BETA.HEALTH®
INNOVATION READINESS LEVEL

USER READINESS LEVEL (URL)

User Readiness Level (URL) – Short form (one-line descriptions).

1	Hypothesis that a need/problem might exist
2	Specific needs of the User/Customer identified from secondary research.
3	First feedback from potential users, customers or experts obtained.
4	Problem/need and its importance confirmed by several customers or users.
5	Clear interest and relationships established with target customers/users.
6	Benefits confirmed by first user tests.
7	Customers in extended testing or first test sales; few active users.
8	First commercial sales with implemented sales process; substantial active users.
9	Widespread sales at scale; large and growing number of active users.

LEVEL	DETAILED DESCRIPTION
1	▪ Assumes a market need may exist but without evidence. ▪ No clear view of users/customers, problems, or alternatives.
2	▪ Conducted secondary research to map market, customers, user's needs, and alternatives. ▪ First clear description of problem/need hypothesis.
3	▪ Primary feedback from a few potential users/customers or knowledgeable experts is collected. ▪ Understanding of potential customer segments improves; hypothesis is updated.
4	▪ Problem/need confirmed by multiple customers/users appropriate for the market structure. ▪ Initial segmentation with basic customer profiles; user, payer, and decision-maker identified. ▪ Solution hypothesis and positioning versus alternatives defined from customer/user input.
5	▪ Target customers/users express interest in testing/piloting and confirm the solution can address needs (initial problem–solution fit). ▪ Relationships with target customers/users are established to provide ongoing input. ▪ First value proposition tailored to priority segments is defined.
6	▪ Customer/user testing confirms value and benefits. ▪ Sales pitch and value proposition updated based on feedback. ▪ First structured sales/user acquisition process described and initiated.
7	▪ Customer agreements in place for test sales or extended trials of early versions. ▪ Small number of active users of early versions. ▪ Discussions with partners to reach customers/users have been initiated when relevant.
8	▪ Market-ready solution sold to customers near target price levels. ▪ Substantial number of active users of the market-ready solution. ▪ Sales/user acquisition process implemented with dedicated people and supporting systems; first partner agreements in place when relevant.
9	▪ Repeatable and scalable sales across multiple customers, including through partners when relevant. ▪ Large and substantially growing active user base; focus on growth and demand generation.

TECHNOLOGY READINESS LEVEL (TRL)

Technology Readiness Level (TRL) – Short form (one-line descriptions).

1	Research results or initial technology idea identified.
2	Technology concept and potential applications formulated.
3	Proof-of-concept of critical functions demonstrated in laboratory or another simulated environment.
4	Basic components integrated and validated in laboratory; first integration to system/other equipment explored.
5	Technology validated in a relevant environment; initial system integration tested.
6	Prototype demonstrated in a relevant environment with (partial) integration.
7	Prototype demonstrated in an operational environment; full integration requirements documented.
8	Complete technology demonstrated in actual operations with system compatibility.
9	Complete technology proven and scalable in actual operations across sites.

LEVEL	DETAILED DESCRIPTION
1	▪ Promising research results or initial idea identified with potential benefits. ▪ Early notion of a technology to be developed.
2	▪ Technology concept described with potential applications. ▪ Applications are speculative; no proof the technology will work yet.
3	▪ Analytical and/or experimental lab tests/simulated environment of important parameters indicate feasibility. ▪ Active research and development started; first idea of end-user requirements and use cases.
4	▪ Basic components integrated and shown to work together in the laboratory environment. ▪ Initial validation provides evidence the concept can work. ▪ First integration feasibility with other systems or equipment explored.
5	▪ Basic components integrated and tested in a more realistic, relevant environment. ▪ Validation data indicate the technology will work under key conditions. ▪ Integration with hospital systems or equipment initiated in controlled settings.
6	▪ Representative model or prototype demonstrated to work in a relevant environment. ▪ Evidence meets most important performance requirements. ▪ Partial integration achieved with electronic health record systems, imaging systems, or monitoring equipment.
7	▪ Prototype near or at complete technology demonstrated in an operational environment used by end-users. ▪ Complete end-user requirements/specifications and use cases are in place. ▪ Integration requirements (interfaces, data flows, workflows) documented for operational use.
8	▪ Complete technology proven to work in actual operations by first users and meets all performance requirements. ▪ Complete means functional, compatible with people/processes/systems, and producible at reasonable cost. ▪ Compatibility with hospital infrastructure and workflows demonstrated.
9	▪ Complete technology is scalable and proven across multiple users/sites over time. ▪ Continuous improvement and optimisation of technology and production ongoing.

