

# Cloud Computing in a Regulated Pharma Environment

Issues and Concerns about Data Security and Safety

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Introduction

## Technologies and Trends

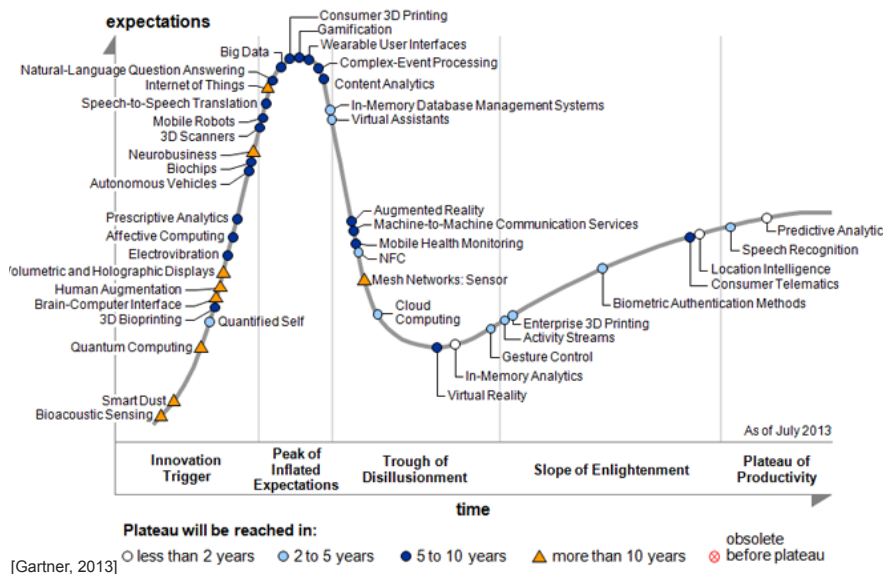
### Cloud Computing

- an emerging technology that has a broad, cross-industry relevance
- transformational and high impact in potential
- a topic that has gained momentum in the last years.

[Cf. Avanade, 2011; Forrester Research, 2011; Gartner, 2011]

### “With Cloud Computing against cancer and Alzheimer”

[Handelsblatt, 2011]



## Findings from the research include:

„... Moreover, **security concerns** are already making companies delay implementation of cloud and mobile technology capabilities.“

„In a best-case scenario, in which a solid cyber resilience ecosystem accelerates digitization, the private and public sectors see greater use of public cloud technologies, with enhanced security capabilities for non-critical workloads. Better use of private clouds handles critical workloads. Both public and private clouds continue to offer similar features. Enhanced security for private clouds comes at minimal performance penalty, and at a more noticeable performance penalty for public clouds. **Under this case, cloud computing has the potential to create US\$ 3.72 trillion in value by 2020.**“

[World Economic Forum, Jan. 2014]

**1. Could Cloud Computing lead to a decisive change in the way business software is deployed in pharmaceutical companies?**

**2. What is the impact on systems operation in Regulatory Affairs?**

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- How to define and address the risks to non- compliance and potential auditing shortfalls with cloud solutions?
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“... is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction.”

[Mell, P. & Grance, T., 2011]

From a user perspective, the provided abstracted IT infrastructure seems distant and opaque, like in a "cloud".

“The appearance of infinite computing **resources available on demand**, quickly enough to follow load surges, thereby eliminating the need for cloud computing users to plan far ahead for provisioning.

**The elimination of an up-front commitment by cloud users, thereby allowing companies to start small and increase hardware resources only when there is an increase in their needs.**

**The ability to pay for use of computing resources on a short-term basis as needed** (for example, processors by the hour and storage by the day) and release them as needed, thereby rewarding conservation by letting machines and storage go when they are no longer useful.”

