Investment & Fundraising Guide for Medical Device Startups

Term Sheets, Funding Rounds, Valuation, and the 510(k) Bridge Strategy

Arch Medical Management
Pilot Software LLC dba Arch Medical Management
March 2026

Section 1: Funding Rounds

How startup financing evolves from idea to IPO

Startup fundraising happens in sequential 'rounds,' each with a distinct purpose, investor type, and typical valuation range. For medical device companies, the regulatory pathway (510(k), De Novo, PMA) heavily influences timing and size of each round.

Pre-Seed

The earliest stage. Founders use personal savings, friends & family money, or small grants to prove the concept is worth pursuing.

- **Amount:** $25K - $500K typical
- **Sources:** Founders, friends & family, university grants, SBIR/STTR Phase I
- **Valuation:** None or very early (pre-product, concept only)
- **Use of Funds:** Proof of concept, initial IP filing, preliminary market research

KEY INSIGHT: For medical devices, pre-seed often funds the initial predicate device research, feasibility prototyping, and provisional patent filings. No FDA interaction yet.

Seed Round

The first 'real' fundraising round. You have a working prototype or strong technical data and need capital to advance toward regulatory submission.

- **Amount:** $500K - $3M typical for medical devices
- **Sources:** Angel investors, angel groups, micro-VCs, accelerators (Y Combinator, HAX, TMCx)
- **Valuation:** $2M - $10M pre-money valuation
- **Use of Funds:** Design verification testing, Pre-Submission meeting (FDA), bench testing, initial clinical data
- **Structure:** SAFE notes, convertible notes, or priced equity rounds

KEY INSIGHT: This is the sweet spot for 510(k) device companies. Seed capital funds the Pre-Sub through submission -- the most capital-efficient stretch of the regulatory pathway.

Series A

The first institutional venture capital round. Typically raised after significant de-risking -- for medtech, this often means FDA clearance or submission.

- **Amount:** $3M - $15M typical
- **Sources:** Venture capital firms (medtech-focused: MedTech Ventures, Gilde Healthcare, Hatteras Venture Partners)
- **Valuation:** $10M - $40M pre-money valuation
- **Use of Funds:** Commercial launch, sales team buildout, QMS implementation, manufacturing scale-up
- **Key Term:** Board seat for lead investor, preferred stock with protective provisions

Series B and Beyond

Growth-stage financing for companies with proven product-market fit and revenue traction.

- **Amount:** $15M - $50M+ typical
- **Sources:** Growth-stage VCs, strategic investors (J&J Innovation, Medtronic Ventures, GE Healthcare Ventures)
- **Use of Funds:** Sales expansion, international regulatory (CE marking, NMPA), next-gen product development

Funding Rounds Summary Table

Round	Amount	Valuation	Investors	MedTech Milestone
Pre-Seed	$25K-500K	Pre-valuation	F&F, Grants	Concept, IP filing
Seed	$500K-3M	$2-10M pre	Angels, Micro-VC	Pre-Sub to 510(k) filing
Series A	$3-15M	$10-40M pre	VC firms	FDA clearance, launch
Series B	$15-50M+	$40-150M+	Growth VC	Scale, international

Section 2: Term Sheets

The blueprint of a deal -- what every clause means and why it matters

A term sheet is a non-binding document that outlines the key financial and governance terms of an investment. It is typically issued by the lead investor after initial due diligence and before the definitive legal documents are drafted. Think of it as a 'letter of intent' for investment.

Economics Terms

These terms determine how much the company is worth and how returns are distributed.

- **Pre-Money Valuation:** The company's worth before new investment money comes in. If your pre-money valuation is $5M and an investor puts in $1M, the post-money valuation is $6M and the investor owns 1/6 (16.7%) of the company.
- **Post-Money Valuation:** Pre-money + new investment = post-money. Your ownership percentage is calculated from the post-money number. Always negotiate on pre-money.
- **Price Per Share:** The price per share the investor pays. Calculated as pre-money valuation divided by total shares outstanding (including the option pool).
- **Option Pool:** A reserved pool of shares (typically 10-20% of post-money) set aside for future employee stock options. CRITICAL: Investors usually insist the option pool comes from the pre-money valuation, which effectively lowers the true pre-money for founders.

