Assessing the Value of Launching First in the EU vs. USA

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Thank you to my two discussants

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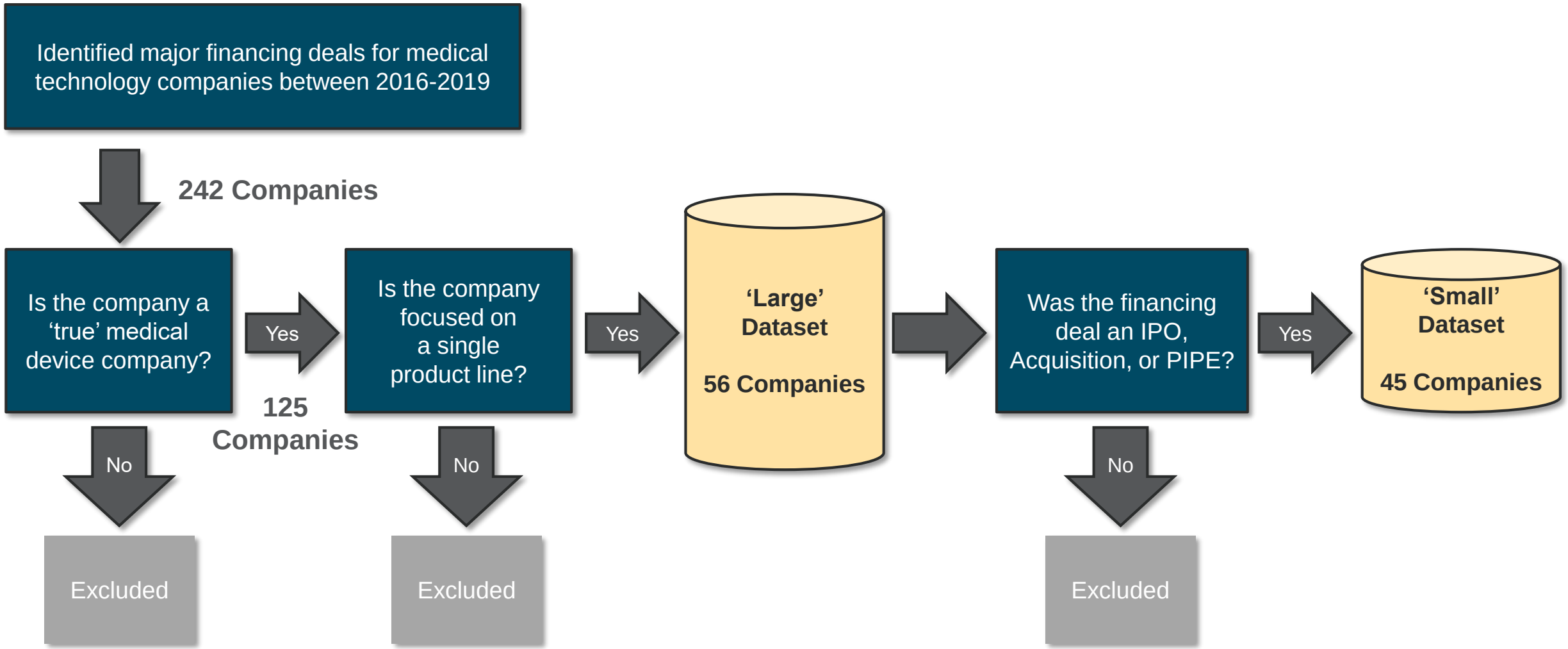
Question: Is it clearly better to commercialize first in the USA or the EU?

- The commercial launch strategy is a pivotal value driver for any company
  - A wide range of variables come into this complicated decision
- Navigant explored the question: are there any trends to suggest initially targeting the EU or the US market is more beneficial?
- We assessed the last ~3 years of medtech financing deals and compared companies that initially pursued a CE Mark or FDA clearance
  - CE Mark or FDA clearance does not necessarily mean full commercial launch!
  - At exit most companies had both FDA clearance and CE Mark

Audience poll: your prediction?

