



Pulse of the industry

**Current Trends and Challenges
in Life Sciences**

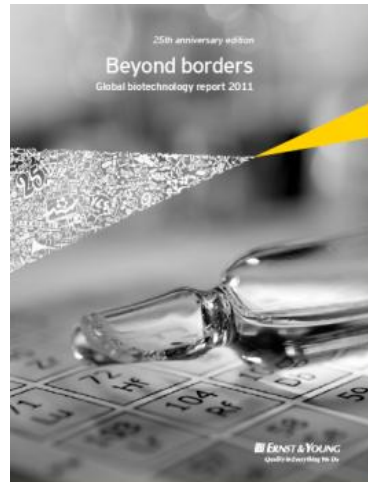
Ifit Quarterly

Zurich, 16 March 2012

A long tradition of industry insights



**Medtech
insights**
*Pulse of the
industry*



**Biotech
insights**
Beyond borders



**Pharma
insights**
Progressions



**Current
issues**
*Life sciences
insights*

The Big Picture

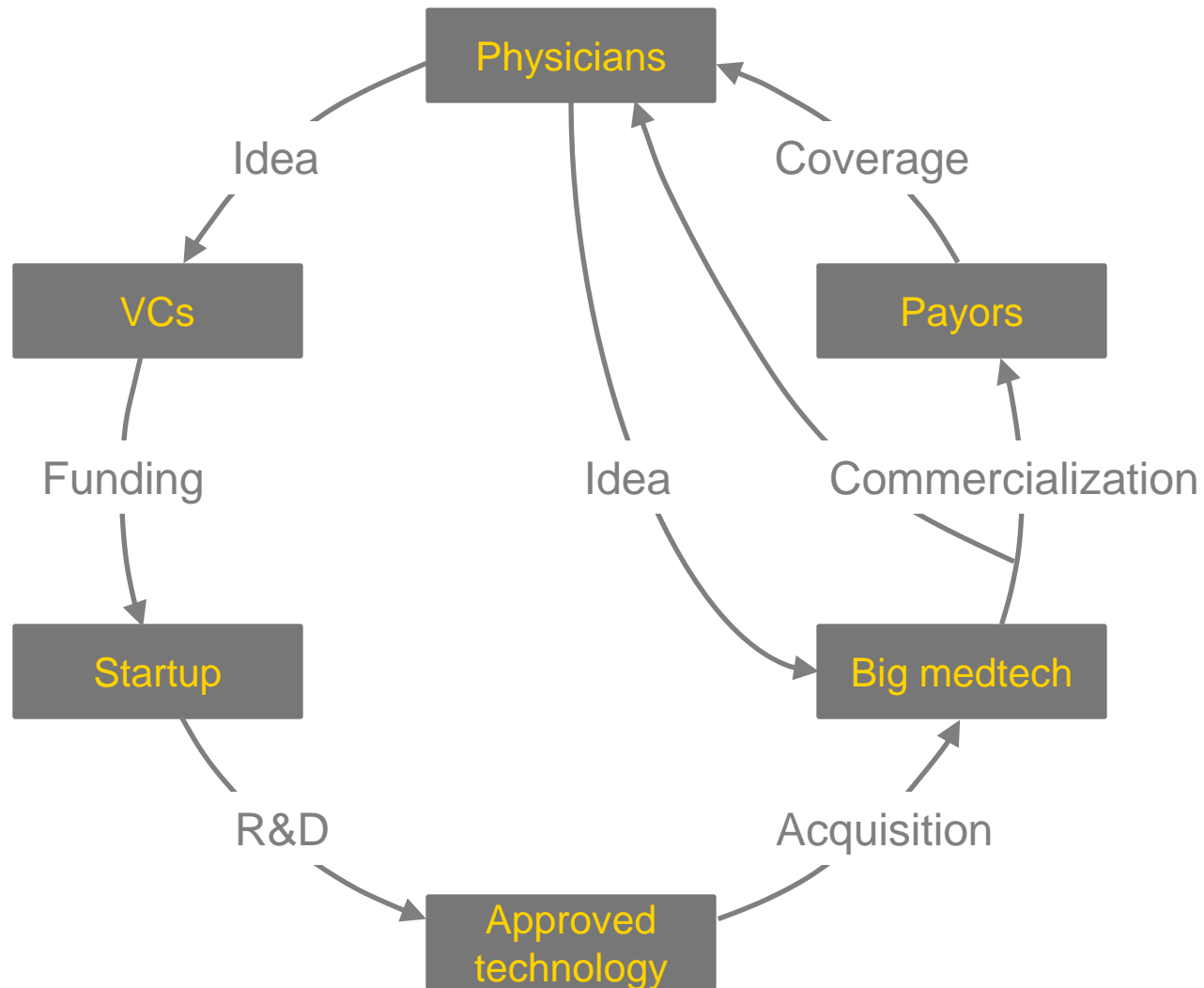


A unique innovation model for a unique industry

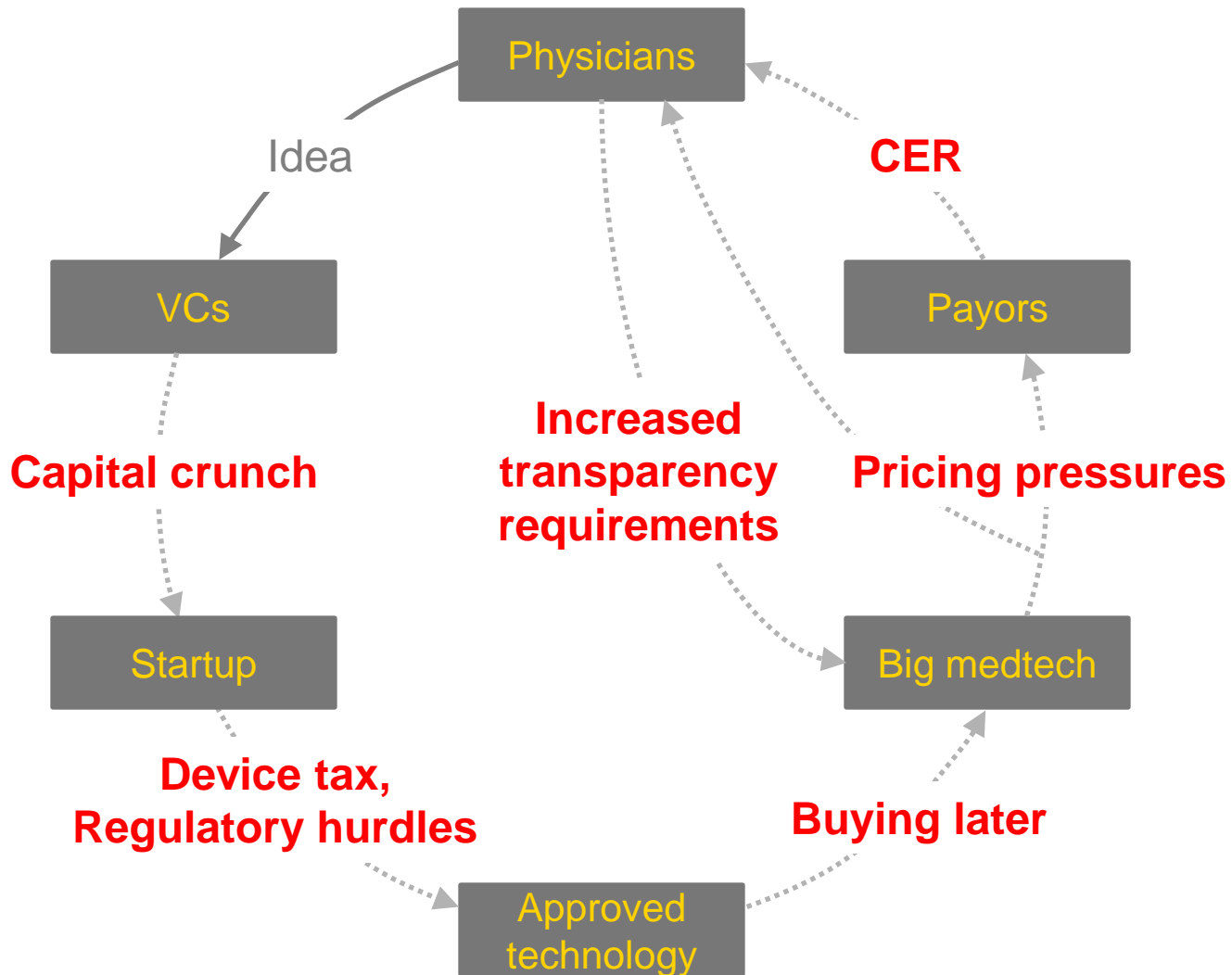
	Biotech/pharma	IT	Medtech
Basic technical challenge	▶ Human biology	▶ Electrical engineering	▶ Electrical engineering
Product development cycles	▶ 10+ years	▶ 18-24 months	▶ 18-24 months
VC model	<ul style="list-style-type: none"> ▶ Larger, longer investments ▶ High risk/high return 	<ul style="list-style-type: none"> ▶ Smaller, shorter investments ▶ Low risk/low return 	<ul style="list-style-type: none"> ▶ Smaller, shorter investments ▶ Low risk/low return
Regulatory framework	▶ Market approval requires clinical trials	▶ No marketing approval required	▶ Varied approach based on risk class
Innovation	▶ “Linear”	▶ “Cyclical”	▶ “Cyclical”