WARNING: The option pool shuffle is one of the most important dynamics to understand. A $5M pre-money with a 20% option pool carved from pre-money is effectively a $4M pre-money valuation for the founders. Always model the dilution both ways.

WHAT IF: Your seed investor insists on a 20% option pool from pre-money at a $5M valuation, but you only need 10%. With a 20% pool the effective pre-money drops to $4M, so the investor's $1M buys 20% instead of 16.7%. With a 10% pool the effective pre-money is $4.5M and the investor gets 18.2%. That 10-point difference in pool size costs founders roughly $500K in implied value. Always negotiate pool size with a bottoms-up hiring plan showing exactly which roles you need to fill.

Liquidation Preference

Liquidation preference determines who gets paid first (and how much) when the company is sold, merged, or liquidated. This is the single most important economic term besides valuation.

- **1x Non-Participating:** 1x non-participating preferred: The investor gets their money back OR converts to common stock and shares pro-rata. This is the most founder-friendly version.
- **1x Participating:** 1x participating preferred: The investor gets their money back FIRST, then also shares in the remaining proceeds pro-rata. This is a 'double dip' -- the investor gets paid twice.
- **Multiple Preferences:** 2x or 3x preference means the investor gets 2x or 3x their investment back before common shareholders see a penny. Avoid if possible.

KEY INSIGHT: Example: Investor puts in $2M for 20% at 1x participating preferred. Company sells for $10M. Investor gets $2M back (preference) + 20% of remaining $8M ($1.6M) = $3.6M total. Founders/common get $6.4M. With 1x non-participating, investor would choose to convert: 20% of $10M = $2M. Same result here, but at a $50M exit the participating preferred investor gets $2M + 20%($48M) = $11.6M vs. just $10M non-participating.

WHAT IF: Your 510(k) device company receives a $30M acquisition offer. Investor put in $3M for 25% with 1x participating preferred. Participating: investor gets $3M preference + 25% of remaining $27M ($6.75M) = $9.75M. Founders split $20.25M. Non-participating: investor converts -- 25% of $30M = $7.5M. Founders split $22.5M. The participating preference costs founders $2.25M on this exit. Now imagine a disappointing $6M exit: participating investor gets $3M + 25% of $3M = $3.75M, leaving founders $2.25M. Non-participating investor takes the $3M preference (better than 25% of $6M = $1.5M). Founders get $3M. At lower exits, participating preferred hurts most.

Anti-Dilution Protection

Protects investors if the company raises a future round at a lower valuation (a 'down round'). The investor's conversion price is adjusted downward, giving them more shares.

- **Weighted Average (Broad-Based):** The conversion price is recalculated using a weighted average formula that accounts for the size of the down round relative to total shares. This is the standard and more founder-friendly approach.
- **Full Ratchet:** The conversion price drops to the new lower price -- as if the investor had invested at the lower valuation. Very investor-friendly and punitive to founders. Rare in modern deals.

WHAT IF: Your seed investor buys 20% at $10M pre-money. Six months later, your clinical trial produces mixed results and you must raise a Series A at $5M pre-money (a 'down round'). With FULL RATCHET: the seed investor's shares reprice to the $5M valuation, increasing their ownership from 20% to roughly 35% -- wiping out 15 points of founder equity. With BROAD-BASED WEIGHTED AVERAGE: the formula accounts for the relative size of the down round, and the seed investor increases to about 24%. The difference between these two mechanisms is 11 percentage points of founder dilution. In a $50M exit, that difference is worth $5.5M to the founders.

Governance & Control Terms

- **Board Seats:** Investors (especially Series A leads) typically get one board seat. Common structure: 2 founders + 1 investor + 1 independent = 4-member board. Be cautious about giving investors board majority.
- **Protective Provisions:** Specific actions that require investor approval regardless of board vote. Typical protective provisions: new share issuance, sale of company, changes to charter, taking on debt above a threshold, hiring/firing CEO.
- **Drag-Along Rights:** If a majority of investors want to sell the company, they can force all shareholders (including founders) to agree. Usually requires 50-67% of preferred to trigger.
- **Pro-Rata Rights:** Investors can participate in future rounds to maintain their ownership percentage. Standard and generally non-controversial.
- **Registration Rights:** In a future IPO or acquisition, investors with registration rights can require the company to include their shares in the registration. Standard provision.

