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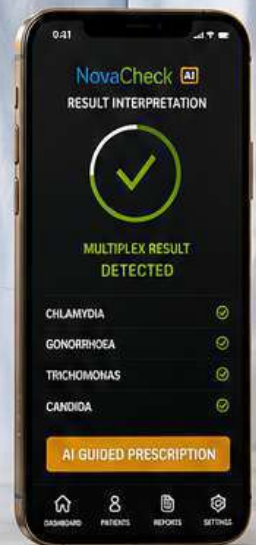
creating endless opportunity

INDEPENDENT FEASIBILITY STUDY

for



NovaLabs
— DIAGNOSTICS —



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Disclaimer

This feasibility study has been prepared by Dream Team Capital as an independent assessment of the commercial, technical, financial, and operational viability of Nova Labs Women's Health Care Diagnostics NPC. It has been compiled in good faith using information provided by the organisation's Board and founding team, supplemented by publicly available industry data, government publications, and secondary research sources, and reflects a deeper analytical review intended to meet the standard expected by Development Finance Institutions (DFIs), international donors, and large government funding programmes.

The findings, projections, and recommendations contained herein are based on assumptions and information available at the time of preparation. Dream Team Capital does not warrant the accuracy, completeness, or currency of any information supplied by third parties. Financial projections, sensitivity ranges, and scenario analyses are inherently uncertain and are illustrative of the range of plausible outcomes rather than guarantees. Actual results may differ materially from those projected, and the organisation's cash flow forecasts assume the successful and timely raising of the donor and grant capital described in this study.

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1. Executive Summary

1.1 Organisational Overview

Nova Labs Women's Health Care Diagnostics NPC is a newly registered South African non-profit company established to close the sexual and reproductive health diagnostic gap faced by women and girls in under-served communities. The organisation will establish a manufacturing and laboratory operation within the Dube TradePort Special Economic Zone in Durban, KwaZulu-Natal, to produce the NovaCheck AI multiplex lateral flow rapid diagnostic test kit for sexually transmitted infections (STIs), detecting bacterial, viral, fungal, and protozoal infections from a single sample in under 20 minutes, with an AI-driven antibiotic guidance module compressing the diagnosis-to-treatment pathway to under 45 minutes.

Field	Detail
Registration No.	2026/518697/08
Enterprise Type	Non-Profit Company (NPC), no shareholders, no distributable profit
Registered	1 July 2026
Location	3 Coull Drive, Dube TradePort SEZ, La Mercy, Durban, KwaZulu-Natal, 4399
Regulatory Status	SAHPRA registration in progress
Financial Year End	February

1.2 Purpose of the Feasibility Study

This feasibility study evaluates the technical, commercial, financial, regulatory, governance, and operational viability of establishing Nova Labs Women's Health Care Diagnostics NPC as a sustainable, public-benefit going concern. The central question is not whether the venture can generate a competitive return for shareholders - it has none - but whether it can convert donor, grant, and blended capital into a durable, cost-effective, and scalable public health intervention, governed to a standard that satisfies institutional funders.

1.3 Objectives of the Study

- Assess the size and growth trajectory of the South African STI diagnostics market and the scale of unmet need among women and girls.
- Evaluate the technical feasibility, manufacturing readiness, and regulatory pathway for the multiplex diagnostic kit.
- Project capital requirements, operating costs, cost-recovery income, and the pathway to financial sustainability, including sensitivity and scenario analysis.
- Assess the organisation's governance framework, internal controls, and operational readiness against the standard expected by DFIs and institutional donors.
- Identify key risks - strategic, financial, technical, cybersecurity, regulatory, environmental, and reputational - specific to a donor-funded non-profit model, with defined ownership and monitoring methodology.
- Quantify anticipated social and public health impact and define measurable outcomes and KPIs over a five-year horizon.

1.4 Scope and Methodology

This study draws on the organisation's Non-Profit Business Plan and five-year financial model, supplemented by secondary research, public STI surveillance data, and analytical modelling conducted by Dream Team Capital, including illustrative sensitivity and scenario analysis (Section 9.7-9.8) constructed specifically for this study. Where figures are drawn directly from the organisation's own financial model they are presented as such; where Dream Team Capital has constructed an estimate, range, or scenario for illustrative purposes, this is stated explicitly.

1.5 Investment and Funding Rationale - Why Now

- **Unmet, quantified need:** documented STI prevalence exceeding 40% among adolescent girls and young women in KwaZulu-Natal and the Western Cape represents a public health emergency that existing imported, single-target testing infrastructure is not designed to address at scale.
- **First-mover, non-competitive positioning:** no local manufacturer currently offers a multiplex, AI-enabled STI kit; every year of delay allows the diagnostic gap to widen and cedes the local-manufacturing advantage to potential future entrants.
- **Regulatory and policy tailwind:** the National Health Insurance rollout and national AMR stewardship programmes are actively creating procurement and policy demand for exactly this category of point-of-care, test-before-treat solution.
- **Capital-efficient de-risking:** the funding requirement is phased against clear milestones (Section 9.1), so funders are not asked to commit R59.5 million upfront but to fund success sequentially, with each tranche contingent on the prior phase's technical and regulatory outcomes.
- **A structurally mission-locked recipient:** the non-distribution constraint (Section 2.2) gives funders assurance that capital deployed cannot be converted into private equity value, addressing a common funder concern when supporting technology-enabled health ventures.

1.6 Anticipated Social Impact at a Glance

The table below summarises the organisation's core anticipated impact metrics over the five-year forecast period, drawn from the Non-Profit Business Plan and the financial model, together with derived estimates clearly marked as such.

Metric	Year 1-2	Year 5 / Cumulative
Direct jobs created	10-15 (Year 1) rising to ± 26 (Year 2)	± 26 permanent positions sustained, plus outreach and campaign roles
Women's participation	Board and workforce policy adopted	Minimum 50% women across the workforce, targeted management representation
Cost-recovery kits sold (illustrative, derived from turnover and blended pricing)	Est. 6,000-13,000 kits (Year 1)	Est. 150,000-250,000+ kits (Year 5), before subsidised/donated volumes
Subsidised and donated kits	Programme established, funded from surplus and grant income	Growing year-on-year in line with surplus reinvestment (Section 9.5)
Community health education sessions	Programme launched with facility fit-out	Scaling annually with the community access allocation
Epidemiological data sharing with NDoH	Framework established during regulatory phase	Ongoing, anonymised, real-time surveillance contribution

The illustrative kit-volume estimates above are derived by Dream Team Capital from the organisation's own turnover forecast divided by a blended average selling price across the single-target (R75) and multiplex (R350) product lines; they are presented as an indicative range only, since the underlying financial model does not itself specify a unit sales split. The organisation is recommended to track and report actual kit volumes from Year 1 (see Section 9.11 and Section 12.5).

1.7 Total Funding Requirement and Deployment

Based on the organisation's own five-year cash flow model, which assumes no debt or equity financing, the cumulative funding requirement peaks at approximately R59.5 million by the end of Year 3, before the organisation's own operating surpluses begin to close the gap. Of this, capital expenditure on facility fit-out and manufacturing equipment (per the Fixed Asset Investment Schedule) accounts for approximately R52.8 million (circa 89%), with the balance of approximately R6.7 million (circa 11%) attributable to funding working capital through the pre-

revenue and early cost-recovery period, consistent with the four priority funding categories set out in the Non-Profit Business Plan.

Funding Category	Approx. Share	Purpose
Regulatory and product validation	Embedded in Year 1 opex	Clinical validation, SAHPRA licence application, IVD registration
Facility and manufacturing set-up	±89% (±R52.8m)	Dube TradePort SEZ fit-out, GMP/ISO 13485 certification, lateral-flow manufacturing equipment, land and buildings, motor vehicles (Years 1-3)
Working capital	±11% (±R6.7m)	Raw materials, staff costs, and operating expenses through the pre-revenue and early cost-recovery period
Community access programme	Funded from surplus from Year 2	Subsidised and donated kits, community health education, outreach

Funders should treat the R59.5 million figure as a multi-year, milestone-gated fundraising target rather than a single upfront grant request; disbursement is recommended to be phased and contingent on the de-risking milestones set out in Section 12.4.

1.8 Implementation Timeline

Phase	Indicative Timing	Key Milestones
Phase 1: Funding Close & Regulatory Initiation	Months 1-6	Initial grant/donor capital secured; SAHPRA pre-submission consultation; facility lease and design finalised
Phase 2: Facility Fit-Out & Registration	Months 6-18	GMP/ISO 13485 certification; manufacturing equipment installed; SAHPRA Medical Device Establishment Licence and IVD registration secured
Phase 3: Production Ramp-Up & Market Entry	Months 18-24	First commercial batches released; public sector pilot programmes; initial cost-recovery sales commence (Year 1-2 of financial model)
Phase 4: Scale-Up & Community Access Roll-Out	Year 2-3	Multi-province public sector supply; subsidised/donated kit programme scaled; facility capacity expansion (land, buildings, additional equipment)
Phase 5: Sustainability & Expansion	Year 4-5	Operating surpluses fund a growing share of the community access programme; geographic expansion planning; reduced marginal reliance on new donor capital

1.9 Five-Year Measurable Outcomes

Outcome	Year 1	Year 3	Year 5
Turnover (cost-recovery income)	R2.11m	R32.72m	R38.14m
Gross margin	49%	93%	93%
Reinvestable surplus (after tax)	-R4.16m (deficit)	R1.94m	R5.80m
Permanent jobs	10-15	±26	±26+
Break-even revenue	R13.65m	R29.87m	R29.60m
Cumulative funding drawn (illustrative)	R8.79m	R59.49m (peak)	Declining, residual ±R37.2m

1.10 Evidence-Based Competitive Advantage

The organisation's competitive position rests on verifiable, structural facts rather than aspirational claims. No current South African manufacturer - commercial or non-profit - combines local manufacture, multiplex pathogen detection, and AI-driven prescription support in a single product (Section 4.5). ICT Diagnostics, the only local manufacturer of comparable rapid tests, offers single-panel products only. FAMKA and Humor Diagnostica are importers exposed to currency and supply risk, with no local manufacturing or AI integration. This is a structural gap in the market, evidenced by the absence of a competing product specification anywhere in the publicly available competitor literature reviewed for this study, rather than a claim of superiority based on unverified performance data. The organisation's own clinical validation data, once generated during the regulatory phase (Section 7.4), should be used to substantiate accuracy and performance claims in future funder communications.

1.11 Why the NPC Model Is More Sustainable Than Traditional Grant-Funded Healthcare Initiatives

Many donor-funded healthcare initiatives in South Africa are structured as pure cost centres: 100% of programme cost is met by grant income indefinitely, with no internally generated revenue stream, so the programme's scale is permanently capped by, and fully exposed to, the funding cycle of its donors. Nova Labs Women's Health Care Diagnostics NPC is structured differently, and the difference is the basis of its sustainability case:

- **A blended, not purely grant-dependent, income model:** cost-recovery sales to public sector, private healthcare, and direct-to-consumer channels are projected to fund an increasing share of operating costs from Year 2 onward (Section 9.5), so donor capital is used to build productive capacity rather than being consumed entirely by recurrent programme cost.
- **A self-funding cross-subsidy for the free/subsidised programme:** unlike a grant-funded clinic that must raise new donor capital for every free test provided, this model's own cost-recovery surplus (93% gross margin at scale) directly and automatically funds the subsidised and donated kit programme (Section 9.5), decoupling the pace of free access expansion from the pace of new grant fundraising.
- **A declining marginal funding requirement:** the financial model shows operating cash flow turning strongly positive from Year 3 (Section 9.6), meaning that, unlike many grant-funded programmes whose annual funding ask grows indefinitely with beneficiary numbers, this organisation's annual external funding requirement is designed to shrink over time even as beneficiary reach grows.
- **An asset base, not just a service, is built:** donor capital is converted into owned manufacturing infrastructure (Section 9.1, Fixed Asset Schedule) with a useful life well beyond the initial funding period, rather than being entirely consumed by once-off service delivery.

This does not eliminate donor dependency - the model still requires approximately R59.5 million in phased capital before it becomes substantially self-funding, and a residual funding requirement persists even in Year 5 (Section 9.6) - but it materially differentiates the organisation from a pure grant-recipient model and gives funders a credible basis to expect a shrinking, rather than perpetually growing, funding relationship.

2. Organisational Description

2.1 Legal Structure and Governance

Nova Labs Women's Health Care Diagnostics NPC is registered as a non-profit company under the Companies Act of 2008, registered with CIPC on 1 July 2026 under registration number 2026/518697/08, with its registered office at 3 Coull Drive, Dube TradePort Special Economic Zone, La Mercy, Durban, KwaZulu-Natal, 4399. The organisation is registered for tax under reference number 9088147302, with a February financial year end, and is governed by a Board of Directors rather than shareholders.

2.2 Non-Distribution Constraint and Ownership Structure

No surplus, dividend, or asset value may be distributed to any director, member, or other private person, either during operation or upon winding-up, when remaining assets must transfer to another non-profit entity with similar objectives. This is the central governance distinction from a conventional commercial start-up and the primary basis for the organisation's eligibility for donor, grant, and CSI capital unavailable to for-profit entities.

Full Name	Role	Location
Dr Vischal Dhurumraj	Founding Director, Managing Director & R&D Lead	La Mercy, Durban
Ms Daksha Maharaj	Director	Ladysmith, KZN
Mr Gavin Mark Phillips	Director	Chatsworth, KZN

Mr Yash Dhurumraj, a founding contributor to the underlying diagnostic technology, resigned as a director on 7 July 2026 following the organisation's conversion to a non-profit company, and continues in a technical advisory capacity on the AI platform. Funders should note that the NPC is a distinct legal entity from any commercial vehicle associated with the same underlying diagnostic technology, and that grant and donor funds raised by the NPC must be applied exclusively to the NPC's own public-benefit activities, consistent with the non-distribution constraint and standard conflict-of-interest governance (Section 2.5).

2.3 Key Personnel, Scientific Leadership and Track Record

Dr Vischal Dhurumraj, Managing Director and R&D Lead, brings over 15 years of experience in GMP-compliant manufacturing, infection control, and healthcare business management as founder of Ivy Jade Pharmaceuticals, a track record that included establishing GMP-compliant production and quality systems from the ground up - directly relevant capability for the facility fit-out and ISO 13485 certification described in Section 6 and Section 8. The organisation continues to draw on scientific and regulatory advisory relationships established during the founding development phase of the underlying diagnostic technology, including collaboration with academic and clinical research partners in KwaZulu-Natal. Formalising these relationships into a documented, named scientific advisory board - with individual members' qualifications, prior publications, and regulatory experience disclosed to funders - is recommended as a near-term governance action (Section 12.3), both to strengthen technical credibility and to reduce key-person risk (Section 11.3).

2.4 Governance Framework: Board Responsibilities and Decision-Making

The Board of Directors holds overall fiduciary and strategic responsibility for the organisation, including approval of the annual budget and business plan, oversight of financial management and reporting, approval of major capital expenditure and grant agreements above a defined threshold, appointment and oversight of the Managing Director, and oversight of compliance with donor and grant funding conditions. Day-to-day executive management is delegated to the Managing Director, who is accountable to the Board.