CLINICAL READINESS LEVEL

Clinical Readiness Level – Short form (one-line descriptions).

1	Clinical problem hypothesis formulated; no systematic data collected.
2	Retrospective data confirm problem relevance; no solution testing yet.
3	Retrospective analysis linked to potential solution; hypotheses for effect defined.
4	Small-scale prospective observations in simulated or relevant clinical environment.
5	Prospective feasibility study started in relevant clinical context; first safety/usability/performance indications.
6	Prospective single-site study completed with preliminary safety, performance, and effect.
7	Multi-site prospective study completed with predefined endpoints and positive results.
8	Pivotal or equivalent study completed; results broadly recognised and disseminated.
9	Documented clinical effect in routine care across multiple sites; continuous monitoring in place.

LEVEL	DETAILED DESCRIPTION
1	▪ Clinical problem hypothesis formulated without systematic documentation. ▪ No data collected to substantiate assumptions.
2	▪ Retrospective data (records, registries, literature) confirm the problem exists and matters. ▪ No prospective testing of the solution undertaken..
3	▪ Retrospective analysis extended to evaluate how the proposed solution could address the problem. ▪ Hypotheses defined for expected clinical effect and outcome measures.
4	▪ Small-scale prospective observations conducted in simulated or otherwise relevant environments. ▪ Early clinician and user feedback integrated into the solution and study preparations.
5	▪ Prospective feasibility study initiated in a relevant clinical setting. ▪ First indications of safety, usability, and clinical fit documented; protocol and ethics submissions prepared.
6	▪ Prospective single-site study completed with structured data collection. ▪ Evidence on safety, functional performance, and preliminary clinical effect collected and analysed.
7	▪ Multi-site prospective study completed with predefined endpoints and appropriate statistics. ▪ Results show clinically meaningful effect and acceptable safety profile; informs implementation approach.
8	▪ Pivotal or equivalent high-level evidence completed, meeting primary endpoints. ▪ Results accepted by the professional community; publications or peer review in progress. ▪ Comprehensive implementation materials prepared (training, integration guidelines).
9	▪ Clinical effect demonstrated in routine care across multiple settings. ▪ Continuous real-world data collection and evaluation support ongoing adoption and optimisation.

TEAM READINESS LEVEL (TMRL)

Team Readiness Level (TMRL) – Short form (one-line descriptions).

1	Lack of necessary competencies/resources; little insight into team needs.
2	Limited competencies present; first idea of additional team needs.
3	Some competencies in place; needed competencies identified and planned.
4	Champion present with clear idea of direction (startup/other way); several competencies in place; plan initiated to complement.
5	Initial organisation with main competencies; ownership and roles agreed.
6	Complementary, diverse, and committed team and organisation in place.
7	Well-functioning team and culture; plan for building lasting organisation over time.
8	Professional organisation in place (board, leadership, staff).
9	High-performing, well-structured organisation sustained over time.

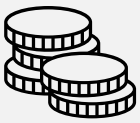
LEVEL	DETAILED DESCRIPTION
1	▪ Typically an individual lacking key competencies in technology, business, etc. ▪ Little insight into needed competencies and resources to verify the idea.
2	▪ One to two people with limited competencies and capacity. ▪ First idea of which additional people/competencies are needed and overall project goal.
3	▪ Some necessary competencies and capacity present to start verification. ▪ Gaps and diversity needs identified; initial plan for near-term recruitment.
4	▪ Clear idea on route to market (startup, licensing, internal implementation). ▪ At least one champion drives the project; several competencies present. ▪ Plan initiated to add missing competencies and capacity; roles discussion started.
5	▪ Team/Organisation working together with significant time commitment. ▪ Roles, goals, visions, and ownership share agreements clarified and signed. ▪ Initial processes/tools to share knowledge within the team.
6	▪ Complementary and diverse founding team capable of starting to build the business. ▪ All key near-term competencies and capacity present, including a clear leader. ▪ Recruitment of advisors/board started; awareness of team performance risks.
7	▪ Well-functioning team with clear roles and documented goals, vision, and culture. ▪ Plan for building organisation over longer term (~2 years). ▪ Learning and staff development processes implemented; board/advisors support development.
8	▪ Clear leadership and management team with relevant professional experience. ▪ Competent and diverse board and advisors in place and used professionally. ▪ HR processes ensure good practices and team diversity; necessary recruitments ongoing.
9	▪ Organisation is high performing and well-functioning. ▪ Continuous learning and improvement across all levels; incentives aligned to performance. ▪ Management team is maintained, developed, and performs over time.

