EBF

16th Open Symposium

Science Winning the Race

Pitlane 3 – Moving into the cloud ….

Arranged by the EBF e-environment team on behalf of the EBF

15-17 November 2023, Barcelona

Welcome – Agenda for this workshop

➢ Introduction
  – the EBF e-environment team's focus for 2023: cloud based applications
  – a brief, very simple introduction to cloud computing
  – feedback from EBF Zoom meeting on cloud based approaches
  – OECD Advisory Document No17
  – the purpose and desired outcomes of this workshop

➢ Case studies
  – To set the scene for the discussions

➢ Discussion
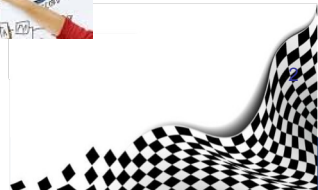
EBF e-environment team focus for 2023

We see an increased interest and use of cloud-based applications in the bioanalytical labs.

➤ A Finger on the Pulse Survey (FotP) was sent out to EBF Core community in July 2023 to collect some additional insight to what extent the bioanalytical community understands 'the cloud' and to what extent it has been implemented in our labs.

➤ Do you think that you know enough about cloud-based services and applications??

Pie chart values: 5%, 24%, 71%
Legend: ■ Yes ■ No ■ I do not know
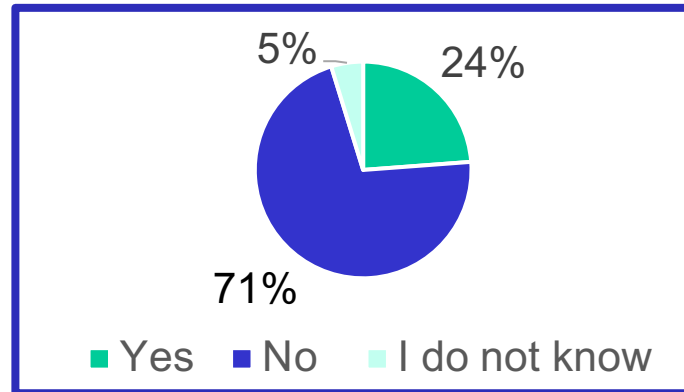
What is the Cloud?

A service model.

IT resource made available via Internet

Virtual server outsourced to a third-party specialized company that fulfills the 21CFR requirements

A server which can be used remote for the saving of data generated by computers and computerized systems.

Public, decentralised data storage area accessible through the internet where the physical servers are provided, monitored and administered by a third party

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A brief, very simple, introduction to Cloud Computing

Presented by Katja Zeiser on behalf of the EBF (slides with courtesy from Werner Schauerte)

15-17 November 2023, Barcelona

What is the Cloud?

➢ VERY simply put "Cloud Computing" means **accessing computing resources over the internet**

➢ So while traditional IT infrastructure (on premises/on-prem) has software running in a local environment, accessing the same kind of resources over the internet is "Cloud Computing"

➢ The word "Cloud" is used to describe the complex web of software, servers, computers, networks, and security systems that are required for this process

Cloud types

➢ **Private** – dedicated cloud for your business either in own data centre or a dedicated environment from an external provider, but still accessed via the internet (because that is what makes it "Cloud"). May be used if business already owns a lot of infrastructure or data needs to be kept on-prem for regulatory reasons.

➢ **Public** – computing resources provided by a third party provider like Google/Microsoft/AWS and shared with multiple organisations through the public internet

➢ **Hybrid** – a mixture of private/on-prem and public cloud, allowing business to use existing facilities while taking advantage of public cloud. Allows a business to migrate to the cloud at the right pace.

➢ **Multi-cloud** – uses at least two public cloud providers. A business may want to use key strengths of different cloud providers

➢ **Hybrid/Multi-Cloud mix** - this is currently the most common setup that companies have
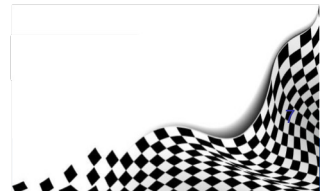
Cloud Service Models

➢ Definition - "as a service" means that a business consumes IT resources which a third party cloud service provider owns, manages and maintains.

