LIFA.VC MedTech Founder Readiness Questionnaire

A free resource from LIFA Ventures

Prepare for investor meetings • Identify strategic gaps • Build better companies

A Free Resource From LIFA Ventures

This is the exact framework we use to evaluate MedTech companies for investment. We're making it public because we believe transparency builds better companies.

Use it to prepare for ANY investor, not just LIFA.

About This Questionnaire

This questionnaire covers the critical factors that determine MedTech success — from clinical validation to reimbursement strategy to regulatory pathways.

It's designed to help you:

- *Prepare for investor meetings (with LIFA.VC or anyone else)*
- *Identify gaps in your strategy before fundraising*
- *Pressure-test your assumptions*
- *Build stronger pitch materials materials*

Completing it takes 3-4 hours, but founders tell us they reuse these responses for all investor conversations, board updates, and strategic planning.

This is a free resource. No strings attached.

What We Won't Ask About

To keep this manageable, we're not asking for:

- *Detailed technical specifications or design files*
- *Complete regulatory submission packages*
- *Full financial projections (5-year P&L)*
- *Comprehensive competitive analysis*
- *Detailed manufacturing SOPs*
- *IP filing copies or details on your IP*

This questionnaire focuses on strategy, traction, and team.

Purpose

This questionnaire helps you think deeply about the critical factors that determine MedTech success. It typically takes 3-4 hours to complete thoughtfully.

Many founders tell us they reuse these responses for investor conversations, board updates, and strategic planning — so it's time well-invested regardless of whether you talk to LIFA.VC or not.

How to Complete This

- *Be specific — Numbers, dates, names > vague statements*
- *Use examples — Real pilot data, customer quotes, regulatory feedback*
- *Leverage AI — Feel free to use LLMs to organize/refine responses (we do too)*
- *Flag gaps — If you don't have data yet, explain your plan to get it*

Format

We recommend completing this in a Google Doc or Word document that you can save and reuse for investor conversations.

Before You Start: Gather These Materials

- *Your pitch deck*
- *Cap table*
- *Financial model or budget (if you have one)*
- *Any regulatory correspondence (FDA, Notified Body)*
- *Clinical data or pilot results (if available)*

Don't have everything? That's fine — just note what's missing

1. OVERVIEW *(5 minutes)*

💡*What we're looking for: A crisp articulation of what you do, who it's for, and why it matters. Think "investor cocktail party test" - can someone repeat your pitch accurately after one conversation?*

1.1. Company name & URL

1.2. One-liner / elevator pitch

1.3. Mission & differentiator - one short paragraph, explain your overarching vision & mission.

2. MARKET SIZE & CLINICAL IMPACT *(30 minutes)*

💡*What we're looking for: Evidence that you're solving a real, quantifiable clinical problem — not just building cool technology. We want to see that you've talked to clinicians, understand the current workflow, and can articulate why your solution is 10x better (not 10% better).*

2.1. Problem Definition & Significance

What specific unmet clinical, healthcare or industry needs are you addressing? Who experiences this problem (patients, clinicians, health systems), and how severe is it?

💡*Please cite 2-3 sources (peer-reviewed publications, market reports, or clinical guidelines) that quantify the problem.*

2.2. Your Solution

Describe your technology in 2-3 sentences.

💡*Example: "Our AI-powered diagnostic analyzes retinal scans to detect diabetic retinopathy in 2 minutes, with 95% accuracy."*

2.3. Clinical Differentiation

What is the primary clinical breakthrough? (improved accuracy, reduced cost, faster diagnosis, better outcomes, expanded access)

Why does this matter to clinicians and patients?

💡 *Example: "Current standard requires specialist referral and takes 2 weeks. Our device enables same-day diagnosis in primary care, reducing time-to-treatment by 90%."*

2.4. Current Workflow & Your Impact

Current workflow (step-by-step):

[Step 1]

[Step 2]

[Step 3] etc.

Where your solution fits: [Which step does it replace/improve?]

Impact: [What changes? Time saved? Cost reduced? Outcomes improved?]

💡 *Example:*

- *Current: (1) GP referral → (2) Specialist appointment (2 weeks wait) → (3) Diagnostic test → (4) Results (1 week) → (5) Treatment plan*

- *Our solution: Replaces steps 2-4. GP uses our device during visit → Immediate diagnosis → Same-day treatment plan*
- *Impact: 3-week process reduced to same-day; 80% cost reduction; earlier intervention improves outcomes*

2.5. Health Equity (if applicable)

Does your solution address access gaps or reduce disparities? If yes, how specifically?

