Digital Innovation in a Regulated Industry: Evidence from Software-Driven Medical Devices

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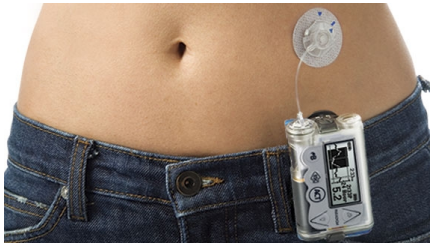
The software-driven, digitized future of health care



"The heart failure patient will have his state of hydration and vital signs monitored through sensors embedded in a watch, a wristband, or a stick-on device. The diabetic or the kidney-failure patient who needs periodic blood monitoring will be able to prick a finger at home (assuming that test still requires a drop of blood; many of today's blood tests will be replaced by sophisticated skin sensors). The specimen will be processed in seconds through a smartphone attachment, and the result will be automatically entered into the electronic record"

-Robert Wachter in *The Digital Doctor*

Definitions & research question

Digitization → digital data

Digital Transformation → industry-level changes

This project takes advantage of new *digital data* from regulatory documents describing newly-approved medical devices to study the *digital transformation* of the medical technology industry

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Questions:

- How *much* digitization are we talking about here?
- Who are the actors (firms) digitizing medical technology?
- What capabilities and/or resources are most important for digital innovation in this setting?
- Does technological innovation in this sector enable the rise of new entrants, or reinforce incumbent advantages?

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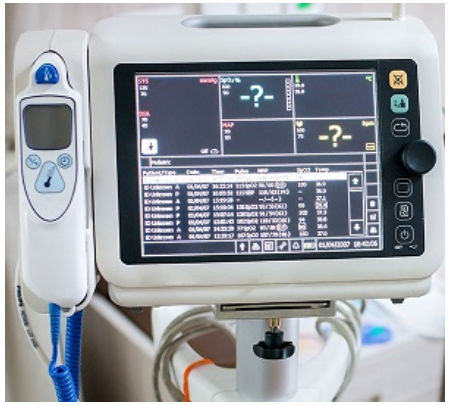
  →unique barriers to entry, role of incumbency

Health care applications



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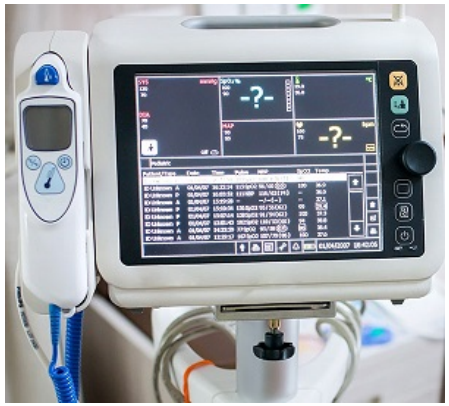

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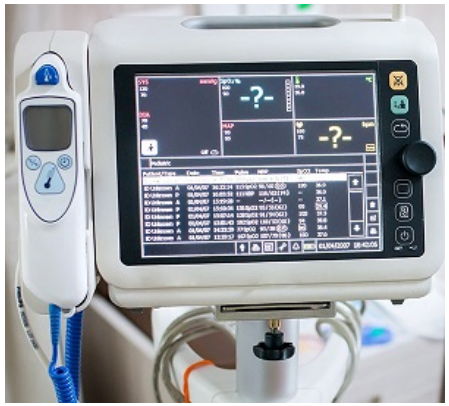

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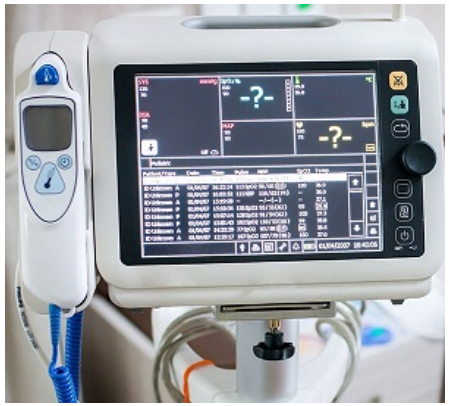

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- Today, 10-15 connected devices *per bed* in typical U.S. hospital
- Medical technology = $140b annual market in United States alone

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- Document (substantial) software-driven innovation in medical technology over past 15 years
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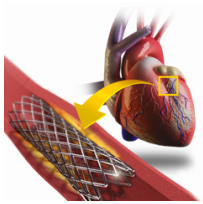
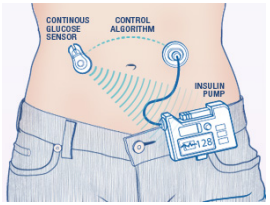
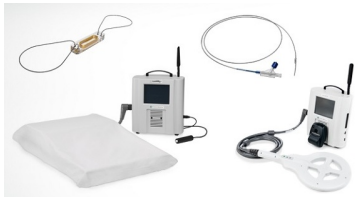
- Consider financial resources available to firms:
  - Little predictive power of access to public capital markets
  - **Venture capital** funding predicts digital innovation (superficially only)
  - Role of financial resources smaller than role of other capabilities

Medical devices

Heterogeneous category, includes a wide range of medical products that you don't inject or ingest:





- Can be "analog" (simple catheter, coronary stent) or "digital" (recent ultrasound equipment, insulin pumps, implantable heart failure monitors)
- Consider all devices subject to (FDA) regulatory process (includes all high-risk and moderate-risk products)

Device regulation in the United States

- Class III (high-risk): implantable and/or life-sustaining devices. Premarket Approval (PMA) process, requires most paperwork & time, evidence from clinical studies of safety and effectiveness [e.g. pacemaker, replacement heart valve]

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- Class II (moderate-risk): devices require special controls. "510(k)" process, requires significant paperwork & time (but less than PMA), typically clinical studies are not required, but applicant must compare their device "to one or more similar legally marketed devices" [e.g. blood pressure monitor, hearing aid]

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- Class I (low-risk): subject only to "general controls" (e.g. manufacturing and registration), no formal regulatory process, not considered here [e.g. dental floss, stethoscope]

Role of firm capabilities & resources

Both external and internal **capabilities**:

- *Geography*
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Financial resources of various kinds

