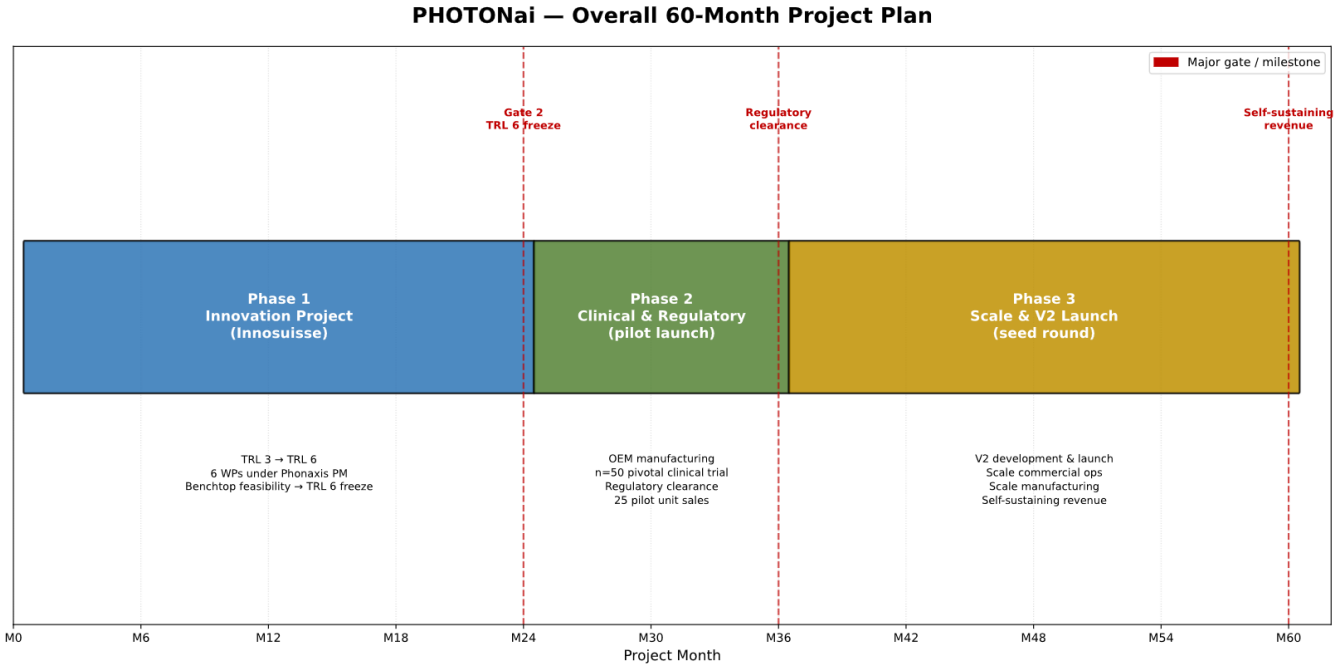
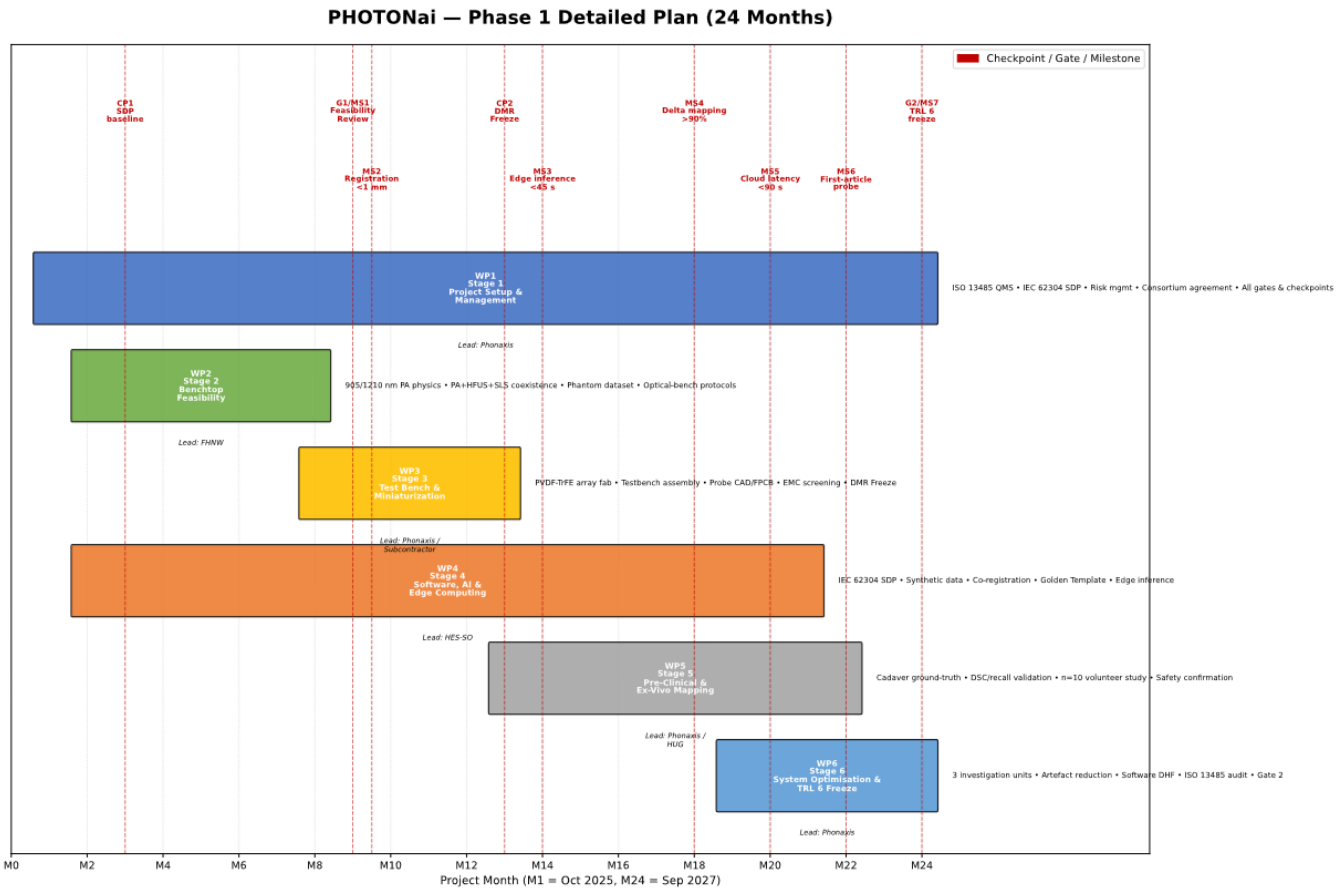
Project Plan