[Armbrust, M. et al., 2010]

### **Kelton Research Survey**

- Organized by market research firm Kelton Research on behalf of Avanade
- 573 interviews with managers, IT executives and department managers in Germany and 17 other countries

### **Cloud Advantages**

- Cost Benefits (58%)
- Flexible IT (52%)
- Simplified IT processes (36%)
- Focus on key operational issues (27%)
- Scalability (24%)
- Productivity and employee satisfaction (20%)

[Avanade, 2011]

**Surveys show that 80% of businesses** already using the cloud reported **10%-20% lower IT costs**, while 20% of them reported **savings rising to 30% or above**.

The Commission will work with the support of ENISA and other relevant bodies to assist the development of an EU-wide voluntary certification schemes in the area of cloud computing (including data protection) and establish a list of such schemes by 2014.

[European Commission, Sept. 2012]

### **Report by Verizon Enterprise Solutions**

- company data between January 2013 and June 2013
- examines cloud adoption and usage trends

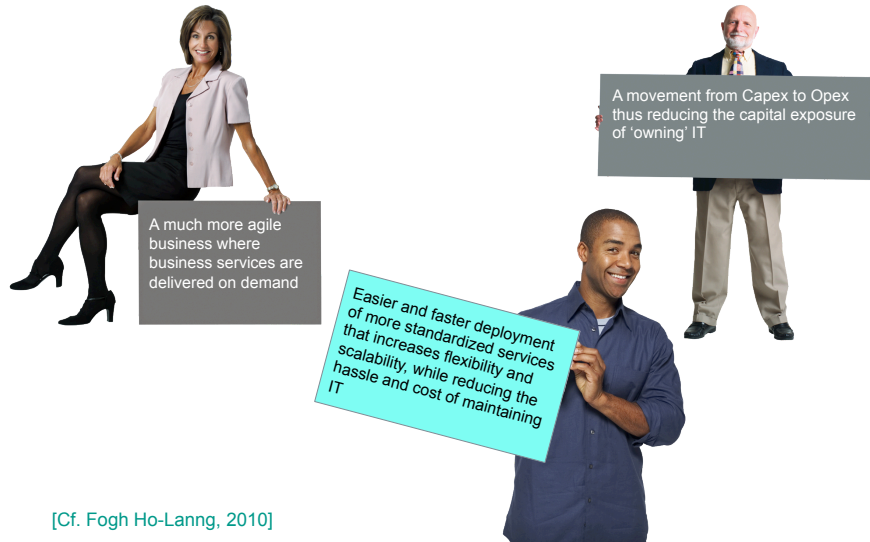
### **Cloud Adoption, Usage Increases**

- cloud-based storage has increased by 90% during the time studied and
- cloud- based memory by 100%, driven by the shift of business-critical applications to the cloud.
- enterprises have increased their average monthly spend on cloud by 45%

### **Additional remarks**

- as more critical applications reside in the cloud uptime and availability are now essential
- security and related compliance requirements are driving an increased focus on the cloud provider's data center.

[FEI, Oct. 2013]



[Cf. Fogh Ho-Lanng, 2010]

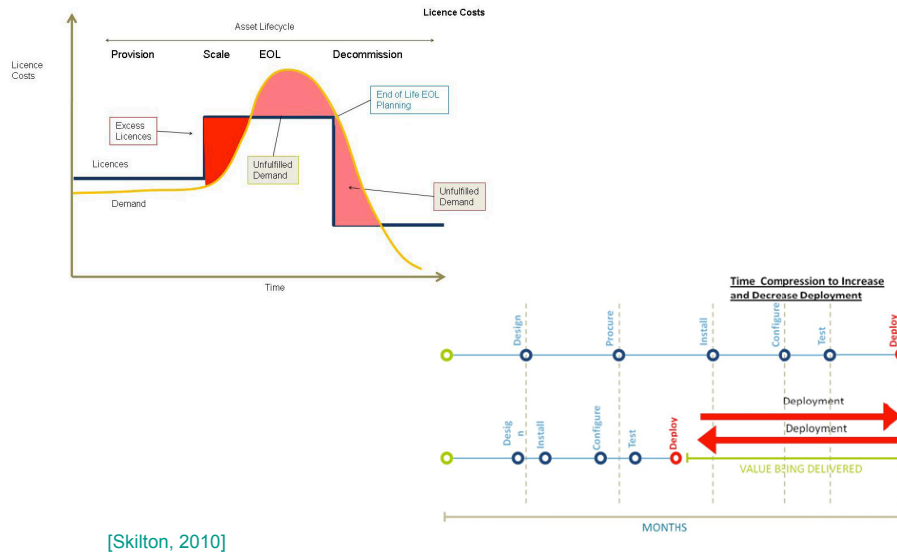
**... is an important benchmark to assess the performance of companies in volatile markets**