- Although there was no large difference, CE Mark trended towards a slight benefit
  - "CE mark first" companies tended to reach an exit more rapidly (1-3 years faster)
  - "CE mark first" companies trended toward higher valuations in M&A (but not IPOs)
- ***Alas, with the changing EU regulatory environment, these recent trends may not predict future results!***

Our aim was to assess ‘single product line’ medtech firms with an exit in 2016-19



Primary sources: Pitchbook, Navigant research

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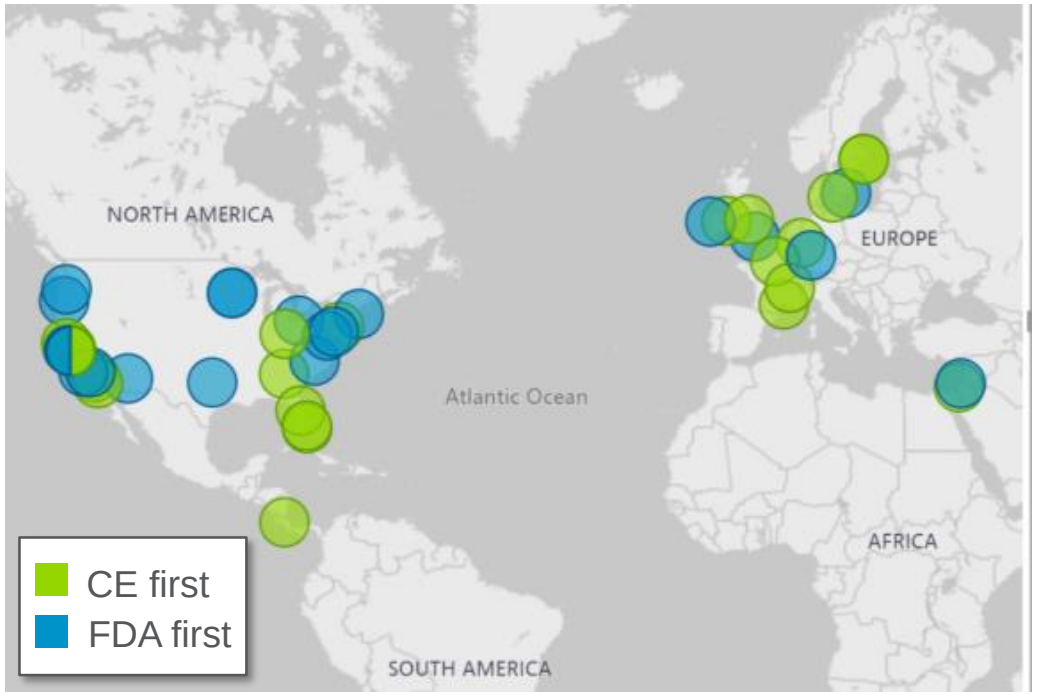
CE Mark is slightly more common as an initial target, particularly among EU HQ firms

