



# Roadmap for Software Startups



## 01 - Problem and Need Identification

### Purpose

The goal of this step is to confirm that you are solving a real and meaningful problem for users, care providers, or healthcare organizations. Before building a product, you need to understand the workflow challenge, who experiences it, and whether the solution may fall under medical software regulation.

### Activities

- **Identify the core user, clinical, or operational problem.** This means understanding where patients, clinicians, administrators, or other users face friction today, what impact that has, and why current tools or processes are not solving the issue well enough.
- **Conduct user research in real settings.** Speak with relevant users and observe how they work in practice to uncover unmet needs, barriers, priorities, and behavior patterns that can shape a more relevant solution.
- **Segment the market and define your most relevant customer groups.** Clarify whether your first target users are hospitals, primary care providers, municipalities, employers, insurers, or consumers, and identify where the need is strongest.
- **Estimate market size and commercial potential.** Build an early view of the market using relevant models for SaaS, licensing, transaction-based pricing, or other software business models.
- **Clarify the regulatory position of the solution.** Determine whether the product is software as a medical device, wellness software, administrative software, or another category, and understand what that means for development and compliance.
- **Assess privacy and security requirements from the beginning.** Review what data the software will process and what legal, technical, and security obligations may apply, such as GDPR, HIPAA, NIS2, or internal hospital requirements.

### Milestones and Outputs

- A clearly documented problem and prioritized use cases
  - An initial value proposition for key user groups
  - Early clarity on regulation, privacy, and security requirements
  - A stronger basis for product and market decisions
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### Materials from LSA Training Camps

#### Business model design 1

Business Model Design Level 1 helps early-stage startups build a strong business model through practical work with the Value Proposition Canvas and Business Model Canvas. The training camp helps founders clarify customers, value creation, and commercial logic across segments, relationships, channels, revenue, activities, resources, partners, and costs, while making assumptions visible and testable.

#### Master Your Market

Master Your Market will help you learn how to understand the healthcare landscape, identify and prioritize customers, sharpen your value proposition, and communicate your story across presentations and digital channels.

## 02 - Business Model Preparation & Early Investment

### Purpose

The goal of this step is to confirm that you are solving a real and meaningful problem for users, care providers, or healthcare organizations. Before building a product, you need to understand the workflow challenge, who experiences it, and whether the solution may fall under medical software regulation.

### Activities

- **Define the most suitable business model for the product.** Consider whether the company should operate as SaaS, per-site licensing, usage-based pricing, freemium, enterprise contracts, or another model that fits the customer and buying process.
- **Develop early pricing and unit economics assumptions.** Estimate how much value the product can deliver, how customers may be charged, and what customer acquisition and retention could look like over time.
- **Outline the expected sales motion.** Explore whether the product is best sold through self-service, inside sales, enterprise sales, channel partners, or integrations with larger platforms.
- **Prepare a go-to-market plan focused on early traction.** Identify first pilot customers, reference sites, early adopters, and the most realistic path to entering the market.
- **Create an early funding strategy.** Match capital needs to milestones and consider relevant sources such as grants, accelerators, angels, and early-stage investors.
- **Build a 12–24 month roadmap.** Balance product development, compliance work, pilot execution, commercial experiments, and fundraising in a way that shows a clear path forward.

### Milestones and Outputs

- An investment-ready pitch with business model and go-to-market logic
- Clear target customer segments and pilot pipeline
- Early pricing and unit economics assumptions
- A milestone roadmap aligning product, sales, and compliance

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### Materials from LSA Training Camps

#### Basics of Investment & Capital for Life Science Startups

Basics of Investment & Capital helps early-stage Life Science and health tech startups understand investor expectations and prepare for funding. The training camp covers investor readiness, how investors evaluate Life Science opportunities (due diligence), strategic networking, and the role of ESG, EU taxonomy and non-dilutive funding.

