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ProofX — AI-Native Product Launch GTM

A launch GTM for ProofX — an AI-native test-proof / V&V-evidence management platform for SaMD and Medical Devices — and how to push it into adjacent regulated markets.

Product ProofX

Category AI-native test-proof management

Beachhead SaMD · Medical Devices

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What ProofX is

ProofX is the system of record for test proof — it captures, generates, links and defends the verification & validation evidence a medical device or SaMD needs to pass audit, with AI doing the assembly work that today eats engineers' weeks.

In regulated device development, the product isn't done when the code works — it's done when the **evidence** is complete: requirements linked to tests, tests to results, results to a risk, and every artefact traceable and audit-ready. Teams assemble this by hand across spreadsheets, ALM tools and documents. It's slow, brittle, and the #1 cause of submission delay and audit findings.

ProofX is AI-native: it generates test cases from requirements, mines coverage gaps, drafts V&V protocols and reports, auto-builds the requirements-to-test traceability matrix, and keeps an always-current, notified-body-ready evidence file — with a human approver on every artefact that reaches a regulator.

The wedge is narrow and deep on purpose: **test-proof management for SaMD & medical devices first** (IEC 62304, ISO 14971, FDA design controls, EU MDR) — then the same evidence engine into every industry that must prove software is safe.

The problem & the job-to-be-done

PAIN Evidence is the bottleneck

Not the engineering — the proof of the engineering.

- V&V evidence assembled by hand across ALM, spreadsheets & docs
- Traceability breaks on every change; audits find the gaps
- Submissions slip while engineers rebuild the paper trail
- Every audit/notified-body review is a fire drill

JTBD "When a device feature is built..."

...I need its test evidence complete, traceable and audit-ready — without pulling senior engineers off the roadmap to assemble paperwork.

- Generate tests from requirements
- Keep traceability live through change
- Produce a notified-body-ready evidence file on demand

WHY AI-NATIVE The unlock

The assembly work — generation, gap-mining, drafting, linking — is exactly what LLMs do well, with human sign-off.

- Requirement → test generation
- Coverage-gap detection
- Protocol & report drafting
- Auto-traceability + change impact

GUARDRAIL Trust by design

Regulated buyers won't accept a black box.

- Human approver on every regulator-facing artefact
- Full audit trail of AI actions & edits
- Explainable, sourced generation
- Data isolation & validation-ready outputs

ICP — the beachhead

Start where the pain is regulated, acute and repeatable: SaMD and medical-device teams (and their India GCCs) that live or die by V&V evidence.

BEACHHEAD Who buys first

- SaMD / connected-device companies and MedTech GCC device programs
- Team size: 20–500 engineers with active V&V/regulatory load
- Economic buyer: VP R&D / Head of Quality or Regulatory
- Champion: V&V lead, test manager, or design-assurance owner
- User: verification engineers, test leads, RA/QA

TRIGGER When they buy

- EU MDR / IVDR submission or EUDAMED deadline
- An audit or notified-body finding on traceability
- A SaMD / AI feature entering review
- Scaling the team and drowning in evidence work

WEDGE Land narrow

One device family / one submission — prove ProofX cuts evidence time and passes review, then expand across the portfolio.

- Fixed-scope pilot on one program
- Success = evidence-assembly time down, zero new audit findings

DISTRIBUTION EDGE The NovintiX channel

NovintiX's services engagements (SaMD Assurance, Design-Control Accelerator) are ProofX's warm distribution — the tool the pod already uses becomes the product the client buys.

- Services-led product adoption
- Every engagement is a design partner

Positioning & category

Category: "AI-native test-proof management for regulated products." Not a test-automation tool, not an ALM, not an eQMS — the evidence layer that sits across them and makes the proof audit-ready.

Against ALM / test tools (Polarion, Jama, codebeamer, Azure DevOps): they store requirements and tests; ProofX generates the evidence and keeps it audit-ready on top of them — integrate, don't replace.

Against eQMS (Greenlight Guru, MasterControl): they manage quality processes; ProofX produces the V&V/test evidence that feeds them.

Against manual / consulting: ProofX turns a weeks-long human assembly job into a reviewed, always-current artefact — the productized form of what a validation consultant does.

One-liner: "ProofX turns your requirements and tests into audit-ready V&V evidence — automatically, with a human in the loop."