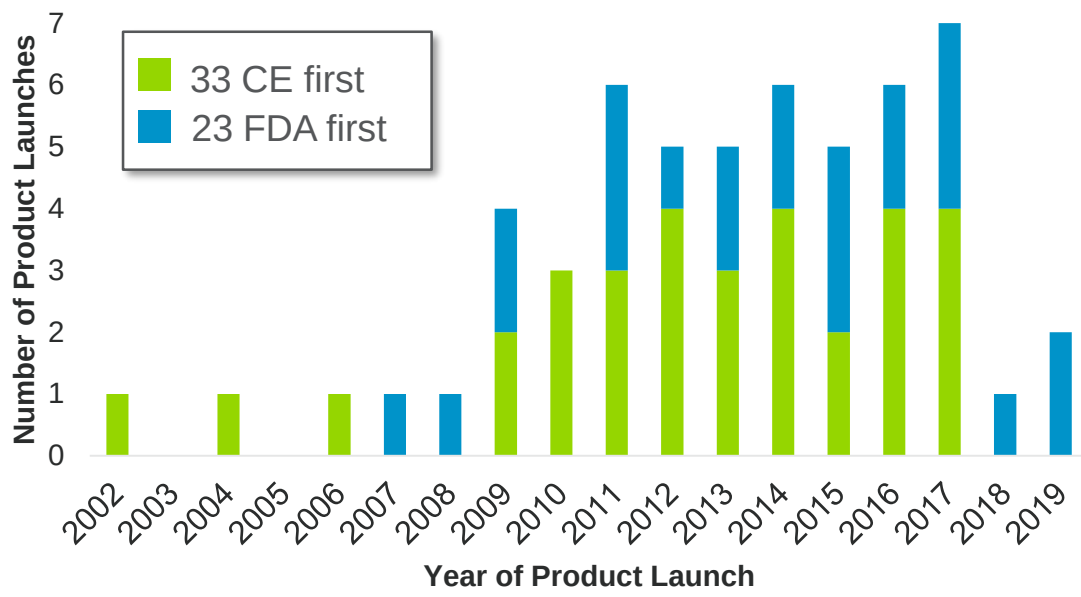
Product Launches by Company HQ

US-based companies are more likely to target the FDA initially. EU-base companies are more likely to pursue a CE Mark.



US Based: 36 **EU Based: 16** **Other: 4**

Product Launches by Year of Launch and Regulatory Path



This dataset leverages medical device companies that had a large financing deal between 2016-2019. The product launches displayed here are the primary products from these companies.

Ref: Large Dataset (56 companies)

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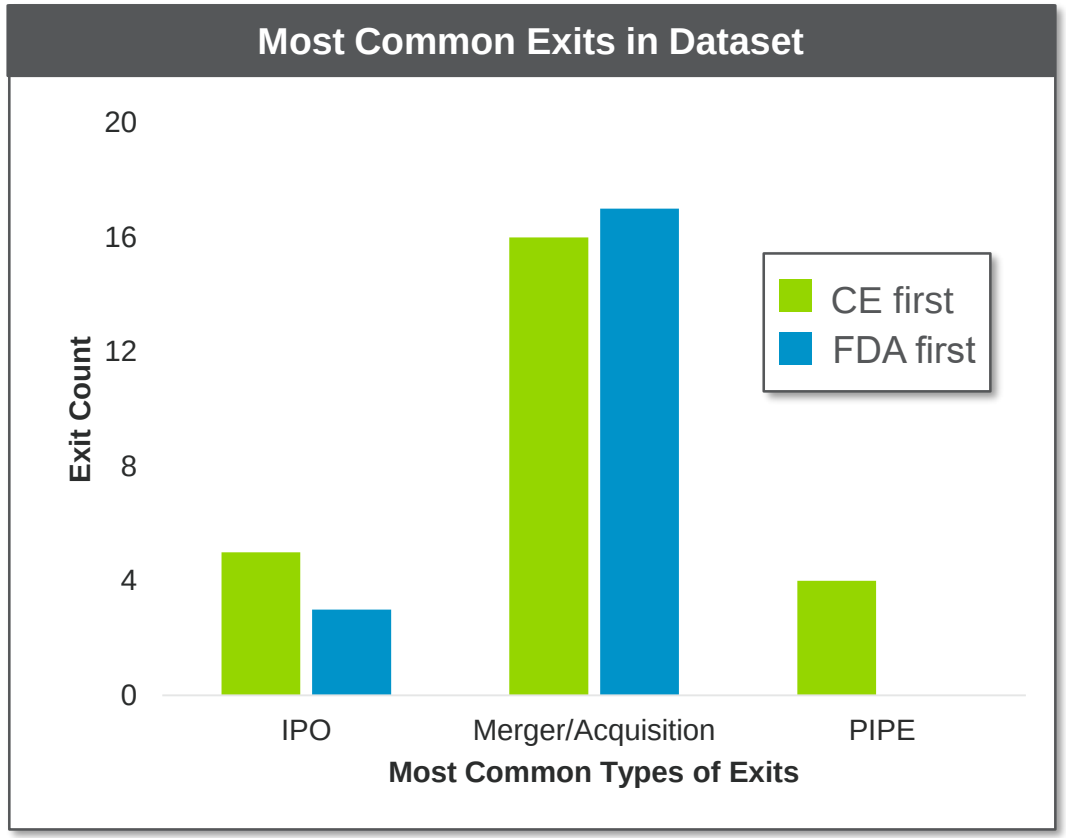
45 companies in our analysis had an exit between 2016-2019