As the organisation scales, the Board intends to formalise a documented decision-making framework specifying: which decisions require full Board approval versus Managing Director authority (a delegation of authority matrix); quorum and voting requirements for Board meetings; and the frequency of Board meetings (recommended quarterly

at minimum, with additional meetings convened for material funding decisions). Establishing a dedicated Finance and Audit Sub-Committee, and commissioning an annual independent audit, are treated as priority governance actions in Section 12.3, consistent with standard practice for non-profit companies of this scale and a near-universal pre-condition for DFI and major institutional donor funding.

2.5 Governance Policies

The following policies are recommended for Board adoption prior to, or as an early condition of, first grant disbursement, and are treated as standard institutional-donor due diligence requirements:

- **Conflict of Interest Policy:** requiring Board members and senior staff to declare any personal, family, or business interest in transactions involving the organisation - including, specifically, any relationship with commercial entities associated with the underlying diagnostic technology (Section 2.2) - with declared conflicts recorded in a register and managed through recusal from the relevant decision.
- **Code of Ethics:** setting expected standards of integrity, confidentiality, and professional conduct for directors, staff, and contractors, including a whistle-blowing mechanism for reporting suspected misconduct.
- **Procurement Policy:** requiring competitive quotation or tender processes above defined thresholds, documented supplier selection criteria, and separation of requisition, approval, and payment authority, consistent with the supplier risk management approach in Section 8.9.
- **Financial Management and Delegation of Authority Policy:** setting expenditure approval limits by role, bank signatory requirements (recommended dual signatory for all payments above a defined threshold), and the annual budgeting and reforecasting cycle.
- **Grant and Donor Compliance Policy:** a standard framework for tracking reporting obligations, milestone conditions, and permitted use of funds across all grant agreements, aligned with Section 10.19.

2.6 Succession Planning

The organisation currently carries material key-person concentration in Dr Dhurumraj, who holds both the Managing Director and R&D Lead roles. Recommended succession measures include: cross-training a deputy or senior technical manager in core regulatory and production oversight responsibilities during Year 1-2; documenting critical institutional knowledge (assay design rationale, supplier relationships, regulatory correspondence) in a structured knowledge-management system rather than relying on individual memory; and formal Board-level succession contingency planning, addressed further under key-personnel risk in Section 11.3.

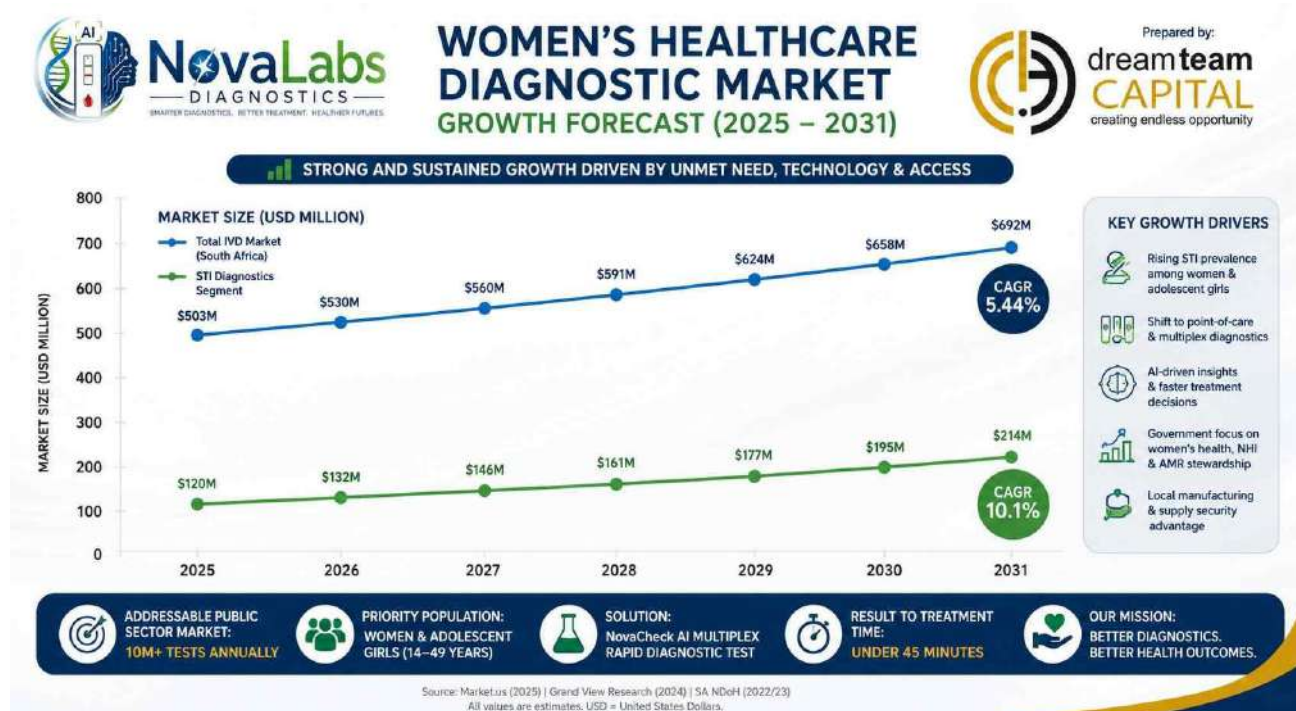
2.7 Organisational Capability and Operational Readiness

The organisation's current operational readiness reflects its status as a newly registered entity building toward full operational capacity: governance structures (Board, registration, tax reference) are in place; technical and scientific foundations exist from prior development work; and the facility, manufacturing equipment, and full staff complement remain to be established, funded, and commissioned as set out in the implementation timeline (Section 1.8). Readiness gaps explicitly identified by this study - PBO/section 18A tax status, a formalised technology licence or assignment agreement, a dedicated finance and audit sub-committee, and documented governance policies - are treated as priority pre-funding or early-funding actions in Section 12.3, consistent with the standard a DFI or major institutional donor would expect to see closed before or shortly after first disbursement.

2.8 Strategic Partnerships and Collaboration Agreements

The organisation's Non-Profit Business Plan identifies collaboration with academic and clinical research partners in KwaZulu-Natal, and describes intended partnerships with the National Health Laboratory Service, provincial Departments of Health, private hospital groups, pathology laboratories, pharmacy chains, women's health NGOs, and university health services. At the time of this study, these relationships are at varying stages of formalisation. Funders should expect, and the organisation is recommended to prioritise, converting expressions of interest into documented Memoranda of Understanding or letters of intent during the funding phase, both to strengthen the market entry case (Section 4.9) and to provide funders with independently verifiable evidence of institutional buy-in.

3. Industry and Market Overview



3.1 Global and Local Industry Trends

The global in vitro diagnostics (IVD) market is shifting from centralised laboratory testing toward decentralised point-of-care diagnostics, a trend accelerated by COVID-19's demonstration of the public health value of rapid, accessible testing. Multiplex testing - simultaneous detection of multiple pathogens from a single sample - is the fastest-growing segment within point-of-care diagnostics. In South Africa, the IVD market is the largest in Sub-Saharan Africa (approximately 60% of regional sales), and remains characterised by significant import dependence.

3.2 South African Healthcare Expenditure Trends

South Africa's health system operates on a dual-tier basis: a tax-funded public sector serving approximately 80-85% of the population, financed through National Treasury allocations to the National Department of Health and provincial health departments, and a private sector serving the remaining 15-20% through medical scheme membership, which accounts for a disproportionate share of total national health expenditure relative to the population it covers. Public health expenditure has faced sustained fiscal pressure in recent budget cycles, alongside continued policy commitment to the phased implementation of National Health Insurance (NHI), which is intended over time to shift a greater share of diagnostic and primary care procurement toward centrally negotiated, standardised pricing and quality frameworks. This dual pressure - constrained absolute budgets alongside a policy shift toward standardised, centrally procured primary care diagnostics - favours suppliers who can demonstrate both cost-effectiveness and consistent quality compliance, which is the basis of the organisation's cost-recovery pricing and ISO 13485-aligned quality strategy (Sections 6 and 8).

3.3 Diagnostics Industry Growth Drivers

- **National Health Insurance (NHI):** the NHI rollout is expected to expand access to primary healthcare, increasing demand for affordable, decentralised point-of-care diagnostics.
- **Antimicrobial Resistance (AMR):** the National Department of Health's AMR stewardship programmes increasingly emphasise test-before-treat protocols, aligning directly with the AI-driven antibiotic guidance module.
- **Technological Advances:** declining costs for multiplex assay components make multi-pathogen detection more accessible, supporting cost-recovery pricing.

- **Government Localisation Policy:** preferential procurement frameworks favour South African producers, particularly non-profit and public-benefit organisations aligned with national health priorities.
- **Donor and CSI Prioritisation of Women's Health:** growing donor, multilateral, and corporate social investment focus on women's health, HIV/STI prevention, and gender equality (SDG 5) is expanding the pool of capital available to credible, mission-locked non-profit structures.

3.4 International Best Practice Influencing the Market

International experience with decentralised, multiplex point-of-care testing programmes - notably WHO-supported point-of-care HIV and syphilis testing initiatives in sub-Saharan Africa, and multiplex respiratory panel roll-outs in higher-income health systems following the COVID-19 pandemic - has established the operational template the organisation intends to follow: single-visit test-and-treat pathways, decentralisation from central laboratories to primary care and community settings, and integration of digital results reporting into national surveillance systems. WHO pre-qualification pathways and regional regulatory reliance frameworks (referenced in Section 6.11) offer a template for eventual regional expansion once South African registration is secured.

3.5 Future Technology Trends Affecting Diagnostics

- Continued miniaturisation and cost reduction of lateral flow and biosensor components, likely to compress direct unit costs further over the forecast period.
- Increasing integration of computer-vision and machine-learning result interpretation (as used in the NovaCheck AI platform) to reduce reliance on subjective visual reading and improve consistency, particularly relevant in resource-constrained clinic settings.
- Growing regulatory attention to AI-enabled medical devices specifically (Section 6.8-6.9), with SAHPRA's framework for such devices still developing - a trend the organisation must track closely given its own AI-driven prescription workflow.
- Expansion of digital health interoperability standards, increasing the long-term value of the organisation's doctor portal and data-sharing capability, but also raising the bar for data security and standards compliance (Section 6.10).

3.6 Healthcare Policy Changes Influencing Demand

Beyond NHI, relevant policy developments include the National Department of Health's continued prioritisation of adolescent girls and young women as a designated priority population for expanded HIV and STI testing access, national and provincial AMR strategic plans, and the Preferential Procurement Policy Framework Act's continued support for local content and B-BBEE-aligned suppliers in public procurement. Any material changes to any of these policy settings - for example, a reprioritisation of NHI implementation timelines, or a change to local-content procurement preferences - would directly affect the demand and procurement assumptions underlying this study, and is tracked as a strategic risk in Section 11.2.

3.7 Market Size, Growth Rate and Future Demand Forecast

The South African IVD market was valued at approximately USD 503 million in 2025 and is projected to reach USD 692 million by 2031 (CAGR 5.44%). The STD diagnostics segment is growing more rapidly, at approximately 10.1% CAGR globally through 2031. The public sector alone procured approximately 102 million HIV rapid test kits in the 2022/23 financial year at a value of R1.2 billion, illustrating the scale of government demand for rapid diagnostics generally. Applying the same order-of-magnitude reasoning to the STI multiplex category, and given that the addressable public sector market for STI rapid tests exceeds 10 million units annually, sustained double-digit segment growth over the forecast period is a reasonable base-case demand assumption; this is treated as a base-case, not a guaranteed, demand trajectory in the scenario analysis in Section 9.8.

3.8 Macroeconomic Risks Affecting the Industry

- Rand volatility affecting the cost of imported raw materials (nitrocellulose membranes, biochemical reagents), addressed as a specific financial risk in Section 11.3 and modelled in the sensitivity analysis in Section 9.7.
- Elevated domestic interest rates increasing the cost of any future debt financing, relevant should the organisation supplement grant funding with concessional development finance debt.
- Constrained public sector fiscal space limiting the pace of new tender awards and grant disbursement from government sources, reinforcing the funding diversification strategy in Section 10.22.
- Global donor funding contraction in the health sector generally, a macro trend affecting the availability of international donor capital across all recipient organisations, not specific to this venture, but relevant to realistic fundraising pipeline planning (Section 10.18).

4. Market Research and Analysis

4.1 Market Overview

The South African STI diagnostics market operates within the dual healthcare system described in Section 3.2. The National Health Laboratory Service (NHLS) operates approximately 260 laboratories across the public system, processing over 250 million tests annually. The private sector is served by three dominant pathology groups: Ampath, Lancet, and PathCare. The market for rapid STI tests is currently dominated by imported single-target products, with no local manufacturer offering multiplex, AI-enabled kits - the central opportunity the organisation is positioned to fill on a non-profit, cost-recovery basis.

4.2 Target Beneficiary Population and Demographics

The organisation's primary beneficiaries are women and adolescent girls, with initial focus on under-served communities surrounding the Dube TradePort SEZ before provincial and, subject to funding, national expansion. National Department of Health STI surveillance data record estimated national prevalence among the sexually active population (15-49 years) of approximately 22% for HPV, 17% for chlamydia, 15% for gonorrhoea, 7.5% for syphilis, 7% for trichomoniasis, 5% for herpes (HSV-2), and 3.5% for HIV.

Age Group	Key Finding
Adolescent girls, 14-19	62.8% STI prevalence recorded in the Western Cape and 42.5% in KwaZulu-Natal - significantly higher than in women aged 25-35.
Young women, 16-29 (rural KZN)	23.7% prevalence for any STI; chlamydia 17.9%, gonorrhoea 5.0%, trichomoniasis 5.4%.
Women, 30-49	Highest HIV prevalence of any age band, with clinically significant STI co-occurrence, underscoring the need for continued testing access across the adult lifespan.

The addressable public sector market for STI rapid tests exceeds 10 million units annually.

4.3 Market Segmentation and Targeting Strategy

The market is segmented by channel into public sector healthcare facilities, private hospitals and clinics (cost-recovery, cross-subsidising the mission), pathology laboratories, retail pharmacies, and a direct-to-beneficiary channel including the subsidised and donated kit programme. All channels are priced on the same cost-recovery basis. The targeting strategy prioritises the public sector for volume and mission alignment, while private sector channels generate the surplus that cross-subsidises subsidised and donated kits.

4.4 Beneficiary and Partner Analysis

4.4.1 Needs, Preferences, Pain Points and Adoption Barriers

Women and girls face barriers of cost, distance, stigma, fear of judgement, and lack of privacy. Public sector clinics face delayed laboratory turnaround, high STI burden straining resources, and vulnerability to imported-kit supply disruption. Healthcare professionals - the clinicians and nurses who will actually administer the test - present a distinct adoption barrier set: unfamiliarity with a new multiplex format and AI-generated prescription guidance, concern about liability for AI-assisted clinical decisions, and the time cost of training on a new workflow within already stretched clinic schedules. These barriers are directly addressed through the CPD-accredited training and simple, standardised workflow design referenced in Section 8.13 and Section 10.7, and should be tracked as an explicit adoption metric (Section 8.14) rather than assumed away.