Source: Ernst & Young

Medtech's long-standing "cycle of innovation" ...



... now faces new challenges at every stage



Global medtech headlines

- ▶ Industry turned in solid financial performance – all major indicators outpaced growth rates from the year before
 - ▶ Healthcare reforms, hospital consolidation, austerity measures & increased regulatory hurdles are increasing uncertainty and risk
-
- ▶ Fundraising up – propped up by a few large debt offerings
 - ▶ VC funding model under strain – longer runways, higher bar for exits, diluted returns, more risk-averse investors and less capital available
-
- ▶ After bottoming out in 2009, market for M&As has rebounded
 - ▶ Buyers continued to shy away from riskier, early-stage M&As in favor of later stage companies with revenue / profits
 - ▶ Private equity returned to the scene

A photograph of a surgeon in a blue surgical cap and white face mask, looking intently at a computer monitor in an operating room. The background is blurred, showing other surgical lights and equipment. The text "Innovation at risk?" is overlaid on the right side of the image.

Innovation at risk?

A new normal for medtech

Regulatory
and pricing
pressures



Customer
realignment



A new
funding
environment



Innovation
at risk?



Innovation at risk?

Regulatory
and pricing
pressures



Customer
realignment

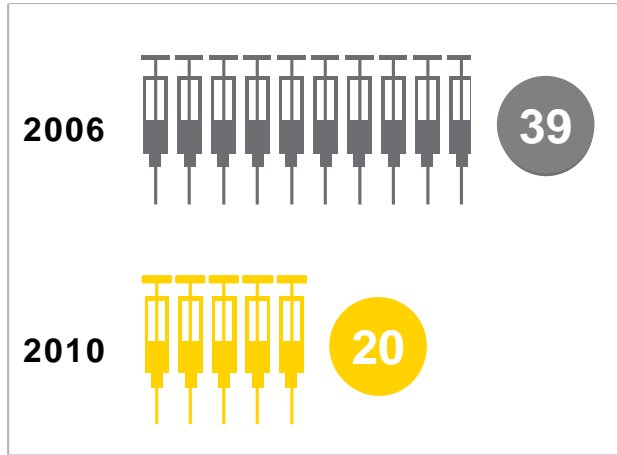


A new
funding
environment



Fewer product approvals in the US...

