



TT08: PhUSE is Moving Cloud Adoption Forward in Life Sciences

Presentation at PhUSE Annual Conference, Edinburgh

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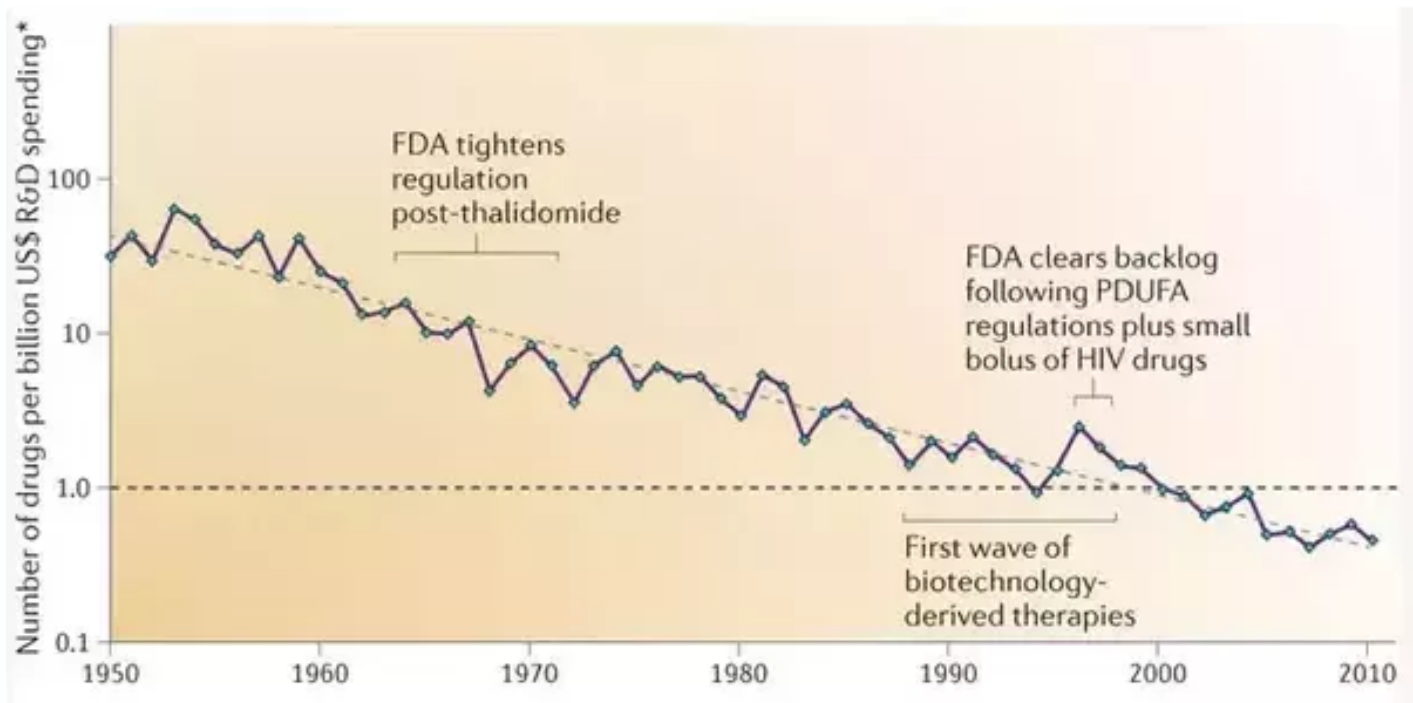
October 2017

