



# Electronic (Raw) Data in a GLP Environment – Swiss AGIT Working Group Guidelines

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# Agenda

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- Working Group on Information Technology (AGIT)
- Electronic (Raw) Data - Acquisition, Processing and Archiving
- Issues – Retention of electronic (raw) data

# AGIT (ArbeitsGruppe InformationsTechnologie)

- AGIT was founded in 1998
- AGIT intends to set up guidelines based on legislative requirements and practical experience to support test facilities in applying information technology in a GLP area
- The members of the AGIT are representatives of the three Swiss GLP Monitoring authorities and from industry

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Novartis Pharma AG  
Innovative Environmental Services (IES) Ltd  
DSM Nutritional Products Ltd

# AGIT Guidelines

- Guidelines for the Validation of Computerised Systems (2007)  
*Qual. Assur. J.* 2007; 11, 208-220
- Guidelines for the Management of Electronic SOPs in a GLP Environment (2001)
- Guidelines for the Acquisition and Processing of Electronic Raw Data in a GLP Environment (2005) *Qual. Assur. J.* 2006; 10, 3-14
- Guidelines for the Archiving of Electronic Raw Data in a GLP Environment (2003) *Qual. Assur. J.* 2003; 7, 262-269
- Guidelines for the Change Management and Risk Assessment of Validated Computerised Systems in a GLP Environment (2012)
- Guidelines for the Development and Validation of Spreadsheets (2010)  
*Qual. Assur. J.* 2010; 13, 41-56
- Position Paper: Is it acceptable to destroy the paper originals of raw data and related study documentation, if an image of the paper is captured in an electronic form (e.g. scanned)? (2014)



# AGIT Guidelines

Guidelines are available at:

[www.glp.admin.ch](http://www.glp.admin.ch)

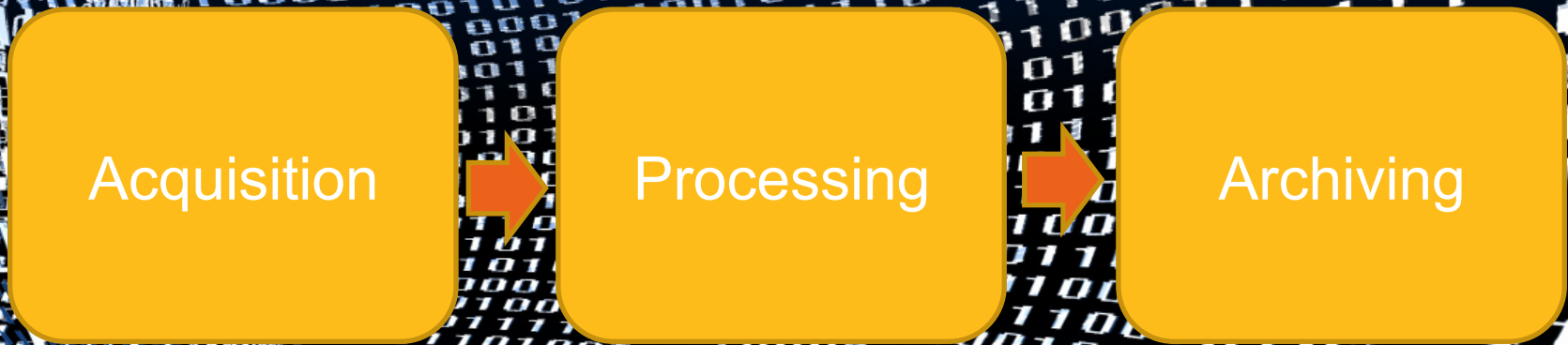
or

- <http://www.bag.admin.ch/anmeldestelle/12828/12832/index.html?lang=de>

The screenshot shows the website of the Swiss Federal Administration (Bundesverwaltung) for the Federal Office of Health (Bundesamt für Gesundheit (BAG)). The page is titled "Anmeldestelle Chemikalien" (Registration Office for Chemicals). The navigation menu includes "Aktuell", "Themen", "Dokumentation", "Dienstleistungen", and "Das BAG". The "Themen" menu is expanded, showing a list of topics: "Aktuelles", "Glossar", "REACH Helpdesk", "Biozidprodukt", "Selbstkontrolle", "Formulare und Prozeduren", "Marktkontrolle", "Gute Laborpraxis (GLP)", "News and Links", "GLP Überwachungsprogramm", "GLP-Prüfeinrichtungen", "GLP-Interpretationen", "AGIT", "GLP Behörden", "GLP monitoring (English only)", "Tierversuch", "Gesetzgebung Chemikalien", "Über uns", and "Kontakt". The "AGIT" item is highlighted. The main content area shows the "AGIT" section, which is currently in English. It includes a description of the Working Group of Information Technology and lists several guidelines, such as "Guidelines for the Change Management and Risk computerised systems in a GLP environment" (valid from 01.12.2012, 64 kb) and "Guidelines for the validation of computerised systems" (last updated 17.12.2007, 344 kb).