Number of premarket approvals (PMA) in the US

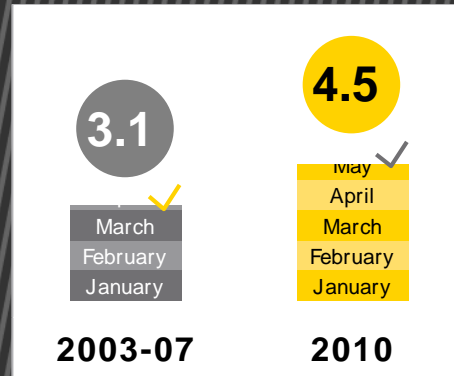


Number of 510(k) approvals

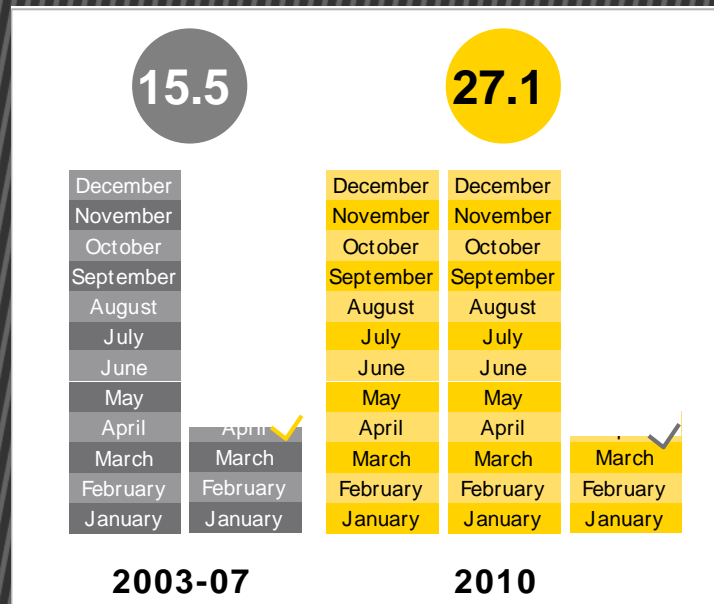


...approvals are taking longer to secure

Average 510(k)
approval times
(months)

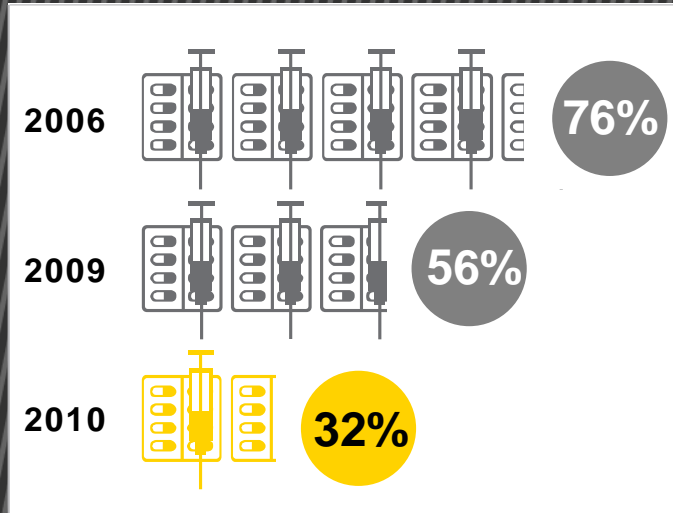


Average PMA
approval times
(months)



Number of first review IDEs has decreased

Devices receiving
FDA investigational
device exemptions
(IDE) after first review

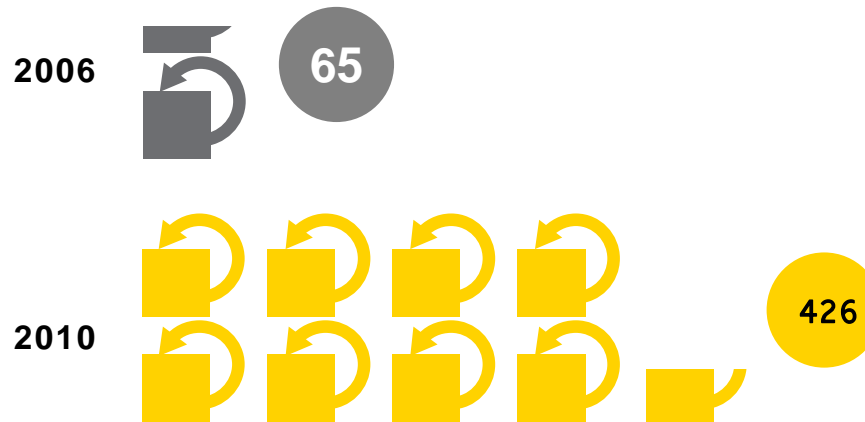


Post-market scrutiny has increased

Number of warning letters issued by the CDRH



Number of Class I product recalls



Innovation at risk?

