need to discuss the different types of TRLs.
The technology that you buy from the supplier is integrated into your manufacturing process. That technology then has a new TRL within your process. The process leads to a product with a new TRL. Therefore we can summarise the different TRLs into three uses:
1. The TRL the supplier promises when you buy a product from them and
2. The TRL that you experience when using the product.
3. The TRL of the process of manufacturing the product.

3.2.2 "Emerging technologies"

AM is not only an emerging technology that has the potential to replace many conventional manufacturing processes, but also an enabling technology allowing new business models, new products and new supply chains to emerge [8]. Emerging technologies are technological advances that are currently in development. They have the potential to replace current technology in the workplace and are within the development phase of their technological life cycle. Emerging products are becoming more complex and require multiple capabilities within the company. Without the certain manufacturing capabilities, companies are vulnerable to market shift [9]. This is just some characteristics of emerging

technologies. Many others exist; the researcher found that these are the ones relevant to this study.

3.2.3 "Readiness" and "maturity"

When companies want to implement an emerging technology, it is important to consider whether they are ready to implement it. "Readiness" is a measure of the suitability of a technology or products for use within a larger system in a particular context [10]. Smith [10] recognised that the terms readiness and maturity are sometimes used interchangeably and argues that a mature product can have a greater level of readiness for a specific use or system than one with lower maturity. The individual readiness components and their contributions to the system or product make it difficult to determine the overall readiness of the technology and also the overall risk assessment [11]. This statement led to many articles on Technology Readiness Levels in general.

3.3 Technology Readiness (TRL)

The concept of "technology readiness levels" (TRLs) was first introduced by the National Aeronautics and Space Administration (NASA), in 1970 [5]. TRLs were initially introduced as a concept for an independent, programmatic figure of merit (FOM) to allow for effective assessment and communication of maturity of new technologies. In 1995, the TRL scale was strengthened by the articulation of definitions of each level [12]. Since then, TRLs have proven to be effective in communicating the status of new technologies within organizations.

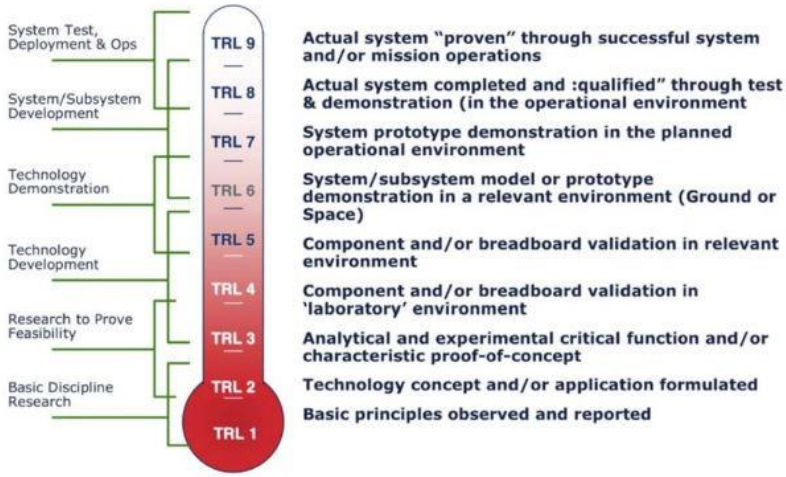

Figure 2: Technology Readiness Level (TRL) [12]

TRLs defines the gap between the technology's maturity and the maturity needed for it to be successful [13].The basic model of TRLs is shown in Figure 2.
In South Africa, TRLs have been used within AM by the CSIR [7]. NASA used TRL to assess the maturity of a particular technology and a scale to compare technologies [14]. NASA originally created TRL to mature to TRL 6 which states that only at level 6 can a mission assume responsibility [15]. In 1999, the Department of Defence (DoD) embraced the TRL concept and expanded it to reach TRL 7 before the technology can be included in their program [14].