# Electronic (Raw) Data



# Raw Data and its attributes

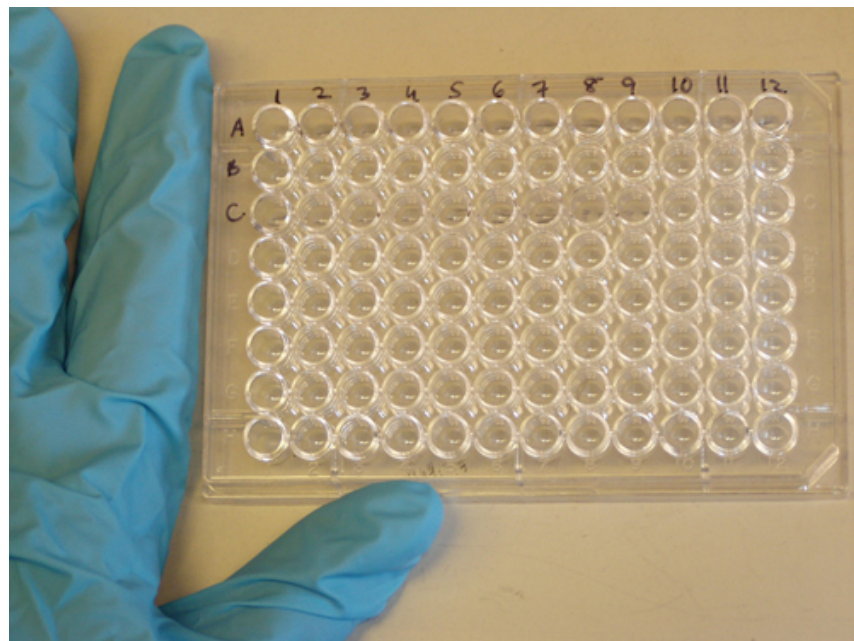
Study	Test Item	Sample	OD	Well	Date	Operator
111-111	ABC123	0078	(450 nm)	B4	28-Mar-09 10:23:49	HKL

0.957

Metadata

Raw Data  
Element

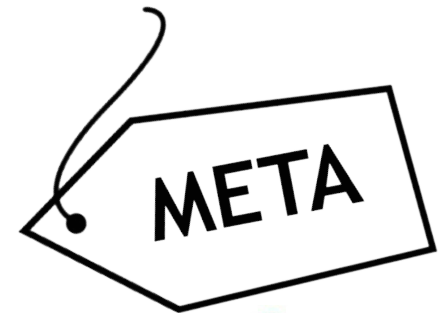
Analytical method



# Raw Data and Metadata

**Raw data** means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. (OECD No. 1)

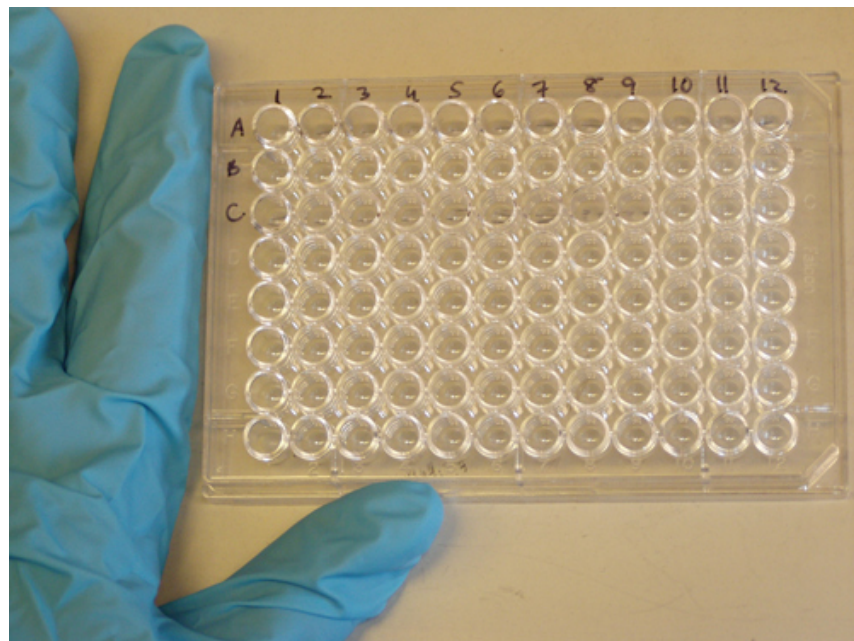
**Metadata:** Data that describe the attributes of other data. Most commonly these are data that describe the structure, data elements, inter-relationships and other characteristics of electronic records. (OECD Advisory Document No. 15)