Regulatory
and pricing
pressures



Customer
realignment

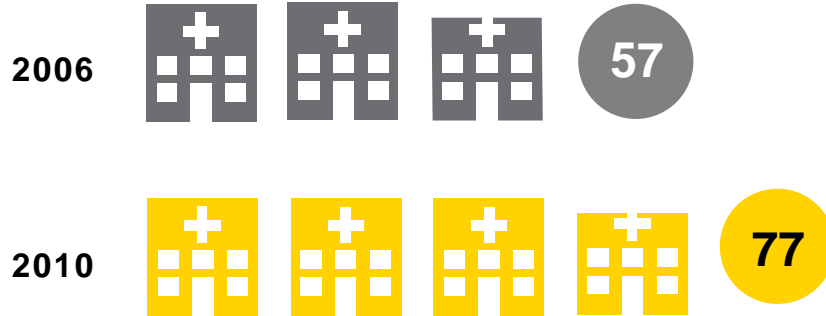


A new
funding
environment



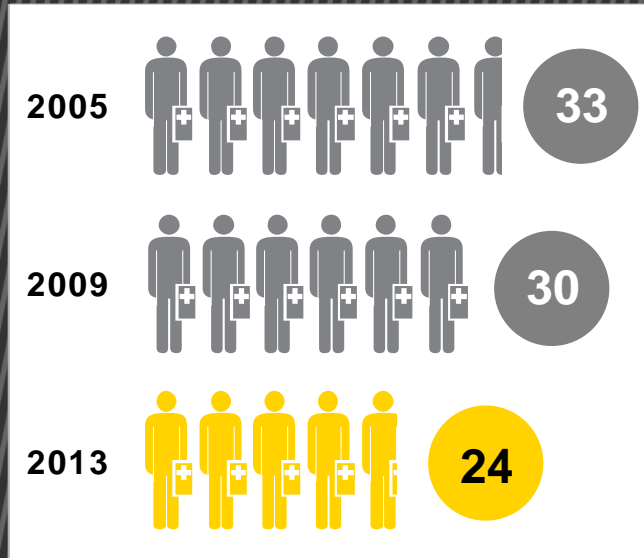
Hospitals continue to consolidate

Number of US hospital M&As announced



Independent physicians are decreasing

Percentage of US private practice physicians



A changing hospital environment

Implications for medtech companies

**Governments
squeeze HC costs,
health care reform**

**Pressure from
payers**

**Global economic
downturn**

**Hospital face
tighter margins,
cost pressures**

- ▶ **Customer moves beyond the physician → hospitals more prominent**
- ▶ **Realign sales/marketing approach**
- ▶ Implications for what you sell, how you sell and how you develop new offerings

Innovation at risk?