Switching barriers from existing diagnostic products are relatively low at the level of the individual test - clinics already stock and rotate between multiple single-target rapid test brands - but are higher at the level of the procurement relationship, where incumbent suppliers (Section 4.5.1) benefit from existing three-year tender relationships and established delivery logistics. This makes public sector tender cycle timing (Section 4.6) a more material barrier than clinical switching cost.

4.4.2 Funding and Partnership Decision-Making Process

Public sector procurement follows a competitive tender process governed by the PPPFA, typically for multi-year contract periods. Donor and grant funding decisions typically follow a proposal, due diligence, and milestone-based disbursement process, evaluating governance, financial transparency, cost-effectiveness per beneficiary, and strategic alignment. CSI partners generally require demonstrable B-BBEE and enterprise or supplier development alignment alongside health impact.

4.4.3 Beneficiary and Partner Personas

- **Public Sector Procurement Officer:** responsible for sourcing diagnostic supplies across hundreds of facilities; motivated by budget compliance, regulatory adherence, and supply reliability.
- **Donor / Grant Programme Officer:** motivated by measurable health outcomes, cost per beneficiary reached, and robust financial and impact reporting.
- **Corporate Social Investment Manager:** motivated by verifiable community impact, B-BBEE scorecard alignment, and a credible non-profit partner with strong governance.
- **Beneficiary - Woman or Adolescent Girl:** motivated by speed, privacy, dignity, and affordability of testing.

4.5 Competitive and Collaborative Landscape

4.5.1 Direct Competitors and Pricing Comparison

ICT Diagnostics is a Cape Town-based manufacturer of single-panel rapid point-of-care tests for HIV, malaria, and COVID-19, with established SAHPRA approvals and private sector distribution partnerships, but no multiplex STI panel or AI integration. FAMKA is an importer and distributor of single-target STI kits reliant on imported products, exposed to currency volatility. Humor Diagnostica imports a commoditised range of rapid tests from China and the United Kingdom, competing on price with no differentiation.

Supplier	Product Type	Local Manufacture	Multiplex	AI Integration	Indicative Positioning
Nova Labs Women's Health Care Diagnostics	Multiplex STI kit	Yes	Yes	Yes	Cost-recovery, non-profit
ICT Diagnostics	Single-panel rapid test	Yes	No	No	Commercial, established SAHPRA approval
FAMKA	Single-target STI kit (imported)	No	No	No	Commercial, currency-exposed
Humor Diagnostica	Commoditised rapid tests (imported)	No	No	No	Commercial, price-competitive

4.5.2 Indirect Competitors

Multinationals including Abbott, Roche, and Becton Dickinson maintain substantial R&D resources and global distribution networks. While currently focused on laboratory-based testing, they could enter the point-of-care STI market if conditions become sufficiently attractive - though none currently offer a non-profit, access-first distribution model.

4.5.3 Competitive Mapping

No current provider in South Africa offers the organisation's combined proposition of local manufacture, multiplex detection, AI integration, and a non-profit, access-first distribution model. As a non-profit, the organisation is positioned to collaborate with, rather than purely compete against, the NHLS, provincial health departments, and women's health NGOs.

Differentiator	Nova Labs Women's Health Care Diagnostics	Commercial Competitors
Local manufacturing	Yes	Partial (ICT Diagnostics only)
Multiplex STI capability	Yes	No
AI-driven antibiotic guidance	Yes	No
Non-profit, mission-locked model	Yes	No
Subsidised access for low-income women	Yes	No

4.6 Procurement Behaviour of Public Healthcare Buyers

Public sector procurement decisions are made by multi-member procurement committees evaluating bids against price, local content, B-BBEE status, and technical compliance, typically for contracts of three years' duration. Committees generally favour suppliers with an existing SAHPRA registration, a demonstrable local manufacturing footprint, and a track record of on-time delivery; new entrants without a delivery track record often first secure smaller pilot or single-source procurement before larger tender awards, which is why the organisation's pilot programme strategy (Section 10.5) is treated as a prerequisite to, rather than a substitute for, larger-scale tender participation.

4.7 Reimbursement Environment

Within the public sector, diagnostic test kits are procured directly by government rather than reimbursed on a fee-for-service basis, so the organisation's revenue model does not depend on a separate medical scheme reimbursement code in that channel. Within the private sector, uptake by pathology laboratories and private hospital groups may be influenced by whether the test attracts a distinct National Health Reference Price List (NHRPL) or scheme-specific reimbursement code; securing appropriate coding recognition, once SAHPRA registration is complete, is recommended as an explicit private-sector market access work stream, since its absence would constrain private channel uptake even where clinical demand exists.

4.8 Market Penetration Assumptions and Justification for Projected Market Share

The financial model's revenue trajectory (turnover growing from R2.1 million in Year 1 to R38.1 million in Year 5) implies a market penetration path that remains a small fraction of the addressable public sector market of 10 million-plus units annually, even under the higher end of the illustrative kit-volume range in Section 1.6. This is a conservative, not an aggressive, penetration assumption: it does not require the organisation to displace incumbent suppliers at scale, only to secure an initial provincial foothold (KwaZulu-Natal, per Section 10.4) and a small number of private sector and direct-to-consumer accounts. The organisation is nonetheless recommended to commission an independent bottom-up market sizing exercise - by province, facility count, and estimated testing volume per facility - once SAHPRA registration is imminent, to replace this top-down justification with a fully evidenced penetration model ahead of large-scale tender participation.

4.9 Partnership Development Strategy with Healthcare Institutions

The partnership development strategy proceeds in three stages: (i) pilot and evaluation partnerships with a small number of clinics and hospitals in KwaZulu-Natal, generating real-world performance data at no or reduced cost; (ii) formal supply agreements with provincial Departments of Health and the NHLS, building on pilot evidence; and (iii) longer-term framework or preferred-supplier arrangements with private hospital groups and pathology laboratories. Each stage is designed to generate the evidence and track record required to unlock the next, consistent with the procurement behaviour described in Section 4.6.

4.10 Market Barriers and Challenges

- Regulatory timelines: SAHPRA registration for novel IVDs typically requires 12-24 months.
- Procurement cycle length: public sector procurement cycles are multi-year; missing a tender cycle can result in a lengthy wait.

- Distribution relationships: private sector access requires building relationships with pathology groups and pharmacy chains.
- Beneficiary stigma: limits uptake and requires sustained community health education investment.
- Donor funding cyclical: requires a diversified funding base (Section 10.22).

4.11 Regulatory Environment

Medical devices and IVDs in South Africa are regulated by SAHPRA under the Medicines and Related Substances Act of 1965. Manufacturers must obtain a Medical Device Establishment Licence under section 22C(1)(b), demonstrating GMP compliance, and ISO 13485 certification is mandatory. The NovaCheck AI kit will likely be classified as a Class C or D medical device, requiring comprehensive technical documentation and clinical validation evidence, and the platform must comply with POPIA for patient health data. As a non-profit supplying into public procurement, the organisation will register on the Central Supplier Database and comply with the PFMA and PPPFA. Critically, NPC registration is distinct from Public Benefit Organisation (PBO) tax status under section 30 of the Income Tax Act; the organisation does not yet hold PBO or section 18A approval (Section 11.4, Section 12.3).

4.12 Market Entry Barriers

4.12.1 Beneficiary and Healthcare Professional Adoption Barriers

Beneficiary adoption is significantly influenced by stigma, fear of judgement, and privacy concerns, addressed through the discreet testing option including at-home use. Residual behavioural barriers include limited public awareness of STI risk, fatalistic attitudes, and competing life priorities. As set out in Section 4.4.1, healthcare professional adoption carries its own distinct barrier set - training time, liability concerns around AI-assisted prescribing, and workflow disruption - requiring dedicated training investment rather than being addressed solely through beneficiary-facing marketing.



5. Opportunities for Growth and Expansion



5.1 New Product and Service Development / Future Product Roadmap

- **Expanded pathogen coverage:** an enhanced multiplex panel offering broader screening within the same manufacturing platform, subject to future SAHPRA registration.
- **HIV-syphilis combination kits:** addressing antenatal screening to prevent mother-to-child transmission, aligned with WHO elimination targets.
- **Subsidised and donated kit programme:** a defined share of cost-recovery surplus and grant income allocated to free and subsidised kits for low-income women.
- **Community health education services:** sexual and reproductive health education delivered alongside testing, funded from the same blended income base.

5.2 Phased Expansion Strategy

Expansion is phased to match funding availability and de-risking evidence: Phase 1 - single-facility manufacturing and KwaZulu-Natal public sector supply (Years 1-2); Phase 2 - multi-province public sector supply and private sector channel development (Years 2-3); Phase 3 - facility capacity expansion (land, buildings, additional equipment, per the Fixed Asset Schedule) and national roll-out (Years 3-4); Phase 4 - regional (SADC) export exploration, contingent on continued funding and demonstrated domestic impact (Year 5 onward).

5.3 Geographic and Demographic Expansion / Commercialisation Beyond South Africa

The organisation will begin in KwaZulu-Natal, leveraging the Dube TradePort SEZ location and King Shaka International Airport logistics access, before expanding to Gauteng, the Western Cape, and the Eastern Cape. Longer-term regional expansion into the SADC region - where similar disease burdens and comparatively accessible regulatory frameworks exist, given shared reliance on WHO-aligned regulatory reference frameworks - is a future opportunity contingent on continued funding and demonstrated domestic impact. Any cross-border activity would need to be structured carefully to preserve the organisation's non-profit, non-distribution status and to comply with the receiving country's own non-profit or NGO registration requirements.

5.4 Technology Licensing Opportunities

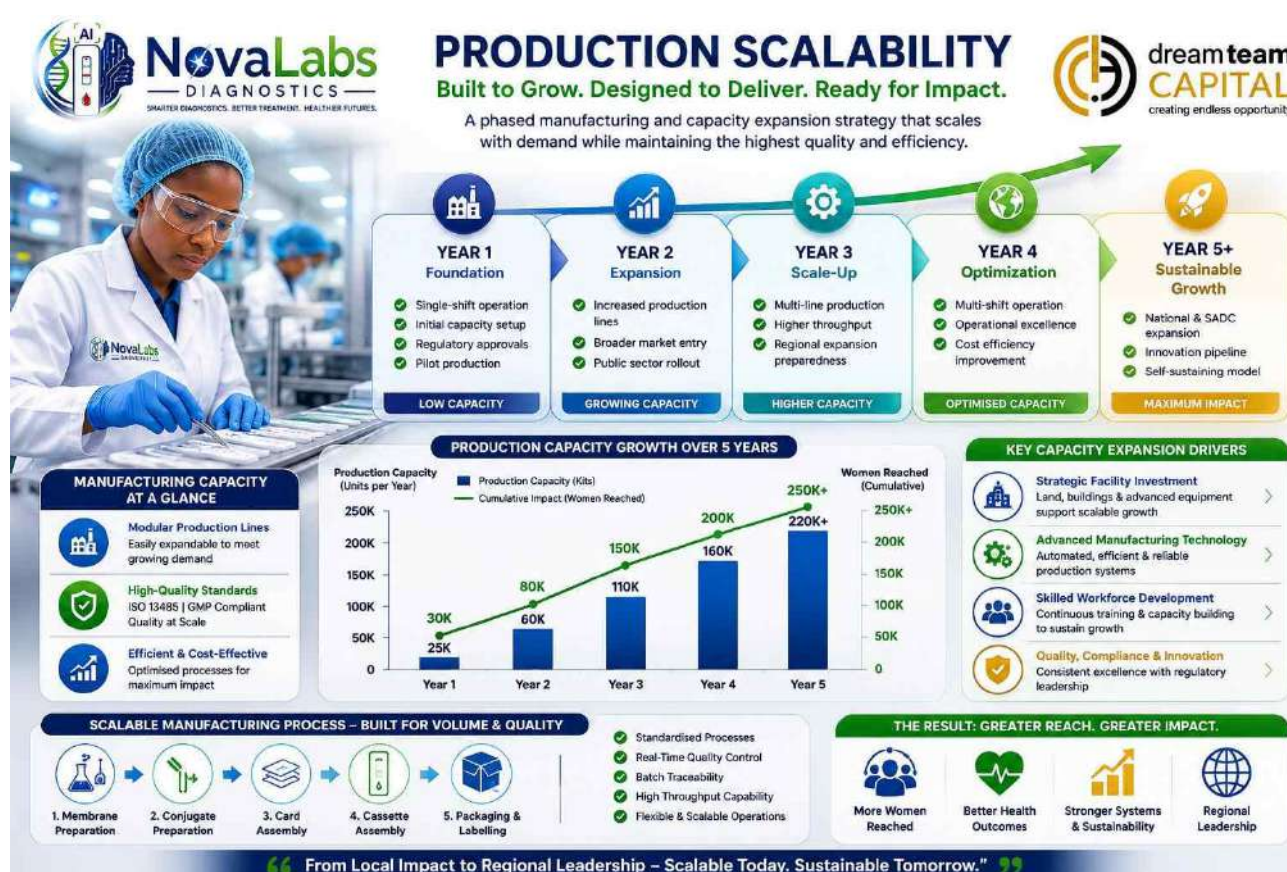
Should the organisation's AI-driven prescription workflow or multiplex assay design prove independently valuable beyond its own manufacturing operation, a structured technology licensing arrangement - to other non-profit or public health manufacturers in other jurisdictions, on terms consistent with the organisation's public-benefit mandate - could generate a supplementary, non-dilutive income stream. Any such arrangement would need to be assessed against, and structured to comply with, the non-distribution constraint (Section 2.2) and the underlying IP/licensing position described in Section 6.11 and Section 7.8.

5.5 Research Collaboration Opportunities

Formalised research collaboration with KwaZulu-Natal academic and clinical research institutions (Section 2.3, Section 7.6) offers opportunities for joint clinical validation studies, co-authored peer-reviewed publications strengthening the organisation's scientific credibility with funders, and access to postgraduate research capacity for ongoing assay improvement, at limited direct cost to the organisation.

5.6 Manufacturing Expansion Strategy

Manufacturing capacity is planned to scale progressively with facility investment: a modest single-shift operation in Year 1, expanding through additional equipment, land, and buildings by Year 3 (Section 9, Fixed Asset Schedule), and potential multi-shift operation from Year 3-4 onward if demand growth requires it. Capacity expansion decisions are recommended to be triggered by defined utilisation thresholds (Section 8.2) rather than calendar dates alone, to avoid premature capital commitment ahead of demonstrated demand.



5.7 Long-Term Sustainability Beyond Donor Funding

The organisation's long-term sustainability case rests on the trajectory described in Section 1.11: a growing share of operating costs met from cost-recovery income, a self-funding subsidised kit programme, and a declining marginal external funding requirement from Year 3 onward. Full independence from external funding is not projected within the five-year forecast horizon - a residual funding requirement persists even in Year 5 (Section 9.6) - but the trend is

toward materially reduced, rather than static or growing, donor dependency, which is the standard a DFI or major donor typically expects to see evidenced in a credible sustainability case.