2.6. Initial Market Segments

Which customer segment are you targeting first? (e.g., cardiology departments in teaching hospitals, outpatient imaging centers, home care providers, facilities, laboratories)

Why this segment first? What makes it the best entry point?

2.7. Market Size (TAM/SAM/SOM)

Total Addressable Market (TAM)
Provide a bottom-up calculation:
[# of target customers] × [annual procedures/units] × [price] = €_____

💡 *Example: "5,000 cardiology departments in US × 2,000 applicable procedures/year × €500/procedure = €5B TAM"*

Serviceable Addressable Market (SAM):
What portion can you realistically reach? €_____

Serviceable Obtainable Market (SOM):
What's your realistic 3-year target? €_____

💡*Show assumptions and sources used. Then provide SAM and SOM with rationale.*

2.8. Competitive Landscape:

List your top 3-5 alternatives (including "do nothing" or current standard of care).

For each alternative, be specific. 'Current standard of care' should describe the actual process, not just say 'manual process.

Competitor	Key Strength	Key Weakness	Why Customers Choose You Instead
1.			
2.			

3. (optional)			
4. (optional)			
5. (incl. Do nothing)			

⚠️ *If you say "no competitors," that's a red flag. Every solution has alternatives, even if it's "do nothing" or "current manual process."*

3. GO-TO-MARKET & REIMBURSEMENT *(30 minutes)*

💡*What we're looking for: MedTech companies fail more often from commercial/reimbursement issues than technical ones. We want to see that you've thought deeply about who pays, how they pay, and what it takes to get them to pay.* ***Specificity matters here*** *- "we'll figure out reimbursement later" is a red flag.*

3.1. Traction & Proof Points

What traction do you have today? Please be specific:

- Pilots: # active, # completed, key learnings
- LOIs/MOUs: # signed, expected conversion timeline
- Clinical studies: # patients enrolled, preliminary results
- Revenue: Amount (if any), from how many customers
- KOL endorsements: Names/institutions (if shareable)

💡 *If you have monthly/quarterly metrics, please include them.*

3.2. Path to Paying Customers

Of your current pilots/users, how many have a realistic path to becoming paying customers within 12 months?

What's blocking conversion? (e.g., budget cycles, reimbursement uncertainty, regulatory approval)

3.3. Key Opinion Leader (KOL) Strategy

Have you identified 3-5 KOLs who can champion your solution?

What's your plan to engage them?

3.4. Go-to-Market Strategy

How do you plan to acquire customers? (select all that apply and explain)

- [ ] Direct sales (field reps, inside sales)
- [ ] Distribution partners (name key targets if identified)
- [ ] Strategic partnerships (e.g., co-marketing with established players)
- [ ] Licensing model
- [ ] Other: _____

Which territories first, and why? (Consider regulatory pathway, reimbursement clarity, market size, competitive landscape)

💡 *Example: "US first (510(k) pathway clear, strong reimbursement, 60% of global market). EU second (CE mark for market expansion). Asia later (complex reimbursement).*

3.5. Sales Process

a) **Who's the buyer?** (e.g., Department head, Procurement, C-suite, Clinician champion)
b) **Budget cycle:** (Annual? Quarterly? Ad-hoc?)
c) **Typical sales cycle:** (From first contact to signed contract — weeks? months?)
d) **Customer concentration:** How many customers do you need to hit €1M ARR? €5M ARR?

3.6. Pricing & Business Model

How are you pricing today? (One-time sale, subscription, disposable components, other)

What's your expected revenue model across geographies?

3.7. Reimbursement Strategy

💡*This is the #1 reason MedTech companies fail commercially. We need to see that you've thought deeply about who pays, how they pay, and what it takes to get them to pay.*

US Market:

- What CPT/DRG/APC codes apply today? (List specific codes)
- If no codes exist, what's your coding strategy? (e.g., CPT Cat III application, new code request)
- Timeline to reimbursement coverage?
- Have you engaged with CMS or private payers? What feedback?