- Before reaching an exit, most of these companies accomplished both a CE Mark and FDA approval
- Other types of exits not included in this breakdown are: secondary transaction (private or open market), public investment 2nd offering, or late-stage VC

Ref: Small Dataset (45 companies)

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The 45 companies included in analysis with a successful IPO, PIPE or acquisition

The "Small" Dataset (45 Companies)

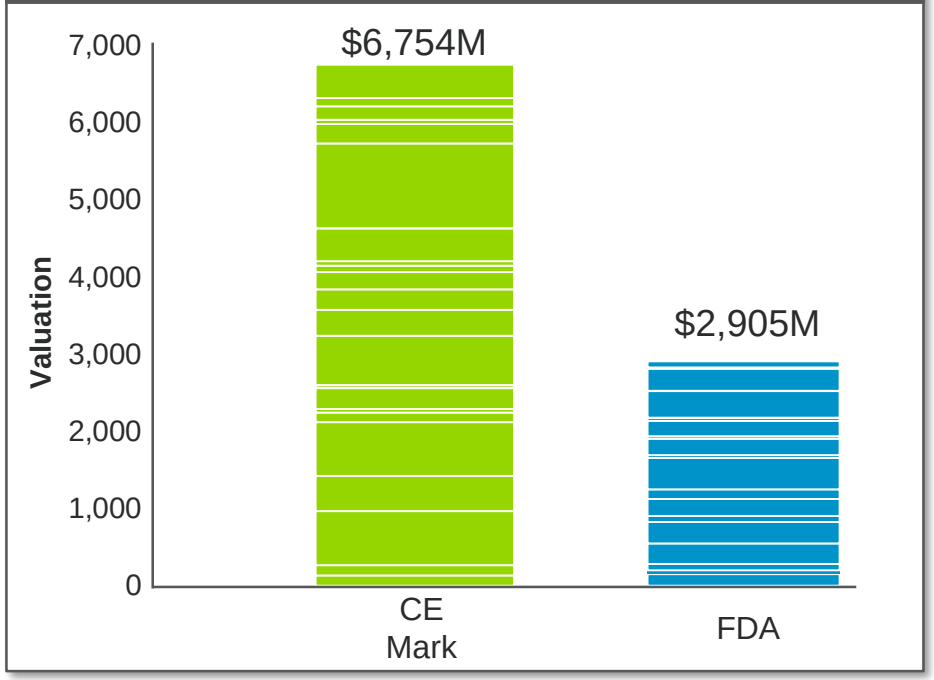
Initially Targeted CE Mark	
Biom'Up	ImThera Medical
Phagenesis	InnFocus
Transcend Medical	AirXpanders
Axonics Modulation Tech.	Sividon Diagnostics
ViewRay	ElectroCore
Mainstay Medical	BeneChill
Acarix	NeoTract
Avita Medical (Respiratory Bus.)	TriVascular
Claret Medical	Ioptima
Obstecare	Bolton Medical
Miramar Labs	Spinal Kinetics
Veniti	Cartiva
Establishment Labs	