Regulatory and
pricing pressures



Customer
realignment

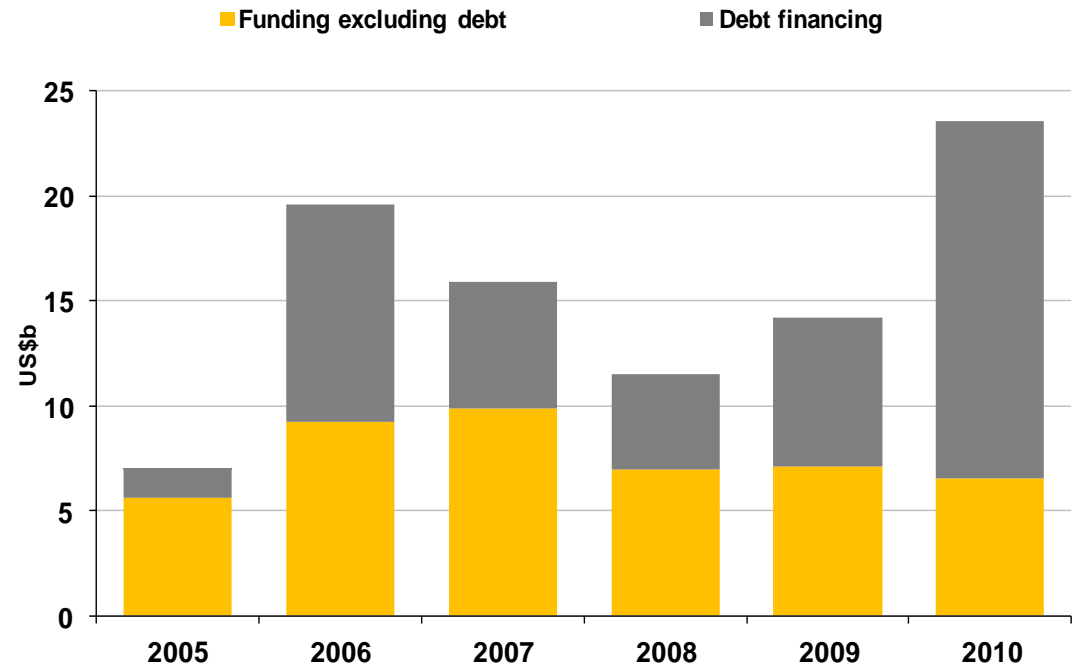


A new funding
environment



Funding is up...or is it?

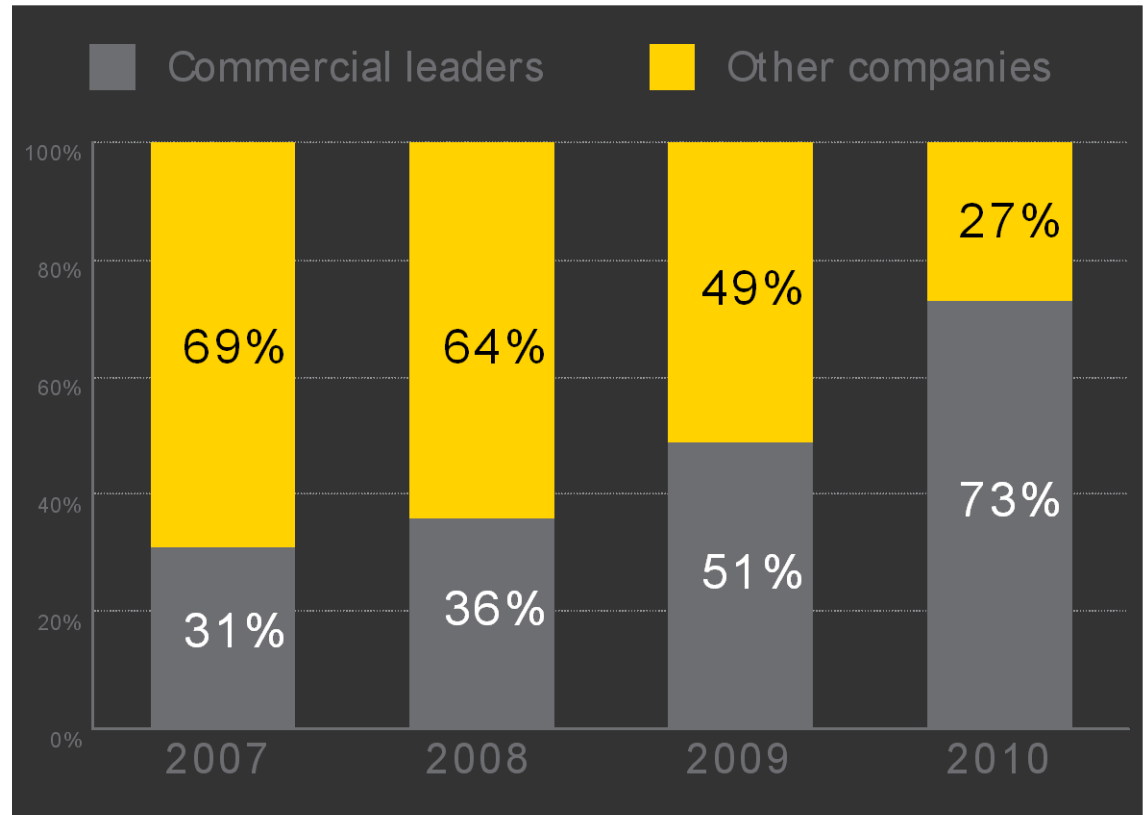
US and European capital raised by year



The rich get richer?

Large companies' share of total capital raised has grown dramatically

However, venture capital has dropped for the third consecutive year



Thank you

Stay tuned:

ey.com/medtech

Heinrich Christen

Partner, Industry Leader Medtech EMEIA

Ernst & Young Ltd.

Maagplatz 1

CH-8010 Zürich

Phone +41 58 286 34 85

Mobile +41 58 289 34 85

Fax +41 58 286 30 00

eMail heinrich.christen@ch.ey.com

