

The CHF 1.5M Productization Plan

From working prototype to a design-frozen, pilot-validated wheelchair control system.

18 MONTHS

Investment case • August 2026



CONCEPT VISUAL — FINAL INDUSTRIAL DESIGN TO BE DEVELOPED

The round turns promise into a product asset

TODAY

Working prototype

Core loop: non-invasive EEG signals translated into wheelchair control intent.

Early performance: founder-reported accuracy above 90%; independent replication is still required.

Open risks: safety architecture, user variability, integration, evidence and repeatable manufacturing.



MONTH 18

Final product v1.0

Design freeze with traceable requirements and verified safety controls. 10–15 pilot units plus a costed, supplier-ready manufacturing package.

Pilot evidence, technical documentation and conformity-assessment readiness. A focused commercial offer for 1–2 wheelchair platforms and partner sites.

The round retires product, safety, user, regulatory and supply-chain risk.

The final product is a complete control system

V1.0 combines intent decoding, shared control and independent safety — not just an AI model.

FOCUSED V1.0 SCOPE

Non-invasive EEG input and rapid per-user calibration.
Shared-control driving with obstacle avoidance and safe stop.
Local, safety-critical operation without a cloud dependency.
Caregiver override, setup workflow and secure audit logs.
Initial support for 1–2 wheelchair platforms.

Scope discipline makes the 18-month plan credible.

01

EEG interface

Signal quality, calibration and user intent input

02

On-device intent decoder

Real-time inference with confidence gating

03

Independent safety supervisor

Hazard rules, safe stop and caregiver override

04

Shared-control + wheelchair gateway

Obstacle avoidance and platform adapter

05

Setup app + secure logs

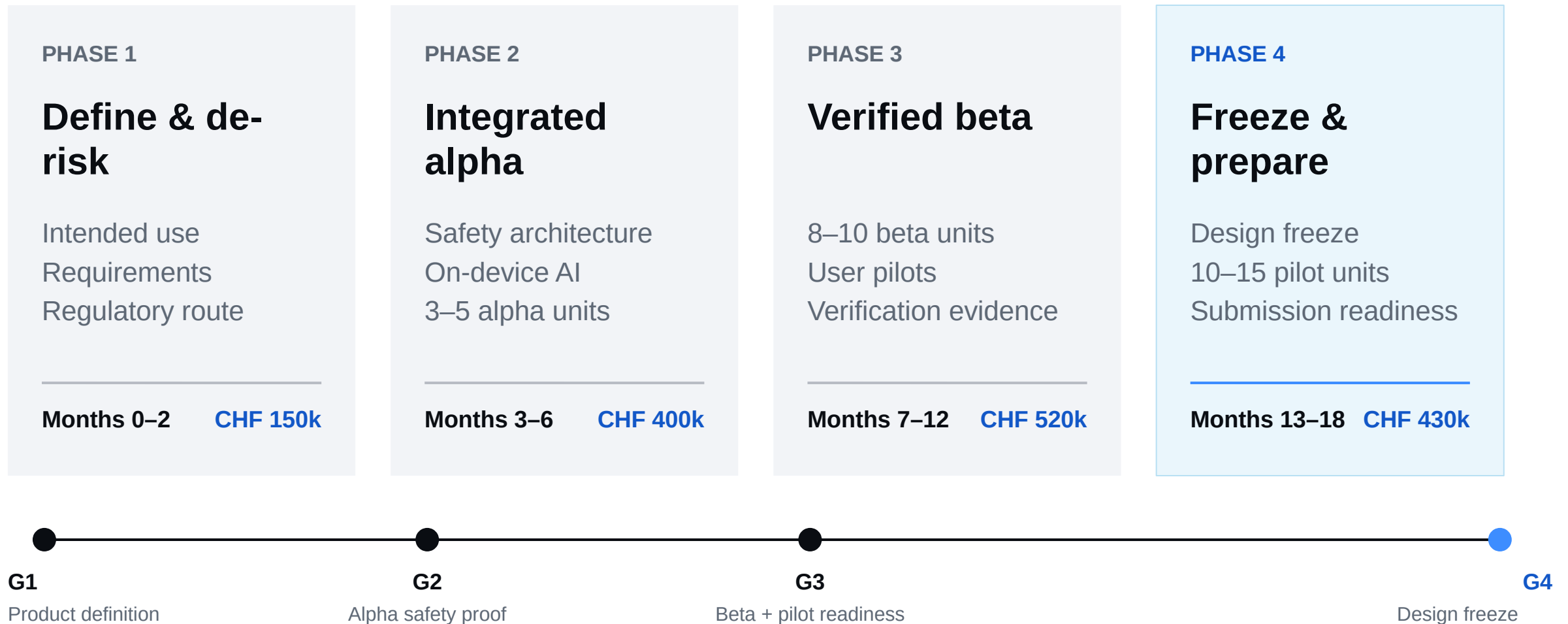
Configuration, diagnostics and traceable evidence

Five workstreams move in parallel

Each release is gated by safety evidence, usability evidence and traceable design controls.