MANAGEMENT READINESS LEVEL

Management Readiness Level – Short form (one-line descriptions).

1	No formal leadership structure; ad hoc decisions by individuals.
2	Roles and tasks outlined; informal coordination in place.
3	Basic project plan with milestones and responsibilities defined.
4	Leadership structure with clear accountability and regular follow-up established.
5	Leadership team manages resources, risks, and progress systematically.
6	Leadership coordinates development and early implementation strategically.
7	Strategic leadership supports scaling; processes adapted to growth.
8	Professional leadership for national implementation or market launch.
9	Fully developed organisation with sustained governance and high performance.

LEVEL	DETAILED DESCRIPTION
1	▪ No formal leadership structure or defined responsibilities. ▪ Decisions made on an ad hoc basis by one or few individuals.
2	▪ Roles and responsibilities outlined; initial coordination between key actors. ▪ Limited alignment on priorities, timelines, and deliverables.
3	▪ Basic project plan with milestones, timeline, and assigned responsibilities in place. ▪ Project manager or equivalent leadership role identified; early progress tracking started.
4	▪ Leadership structure established with documented responsibilities and accountability. ▪ Regular follow-up meetings and reviews; resource monitoring in place; core governance identified.
5	▪ Defined leadership team with decision-making authority; systematic progress and risk reporting. ▪ Effective coordination across team members and external partners.
6	▪ Leadership team coordinates development and early implementation efforts. ▪ Partnerships, stakeholders, and resources managed to achieve goals; adaptive planning in place.
7	▪ Strategic leadership guides scaling and cross-functional collaboration. ▪ Organisational structure and processes adapted for growth; mechanisms for learning and change applied.
8	▪ Professional leadership and governance in place for national implementation or full market entry. ▪ Capability to coordinate complex multi-site operations and adapt processes continuously.
9	▪ Fully developed organisation with high-performing leadership culture. ▪ Sustained governance and long-term capability for scaling, including international operations.



FUNDING READINESS LEVEL (FRL)

Funding Readiness Level (FRL) – Short form (one-line descriptions).

1	Little insight into funding needs/options; no funding for development and validation.
2	Funding needs and options for development and validation identified; efforts initiated. Early narrative for pitch in place.
3	Insight into overall funding options; initial funding for development and validation secured.
4	Funding to initiate development secured; next-stage pitch in place.
5	Funding secured for testing; First financial projections and roadmap,
6	Improved funding pitch based on feedback; discussions with sources started. Funding secured for first production of prototype
7	Funding for activities leading up to test of final product secured. Term-sheet level discussions; due diligence material in place.
8	Funding for all phases leading up to the first sale/use in actual operation has been secured. financial monitoring and forecasting in place.
9	Funding in place that enables scaling of the solution. Long-term strategy in place; next funding prepared with interested sources.

LEVEL	DETAILED DESCRIPTION
1	▪ Little insight into costs and activities for validation of the idea. ▪ No insight into funding options and no funding secured.
2	▪ Insight into costs and activities for initial validation (1–6 months). ▪ Potential funding sources for validation identified and outreach initiated. ▪ Early narrative for pitch in place build upon innovation model 3 core elements and 9 key areas
3	▪ Draft development plan (6–12 months) with activities and costs. ▪ Understanding of sources and types of funding and their requirements. ▪ Initial validation funding (often grants) secured.
4	▪ Development plan defined with budget, risks, milestones. ▪ Relevant funding sources for next stages identified. ▪ Sufficient funding to initiate first steps is secured; next-stage pitch prepared.
5	▪ Funding needs over time outlined with initial projections (budget, profit & loss). ▪ Funding roadmap with desirable sources/investors and cap table impact considered. ▪ Pitch tested with relevant audience (investors/funders).
6	▪ Funding needs clarified with more detailed projections including cash flow. ▪ Roadmap updated based on feedback to cover future rounds. ▪ Discussions initiated on ask and valuation with relevant funding sources.
7	▪ Basic accounting shows financial status; multiple funding scenarios outlined. ▪ Concrete discussions (term-sheet level) with clearly interested sources. ▪ Supporting material compiled to pass due diligence.
8	▪ Financial monitoring and accounting enable control of status and forecast of needs. ▪ Funding received for approximately 12 months runway or predictable recurring revenue. ▪ Funding roadmap updated based on progress and forecasts.
9	▪ Next needed funding defined reflecting scale-up plans and forecasted status. ▪ Long-term funding strategy in place and interest established from suitable sources. ▪ Pitch, business plan, and supporting materials continuously updated.