- Access to *public capital markets*
- *Venture capital*

Conceptual Framework

Stylized 2-period model of the impact of:

- **Firm capabilities** (local expertise, firm-specific experience, and class-specific versions of both) on the cost of innovation/new product commercialization
- **Firm financial constraints** (access to public capital markets and VC-funding) on the cost of innovation/new product commercialization

Firms face investment costs in t=1 and realize revenues in t=2

- Firms invest in developing new products when revenue>cost
- Take-aways:
  - Already-existing capabilities (e.g. local expertise and/or within-firm experience) will lower investment required, cost of NPD
  - Access to financing (public firms, VC) will lower cost of borrowing, cost of NPD

Data and methods

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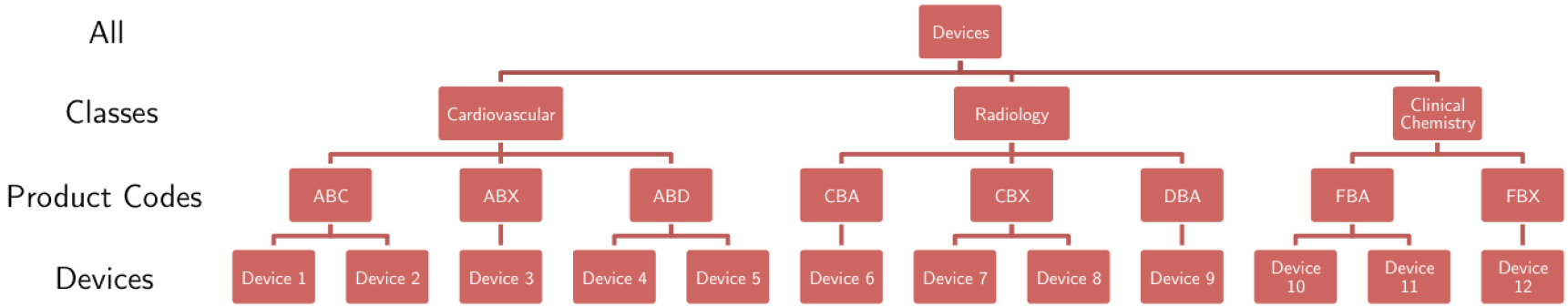
→ **Consider over 35k new medical devices, in 8 most common specialty areas, over 15 recent years (2002-2016)**

Data and methods, cont.

Approach:

- Characterize growth of digital technology in newly approved medical devices, by specialty area and over time
- Consider characteristics (e.g. geography/experience, and financial resources) of firms bringing new technologies to market
- Differentiate among *types* of digital products

Device classification



1. Medical device sample

Data source 1a: FDA's 510(k) clearance database (moderate-risk)
Data source 1b: FDA's PMA clearance database (high-risk)

- Consider all FDA-regulated medical devices approved January 1, 2002 through December 31, 2016 (15 years)
- Full set of device names, product codes (specific classifications of a device's site of use and purpose), product class (medical specialty area) submission & approval dates
- Identify eight most common classes:
  - Account for >3/4 of devices in period
  - Each class has >2,000 unique devices, each year has >2,000 unique devices
  - Total of 36,496 unique product approvals

2. Text database

Data source 2: medical device summary/statement documents

- Part of application for clearance/marketing approval sent to FDA
- Published (as component of larger document packet) when new FDA-regulated device is cleared/approved
- Standardized format
- 98.1% machine-readable PDFs (with OCR software)[1]
- In total, 35,794 computer-readable text documents form basis of device-specific rich text database

[1] no systematic concerns with "missing" data

Frequencies in device + machine-readable text sample:

Table: Summary statistics by medical specialty (class)

	Unique devices at p-y* level		Unique devices at f-p-y* level		Unique devices at f-p-y level**	
	N	%	N	%	N	%
Cardiovascular	6,092	17.0 %	4,643	17.0 %	2,761	17.6 %
Clinical Chemistry	2,353	6.6 %	1,845	6.8 %	956	6.1 %
Dental	3,942	11.0 %	3,207	11.7 %	1,718	10.9 %
Gastroenterology, Urology	2,571	7.2 %	2,156	7.9 %	1,281	8.1 %
General Hospital	3,779	10.6 %	3,037	11.1 %	1,432	9.1 %
General, Plastic Surgery	4,959	13.9 %	3,851	14.1 %	2,285	14.5 %
Orthopedic	7,228	20.2 %	5,194	19.0 %	3,566	22.7 %
Radiology	4,870	13.6 %	3,377	12.4 %	1,732	11.0 %
Total	35,794	100.0 %	27,310	100.0 %	15,731	100.0 %

*f=firm, p=product, y=year

**post 2005, US only

Columns 1-2 present the full sample of products observed. Columns 3-4 present the same data collapsed to the firm-product-year level; these data are used to generate measures of firm experience, but not all observations are used in regression models. Columns 5-6 present summary statistics for the analysis sample used in estimation.

Text analysis

Text files of all product summaries processed in two ways: #1 is *ad hoc* but transparent, #2 is externally validated, not transparent

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1. Supervised document classification focused on keywords from glossary of computer terminology
   - Scan for keywords (unambiguously) associated with software and/or digital technology, e.g. *"software"*
   - Due to standardized format, words not used if functionality of device does not involve components/concepts referenced
   - Focus on one (or more) of these terms; "software" = most common and strongly associated with others

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2. Validate using National Library of Medicine algorithm ("MTI") for medical document classification (gives MeSH® descriptors from NIH)
   - High success rates with validation: 100% of MTI-defined software devices use the keyword "software," 73% of keyword-defined digital devices are flagged by MTI as being about (MeSH) "Software"

Summary statement example

510(K) SUMMARY JAN 1 1 2008

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K073198

1. **Submitter's Identification:**

   Microlife Intellectual Property GmbH, Switzerland

   Espenstrasse 139
   9443 Widnau / Switzerland

   Date Summary Prepared: October 30, 2007

2. **Name of the Device:**

   Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1).

3. **Information for the 510(k) Cleared Device (Predicate Device):**

   Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3AC1-1 PC, K#060686.