6. Technical Feasibility

6.1 Detailed Product and Service Description

The NovaCheck AI multiplex test kit is a lateral flow rapid diagnostic device detecting bacterial, viral, fungal, and protozoal STIs from a single urine, blood, or swab sample. The kit comprises a plastic cassette housing a nitrocellulose membrane onto which capture antibodies or antigens specific to each target pathogen are immobilised in discrete test lines, with control lines verifying test validity. A QR code links to the NovaCheck AI mobile application, which interprets results using computer-vision analysis of the test line pattern, generates a personalised clinical report with treatment recommendations, and facilitates automated prescription generation, with the complete testing-to-treatment process designed for completion in under 45 minutes. A complementary web-based doctor portal enables healthcare professionals to register patients, access results, and manage records (Section 8.15).

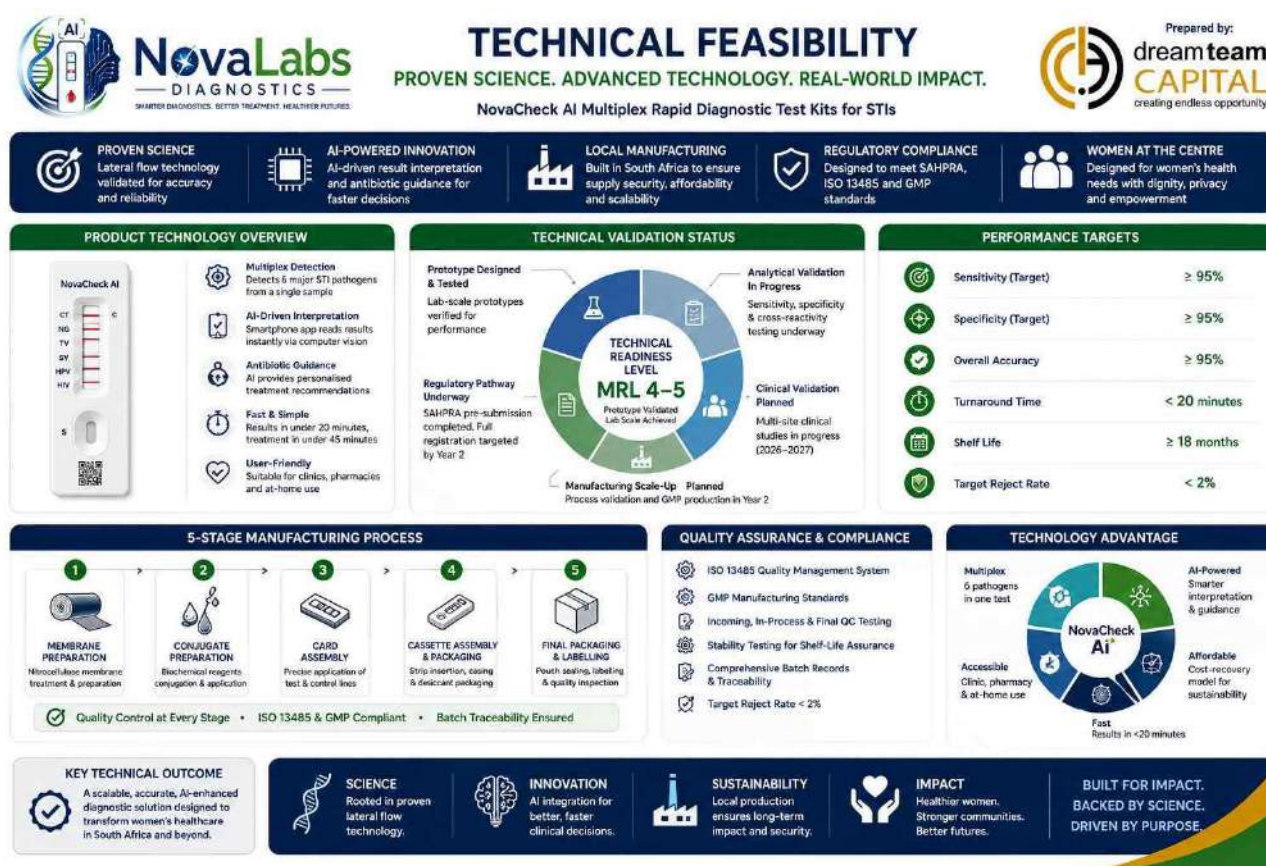


6.2 Manufacturing Readiness Level

Using a manufacturing readiness level (MRL) framework consistent with medical device industry practice, the organisation's technology is assessed as being at approximately MRL 4-5: prototype design and laboratory-scale production have been demonstrated from the underlying technology's prior development work, but pilot-scale production on qualified manufacturing equipment, process validation at commercial scale, and full ISO 13485 quality system certification remain outstanding and are the explicit purpose of the Year 1-2 funding phase (Section 1.8, Section 9.1). Funders should treat MRL 7-8 (validated, qualified production ready for commercial-scale output) as the target milestone for release of the facility and manufacturing tranche of funding.

6.3 Production Scalability

The five-stage lateral flow manufacturing process (membrane preparation, conjugate preparation, card assembly, cassette assembly and packaging, and final packaging) is a well-established, modular process in the diagnostics industry, meaning capacity scales primarily through additional equipment lines and shifts rather than through fundamental process redesign. This supports the phased capacity expansion strategy in Section 5.6 and reduces (without eliminating) technical execution risk relative to a novel, unproven manufacturing process.



6.4 Quality Assurance Methodology

The quality management system (QMS) will be aligned with ISO 13485 and GMP standards from inception, encompassing: incoming quality control of raw materials against supplier certificates of analysis; in-process quality control at each of the five manufacturing stages, with defined in-process specifications and equipment calibration checks; finished-product testing of every batch against sensitivity, specificity, and functional performance criteria; and stability testing to establish and verify shelf-life claims. Comprehensive batch records will document raw material lot numbers, equipment used, environmental conditions, and personnel involved. The target reject rate is less than 2% of finished product, consistent with industry benchmarks for established lateral flow operations.



6.5 Validation Protocols

Analytical validation (sensitivity, specificity, precision, and cross-reactivity testing against known-status samples) and clinical validation (performance against a reference-standard comparator method in a defined patient population) are both required as part of the SAHPRA submission dossier. The organisation's Research and Development Plan (Section 7.4) sets out the clinical validation programme required to generate this evidence, which is treated as a critical-path, milestone-gated activity ahead of full commercial launch.

6.6 Product Life Cycle

The NovaCheck AI test kit is at the introduction stage of its product life cycle. Prototype development has been completed, but full deployment is contingent on SAHPRA registration (12-18 months from commencement of funded activity). The growth stage is expected in year two or three following registration, coinciding with the organisation's transition to public sector supply at scale and growth of the subsidised kit programme.

6.7 Product Differentiation and Innovation

- **Multiplex capability:** simultaneous detection of multiple pathogens from a single sample, ensuring co-infections affecting fertility and pregnancy outcomes are not missed.
- **AI-driven prescription workflow:** automates the pathway from test result to treatment prescription.
- **Real-time epidemiological intelligence:** anonymised, aggregated data shared with the National Department of Health strengthens national women's health surveillance.
- **Local manufacturing advantage:** manufacturing within the Dube TradePort SEZ eliminates import lead times, currency exposure, and supply chain risk.

6.8 Cybersecurity Considerations Relating to AI

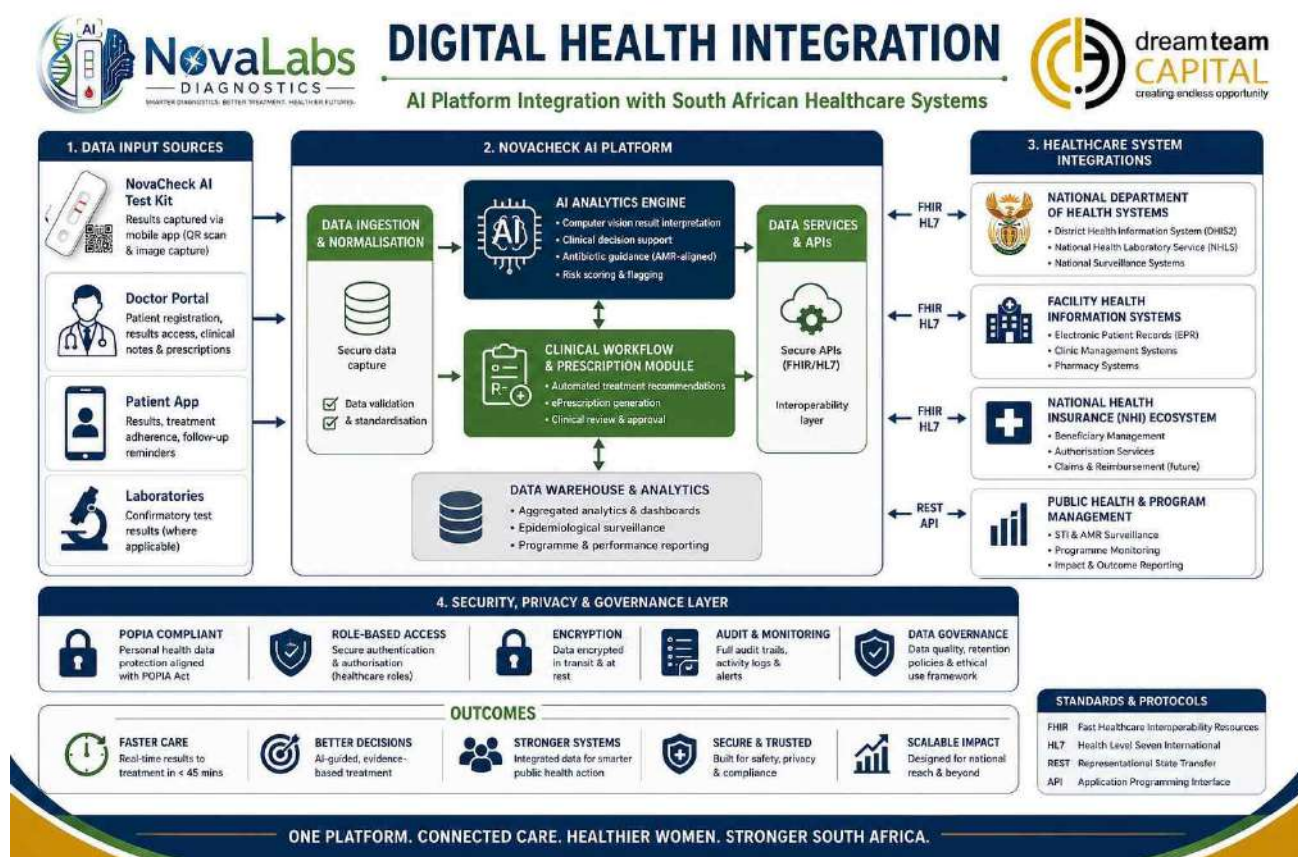
The NovaCheck AI mobile application and doctor portal process sensitive patient health information and generate AI-assisted clinical recommendations, creating a cybersecurity risk surface distinct from the physical manufacturing operation. Recommended controls include: encryption of patient data in transit and at rest; role-based access control on the doctor portal, limiting result and record access to authorised, authenticated clinical users; regular penetration testing and vulnerability scanning of the application and portal prior to and following launch; a documented incident response plan specifically for a data breach or AI-system compromise (Section 11.10); and monitoring for adversarial manipulation of the computer-vision result-interpretation model, given the direct clinical consequence of a manipulated or erroneous result. These are addressed further as a specific risk category in Section 11.14.

6.9 Software Maintenance and Updates

The NovaCheck AI platform requires an ongoing software maintenance function distinct from physical product manufacturing, covering: routine security patching and dependency updates; monitoring and retraining of the computer-vision interpretation model as real-world result data accumulates, to guard against model drift; version control and change management, with any change to the clinical decision-support logic subject to a documented review and revalidation process before deployment; and a defined support and uptime commitment to institutional users of the doctor portal. Resourcing this function - either through the technical advisory relationship described in Section 2.3 or a dedicated in-house role - should be an explicit line item in the operating budget from Year 1 (Section 8.14).

6.10 Interoperability with Healthcare Systems

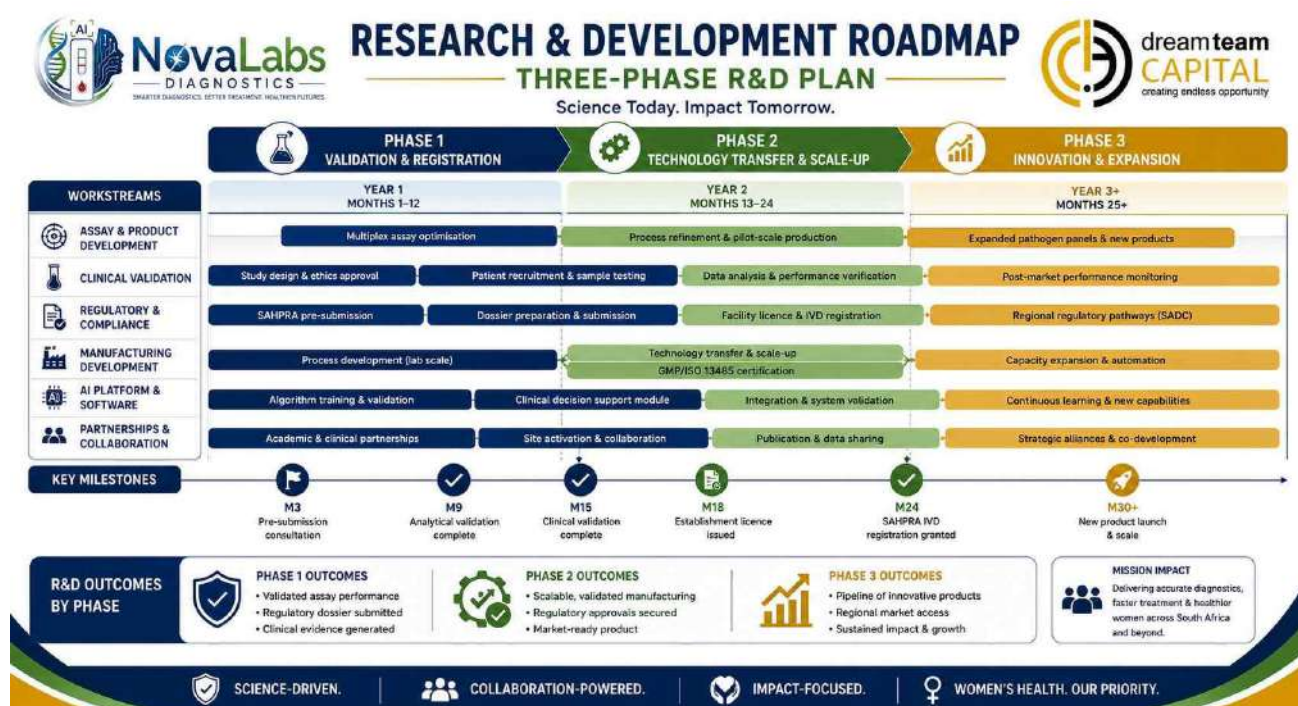
Longer-term value to public sector partners, and alignment with the NHI's data standardisation objectives (Section 3.6), depends on the doctor portal's ability to exchange data with existing public health information systems (such as the District Health Information System) rather than operating as a standalone silo. The organisation is recommended to engage the National Department of Health's digital health standards function early in the regulatory phase to confirm the data exchange standards the platform should target, avoiding costly retrofitting once public sector integration is sought at scale.