[Gebauer et al., 2008]

**Can be approached by SOA (Service Oriented Architectures)**

simpler, more timely and cost-efficient way of implementing standard components and/or ...

**... by Cloud Computing**



[Skilton, 2010]

**Cloud Computing as a Business and IT Service Model offers:**

- Multi-Tenant Support
- Fast Provisioning and Self-Service-Model
- Simple and faster HW- and SW-Maintenance awa Updates & Patches
- On-Demand Service / Pay per Use / Pay as you Go
- Geographic Distribution, Partition Tolerance
- Availability, Reliability and Scalability
- Measurability and Verifiability / Testability / QoS and SLAs
- Freedom from Licensing / License Clarity

### **Companies lower their overall total cost of ownership**

- aggressive publishing outsourcing within the past two years
- analysis of alternative solution hosting concepts such as Software as a Service (SaaS) and cloud computing
- **increase in the investigation and use of the SaaS model in small and mid-tier companies**
- but, a significant adoption level is still a few years away.

### **Distinct stages of investment / believe that industry is transitioning into stage two:**

- Information consolidation to realize a true global authoritative source (2008 – 2015)
- Incorporate health authority and industry data standards; improve usability (2011 – 2015)
- **Cloud or SaaS based options (2014 – 2018)**

[Gens & Brolund, 2013]

### **Usability standpoint**

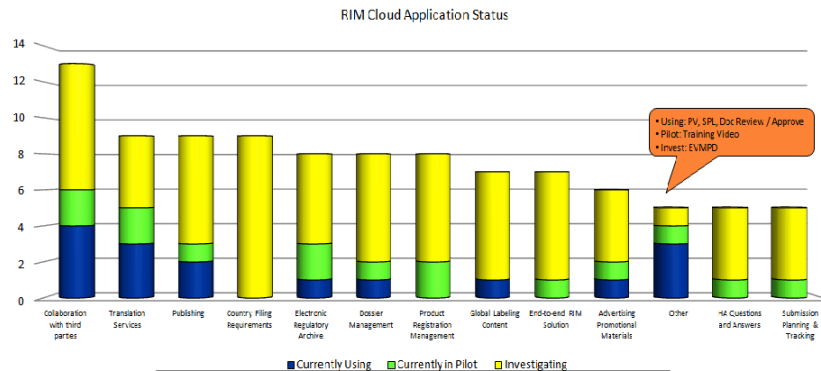
1. data entry flexibility by role or location
2. device independent consumption (laptop, table, smartphone, and desktop),
3. simple user interface, smart reporting and analytics, and
4. connectivity regardless of location (mobility which is more a general business requirement).

### **Publishing sourcing trend**

dramatic as companies are moving aggressively towards outsourcing or internal work redistribution to internal sites in India and China.