4. **Device Description:**

   Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Home is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".
   The device has <DIAG> and <USUAL> measurement mode. In additional, the device can be used in connection with your personal computer **(PC)** running the WatchBP 1.0 software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

Summary statement example

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Continuous Glucose Monitoring (CGM) System
Device Trade Name:	iPro2 Continuous Glucose Monitoring (CGM) System
Device Procode:	MDS
Applicant's Name and Address:	Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P150029
Date of FDA Notice of Approval:	June 17, 2016
Priority Review:	*Not Applicable*

II. **INDICATIONS FOR USE**

iPro2 CGM System (MMT-7745)
The iPro2 Recorder is to be used with either Enlite sensor or Sof-Sensor and is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using a standard home glucose-monitoring device. The information collected by the iPro2 Recorder may be uploaded to a computer (with Internet access) and reviewed by healthcare professionals. This information may allow identification of patterns of glucose level excursions above or below the desired range, facilitating therapy adjustments which may minimize these excursions.

VI. Software

The current software version for the iPro2 CGM system is v1.1A. Software verification and validation were carried out in accordance with the FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: General Principles of Software Validation: Final Guidance for Industry and FDA Staff (2002).* Software development activities included establishing detailed software requirements, linking requirements with associate verification tests, software code reviews, unit testing, system level testing and defect tracking and dispositioning to ensure the software conforms to patient needs and intended uses. Software was previously reviewed under P980022/S071.

VII. Human Factors Testing

The sponsor referenced human factors testing from previous submissions (P980022 and P120010) and provided new testing to support the proposed system configuration. New testing included the following:

- Evaluation of tasks regarding the removal of the iPro2 recorder from the Enlite sensor and inspection of fluids on the recorder before initiating contact with the iPro2 docking station.
- Evaluation of specific tasks performed in the software.

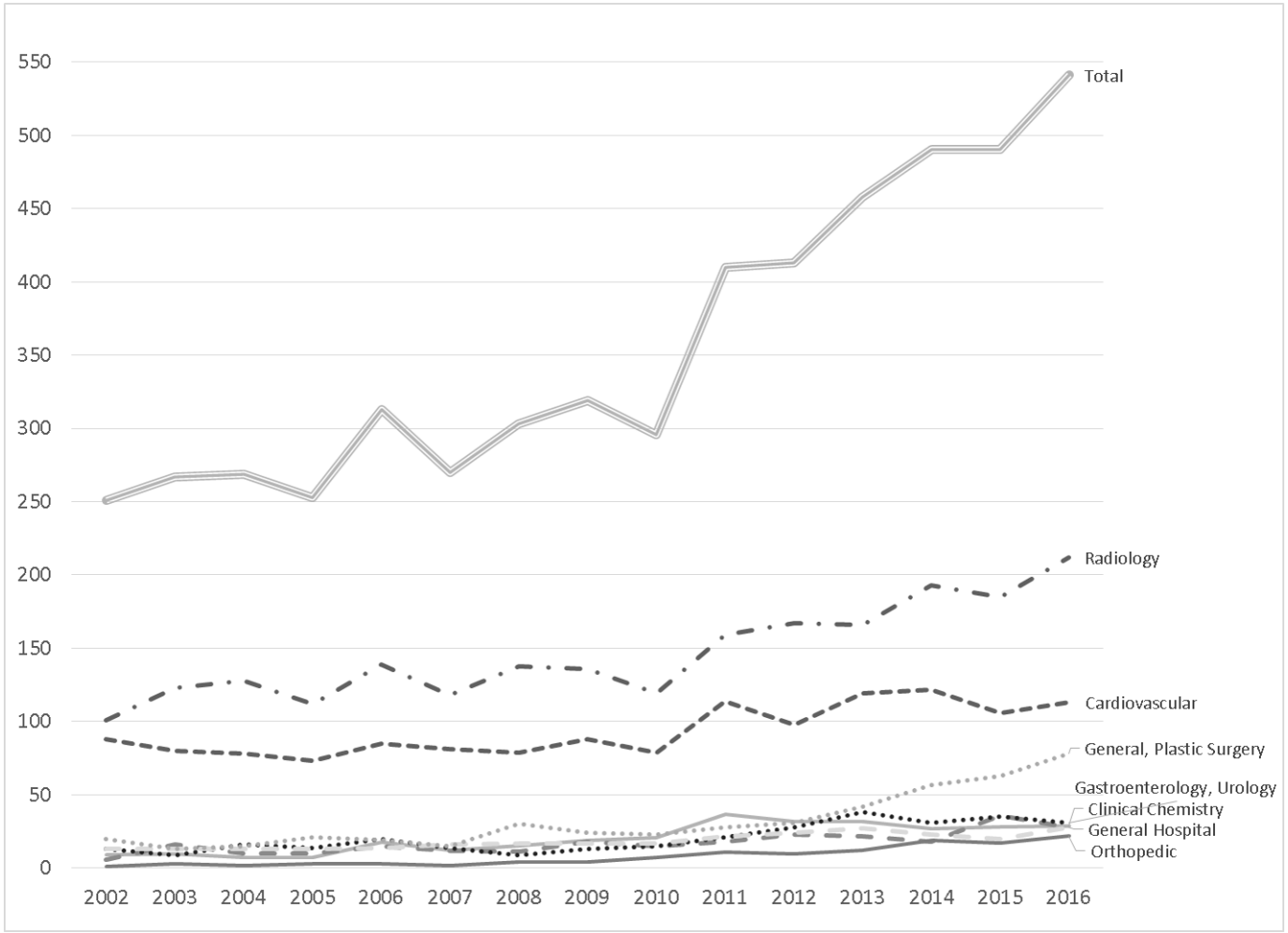
PMA P150029: FDA Summary of Safety and Effectiveness Data Page 7