6.11 Intellectual Property Protection Strategy

Provisional intellectual property protections have been filed covering the multiplex assay design and the AI application software, developed prior to the organisation's registration as a non-profit company. As the organisation has no shareholders or distributable equity, its interest in this technology is as a licensed or assigned user for public-benefit purposes rather than as a commercial IP owner. Formalising a written licence or assignment agreement, on arm's-length and non-profit-appropriate terms, with the technology's originators is treated as a priority governance action (Section 12.3), so that donor capital is clearly understood to fund the non-profit's manufacturing, regulatory, and distribution activity under a secure and durable right to use the technology, rather than resting on an informal or undocumented arrangement.

7. Research and Development Plan



7.1 Phased R&D Roadmap

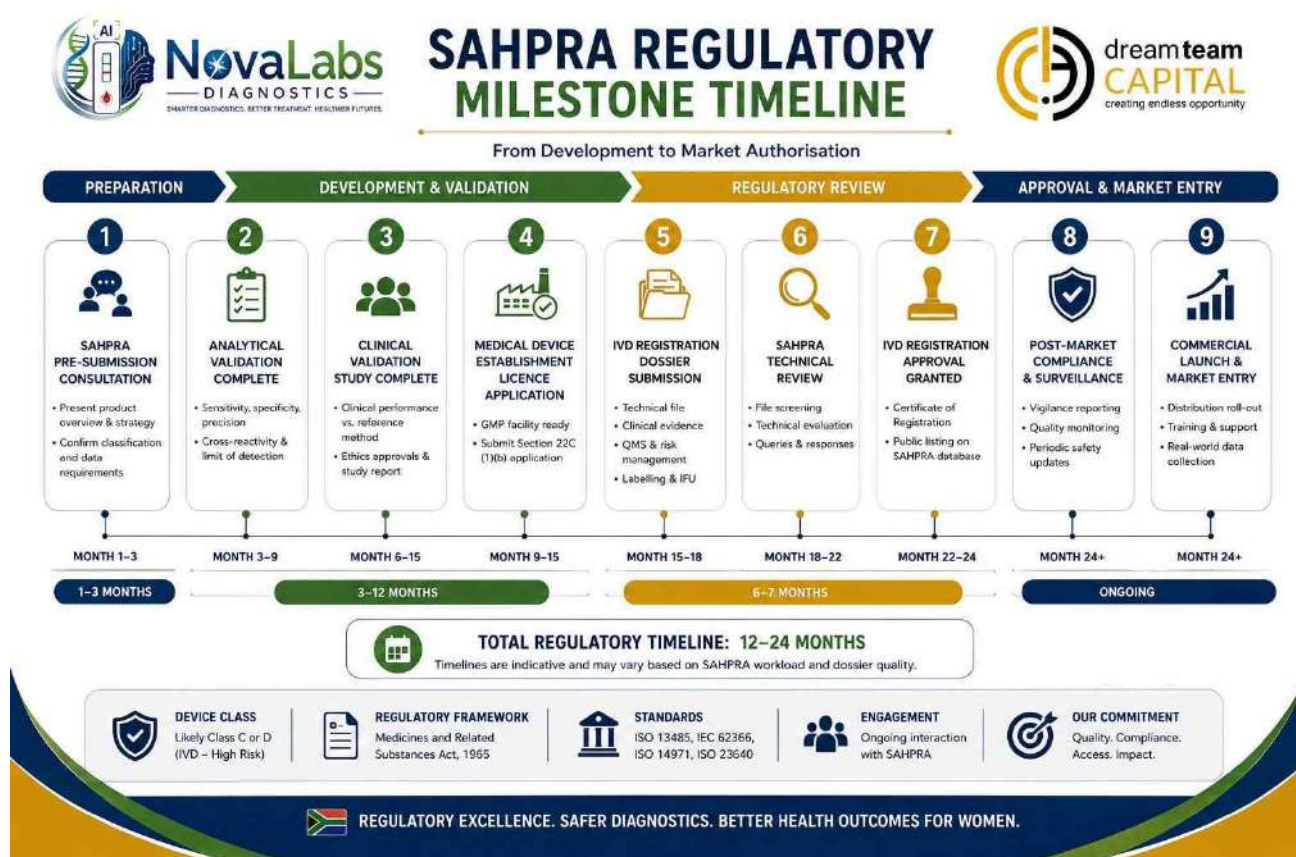
The R&D plan is phased against the funding structure in Section 9.1: Phase 1 (Year 1) - completing analytical and clinical validation of the multiplex assay, finalising the AI prescription workflow module, and progressing the SAHPRA submission; Phase 2 (Year 2) - technology transfer from development to manufacturing scale, process validation, and stability studies; Phase 3 (Year 3 onward) - expansion of pathogen coverage and exploration of regional regulatory pathways.

7.2 Future Innovation Pipeline

Beyond the flagship multiplex STI kit, the organisation's innovation pipeline (contingent on future funding and demonstrated demand) includes an expanded-pathogen-coverage panel, HIV-syphilis combination kits for antenatal screening, and potential extension of the AI result-interpretation platform to other point-of-care test formats. Prioritisation among these should be revisited annually based on demonstrated public health need and available funding, rather than pursued simultaneously.

7.3 Regulatory Milestone Planning

Milestone	Indicative Timing	Dependency
SAHPRA pre-submission consultation	Month 1-3	Funding close
Analytical validation complete	Month 3-9	Laboratory access, reference samples
Clinical validation study complete	Month 6-15	Research ethics approval, clinical site partnership
Medical Device Establishment Licence application	Month 9-15	GMP facility readiness
SAHPRA IVD registration granted	Month 15-24	Complete technical dossier
POPIA compliance sign-off for AI platform	Month 12-18	Data protection controls implemented (Section 6.8)



7.4 Clinical Validation Programme

The clinical validation programme requires testing the multiplex assay against a reference-standard comparator method (typically PCR-based testing for the relevant pathogens) in a defined patient population, generating the sensitivity, specificity, and predictive value data required for the SAHPRA submission and for credible external performance claims (Section 1.10). This requires research ethics committee approval, a clinical site partnership (building on the academic and clinical research relationships in Section 2.3), and a defined sample size calculated to the statistical power required for the target patient population. The organisation is recommended to publish clinical validation results, once available, in a peer-reviewed journal to strengthen external scientific credibility.

7.5 Ongoing Product Improvement Process

Post-launch, a structured product improvement process is recommended: systematic collection of field performance data (false positive/negative reports, user feedback on workflow) through the doctor portal; a defined threshold for triggering a formal design review; and a documented change-control process (Section 6.9) ensuring any change to the assay or AI logic is revalidated before deployment, consistent with ISO 13485 requirements for post-market surveillance.

7.6 University and Research Institution Partnerships

Formalised partnerships with KwaZulu-Natal universities and research institutions can supplement the organisation's own R&D capacity at limited direct cost, provide independent scientific validation, and create postgraduate training and internship pathways that also serve the organisation's skills development and women's participation objectives (Section 8.13). These relationships should be documented through formal collaboration agreements specifying IP treatment, publication rights, and any data-sharing arrangements.

7.7 Funding Requirements for Future R&D

The Year 1 Development Fees (MPV) line in the organisation's financial model (R1,500,000, reducing to R320,100 by Year 5) reflects the front-loaded nature of core assay validation cost, which declines as the flagship product matures. Funding for the future innovation pipeline described in Section 7.2 (expanded pathogen panels, combination

kits) is not included in the current five-year model and would represent an incremental funding requirement to be scoped and requested separately once the core product is registered and generating cost-recovery income, rather than being assumed within the current R59.5 million funding ask.

7.8 Intellectual Property Development, Ownership and Commercialisation of Future Innovations

Any future innovation developed using the organisation's own funded R&D activity (as opposed to technology licensed in from the original developers, per Section 6.11) should, consistent with the non-distribution constraint, be owned by or irrevocably licensed to the non-profit itself rather than accruing to any individual or affiliated commercial entity. The organisation is recommended to adopt a written IP policy confirming that IP arising from grant-funded R&D vests in the non-profit, addressing a due diligence question institutional donors routinely ask before funding applied health R&D.

8. Operations and Production Plan



8.1 Operational Workflow

The end-to-end operational workflow spans: raw material procurement and incoming quality control; the five-stage manufacturing process (Section 8.6); finished-product release; warehousing under controlled conditions; distribution to public sector, private sector, and direct-to-consumer channels; beneficiary testing and, via the doctor portal, prescription and pharmacy collection; and, finally, anonymised data flow into the organisation's epidemiological reporting to the National Department of Health.

8.2 Manufacturing Capacity Planning

Capacity is planned to scale from a modest single-shift Year 1 operation in line with the Fixed Asset Investment Schedule (Section 9), with defined utilisation thresholds - rather than calendar triggers alone - recommended to govern the decision to add shifts or equipment lines (Section 5.6). The organisation is recommended to track manufacturing line utilisation as a standing operational KPI (Section 8.14) from first commercial production.

8.3 Key Suppliers and Vendor Relationships

Supplier	Product / Service
Ahlstrom-Munksjö	Nitrocellulose membranes
Merck Life Science / Sigma-Aldrich	Biochemical reagents
AntiTeck	Lateral flow components; strip and cassette assembly
Desiccare SA	Desiccant sachets
FlexPak SA	Moisture-resistant pouches

8.4 Procurement Methodology

Raw material and equipment procurement will follow the Procurement Policy described in Section 2.5: competitive quotation above defined thresholds, documented supplier selection criteria (price, quality certification, lead time, and, for imported inputs, currency risk), and separation of requisition, approval, and payment authority. Long-term supply

agreements with the key suppliers listed in Section 8.3 are recommended once volumes justify it, to secure pricing and priority allocation.

8.5 Inventory Management Strategy

The financial model's Inventory Days ratio (Section 9.9) rises from approximately 54 days in Year 1 to approximately 91 days from Year 2 onward, reflecting a deliberate safety-stock buffer against import lead times and currency volatility for critical raw materials (Section 8.9), balanced against the working capital cost of holding that stock. Inventory levels should be reviewed quarterly against actual lead-time and demand experience, with the target days-on-hand adjusted as local sourcing alternatives (Section 8.9) are qualified.

8.6 Quality Control and Assurance

The QMS is aligned with ISO 13485 and GMP standards, encompassing incoming, in-process, and finished-product quality control, and stability testing to verify shelf-life claims. Target reject rate is less than 2% of finished product (Section 6.4).

8.7 Manufacturing Process Workflow

The five-stage manufacturing process: membrane preparation and treatment; conjugate preparation and application; card assembly; cassette assembly and packaging; and final packaging and labelling, with quality control samples taken at each stage and comprehensive batch records maintained.

8.8 End-to-End Diagnostic Supply Chain, Logistics and Distribution Planning

The supply chain spans global and local suppliers, inbound logistics, receiving and quality checks, manufacturing operations, quality control and release, distribution and logistics, and beneficiaries and health outcomes. Distribution planning leverages the Dube TradePort SEZ's proximity to King Shaka International Airport for inbound raw material logistics and outbound distribution to provincial health department warehousing and private sector distribution centres, with controlled-condition (climate-controlled) storage and transport for temperature-sensitive components.

8.9 Supplier Risk Management

Dependence on imported raw materials - nitrocellulose membranes and biochemical reagents in particular - creates supply concentration and currency risk (Section 11.3). Mitigation includes maintaining safety stock (Section 8.5) of critical imported materials, qualifying at least one alternative supplier for each critical input where feasible, and actively exploring local sourcing alternatives to reduce both currency exposure and lead time over the medium term.

8.10 Production Scalability

As set out in Section 6.3, the lateral flow manufacturing process scales primarily through additional equipment lines and shifts rather than fundamental process redesign, supporting the phased capacity expansion strategy without requiring a new technology qualification each time capacity is added.

8.11 Maintenance Planning

Manufacturing equipment will be maintained under a preventive maintenance schedule aligned with manufacturer specifications and ISO 13485 equipment-calibration requirements, with maintenance records forming part of the batch quality documentation (Section 8.6). A defined spares-holding policy for critical equipment components is recommended to limit unplanned production downtime.

8.12 Business Continuity Planning

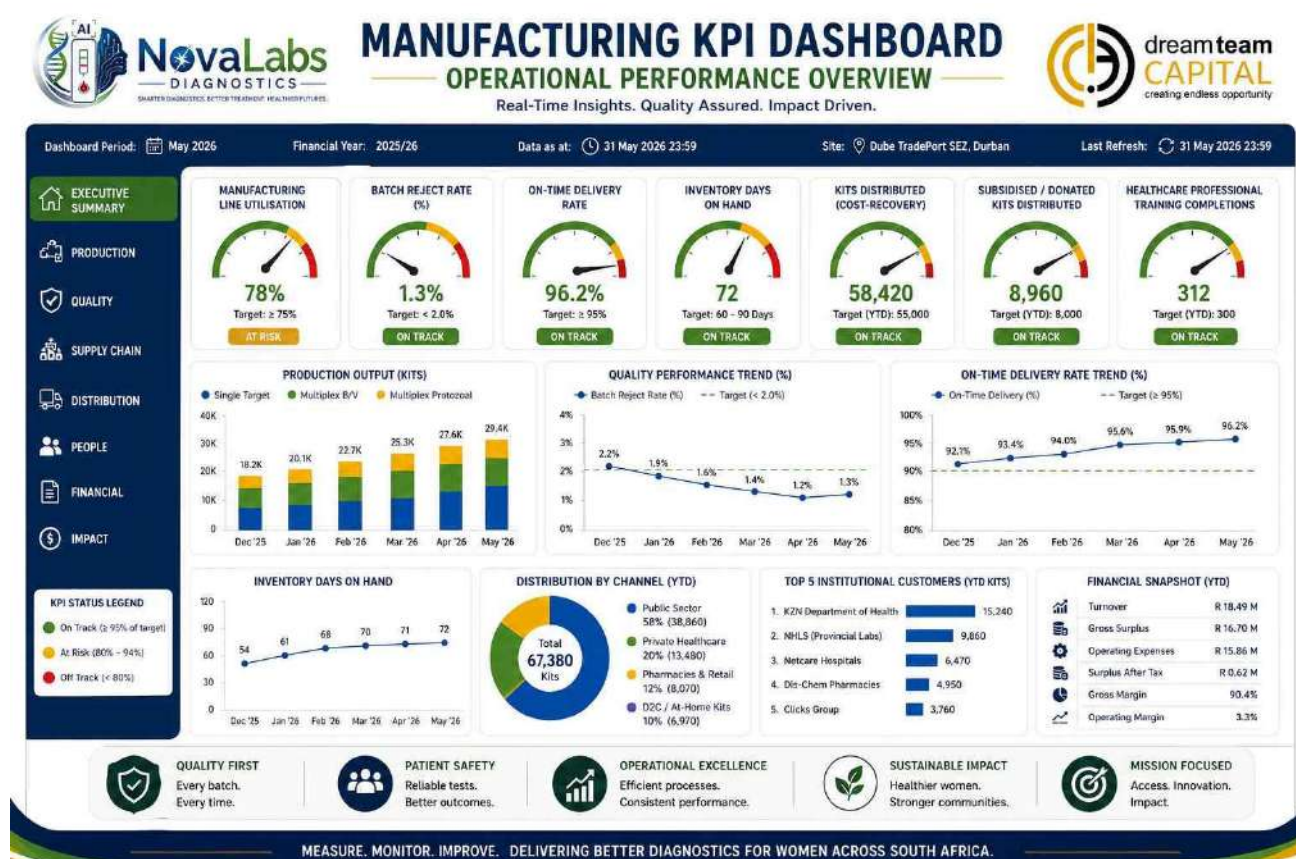
Business continuity planning covers: a documented response to loss of a critical supplier (Section 8.9, Section 11.10); facility-level contingency for utility interruption or physical damage, supported by property and business interruption insurance (Section 11.9); IT and data continuity for the doctor portal and AI platform (Section 6.8-6.9), including backup and disaster recovery procedures; and financial contingency planning for funding disruption (Section 9.6, Section 11.10).