[\*cf. Gens & Brolund, 2013]





- 3X increase in overall activity as measured by product + pilot + investigating since 2011

[Gens & Brolund, 2013]

## 2<sup>nd</sup> Conclusion for Question 1

### Cloud technologies gained momentum in pharmaceutical companies

- Increase in the investigation and use of the SaaS model in small and mid-tier companies
- Transition to Cloud or SaaS based options (2014 – 2018)

[cf. Gens & Brolund, 2013]

### RIM Cloud application Status

- Few vendors offering true cloud services tailored to support the requirements of regulatory information management.  
 [Gens & Brolund, 2013]
- Solutions available from: Aris Global, Assured PV, EMC D2, EXTEDO, Lorenz, Mission3, Qumas, Samarind, Veeva (vendor selection in alphabetical order; there is no claim for completeness)
- Partnerships between DMS and Publishing providers

**The concepts of Cloud Computing are applicable to pharmaceutical firms, because of:**

- ever-growing datasets
- unpredictable traffic patterns
- demand for faster response times
- reduced time to market
- Business Continuity
- reducing the capital exposure of 'owning' IT
- ...

**Could Cloud Computing lead to a decisive change in the way business software is deployed in pharmaceutical companies?**

- Yes

**1. Could Cloud Computing lead to a decisive change in the way business software is deployed in pharmaceutical companies?**

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### Cloud-specific security risks



These relate mainly to:

- Multi-tenancy and shared resources character of cloud computing (that means that the same physical infrastructure will often serve many different customers of a cloud provider).
- Client cedes control of security to some extent to the service provider, making it important to be able to assess whether the cloud service provider complies with the security requirements.

### Recommendations and measures

- Certification schemes will play an important role because they help providers signal compliance to prospective users in a reliable way (e.g. ISO 27001).
- Increase security (for non-IT security experts) by leaving security issues to the professionals working for the cloud service provider  
[cf. European Commission, Sept. 2012; Tsvihun, 2010]
- Certification for Cloud providers
  - EuroCloud SaaS-Star Audit Certificate [Giebichenstein/Weiss, 2011]
  - ISO/IEC 27001

### Related Surveys



#### [Avanade Survey, 2011]

**Security concerns: 63%**

Not enough know-how for the use of cloud technologies: 63%

Trust in the provider of cloud-based services: 38%

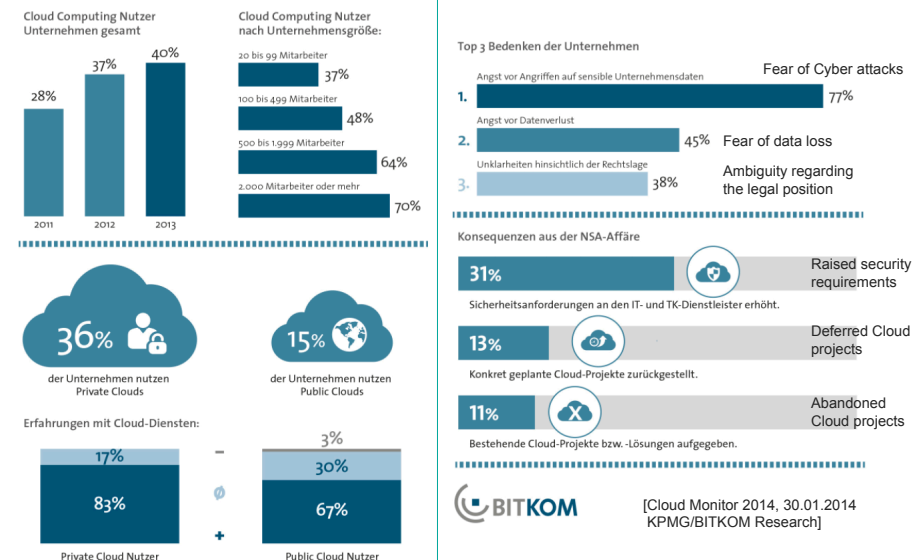
Costs that might be associated with the introduction of such technologies: 38%

#### [IDC Survey, 2011]

Governance: 34%

**Compliance: 24%**

Performance and Availability of Services: 24%



### Cloud Security Alliance Survey:

- 1 from 10 non US members have cancelled their contracts with US based Cloud providers
- 50% probably won't choose an US based Cloud provider

[CSA, 2011]

### Information Technology & Innovation Foundation

- The U.S. cloud computing industry stands to lose \$22 to \$35 billion over the next three years as a result of the recent revelations about the NSA's electronic surveillance programs.