Keyword counts

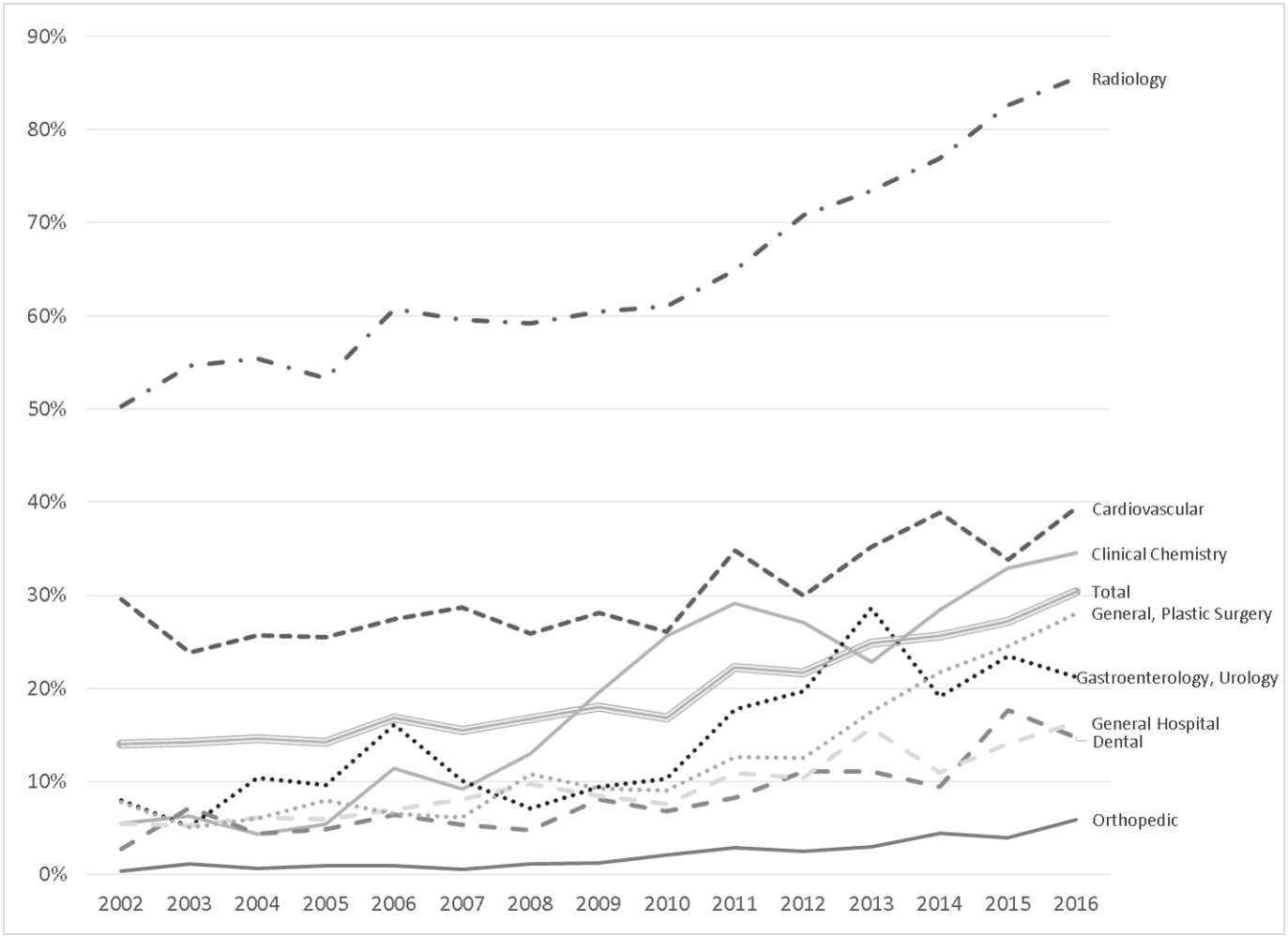
Keyword (& acronyms thereof)*	Counts**
software (general)	6,788
additional terms (N=38)	
computer (general)	2,779
screen (display)	2,278
network (communication)	1,187
wireless (communication)	906
database (storage)	757
server (storage)	731
digital image (display)	312

*Source: glossary of computer and networking terminology

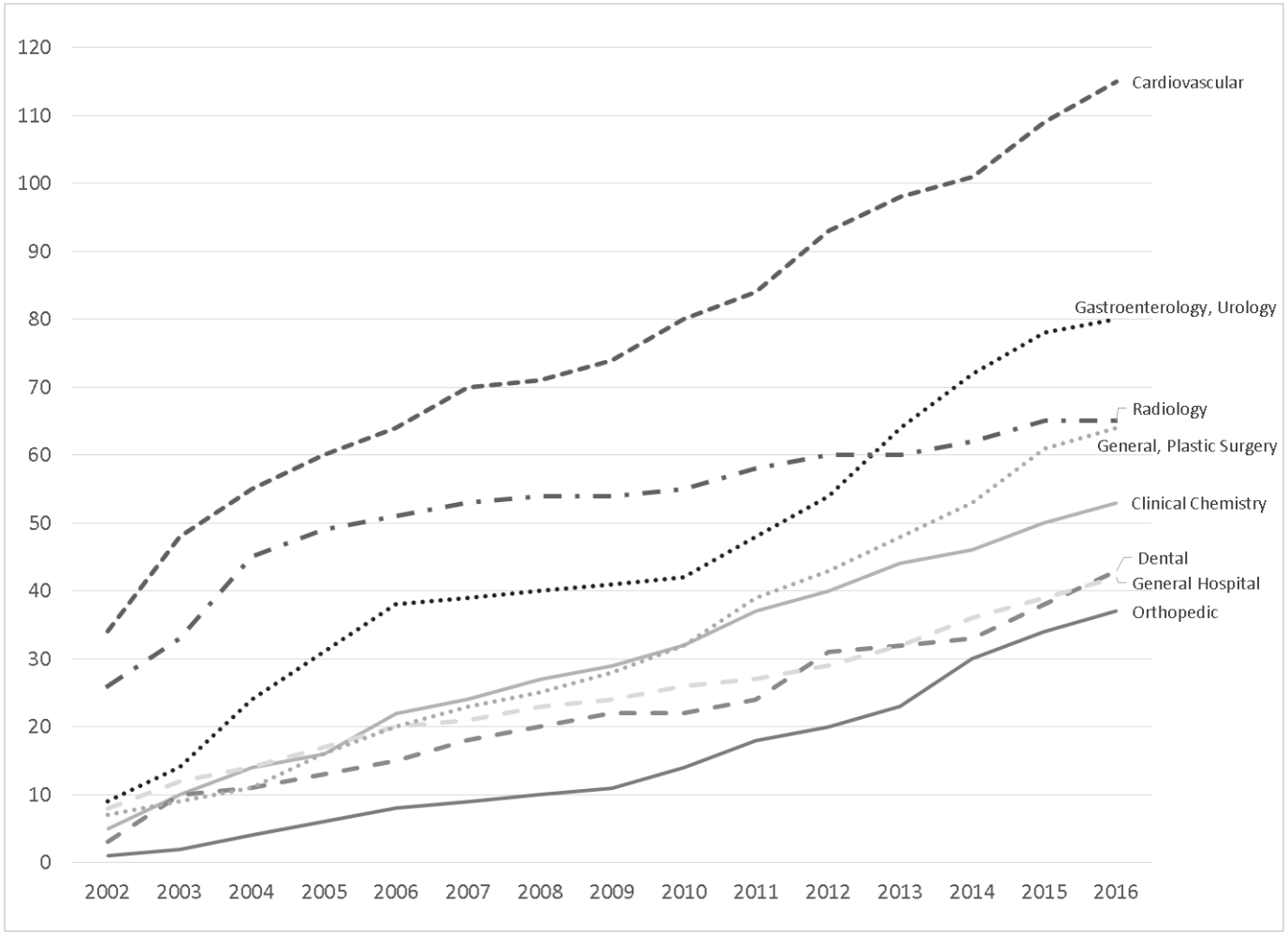
Approved devices with software (approvals per year)