Agenda

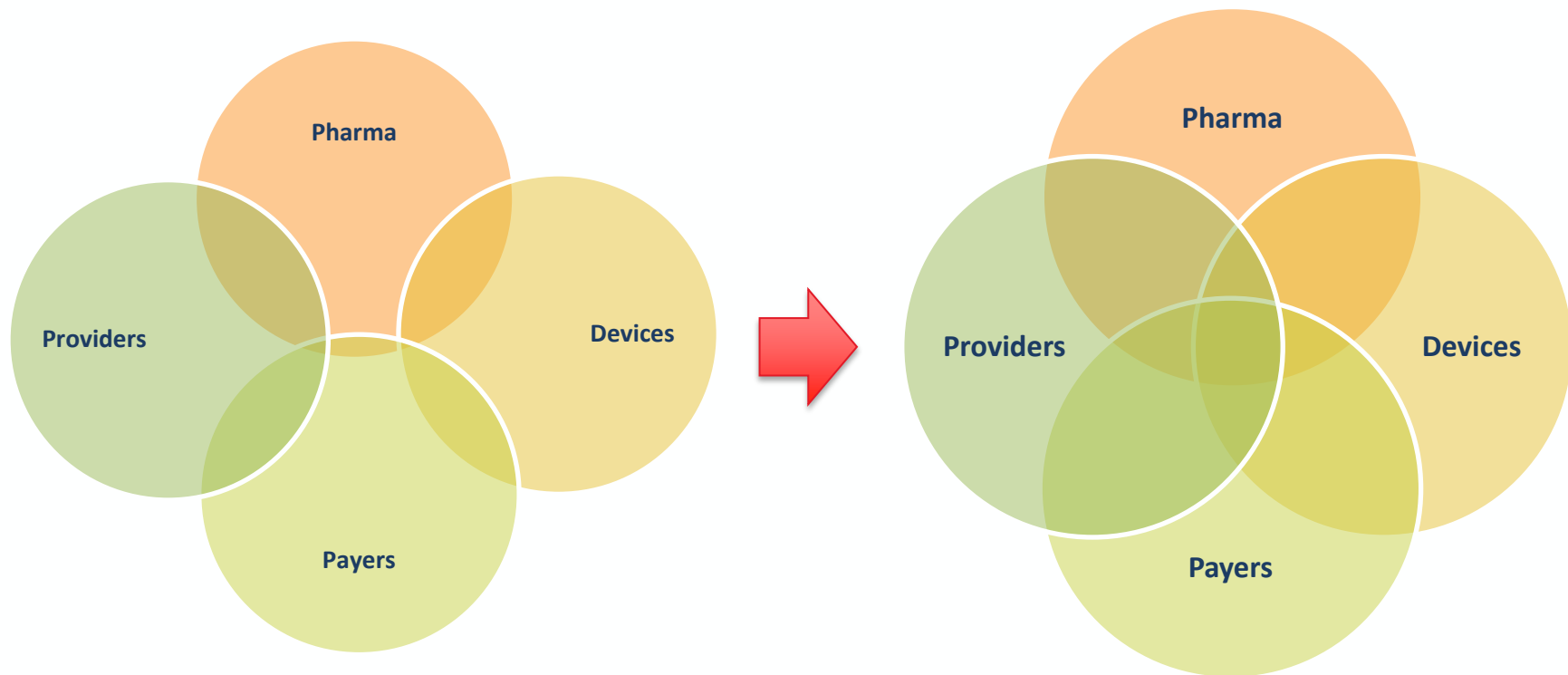
- Eroom + 6 Trends
- FDA
- Enhancing productivity
- Leaders - & Laggards
- Adoption barriers today
- Traceability and responsibilities – it can get complex!
- FDA 21CFR11 Q&A draft
- Q&A

Eroom's Law

- The cost of developing a new drug is 2X every 9 years
- No sign of this trend reversing anytime soon!



Trend #1 – Continents Shifting



Trend #2 – Power to the Patient



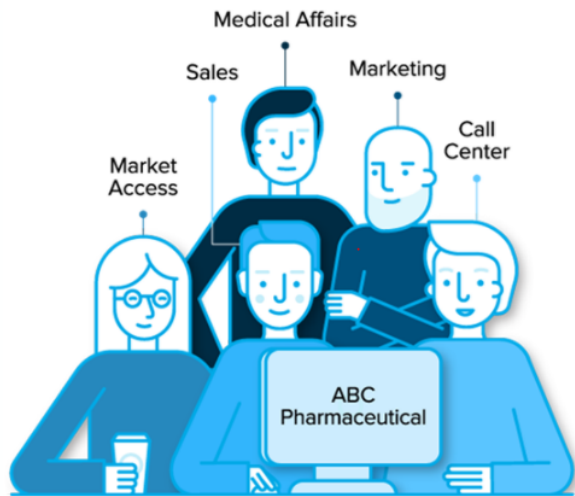
smartphones, big data and artificial intelligence are helping to prevent, intercept and manage disease

Empowerment & Engagement

“The systems in the U.S. are so fragmented. We need to figure out how to actually unleash all of that data.”