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### Business model design 2

Business Model Design Level 2 builds on the work from Level 1 and helps startups turn business model assumptions into structured learning. Through practical exercises, founders identify key hypotheses, design experiments, and use evidence to refine their strategy and business model. The training camp introduces experimentation as a way to test desirability, feasibility, and viability, and includes work on validation methods, business strategy, and different commercialization paths such as direct sales and licensing.

### How venture capital works & the key elements of raising capital

How Venture Capital Works & the Key Elements of Raising Capital gives a practical introduction to venture capital, what makes a company investable, and how to prepare for fundraising. The training camp covers financing options across stages, how investors assess risk and return, and how to communicate a credible equity story.

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### Winning the deal – Selling to public sector

Winning the deal – Selling to public sector helps life science startups understand how public healthcare systems buy, decide and implement new solutions. The training camp introduces procurement logic, key decision-makers, value propositions, business cases, partnerships and market entry strategies. Participants work hands-on with where their solution fits, who to approach, and how to communicate value in a way that resonates with public buyers.

## 03 - Company Formation

### Purpose

The purpose of this step is to establish the legal, organizational, and IP foundation of the company. This ensures that ownership, data rights, governance, and founder alignment are in place early.

### Activities

- **Incorporate the company and define the ownership structure.** The legal setup should support future fundraising, operations, and long-term company development.
- **Agree on founder roles, vesting, and decision-making.** Define who leads product, technology, commercial work, and operations, and make sure responsibilities and ownership terms are clearly agreed from the start.
- **Secure ownership of code, models, and datasets.** Ensure that the company controls the assets it needs, especially if parts of the work come from external developers, universities, or collaborators.
- **Put essential legal and privacy arrangements in place.** This may include shareholder agreements, employment terms, privacy policies, data processing agreements, and confidentiality terms.
- **Set up basic governance and external support.** Build an advisory board or mentor structure that can support product, commercial, regulatory, and technical decisions as the company grows.
- **Prepare the company to operate professionally.** Even at an early stage, it is useful to establish basic routines for reporting, documentation, and compliance-minded decision-making.

### Milestones and Outputs

- A legal entity with clear ownership of code, data, and IP
- Founder agreements and governance basics in place
- Foundational privacy and legal documentation started
- A company structure ready to support early execution

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### Materials from LSA Training Camps

#### Dynamic Leadership & Team Excellence for Life Science Startups

Dynamic Leadership & Team Excellence will help you understand and develop your leadership and communication skills so you can lead clearly and confidently. You learn how to create a strong, healthy team with clear roles and responsibilities, and how to build a supportive structure. Throughout, the workshop connects sustainable leadership and culture to building a long-term, resilient business.

#### IP strategy for life science in medtech and healthtech

IP strategy for life science in medtech and healthtech helps founders understand how intellectual property can protect value, reduce risk and support investment readiness. The training camp shows how IP links to product development, ownership, market access and go-to-market decisions from an early stage.

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**IP strategy for life science in pharma and biotech**

IP strategy for life science in pharma and biotech helps founders understand how intellectual property supports company value, market position and long-term growth. The workshop introduces the essentials of patents, trademarks, designs, trade secrets and ownership, and shows how IP strategy should be integrated with R&D, financing and go-to-market planning. It also highlights the importance of timing, especially in relation to publication, clinical development and future market entry.

## 04 - MVP and Technical Feasibility

### Purpose

This step is about proving that the software solution can work in practice. The focus is to build an MVP, test the most critical assumptions, and validate that users can engage with the product in a meaningful way.

### Activities

- **Build an MVP or early product version.** Develop a first usable version of the software that includes the core functionality needed to test the concept with real users.
- **Design the user experience around actual workflows.** Create UX and UI that reflect how users think and work, and use usability testing to identify friction early.
- **Test the most important product assumptions.** Focus on things like onboarding, engagement, workflow fit, retention, data quality, and whether the product solves a problem users truly care about.
- **Define a technical architecture that can evolve.** Make early decisions about cloud setup, interoperability, scalability, data structure, and security with future growth in mind.
- **Build the first integrations where needed.** If the solution depends on EHRs, LIMS, wearables, devices, or third-party systems, start validating how integration will work in practice.
- **Learn quickly and iterate.** Use feedback from real user interaction to refine features, workflows, and technical choices before scaling too early.