➢ **IaaS** – Infrastructure as a service. Most like traditional IT infrastructure, but leased, not owned. Offers compute, networking, storage and databases as services. Offers the most control but requires most management and most technical expertise. Running a virtual PC in Microsoft Azure is an example of IaaS.

➢ **PaaS** – Platform as a service – Cloud based platform for developing, deploying running and managing applications.

➢ **SaaS** – Software as a service - delivers entire applications as a service on a subscription basis. Accessed through a browser. No need to download or install. Vendors manage technical issues. Can be accessed from anywhere. Good for standard software solutions that need limited customisation. Using Microsoft Office 365 online (in a browser) is a well known example of a SaaS application.
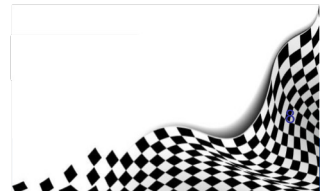
Shared Responsibility Model (example from Google)

➢ One area of responsibility where each of the cloud computing models differ is security. When an organization manages its data in its own data centres, that organization is responsible for all aspects of its security. **As infrastructure is moved to the cloud, some aspects of the responsibility shift to the cloud provider.** This concept is called the shared responsibility model.

	On-prem	IaaS	PaaS	SaaS		
Content						
Access policies						Customer
Usage						
Deployment						Could Provider
Web App security						
Access and authentication						
Operations						
Network Security						
Guest OS, data and content						
Audit logging						
Network						
Storage and encryption						
Hardened Kernel and IPC						
Boot						
Hardware						
Physical security						

➢ A key point here is that the **customer is always responsible for their data**:
It is therefore crucial that a business has a robust TPRM (**Third Party Risk Management**) process in place

➢ TPRM is not unique to Cloud providers and should be in place for all third parties that the business uses
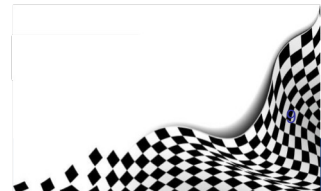
EBF arranged Zoom Meeting on 28th September

➢ Agreed on the definitions used in the context of the cloud (so that we are all talking about the same)

➢ Sharing of learnings, experiences and concerns with implementation of cloud-based applications so far

➢ But one important question is still to be answered…
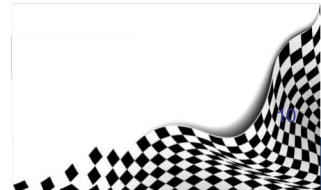
Implementation of Cloud Based Applications

➢ What are the **bioanalytical labs' responsibilities** in the interfaces with other collaborating expertise functions?

  – Engage with these interfaces and expertise functions
  – Collect their feedback on the role of the BioA lab and what responsibilities they see lay with the BioA lab

OECD Advisory Document No17

What does the OECD Advisory Document No17 say?

"[…] the **potential impact** on GLP compliance **should be considered when using cloud solutions**. GLP test facilities have the ultimate responsibility for GLP compliance **to assess risks to data integrity, data quality, data availability, data retention and data archiving**."

"When conducting an inspection with cloud-based services involved in the test facility processes, GLP inspectors expect TFM to be **able to demonstrate that GLP compliance is still ensured with the implemented cloud service** and that TFM has **adequate means to control it.**"

"GLP systems should be validated and operated in a way which ensures the outcome and integrity of GLP data **regardless of whether they are installed locally or provided as a cloud service.**"

# Traditional on-premise validation vs SaaS (example from PerkinElmer)

On-Premise
- Infrastructure dependency
  - Hardware must meet requirement of vendor
  - Disaster recovery plan and testing
  - Backup procedures and testing
  - Availability assurance
- Customer responsibility
  - IQ (installation qualification)
  - OQ (operational qualification)
  - PQ (performance qualification)
- Time effort
  - Several months even with vendor support
  - Updates considered every 2-5 years due to validation efforts