[Castro, Aug. 2013]

### Forrester Research

- „The Cost of PRISM Will Be Larger Than ITIF projects“
- „... the total could still add another \$10 billion to the overall losses for this market“

[Staten, Aug. 2013]

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**Relevant legal frameworks:**

- EU: Data Protection Directive (95/46/EC)
- UK: Data Protection Act 1998
- US: Health Insurance Portability and Accountability Act 1996

**Suggested approach for new cloud services:**

- Customer should conduct a full due diligence examination (if possible) prior to entering into any arrangement.
- The results of the risk analysis should be captured in the contractual documents between the parties
- The extent of the clauses will depend on the nature and risk of data being placed in the cloud.

[cf. Wilson & Bray, 2013]

### European legislation

- High risk of penalties on data privacy
- Data Processing Agreement (Directive 95/46/EC of the European Parliament) / Commission pursuant to Section 11 BDSG
- Individual written provisions set out in Section 11(2) Nos 1 to 10 of the Federal Data Protection Act [Bundesdatenschutzgesetz – BDSG]
- EU Data Protection Act which offers additional “Joint Controllership” clause to cover responsibility of subcontractors

### Third countries (e.g. US):

- Directive 95/46/EC of the European Parliament and of the Council
- Standard contractual clauses for the transfer of personal data to processors established in third countries

### Recommendations

- Check if you are covered by this security rule (health care provider or health care clearinghouse)
- Put safeguards in place to ensure appropriate protection of electronic protected health information

### Requirements for covered entities

- Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the information;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by their workforce.  
[HHS.gov]

### SaaS suppliers should:

- Consider amending the design of the SaaS software to make it more appropriate for dealing with PHI and to support compliance with HIPAA obligations
- Prohibit PHI from being uploaded into and stored on the SaaS system
- Specific contracts/SLAs

### **Compliance with all Applicable Data Privacy Laws (example)**

- **Directive 95/46/EC** as implemented in the law of any EU Member State **which is applicable to the provision of the hosting services, together with any other laws in any other country which is applicable** to the provision of the hosting services described herein relating to the privacy and protection of personally identifiable information or protected health information (including, as applicable, the **Health Insurance Portability and Accountability Act of 1996** (HIPAA) Privacy and Security Rules, 45 C.F.R. Parts 160-164, and the Health Information Technology for Economic and Clinical Health Act (HITECH), P.L. No. 111-005, Part I, Title XIII, Subpart D, 13401-13409, and U.S. state privacy laws) are collectively referred to as the “Applicable Data Privacy Laws”).
- Each party warrants to the other that it will store, handle, use, disclose and Process all Personal Data, and all personally identifiable information and protected health information which it obtains from the other party pursuant to this Agreement **in compliance with all Applicable Data Privacy Laws.**

