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STARTUP & ACCELERATE

**HEALTHTECH EMERGING COMPANIES: LEGAL STRATEGIES,
VENTURE CAPITAL FINANCING AND MARKET TRENDS**

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Overview

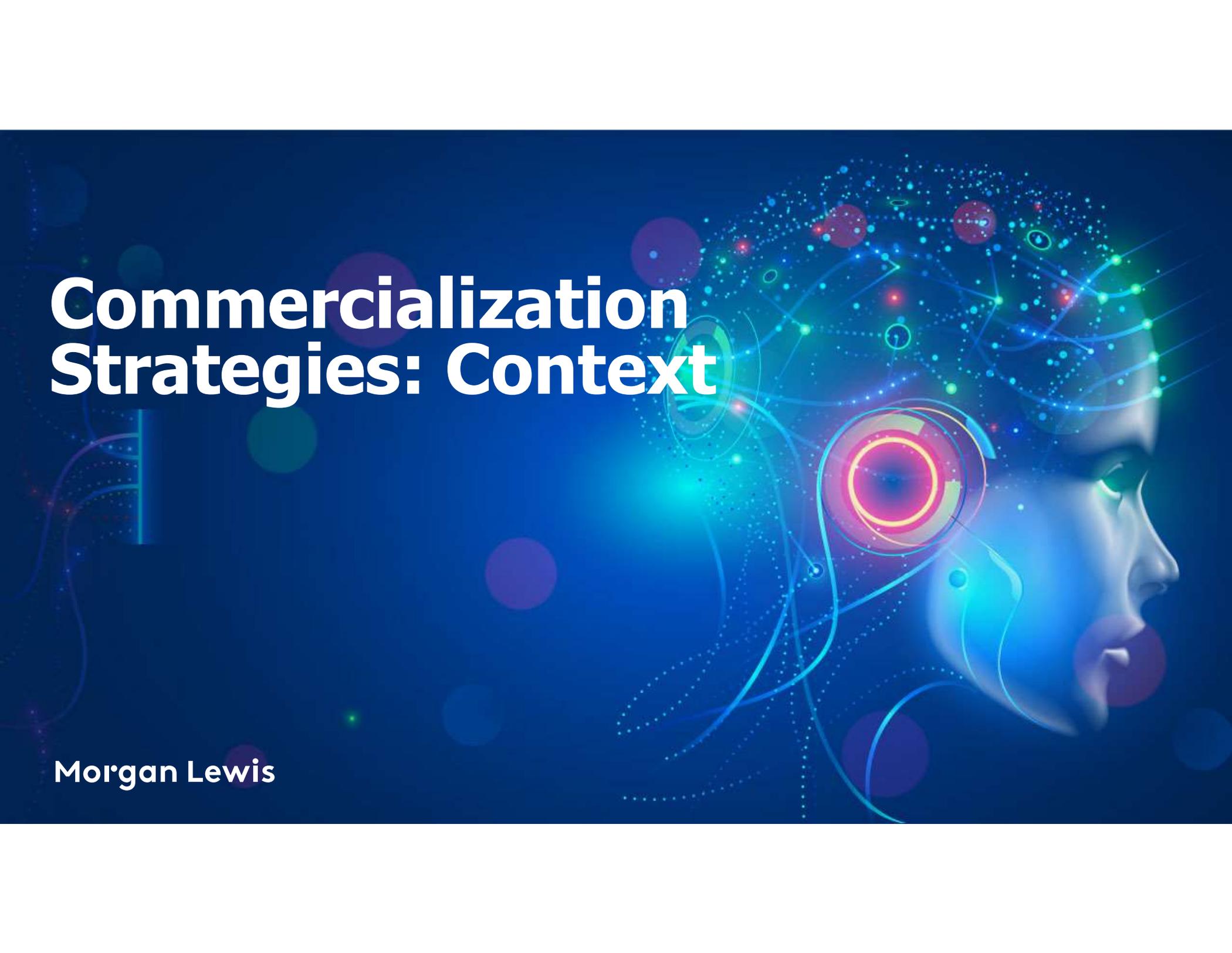
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Overview