Sandi Peterson, Group Worldwide Chair
of Johnson & Johnson

Trend #3 – “CX” is the Buzzword for 2018



- CX in Pharma Call Center
- CX in Physicians and HCP engagements
- CX in Patient Engagement – benchmarked against Amazon, Netflix, Starbucks, Uber



Trend #4 – Disruption and More Disruption

AN INNOVATIVE NEW JERSEY COMPANY
PATENTS “TALKING PILLS”!



...interested parties include:

GSK, Purdue Pharma, Endo, . . . , **Google, Facebook, Qualcomm, Walgreens, and Samsung!**

Who is better geared up for success - Healthcare companies or their tech competitors?

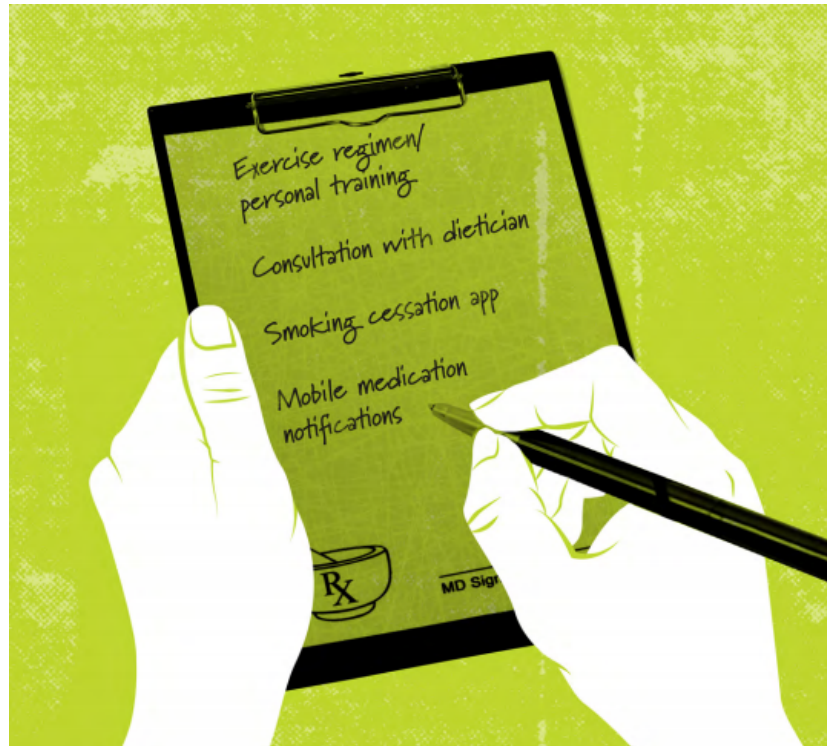
BTW – are you ready for the “Password Vitamin”?

Trend #5 – Shifting Sick Care to Well Care

- Fee-for-service to paying for value – Outcomes Based
- Selling healthcare as a service (HaaS)