SaaS
- Infrastructure dependency
  - NONE
- Customer responsibility
  - IQ (configuration specific)
  - OQ (configuration specific)
  - PQ
- Time effort
  - Several days as system is pre-validated
  - Customer can take updates several times a year

➢ **Same same, but different!**
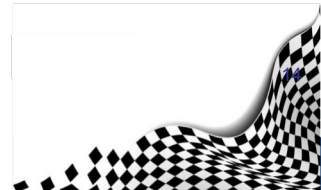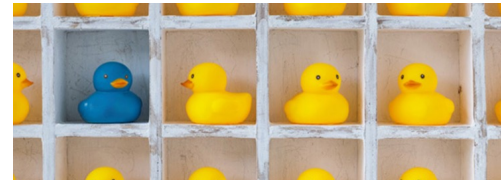
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Science Winning the Race

A few case studies

Presented by Cecilia Arfvidsson on behalf of the EBF (examples with courtesy from Werner Schauerte and Harm Buddiger)

15-17 November 2023, Barcelona

Community feedback from EBF zoom meeting

➢ The regulators are waiting for the industry to lead the way

➢ Someone needs to go first …

➢ Country specific regulations/ expectations on data privacy (where the data is stored) may occur

➢ An impact assessment is critical

➢ End to end cloud-based implementations are still unusual BUT cloud-based applications are already implemented and used in our labs

Examples to try and remove some of the uncertainties …

Example 1 - Cloud Solutions in BioA workflow

➢ Example of a Cloud solution evaluation in a typical bioanalytical workflow process with distinction between Cloud types:
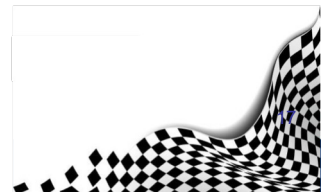
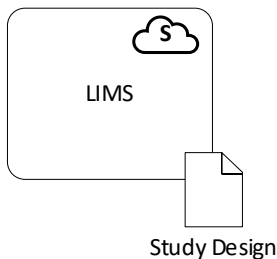IaaS – Infrastructure as a service
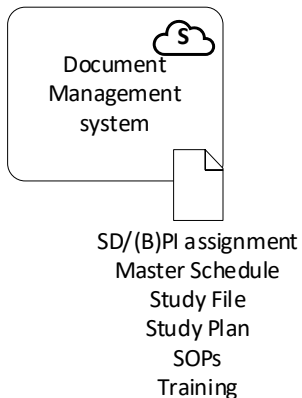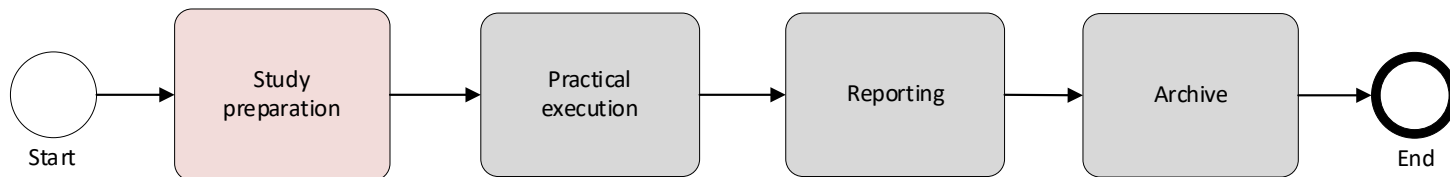
PaaS – Platform as a service