Pricing & packaging

Land with a low-friction pilot; expand on seats + evidence volume; anchor value to the audits passed and engineer-weeks reclaimed.

Why this shape: the pilot removes procurement risk; seats capture team adoption; the platform tier captures the CFO-level value (submissions on time, audits passed). The services-attached tier is the moat — NovintiX delivery makes ProofX sticky and de-risks adoption for cautious buyers.

Offer	Promise	Price · time
Pilot (one program)	Fixed-scope proof on a single device family / submission	\$15k–\$30k · 6–8 weeks
Team	Per-seat for a V&V/RA team + a program allowance	\$1.5k–\$3k / seat / yr
Platform	Org-wide, unlimited programs, SSO, audit exports, integrations	\$120k–\$400k / yr
ProofX + NovintiX pod	The product plus an expert pod that runs it for you (services-led)	custom
Regulated-cloud / on-prem	Validated deployment, data isolation, compliance add-ons	+ premium

Launch motion

1. **Design partners** — Recruit 3–5 SaMD/MedTech design partners (warm from NovintiX engagements). Build with them; earn the first proof points and case studies.
2. **Private beta** — Ship the wedge — requirement → test generation, auto-traceability, evidence export — to design partners on real submissions. Instrument time-saved and audit outcomes.
3. **Reference launch** — Publish 2–3 case studies with hard numbers (evidence time ↓, findings = 0). Launch to the SaMD/MedTech market via those references, not a splashy GA.
4. **Services-led scale** — Attach ProofX to every NovintiX SaMD/Design-Control engagement; convert services clients to product seats. Founder-led sales to buyers the case studies attract.
5. **Land & expand** — Grow pilots to team, team to platform; each passed audit is the expansion trigger.

Competitive landscape

The defensible edge: regulated-domain depth (62304/14971/MDR built in), a human-in-the-loop trust model auditors accept, and a services channel (NovintiX) that no pure-software competitor has.

Category	Examples	ProofX angle
ALM / requirements & test	Polarion, Jama, codebeamer, Azure DevOps	Integrate; ProofX adds AI evidence generation + audit-ready assembly on top
eQMS	Greenlight Guru, MasterControl, Qualio	Feed them — ProofX produces the V&V/test evidence their processes consume
Test automation / gen	Copilot-style code/test tools	Domain-specific + regulated: traceability, risk linkage, notified-body-ready output
Manual / consulting	Validation consultancies, in-house	Productizes the weeks-long human assembly job with a human-in-the-loop AI

Pushing ProofX into other markets

The evidence engine is the product; the standard is a plug-in. Every safety-critical and regulated industry has the same job-to-be-done — prove the software is safe — so ProofX expands by adding standard packs, not rebuilding.

Sequence expansion by **regulatory adjacency and pull**: markets whose evidence discipline is closest to MedTech go first, and each is entered on a design partner + a standard pack (the compliance mapping, artefact templates and rule set for that standard).

Market	Standard / driver	Why ProofX transfers	Entry
Pharma / GxP software	GAMP5, 21 CFR Part 11, CSV	Computer-system validation is the same requirement → test → evidence job	Warm via Novintix pharma work + a GAMP5 pack
Automotive	ISO 26262, SOTIF, ASPICE	Functional-safety V&V & safety cases need identical traceability & evidence	One ADAS/EV software design partner + a 26262 pack
Aerospace & Defense	DO-178C / DO-254	Certification evidence is traceability + V&V artefacts — ProofX's core	One avionics-software partner + a DO-178C pack; ITAR-aware hosting
Industrial / OT	IEC 61508 / IEC 62443	Functional-safety + security evidence for industrial control software	One industrial-controls partner + a 61508 pack
BFSI model risk	SR 11-7, EU AI Act	Model validation & documentation is evidence management for AI	One bank/insurer AI team + a model-risk pack
Horizontal QA/test evidence	SOC2, internal audit	Any team that must prove test coverage & traceability	Self-serve tier once the regulated packs mature

Expansion rule: never enter a market without (1) a design partner in it and (2) a standard pack that makes ProofX speak that industry's evidence language on day one. The core generation/traceability/human-in-the-loop engine never forks — only the packs multiply.