PHOTONai's development and commercialization follows a three-phase plan spanning 60 months. Phase 1 (M1–24) advances the device from TRL3 to TRL6. This innovation project is structured across six work packages.Phase 1 is about developing a test bench and the pilot product. We are currently looking for grants and funding to cover this phase of 24 months. Phase 2 (M25–36) covers the combined activities of OEM manufacturing, the n=50 pivotal clinical trial, and regulatory clearance, culminating in initial commercial sales of 25 pilot units. Phase 3 (M37–60) builds and launches V2, scales commercial operations and manufacturing, and drives PHOTONai toward market penetration and self-sustaining revenue, funded by an institutional seed round.



1 Detailed Plan - Phase 1

The 24-month programme follows a Stage structure covering Project Setup & Management → Benchtop feasibility → Testbench validation → Miniaturization → Ex-vivo cadaver validation → System optimization → TRL6 freeze.



Stage 1 — Project Setup & Management (M1–M24)

Project management is led by Phonaxis, which holds overall accountability for coordination, budget oversight, and delivery across all work packages (WP1), including instances where technical execution is delegated to a subcontractor, as with WP3. We planned to build a consortium with research partners under signed consortium and confidentiality agreements, a specialized subcontractor for custom array and testbench fabrication, and SFITS/HUG Geneva for clinical validation infrastructure. A formal Consortium Agreement governs foreground IP allocation, background IP retention, and publication rights. Quality management is established from project outset under ISO 13485 and IEC 62304 frameworks, ensuring documentation and change-control practices developed during Phase 1 carry forward without rework into Phase 2's investigational device manufacturing.

ID	Name	Month	Go / No-Go Criteria
MS1	Project Governance & Quality Management System Established	M2	Early setup of off-the-shelf reference equipment and benchmark protocols against which PHOTONai performance will be measured.
CP1	SW Dev Plan baseline,	M3	IEC 62304 Class B SDP approved
MS2	Multi-Modal Coexistence Demonstrated	M8	Benchtop proof that PA + HFUS + structured light can operate together without cross-interference; feeds into Gate 1 feasibility review.
G1	Feasibility Review	M9	QMS operational; FTO clear; risk file current; WP2 benchtop results acceptable