EU Market:

- What's your reimbursement pathway? (e.g. National HTA, DRG inclusion, private pay)
- Which countries first, and why?
- Have you identified payer champions?

Other Markets:

- What's your strategy for [Japan/Australia/other]?

Payer Value Proposition:
Why would a payer (CMS, private insurer, national health system) want to reimburse your device?

What's the economic argument? (Cost savings? Better outcomes? Reduced complications?)

💡 *Example: "Our device reduces hospital readmissions by 30%, saving payers $5,000 per patient. ROI positive within 6 months."*
💡 *If reimbursement is uncertain, explain your fallback plan (e.g., cash-pay, research-use-only).*

3.8. Unit Economics (if available)

If you have data (or reasonable estimates):

- Customer acquisition cost (CAC): €____
- Cost of goods sold (COGS): €_____
- Gross margin: _____%
- Expected payback period:_____ months

💡*If you don't have actual data yet, provide your assumptions and explain your reasoning. "I don't know" is acceptable if you explain when you'll know.*

3.9. Future Growth Opportunities

Beyond your current plan, where do you see expansion opportunities? (New segments, geographies, adjacent products, platform extensions)

4. TEAM *(15 minutes)*

💡*What we're looking for: We invest in people first, technology second. We want to understand your team's relevant experience, commitment level, and ability to execute in MedTech specifically. We also want to see that you're self-aware about gaps and have a plan to fill them.*

4.1. Founders & Key Team

Name	Current Role	Time commitment	LinkedIn	MedTech experience

Previous Exits or Relevant Experience:
Have any founders previously founded or exited companies? If yes, please describe briefly.

4.2. Team Size & Composition

What is the current composition of your team by major function? (e.g., 2 engineers, 1 regulatory consultant, 1 commercial advisor)

Who owns what? Include consultants/advisors.

4.3. Key Hires

What are your top 2-3 hires in the next 12 months?

For each hire:

- What role?
- What gap does it fill?
- How will you attract them? (Compensation, equity, network, other)
- Timeline to hire?

5. PRODUCT READINESS *(20 Minutes)*

💡*What we're looking for: We need to understand how far you are from regulatory submission and what risks remain. We're not expecting perfection — we invest at seed stage — but we do expect a credible plan and awareness of what's required.*

5.1. Product Development Stage

What TRL is your product today?

Where is your product today? (Select one and provide evidence)

- **[ ] Proof of concept** — Lab prototype, feasibility data only
- **[ ] Engineering prototype** — Works in controlled settings, early V&V
- **[ ] Design verification complete** — V&V done, ready for clinical validation
- **[ ] Clinical validation underway** — Pilot studies, early user feedback
- **[ ] Design freeze** — Final design locked, manufacturing ready
- **[ ] Regulatory submission ready** — All V&V complete, submission imminent

💡*Please provide specific evidence (e.g., "completed bench testing per IEC 60601-1" or "3 pilot sites, 50 patients treated")*

5.2. Quality Management System (QMS)

- Do you have ISO 13485 certification? (Yes / No / In progress)
- If not certified, what's your current QMS status? (e.g., using consultant, building in-house, planning to outsource)
- Timeline to certification?
- Who owns quality/regulatory on your team? If no one full-time, what's your plan? (Consultant? Fractional? Hire?)

5.3. Design Controls

What's the status of your Design History File?

Have you completed design inputs, outputs, verification?

Timeline to design freeze?

5.4. V&V Status

What verification and validation testing have you completed?

What's remaining before submission?

5.5. Usability

Have you conducted formative usability studies? Summarize findings.

What's your plan for summative testing?

5.6. Manufacturing & Supply Chain

Current manufacturing: (In-house prototype shop / Contract manufacturer / University lab / Other)

Commercial-scale plan:

- Where will you manufacture at scale? (Geography, in-house vs. CMO)
- Have you identified manufacturing partners? (Names, status of discussions)
- What's your estimated COGS at commercial scale?

Supply chain:

- Any single-source components or suppliers?
- Any supply chain risks we should know about?

6. REGULATORY & CLINICAL PATHWAY *(25 minutes)*

💡*What we're looking for: We need to understand your regulatory strategy and clinical evidence plan. We're not expecting you to have everything figured out, but we do expect a credible pathway and awareness of requirements.*

We understand that BioTools/LifeScience Tools might not be able to answer all of these questions for now.