8.13 Workforce Development Strategy

Training is structured across three levels: foundational GMP and health and safety training for all staff; technical, role-specific training covering the full production process; and advanced training for high-potential employees identified for supervisory and management progression. Learnership and internship partnerships with regional universities and TVET colleges (Section 7.6) provide formal qualifications alongside practical training, with a specific focus on creating pathways into the diagnostics sector for women, consistent with the organisation's minimum 50% women's workforce participation commitment (Section 1.6).

8.14 Operational KPIs

KPI	Purpose
Manufacturing line utilisation (%)	Informs capacity expansion timing (Section 8.2)
Batch reject rate (%)	Quality control performance against the <2% target (Section 6.4)
On-time delivery rate to institutional customers	Reliability track record supporting tender and grant renewal (Section 4.6)
Inventory days on hand	Working capital efficiency (Section 8.5)
Kits distributed (cost-recovery vs subsidised/donated)	Core impact and financial tracking metric (Section 1.6, Section 9.11)
Healthcare professional training completions	Adoption barrier tracking (Section 4.12.1)



8.15 Doctor Portal and Beneficiary Fulfilment Model

In addition to the physical test kit, the organisation provides a secure, web-based doctor portal enabling healthcare professionals employed by, or contracted to, its institutional partners to register patients, access and interpret test results, and generate clinical and administrative reports. The organisation's operational responsibility is limited to the supply of diagnostic kits and the patient application and doctor portal technology platform; remuneration of clinical

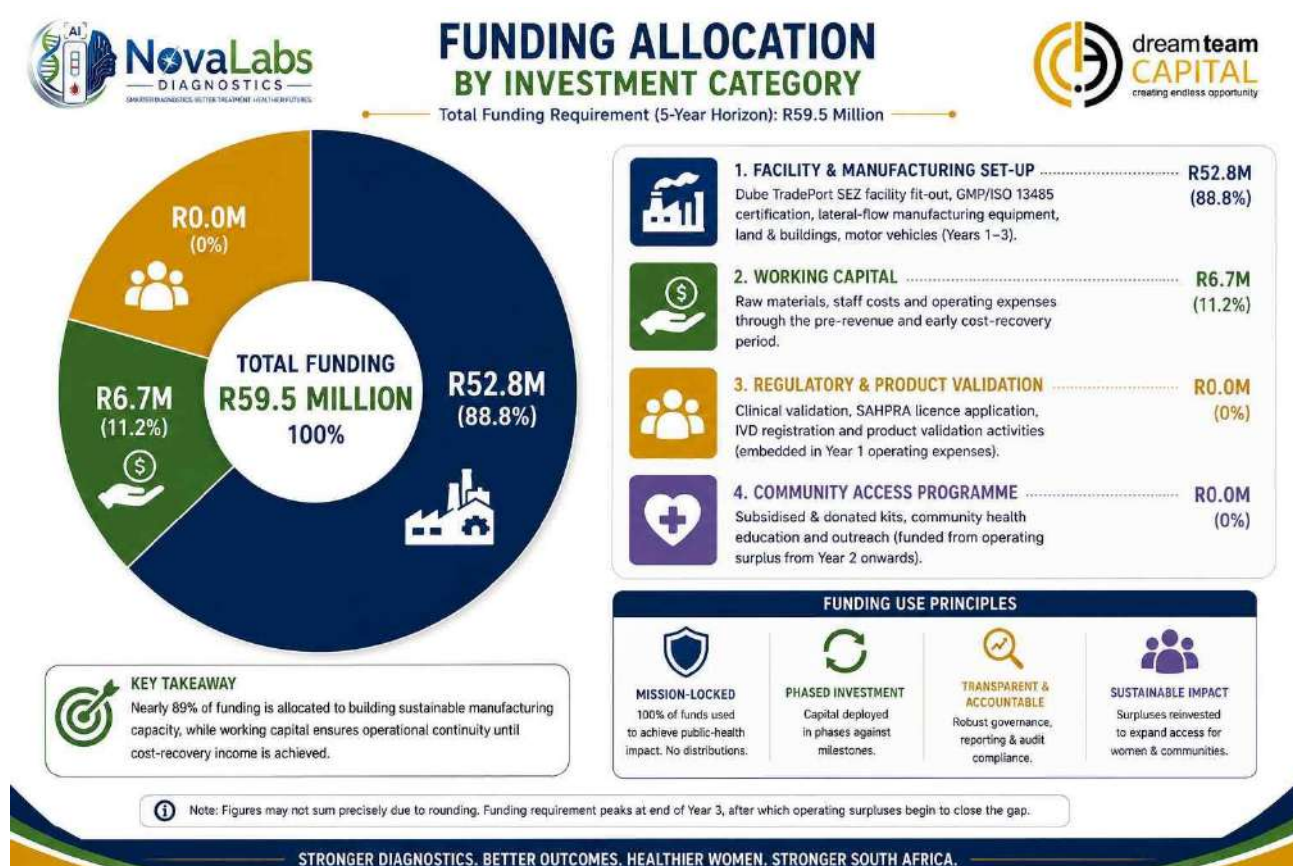
staff who use the portal remains the responsibility of the institutional partner, keeping the organisation's cost structure free of clinical staffing costs and preserving donor and grant funding for its core manufacturing, regulatory, and community access mission.

9. Financial Feasibility

The financial analysis reflects the organisation's own five-year financial model, prepared on a non-profit basis in which every rand of surplus is retained and reinvested. There is no shareholder return, dividend, or equity value to assess; the relevant tests of financial feasibility for a non-profit are: (i) is the capital requirement clearly defined and phased against de-risking milestones; (ii) does the model demonstrate a credible, evidenced pathway to reduced donor dependency; and (iii) is the cost per beneficiary reached, and the surplus reinvested into the community access programme, a defensible use of donor capital relative to alternative interventions. This section has been expanded to include sensitivity and scenario analysis, financial ratios, and donor return-on-investment metrics consistent with DFI and institutional donor expectations.

9.1 Capital Requirements and Funding Strategy

Based on the organisation's own cash flow model, which assumes no debt or equity financing, the cumulative funding requirement peaks at approximately R59.5 million by the end of Year 3, before internally generated operating surpluses begin to close the gap. Capital expenditure on facility fit-out and manufacturing equipment accounts for approximately R52.8 million (circa 89%) of this, with the balance (circa 11%, approximately R6.7 million) attributable to working capital through the pre-revenue and early cost-recovery period. Funding is applied across four sequenced priority areas: regulatory and product validation; facility and manufacturing set-up; working capital; and the community access programme (Section 1.7).



9.2 Financial Assumptions

9.2.1 Revenue Forecast and Pricing Methodology

Revenue is forecast from cost-recovery sales of three product categories at the pricing set out in Section 9.3, escalated over the forecast period broadly in line with the organisation's own operating cost growth. Pricing is set on a cost-recovery, not profit-maximising, basis: prices are intended to cover direct unit cost plus an allocated contribution to operating overhead and the community access programme, rather than being benchmarked to what the market would bear. This is a deliberate methodological choice appropriate to a non-profit's mission, but means the pricing has not

been independently benchmarked against public sector reference pricing for comparable rapid diagnostic tests; doing so once SAHPRA registration is imminent is recommended to confirm the pricing remains both mission-appropriate and commercially realistic for public sector tender purposes.

9.2.2 Sales Forecast Methodology

The turnover trajectory in the underlying financial model reflects a top-down build based on assumed market entry timing (SAHPRA registration and facility readiness) and a phased ramp-up in institutional accounts, rather than a bottom-up build from named facility-level order commitments. As noted in Section 4.8, an independent bottom-up market sizing and account-level pipeline exercise is recommended ahead of large-scale tender participation, both to validate this forecast and to strengthen the evidentiary basis of future funding proposals.

9.2.3 Inflation and Exchange Rate Assumptions

The underlying financial model is presented in nominal Rand terms without an explicit stated inflation escalation methodology or exchange rate assumption for imported raw materials. This is treated as a modelling limitation rather than an error: Dream Team Capital recommends the organisation's Board adopt an explicit annual inflation escalation assumption for salaries and domestic operating costs (benchmarked to South African CPI), and an explicit USD/ZAR exchange rate assumption with a defined sensitivity band for imported raw material costs (nitrocellulose membranes, biochemical reagents), and re-issue the five-year model with these assumptions stated, as a near-term action ahead of formal funder due diligence.

9.3 Revenue, Cost of Sales, Gross Surplus Analysis and Unit Economics

Turnover grows from R2,108,163 in Year 1 to R38,140,762 in Year 5. Cost-recovery pricing across the product mix is as follows, together with the implied per-kit contribution margin:

Product	Price (ZAR)	Direct Unit Cost (ZAR)	Contribution per Kit	Contribution Margin
Single-target test kits	R75	R8	R67	89.3%
Bacterial / viral multiplex kits	R350	R75	R275	78.6%
Protozoal multiplex kits	R350	R18	R332	94.9%

Gross surplus improves from R1,040,987 (49% margin) in Year 1 to R35,515,973 (93% margin) by Year 5. This surplus is the organisation's primary internally generated source of funding for the subsidised and donated kit programme and is never distributed.

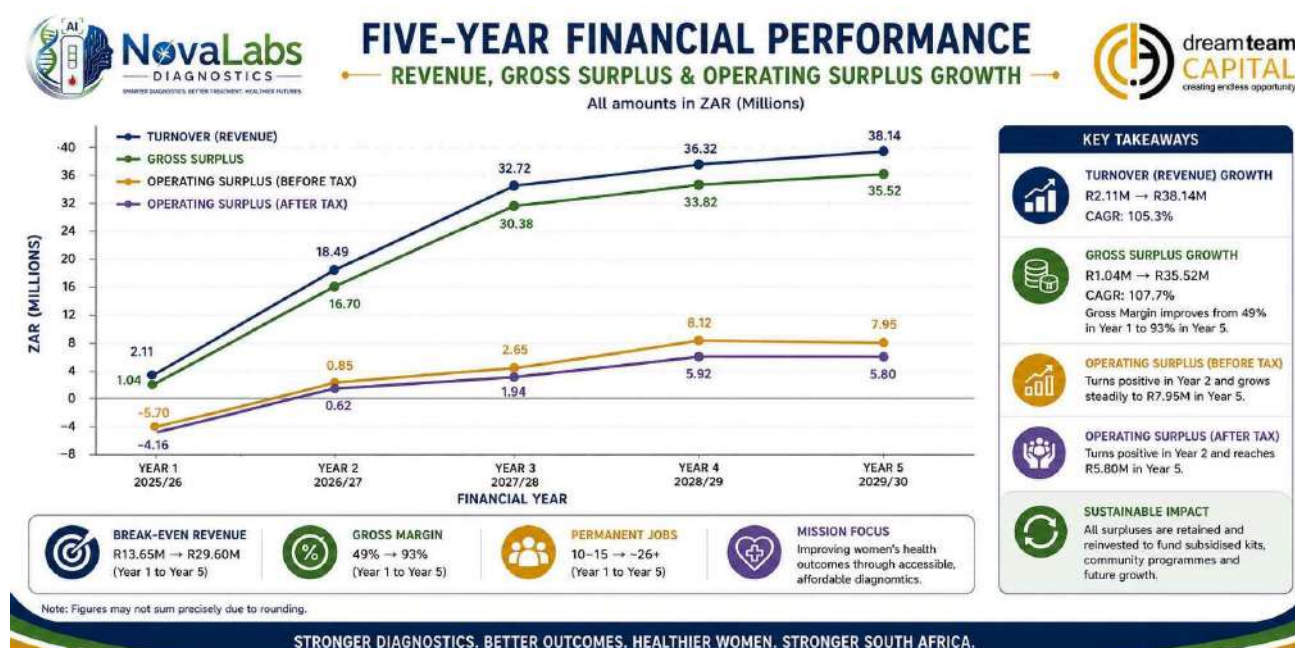
9.4 Operating Expenses Analysis

Operating expenses increase from R6,741,069 in Year 1 to R27,565,751 in Year 5, reflecting workforce expansion from 10-15 to approximately 26 permanent positions, facility scale-up, and expansion of the community access programme. Year 1 reflects the expected upfront investment phase common to newly established diagnostics manufacturing operations, prior to SAHPRA registration and full-scale production.

9.5 Surplus Analysis - Reinvestment Capacity

ZAR	Year 1	Year 2	Year 3	Year 4	Year 5
Turnover	2,108,163	18,488,591	32,724,807	36,324,535	38,140,762
Gross Surplus	1,040,987	16,701,396	30,375,055	33,824,736	35,515,973
Operating Expenses	6,741,069	15,855,357	27,720,648	25,709,359	27,565,751
Surplus / (Deficit) Before Tax	-5,700,081	846,038	2,654,407	8,115,377	7,950,222
Surplus / (Deficit) After Tax	-4,161,059	617,608	1,937,717	5,924,225	5,803,662
Gross Margin	49%	90%	93%	93%	93%

Break-even revenue rises from R13.65 million in Year 1 to approximately R29.60 million in Year 5, but the organisation's own turnover overtakes break-even revenue from Year 2 onward, evidencing a credible path to reduced donor dependency.



9.6 Cash Flow, Funding Sustainability, and Contingency Planning

ZAR	Year 1	Year 2	Year 3	Year 4	Year 5
Net Cash from Operations	-4,118,216	895,150	6,492,378	11,120,350	11,179,643
Net Cash from Investing	-4,666,826	-9,250,000	-38,844,000	-	-
Net Change in Cash	-8,785,042	-8,354,850	-42,351,622	11,120,350	11,179,643
Cumulative Cash Position	-8,785,042	-17,139,892	-59,491,514	-48,371,164	-37,191,520

The residual cumulative shortfall of approximately R37.2 million still present at the end of Year 5 is a direct consequence of the non-profit funding assumption: the model assumes the shortfall continues to be met through ongoing grant, donor, and CSI capital rather than debt or equity. Funders should treat these figures as a multi-year fundraising target, updated at least annually against actual grant income secured. Recommended funding contingency measures include: maintaining a minimum three-month operating expense cash buffer once cost-recovery income commences; a pre-agreed bridge funding facility or standby CSI commitment to cover short-term grant disbursement delays; and a documented, Board-approved expenditure deferral plan (deferring discretionary community access or expansion spend, not core regulatory or quality activity) that can be activated if funding falls materially short of target in any given year.