BUSINESS READINESS LEVEL (BRL)

Business Readiness Level (BRL) – Short form (one-line descriptions).

1	No or unclear business idea, market potential, or business case.
2	Business concept and market opportunity described; first view on business case. Path towards implementation/commercialisation decided (spinout, licensing or internal implementation)
3	Payment model, target market(s) and early business case described.
4	First calculations indicate an economically viable business model; initial business case outlined.
5	Market feedback on key assumptions; business case reinforced by willingness-to-pay and provider value.
6	Business model validated by target customers in pilots/test sales; business case quantified.
7	Business model validated by commercial sales; business case supported by market data.
8	Sales and metrics show a viable business model; business case supports adoption and scaling.
9	Business model proven to meet expectations on profit and growth; business case validated at scale.

LEVEL	DETAILED DESCRIPTION
1	▪ Business model: Vague or unspecified description of business idea/value proposition. ▪ Market opportunity: Little insight into market size and target customers. ▪ Business case: No awareness of economic value for hospitals/health systems.
2	▪ Business model: Business concept described (e.g., value proposition). ▪ Market opportunity: Initial overview of markets and potential size. ▪ Business case: Early reflection on drivers of cost and value in care pathways.
3	▪ Business model: Draft business model described (e.g., canvas format). ▪ Market opportunity: First target market(s) and sizing (e.g., total and serviceable markets). ▪ Business case: Preliminary estimates of resource use, savings, or revenue impact for providers.
4	▪ Business model: First calculations of costs, revenues, and pricing indicate possible viability. ▪ Market opportunity: Well-defined target market description (segments, value chain, geography). ▪ Business case: First structured assessment (e.g., budget impact drivers, coding/reimbursement context).
5	▪ Business model: Key assumptions (willingness to pay, pricing) validated by market feedback. ▪ Market opportunity: Positioning updated based on market input and competitive realities. ▪ Business case: Provider feedback supports expected savings or value (time, outcomes, throughput).
6	▪ Business model: Validated by target customers in realistic scenarios (pilot/test sales/pre-orders). ▪ Market opportunity: First target market decided (including geography) based on data. ▪ Business case: Quantified budget impact for providers documented.
7	▪ Business model: Validated by first commercial sales to several customers. ▪ Market opportunity: Target market and sales estimates validated by the market. ▪ Business case: Demonstrated in commercial use (procurement/reimbursement support).
8	▪ Business model: Sales and operating metrics show viability and growth. ▪ Market opportunity: Future target markets and internationalisation described and tested. ▪ Business case: Evidence package supports adoption at scale (decision-maker materials, templates).
9	▪ Business model: Operational and proven against expectations on profit and growth. ▪ Market opportunity: Active expansion into additional target markets. Business case: Validated at system level with real-world evidence of economic impact.

IPR READINESS LEVEL (IPRL)

IPR Readiness Level (IPRL) – Short form (one-line descriptions).

1	Hypothesising about possible intellectual property rights (IPR).
2	Different forms of IPR identified; ownership clarified; rationale if not protecting.
3	Possible key IPR described and initially evaluated; rationale documented if not protecting.
4	Protection possibilities confirmed, and priorities set; rationale tested with experts and recorded if no filing.
5	Draft IPR strategy created; first application filed or clear rationale for not filing.
6	Complete IPR strategy in place and validated; positive responses or justified non-protection.
7	Applications progressed to key regions; freedom-to-operate assessed.
8	IPR strategy implemented; key rights granted and complementary filings made; rationale reviewed where not protecting.
9	Strong IPR support for business; rights granted and maintained; access to necessary external IPR.

