



Roadmap for Medtech and Pharma Startups



01 - Problem and Need Identification

Purpose

The goal of this step is to confirm that you are solving a real and important clinical problem. Before building a company or product, you need to understand the unmet need, who experiences it, and why current solutions are not good enough.

Activities

- **Identify the unmet clinical need and map the real-world problem in detail.** This means understanding where patients, clinicians, or healthcare systems face pain points today, what the consequences are, and why existing solutions fail to fully solve the issue.
- **Study patient journeys and stakeholder perspectives.** Look at how patients move through diagnosis, treatment, monitoring, and follow-up, and speak with clinicians, care teams, hospitals, and payers to understand where value can be created.
- **Segment the market and define the most relevant target groups.** Clarify which patient populations, indications, clinical settings, or customer groups are most attractive and where the problem is urgent enough to support adoption.
- **Assess market size and commercial potential.** Build an early view of the total market opportunity and estimate how much of that market could realistically be served over time.
- **Review the IP landscape and freedom-to-operate.** Identify relevant patents, competing technologies, and potential barriers that could affect development, partnering, or commercialization.
- **Explore the likely regulatory pathway at an early stage.** Determine whether you are developing a drug, device, combination product, or another regulated solution, and understand what that may mean for timelines, evidence requirements, and risk.

Milestones and Outputs

- A clearly documented clinical problem and set of use cases
 - An initial value proposition
 - Early clarity on IP and regulatory risks
 - A stronger foundation for choosing indication and product direction
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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.

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.

Master Your Market

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02 - Business Model Preparation & Early Investment

Purpose

This step is about making the project investable. You translate the identified need into a credible business case and show how the company could create value for patients, healthcare systems, and investors.

Activities

- **Translate the problem into a compelling value proposition.** Describe how the solution could improve clinical outcomes, reduce burden on care teams, increase efficiency, lower costs, or improve quality of life for patients.
- **Develop early business model assumptions.** Explore how the company may eventually generate revenue, what pricing logic could apply, and how reimbursement or procurement might influence adoption.
- **Build early financial logic around the opportunity.** Estimate the economics behind the business, including assumptions around development costs, customer value, market entry, and long-term commercial potential.
- **Outline a go-to-market approach.** Consider who the first users, buyers, and influencers will be, how you will gain clinical credibility, and what early sales or partnership strategy could look like.
- **Prepare an early funding strategy.** Identify relevant sources of capital such as grants, incubators, angels, family offices, or early-stage VC, and match financing needs to the most important milestones.
- **Create a 12–24 month roadmap.** Define the key technical, clinical, regulatory, and commercial milestones that will show progress and reduce risk in the eyes of investors and partners.

Milestones and Outputs

- An investment-ready pitch deck
- A clear business model and go-to-market hypothesis
- A roadmap with technical, clinical, and regulatory milestones
- Better alignment between company vision and investor expectations

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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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03 - Company Formation

Purpose

The goal here is to create the legal and organizational foundation for building the company. This step ensures that ownership, IP, governance, and decision-making are set up properly from the beginning.

Activities

- **Incorporate the company and choose the most suitable legal structure.** The setup should reflect your fundraising plans, ownership expectations, and long-term ambitions, while also being practical for day-to-day operations.
- **Agree on founder roles and ownership terms early.** Define who is responsible for which areas, how decisions are made, how equity is split, and how vesting protects the company if roles change over time.
- **Secure control of intellectual property.** Make sure relevant inventions, know-how, data, and future developments are properly assigned or licensed into the company, especially if the project originates from a university or hospital.
- **Put core legal agreements in place.** This may include founder agreements, shareholder agreements, employment terms, confidentiality agreements, and advisory arrangements.
- **Build an initial governance structure.** Establish a board or advisory setup with access to clinical, regulatory, technical, and commercial expertise that can help guide the company through early decisions.
- **Raise the first capital needed to start operating.** This can include grants, pre-seed investment, soft funding, or convertible instruments that allow the company to move from project to venture.