6.1. Classification & Pathway

What is your intended regulatory classification? (FDA Class, EU Class)

What pathway? (510(k), De Novo, PMA, CE under MDR/IVDR)

For 510(k): What predicate(s) are you using?

💡 *Example: "FDA Class II, 510(k) pathway. Primary predicate: [Device Name, K123456]. Key differences: Our device uses AI for automated analysis (predicate is manual), which may require clinical validation per FDA AI/ML guidance."*

6.2. Key Differences from Predicate (if 510(k)

What are the key differences between your device and the predicate that might require additional clinical data?

6.3. Regulatory Engagement

Have you had FDA engagement? (Pre-Sub, Q-Sub)

Have you had Notified Body engagement? (Pre-submission meetings, NB selection)

For EU: Have you selected a Notified Body?

Are there other territories on your radar? (Japan, Australia, other)

6.4. Clinical Evidence Plan

Do you have an upcoming clinical investigation/performance study? (if yes, answer below, if not explain why)

Primary Endpoint:
What will you measure? Why is this endpoint meaningful to clinicians and payers?

Improvement Threshold:
What level of improvement is clinically meaningful? (Not just statistically significant)

💡 *Example: "Reduce time-to-diagnosis by ≥50%" or "Improve sensitivity from 85% to ≥95%"*

Study Design:

- Type: (Bench testing only / Observational / RCT / Other)

- Sample size: (# of patients/procedures, with rationale)
- Sites: (# of sites, types of institutions)
- Timeline: (Start date, enrollment period, completion date)

Regulatory Status:

- IRB/EC approval status?
- Any regulatory feedback on study design?

💡 *Example: "Primary endpoint: Diagnostic accuracy ≥95% vs. gold standard (biopsy). Secondary: Time-to-diagnosis reduction. Planned study: 150 patients, 3 sites, 6-month enrollment. IRB approved at 2/3 sites."*

6.5. Timeline & Risk

Timeline to:

- Target NB/FDA engagement: [Month/Year]
- Target submission date: [Month/Year]
- Key dependencies: (e.g., "Complete V&V testing by Q2 2026, finalize labeling by Q3 2026")

Biggest regulatory risk:
What's the single biggest thing that could derail your regulatory timeline?
Likelihood of this risk: (High / Medium / Low)

Fallback plan:
If your primary pathway fails (e.g., FDA requires clinical trial instead of bench testing), what's Plan B?

💡 *Example: "Risk: FDA requires clinical trial. Likelihood: 30% based on Q-Sub feedback. Fallback: Pivot to EU-first strategy (CE mark, then FDA)."*

7. IP & DEFENSIBILITY *(15 minutes) !OPTIONAL!*

💡What we're looking for: We don't expect a patent fortress at seed stage, but we do want to see that you've thought strategically about IP, freedom to operate, and other defensibility moats (data, network effects, switching costs).

7.1. IP Portfolio

FILING TYPE	FILING DATE	JURISDICTION	STATUS	KEY CLAIMS

7.2. Freedom to Operate (FTO)

Have you conducted a Freedom to Operate (FTO) analysis?

- [ ] Yes — Summarize findings
- [ ] Interim/preliminary — Summarize findings
- [ ] Not yet — What's your plan and timeline? Why not?

7.3. Data Strategy & Network Effects

Does your product generate unique clinical data? (Yes / No)

If yes:

a) What data do you collect? (e.g., patient outcomes, device performance, usage patterns)
b) How does this data improve your product over time? (e.g., AI model training, clinical insights)
c) Does this create a competitive moat? How?
d) Any data partnerships or monetization plans?

If no:

What other defensibility do you have beyond IP? (e.g., switching costs, brand, regulatory barriers)

7.4. Switching Costs & Scalability

Once users integrate your device into clinical routines, how easy or difficult is switching to a competing solution? Why?

💡 Example: "Once clinicians are trained on our device and integrate it into their workflow, switching would require: (1) retraining staff (2-3 weeks), (2) new capital purchase ($50k), (3) disruption to patient care. High switching cost."