These differences caused researchers [14] to state that TRL:

1. Does not demonstrate the difficulty of integrating technologies into an operational system [13], [16], [10], [11]
2. Does not include guidance towards uncertainty within maturity movement of TRL [15], [16], [10], [17]

3. Shows no alternatives to analysing alternative TRLs [13], [16], [10]

When TRLs are now drawn from their individual level of technology to the system context, more concerns arise between the interaction of the multiple technologies [14]. Different views on how to integrate individual TRLs within a project or system has been explained [14], [18], [19]. The experts mentioned, explain that an Integration Readiness Level (IRL) can be used to determine the relationship of technologies within a system and then using the IRL to set-up the System Readiness Level (SRL).

The concerns of Sauser et al.[14] and Graettinger [20] stated that technology must be integrated within a system. Although the SRL is considered in literature as an indicator of system readiness it does not address all the indicators required for CRI. Therefore, addressing the concerns of Sauser et al.[14] and Graettinger [20] we will attempt to draw the individual level of technology to a process context. The technologies will be investigated within a process context Graettinger [20] to examine the processes to manufacture a product.

Several literature articles [5], [12], [13], [15], [16], [10], [11], [17], [20]–[25] talk about technology readiness without the process chain and others [7], [26]–[29] about the process chain and process readiness without the technologies. A gap within this research is that the two differing views are not merging. In this research, the fundamental technologies meet the process chain and that is why we can argue that the lowest TRL is what we are interested in. The reason being that the weakest technology (lowest TRL) in the process chain is most likely to have the most adverse effect on the entire process chain. If one technology fails, the entire chain will fail.

The TRLs provide a good framework for gauging technology readiness; they are insufficient to gauge commercial readiness, since other, non-technological aspects also determine commercial viability. This then provide the motivation for the development of a CRI framework which links back to but extends the TRL framework. A viable way of setting this up is to determine the future or to-be TRLs of the technologies. This is then referred to as the goals that have to be obtained in order to achieve the to-be state.

3.4 Commercial Readiness Index (CRI)

The CRI framework developed by the Australian Renewable Energy Agency (ARENA) aims to complement the TRLs by assessing the commercial maturity of technologies across six indicators [4].
The CRI determines the commercial ranking of the project, and the TRL index is a tool used for benchmarking the progress and development of specific technologies through the development chain [24].

The CRI begins once the technology is at a stage where there is proof that is feasible in the field [3]. This is at TRL 2. The CRI ranges until the technology is commercially deployed, Figure 3. ARENA [3] argues that in order to improve commercial readiness of a technology, it needs to progress along certain commercial indicators.

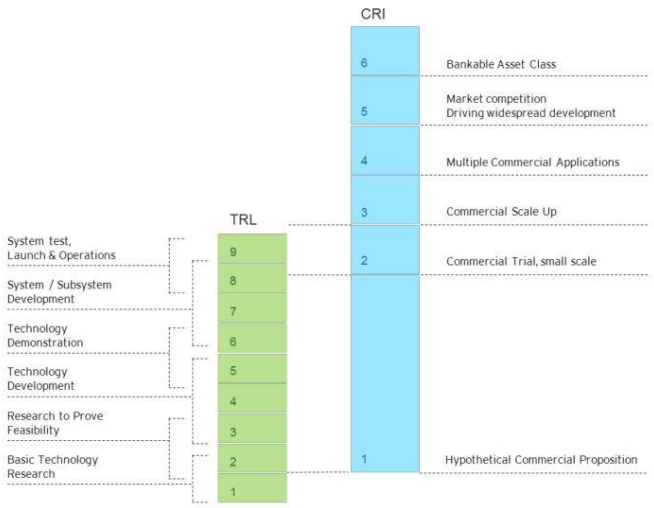

Figure 3: TRL and CRI [3]

3.4.1 Commercial Readiness indicators

Companies can determine new technologies' attractiveness by evaluating their technical and economic viability, market potential and value capture [30]. The financial overheads for running machines and buying feedstock are potential barriers to the commercialization of AM [8]. Accelerators in commercialization are organizational support, market proficiency and organizational-integration [26]. "Maturity" is encapsulated within the notion of "readiness" [31]. They are used interchangeably. ARENA [3] has identified indicators to reflect on the commercialization process of their industry. The indicators were drawn from experience, consulting with stakeholders and reviewing literature.