- HealthTech and Digital Health companies remain at the forefront of healthcare innovation
- Smart growth and legal strategies for these companies center around a number of different commercialization strategy focus areas, each of which will be covered in today's session
- Venture capital financing is often a key driver of growth for these companies and the current venture capital funding climate will also be discussed today

Commercialization Strategies: Context



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Opportunities

- Rapid growth in devices, platforms, applications, sophistication (and discernment), and adoption
 - Wearable forecast: \$120B in 2023 -> \$930B in 2030
 - Consumers demanding more functionality, connectivity, and interoperability
- Increased efficiencies and better outcomes will eventually bolster alternative models (e.g., value-based care)
 - Will help alleviate lack-of-reimbursement headwinds
 - About $\frac{3}{4}$ of users say their wearable device helps manage a chronic condition
- Gap between health/wellness activities and health care

Needs

- Needs: discovering, finding, evaluating, procuring, integrating, customizing, promoting, managing, updating, and replacing applications (and data)
 - Journeys – continuous, frictionless healthcare experiences
 - Marketplaces/platforms can facilitate optimization
 - Scale, speed, connections, and tools
 - Operational, technical, field, etc. filters
 - Interoperability (e.g., information exchange)
 - Verification
- Must be easy for physicians/providers – incorporated into their workflow



Environment

- Potential culture clash
 - Attracting new players – convergence of digital products and FDA-related products
 - Move fast vs. proceed with caution (product risks; product development timelines)
 - Procurement vs. development
 - Learn vs. predict
 - “failure” vs. “failure”
 - Integrated or standalone product?
- Business drivers for each party
 - Objectives/Concerns
 - Communication; Alignment
 - Leverage/Expertise



Business Models

- Types of Consideration
 - Fee / grant for services (e.g., time and materials; fixed; subscription; milestone-based)
 - Revenue sharing; royalties
 - Equity (e.g., strategic investment; new JV entity)
 - Data & feedback
 - Exclusivity / channel
 - First to market; platform or standard adoption
 - Mission / purpose
- Duration / Integration
 - Foundational research
 - Milestone-specific research (e.g., regulatory clearance)
 - One-off development
 - Add-on to existing product / platform – portability?



IP Assessment

- Off-the-shelf or customizations?
- Which party is driving development (or true joint effort)?
- Development plan/responsibilities?
- How is development funded?
- What background materials/data/IP will be used?
- What outputs are expected?
- Can the new IP be used independently (or merely platform add-ons)?
- Feedback / residuals / improvements (e.g., model training)?
- License rights for non-owner (e.g., FTO)? Scope & duration?

Commercialization Strategies: Artificial Intelligence

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Sample Questions for Vendors

- Do you or any of your subcontractors use artificial intelligence tools with respect to services proposed to be provided to Company? If so, please describe.
- If you use artificial intelligence tools:
 - How do you oversee, monitor, and evaluate performance of those tools?
 - Do the tools perform algorithmic decision-making? If so, please describe.
 - How do you ensure that the tools do not illegally discriminate?



Sample Questions for Vendors (cont.)

- If you use artificial intelligence tools:
 - What type of data does the AI model use?
 - Does the model use scraped datasets?
 - How often are the training datasets refreshed?
 - Will the AI use the covered entity's data?
 - For training?
 - Will it be segregated?
 - What is the vendor's history with compliance (e.g., data breaches)?
 - Has the vendor established a risk management system related to its AI program?
 - How does the AI system mitigate inaccurate or biased outputs?



Sample AI Provision for Vendor Agreements

- Artificial Intelligence. If the Services incorporate, or are expected to incorporate, the use of artificial intelligence tools, Contractor shall provide advance written notice to Company that describes (i) Contractor's use of AI tools and (ii) how Contractor oversees, monitors and evaluates the performance and legal compliance of such AI tools. For purposes of this Section, "artificial intelligence" means a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments.
- Some alternative concepts of "artificial intelligence":
 - the ability of a computer to perform tasks that previously required human intelligence
 - A machine that mimics human intelligence

Commercialization Strategies: Data

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What data is being shared?

- What data is each party sharing?
 - For what purpose / consideration?
 - Sensitive / regulated / valuable?
 - Practical methods to minimize concerns (e.g., de-identified or synthetic data; federated learning)?
 - Results / analyses flowing back?