Metrics & the north star

North star: *audit-ready evidence artefacts produced & accepted* — the unit of value that ties to submissions on time and audits passed.

Activation: first program traced end-to-end in ProofX. **Value proof:** evidence-assembly time reduced (target 50–70%) with zero new audit findings.

Growth: pilots → team → platform conversion; seats per account; standard-packs adopted. **Retention/moat:** programs under management, services-attached accounts, audits passed on ProofX evidence.

The launch plans — 30, 90, 180 days and 1 year

30 days Design partners & the wedge

Goal. Lock design partners and define the narrowest lovable wedge.

- **Design partners.** Sign 3–5 SaMD/MedTech design partners (warm from NovintiX). One real submission each.
- **Wedge spec.** Scope MVP to: requirement → test generation, auto-traceability matrix, evidence export — with human sign-off & audit trail.
- **Trust model.** Define the human-in-the-loop, explainability and data-isolation model regulated buyers require.
- **Baseline.** Instrument each partner's current evidence-assembly time & audit-finding rate to prove ROI later.
- **Positioning.** Lock the category, one-liner, and the integrate-don't-replace stance vs ALM/eQMS.

Exit. 3–5 design partners signed, MVP wedge spec'ed, trust model defined, baselines captured.

90 days Private beta on real submissions

Goal. Ship the wedge to design partners and prove time-saved on live V&V work.

- **Beta build.** Ship generation + traceability + export to design partners on real programs.
- **Integrations.** Connect the top ALM (Jama/Polarion/Azure DevOps) so ProofX layers on, not rips out.
- **Prove ROI.** Measure evidence-time reduction & findings; target 50%+ time saved, zero new findings.
- **Case studies.** Draft 2–3 case studies with hard numbers from beta partners.
- **Pricing test.** Validate the pilot → team → platform ladder with beta accounts.

Exit. Beta live on real submissions, 1–2 integrations, measured ROI, 2–3 case studies drafted, pricing validated.

180 days Reference launch + services-led scale

Goal. Launch to the SaMD/MedTech market on references and convert NovintiX engagements into product revenue.

- **Launch.** Publish case studies; reference-led launch to SaMD/MedTech (no vanity GA).
- **Services attach.** Attach ProofX to every NovintiX SaMD/Design-Control engagement; convert to seats.
- **Convert pilots.** Move beta/design partners to paid Team/Platform tiers.
- **First standard pack.** Build the GAMP5 (pharma) pack — the closest adjacency — with a warm pharma design partner.
- **Motion.** Founder-led sales + a lightweight self-serve pilot on-ramp for inbound.

Exit. Public references, paying customers, ProofX attached to services deals, first adjacency pack (GAMP5) started.

1 year **A category product with an expansion engine**

Goal. Establish ProofX as the SaMD/MedTech evidence standard and prove the standard-pack expansion model in one adjacent market.

- **Category leader.** Recognized SaMD/MedTech test-proof product with a roster of reference customers.
- **Recurring revenue.** Team + Platform ARR; healthy pilot → platform conversion; net-retention from expansions.
- **Second market.** One adjacency live (Pharma/GxP most likely) via a standard pack + design partner — proving the model.
- **Moat.** Services-attached accounts, programs-under-management, and audits passed on ProofX evidence.
- **Roadmap.** Standard packs for automotive (26262) and aerospace (DO-178C) scoped for year two.

3–5 → 10+

Design partners →
customers

50–70%

Evidence time saved

**2 (MedTech
+ GxP)**

Standard packs live

**all NovintiX
SaMD deals**

Services-attached
accounts

1

Adjacent markets
proven

**audits
passed on
ProofX**

North star

Exit. Category presence in SaMD/MedTech, recurring ARR, one adjacent market proven via a standard pack, packs roadmapped for year two.

Illustrative product & GTM plan for ProofX, an AI-native test-proof / V&V-evidence management concept for regulated markets. Standard names (IEC 62304, ISO 14971, EU MDR/IVDR, GAMP5, ISO 26262, DO-178C, IEC 61508, SR 11-7) and competitor/tool names are real and referenced for positioning only — verify current requirements and competitive facts before acting. Any AI that touches regulatory evidence must keep a qualified human approver in the loop and meet the applicable validation and data-governance requirements. Not affiliated with any named company or product.