WORKSTREAM	18-MONTH OUTPUT
01 Product & AI	Stable intent decoding, shared control, calibration and release software
02 Hardware & integration	EEG interface, safety controller, sensors and 1–2 platform adapters
03 Quality & regulatory	QMS, risk file, V&V, usability and technical documentation
04 User validation & pilots	Partner sites, representative users, pilot evidence and support workflow
05 Supply chain & launch	Costed BOM, qualified suppliers, manufacturing package and first offers

An 18-month roadmap creates four decision gates



Phase 1 locks the right product before scaling

0–2

MONTHS

CHF 150k

WHAT WE COMPLETE

Intended use, user needs and a focused v1.0 product definition.

System requirements, interfaces and preliminary architecture.

Regulatory qualification/classification and conformity path.

Preliminary hazard analysis and safety case outline.

QMS design controls, evidence plan and data protocol.

Target agreements with two pilot sites and integration partners.

EXIT GATE G1

Proceed only if:

Product requirements are approved.

Regulatory route is documented.

Top hazards have defined controls.

Pilot and platform targets are credible.

Outcome: the team builds one certifiable product — not several competing prototypes.

Phase 2 delivers an integrated alpha

The learned intent model is wrapped in deterministic safety controls and repeatable tests.

BUILD

EEG pipeline: signal quality, calibration and real-time decoding.

On-device AI: confidence thresholds and reproducible model releases.

Safety supervisor: safe stop, watchdogs and caregiver override.

Shared control: obstacle avoidance and wheelchair gateway.

Evidence engine: HIL simulator, automated tests and secure logs.

MONTHS 3–6

CHF 400k

Exit gate G2

Integrated alpha passes the locked bench and hardware-in-the-loop safety protocol.

3–5

integrated alpha units

≥100

bench / HIL test hours

≥90%

locked-protocol accuracy target

Phase 3 proves reliability with real users

USER PILOT

Can people use it safely and repeatedly?

Representative users across two target partner sites.

Calibration, task completion, fatigue, workload and caregiver workflow.

Defined reporting for adverse events, near misses and usability issues.

VERIFICATION

Does the beta meet its requirements?

Software, safety, cyber and wheelchair-interface verification.

EMC and electrical pre-compliance; reliability and misuse scenarios.

Traceability from user need to test result and residual risk.

8–10

verified beta units

12–20

target users, subject to approvals

≥500

cumulative device-hours target

Phase 4 freezes the design for repeatable delivery

MONTHS

13–18

CHF 430k

Exit gate G4

Final v1.0 baseline approved for conformity assessment and controlled pilots.

DESIGN FREEZE

Released hardware, firmware, AI model, safety rules and configuration.

EVIDENCE PACKAGE

V&V report, usability evidence, risk file and technical documentation.

MANUFACTURING PACKAGE

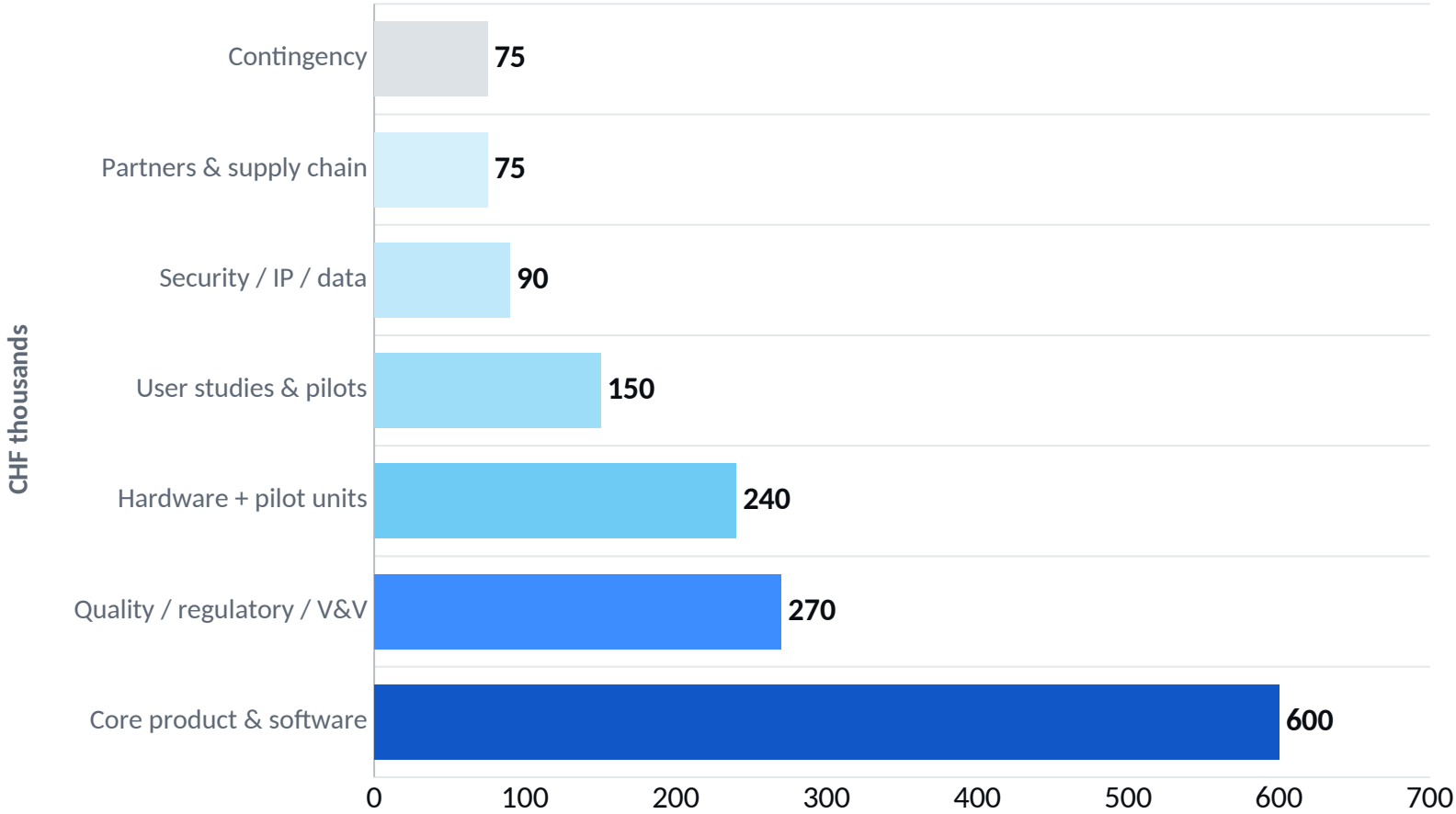
Costed BOM, drawings, test fixtures, suppliers and build instructions.