From the literature it is evident that commercial readiness indicators should include stakeholders [32], technical viability [30], market opportunities and proficiency [26], [28], [30], [33], economic viability and value capture [30], [34], organizational support [26] and strong R&D efforts [35]. The ARENA [3] CRI framework includes all the above indicators with descriptions of each, tailored for application for renewable energy projects. These indicators are Regulatory Environment, Stakeholder Acceptance, Technical Performance, Financial Performance – Cost, Financial Proposition – Revenue, Market Opportunities, Industry Supply Chain and Skills, and Company Maturity.

Each indicator has a Level 1-6 maturity. This means that they are further described based on different level of maturity. Level 1 being the least mature for that specific indicator and Level 6 being classified as the highest maturity for that indicator. ARENA makes use of a *Status Summary*, described by the indicators, to evaluate at which level of business the project is.

In the present work, the CRI framework developed by ARENA is used as a basis for the development of a customised CRI indicators and framework for assessing the commercial readiness of AM technologies.

The TRLs can be averaged and then transferred to the corresponding CRI levels of *Hypothetical Commercial Proposition, Commercial Trial, Commercial Scale up, Multiple Commercial applications, Market Competition driving widespread deployment* and *"Bankable" Grade Asset Class*.

4. FINDINGS

4.1 Definition of CRI Indicators for AM

The CRI indicators were transformed from the renewable energy case study to the medical AM case -study. Seventeen experts in the industry were interviewed and their combining opinion on each indicator was documented. The Indicator descriptions are summarized in Table 1.

Table 1: CRI level indicators

Level	CRI indicators
Regulatory Environment	
6	Regulatory and planning process documented and defined with ongoing process of review and refinement. To have an internally flexible robustness to change to conform to. Investment markets see company policy settings long term, robust and proven.
5	Regulatory, planning and permitting standards conformed to and accredited.
4	Key findings published on planning, permitting and regulatory challenges based on actual evidence. Quality management strategy agreed for accreditation.
3	Manufacturing quality checks and standards are in place. Process development address key barriers in order to gain certification.
2	Key regulatory barriers emerge and require project specific consideration. Reference model with set of rules are referred to when decisions are made.
1	Quality checks and operations are developed to meet specific standards. Operators are being trained to perform to specified standards. Regulatory body has not yet approved operations.
Stakeholder Acceptance	
6	Processes for change are in place to ensure robustness.
5	Stakeholders transparently represented in all aspects of the business. IP risk mitigated. Stakeholders would like to see the full clinical benefits AM can bring - shorter theatre and recovery time.
4	Evidence and experience is available to inform stakeholders increasing their acceptance. Market dictates policy settings and consumerism drives thinking. Stakeholder networks based on trust result in funding.
3	Systematic process to manage stakeholders' input. A plan to mitigate risks is in place. Technology features are publically explained to end users in order to develop market understanding of benefits.
2	Stakeholder support is on a case-by-case basis with technology developer skills a critical success factor. Processes are based on best practice principles and documented accordingly. Intellectual Property (IP) risk identified and mitigation policy in place.
1	Stakeholder support is limited to collaborative research group. A plan to mitigate risks is in progress.
Clinical Performance	
6	The product as well as the procedure is internationally recognised for a high number of successful cases.
5	Regular credit from peer reviewers. Standard operating procedure is in place. One component associated with procedure decreasing the risk.
4	The research and proven studies must be published in several international journals and presented at medical conferences. Procedure is faster than the typical procedures. Patient has a high chance of survival.
3	The research and proven studies must be published in several journals. Several successful procedures have been done. Product is available for purchase.