9.7 Sensitivity Analysis

Dream Team Capital has constructed the following illustrative sensitivity analysis, applying single-variable shocks to the Year 3 and Year 5 base case, to test the resilience of the funding requirement and reinvestment trajectory. These are constructed for this study; they are not part of the organisation's own underlying model.

Sensitivity	Effect on Year 3 Cumulative Funding Requirement	Effect on Year 5 Surplus
Base case	R59.5m	R5.80m
6-month SAHPRA registration delay	Increases by an estimated R3-5m (extended pre-revenue opex funding)	Compresses toward R4-5m as revenue ramp-up shifts later
10% rand depreciation (imported input cost)	Increases by an estimated R1-2m via higher cost of sales	Reduces by an estimated R1-2m via margin compression
15% shortfall in cost-recovery revenue vs base case	Increases by an estimated R3-6m (higher reliance on grant funding to cover opex)	Reduces materially, delaying return to strong reinvestable surplus by approximately one year
10% reduction in operating expenses (efficiency gains)	Decreases by an estimated R2-4m	Improves by an estimated R1-2m

The model's key sensitivity is to SAHPRA registration timing and to cost-recovery revenue achievement, both of which directly extend the pre-surplus funding period; currency movements affect the margin trajectory materially but the funding requirement only moderately, given the small share of directly imported cost relative to total operating expenditure.

9.8 Scenario Analysis: Best, Expected and Worst Case

Scenario	Key Assumptions	Year 5 Turnover (illustrative)	Year 5 Surplus (illustrative)	Funding Requirement Trajectory
Best case	On-time SAHPRA registration; faster-than-base-case public sector uptake; stable currency	R45-50m	R8-10m	Peak funding requirement lower and shorter in duration than base case
Expected case (base case)	Per the organisation's own financial model	R38.1m	R5.8m	Peaks at ±R59.5m in Year 3, declining thereafter
Worst case	6–12-month SAHPRA delay; slower public sector uptake; 10%+ rand depreciation	R25-30m	R1-3m (or a further Year 4 deficit)	Peak funding requirement materially higher and delayed by 12-18 months

This scenario range is constructed by Dream Team Capital for this study to illustrate the range of plausible outcomes; funders should request an updated, quantitatively modelled scenario set directly from the organisation's Board once SAHPRA pre-submission feedback narrows the regulatory timeline uncertainty.

9.9 Financial Ratios

The following ratios are drawn directly from the organisation's own five-year balance sheet forecast:

Ratio	Year 1	Year 2	Year 3	Year 4	Year 5
Debtors Days	142.1	36.5	36.5	36.5	36.5
Creditors Days	151.6	127.8	182.5	182.5	182.5
Inventory Days	54.5	91.3	91.3	91.3	91.3
Current Ratio	-15.3	-19.4	-46.2	-34.9	-24.6
Asset Turnover	-0.51	-5.22	-20.38	8.41	3.77
Return on Total Assets	1.14	-0.30	-6.62	1.45	0.69
Return on Equity (Reserves)	1.00	-0.17	-1.21	1.37	0.57
Debt Ratio	0.00	0.00	0.00	0.00	0.00

The negative current and asset turnover ratios in Years 1-3 are a direct arithmetic consequence of the negative cash balances discussed in Section 9.6 (the model does not yet reflect the donor capital that funds those balances as a balance sheet inflow), and should be read alongside that context rather than as a conventional liquidity red flag. The zero-debt ratio throughout confirms the organisation carries no financial leverage, consistent with its non-profit, grant-funded structure. Extended creditor days from Year 3 onward (182.5 days) should be reviewed by the Board to confirm this is a deliberate working-capital strategy that suppliers have agreed to, rather than a payment-term risk.

9.10 Donor Return on Investment in Measurable Terms

Because the organisation has no shareholders, funders' return is measured in social and public health terms rather than financial yield. Recommended measurable donor ROI metrics, to be tracked and reported from Year 1, include:

- **Funding leverage ratio:** by Year 5, the model shows accumulated capital and reserves (retained surplus) of R10,122,153 built from a peak cumulative funding requirement of R59,491,514 - meaning that, within five years, approximately 17% of peak donor capital deployed has already converted into a growing, self-sustaining reinvestment base, with the ratio continuing to improve as annual surpluses grow (Section 9.5).
- **Cost per beneficiary reached:** to be calculated as total annual operating expenditure divided by the number of women and girls tested (cost-recovery plus subsidised/donated), and tracked from Year 1 as a standing KPI (Section 8.14).
- **Cost per subsidised/donated kit:** to be reported separately from cost-recovery kit economics, to give funders a direct, auditable measure of the cost of expanding access to low-income beneficiaries specifically.
- **Surplus reinvestment rate:** the proportion of annual surplus allocated to the community access programme versus retained for facility/capacity investment, reported annually against Board-approved targets.

9.11 Long-Term Financial Sustainability

The organisation's long-term financial sustainability rests on the trajectory set out in Section 1.11: cost-recovery income funding a growing share of operating cost, gross margins stabilising at 93% from Year 3, and operating cash flow turning strongly positive from Year 3 onward. Full independence from donor funding is not achieved within the five-year forecast horizon - a residual cumulative shortfall of approximately R37.2 million persists at the end of Year 5 under the base case - but the trajectory is one of materially reducing, rather than static or growing, external funding dependency, and this trend should be the primary metric by which funders assess the organisation's progress toward sustainability at each annual review.

10. Fundraising and Stakeholder Engagement

10.1 Engagement Strategy

The organisation's stakeholder engagement strategy is built on four pillars: awareness of the NovaCheck AI brand and mission among funders, health system partners, and beneficiaries; education of healthcare providers, pharmacists, and communities; positioning as South Africa's first locally manufactured, non-profit, AI-enabled multiplex STI diagnostic service; and direct engagement with government procurement officials, donor programme officers, CSI managers, and community health partners.

10.2 Engagement Goals and Objectives

- Funder awareness: secure engagement with at least three donor, DFI, or CSI programmes aligned with women's health within 12 months of SAHPRA registration.
- Public sector engagement: secure meetings with the KwaZulu-Natal and at least one further provincial health department within six months of registration.
- Grant conversion: convert at least one letter of intent into a signed grant or cost-recovery supply agreement within three months of registration.
- Partner retention: achieve a high renewal rate on multi-year public sector and donor-funded supply agreements.

10.3 Positioning

Nova Labs Women's Health Care Diagnostics NPC will position itself as South Africa's leading non-profit manufacturer of multiplex STI diagnostic test kits for women's health, combining local manufacturing, regulatory compliance, technological innovation, and a mission-locked, non-distribution governance structure no commercial competitor can replicate.

10.4 Market Penetration and Growth Strategy

The penetration strategy prioritises the public sector in KwaZulu-Natal as the initial beachhead, before expanding provincially and, longer term, into SADC export markets.

10.5 Early Engagement Plans

- Public sector: pilot programmes at no or reduced cost to selected clinics and hospitals.
- Donor and CSI partners: a structured proposal and due diligence pack, including this feasibility study, the Non-Profit Business Plan, and the five-year financial model.
- Community and NGO partners: co-developed outreach and referral pathways with women's health NGOs and community health workers.
- Direct beneficiary channel: discreet home testing kits distributed through e-commerce and community health partners, supported by digital education campaigns.

10.6 Long-Term Growth Strategies

Long-term growth is anchored in geographic expansion, programme diversification, and funding base diversification (Section 10.22), so no single funding source represents an unmanageable concentration risk.

10.7 Advocacy and Promotional Plan

Engagement is tailored by audience: government officials through direct presentations and tender submissions; donor and CSI programme officers through structured proposals, site visits, and impact reporting; healthcare providers through CPD-accredited training addressing the adoption barriers identified in Section 4.4.1 and Section 4.12.1; and beneficiaries through community health education and referral networks.

10.8 Communication Channels

- Direct engagement with government, donor, and CSI decision-makers.
- A mission-focused website and social media presence for funders, health partners, and beneficiaries.
- Community partnerships with health workers, women's health NGOs, and university health services.
- Earned media coverage of South Africa's first locally manufactured, AI-enabled, non-profit multiplex STI diagnostic service.

10.9 Budget Allocation for Engagement Activity

Community health education and outreach activity is funded from the community access programme allocation, growing from R72,000 in Year 1 to approximately R2.55 million in Year 5, reported separately in the organisation's annual impact report as mission delivery expenditure rather than commercial marketing spend.

10.10 Key Metrics and KPIs for Success

- Impact metrics: women and girls tested; subsidised/donated kits distributed; community health education sessions delivered.
- Funding metrics: value and diversity of grant, donor, and CSI income secured; proportion of income from cost-recovery sales versus donor capital over time.
- Efficiency metrics: cost per kit distributed; cost per subsidised kit; proportion of expenditure allocated to community access versus administration.
- Health system metrics: volume and quality of anonymised epidemiological data shared with the National Department of Health.

10.11 Fundraising and Partnership Strategy

Public sector partnerships are tender- and procurement-driven; donor and grant partnerships are relationship-driven, guided by a structured proposal, due diligence, and reporting process; private sector partnerships are supplied on a cost-recovery basis; and the direct-to-beneficiary channel is digital-first, supported by community and NGO referral partnerships.

10.12 Fundraising Goals and Targets

Segment & Year	Target
Public Sector - Year 2	KwaZulu-Natal Department of Health partnership plus one further province
Public Sector - Year 3	Multi-province and national Department of Health engagement
Donor / Grant - Year 1-2	Secure grant and donor capital sufficient to fund the Year 1-3 cumulative shortfall of approximately R59.5 million
CSI Partnerships - Year 2	At least two corporate social investment partnerships supporting the community access programme
Community Access - Year 3	Meaningful year-on-year growth in subsidised and donated kits distributed

10.13 Donor and Partner Journey Mapping

For government and donor partners, the journey progresses from awareness, through qualification, proposal preparation, due diligence, negotiation, agreement, disbursement and delivery, to reporting and renewal. For the direct-to-beneficiary channel, the journey is community- and digital-first: awareness, referral or online consideration, testing, results and treatment pathway, and follow-up.

10.14 Funding Pipeline and Conversion

Target conversion rates mirror a well-run development-sector fundraising function: opportunity identified to proposal submitted; proposal submitted to due diligence; due diligence to signed agreement; and signed agreement to first disbursement, tracked to identify where the pipeline requires strengthening.

10.15 Digital Engagement Strategy

The organisation's website will serve as the central hub for funder, health-partner, and beneficiary engagement, with dedicated content for government and donor audiences, healthcare providers, and the public, including transparent reporting on impact and financial stewardship.

10.16 Public Relations and Media Strategy

The PR strategy focuses on generating credible media coverage that builds trust with funders and the public, centred on the organisation's local manufacturing, non-distribution governance, and contribution to job creation, skills transfer, and public health surveillance.

10.17 Crisis Management and Communication Plans

A crisis management and communication plan designates a response team comprising the Managing Director, the Board, and external legal and communications advisors as required, convening immediately upon identification of a potential crisis to assess severity, determine response, and communicate transparently with funders and partners.

10.18 Grant Pipeline Management

A structured grant pipeline should be maintained by the Board and Managing Director, tracking each prospective and active funder through the stages in Section 10.14, with defined ownership for each relationship, target proposal submission dates, and disbursement schedules. Given the scale of the funding requirement (Section 9.1) relative to any single likely grant size, the pipeline should be sized to include a materially larger number of prospective funders than the minimum required, to absorb the inevitable attrition between opportunity identification and signed agreement.

10.19 Fundraising Governance

All grant and donor agreements above a Board-defined threshold require full Board approval prior to signature (Section 2.4). A designated grant compliance function - initially the Managing Director, transitioning to a dedicated role as funding scales (Section 2.7) - is responsible for tracking each agreement's reporting obligations, milestone conditions, and permitted use of funds, consistent with the Grant and Donor Compliance Policy in Section 2.5.

10.20 Donor Stewardship and Partnership Retention Strategy

Donor stewardship extends beyond compliance reporting to proactive relationship management: scheduled site visits and demonstrations for active funders, transparent and timely communication of both successes and setbacks (including funding shortfalls or delays, per Section 9.6), and public acknowledgement of funder contributions where appropriate and agreed. Retention is treated as materially cheaper than new-funder acquisition, and is tracked through the partner retention target in Section 10.2.

10.21 Monitoring and Reporting Commitments

The organisation commits to an annual integrated report covering financial performance, regulatory progress, and the socio-economic and public health impact metrics defined in Section 10.10 and Section 9.10, supplemented by more frequent (at minimum quarterly) financial and milestone reporting to active grant funders as required by individual grant agreements, consistent with standard development-sector reporting practice.

10.22 Donor Diversification Strategy

Given the scale of the funding requirement and the funding concentration risk identified in Section 11.3, the organisation targets a blended funding base across government and provincial health grants, international donor and multilateral health funding, corporate social investment partnerships, philanthropic and foundation grants, and growing cost-recovery income, with no single source targeted to exceed a defined proportion (recommended no more than 30-40%) of any given year's funding requirement once the funding base has matured beyond the initial establishment grants.

11. Risk Analysis and Mitigation

11.1 Identification of Risks

The organisation has identified a comprehensive set of risks across strategic, financial, technical, cybersecurity, legal, regulatory, environmental, operational, and reputational categories. As a non-profit dependent on donor and grant capital rather than commercial revenue, funding concentration and grant-cycle risk are treated as materially more significant than for an equity-funded commercial peer.

11.2 Strategic Risks

Strategic risks include the emergence of competing multiplex or AI-enabled products, changes in government procurement or grant-making policy disadvantaging local non-profit manufacturers, and failure to achieve projected beneficiary reach. Government procurement is conducted through competitive tender processes governed by the PFMA, PPPFA, and Treasury Regulations; no supplier can be guaranteed a specific procurement outcome. The organisation's non-profit, collaborative positioning and the absence of a direct local competitor offering a comparable solution are assessed to materially strengthen its position relative to an ordinary commercial tender participant. Mitigation includes continuous health-system-partner engagement, active donor and CSI stakeholder relationships, and funding source diversification (Section 10.22).

11.3 Financial Risks

- **Funding Risk:** delayed, reduced, or unsuccessful grant and donor fundraising could stall development. This is the organisation's single largest financial risk given the absence of any equity or debt fallback in the current model. Mitigated by pursuing multiple funding sources simultaneously and phasing capital deployment against de-risking milestones.
- **Currency Risk:** a 10%-rand depreciation would materially increase imported raw material cost (quantified in Section 9.7). Mitigated through forward exchange contracts where feasible and conservative budget assumptions.
- **Cash Flow Risk:** the cumulative funding requirement of approximately R59.5 million by Year 3 means any shortfall in grant disbursement timing directly threatens operational continuity. Mitigated by a diversified, staged funding pipeline and the contingency measures in Section 9.6.
- **Donor Concentration Risk:** reliance on a small number of large donors would expose the organisation to significant disruption if any one relationship ends. Mitigated by the diversification strategy in Section 10.22.