Milestones and Outputs

- A legally established company with clear ownership
- IP assigned or licensed into the company
- Founder and governance structure in place
- A basic organizational setup ready for execution

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.

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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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04 - Early Technical / Biological Proof-of-Concept

Purpose

This step is about showing that the solution can actually work. The focus is to reduce early scientific and technical uncertainty by testing the core concept and validating the main assumptions.

Activities

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Milestones and Outputs

- Preclinical or technical data showing feasibility
- An initial prototype or formulation
- A stronger IP position supported by data
- A refined value proposition based on early results

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05 - Extended Preclinical Development

Purpose

The purpose of this step is to reduce technical, clinical, and regulatory risks before entering human studies or formal submissions. You move from early feasibility to a more robust and documented development program.

Activities

- **Expand the evidence base with more rigorous preclinical studies.** This often includes toxicology, safety pharmacology, GLP studies, verification work, and other tests needed to demonstrate that the product is sufficiently understood and controlled.
- **Improve product robustness and consistency.** Refine formulation, delivery, device performance, stability, and manufacturing-related parameters so that the product behaves reliably and can be reproduced at the required quality level.
- **Prepare manufacturing for the next stage of development.** Begin establishing the CMC strategy, identify manufacturing partners if relevant, and put quality systems and documentation practices in place.
- **Refine the regulatory strategy in detail.** Clarify which studies, endpoints, standards, and submission pathways are required, and align the development plan with expectations from authorities or notified bodies.
- **Start preparing the formal documentation package.** Build the technical, quality, and scientific materials needed for IND, CTA, IDE, or equivalent applications.
- **Use findings to reduce downstream risk.** This step is not only about generating data but about identifying weaknesses early enough to improve the product before clinical or pivotal stages.

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Roadmap to market – Medical Device

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06 - Early Clinical Development / Pilot Market Validation

Purpose

This step is where you begin to document safety, early efficacy, and real-world relevance. At the same time, you start validating whether the solution has a credible path to market adoption.

Activities

- **Conduct early clinical studies designed to answer the most important questions.** Depending on the product type, this may include Phase I studies, pilot studies, first-in-human work, feasibility trials, or early device performance studies.
- **Generate evidence on safety and early performance.** The goal is to show that the product can be used as intended and that there are credible signs of clinical or functional benefit in the target setting.
- **Refine the clinical development strategy based on early results.** Use insights from study execution, patient response, investigator feedback, and operational challenges to improve trial design and development priorities.
- **Begin validating the commercial case alongside the clinical work.** Engage clinicians, hospitals, and payers to understand how the early evidence is perceived and what additional proof will be needed for future adoption.
- **Align financing with value-inflection points.** Use the clinical plan and emerging data to support fundraising from seed investors, venture capital, strategic partners, or grant providers.
- **Strengthen your network of clinical supporters.** Early key opinion leader engagement can help improve the product, support study execution, and build trust in the company's direction.

Milestones and Outputs

- Early clinical data on safety and performance
- Initial evidence of efficacy or proof-of-concept in the target population
- Stronger support from key opinion leaders and early partners
- A refined business model and market positioning

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07 - Advanced Clinical Development / Market Access

Purpose

The purpose of this step is to achieve regulatory approval readiness and prepare for market access. You are no longer only proving the product works — you are building the evidence and strategy needed for launch.

Activities

- **Run pivotal or confirmatory studies that can support approval.** These studies are typically larger, more structured, and designed to meet formal regulatory and market access requirements.
- **Prepare and manage interactions with regulators.** This includes submission planning, dossier preparation, addressing questions, and ensuring that the product, evidence package, and documentation meet the required standards.
- **Develop the market access strategy in parallel.** Work on pricing, reimbursement, coding, health economic evidence, and country-specific access plans so commercialization does not start too late.
- **Clarify the target launch markets and sequencing.** Decide where to launch first based on regulatory feasibility, reimbursement attractiveness, clinical need, and commercial readiness.
- **Prepare for post-market obligations.** Build plans for pharmacovigilance, post-market surveillance, real-world evidence, and ongoing safety or performance monitoring.
- **Coordinate clinical, regulatory, and commercial planning.** At this stage, success depends on the company being aligned across functions rather than treating approval and launch as separate processes.