WHAT IF: Your board is 2 founders + 2 investors. A strategic acquirer offers $30M for your cleared 510(k) device, which would give each founder $8M after preferences. The investors want to hold out for $100M in 3 years. With a tied board, the deal stalls -- and the acquirer moves on to a competitor. Six months later, a new competitor enters the market and your company's value drops. Always maintain at least one independent director who can break ties, and be cautious about giving investors board majority before Series B.

Founder-Specific Terms

- **Founder Vesting:** Even though founders already 'own' their shares, investors often require founder shares to be subject to vesting (typically 4 years with a 1-year cliff). This protects against a founder leaving early. Common compromise: credit founders for time already spent (e.g., 1 year of vesting already earned).
- **Non-Compete / Non-Solicit:** Founders commit to work full-time on the company and not compete with it during or for some period after employment. 1-2 years post-departure is standard; longer is aggressive.
- **IP Assignment:** All intellectual property created by founders related to the company's business is assigned to the company. Essential and non-negotiable.
- **Right of First Refusal (ROFR):** Prevents shareholders (founders and investors) from selling shares without company/board approval. Typical for private companies until IPO.

WHAT IF: Your CTO co-founder with 40% equity leaves at month 18 of a 4-year vesting schedule (1-year cliff already passed). WITH vesting: the CTO keeps 18/48 = 15% of the company (37.5% of their allocation). The remaining 25% returns to the company for reallocation. WITHOUT vesting: the CTO walks away with the full 40% -- creating a massive 'dead equity' block that makes the company nearly unfundable. No investor will put money into a company where 40% is held by someone who left. This is why investors require founder vesting even for shares founders already 'own.'

WHAT IF: Your non-compete clause says 2 years post-departure, covering 'any medical device company.' You leave after disagreements with investors. For 2 years you cannot work in your own field -- including consulting, joining a competitor, or starting a new medtech venture. Most enforceable non-competes are 12 months and narrowly scoped to the specific device category. Push back on anything broader than 12 months or your specific product area. Note: California and several other states do not enforce non-competes at all.

Term Sheet Red Flags

Red Flag	Why It Matters
Full ratchet anti-dilution	Severely punishes founders in any down round
Participating preferred >1x	Double-dip: investor gets money back + share of upside
Investor board majority	Founders lose control of strategic decisions
Excessive protective provisions	Investor has veto power over routine operations
No-shop clause >60 days	Locks you out of talking to other investors too long
Cumulative dividends	Investment grows at 8%+ annually before founders see returns
Multiple liquidation pref (2x+)	Investors recover 2-3x before common shareholders receive anything

Section 3: Valuation Methods

How medical device startups are valued at each stage

Valuation is more art than science for early-stage medical device companies. Unlike SaaS startups with predictable MRR metrics, medtech valuations are heavily driven by regulatory milestones and clinical risk.

Pre-Revenue Valuation Approaches

- **Risk-Adjusted Market Approach:** Value = total addressable market for the device category, discounted by probability of FDA clearance, time to market, and competition. A $1B TAM with 70% probability of clearance and 24-month timeline might support a $5-10M pre-money at seed.
- **Comparable Transactions:** Compare to similar medtech companies at the same stage. Recent public data from similar 510(k) device companies that raised seed rounds. Adjust for your specific indication and market size.
- **Acquisition Comps / Exit Analysis:** What would a strategic acquirer pay for this technology? For 510(k) devices, acquirers typically pay 3-8x revenue (post-clearance) or $20-50M+ for cleared devices with initial revenue. Work backward from exit to determine a fair entry valuation.
- **VC Method:** Investors target a specific return (e.g., 10x in 7 years). If they expect a $100M exit and want 10x, they'll invest $1M-$2M at a $10M post-money for 10-20% ownership.

Valuation Step-Ups by Milestone

Medical device valuations increase in a staircase pattern, with each regulatory milestone creating a 'step-up' in value:

Milestone	Typical Step-Up	Pre-Money Range	Why
Concept/Patent	Baseline	$1-3M	Idea risk, no FDA contact
Pre-Sub Filed	+30-50%	$2-5M	FDA engagement signal
Pre-Sub Feedback	+50-80%	$4-8M	Regulatory de-risked
510(k) Submitted	+100-200%	$6-15M	Submission = inflection
510(k) Cleared	+200-400%	$10-30M	Market-ready device
First Revenue	+300-500%	$15-50M	Product-market fit

KEY INSIGHT: The single biggest valuation jump in medtech is from '510(k) Submitted' to '510(k) Cleared.' This is why strategic fundraising BEFORE clearance gives investors the best return and gives founders the most favorable entry point for their cap table.