SaaS – Software as a service

➢ "as a service": business consumes IT resources which a third-party cloud service provider owns, manages and maintains.
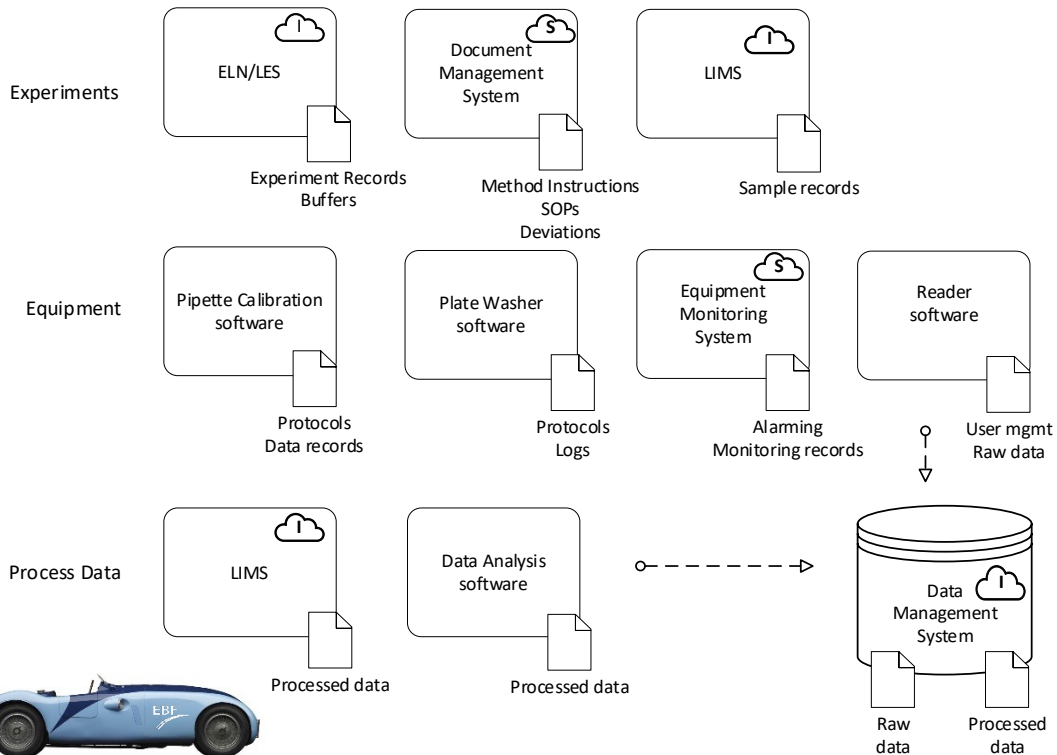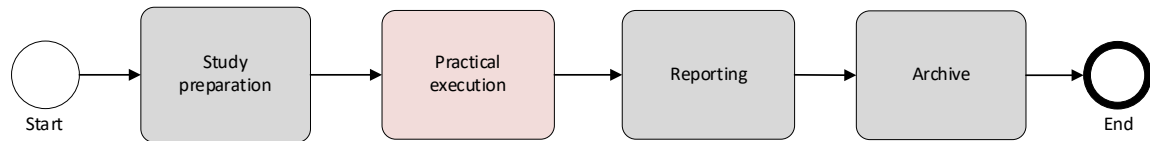
Cloud Solutions in BioA workflow – Study preparation

Document Management System: SaaS (out of the box, web-based)

Laboratory Information Management System: IaaS (high customization grade, web-based)
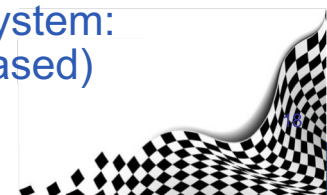
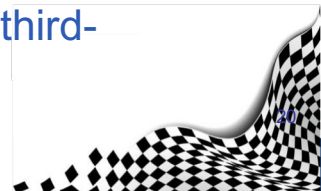# Cloud Solutions in BioA workflow – Practical execution

- ➤ ELN/LES: IaaS (high customization grade, private or public server)

- ➤ Equipment Monitoring System: SaaS (entire application as a service)

- ➤ Local installed software - no cloud functionalities. User mgmt can be cloud based. Data storage in Cloud based Data Management System.