MS3	Data fusion & registration <1 mm	M10	Zero drops; mean TRE <1.0 mm
CP4	DMR Freeze	M13	Hardware BOM, software architecture, and probe design locked
MS4	Edge inference benchmark met	M14	Inference <45 s on Jetson Orin Nano; FID <20
MS5	Delta mapping and recall >90%	M18	DSC >0.80 (thin) / >0.85 (thick); volumetric error <0.1 mL; vascular recall >90%
MS6	Cloud telemetry latency	M20	End-to-end latency <90 s; security audit passed
MS7	First-article probe accepted	M22	Units meet WP3 specifications; CAPA closed or accepted
MS8	Investigation Devices Released & DHF Complete	M24	Final technical milestone before Gate 2: 3 investigation-grade units accepted, software release package delivered, and Design History File completed.
G2	TRL 6 & Regulatory Readiness	M24	Technical file complete; investigation devices accepted; clinical protocol approved

Table: Project's Critical CPs, Gates and MSs

CP = Checkpoint | G = Gate | MS = Technical milestone

Stage 2 — Benchtop Feasibility (M2–M8)

WP2 - Hardware Interleaving & Benchtop Feasibility Early work uses off-the-shelf reference equipment serves as a benchmark reference device providing real, empirical comparison data against an existing commercial PA+HFUS system and structured light scanner while establishing the optical-bench protocols and phantom dataset that feed WP3/WP4.

Stage 3 — Integrated Multi-modality Test Bench & Miniaturization (M8–M13)

WP3- Testbench Assembly & Miniaturization comprises custom tri-modal array design, fabrication, and testbench assembly, executed by a specialized subcontractor conducting testbench-level characterization and validation (not fabrication). Laser safety classification under IEC 60825-1 is completed ahead of human-adjacent work

Stage 4 — Software Architecture, Computational Fusion & Edge AI (M2–M21)

WP4 runs in parallel across Phase 1. Includes IEC 62304 SDP, synthetic data generation, cross-modal co-registration.

Stage 5 — Pre-Clinical Validation & Ex-Vivo Tissue Mapping (M13–M22)

In this stage (WP5), Pre-Clinical Validation confirms safety and performance before any human use, with Ex-Vivo Tissue Mapping as the specific method used to achieve it: cadaver-based ground-truth testing following DMR Freeze,

Stage 6 — System Optimisation, Investigation Device Assembly & TRL 6 Freeze (M19–M24)

Manufacture of three investigation-grade probe units, system-level artefact reduction and calibration re-verification, uncertainty quantification, final software Design History File (DHF), cybersecurity dossier, and ISO 13485 compliance audit. Concludes with TRL 6 freeze and Gate 2 (M24).

Work Package Ownership across Phase 1

WP	Focus
WP1	Project setup, QMS & regulatory strategy
WP2	Hardware interleaving & benchtop feasibility testing
WP3	Testbench assembly & miniaturization
WP4	Software architecture, data fusion & AI engines

WP5	Pre-clinical validation, ex-vivo mapping & volunteer feasibility study
WP6	System optimization, investigation device assembly & TRL 6 freeze

Table: Phase 1 Project Work-packages and Ownership

2 Phases 2 and 3 — Institutional Seed Round

Beyond Phase 1, PHOTONai's path to commercialization requires additional capital to fund the pivotal clinical trial, regulatory submission, and initial commercial scale-up, structured as two milestone-triggered seed tranches.

3 Solvency Protection

Founder capital invested to date: CHF 120,000, covering patent filing costs, a contracted engineer, and company setup activities — already reflected in the Y1 opening cash position above. AWS credits (agreed): CHF 100,000/year for 2 years (CHF 200,000 total.

4 Regulatory Pathway

- Classification (by M8): formal device classification under EU MDR 2017/745 and Swissmedic. Expected Class IIa or IIb, pending final classification.
- Laser safety: IEC 60825-1 laser safety classification.
- Ethics approval: CCER (Geneva) submission acknowledged at Gate 1.
- Quality management : ISO 13485 QMS and IEC 62304 software lifecycle processes.
- EU MDR technical file and CE marking/US 510(k) pathway: the basis of substantial equivalence to predicate ultrasound/imaging devices.

5 Manufacturing

Device manufacturing is outsourced to a contract electronics manufacturing (CEM)/OEM partner rather than performed in-house. Custom transducer array design and fabrication is being sourced from a specialized subcontractor with direct PVDF-TrFE and dual-mode array experience (evaluation ongoing). Investigational-grade unit manufacturing (3x units, Phase 2) requires ISO 13485-certified regulated manufacturing capability, which may be provided by the same subcontractor or a separate certified manufacturing partner, to be confirmed.