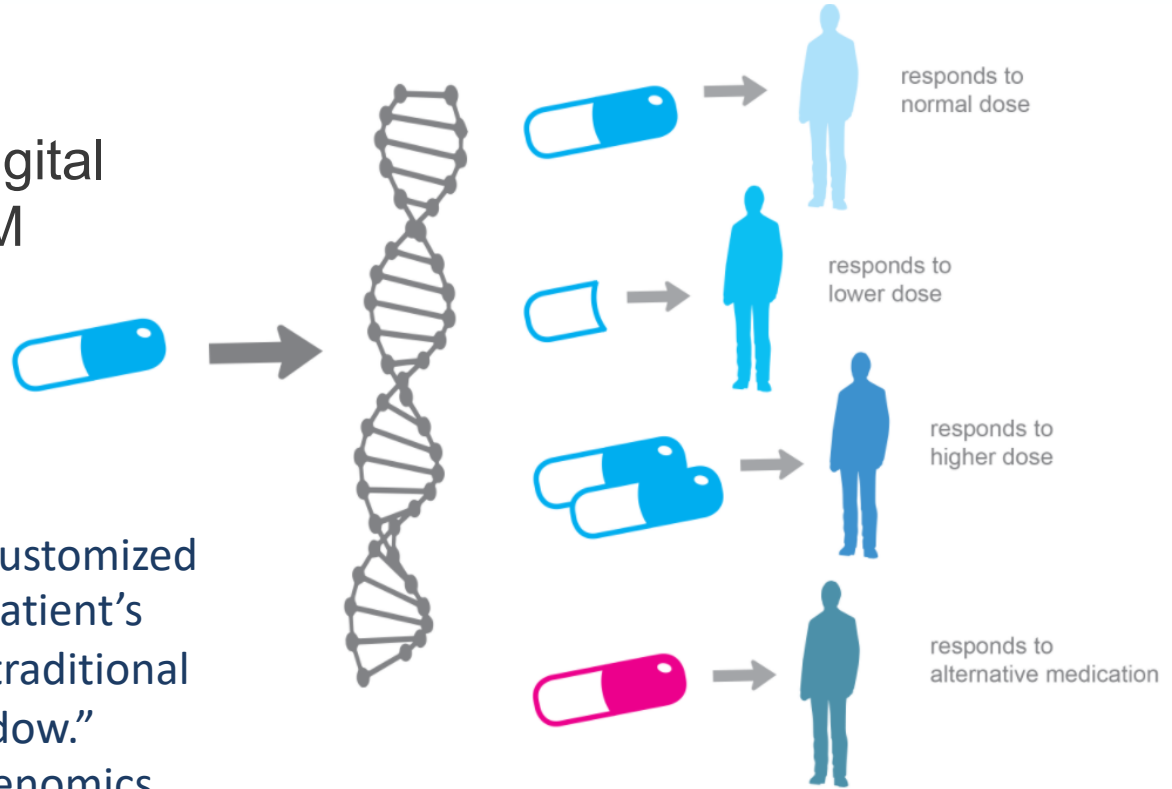
“...but these kids don’t play sports, so actually they cost us less because they get fewer injuries.” Anonymous Payer about fighting child obesity

“We have been in the sick care business for 100 years,” says Johnson & Johnson’s Sandi Peterson. “But what we really want to be in is the well care business.”



Trend #6 – Personalized Medicine at Scale

- Reversing Eroom's law
- Imagine the extent of digital transformation and BPM required



"If you can start thinking about customized printing of medicines based on patient's information, all of a sudden the traditional estimates of cost go out the window."
Oliver Fetzer, CEO of Synthetic Genomics

Applications Digital Strategy



OIMT | Office of Information Management and Technology

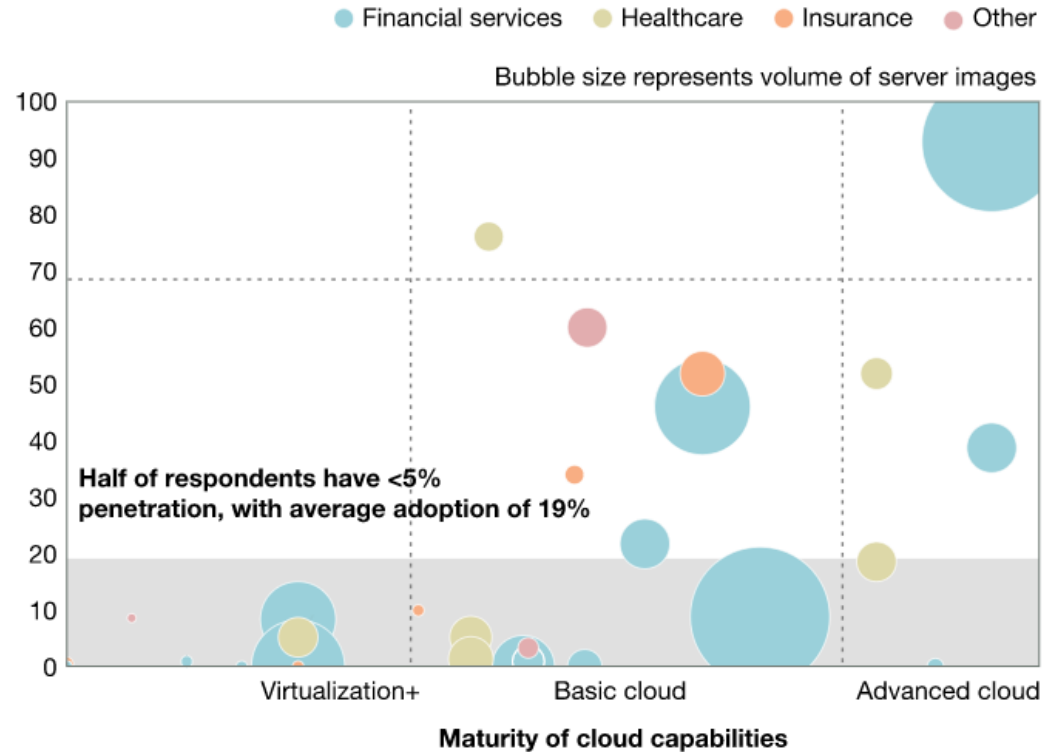
How Do We Enhance Productivity?