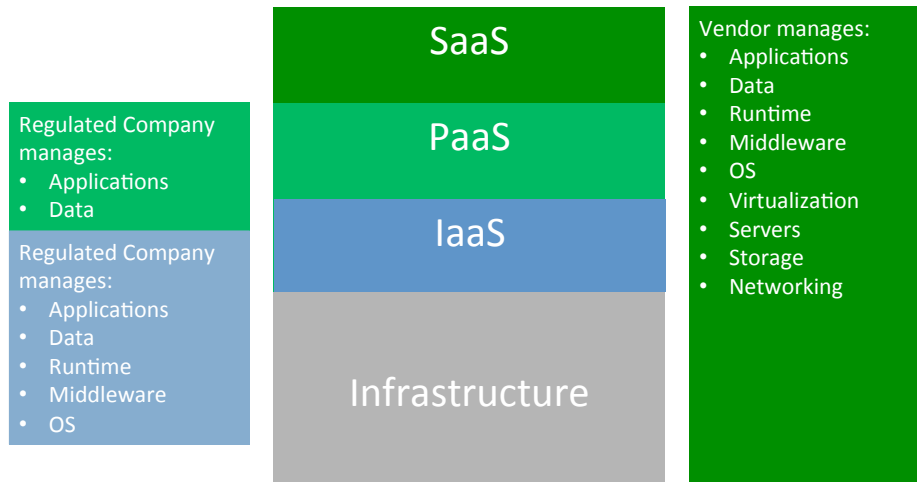
### **Quality paradigm shift**

- „... from quality processes contained within a regulated company to a model where quality is achieved as a result of partnership between the regulated company, service providers and regulators.“
- “... movement of control toward the supplier, but still leaves the responsibility for the data and process with the regulated company supplier.”

### **Suggested approach:**

- Cost optimization should be obtained without any impact on product quality and patient safety
- A flexible risk based approach for risk identification and analysis should be used
- Manage these risk in house and as part of the supplier management processes

[GAMP Cloud Computing Special Interest Group, 2014]



[cf. GAMP Cloud Computing Special Interest Group, 2014]

### Specific Compliance

- Specific policies from FDA CGMP or the PIC/S with GAMP® for the validation of an SOA [Stokes, 2011] and/or Cloud Computing (partly) missing
- The current standard for SW development – which was originally designed for monolithic applications – should be applied
- GxP certification for regulated companies unfortunately does not exist [GAMP Cloud Computing Special Interest Group, 2014]

### Validation

- A flexible and Risk-based approach can be used [Stokes, 2011; Reid, 2012]
- Recommendations on how to assess the risks, identify gaps and provide guidelines for the changing landscape of IT controls will follow ... [cf. GAMP Cloud Computing Special Interest Group, 2014]



**What are regulators interested in when they discover IT is outsourced?**

- Integrity of the Data is assured
- Risks clearly identified & mitigated
- Client/Provider Contracts
- Provider Quality Systems
- SOP's, validation, change control, training
- Cyber security for Networked Systems
- Data Backup/Recovery
- Audits of Providers by FDA/Clients

[cf. Tollefsen/FDA, Reid, 2012]

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### **Are clouds interoperable?**

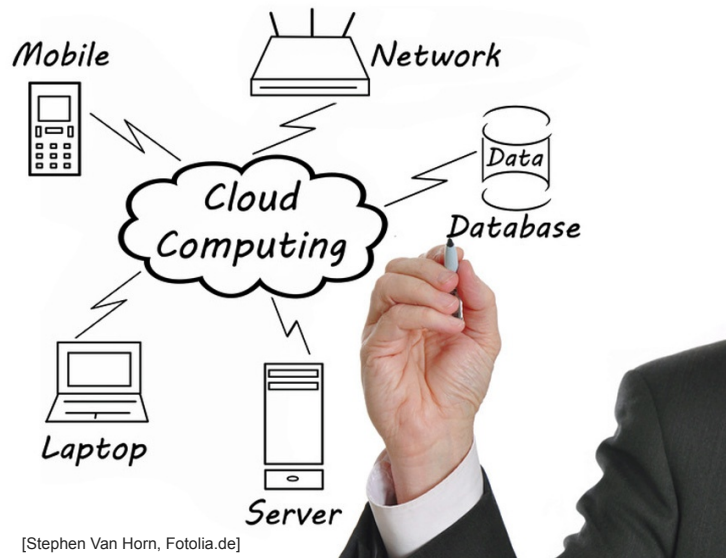
- At the moment not as interoperable as they could be
- Possible dependency from one service provider ("lock-in")
- Unforeseen / unforeseeable technical errors
- (New) Threats

### **Is it possible to easily change your cloud service provider?**

- Probably not (due to lock-in effects and missing interoperability standards)
- Service offerings
- Data Disclosure
- SLAs

### **European Commission statements**

- Fragmentation of the market due to differing national legal frameworks and uncertainties over applicable law, digital content and data location
- Problems with contracts
- Standards  
"jungle" of standards that generates confusion and suggests a lack of certainty as to which standards provide adequate levels of interoperability of data formats, or permit appropriate data portability.