2	The procedure is done in a proven clinical study operating theatre. Many components associated with procedure and product, several components are used within complex procedure. Products are modified during procedure. High customisation of product is needed.
1	Clinical performance is in progress. Patient has a chance of survival. The reaction of the body to the product is unproven.
Technical Performance	
6	Secondary markets exist to access externally verified performance information for routine due diligence. Performance review and warranty credit rating transparent.
5	Multiple data sets discoverable on our commercial products operating in a rang of applications. Medical regulation approval. Proof of what you promise for example a certificate on the wall.
4	Performance yield, efficiency vs. forecasts published and key drivers understood. Performance evaluation methodology and warranties becoming standard. High confidence in production viability.
3	Quality standards and accreditations on technical performance proven. Product complies with customer expectation. Tacit knowledge of production process ensures 100% capability. Production becomes viable for venture capitalists. International evidence key in investment. Finite Element Analysis (FEA) procedure in place. The design criteria lead to an effective and sustainable product with low risk.
2	Production performance forecasts based on simulation models from research & development or pilot scale demonstration. International performance used to support investment case.
1	Standards and accreditation are in progress. Machine performance improvement in progress. Production data based on prototypes and forecasts with little or no prior data to substantiate. Design does not yet lead to a sustainable product.
Financial Proposition -Costs	
6	Cost detail indices widely published and accepted for multiple similar applications. System cost competitive to drive uptake.
5	The cost model reliably reports the recommended retail price of the product. Product price and value proposition clear and attractive.
4	The cost model is flexible to allow for product variations. Commoditisation of major components occurring. Cost drivers are publically understood with roadmaps to market competitiveness.
3	The cost model is verified to accurately forecast products cost for quotations. Focus moving towards lowering unit costs and risk.
2	Key costs based on projections with some actual data available to verify. The cost model is being validated to actual accounting data. Supply chain stages' engineering costs based on time and materials with high degree of risk loading.
1	Cost model is being developed to determine the risk management strategy for the feasible region in which we are operating. Cost data based on projections and forecasts with some data to substantiate.
Financial Proposition - Revenue	
6	Transparent benchmarking is evident. Revenue sustainably robust through market variations.
5	Revenue projections based on proven forecasts and accepted commercial data. Product price sustainable to ensure market share increases.
4	Revenue projections backed by commercial data. Price gaps understood and roadmaps in place to address. Revenues generating sufficient cash flow to service debt and equity expectations.
3	Revenue sufficient to break-even production costs. Overheads subsidised by research and development funding. Revenue projections being tested in commercial context by investors. Tax subsidies applied for.

2	Some revenue is generated and cash is received. Revenue projections highly discounted by investors.
1	Revenue data based on projections and forecasts with little data to substantiate.
Funding	
6	Stock exchange generated public funding.
5	Recurring funding from investors based on underlying value of proposed asset.
4	Investors comfortable to secure debt based on financial ratio such as recurring revenue as a % of operating expenses.
3	Funding gaps between net present value of revenue and cost benchmarked to sector indicators. Capital invested is partially subsidised by research grants.
2	Small scale production trials funded through research grants.
1	Funding for prototyping established.
Industry Supply Chain and Skills	
6	Multiple alternatives with proven capability. Product and service is key differentiation selection factor. Process flexible to react timeously to change in trends.
5	The supply chain is set up for future development. Specialisation occurring along supply chain with standards defined and supplier performance externally benchmarked. Service level agreements are in place.
4	Key skills demonstrate batch process efficiency with replicable results. Industry supply chain and market channels proven to deliver. Time-to-build measured as a key driver of efficiency.
3	The supply chain is set up through several businesses to spread risk. Limited availability of key components and manufacturing, operational and maintenance skills. Business plan to move from start-up to scale-up approved by stakeholders.
2	Most supply chain stakeholders conform and are willing to participate. The manufacturing process policy is in place as engineer-to-order. SCOR reference framework is used in collaboration with best practices.
1	Key elements in supply chain identified and from specialist source. Service level agreements are being negotiated, often under technology proponent's specifications.
Market Opportunities	
6	The company has a large market share.
5	Market driving the investment process. Management policy robust to external factors.
4	Market demand primary driver of the investment case with some concessional policy support. Market size widely available and verified by third parties competitors. Target segment customers are key stakeholders in the investment decision process.
3	There must be proof of an irrevocable offer to purchase. Active advertising and marketing system to generate leads with follow up action plan. Detailed market research to understand the size, interest and readiness of the market available.
2	Commercial trial has identified the target market segment proving to investors that the technology is clinically reliably. Market research has been done to enable proponents to estimate the market size locally and internationally.
1	Some opportunities available. Expert opinion confirms commercial evidence for investment case based on market size and early channel to market.
Company Maturity (CRPM Medical Pty Ltd.)	
6	The company can be listed as a public company. Company is resilient to react to external factors.
5	Company lead by governance policy to ensure shareholder value. Company KPIs are aligned with shareholder value and met.