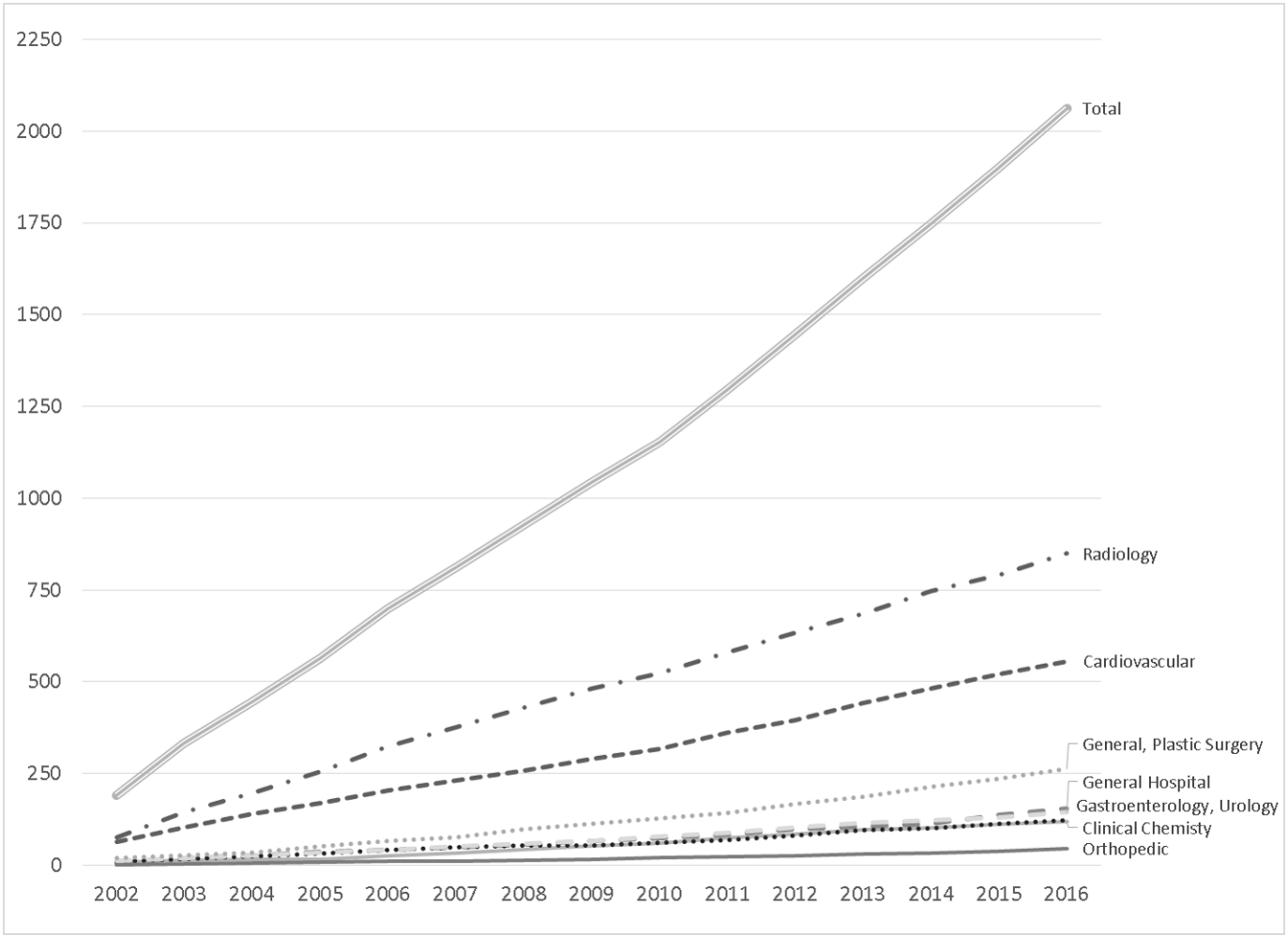
Share of newly-approved devices with software by year