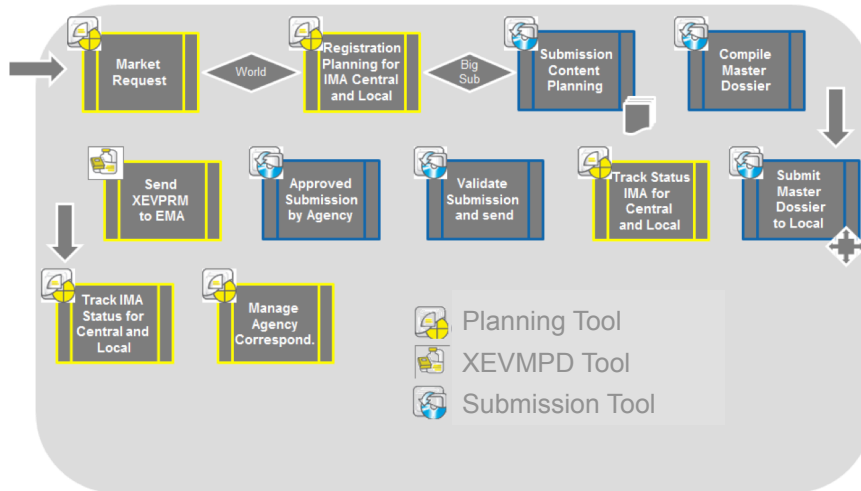


**Facts:**

- The architecture of Cloud Computing has a service-oriented basis.
- Companies which started SOA initiatives, can use Cloud Computing faster and easier.

[Schuster & Reichl, 2010]

Merging in-house applications with SaaS



[EXTEDO, 2012]

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## Premises



### Technical / Network Infrastructure

- Bandwidth
- Connectivity between/from locations/countries
- Systems integration opportunities (on-premise with Cloud)

### Specific SLA's

- Responsibility for application management and performance with the service provider
- Responsibility for data integrity and security with service provider
- Responsibility for Privacy (e.g. Data Processing Agreement)
- Availability, business continuity / disaster recovery
- Management of service change or contract exit
- Service provider business failure

### Premises

- The basic premises do not change in an outsourced environment – what changes is the chain of command and trust  
[Reid, 2012]

## Problem Statements



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**Consider legislation and regulatory requirements for certain countries and industries**

- Data Privacy / EU and national legislations
- Moving data to the cloud is not always allowed

**Understand Compliance Requirements**

- Lack of control over the individual services (Web/Cloud Services, as well as concerns about the compliance of quality standards

[Stokes, 2011]

- Risk Analysis is a must!

**Consider GAMP® and cross industry guides**

- e.g. ISO 27001, ITIL, CMMi on Application and Infrastructure Development, Validation / Qualification, Operation, Support and Retirement

**Plan on legal advice!**

**Perform Pilot Projects!**

**‘Good Practice’**

Development of cloud computing systems relies on input from all organizations using the services

**Fast Deployment**

New functionality in e.g. eSubmission System becomes available to the organization fast

**Performance, Scalability & Availability**

Conformance with changing demands

Dynamic load balancing

**Cost volatility**

Pay as you go

SLA-approach with fixed service level, fixed fee, fixed duration of contract

**Convenience**

80% of needs are identical, standard will be ‘good enough’!

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### Questions

THANK YOU  
MERCI  
DANKE  
GRACIAS



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