4	A recognised quality management system imbeds trust with stakeholders. Company structure is in place and systems are automated to support perceived shareholder value. The company is the main driver of the technology.
3	Industry stakeholders in place and strongly represent the sector. Industry sector still driven by technology proponents within research institutes. The company has started developing a corporate governance system.
2	Internal management systems are being developed and the company now has several decision makers with a unanimous goal. Industry stakeholders are weaker than research institutes.
1	Company structure is in progress. Several high level responsibilities resides in one person. Manufacturing and technology capability is being transferred from research institutes to industry stakeholders.

It will be noted that a ninth indicator called *Clinical Performance* and a tenth indicator *Funding* was added to the list. This is because medical AM products critically depend on clinical performance measures in order to be commercially ready and funding that was previously included within Revenue now forms an independent indicator.

4.2 Definition of CRI Framework for AM

The Status Summary Levels previously mentioned are described in Table 2.

Table 2: Status Summary Levels

Level	Status	Summary
6	Bankable Grade Asset Class	Considered as a "Bankable" grade asset class with known standards and performance expectations. Market and technology risks not driving investment decisions.
5	Market Competition Driving Widespread Deployment	Competition emerging across all areas of supply chain. Verifiable data on technical and financial performance in the public domain.
4	Multiple commercial application	Becoming evident locally although still subsidised. Verifiable data on technical and financial performance in the public domain driving interest from variety of debt and equity sources however still requiring government support. Regulatory challenges are addressed in multiple jurisdictions.
3	Commercial Scale-up	Small scale, first of a kind project funded by equity and government project support.
2	Commercial Trial	Small scale, first of a kind project funded by equity and government project support. Commercial proposition backed by evidence of verifiable data typically not in the public domain.
1	Hypothetical Commercial Proposition	Technically ready – commercially untested and unproven. Still subsidized by government.

Each indicator level is mapped on the Status Summary Matrix, in Figure 4.

			Indicators									
			Regulatory Environment	Stakeholder Acceptance	Clinical Performance	Technical Performance	Financial Performance Costs	Financial Proposition Revenue	Funding	Industry Supply Chain and Skills	Market Opportunities	Company Maturity
Status Summary Level	Bankable Grade Asset Class											
	Market Competition Driving Widespread Deployment											
	Multiple Commercial Applications											
	Commercial Scale-up											
	Commercial Trial											
	Hypothetical Commercial Proposition											

Figure 4: Simplified Status Summary Matrix

4.3 Case study to demonstrate the AM CRI framework

The AM CRI framework is demonstrated by example of medical AM products.

4.3.1 Case Study: Maxillofacial AM manufactured in Ti6Al4V

The case study is now used to help in understanding the methodology approach used to determine the CRI for medical AM products. The indicator levels are assesed according to an as-is and a to-be state. The to-be state is where we want to be in the future and the as- is state is our current state. Table 3 shows the results. The as-is and to-be states are indicated in red and yellow respectively.