LEVEL	DETAILED DESCRIPTION
1	▪ Suspects results/ideas may contain IPR but without description or documentation. ▪ Limited knowledge of legal aspects, uniqueness, or state-of-the-art.
2	▪ Mapped different types of possible IPR (patents, trademarks, designs, copyright, trade secrets, digital assets, etc.). ▪ Ownership clarified and relevant agreements identified; explicit note if protection is not relevant and why.
3	▪ Key IPR described in sufficient detail to assess protectability. ▪ Initial protection evaluation via searches of publications/state-of-the-art (and possibly professional input). ▪ If choosing not to protect, rationale documented (e.g., trade secret, open-source, speed-to-market).
4	▪ Professional searches/analyses confirm protection possibilities and business-relevant priorities. ▪ May file first simple application/registration (e.g., trademark, provisional patent). ▪ If not filing, rationale documented (e.g., strategic openness, time-to-market).
5	▪ Draft IPR strategy prepared (how different IPR protect and create value). ▪ First formal application/registration of key IPR filed with professional support. ▪ Basic agreements in place to control key IPR (assignments, ownership).
6	▪ Complete IPR strategy aligned with business strategy and validated by a professional. ▪ Initial freedom-to-operate assessment performed to understand landscape and dependencies. ▪ Positive authority responses analysed; if not positive, plan developed with professional; if no protection is pursued, rationale documented.
7	▪ Entered national/regional phases for key filings (e.g., United States, European Union, Japan). ▪ More complete freedom-to-operate assessment clarifies dependencies or restrictions from others' IPR.
8	▪ IPR used proactively to support/protect business; agreements professionally managed; process for new IPR in place. ▪ Key IPR granted in first regions and complementary applications/registrations filed. ▪ Rationale is maintained and reviewed for any areas intentionally left unprotected.
9	▪ IPR strategy proven to create value for the business with granted rights maintained across relevant countries. ▪ Agreements in place to access all necessary external IPR.

REGULATORY READINESS LEVEL (RRL)

Regulatory Readiness Level (RRL) – Short form (one-line descriptions).

1	No or limited knowledge of regulatory frameworks in relation to the product/technology
2	Potentially relevant regimes identified; rationale documented if not applicable.
3	Initial dialogue with advisors or authorities; basic understanding of pathways.
4	Classification completed within relevant regulatory regimes; explicit justification if solution is outside certain regimes.
5	Detailed multi-regime strategy and documentation plan in place; exclusions argumentation with feedback experts/authorities documented.
6	Evidence gathering, verification, and compliance documentation underway.
7	Documentation complete for at least one regime; submission or review initiated.
8	Approval, certification, or formal compliance confirmation obtained; monitoring established.
9	Full ongoing compliance(Post Market Surveillance) across all relevant regimes and markets.

LEVEL	DETAILED DESCRIPTION
1	▪ No or minimal knowledge of applicable laws, standards, or guidance. ▪ No assessment of potential compliance obligations.
2	▪ Potentially relevant regimes identified (e.g., medical device, data protection, artificial intelligence, national sector rules). ▪ If considered not applicable, rationale documented (e.g., not a medical device, does not process personal data).
3	▪ Initial dialogue with regulatory advisors, consultants, or authorities started. ▪ Basic understanding of requirements and plausible pathways formed.
4	▪ Classification completed for applicable regimes and standards (including risk class where relevant). ▪ Explicit justification documented if outside certain regimes.
5	▪ Detailed strategy with milestones and documentation requirements covering all applicable regimes. ▪ Strategy includes rationale for exclusions and evidence required to maintain those decisions.
6	▪ Evidence collection, verification, and validation activities in progress to support compliance claims. ▪ Cross-regime considerations integrated (e.g., data protection and algorithmic transparency).
7	▪ Documentation complete for one or more regimes and submitted to the relevant authority, auditor, or body. ▪ Prepared for reviews, inspections, or audits.
8	▪ Approval, certification, or formal compliance confirmation obtained for one or more regimes. ▪ Processes established for ongoing monitoring and maintenance of compliance.
9	▪ Full compliance across all applicable regimes in target markets. ▪ Continuous monitoring, maintenance, and updates ensure sustained compliance; rationale for scope maintained.