- Moore's law at the individual microchip level is slowing down
- The power that is available on demand [in the cloud](#) continues to increase
- Pairing innovative tools for BPM, data visualization, and Machine Learning enables granular analyses at scale

Uncover a deeper, more nuanced understanding of performance

The average adoption rate for x86 workloads in the cloud is less than 20 percent.

% of server images deployed in private or public cloud¹



Source: Horizon360 by McKinsey; McKinsey Cloud Infrastructure Survey

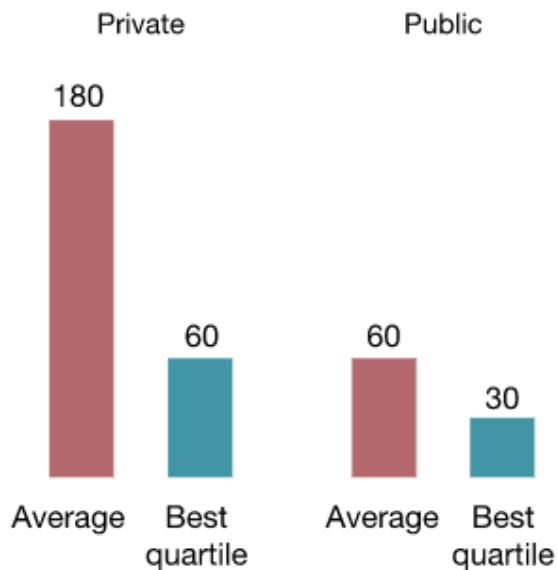
Leaders & Laggards

- Accepting cloud-based infrastructure is critical for enabling digitization
 - Some emerging as cloud-savvy leaders; others continue 'science projects'
 - Most time and resources is spent building complex private-cloud platforms
 - No correlations involving particular industries
 - Sophistication of the cloud platform being developed didn't matter
- **Cloud programs succeed because IT and business leaders stay focused on simpler sets of cloud capabilities and pilot projects**
 - **The gap (between leaders and laggards) grows quickly the longer that cloud programs were under way**