Table 3: Indicator levels - maxillofacial implant

Level	**CRI indicator** - maxillofacial implant
Regulatory Environment	
6	Make use of automatic software and streamline the technical files.
5	Limited standards exist for manufacturing and implanting prosthesis into the human body. Standards are based on best practices and Standard Operating Procedures (SOPs). ISO system is in place and we know the regulatory body.
Stakeholder Acceptance	
5	Tacit knowledge skills transfer program. Multiple successful case studies can be achieved.
3	Design follows a process. The plan to mitigate risks is in place. Stakeholders are sometimes still uncertain. Number of doctors needed unknown if process gets commercialized. Many outsourced processes that bring uncertainties.
Clinical Performance	
5	Hospitals and medical insurance companies use AM implants as the norm and medical assurance authorisation codes are developed for custom procedures.
3	Product has been tested to render acceptable results.
Technical Performance	
4	Successful ramp up of production to support a portion of SA market. Technical performance constant with higher production values. Process monitoring systems are in place to log process conditions.
3	Yearly successful ISO surveillance audits shows that technical performance is sound. Production still limited but repeatable.
Financial Proposition –Costs	

4	Publish more articles on cost structures. Cost structures should be benchmarked with other institutions. ROI is clearly understood if other similar spin-offs needs to be established
3	Key costs not yet in the public domain.
Financial Proposition – Revenue	
4	Proof of concept with the investors to see real revenue and market opportunities.
3	Know where the profit lies, but market size unknown.
Funding	
4	Private companies are investing into this venture. The manufacturing bureau is financially sustainably.
3	Some of the activities are subsidised through research grants and other commercial activities.
Industry Supply Chain and Skills	
3	Doctor information requirements must be standardised. Procedures from suppliers must be adjusted to comply with the AM process.
2	Product manufacturer typically designing and procuring multiple elements to own specification. AM processes streamlined. Technology proponent specification given to suppliers.
Market Opportunities	
4	Product line partnership with sector specific customers.
1	Market size, locally and internationally not yet estimated. The technology is still in the critical stage of being a promising technical solution moving into a prospective commercial opportunity.
Company Maturity	
5	Independent entity concentrating on manufacturing. Constantly engaging research institute for continuous improvement.
2	Support structure in place for small scale production. The company needs to mature in terms of commercialization.

Table 3 is then mapped in Figure 5. Using the average calculation [3], the as-is Status Summary of this product is at CRI 3 and the to-be Status Summary is as CRI 5. The difference between the as-is and the to-be state is a mechanism to identify actions to be taken by the manufacturer to improve the maturity of the indicators.

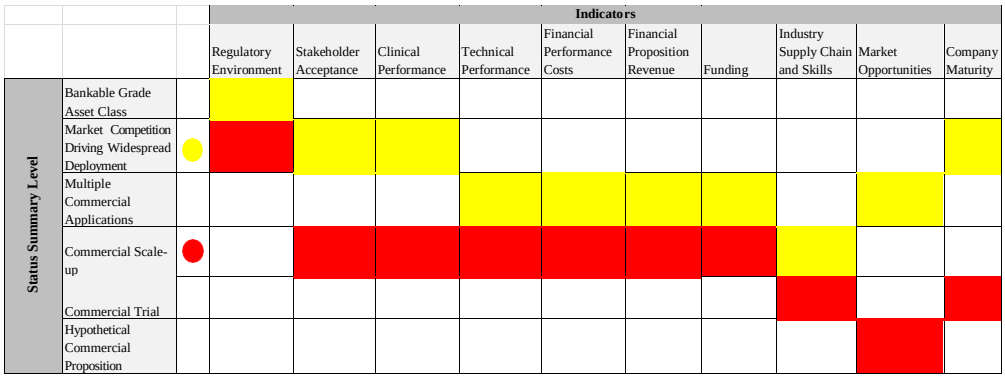

Figure 5: Status Summary Matrix - maxillofacial implant

5. RESULTS

Expert opinions are compiled into different maturity levels of each indicator. Subsequently these indicators are reiterated with individual experts for their conformation. Results from expert opinions provided the different levels of maturity for each indicator. The case study on maxillofacial implants was tested against this framework and the CRI reported accordingly. CRI determined at status of *Commercial Scale-up* at CRI 3.