Section 4: Investment Vehicles

SAFEs, convertible notes, and priced rounds explained

SAFE (Simple Agreement for Future Equity)

Created by Y Combinator. A SAFE is not debt -- it's a contract that gives the investor the right to receive equity in a future priced round. No interest, no maturity date.

- **How it works:** Investor gets equity at the lower of: (a) the valuation cap, or (b) a discount to the next round's price
- **Valuation Cap:** The maximum valuation at which the SAFE converts. Example: $5M cap means no matter how high the Series A valuation, the SAFE investor converts at $5M.
- **Discount Rate:** Typically 15-25%. If the Series A is at $10M pre-money and the SAFE has a 20% discount, the SAFE investor converts at $8M.
- **Pros:** Simple, fast (one document), no interest accrual, no maturity date pressure. Standard for pre-seed and seed.
- **Cons:** No investor rights until conversion, dilution is uncertain until priced round, can stack up multiple SAFEs creating a 'SAFE pile' problem.

WHAT IF: You raise $500K on a SAFE at $5M cap, then another $300K on a second SAFE at $8M cap, then do a Series A at $12M pre-money raising $2M. The first SAFE converts at $5M (very favorable -- 10% ownership for $500K). The second converts at $8M (3.75%). The Series A investor prices at $12M. After conversion, the SAFE stack owns 13.75% combined before the Series A investor takes their share. You expected ~6% dilution from $800K but got 13.75%. Each SAFE converts independently at its own cap, and the dilution compounds. Limit yourself to a single SAFE cap whenever possible.

Convertible Notes

Convertible notes are short-term debt that converts to equity. Unlike SAFEs, they accrue interest and have a maturity date.

- **Interest Rate:** Typically 4-8% annually. Interest converts to equity along with principal.
- **Maturity Date:** Typically 18-24 months. If no priced round occurs by maturity, the note is technically due -- creating potential for conflict.
- **Conversion:** Same as SAFEs: valuation cap and/or discount to the next priced round.
- **Pros:** More investor protection than SAFEs (it's debt). Some investors prefer the forced conversion timeline.
- **Cons:** Interest accrual costs you equity. Maturity date creates pressure. More complex legally than a SAFE.

WARNING: For medical device startups, convertible notes can be risky because FDA timelines are unpredictable. If your 510(k) review takes longer than expected and the note matures before your priced round, you may face a forced repayment or unfavorable renegotiation.

WHAT IF: You issue a $500K convertible note at 6% interest with a 24-month maturity and $5M cap. Your 510(k) review takes 14 months instead of the expected 6 -- an FDA Additional Information request adds 8 months. At month 24, the note matures with $60K in accrued interest ($560K total). You haven't raised Series A because you don't have clearance yet. The investor can now demand cash repayment of $560K -- money you don't have -- or renegotiate conversion at a much lower cap ($3M instead of $5M), effectively doubling their ownership. Had you used a SAFE (no maturity date, no interest), there would be no ticking clock and no renegotiation leverage for the investor.

Priced Equity Round (Preferred Stock)

A priced round sets a specific valuation, price per share, and creates a new class of preferred stock with defined rights. This is the standard structure for Series A and beyond.

- **Key Documents:** Definitive legal documents: Stock Purchase Agreement, Investors' Rights Agreement, Right of First Refusal, Voting Agreement, Certificate of Incorporation amendment.
- **Legal Costs:** $15K-$50K+ in legal fees for a standard Series A. Both sides typically have counsel.
- **Pros:** Clean cap table, clear governance, investor rights codified. Required for institutional VC investment.
- **Cons:** Expensive, time-consuming (4-8 weeks to close), requires board approval and shareholder consent.

