**Pre-Application Guidelines**

**2026 South Africa MedTech Innovation Challenge**

These Pre-Application Guidelines are intended to assist prospective applicants in preparing their submissions. They should be read together with the official Competition Terms and Conditions. In the event of any inconsistency between these Guidelines and the Terms and Conditions, the Terms and Conditions shall prevail.

## 1. Introduction

The 2026 South Africa MedTech Innovation Challenge ("Challenge") is designed to identify and support innovative technologies that modernise healthcare delivery through the integration of smart devices, artificial intelligence (AI), and digitally connected clinical workflows.

These Pre-Application Guidelines are intended to assist prospective applicants in preparing competitive submissions and understanding the Challenge requirements before completing the official application process.

Applicants are encouraged to review these Guidelines together with the Competition Terms and Conditions published on the Challenge website. In the event of any inconsistency between these Guidelines and the Competition Terms and Conditions, the Terms and Conditions shall prevail.

A well-prepared application that clearly demonstrates eligibility, innovation, impact, and implementation potential is more likely to progress through the evaluation process.

## 2. Understanding the Challenge Requirements

Before applying, applicants should carefully review the Challenge objectives. The Challenge focuses on technologies that address the need to modernise mechanical, analogue, and legacy diagnostic, therapeutic, and assistive systems through the integration of artificial intelligence and secure, accessible clinical workflows.

The Challenge is structured around three tracks. While applicants must select one primary track aligned to the core value proposition of their product or technology, they are encouraged to demonstrate how their innovation contributes to, integrates with, or enables the broader MedTech ecosystem.

Applicants should ensure that their product or technology demonstrates system-level integration across three core components:

- Hardware or device capability;
- AI-enabled functionality and decision support; and
- Secure workflow integration supporting triage, referral, and healthcare service delivery.

### 2.1 Technology Readiness Levels (TRL) – Guidance for Applicants

Applicants are required to classify their product or technology according to Technology Readiness Levels (TRLs), which indicate the maturity of a technology from early-stage validation through to full deployment.

**TRL 4:** Proof of concept and safety of candidate devices, systems or therapeutics demonstrated in a defined laboratory or animal models**.**

**TRL 5:** Review by the regulatory body to determine that the clinical investigation may begin. Preliminary findings should suggest the device or therapeutic will be substantially equivalent to a predicate device or therapeutic.

**TRL 6:** Data from the initial clinical investigation demonstrate that the device or therapeutic meets safety requirements and supports proceeding to clinical safety and effectiveness trials.

**TRL 7:** The information and data demonstrate substantial equivalence to a predicate device or therapeutic and safe use in an operational environment**.**

**TRL 8:** Investigation of final Class III prototype in clinical trials**.**

**TRL 9:** Production and distribution, with additional post-marketing studies and surveillance as required.

Applicants must ensure that their selected TRL accurately reflects the maturity of their product or technology and is supported by appropriate evidence.

**Applicants must select the appropriate category:**

Category A (TRL 4–7): Prototype-stage technologies undergoing validation.

Category B (TRL 8–9): Market-ready or deployed technologies.

**3. Selecting the Appropriate Challenge Track**

Applicants are required to select one primary track that best reflects the principal value proposition of their product or technology.

Applicants should demonstrate how their innovation contributes to an integrated MedTech ecosystem encompassing devices, AI-enabled functionality, and secure clinical workflows.

For Category A applicants, integration may be demonstrated through prototypes, system architecture, development plans, or partnership arrangements.

For Category B applicants, integration should be supported by implementation evidence, deployment records, user adoption, or operational outcomes.

**3.1 Track 1: Diagnostics/Therapeutics and Devices – From Mechanical to Smart Systems**

Applicants should demonstrate the development of new digital diagnostic or therapeutic technologies, or the modernisation of existing mechanical or analogue systems through sensors, imaging technologies, embedded electronics, automation, or connected devices.

The emphasis is on transforming traditional technologies into smart, connected healthcare systems.