Cumulative device product codes with software



Cumulative firms with software devices



3. Firm-level financial data

Evaluate MedTech, S&P Capital IQ, Prequin

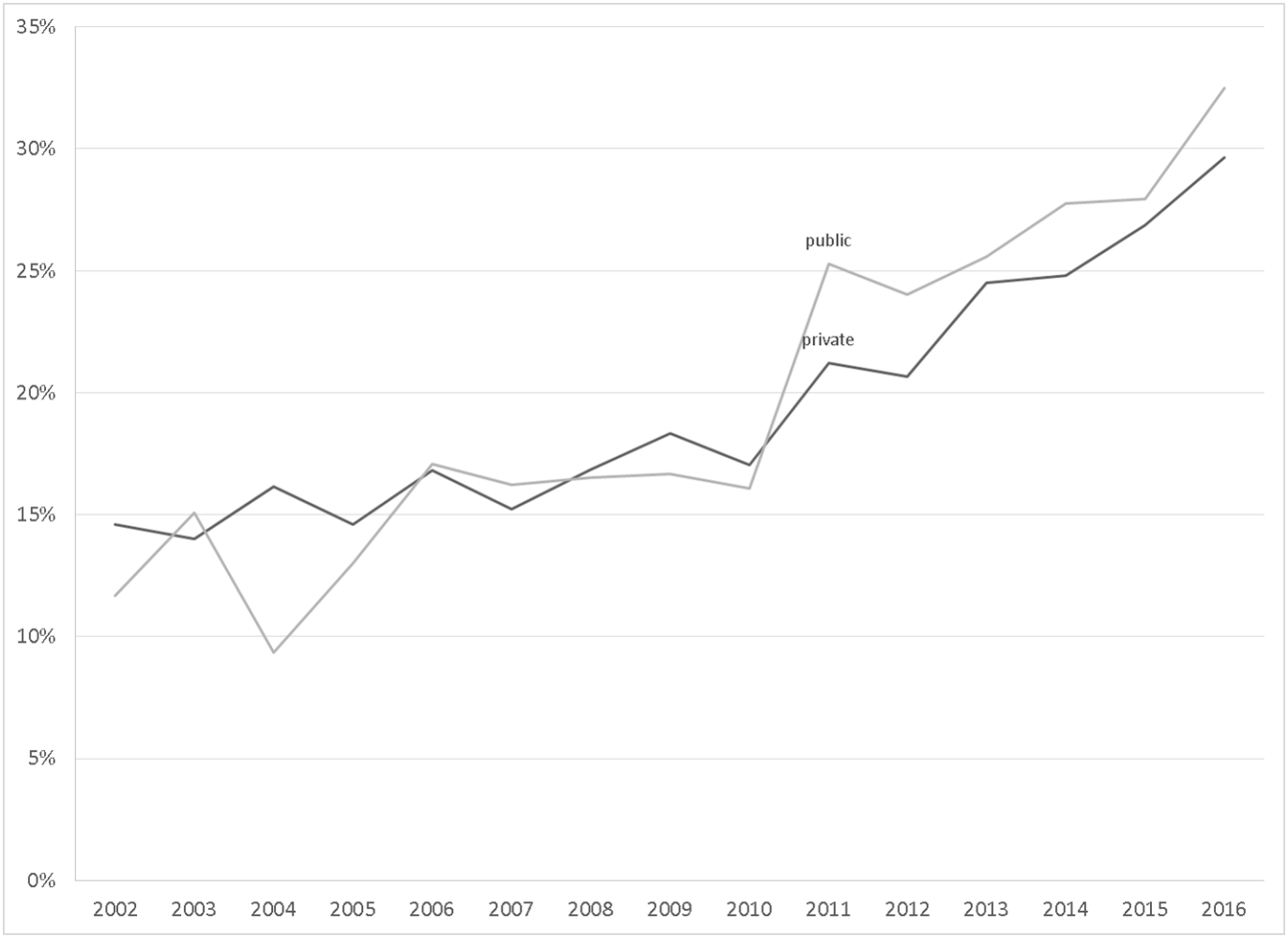
- Detailed firm financial data from EvaluateMedTech and S&P Capital IQ: publicly listed (if so, IPO year); for roughly 1/3 of firms, annual revenues
- Known VC deals + amounts from Prequin, EvaluateMedTech
- Firms linked to "parents" (and their financials) in cases when regulatory approval before an acquisition, correct commercializing firm established

Table: Firm financial data

Metric	Sample Mean (± SD)
Share of software engineers in state	0.053 ± 0.043
Prior digital devices (all)	4.23 ± 14.53
Prior digital devices (class-specific)	2.19 ± 8.52
Total venture funding, cumulative	5.96 ± 22.98
In digital device cluster (general), %	14.36
In digital device cluster (class-specific), %	47.57
Publicly listed, %	28.95
VC funded (applicant), %	16.17

Non-binary variables are given as mean ± SD
n=15,731
Prior digital devices calculated using keyword-based definition

Software device share



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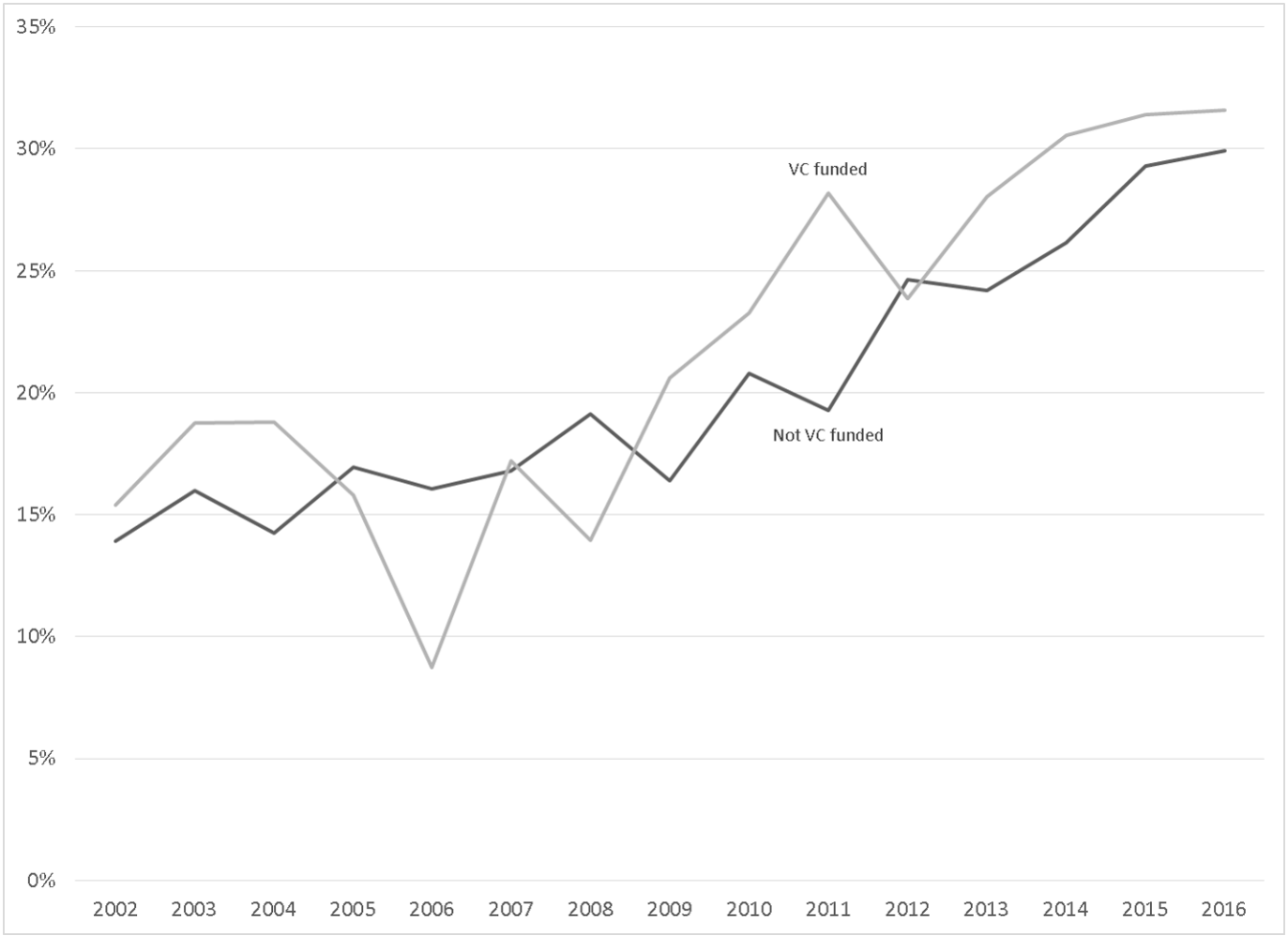