- ➤ Data Management System: IaaS (customized, private or public server)
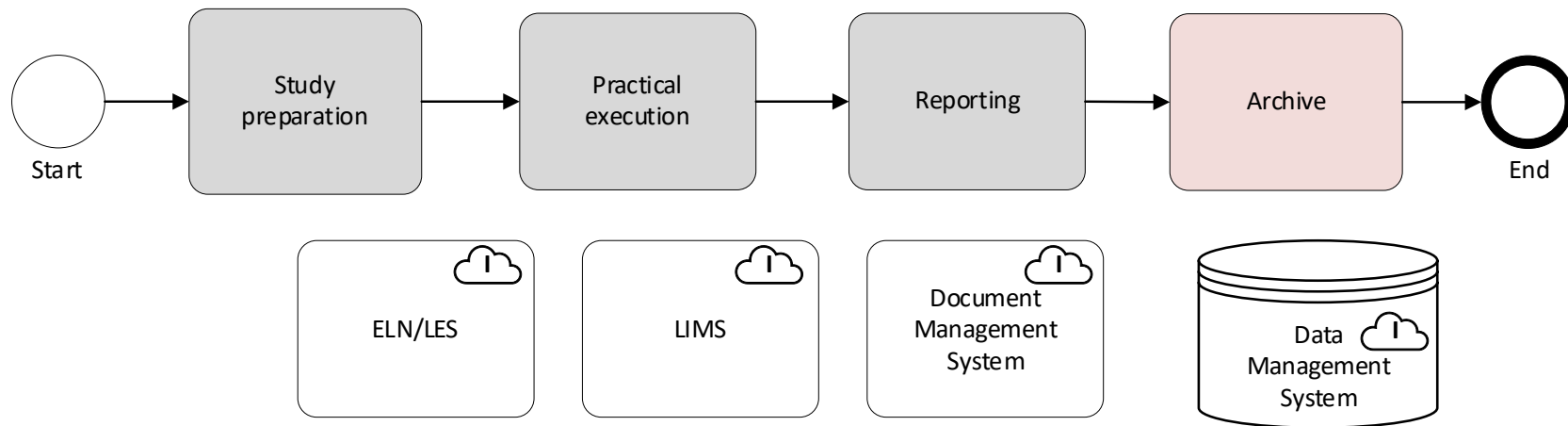
Cloud Solutions in BioA workflow – Reporting
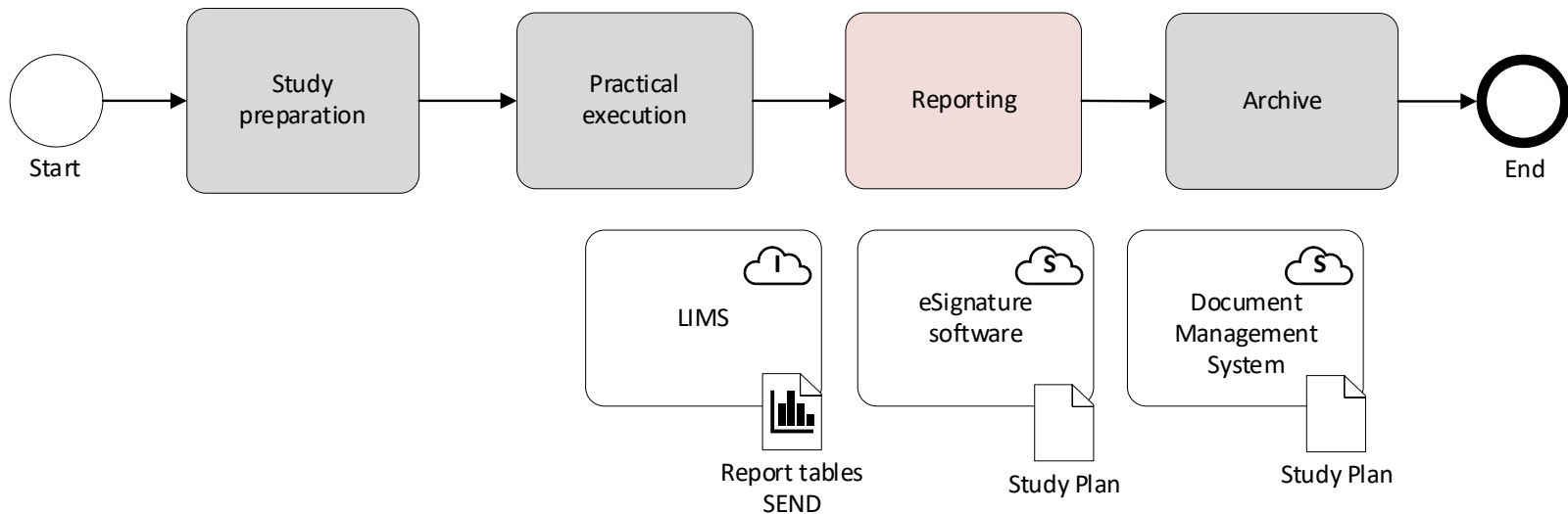
- ➢ Laboratory Information Management System: IaaS (high customization grade, third-party server)
- ➢ eSignature software: SaaS (out of the box, web-based, third-party server)
- ➢ Document Management System: SaaS (out of the box, web-based, third-party server)