How was the data collected/generated?

Source(s) of the data?

- How was it collected / generated?
- Data subject consents/terms?
 - Explanations & other procedures?
 - Other lawful processing ground vs. patient informed consent



Does HIPAA apply to data collected?

- The Health Insurance Portability and Accountability Act of 1996 (**HIPAA**) is the primary set of regulations for healthcare information
 - HIPAA protects the privacy and security of protected health information (PHI) held by covered entities and business associates
 - HIPAA prohibits sharing PHI absent an authorization or exception
 - When sharing from a covered entity to business associate to subcontractor, need to have business associate agreements (BAA) in place
 - Or, de-identification of the data (if permitted by BAA)



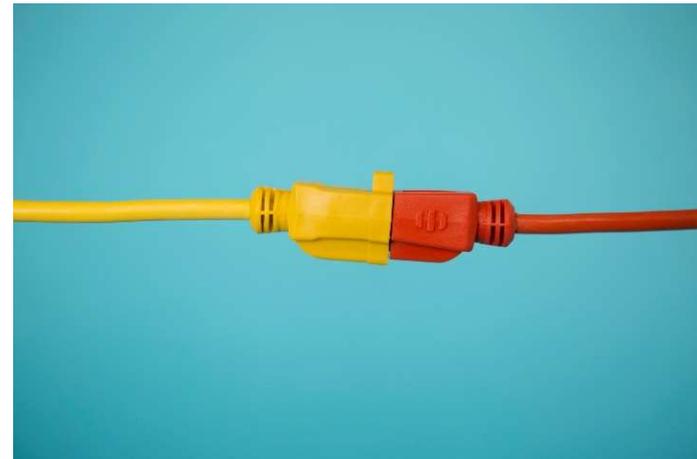
Do the new healthcare consumer privacy acts apply?

- Washington, Nevada and Connecticut have newly enacted healthcare consumer privacy acts
 - Intended to fill the gap for consumer healthcare information not covered by HIPAA
 - Restricts how entities collect, use and process “consumer health data”
 - Have similar privacy policy and other compliance features to the myriad state consumer privacy acts
 - Numerous requirements to sell data



How will the data be transferred?

- One-time disclosure or ongoing feed?
 - Integration / interface?
 - API terms?
 - Locally stored or hosted?
 - Availability & support?
 - Updates?



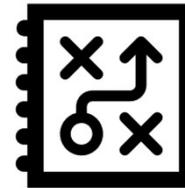
How may (or may not) the data be used?

- Purpose(s) / field / territory / duration?
 - e.g., “research and development”
 - Exclusivity?
- Modifications / aggregations?
 - solely extent necessary?
 - What does “de-identified” mean?
- Restrictions?
 - Regulatory requirements / limitations?
 - Different categories?
 - Competitive / circumventive uses?



How will the data impact the model?

- Model Impact (e.g., AI / ML)
 - How affect algorithmic decision-making?
 - How affect model validation, transparency, and accountability?
 - How embedded / dependent (e.g., termination)?
- Reminder (Players):
 - Tech: accustomed to freedom to update / modify products
 - Life Sciences: potential regulatory limits on modifications



Further disclosure of the data?

- Who will have access?
 - Which personnel?
 - Subcontractors / sublicensees?
 - End customers (e.g., practitioners / patients)
 - Scope / field / duration?
 - Flow-down requirements?
 - Who may not have access (e.g., competitors)
 - Publications?



Data: Warranties

- All necessary rights and consents (for receipt and authorized use of the data)
- All necessary rights to grant licenses
- Complete and accurate – how critical?
- Compliance with law
- Performance (e.g., standards, service levels, specifications, etc.) – how critical?
- Potential risks / impacts of defects / errors?
- Flow-down requirements (as applicable)

Commercialization Strategies: Suspension/Exit

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Suspension: Considerations



Trigger: Review reasons for suspension (e.g., unauthorized use; non-payment; security; compliance).



Discretion: Is the exercise of a suspension right at the vendor's sole, reasonable, or other standard of discretion?