Geographic data

Historical data on all regulated, new product commercializations by sate and class (FDA) and state software expertise (BLS)

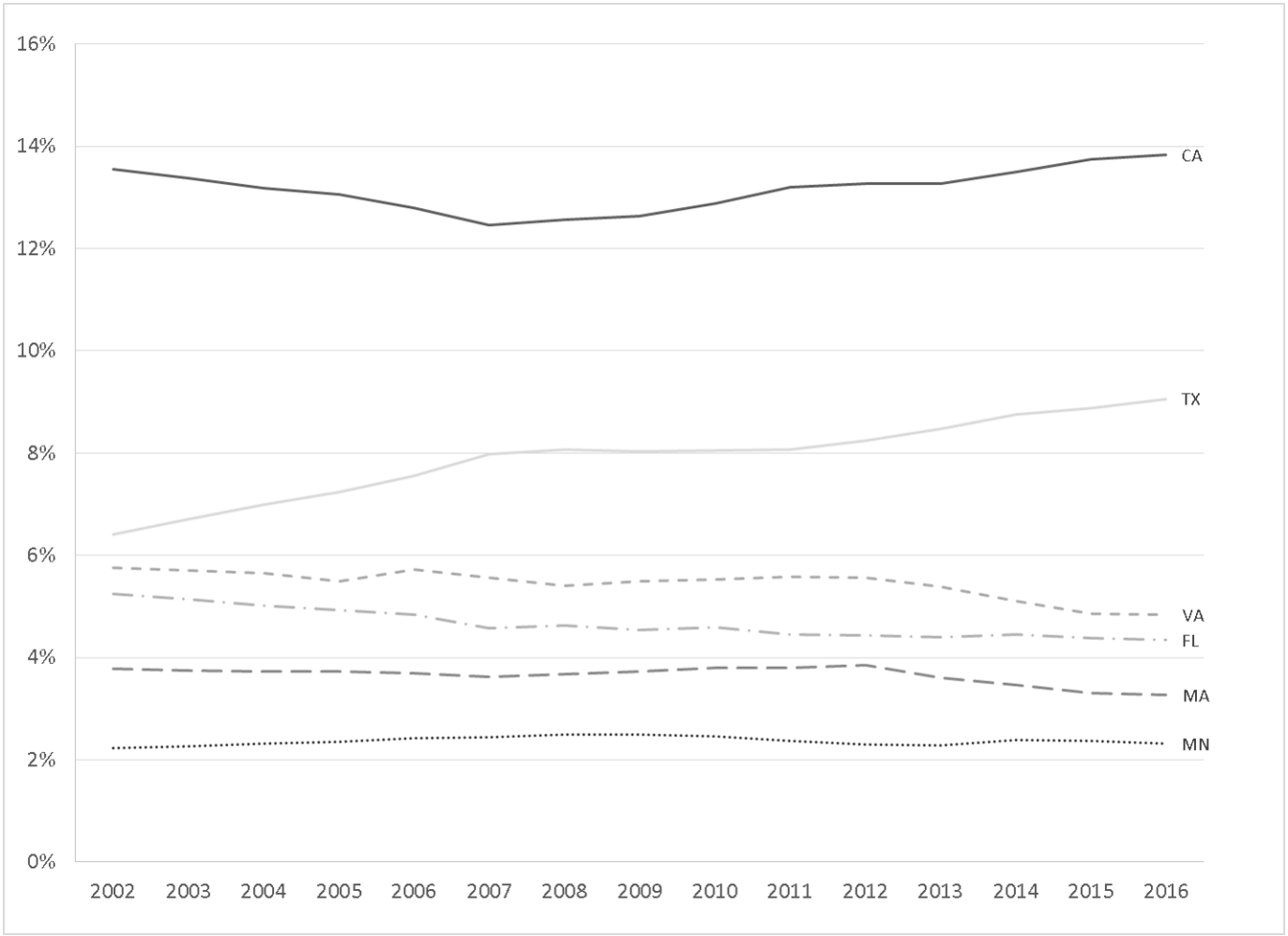
- Full history of all device commercializations in FDA's databases (since 1976 for high-risk; since 1996 for moderate-risk)
- BLS data on state's percentage of software engineers in labor force: skilled workforce as a prerequisite for software-driven R&D

Table: Firm experience summary statistics by product type

Software	Analysis sample (Full) (n=15,731)	Non-Digital Devices (n=12,673)	Digital Devices (n=3,058)	T-Statistic (Digital vs. Non) (n=15,731)
Prior digital devices	4.23	2.71	10.51	-17.17
Prior digital devices (same class)	2.19	1.05	6.93	-19.54
Prior digital devices (different class)	2.04	1.66	3.58	-8.94

Notes: Digital devices defined using keyword-based classification. T-statistic is from a difference-in-means t-test with unequal variances comparing the non-digital vs. digital samples. All tests have a corresponding p-value of < 0.000.