COMMERCIAL PACKAGE

Support process, partner offer, unit economics and first deployment plan.

Next-round scope: high-volume tooling, broad OEM expansion and international commercial rollout.

CHF 1.5M concentrates on product and evidence



Planning allocation — final mix depends on classification, supplier quotations and partner agreements.

74%

product, hardware and quality / regulatory evidence

CHF 83k

average planned monthly burn

10–15

final pilot units and build package

A lean core team is amplified by specialists

4–5

AVERAGE CORE FTEs

A blended European team keeps the runway credible while specialist work is bought when evidence is needed.

CORE OWNERSHIP

CEO / product & accessibility • AI/ML lead • embedded/robotics engineer • full-stack/data engineer

QUALITY & EVIDENCE

RA/QA lead • usability/clinical advisor • cybersecurity specialist • accredited test laboratories

DELIVERY PARTNERS

Rehabilitation sites • wheelchair platform partner(s) • industrial design • contract manufacturer

Governance: monthly burn review • gate review at G1–G4 • risk register owned by the product and QA leads

Compliance starts on day one

Classification first. Standards drive the requirements and test plan — not late-stage paperwork.

FRAMEWORK	ROLE IN THE PROGRAM
EU MDR + Swiss MedDO	Qualification, classification, conformity assessment and market access
ISO 13485	Quality management system and design controls
ISO 14971	Lifecycle hazard analysis, risk controls and residual-risk evidence
IEC 62304 + IEC 62366-1	Software lifecycle and safety-related usability engineering
ISO 7176-14 + ISO 7176-21	Powered-wheelchair control systems and EMC testing
IEC 81001-5-1	Secure health-software development and maintenance lifecycle

REGULATORY CAVEAT

The final route cannot be assumed today. It depends on intended purpose, system boundary, supported wheelchair platform and device classification.

Specialist determination is a first-60-day deliverable.

Five risks are designed out before launch

RISK	DESIGN RESPONSE	EVIDENCE GATE
User variability	Fast calibration, personalization, signal-quality checks and confidence gating	Locked multi-user protocol
Unintended motion	Independent safety supervisor, safe stop, caregiver override and misuse analysis	Hazard + HIL verification
Platform fragmentation	Start with 1–2 platforms; isolate interfaces behind a modular gateway	Integration verification
Regulatory rework	RA/QA ownership from month one and traceable design controls	G1 route + full V&V
Pilot / supply delay	Early site agreements, pre-selected parts and alternatives for critical components	Site + supplier readiness

Month 18: a financeable product platform

What CHF 1.5M delivers

A controlled v1.0 design freeze.
10–15 pilot units and a manufacturing package.
Verified software, hardware, safety and usability evidence.
A QMS-backed technical file and conformity-assessment readiness.
Pilot partners, support process and a focused commercial offer.

THE ASK

CHF 1.5M

18-month productization round

Target outcome: design-frozen, pilot-validated and ready for the selected conformity-assessment path.

Decision requested: approve the productization round and start Phase 1.