Initially Targeted FDA Approval	
NOvate Medical Technologies	Rotation Medical
Securus Medical Group	Medical Surgery Technologies
ThermiGen	Restoration Robotics
Invendo Medical	Electrical Geodesics
nVision Medical	Sensium Healthcare
Spirox	SI-BONE
HyperBranch Medical Tech.	Bioject Medical Technologies
Focal Therapeutics	Neuronetics
NxThera	Myomo
SafeOp Surgical	Paragon Vision Sciences

Initially targeting a CE Mark trended toward higher valuations and slightly shorter time to exit

Company Valuations

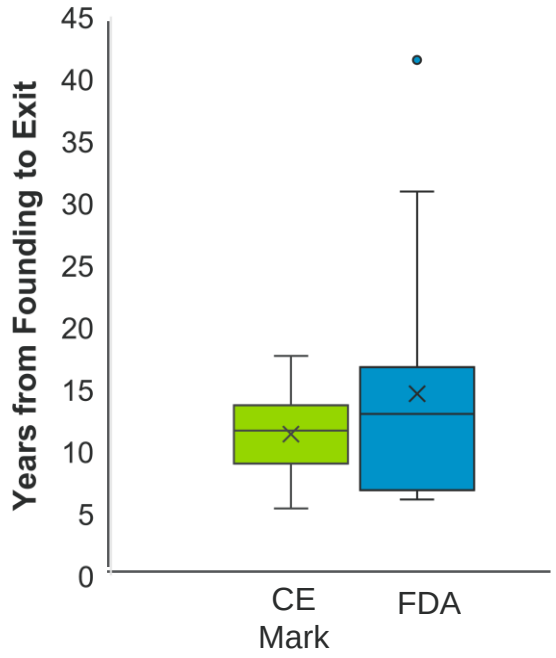
In general, groups that first targeted a CE Mark were valued higher



	CE Mark	FDA
Mean	$270M	$145M
Median	$174M	$103M

Founded-to-Exit Timelines

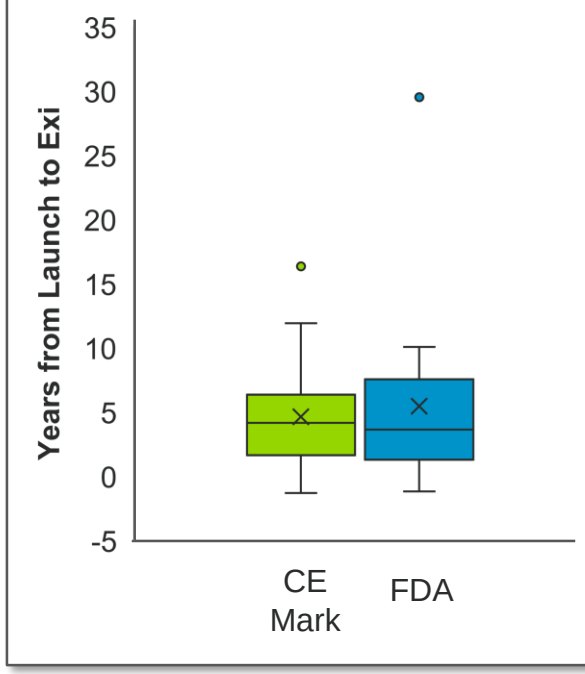
Companies exited at similar times, skewing longer in the FDA group



	CE Mark	FDA
Mean	11.4 Years	14.6 Years
Median	11.7 Years	13.0 Years

Launch-to-Exit Timelines

Companies exited on similar timelines



	CE Mark	FDA
Mean	4.6 Years	5.4 Years
Median	4.1 Years	3.6 Years

Ref: Small Dataset (45 companies)