### 3.2 Track 2: AI-Enabled Care and Triage- Intelligent Pre-Analysis

Applicants should demonstrate how artificial intelligence is used to provide clinical decision support, triage, risk scoring, pattern recognition, or similar healthcare functions.

Technologies designed for resource-constrained environments, including offline or edge-based AI capabilities, are particularly encouraged.

### 3.3 Track 3: Secure Workflow and Referral Systems -Connected Clinical Pathways

Applicants should demonstrate how their technology enables secure, POPIA-compliant information exchange and referral management.

Technologies should support low-bandwidth and offline-first environments and facilitate connectivity between devices, AI outputs, healthcare practitioners, and health system stakeholders.

## 4. Preparing Your Application Information

### 4.1 Applicant and Organisation Information

Applicants must prepare accurate personal and organisational information, including contact details, organisation type, and institutional affiliations where applicable.

For companies, CIPC registration information may be requested.

For academic institutions, universities, or research teams, institutional confirmation or authorisation may be required.

Applicants should also clearly describe their team composition, including relevant qualifications, expertise, and roles within the project.

Strong applications typically demonstrate multidisciplinary technical, clinical, business, or implementation expertise.

### 4.2 Product or Technology Description

The Challenge aligns with the principles of Health Technology Assessment (HTA), which considers the clinical, economic, ethical, legal, social, cultural, organisational, and environmental dimensions of health technologies.

Applicants should prepare a detailed and well-structured description of their product or technology, including:

- A clear description of the product or technology supported by available evidence.
- An explanation of how the product or technology functions.
- The technologies used, including hardware, software, AI, or connected systems where applicable.
- Evidence of testing, validation, piloting, or deployment.
- The intended users and healthcare context.
- The problem being addressed and the value proposition offered.

The description should clearly demonstrate how the innovation improves upon existing approaches, particularly in relation to accessibility, affordability, clinical effectiveness, operational efficiency, and potential health system impact.

**4.3 Innovation and Differentiation**

Applicants should clearly explain what makes their product or technology innovative.

This may include:

- Novel technical approaches;
- New clinical applications;
- Improved performance or usability;
- Proprietary methodologies;
- Intellectual property protections; or
- Distinguishing features compared to existing technologies.

**4.4 Market and Impact Considerations**

Applicants should provide an overview of the target market and intended end users.

Applications should also describe the anticipated impact of the product or technology, including potential:

- Health outcomes;
- Healthcare access improvements;
- Cost efficiencies;

- System-level benefits;
- Economic benefits; and
- Social impact, particularly within resource-limited environments.

**5. Preparing Compliance and Supporting Documents**

Depending on the applicant category, stage of evaluation, and information requested through the application process, applicants may be required to provide supporting documentation such as:

- CIPC registration documents (where applicable);
- SARS Tax Compliance information (where applicable);
- Institutional authorisation or confirmation (for academic applicants);
- Evidence of prototype development, testing, validation, or deployment;
- Product documentation or technical specifications;
- Images, demonstrations, videos, publications, or research outputs; and
- Any other supporting information requested during the evaluation process.

All supporting documentation should be accurate, current, legible, and relevant to the product or technology submitted.

**6. Operational and Implementation Readiness**

Applicants should be prepared to demonstrate the feasibility, sustainability, and scalability of their product or technology.

Depending on the maturity level of the technology, applicants may be asked to describe:

- Operational capacity;
- Commercialisation plans;
- Clinical adoption pathways;
- Partnerships;
- Manufacturing or implementation readiness; and
- Approaches for scaling and sustainability.

Category A applicants should focus on technical feasibility, validation progress, and future development plans.

Category B applicants should demonstrate implementation readiness, adoption outcomes, operational performance, or market traction where available.

**7. Understanding the Evaluation Criteria**

Applications will be assessed against structured evaluation criteria designed to evaluate innovation, impact, feasibility, scalability, and implementation potential.