11.4 Legal and Regulatory Risks

- **SAHPRA Registration Delay:** a 12-month delay would postpone all cost-recovery revenue while donor-funded costs continue to accrue. Mitigated through early pre-submission consultations and a complete, high-quality technical dossier.
- **PBO / Section 18A Tax Status:** NPC registration does not, of itself, confer income tax exemption or donor tax-deductibility. Failure to secure PBO and section 18A approval would reduce both tax efficiency and donor attractiveness. Priority recommendation (Section 12.3).
- **Intellectual Property and Licensing Risk:** the underlying technology's origin outside the non-profit structure creates a risk that the organisation's right to use it is not clearly documented. Mitigated by formalising a written licence or assignment agreement (Section 6.11).
- **Data Protection and Privacy Risk:** POPIA obligations regarding patient health information. Mitigated through encryption and role-based access controls (Section 6.8).
- **Product Liability Risk:** false results or incorrect AI guidance could result in patient harm and legal liability. Mitigated through the ISO 13485-aligned QMS, rigorous testing, and product liability insurance.

11.5 Risk Assessment and Prioritisation

Risks are assessed using a four-by-four likelihood-versus-impact matrix. High-priority risks requiring active mitigation are grant and donor funding delay or shortfall, SAHPRA registration delay, product quality failure, and currency volatility.

11.6 Risk Likelihood and Impact Matrix

Risk	Likelihood	Impact	Priority
Grant / donor funding delay or shortfall	Possible	Major	High
SAHPRA registration delay	Likely	Major	High
Product quality failure	Possible	Major	High
Currency volatility	Likely	Moderate	High
Cybersecurity / AI system breach	Possible	Major	High
Donor concentration	Possible	Moderate	Medium
Competing products emerge	Possible	Moderate	Medium
Loss of key personnel	Possible	Moderate	Medium
Data breach	Unlikely	Major	Medium
PBO / s18A status not secured	Possible	Moderate	Medium
Supplier dependency / disruption	Possible	Moderate	Medium
Implementation delay (facility/equipment)	Possible	Moderate	Medium
Environmental / climate disruption	Unlikely	Moderate	Low
Political / policy instability	Unlikely	Moderate	Low

11.7 Severity and Probability of Risks

Severity is assessed by impact on mission delivery: catastrophic (threatens organisational solvency or continuity); major (forces significant scaling back of the community access programme); moderate (delays but does not derail delivery); minor (limited operational impact). SAHPRA registration delay, grant funding shortfall, product quality failure, and a material cybersecurity or AI-system breach are assessed as major to catastrophic given the organisation's limited financial buffers as a start-up non-profit.

11.8 Risk Mitigation Strategies

- **SAHPRA Registration Delay:** early pre-submission consultations; a complete technical file; budgeted regulatory consulting fees; contingency reserves.
- **Grant / Donor Funding Delay or Shortfall:** simultaneous pursuit of multiple funding sources; a lean, phased cost structure; early and continuous funder engagement and transparent reporting.
- **Product Quality Failure:** ISO 13485-aligned QMS; rigorous testing; comprehensive batch records; product liability insurance.
- **Currency Volatility:** forward exchange contracts; safety stock; exploration of local sourcing alternatives.
- **Cybersecurity / AI System Breach:** encryption, role-based access control, regular penetration testing, and model-drift monitoring (Section 6.8-6.9).

11.9 Risk Avoidance, Reduction, and Transfer

Risk avoidance includes qualifying alternative suppliers and deferring entry into markets with unstable regulatory or political environments. Risk reduction includes the ISO 13485-aligned QMS, regular security testing, and safety

stock maintenance. Risk transfer includes product liability insurance, directors' and officers' insurance, property and business interruption insurance, cyber-liability insurance, and forward exchange contracts.

11.10 Contingency Planning and Crisis Management

- **Prolonged SAHPRA Delay (12+ months):** reduce discretionary operating expenditure to extend runway; explore interim, non-regulated revenue-generating activity where appropriate; engage funders proactively for bridge grant funding.
- **Major Product Quality Failure:** activate a product recall plan; notify partners and SAHPRA; conduct root cause analysis and implement corrective actions.
- **Data Breach / Cybersecurity Incident:** isolate affected systems; conduct a forensic investigation; notify affected individuals and the Information Regulator under POPIA.
- **Loss of Key Supplier:** activate alternative supplier relationships; use safety stock; expedite alternative supplier qualification.
- **Loss of Key Personnel:** cross-train existing staff; activate succession plans (Section 2.6); engage external recruiters.

11.11 Monitoring and Controlling Risks

A structured risk monitoring and control process includes quarterly risk assessments, continuous tracking of key risk indicators, internal reviews, and Board oversight, consistent with the governance framework in Section 2.4.

11.12 Risk Monitoring Systems and Tools

- **Risk Register:** documenting each identified risk, its current assessment, assigned owner, mitigation status, and key risk indicators, reviewed at each quarterly risk assessment.
- **Quality Management System:** certified to ISO 13485, incorporating non-conformance, corrective action, and preventive action (CAPA) processes.
- **Financial Planning and Reporting:** scenario modelling of the funding requirement (Section 9.8), updated at least annually against actual grant and donor income secured.
- **Grant Compliance Tracking:** a compliance calendar tracking reporting obligations, milestone conditions, and disbursement schedules (Section 10.19).

11.13 Ongoing Risk Reviews and Adjustments

Risk management is embedded in regular governance routines: management attention to emerging operational risks on an ongoing basis, monthly financial reviews for funding and cash flow risk, and quarterly Board meetings for review of the overall risk profile and funding pipeline.

11.14 Technology, Cybersecurity and AI Governance Risks

Beyond the general cybersecurity controls in Section 6.8, AI-specific governance risk requires distinct attention: the risk that the computer-vision result-interpretation model produces a systematically biased or degraded result for a subset of beneficiaries (for example, due to image quality variation across different kit lighting or camera conditions) without this being immediately detected; the risk that AI-generated prescription guidance is followed without adequate clinical override capability; and the general reputational and liability exposure of any diagnostic AI system operating in a low-connectivity, resource-constrained environment. Recommended governance measures include a documented AI model validation and monitoring protocol (distinct from, but linked to, the clinical validation programme in Section 7.4), a mandatory clinician override and reporting pathway for any AI-generated recommendation, and periodic independent audit of model performance across different beneficiary sub-groups and device/connectivity conditions.

11.15 Environmental and Climate-Related Risks

Environmental risks relevant to the organisation include: load-shedding and grid instability affecting climate-controlled manufacturing and storage conditions (mitigated through backup power provisioning at the Dube TradePort SEZ facility); extreme weather events affecting the KwaZulu-Natal coastal logistics corridor, including the King Shaka International Airport supply route, given the region's documented exposure to severe flooding events; and longer-term water security risk affecting manufacturing operations. These are assessed as lower-probability, moderate-impact risks relative to the organisation's core funding and regulatory risks, but are recommended to be addressed in the business continuity plan (Section 8.12) given the region's demonstrated exposure to climate-related infrastructure disruption.

11.16 Reputational Risk Scenarios

- A product quality or false-result incident receiving public or media attention, particularly damaging given the organisation's public health and women's health mission.
- Perceived or actual misuse of donor funds, or failure to meet grant reporting obligations, undermining funder trust and future fundraising capacity.
- Public perception that the underlying technology's commercial origins (Section 2.2, Section 6.11) compromise the organisation's non-profit, mission-first positioning, if the relationship with any related commercial entity is not transparently disclosed and managed.
- Data privacy failure affecting sensitive sexual health information, carrying acute reputational sensitivity given the stigma dynamics described in Section 4.12.1.

11.17 Supplier Dependency Risks

As set out in Section 8.9, the organisation's five key suppliers each represent a single point of failure for a critical manufacturing input. Supplier dependency risk is elevated for imported inputs (Ahlstrom-Munksjö membranes, Merck Life Science / Sigma-Aldrich reagents) given the additional currency and logistics exposure, and is mitigated through safety stock, alternative supplier qualification, and long-term supply agreements once volumes justify them.

11.18 Implementation Risks

Beyond funding and regulatory risk, execution risk exists at each phase of the implementation timeline (Section 1.8): facility fit-out delays (contractor availability, SEZ approval processes); equipment delivery and commissioning delays (particularly for imported manufacturing equipment); and staff recruitment delays for specialised regulatory, quality, and manufacturing roles in a competitive KwaZulu-Natal life sciences labour market. These are mitigated through the phased milestone structure itself (Section 12.4), which is designed to absorb moderate slippage in any single phase without cascading failure across the whole funding plan, provided funders are kept informed of timeline changes as part of the reporting commitments in Section 10.21.

11.19 Risk Ownership and Monitoring Methodology

Risk Category	Owner	Monitoring Method	Frequency
Funding / financial	Managing Director & Board Finance Sub-Committee	Cash flow forecast vs actual; grant pipeline review	Monthly
Regulatory (SAHPRA)	Managing Director / Regulatory Affairs Lead	Milestone tracker vs regulatory timeline (Section 7.3)	Monthly
Quality / product	Quality Manager	Batch reject rate; CAPA log; QMS internal audit	Per batch / quarterly
Technology / cybersecurity / AI	Technical Advisory Lead	Penetration test results; model performance audit; incident log	Quarterly / on incident
Governance / compliance	Board Chair / Company Secretary function	Policy compliance checklist; conflict of interest register	Quarterly

Risk Category	Owner	Monitoring Method	Frequency
Reputational	Managing Director	Media monitoring; funder feedback; complaint log	Ongoing

12. Conclusion and Recommendations

12.1 Conclusion

This independent feasibility study, prepared by Dream Team Capital, has evaluated the technical, commercial, financial, regulatory, governance, and operational viability of establishing Nova Labs Women's Health Care Diagnostics NPC as a non-profit manufacturer of multiplex lateral flow rapid diagnostic test kits for sexually transmitted infections, with integrated AI-driven antibiotic guidance, dedicated to women's health.

The technical feasibility assessment confirms a well-established manufacturing process, available equipment and raw materials, and a technical foundation drawing on prior development work and established academic and clinical research relationships, currently at manufacturing readiness level 4-5 with a clear pathway to full production readiness (Section 6.2).

The commercial and public health feasibility assessment confirms a substantial and growing market opportunity and an even more substantial unmet need, evidenced by STI prevalence among adolescent girls and young women exceeding 40% in the provinces the organisation will initially serve, and by the absence of any comparable locally manufactured, multiplex, AI-enabled competitor product.

The financial feasibility assessment, now including sensitivity analysis, scenario analysis, and financial ratios (Section 9.7-9.9), demonstrates a credible, evidenced, and appropriately caveated pathway to sustainability: cost-recovery turnover growing from R2.1 million to R38.1 million over five years; gross margins improving from 49% to 93%; a clearly quantified, milestone-phased funding requirement of approximately R59.5 million; and a funding leverage ratio showing donor capital already converting into a growing, self-sustaining reinvestment base within the forecast period (Section 9.10).

The governance assessment identifies a sound foundational structure - a non-distribution constraint, an independent Board, and clear separation from any commercial entity associated with the underlying technology - alongside a defined set of near-term actions (PBO/section 18A status, formalised IP licensing, governance policy adoption, a finance and audit sub-committee) that should be completed to bring the organisation to the standard institutional funders expect.

The socio-economic impact assessment confirms substantial public benefit: projected creation of more than 25 direct positions by Year 2; a defined subsidised and donated kit programme; a minimum 50% women's workforce commitment; skills transfer through TVET and university partnerships; import substitution; and anonymised epidemiological data sharing with the National Department of Health.

12.2 Critical Success Factors

- Timely SAHPRA registration, given its position as the critical-path gate to all cost-recovery revenue.
- Securing the Year 1-3 funding requirement on a phased, milestone-gated basis, from a diversified funder base.
- Formalising governance policies and the underlying technology licence/assignment arrangement before or shortly after first disbursement.
- Achieving the projected transition from cost-recovery income covering a minority to a majority share of operating expenditure by Year 3.
- Building a credible, evidenced public sector and donor track record through early pilot programmes before large-scale tender participation.

12.3 Recommended Governance Actions Before Funding

- Secure Public Benefit Organisation (PBO) approval under section 30 of the Income Tax Act, and section 18A approval for donor tax-deductibility.
- Formalise, in writing and on arm's-length, non-profit-appropriate terms, the organisation's licence or assignment right to use the underlying multiplex assay and AI application.

- Adopt the governance policy suite described in Section 2.5: conflict of interest, code of ethics, procurement, financial management/delegation of authority, and grant compliance.
- Establish a Finance and Audit Sub-Committee and commit to an annual independent audit from Year 1.
- Adopt a written IP policy confirming future grant-funded R&D output vests in the non-profit (Section 7.8).
- Re-issue the five-year financial model with explicit inflation and exchange rate assumptions stated (Section 9.2.3).

12.4 Prioritised Implementation Sequence

Timeframe	Priority Actions
Immediate (0-3 months)	Adopt governance policies (Section 12.3); initiate PBO/s18A application; formalise IP licence/assignment; launch donor and grant pipeline (Section 10.18); begin SAHPRA pre-submission engagement
Short-term (3-12 months)	Secure initial funding tranche; commence facility lease/design; progress analytical and clinical validation (Section 7.3-7.4); establish Finance and Audit Sub-Committee; recruit regulatory affairs and quality functions
Medium-term (1-2 years)	Complete facility fit-out and GMP/ISO 13485 certification; secure SAHPRA registration; commence commercial production and public sector pilots; launch community access programme
Long-term (2-5 years)	Scale public sector and private sector supply; expand facility capacity; grow the subsidised kit programme in line with surplus reinvestment; evaluate SADC expansion and future product pipeline

12.5 Measurable Implementation Milestones

Progress against this feasibility study should be tracked by the Board and reported to funders against the following measurable milestones: SAHPRA Medical Device Establishment Licence granted; SAHPRA IVD registration granted; first commercial batch released; first public sector pilot agreement signed; PBO/section 18A approval secured; Finance and Audit Sub-Committee established and first independent audit completed; cost-recovery income covering 50% of operating expenditure (targeted by Year 2-3, per Section 9.5); and operating cash flow turning sustainably positive (targeted from Year 3, per Section 9.6).

12.6 Final Recommendation - Why This Project Is Fundable

Dream Team Capital concludes that Nova Labs Women's Health Care Diagnostics NPC represents a viable, evidence-supported, and fundable public-benefit initiative. It addresses a large, well-documented, and urgent public health need with a technically credible and differentiated product; it is structured, through its non-distribution governance model, to ensure donor capital cannot be converted into private value; it presents a financial model that is transparent about its funding requirement, tested against sensitivity and scenario analysis, and shows a credible, if partial, trajectory toward reduced donor dependency; and it has a clearly defined, prioritised set of governance actions to close the remaining gaps between its current state and the standard expected by major institutional funders.

Dream Team Capital recommends proceeding with the establishment of Nova Labs Women's Health Care Diagnostics NPC, and recommends that donors, grant-makers, development finance institutions, and corporate social investment partners support the organisation with the requested, phased capital, subject to completion of the governance actions in Section 12.3 and ongoing monitoring against the milestones in Section 12.5.