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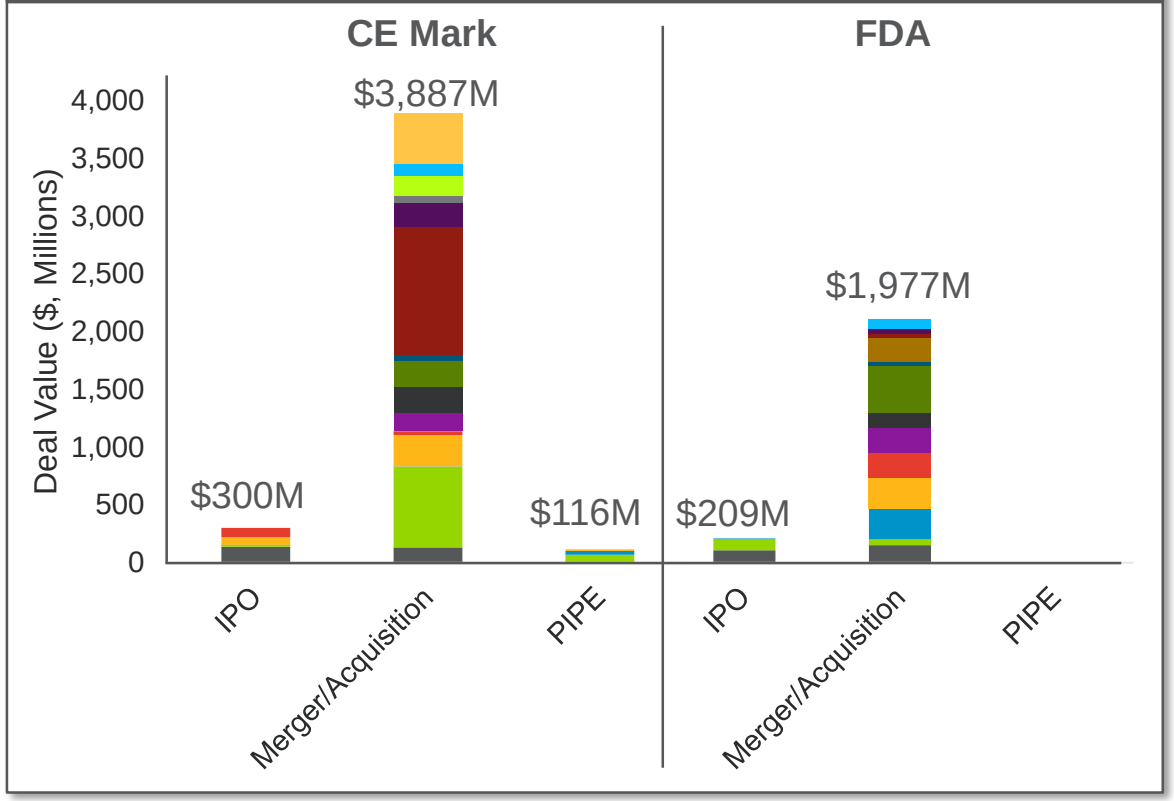
Companies that initially targeted a CE Mark trended toward higher acquisition prices

Financing Deal Size

Companies that first targeted a CE Mark trended to higher value exits



	CE Mark first			FDA first		
	IPO	Merger/ Acquisition	PIPE	IPO	Merger/ Acquisition	PIPE
Mean	$60M	**$243M**	$29M	$70M	**$132M**	--
Median	$68M	**$167M**	$24M	$93M	**$81M**	--

… but not IPO valuations, based on a very small sample

Ref: Small Dataset (45 companies)