Notice: Is the vendor required to give prior notice of suspension, how much notice is required, and is the customer given the opportunity to cure the issue prior to suspension?



Duration: When will access/service be restored?



Requested suspension: if applicable, may add right for customer to request that vendor suspend its services e.g. if the services pose a threat to the security of the customer's systems.

Termination Assistance Services

Upon termination or expiration of the contract, what type of termination assistance services are needed? How big is the “vendor lock-in” risk?

- Data retrieval (including format)?
- Use of the services until a new provider is up and running?
- Any additional (e.g., consulting) services needed?
- Surviving rights / restrictions (e.g., data)?
- Code / technology escrow?
- Regulatory requirements?
- Ongoing patient care?
- Compensation / reimbursement?



Venture Capital Financing Trends

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The Big Question – Where's the Money?

- Turning an idea into a business requires capital
- Funding rounds may include:

Round	Players	Timeframe
Initial Startup	Friends & Family, Incubators/Accelerators, Grants, university or parent company resources (if spinout), bootstrapping (i.e. customer revenue)	Year 1
Pre-seed / Seed	Same plus Angels and Seed Venture Capital Funds	Years 1-3
Series A / Series B / Series C	Same for Series A plus Venture Capital Funds and CVC	Years 1-4
Later Stage and Growth Equity	VC, Growth Equity Funds, Private Equity and CVC	Year 4+

Financing Considerations

- No single pathway or timeframe is correct
- Significant variables including:
 - Perceived market and demand
 - IP protections
 - Regulatory approvals (i.e., FDA)
 - Business model scalability
 - Profitability and capital needs
- Strategic partnerships and customer revenue are often as valuable as capital (and likely even more valuable)



HealthTech Investment Activity

- HealthTech and Digital Health investment continues to be active throughout 2023 and 2024 - but remains down significantly in most cases from prior periods:

CB Insights Data:

- \$13.2 billion total funding (from 1,397 equity deals) in 2023 vs. \$25.5 billion funding (from 2,267 deals) in 2022 and even the \$17.9 billion in funding (2,253 deals) from 2019
- \$3.7 billion total funding in Q1 2024, 48% increase quarter over quarter but still down 12% vs. Q1 2023 and 63% vs. Q1 2022

Rock Health Data:

- \$10.7B across 492 deals in 2023, the lowest annual total in four years. Q4 2023 was the lowest funding quarter since Q3 2019, with U.S. digital health startups raising \$1.9B across 122 deals.
- In Q1 2024, U.S. digital health funding closed with \$2.7B across 133 deals. Q1 2024 was the lowest first quarter by sector funding since 2019, noteworthy given that Q1 was the top-funded quarter of the entire year in 2022 and 2023. However, pace of deal making is strong, even with lower overall funding dollars. Q1 2024 logged 133 fundraises for digital health companies, beating out each of the past six quarters though just edging out Q1 2023's 132 deals.

HealthTech Investment Activity, con't

- Maturation of investors, including tech and enterprise healthcare companies and corporate venture capital arms
- Most active investors according to CB Insights for 2023 and Q1 2024:
 - Venture Capital Funds:
 - a16z, Plug and Play Ventures, Excelerate Health Ventures, Kleiner Perkins, SOSW, The Venture Collective, General Catalyst, Khosla Ventures, B Capital Group, 8VC, BoxGroup, Deerfield Management, Define Ventures, F-Prime Capital, Flare Capital Partners, Longitude Capital, Sands Capital
 - Corporate VCs / Other Investors:
 - Nventures, Maverick Ventures, Cigna Ventures, CVS Health Ventures, Google Ventures, Hana Ventures, Samsung NEXT, Health 54, Kaiser Permanente Ventures, Mass General Brigham Ventures, UPMC Enterprises, Yamaha Motor Ventures

HealthTech Investment Activity, con't

- What does this all mean?
 - Good companies still getting funded but process drawn out so focus on runway extension and disciplined process critical
 - Downward pressure on valuations continues
 - Down rounds and recaps becoming much more prevalent (over 23% of Q1 2024 VC funding rounds were down rounds according to Carta)
 - Likely to see combination of flat or down rounds, exits or wind downs over second half of 2024
 - Corporate VC activity also slowing but remains potentially attractive option