Cloud Solutions in BioA workflow – Archive

```
Start → Study          → Practical      → Reporting → Archive → End
        preparation      execution
```

ELN/LES

LIMS

Document Management System

Data Management System

➢ Documents and data files in various e-systems put under (in)direct control of an Archivist
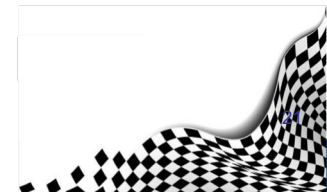
Cloud Solutions in BioA workflow - Summary

➢ The type of Cloud application can vary.

➢ The example is a simplification - in real life many of the Cloud solutions are hybrid

➢ Highlights that **multiple Cloud based applications are already available** and likely used in many labs

➢ Reflect on your own workflow situation

– Do you recognize this hybrid approach?

– What's really the difference between a traditional workflow and a cloud solution?

– What's changed in the BioA role and our responsibilities?

Same, same … but different

Cloud application services – third party vendor hosts the application and web services, stores administrative data and used for bulk storage

Business IT

Business proxy server(s) + Firewall

Office

Wed software accessed via browser on business office computers

Lab

Instrument software installed on lab computers

Data Center

Business file server for automatic lab data storage
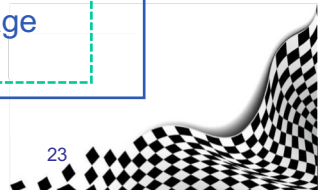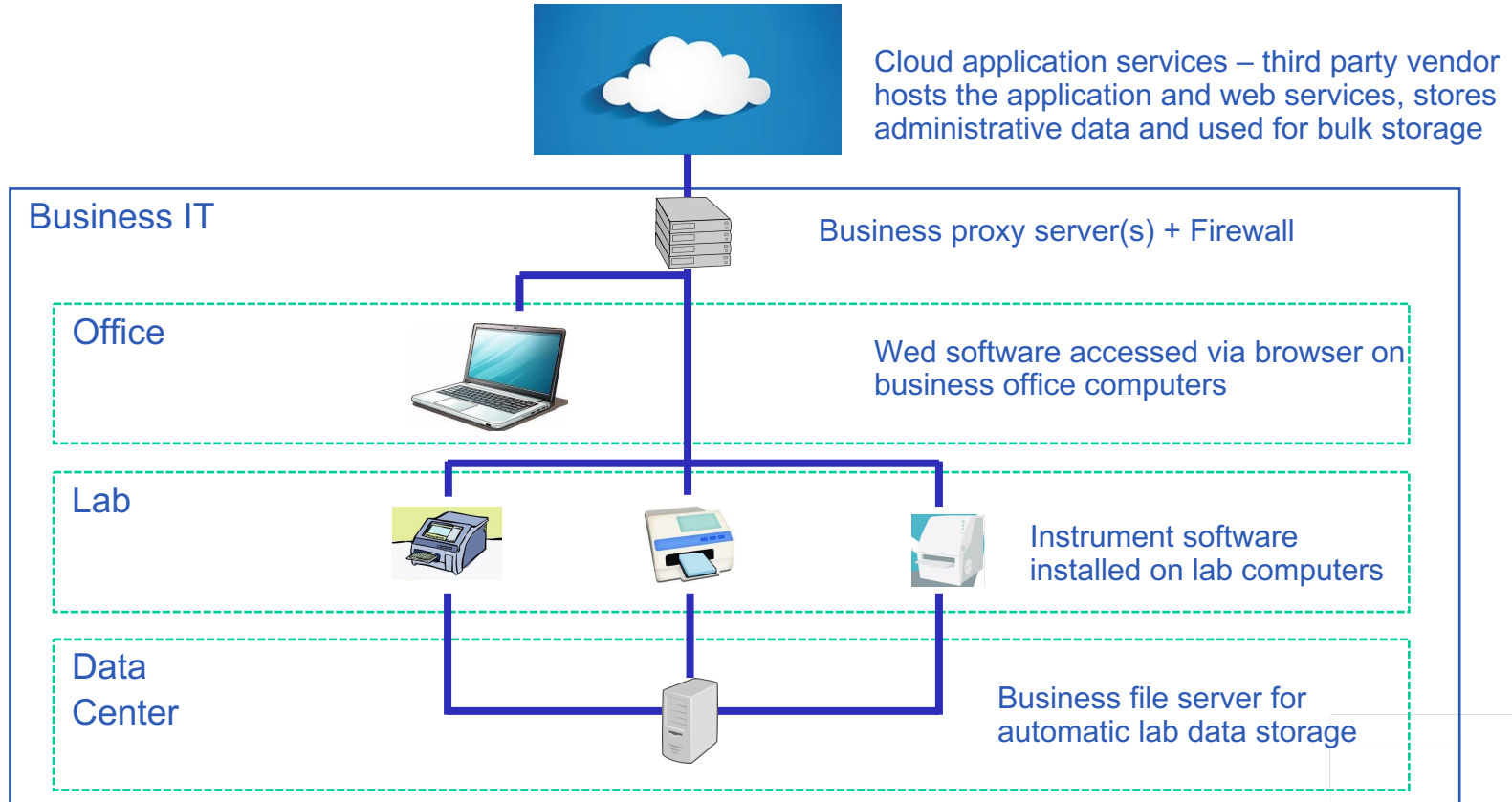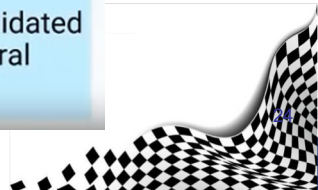
Example 2 - SaaS Electronic laboratory notebook