6. CONCLUSION

A commercial readiness index for additive manufacturing technologies is proposed. The opinions of seventeen experts were compiled into levels of maturity for each independent commercial indicator. Commercial indicators are used to assess the commercial maturity of an enterprise's ability to unlock the potential of emerging technologies. Commercial indicators are independent parameters, averaged to a single Commercial Readiness Index.

The CRI framework helped recognise the KPIs within the case study's manufacturing process. It also helped the expert to understand and learn about the possibilities regarding commercialization of a complex product. The CRI framework helped to identify the main barriers that need to be addressed to move from the as-is state to the to-be state.

The technology framework will help with the technological uncertainty of the product, and show project and process risks associated with the manufacturing of the product. In South Africa it can be implemented within research organisations such as Idea2Product, LaunchLab and Maker Station, among others. This would mean more people embracing AM and enabling the average person to become economically active in the AM industry in South Africa.

REFERENCES

[1] **L. Bezuidenhout, 2016**. "Maxillectomy - an Ishikawa value chain," no. November, 2016.

[2] **G. J. Booysen, A. Van Der Merwe, D. De Beer, C. Van Den Heever, and J. Els, 2016.** "Developing a Patient-Specific Maxillary Implant Using Additive Manufacturing and Design,".

[3] **ARENA, 2014.** "Commercial Readiness Index for Renewable Energy Sectors,".

[4] **D. De Jager, 2017.** "Commercial Readiness Index Assessment,".

[5] **A. J. Shenhar *et al.*, 2005.** "Toward a NASA-specific project management framework," *EMJ - Eng. Manag. J.*, vol. 17, no. 4, pp. 8–16.

[6] **G. H. Snyder, 2014.** "3D Opportunity in Medical Technology," *A Deloitte Ser. Addit. Manuf*.

[7] **D. De Beer *et al.*, 2016.** "A South African Additive Manufacturing Strategy," pp. 1–92.

[8] **Royal Academy of Engineering**, "Additive Manufacturing : Opportunities and Constraints," in *Additive Manufacturing: Opportunities and Constraints*, 2013, no. May 2013, p. 21.

[9] **D. Leonard-Barton, 1995.** "Wellspring of knowledge.," *Harvard Bus. Sch. Press. Boston, MA*.

[10] **J. D. Smith, 2005.** "An Alternative to Technology Readiness Levels for Non-Developmental Item (NDI) Software," *Proc. 38th Annu. Hawaii Int. Conf. Syst. Sci.*, vol. 0, no. C, p. 315a–315a.

[11] **J. D. Smith II, 2004.** "ImpACT: An alternative to technology readiness levels for commercial-off-the-shelf (COTS) software," *Lect. Notes Comput. Sci. (including Subser. Lect. Notes Artif. Intell. Lect. Notes Bioinformatics)*, vol. 2959, pp. 127– 136.

[12] **J. C. Mankins, 1995.** "Technology Readiness Levels," *White Pap. April*, p. 5.

[13] **R. Valerdi and R. J. Kohl, 2004.** "An Approach to Technology Risk Management," *Eng. Syst. Div. Symp.,* pp. 1–8.

[14] **B. Sauser, D. Verma, J. Ramirez-Marquez, and R. Gove, 2006.** "From TRL to SRL: The concept of systems readiness levels," *Conf. Syst. Eng. Res. Los Angeles, CA*, pp. 1–10.

[15] **R. Shishko, D. H. Ebbeler, and G. Fox, 2004.** "NASA technology assessment using real options valuation," *Syst. Eng.*, vol. 7, no. 1, pp. 1–12.

[16] **J. C. Mankins, 2002.** "Approaches to strategic research and technology (R&T) analysis and road mapping," *Acta Astronaut.*, vol. 51, no. 1–9, pp. 3–21.