WHAT IF: You decide to do a priced seed round at $5M pre-money instead of SAFEs. You spend $35K on legal fees and 6 weeks closing. Three months later, you get positive FDA Pre-Sub feedback that significantly de-risks the regulatory pathway. Your company is now worth $8-10M. The entire step-up in value belongs to the seed investors who locked in the $5M price. Had you used a SAFE with a $7M cap, the valuation would have deferred to the Series A -- giving you the benefit of the milestone. Counter-scenario: if your Pre-Sub feedback was NEGATIVE and the company's value dropped to $3M, the priced round at $5M would have protected you from a painful down-round renegotiation. Priced rounds remove uncertainty in both directions.

Vehicle Comparison

Feature	SAFE	Conv. Note	Priced Round
Legal Cost	$0-2K	$2-5K	$15-50K+
Time to Close	Days	1-2 weeks	4-8 weeks
Interest	None	4-8%/yr	N/A
Maturity Date	None	18-24 months	N/A
Valuation Set?	Deferred	Deferred	Yes, fixed
Board Seat	No	Sometimes	Yes (lead)
Best For	Pre-Seed/Seed	Seed/Bridge	Series A+

Section 5: Investor Types

Who invests in medical devices and what they expect

Angel Investors

High-net-worth individuals who invest their own money. Often former executives, physicians, or entrepreneurs with domain expertise.

- **Check Size:** $25K - $250K per investment
- **Stage:** Pre-seed and seed
- **Motivation:** Personal experience, mentor relationship, belief in the founder. Often invest on less formal terms.
- **Watch Out:** Can be slow decision-makers, limited follow-on capital, may not add strategic value.

Angel Groups / Syndicates

Organized groups of angels who pool capital and share due diligence. Examples: Oregon Angel Fund, Alliance of Angels, Tech Coast Angels, Life Science Angels.

- **Check Size:** $100K - $1M per investment (pooled)
- **Stage:** Seed
- **Process:** Formal pitch process, group vote, more structured terms than individual angels.
- **Governance:** Usually one representative on the board or as observer.

Venture Capital (VC)

Professional investment firms that manage pools of capital (funds) from limited partners (LPs). Medtech-focused VCs understand FDA timelines and regulatory risk.

- **Check Size:** $1M - $25M+ per investment
- **Stage:** Series A and beyond (some do seed)
- **Expectations:** Board seat, active governance, follow-on investment, exit-focused (5-7 year horizon)
- **Watch Out:** High return expectations (3-5x fund return). Will push for growth, sometimes at expense of founder control.

Strategic Investors (Corporate VC)

Investment arms of large medical device companies: J&J Innovation, Medtronic Ventures, GE Healthcare Ventures, Philips Health Technology Ventures, Baxter Ventures.

- **Check Size:** $2M - $20M per investment
- **Stage:** Series A-B, sometimes seed for highly strategic technologies
- **Upside:** Access to distribution channels, clinical sites, regulatory expertise, potential acquisition path.
- **Watch Out:** May want technology access rights, right of first refusal on acquisition, or exclusive licensing. Can scare off other acquirers.

KEY INSIGHT: Strategic investors can be a double-edged sword. A Medtronic Ventures investment signals validation but may discourage J&J or Abbott from acquiring you. Negotiate carefully around ROFR and information rights.

WHAT IF: Medtronic Ventures invests $2M in your seed round with a Right of First Refusal on acquisition. Two years later, Abbott offers $50M to acquire your company. Medtronic exercises ROFR and matches the offer -- but takes 90 days during which Abbott's interest cools. Alternatively, if Medtronic declines to match, Abbott may still lower their offer knowing Medtronic saw the deal and passed. Either way, the ROFR reduces your leverage. Counter-scenario: Medtronic's investment gave you access to their clinical sites, distribution network, and regulatory team -- accelerating your clearance by 6 months and increasing the eventual acquisition price by $15M. The ROFR cost you leverage but the strategic value more than compensated.

Government / Non-Dilutive Funding

- **NIH SBIR/STTR:** Phase I ($275K, 6-9 months) for feasibility, Phase II ($1-2M, 2 years) for development. Highly competitive but non-dilutive.
- **NSF SBIR:** Phase I ($200K), Phase II ($1.1M). Good for dual-use medical technologies.
- **BARDA:** BARDA and ASPR for medical countermeasures. Large awards ($5-25M) but very specific use cases.
- **State Programs:** Oregon SBIR matching grants, Oregon Innovation Council, state venture funds.