➢ As a SaaS application, responsibilities are shared between the company business group, the vendor and the company's IT department.

➢ SaaS changes the validation needs for cloud-based services - drive new thinking from bioanalysis to ensure OECD expectations are met.

On-Premise
- Infrastructure dependency
  - Hardware must meet requirement of vendor
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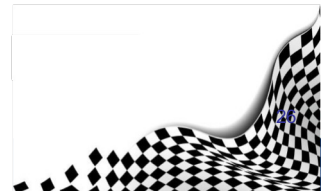
Perkin Elmer literature

Example 2 - SaaS Electronic laboratory notebook

➢ The application is a cloud-based system - certain deliverables and controls are the responsibility of the third-party vendor.

➢ The vendor is an established company supplier and contracts including confidentiality are in place. A service level agreement for the application was established.

➢ The initial vendor evaluation included:
  – A data integrity questionnaire
  – Vendor questionnaire
  – Third Party Controls Assessment
  – An audit of the vendor was performed by the company's computer system quality assurance group.

Example 2 - SaaS Electronic laboratory notebook

➢ The difference between on-premise and SaaS really focuses on
  – assessing the vendor documentation and procedures
  – making sure that the responsibilities are clearly defined.

➢ For a SaaS application the vendor is responsible for a large part of the documentation – reviewed by the company business group validation manager to ensure they met the company's expectations.