Milestones and Outputs

- Regulatory approval or clearance readiness
- A completed or near-complete market access strategy
- Strong clinical evidence for approval and adoption
- Launch readiness from a regulatory and payer perspective

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08 - Commercialization

Purpose

This step focuses on turning regulatory and clinical progress into real market adoption. The company moves from development into launch, sales, and delivery.

Activities

- **Set up manufacturing and supply capabilities for commercial use.** Ensure that production, quality control, logistics, and delivery can support launch volumes and meet the required compliance standards.
- **Build the commercial infrastructure needed to sell and support the product.** This may include sales capabilities, distributor models, customer support, training materials, and launch processes.
- **Engage the healthcare market in a structured way.** Work with hospitals, clinics, physician groups, procurement teams, and payers to drive uptake and remove practical barriers to adoption.
- **Strengthen clinical credibility in the market.** Continue collaborating with key opinion leaders, publish results where appropriate, and support education and awareness among users and decision-makers.
- **Collect post-market data and real-world evidence.** Use early commercial experience to understand product performance, user behavior, clinical outcomes, and opportunities for improvement.
- **Refine the market approach based on adoption signals.** Early commercialization often reveals what messaging, pricing, training, and support models are needed to improve growth.

Milestones and Outputs

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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 the leadership team needed for scaling.** As the company grows, stronger capabilities are needed across medical affairs, regulatory, quality, operations, commercial execution, finance, and people management.
- **Implement clear KPIs and management systems.** Build a more structured way of tracking performance across clinical progress, operational quality, sales, customer adoption, and organizational health.
- **Standardize how the company works.** Develop repeatable processes for manufacturing, regulatory operations, quality management, customer support, reporting, and internal decision-making.
- **Expand into new geographies in a controlled way.** Adapt the product, regulatory strategy, distribution setup, and commercial approach to local market requirements and opportunities.
- **Build strategic partnerships that can accelerate growth.** This may include commercial partners, distributors, co-development relationships, manufacturing partners, or larger industry players.
- **Raise growth capital where needed.** Larger scale often requires additional financing to support international rollout, commercial team expansion, manufacturing scale-up, or pipeline development.

Milestones and Outputs

- A scalable organization with clear roles and processes
- A repeatable growth model across markets or indications
- Stronger operational maturity and cross-functional execution
- A company structure ready for larger commercial expansion

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10 - Strategic Maturity and Exit / Expansion

Purpose

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

Activities

- **Build the company for long-term strategic value.** This means improving governance, reporting quality, financial discipline, and operational maturity so the business is attractive to investors, acquirers, and partners.
- **Evaluate strategic pathways for the future.** Depending on the company's position, this may involve preparing for IPO, acquisition, licensing deals, joint ventures, or continued independent expansion.
- **Expand the portfolio beyond the first product.** Look at adjacent indications, follow-on products, new device generations, combination opportunities, or additional platform applications.
- **Strengthen the company's international footprint.** Mature companies often need broader commercial reach, more advanced partnerships, and a more global operating model.
- **Optimize capital structure and financing strategy.** Consider how equity, debt, partnerships, or public-market options can support long-term ambitions and reduce unnecessary financing risk.
- **Keep adapting the strategy as the market evolves.** Even mature companies need to respond to changes in competition, regulation, reimbursement, technology, and customer expectations.

Milestones and Outputs

- A mature company with a strong strategic position
- A more diversified product or indication portfolio
- Readiness for exit, expansion, or long-term independent growth
- Clear options for future value creation

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