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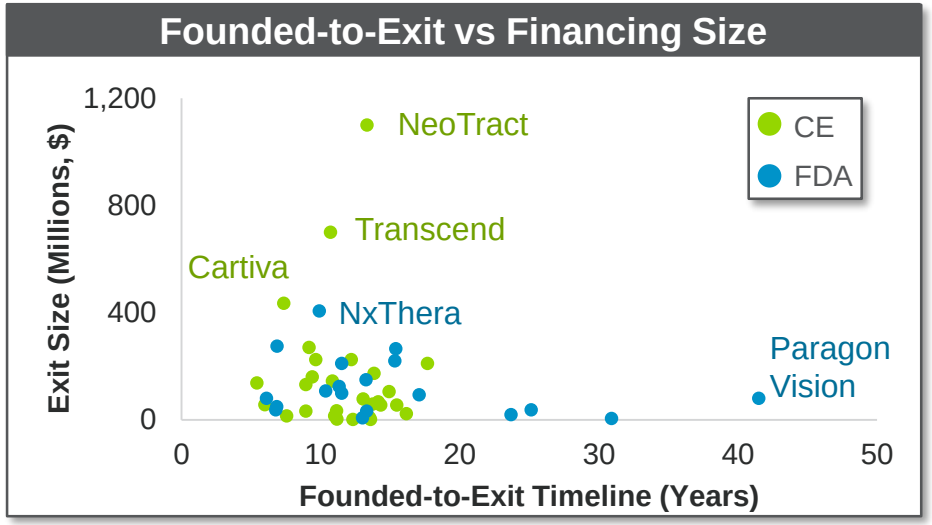
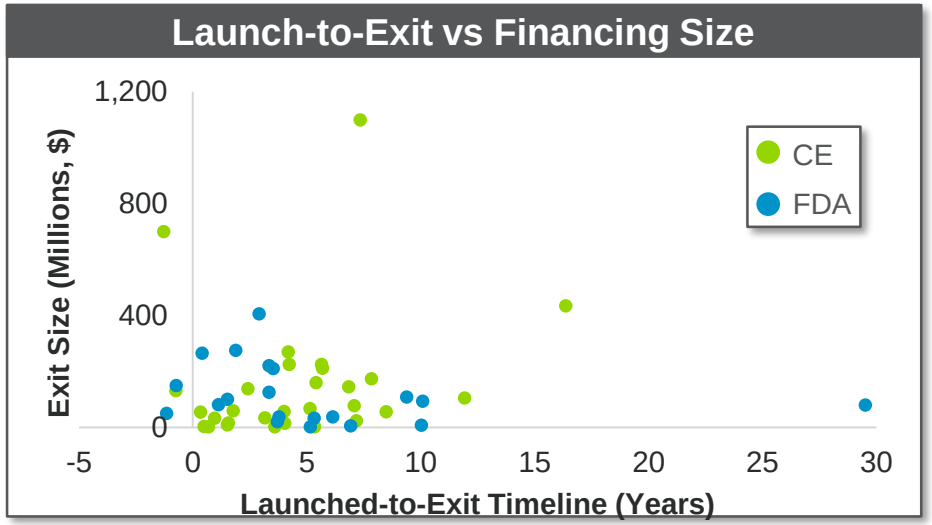
No clear winner when exploring 'higher exit potential' for targeting CE vs FDA

- For medical device start-ups, **"exit success"** could be considered a function of both time to exit and valuation at exit
- Initially targeting CE or FDA has no clear impact on these variables:
  - However, a couple notably large and fast exits went CE Mark first





Ref: Small Dataset (45 companies)

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Conclusions

- Navigant's analysis suggests companies that initially pursued a CE Mark in recent years achieved higher exit value
  - Most successful companies received both CE Mark and FDA Approval
  - Many variables were not accounted for in this analysis
- Companies that first pursued CE Mark may also have had a faster time to exit, although this trend was not consistent
- This is a retrospective analysis, with most companies launching their products 4-10 years ago.
  Recent changes are shifting the cost/benefit calculation of US vs EU commercialization decisions.

US Changes	
Healthcare Politics	• HC system is a focal point of 2020 election, changes seem likely in the coming years
Public Scrutiny	• Journalistic and mass-media sources have been publishing more on the 'lax' medical device regulatory environment • Potential for regulatory pressure to increase

EU Changes	
New MDR/IVDR	• More scrutiny of high-risk devices • Higher costs and infrastructure for post-market surveillance • Device identification requirements
Fewer Notified Bodies	• Longer timelines • Less flexibility
Unresolved Brexit	• Uncertainty with access and regulation for UK market