Share of software engineers in local labor force (BLS)



Regression models predicting software incorporation

At the firm-product-code-year (FPY) level, model likelihood of a product being digital, S:

$$S_{fpct} = f(\beta \mathbf{X})$$

Where **X**s include:

- **Measures of local (extra-firm) expertise**: local software engineers, in a (general/class) cluster for digital innovation
- **Within-firm capabilities**: commercialization experience (incumbent firms) – in general and/or in medical specialty class
- **Firm resources:** whether product emerged from a publicly listed firm or a VC-funded firm
- **Controls** for clearance year and medical specialty class

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Consider predictors of digital innovation. Logit models: marginal effects, SEs clustered at product level

Table: Controls (used in all regression models)

Logit model, software inclusion at FPY level (Basic control variables in two main regression analysis samples)	
Clearance year	0.014***
	(0.001)
Cardiovascular	0.073
	(0.072)
Dental	-0.129*
	(0.061)
Gastroenterology, Urology	-0.058
	(0.060)
General Hospital	-0.087
	(0.065)
General, Plastic Surgery	-0.082
	(0.061)
Orthopedic	-0.192***
	(0.055)
Radiology	0.449***
	(0.092)
N	15,731
Pseudo R^2	0.2208
* p<0.05, ** p<0.01, *** p<0.001	
Omitted group = Clinical Chemistry, marginal effects reported.	

Logit model: digital device innovation							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
State software employees (Ln)	0.007			0.005			0.005
	(0.005)			(0.004)			(0.004)
In digital device cluster		0.068***		0.032**			0.025*
		(0.012)		(0.010)			(0.010)
In digital device cluster for prod. class			0.136***	0.129***			0.112***
			(0.010)	(0.009)			(0.007)
Prior digital devices, internal (Ln)					0.045***		
					(0.006)		
Prior digital devices in class, internal (Ln)						0.085***	0.074***
						(0.009)	(0.008)
Prior digital devices in diff. class, internal (Ln)						-0.033***	-0.028***
						(0.007)	(0.006)
N	15,731	15,731	15,731	15,731	15,731	15,731	15,731

* p<0.05, ** p<0.01, *** p<0.001

All models include full set of time and product class fixed effects, marginal effects reported. Standard errors are clustered at the product code level. Digital devices defined based on keyword method. Firm experience and clusters are defined using data from the prior five years.

Logit model: digital device innovation					
	(1)	(2)	(3)	(4)	(5)
Publicly listed firm	0.009			0.011	0.010
	(0.011)			(0.011)	(0.011)
VC-funded firm		0.029*		0.030*	
		(0.012)		(0.013)	
Total VC funding, $ (Ln)			0.012**		0.013**
			(0.004)		(0.004)
N	15,731	15,731	15,731	15,731	15,731

* p<0.05, ** p<0.01, *** p<0.001

All models include full set of year and product class fixed effects. Standard errors are clustered at product code level, marginal effects reported. Digital devices defined based on keyword method.

Logit model: digital device innovation							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
State software employees (Ln)	0.005		0.002	0.002	0.003	0.003	0.003
	(0.004)		(0.004)	(0.004)	(0.004)	(0.004)	(0.004)
In digital device cluster	0.025*		0.024*	0.024*	0.024*	0.024*	0.024*
	(0.010)		(0.010)	(0.010)	(0.010)	(0.010)	(0.010)
In digital device cluster for prod. class	0.112***		0.112***	0.112***	0.106***	0.112***	0.111***
	(0.007)		(0.007)	(0.007)	(0.008)	(0.007)	(0.007)
Prior digital devices in class, internal (Ln)	0.074***		0.076***	0.076***	0.075***	0.072***	0.067***
	(0.008)		(0.008)	(0.008)	(0.008)	(0.008)	(0.008)
Prior digital devices in diff. class, internal (Ln)	-0.028***		-0.027***	-0.027***	-0.026***	-0.030***	-0.025***
	(0.006)		(0.006)	(0.006)	(0.006)	(0.006)	(0.006)
Publicly listed firm		0.010	-0.017	-0.017	-0.017	-0.017	-0.018
		(0.011)	(0.009)	(0.009)	(0.009)	(0.009)	(0.009)
Total VC funding, $ (Ln)		0.013**	0.012***	0.012***	0.006	0.004	0.000
		(0.004)	(0.003)	(0.003)	(0.004)	(0.004)	(0.004)
VC $ (Ln) * In cluster				-0.001			
				(0.007)			
VC $ (Ln) * In cluster for prod. class					0.012*		
					(0.005)		
VC $ (Ln) * Prior digital devices (Ln)						0.010***	
						(0.003)	
VC $ (Ln) * Prior digital devices in class (Ln)							0.017***
							(0.003)
N	15,731	15,731	15,731	15,731	15,731	15,731	15,731

* p<0.05, ** p<0.01, *** p<0.001

All models include full set of year and product class fixed effects. Standard errors are clustered at product code level, marginal effects reported. Digital devices defined based on keyword method. Firm experience and clusters are defined using data from the prior five years.

Summary:

- Significant growth in (regulated) digital medical devices, heterogeneity across medical specialties
- Method for using supervised document classification to analyze contents of new product descriptions
- Results point to significant incumbent advantages in digital innovation
  - Geographic clusters and prior commercialization experiences matter
  - Money alone does not appear to compensate for geography and experience
- Evidence for within-region and within-firm positive spillovers from past digital innovation
  - Interestingly, factors work largely orthogonally to one another
- Conclusion: this regulated setting favors firms coming from a position of incumbent geographic and/or experiential advantage

Thank you!

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