KEY INSIGHT: Non-dilutive funding should always be pursued in parallel with equity fundraising. An SBIR grant does not dilute your cap table and signals government validation of the technology.

WHAT IF: You win an SBIR Phase I ($275K) while simultaneously raising a $1M seed round on a SAFE at $5M cap. The SBIR reduces how much equity capital you need -- you can now raise only $725K instead of $1M, reducing dilution from 20% to 14.5%. Over three rounds, this compounding effect preserves an additional 5-8% founder ownership. Alternatively: you use the SBIR to extend your runway while waiting for a key milestone (Pre-Sub feedback), allowing you to raise the seed at a higher valuation ($7M vs $5M). The non-dilutive capital didn't just save equity -- it bought you time to increase your valuation.

Section 6: The 510(k) Bridge Strategy

When to engage investors relative to your regulatory milestones

The 510(k) regulatory pathway creates natural inflection points that directly impact your fundraising leverage. Understanding when to engage investors relative to each milestone is crucial for optimizing valuation and terms.

The Investor Outreach Timeline

Not all months are created equal for fundraising. Here is the optimal engagement cadence mapped to a standard 510(k) timeline:

Month	Milestone	Signal	Investor Action	Why This Timing
M+0	Pre-Sub Filed	Warm	Build relationships	FDA engagement proves you're serious -- not just ideas
M+2	Pre-Sub Meeting	Active	Pitch meetings	FDA feedback letter is your best fundraising asset
M+3	Bench Testing	Active	Share data	IEC 60601, EMC, usability data proves technical viability
M+6	510(k) Filed	Peak	Push term sheets	Submission is the inflection -- clearance is 'when' not 'if'
M+9	510(k) Cleared	Close	Close rounds	Maximum leverage -- cleared, market-ready device

Why M+2 to M+6 is the Sweet Spot

The period between your FDA Pre-Submission meeting feedback (M+2) and 510(k) filing (M+6) is the optimal fundraising window for three reasons:

- **1. Regulatory De-Risking:** The FDA feedback letter from R2 is a tangible, third-party validation that your regulatory strategy is sound. This is the single most persuasive document you can show investors.
- **2. Favorable Valuation:** Before clearance, your valuation is still 'pre-event.' Investors who come in before the 510(k) is cleared get the pre-clearance price -- typically 40-60% lower than post-clearance. This is the return they're buying.
- **3. Visible Finish Line:** At M+6 when the 510(k) is submitted, you're 90 days from clearance (standard review). This is close enough that investors can see the finish line but early enough to get in at pre-clearance terms.

KEY INSIGHT: The #1 mistake medtech founders make is waiting until AFTER clearance to fundraise. Post-clearance fundraising gives you better terms but costs 6-12 months of commercial runway. The capital you need for launch should be committed BEFORE the clearance letter arrives.

WHAT IF: Company A raises $2M at M+3 (post-Pre-Sub feedback) at a $6M pre-money valuation. They have capital committed before filing the 510(k). When clearance arrives at M+9, they immediately launch -- hiring sales reps, attending trade shows, shipping first units within 30 days. Company B waits until after clearance to start fundraising. They get better terms ($2M at $12M pre-money -- half the dilution), but the raise takes 5 months. During that time, a competitor launches a similar device and signs two hospital systems. Company A's 'overpayment' in dilution bought them 5 months of market exclusivity and first-mover advantage. In medtech, time-to-market after clearance is often worth more than the valuation difference.

What Investors Want to See at Each Stage

Your pitch materials should evolve as you progress through the regulatory timeline:

- **M+0 (Pre-Sub Filed):** Vision + technical approach, IP landscape, team credentials, TAM/SAM analysis. Pre-Sub filing shows FDA engagement.
- **M+2 (Pre-Sub Meeting):** ALL of the above + FDA feedback letter (the 'de-risking document'), proposed testing protocol with FDA agreement, competitive landscape with predicate device comparison.
- **M+3 (Bench Testing):** ALL of the above + IEC 60601 test reports, EMC data, clinical validation protocol/early results, design freeze documentation.
- **M+6 (510(k) Filed):** ALL of the above + complete 510(k) submission summary, timeline to clearance (90 days), launch plan, revenue projections, first KOL commitments.
- **M+9 (Cleared):** ALL of the above + clearance letter, K-number, post-market plan, commercial traction, first purchase orders or LOIs.