[17] **D. J. Moorhouse, 2001.** "Detailed Definitions and Guidance for Application of Technology Readiness Levels," *J. Aircr.*, vol. 39, no. 1, pp. 190–192.

[18] **B. J. Sauser, J. E. R. Marquez, D. Henry, and D. DiMarzio, 2008.** "A system maturity index for the systems engineering life cycle," *Int. J. Ind. Syst. Eng.*, vol. 3, no. 6, p. 673.

[19] **B. Sauser, J. Ramirez-Marquez, D. Henry, D. Dimarzio, and J. Rosen, 2007.** "Methods for estimating system readiness levels," *Sch. Syst. Enterp. White Pap.*, vol. 1, pp. 1–40.

[20] **C. Graettinger, S. Garcia, J. Sivily, R. J. Schenk, and P. Van Syckle, 2002.** "Using the Technology Readiness Levels Scale to Support Technology Management in the

DoD ' s ATD / STO Environments A Findings and Recommendations," *Spec. Rep. C. Using*, no. September.

[21] **J. (Gloria) Meng, K. M. Elliott, and M. C. Hall, 2009.** "Technology Readiness Index (TRI): Assessing Cross-Cultural Validity," *J. Int. Consum. Mark.*, vol. 22, no. 1, pp. 19–31.

[22] **J. C. Mankins, 2009.** "Technology readiness and risk assessments: A new approach," *Acta Astronaut.*, vol. 65, no. 9–10, pp. 1208–1215.

[23] **J. C. Mankins, 2009.** "Technology readiness assessments: A retrospective," *Acta Astronaut.*, vol. 65, no. 9–10, pp. 1216–1223.

[24] **ARENA, 2014** "Technology Readiness Levels for Renewable Energy Sectors,".

[25] **A. Parasuraman, 2015.** "Index (TRI) A Multiple-Item Scale to Embrace New Technologies," *J. Serv. Res.*, no. May 2000.

[26] **L. Nijland, M. Cloodt, and F. Langerak, 2014.** "Speeding up the Commercialization phase of New Product Development processes," *Alexandria.Tue.Nl*, no. May.

[27] **D. J. Teece, 2010.** "Business models, business strategy and innovation," *Long Range Plann.*, vol. 43, no. 2–3, pp. 172–194.

[28] **J. S. Gans and S. Stern, 2003.** "The Product Market and the Market for," *Res. Policy*, vol. 32, no. 2, pp. 333–350.

[29] **N. Ismail, S. Sidek, M. Jailani, M. Nor, U. Teknikal, and D. Tunggal, 2014.** "Market-driven research approach for a successful research product commercialisation," *Int. Symp. Res. Innov. Sustain.*, vol. 26, no. 4, pp. 1595–1599.

[30] **E. Maine, D. Probert, and M. Ashby, 2005.** "Investing in new materials: a tool for technology managers," *Technovation*, vol. 25, no. 1, pp. 15–23.

[31] **A. Tetlay and P. John, 2009.** "Determining the Lines of System Maturity, System Readiness and Capability Readiness in the System Development Lifecycle.," *7th Annu. Conf. Syst. Eng. Res. (CSER 2009)*, vol. 2009, no. April, pp. 1–8.

[32] **J. J. Keeble, 2003.** "Using Indicators to Measure Sustainability Performance at a Corporate and Project Level," *J. Bus. Ethics*, vol. 44, no. 2, pp. 149–158.

[33] **N. Rosenburg, 1972.** *Technology and American Economic Growth*. New York: White Plains.

[34] **G. Nieman and A. Bennet, 2006.** *Business Management: A Value Chain Approach*. Pretoria: Van Schaik Publishers.

[35] **M. Iansiti and J. West, 1997.** "Technology Integration: Turning Great Research into Great Products," *Harvard Business Review*, vol. 75, no. 3. pp. 69–79.

[36] **W. Du Preez *et al.*, 2017.** "Expert Transcript." p. 5