Corporate Venture Capital (CVC) in HealthTech

- CVC remains entrenched as significant funding source
- CVC in HealthTech / Digital Health has slowed down significantly from all time high in 2021 - but remains a significant component of all funding for these companies and in particular early-stage companies
- Tech / Pharma / Healthcare Systems / Providers / Payers all among active HealthTech CVC investors

CB Insights Data:

- \$4.2 billion total funding (from 218 deals) from CVCs in digital health in 2023 vs. \$7.5 billion funding (from 304 deals) in 2022 and \$5.0 billion in funding (291 deals) from 2019
- \$3.7 billion total funding for digital health in Q1 2024, 48% increase quarter over quarter but still down 12% vs. Q1 2023 and 63% vs. Q1 2022
- Early-stage deal share has remained at an all-time high of 63% of all CVC deals for 2 years running

Why Do CVCs Invest?

- Financial return
- Ability to access disruptive, innovative technology / digital health products
- Circumvention of corporate bureaucracy and enhancement of innovation culture
- Expansion of industry knowledge, including adjacent spaces to core CVC business
- Enhancement of corporate image
- Potential to satisfy strategic growth and marketing initiatives
- Fear of missing out (FOMO)

Why Do Startups Like CVCs?

- Credibility/validation
- Generates business momentum – strategic insights/industry expertise and relationships/customer relationships/distribution networks
- Funding source with potential deep pockets
- May lead to operational/commercial/strategic partnerships and revenue

What's the Catch with CVCs?

- May expect more sophisticated (and implemented) regulatory/compliance strategy than a traditional VC
- Some only co-invest and do not lead rounds
- May expect commercial arrangement at time of investment
- May want a path to control
 - Right of first notice not uncommon, on occasion right of first refusal to match offers from a limited list of competitors is provided, anything more is unusual
- Traditional VC protections (veto rights, protective provisions, preemptive rights, info rights) can be tricky to navigate to achieve appropriate balance of CVC investor protection with company strategic flexibility given potential CVC strategic interest
- Some CVCs not as experienced as others

Bottom line

CVC investment can be a win-win for both the HealthTech startup and the CVC as long as both sides do their homework and investment and commercial expectations are aligned

Biography



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Amy M. Magnano focuses her practice on healthcare litigation and regulatory matters, representing healthcare providers and facilities in complex healthcare, licensing, and disciplinary litigation. She also represents healthcare entities in regulatory investigations and advises on related healthcare compliance issues. Amy counsels legal professionals, healthcare systems, and physician groups on compliance with the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health Act (HITECH), with a particular focus on HIPAA privacy, security, and breach notification requirements. She also counsels healthcare professionals on compliance with 42 CFR Part 2 and state privacy regulations.

Biography



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A. Benjamin Klaber counsels tech companies and research institutions in digital health, fintech, and other industries on strategic commercial contracts, collaborations, and technology transactions, with a particular focus on artificial intelligence, machine learning, big data, the metaverse, quantum computing, and other cutting-edge technologies. He negotiates complex commercial contracts, intellectual property licenses, joint development agreements, joint ventures, and other transactions involving innovative technologies and rapidly evolving ecosystems, and he provides strategic, practical commercial guidance and actionable insight.

For several years, Ben served as a member of the Emerging Leadership Board of the Pittsburgh Venture Capital Association.

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As leader of the firmwide emerging companies and venture capital (ECVC) practice, Jeffrey P. Bodle counsels emerging companies and other innovative high-growth companies at every stage of their business lifecycle—including in mergers and acquisitions (M&A); angel, venture capital, and growth equity financings; IPOs; securities offerings and compliance; corporate partnering; joint ventures; formation advice; and other strategic and outside general counsel matters. Jeff also represents seed, venture capital, growth equity, private equity, institutional, and corporate venture capital (CVC) investors in financing, M&A, and portfolio company transactions. Jeff focuses primarily in the healthcare, life sciences, retail/e-commerce/consumer products, technology, and venture capital and private equity industries.

Jeff nurtures entrepreneurs and startup clients by reviewing their business plans, helping identify appropriate financing sources, and connecting them to various emerging company and venture capital communities.

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