### Milestones and Outputs

- A working MVP tested with a small group of real users
- Early insights into usability, engagement, and workflow fit
- Initial technical architecture and product direction defined
- Evidence that the concept has practical potential

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## 05 - Product Hardening and Compliance Preparation

### Purpose

The purpose of this step is to make the software stable, secure, and ready for pilots or more formal customer use. At the same time, the company begins preparing for relevant compliance and documentation requirements.

### Activities

- **Improve reliability and software quality.** Strengthen performance, error handling, stability, and robustness so the product can be used in real-world settings with lower operational risk.
- **Implement core security practices.** Build in encryption, access controls, logging, monitoring, and other security mechanisms that are expected by enterprise customers and regulators.
- **Set up disciplined development processes.** Introduce automated testing, CI/CD pipelines, incident management routines, and documentation practices to support more reliable releases.
- **Clarify the compliance path based on the product category.** If the product is regulated software, start aligning development and documentation with relevant standards. If it is not regulated, focus on privacy, information security, and enterprise trust requirements.
- **Document risks and mitigation actions.** Identify technical, operational, privacy, and compliance gaps and create a plan for addressing them before pilots or scale-up.
- **Prepare the organization for more formal customer dialogue.** As the product matures, customers will expect stronger answers on security, uptime, support, and quality processes.

### Milestones and Outputs

- A stable and secure version ready for pilots
  - Documented processes for development, testing, and incident handling
  - Compliance gaps identified with a mitigation plan
  - Increased readiness for customer-facing deployments
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## 06 - Pilot Deployments / Early Market Validation

### Purpose

This step is where the company starts proving real-world value. The focus is to test the product with actual customers, demonstrate useful outcomes, and learn what is needed for adoption and commercialization.

### Activities

- **Run pilots with relevant customers or users.** Deploy the product in real environments such as hospitals, clinics, municipalities, employers, or consumer settings to understand how it performs in practice.
- **Measure the outcomes that matter.** Track indicators such as adoption, engagement, retention, workflow improvements, time savings, or outcome-related signals to understand product value.
- **Validate implementation and onboarding.** Learn what is required for setup, training, support, integration, and day-to-day usage so future deployments can become easier and more repeatable.
- **Test commercial assumptions through pilots.** Explore pilot fee models, subscription logic, usage-based agreements, or other pricing structures that fit the product and buying process.
- **Collect proof points that support credibility.** Build case studies, reference sites, testimonials, and early ROI stories that can support future sales and fundraising.
- **Use customer feedback to improve the product.** Early pilots often reveal what matters most for workflow fit, feature priorities, pricing, and long-term product direction.

### Milestones and Outputs

- Documented customer value and user outcomes
- First paying customers or signed pilot agreements
- Reference sites and early case material
- Stronger understanding of implementation and pricing

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## 07 - Advanced Clinical Development / Market Access Preparation

### Purpose

The goal of this step is to secure the approvals, certifications, and commercial readiness needed for broader market access. The company prepares the product and organization for enterprise customers and more scalable deployment.

### Activities

- **Complete required regulatory or certification work.** For regulated software, this means preparing and submitting documentation for MDR, FDA, or other pathways. For enterprise software, it may include certifications such as ISO 27001 or SOC 2.
- **Strengthen the product for enterprise buying processes.** Make sure the software, security posture, documentation, and internal processes can stand up to procurement, IT reviews, legal review, and compliance checks.
- **Develop the commercial playbook for scale.** Create materials and processes that help handle contracting, implementation, onboarding, security questionnaires, SLAs, and customer success at a larger scale.
- **Prepare for multi-site and multi-country rollout.** If relevant, adapt the product and documentation for different languages, legal contexts, deployment settings, and local compliance requirements.
- **Refine commercial contracts and service commitments.** As the company matures, customers expect clearer terms, support models, uptime commitments, and accountability structures.
- **Align compliance and market access planning.** Approvals and customer access should be handled together so the company is ready not just to launch, but to sell.