➢ An extensive review of the third party's procedures was required.

Due Diligence
[dü 'di-lə-jən(t)s]

An investigation, audit, or review performed to confirm facts or details of a matter under consideration.

Investopedia

TPRM - Validation documents reviewed

➢ Validation Plan

➢ Validation Report

➢ User Requirement Specification /Sampling of Testing/Defects

➢ Requirements Traceability Matrix
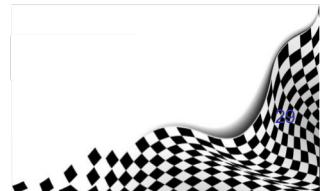
➢ Master Test Strategy notebook
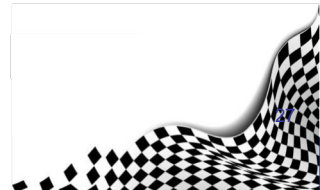
TPRM - Procedural documents reviewed

- Incident Management and CAPAs
- Change Control / Configuration Management
- System Delivery Life Cycle (SDLC)
- Computer System Validation
- Installation Qualifications
- Backup & Restore and Test Results
- Business Continuity Planning and Test Results
- Disaster Recovery Planning and Test Results
- Security and System Admin (including Access Reviews)
- Training
- Record Management
- Penetration Testing
- Service Management & Performance Monitoring (including – Database, file, and user activity monitoring)
- System Retirement (including Disposal and Data Migration)

- Requirements Tracking
- Design Guidelines / Coding Standards / Tools and Business Systems / Builds
- Testing & Defect Tracking
- Release versioning
- Informatics Clouds Service Policy
- 21 CFR Part 11 Complaint-Ready Assessment Guide
- Internal Audit Program
- Cloud Account Management Work Instructions
- Cloud Change Management Work Instruction
- Cloud Cyber Security Incident Response Process Work Instruction
- Cloud Data Classification and Retention Work Instruction
- Corporate Account Management Data Retention Policy and Procedure
- Risk Management
- Historical Verification Summary Report
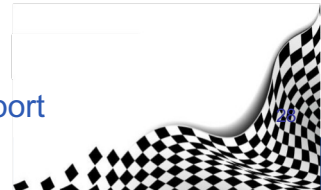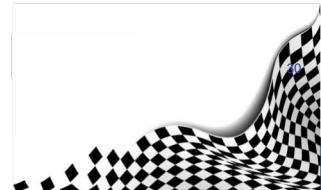
Company IT responsibilities

➤ The company's IT department manages the application on behalf of the business – for this purpose the following was found required:

- – Design Specification
- – Combined TIP and TIR
- – Test Plan
- – Test Cases
- – Test Summary
- – System Access Plan
- – System Release Notification
- – Document Index

Again ….Shared responsibility model

	On-prem	IaaS	PaaS	SaaS
Content				
Access policies				
Usage				
Deployment				
Web App security				
Access and authentication				
Operations				
Network Security				
Guest OS, data and content				
Audit logging				
Network				
Storage and encryption				
Hardened Kernel and IPC				
Boot				
Hardware				
Physical security				

Customer

Could Provider

➢ A robust TPRM process is crucial to have in place

➢ The BioA lab/company is always responsible for their data!!

➢ Any difference between a traditional workflow and a cloud solution?

➢ What's changed in the BioA role and our responsibilities?

Questions??

➢ Any remaining concerns or uncertainties moving into the cloud?

➢ Are Company responsibilities vs Vendor responsibilities clear?

➢ Are roles and responsibilities within your company clear (IT vs. QA vs. BioA lab)?

➢ Any regulatory concerns?

Can EBF facilitate in the continued implementation of cloud based applications?
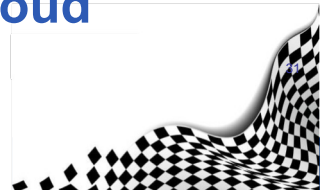
Acknowledgements

➢ All participants in the EBF zoom meeting for valuable input into these discussions

➢ EBF e-environment team for all their valuable input and source material

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