Leaders are seeing significant benefits

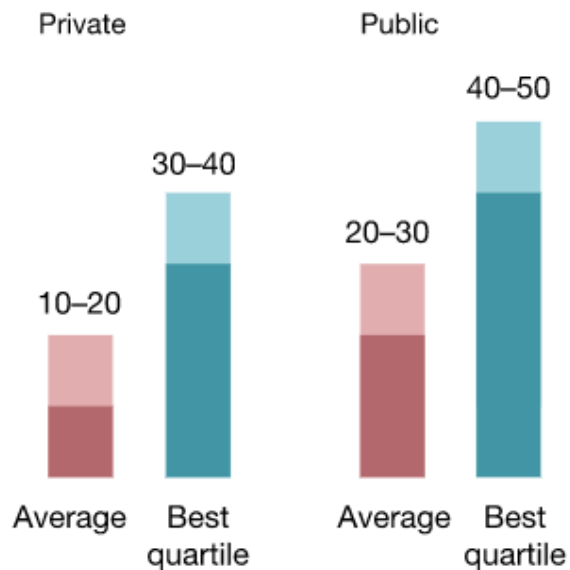
Time to market

Provisioning time of x86 server images in cloud environment, minutes



Cost reduction

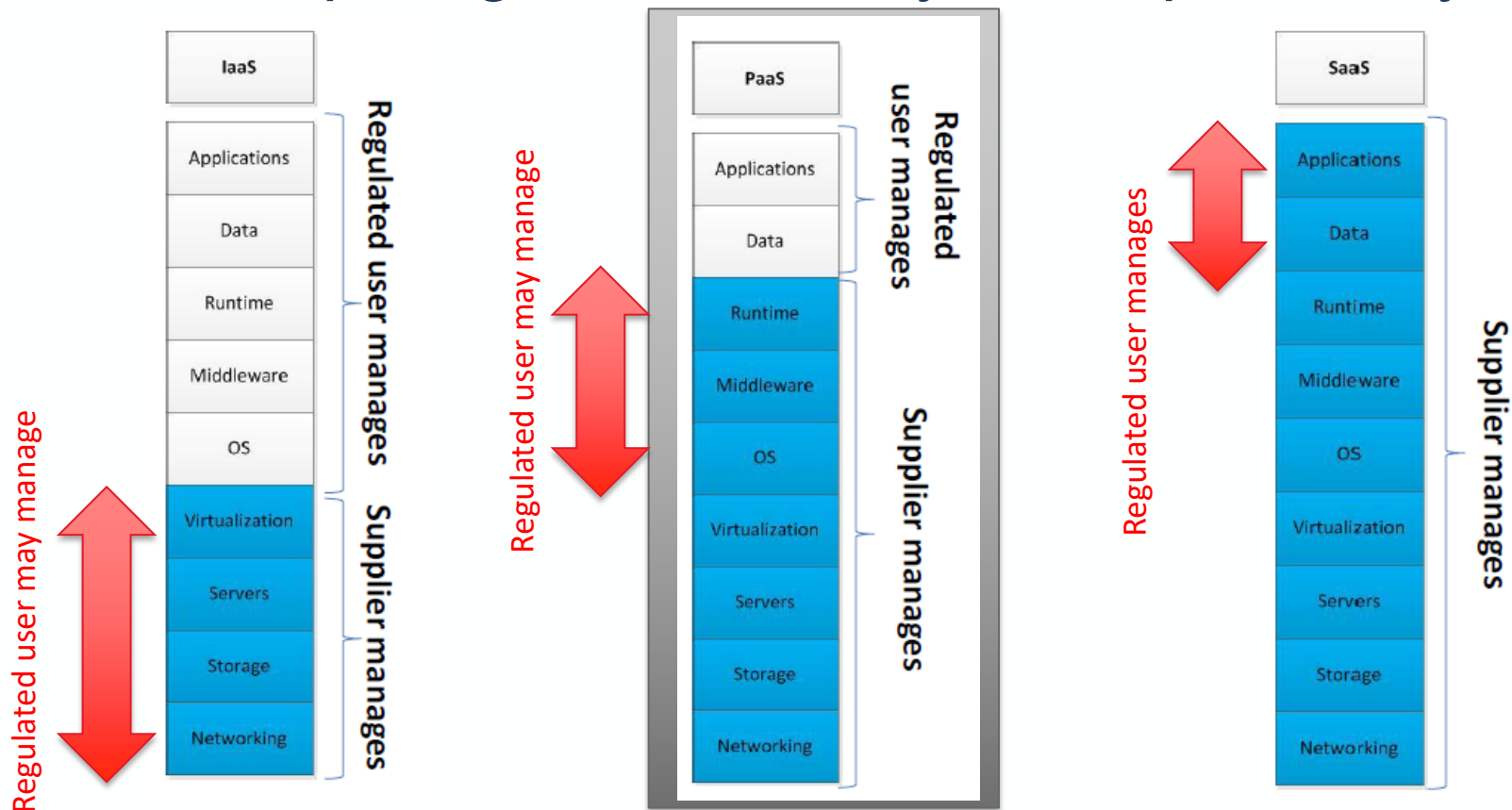
Average savings in total cost of ownership of server images from cloud over legacy, % of total cost of ownership



Barrier and Challenges to Cloud Adoption

- Cost and complexity of moving workloads from in-house data centers to cloud-based servers
 - Shortage of tools and standards that facilitate that migration
 - Concerns relating to the public cloud, including issues with security, regulatory compliance, and vendor lock-in
- **QMS fitness for purpose**
 - **Understanding!**
 - **Conservatism**
 - **“Letting go”**
 - **Multi-tenancy**

Cloud Computing – Traceability & Responsibility



Cloud - FDA Guidance?

- Outsourced Electronic Services
 - Who is responsible?
 - Do we need SLAs?
 - Data distribution?
 - Is Public Cloud appropriate?

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Cheryl Grandinetti or Leonard Sacks at 301-796-2500; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Program Operations Staff or Irfan Khan at 301-796-5640.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)**

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Procedural**

PhUSE - Cloud Adoption in the Life Sciences Industry



Pharmaceutical Users Software Exchange

- <<Placeholder for new edition of framework document>>
- <<Placeholder for new FAQ document>>