### Milestones and Outputs

- Regulatory approval and/or key compliance certifications
  - Enterprise-ready product, documentation, and contracts
  - A clear market access plan for target segments and geographies
  - Increased readiness for broader rollout
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## 08 - Commercialization

### Purpose

This step is about growing revenues and scaling customer adoption. The company moves from pilot-based learning to structured commercial execution.

### Activities

- **Scale sales capacity and channel strategy.** Build the right mix of inside sales, enterprise sales, partnerships, or channel-based selling to support market growth.
- **Standardize onboarding and customer success.** Develop repeatable processes that help new customers adopt the product successfully and achieve value faster.
- **Invest in market visibility and lead generation.** Use events, content, networks, digital campaigns, and thought leadership to create awareness and generate qualified opportunities.
- **Use product analytics to support commercial growth.** Track usage patterns, churn drivers, activation, and engagement to improve product performance and customer retention.
- **Expand integration and ecosystem presence.** Broader adoption often depends on being connected to other systems, devices, and workflows already used by customers.
- **Improve the commercial model through real market feedback.** Continue refining pricing, positioning, packaging, and sales strategy as more customers adopt the product.

### Milestones and Outputs

- Growing recurring revenue
- Adoption across multiple customers or regions
- A more predictable sales pipeline and conversion model
- A stronger commercial position in the market

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## 09 - Organizational Build-Up and Scaling

### Purpose

The purpose of this step is to build a company that can scale sustainably. The product is no longer the only focus — now the organization, processes, and leadership need to support growth across markets.

### Activities

- **Hire leaders for the next phase of growth.** Expand the leadership team with capabilities across product, engineering, sales, customer success, compliance, and operations.
- **Implement company-wide metrics and dashboards.** Track key indicators such as MRR, churn, NRR, NPS, uptime, release quality, and operational efficiency to guide decisions.
- **Formalize how teams work together.** Build more mature ways of working across product development, customer delivery, sales execution, and internal support.
- **Expand into new markets in a deliberate way.** Use local partners or direct presence to grow internationally while adapting to customer expectations and market realities.
- **Raise the capital needed for scale.** Growth often requires additional financing to support hiring, expansion, infrastructure, and strategic opportunities.
- **Continuously refine the organization using performance data.** Strong scaling requires not just adding people, but improving how the company operates as it grows.

### Milestones and Outputs

- A scalable product and go-to-market organization
- A robust operations and service organization
- A repeatable and measurable growth model
- Stronger cross-functional execution
- An organization ready for large-scale expansion

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## 10 - Strategic Maturity and Exit / Expansion

### Purpose

This final step is about long-term strategic positioning and value creation. The company focuses on strengthening its market role while preparing for expansion, acquisition, or public-market readiness.

### Activities

- **Prepare the company for strategic opportunities.** This may include building a strong data room, improving governance, sharpening reporting, and making the company more attractive to acquirers or investors.
- **Evaluate future strategic paths.** Depending on the business, this may involve IPO preparation, strategic M&A, partnerships, continued independent growth, or international expansion.
- **Expand the product portfolio over time.** Consider new modules, AI capabilities, adjacent workflows, or additional customer segments that strengthen the company's market position.
- **Build a broader commercial presence.** Mature software companies often need regional hubs, stronger alliances, and a more developed partner ecosystem.
- **Optimize long-term capital strategy.** Align financing choices with long-term ambitions and create flexibility for future growth or strategic moves.
- **Adjust strategy as technology and regulation evolve.** Market expectations, competition, and compliance requirements will continue to change, and strategy must evolve with them.

### Milestones and Outputs

- A mature software company with a strong product portfolio
- Clear strategic positioning in the market or ecosystem
- Readiness for exit, expansion, or long-term independent growth
- Stronger long-term value creation options

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