The criteria below are provided for guidance only. Detailed scoring methodologies, weightings, and adjudication processes are governed by the Competition Terms and Conditions and the official evaluation framework.

Applicants should ensure that their submissions clearly address:

- Innovation and value addition;
- Clinical utility and usability;
- Technical support & security robustness;
- Scalability & health-system integration impact ;
- Team capability and experience; and
- Overall quality, clarity, and completeness of the submission.

**8. Moderation and Quality Assurance**

To promote fairness, consistency, transparency, and accountability, moderation and quality assurance activities may be undertaken throughout the competition process.

These activities may include:

- Verification of eligibility assessments;
- Review of evaluator scoring and rankings;
- Management of conflicts of interest;
- Validation of finalist recommendations; and
- Verification of adjudication outcomes.

All moderation activities will be conducted in accordance with the Competition Terms and Conditions and approved governance processes.

**9. Queries and Review Process**

Applicants may submit queries regarding eligibility, procedural matters, or competition administration through the official communication channels specified on the Competition website.

The Competition Steering Committee reserves the right to review matters relating to:

- Eligibility determinations;
- Administrative errors;
- Procedural concerns; and
- Compliance with published competition requirements.

Decisions of the Competition Steering Committee shall be final, subject to the Competition Terms and Conditions.

**10. Application Readiness Checklist**

Before submitting an application, applicants are encouraged to confirm the following:

1. The product or technology aligns with the Challenge problem statement.
2. The correct TRL category has been selected.
3. Only one category has been selected.
4. Only one primary Challenge track has been selected.
5. All sections of the application form have been completed.
6. All required supporting documentation has been uploaded.
7. The application clearly demonstrates integration across device, AI-enabled functionality, and secure workflow components.
8. The application has been reviewed for accuracy, completeness, and clarity.

Incomplete or inconsistent applications may be excluded during eligibility screening.

## 11. Frequently Asked Questions (FAQ)

### 11.1 How do I determine my TRL level?

Refer to Section 2.1 for detailed TRL definitions.

As a general guide, products or technologies that are still undergoing prototype development and validation are likely to fall within TRL 4–7 (Category A), while technologies that have been fully developed, tested, and deployed are more likely to fall within TRL 8–9 (Category B).

### 11.2 Can academic institutions or students apply?

Yes. Universities, research institutions, academic laboratories, and student-led teams may apply, subject to the eligibility requirements contained in the Competition Terms and Conditions.

Institutional approval or confirmation may be required.

### 11.3 Do I need a working prototype to apply?

For Category A, applicants should generally be able to demonstrate a prototype, proof-of-concept, or validated technology.

Pure idea-stage concepts may not satisfy the minimum eligibility requirements.

For Category B, technologies should be market-ready, operational, or deployed.

### 11.4 Can I apply to more than one track?

No.

Applicants must select one primary track. However, the product or technology should demonstrate integration across device, AI-enabled, and workflow components where relevant.

### 11.5 What type of evidence should I provide?

**Evidence should be appropriate to the maturity of the technology and may include:**

- Prototype demonstrations;
- Validation results;

- Clinical or pilot data;
- User feedback;
- Research outputs;
- Technical assessments; or
- Deployment records.

**11.6 What happens if my application is incomplete?**

Incomplete, inaccurate, or inconsistent applications may be excluded during screening or evaluation.

**11.7 Will I receive feedback if I am unsuccessful?**

Due to the anticipated volume of applications, individual feedback may not be provided. The Competition Organisers may provide general feedback or insights where practicable.

**11.8 Do I need to be available after submission?**

Yes.

Shortlisted applicants may be required to participate in interviews, presentations, demonstrations, due diligence processes, judging activities, or other evaluation-related engagements.

**12. Support and Enquiries**

Applicants requiring assistance or clarification should contact the Challenge support team using the official communication channels published on the Competition website.

Any official notices, clarifications, or updates issued by the Competition Organisers should be read together with the Competition Terms and Conditions.

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