Section 7: Investor Due Diligence

What investors investigate before writing a check

Due diligence ('DD') is the investigation process investors conduct before finalizing an investment. For medical devices, DD is more rigorous than typical tech startups because of regulatory, clinical, and manufacturing risks.

Technical / Product DD

- **Product Maturity:** Working prototype vs. concept? Design freeze status? Verification and validation testing complete?
- **IP Portfolio:** Patents (filed vs. granted), trade secrets, freedom-to-operate analysis. Has an FTO search been done?
- **Regulatory Status:** Is it cleared/approved? What pathway? What did FDA say in the Pre-Sub? Any known issues?
- **Manufacturing:** Bill of materials, contract manufacturer identified? Can this be manufactured at scale? What are the COGS?

Market DD

- **Market Size:** Total addressable market with credible bottom-up analysis, not just top-down TAM numbers.
- **Reimbursement:** Reimbursement pathway (CPT codes, hospital budget vs. physician preference item), willingness to pay.
- **Competition:** Existing devices, emerging competitors, barrier to entry analysis.
- **Clinical Champions:** Clinician and hospital interest, letters of intent, KOL relationships.

Team DD

- **Domain Expertise:** Regulatory affairs experience, prior FDA submissions, clinical/engineering depth.
- **Founder Commitment:** Full-time commitment, vesting schedules, founder agreement in place.
- **Team Gaps:** Key hires needed, advisory board composition, gaps in expertise.

Financial DD

- **Cap Table:** Existing cap table, prior investments, outstanding SAFEs/notes.
- **Burn Rate & Runway:** Monthly burn rate, runway at current spend, detailed use-of-proceeds for this round.
- **Financial Projections:** Revenue model, pricing strategy, path to profitability, unit economics.

Legal DD

- **Corporate:** Clean corporate structure, no outstanding litigation, proper entity formation.
- **IP Ownership:** IP assignment agreements, employee invention agreements, NDA/NCA obligations.
- **Regulatory Compliance:** QMS in place (ISO 13485), complaint handling, MDR reporting procedures.

Section 8: Negotiation Strategy

Practical tactics for medical device founders

Before the Negotiation

- **Create Competition:** Talk to 15-25 investors simultaneously. Competition creates leverage. Never negotiate with a single interested party.
- **Know Your Investor:** Research the investor's portfolio, fund size, and recent deals. A $50M fund writing $1M checks behaves differently than a $500M fund.
- **Know Your BATNA:** Be clear on your BATNA (Best Alternative to Negotiated Agreement). What happens if this deal falls through? More options = more power.

Key Negotiation Points (Prioritized)

Not all terms are equally important. Focus your negotiation energy on the terms that matter most:

- **1. Valuation (highest priority):** This directly determines your ownership. Fight hardest here.
- **2. Liquidation Preference:** 1x non-participating is standard. Push back hard on participating preferred or >1x multiples.
- **3. Board Composition:** Maintain founder-friendly board composition. 2 founders + 1 investor + 1 independent is ideal.
- **4. Anti-Dilution:** Insist on broad-based weighted average. Reject full ratchet.
- **5. Option Pool:** Ensure the option pool is the right size but push for it to come from post-money, not pre-money.
- **6. Pro-Rata Rights (lower priority):** Standard and not worth fighting. Accept reasonable protective provisions.

Common Mistakes

- **Showing Your Best Card First:** The first investor to see your deal should not be your top-choice lead. Practice your pitch with lower-priority investors first.
- **Waiting Too Long to Start:** Fundraising takes 3-6 months for medtech. Start early, especially around regulatory milestones.
- **Skipping Legal Counsel:** Get startup-experienced legal counsel (not your family attorney). Wilson Sonsini, Cooley, Fenwick -- or local equivalents.
- **Overemphasizing Revenue Projections:** In medtech, a credible 510(k) timeline is more persuasive than hockey-stick revenue projections. Lead with regulatory progress.

KEY INSIGHT: The best fundraising position is when you don't desperately need the money. Start fundraising with 6+ months of runway remaining. Negotiating from a position of need always leads to worse terms.

Section 9: Cap Table Management

Understanding ownership dilution through multiple rounds

Your capitalization table ('cap table') tracks who owns what percentage of the company. Understanding how it evolves is essential for making informed fundraising decisions.