8. FUNDING *(15 minutes)*

8.1. Funding Summary

Please complete this table

Total raised to date (soft/non-dilutive)	€
Total raised to date (dilutive)	€
Current monthly burn	€
Current runway	Months
This round ask	€
Pre-money valuation (or cap if convertible)	€

8.2. Use of Proceeds

CATEGORY	AMOUNT (€)	% OF ROUND	KEY ACTIVITIES
R&D / Product Development			(e.g., V&V testing, design iterations)
Regulatory / Clinical			(e.g., 510(k) submission, clinical study)
Team / Hiring			(e.g., VP Regulatory, 2 engineers)
Commercial / GTM			(e.g., pilot programs, KOL engagement)
Operations / G&A			(e.g., QMS, legal, admin)

8.3. Key Milestones

List 3-5 specific, measurable milestones you'll hit with this capital. For each, include target completion date. If possible/available please include a picture similar to the "funding timeline planner" at platform.lifa.vc- or create one with our tool.

💡 *Example:*

- *Complete V&V testing (Q2 2026)*
- *Submit 510(k) to FDA (Q3 2026)*
- *Enroll first 50 patients in pivotal study (Q4 2026)*
- *Secure 3 pilot site LOIs (Q2 2026)*
- *Hire VP Regulatory Affairs (Q1 2026)*

Your milestones (or picture)

1. _____ (Target: _____)
2. _____ (Target: _____)
3. _____ (Target: _____)
4. _____ (Target: _____)
5. _____ (Target: _____)

⚠️ *Be specific. "Launch product" is too vague. "Complete V&V testing per IEC 60601-1" is specific.*

8.4. Next Round Planning

Expected next round timing: _____ (quarter/year)

Expected next round size: €_____

8.5. Contingency Planning

If this round takes 6 months longer than expected:

- What do you cut first?
- What's your minimum viable runway to reach next milestone?
- Do you have bridge financing options? (e.g., grants, angels, revenue)

9. RISKS & MITIGATION *(15 minutes) !OPTIONAL!*

💡What we're looking for: Self-awareness and strategic thinking. Every early-stage company has risks - we want to see that you've identified yours and have mitigation plans. Honesty is strength, not weakness.

Your Top 3 Risks

For each risk, please explain:

Risk #1:

- What's the risk? (Be specific)
- How likely? (High / Medium / Low)
- Impact if it happens? (Fatal / Serious / Manageable)
- Mitigation plan: (What are you doing to prevent/reduce this risk?)
- Fallback plan: (If mitigation fails, what's Plan B?)

💡 Example:

- *Risk: FDA requires clinical trial instead of bench testing*
- *Likelihood: Medium (30% based on Q-Sub feedback)*
- *Impact: Serious (adds 12 months, €500k cost)*
- *Mitigation: Budget includes €500k clinical contingency; have 3 pilot sites ready*
- *Fallback: Pivot to EU-first strategy (CE mark faster), then FDA*

Risk #2:

- What's the risk?
- How likely?
- Impact if it happens?
- Mitigation plan:
- Fallback plan:

Risk #3:

- What's the risk?
- How likely?
- Impact if it happens?
- Mitigation plan:
- Fallback plan:

10. REFERENCES & DATA ROOM

10.1. Data Room

Do you have a data room? If yes, please provide access.

If not, please share (via Google Drive, Dropbox, or email):

Essential:

- [ ] Pitch deck (latest version)
- [ ] Financial model (if available)
- [ ] Cap table

Helpful (if available):

- [ ] Regulatory correspondence (FDA Q-Sub, NB feedback, etc.)
- [ ] Clinical data or pilot results
- [ ] Customer LOIs or pilot agreements
- [ ] Demo video or product images
- [ ] Patent filings or FTO analysis

💡*Don't worry if you don't have everything - we understand you're early stage.*

10.2. Product Demo (OPTIONAL)

Do you have a video demo of your product in use? (Link or attach)

💡*Seeing your product in action - even early prototype - helps us understand your value proposition.*

10.3. Final Thoughts

Is there anything else we should know - particularly about your global expansion ambitions - that wasn't covered above?

How to Use This Questionnaire

If you're preparing for investor meetings:

- Complete the sections most relevant to your stage
- Use your answers to build pitch materials
- Identify gaps you need to address before fundraising

If you'd like LIFA to evaluate your company:

- Please note that our investment criterias are:
  - Nordic DNA (IS, SE, FI, DK, NO)
  - Class II medical devices or IVD
  - BioTools
  - High clinical impact
  - Founder team of 2-5
- Email your deck to lifa@lifa.vc