Example: 510(k) Medical Device Startup Cap Table Evolution

Starting point: Two co-founders, 50/50 split, 10M authorized shares.

Shareholder	Founding	Post-Seed	Post-Series A	Notes
Founder A	50.0%	37.5%	28.1%	CEO - full vesting
Founder B	50.0%	37.5%	28.1%	CTO - full vesting
Seed Investors	--	15.0%	11.3%	SAFE, $1M at $6M cap
Option Pool	--	10.0%	12.5%	Refreshed at Series A
Series A Lead	--	--	20.0%	$3M at $12M pre-money
Total	100%	100%	100%	

Key observations:

- **Dilution is expected:** Founders go from 100% to 56.2% combined after two rounds. This is normal and healthy.
- **Dilution is not loss:** 56.2% of a $15M company ($8.4M) is better than 100% of a $2M company.
- **Every round dilutes everyone:** Each round dilutes all previous shareholders proportionally (unless they exercise pro-rata rights).

KEY INSIGHT: A useful mental model: founders who keep 40-60% after seed and 25-40% after Series A are in a strong position. If you're below 20% combined before Series B, you may have given up too much too early.

WHAT IF: Two founders each own 40% after seed (80% combined), with a 10% option pool and 10% seed investors. A strong position. Now a Series A investor demands 30% ownership with a 15% option pool refresh (from pre-money). Post-Series A: founders drop to 80% x (1 - 0.30 - 0.075) = 50% combined (25% each). Still healthy. But if the seed round was too dilutive (founders at 55% combined post-seed), that same Series A drops founders to 55% x 0.625 = 34.4% combined (17.2% each). By Series B they could be below 10% each -- losing motivation and control. Protect your ownership aggressively in early rounds; the dilution compounds with every subsequent raise.

Section 10: Glossary

Essential investment terminology

- **Anti-Dilution:** Protection for investors against lower-valuation future rounds. Adjusts conversion price.
- **BATNA:** Best Alternative to Negotiated Agreement. Your fallback if the deal falls through.
- **Bridge Round:** Small round of financing between major rounds, often using convertible notes.
- **Burn Rate:** Monthly cash expenditure. Gross burn = total spend. Net burn = spend minus revenue.
- **Cap Table:** Capitalization table showing all equity ownership, options, warrants, and convertible instruments.
- **Cliff:** Minimum time (usually 1 year) before any shares vest.
- **Convertible Note:** Short-term debt that converts to equity at a future priced round.
- **Down Round:** A financing round at a lower valuation than the previous round.
- **Drag-Along:** Right allowing majority shareholders to force minority shareholders into a sale.
- **Due Diligence:** Investigation conducted by investors before finalizing investment.
- **Equity:** Ownership in the company, represented by shares of stock.
- **Exit:** Liquidity event: acquisition, IPO, or secondary sale.
- **Fully Diluted:** Total shares counting all options, warrants, and convertible instruments as if exercised.
- **Lead Investor:** The investor who sets terms, does primary DD, and often takes a board seat.
- **Liquidation Preference:** Order and amount of payout to shareholders in a sale or liquidation.
- **Lock-Up Period:** Time after IPO during which insiders cannot sell shares (typically 180 days).
- **Non-Dilutive:** Funding (grants, revenue) that doesn't give up equity.
- **Option Pool:** Shares reserved for future employee equity grants.
- **Pari Passu:** Equal treatment -- investors in the same class share proceeds equally.
- **Post-Money:** Company valuation including the new investment.
- **Pre-Money:** Company valuation before the new investment.
- **Preferred Stock:** Stock class with additional rights (liquidation pref, anti-dilution, etc.) over common.
- **Pro-Rata Right:** Right to invest in future rounds to maintain ownership percentage.
- **ROFR:** Right of First Refusal -- company can match any outside offer for shares.
- **Runway:** Months of operation remaining at current burn rate.
- **SAFE:** Simple Agreement for Future Equity. Converts to stock at a future priced round.
- **Secondary Sale:** Sale of existing shares (not new issuance) between shareholders.
- **Tag-Along:** Right of minority shareholders to join a sale on the same terms.
- **Term Sheet:** Non-binding outline of key investment terms.
- **Vesting:** Gradual earning of equity over time (typically 4 years for employees/founders).