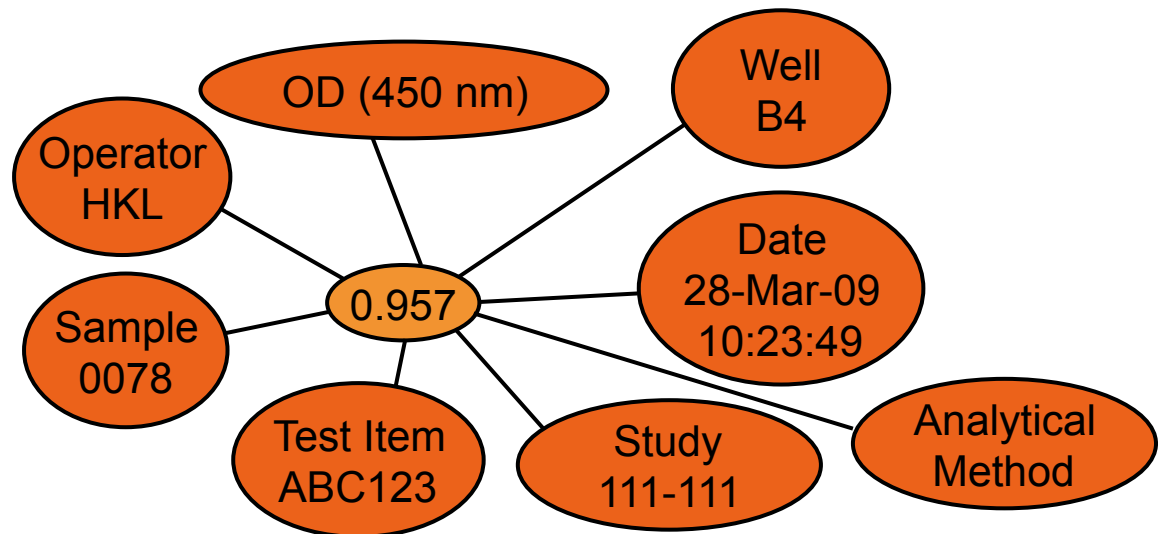
# Audit Trail

Study	Test Item	Sample	OD	Well	Date	Operator
111-111	<del>ABC123</del>	0078	(450 nm)	B4	28-Mar-09 10:23:49	HKL
	ABC132		0.957			
	typing error					
	HKL					
	28-Mar-09					
	10:25:09					

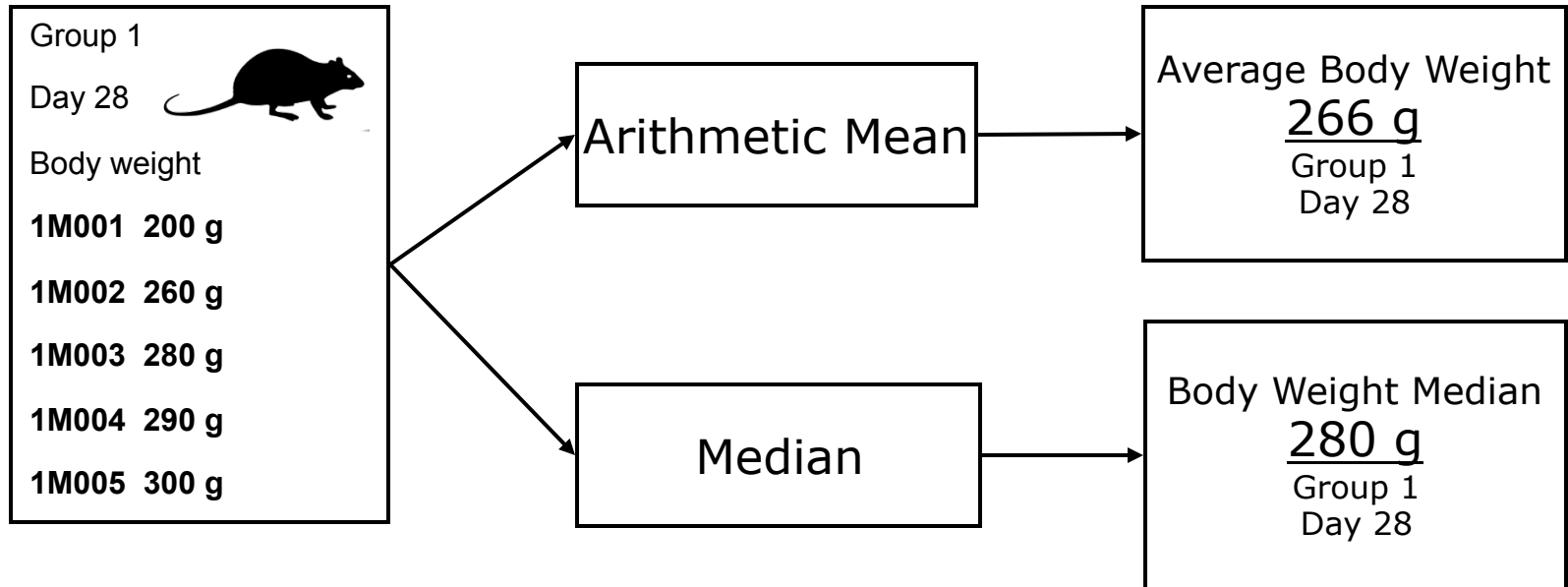


# Raw Data – Metadata - Cluster

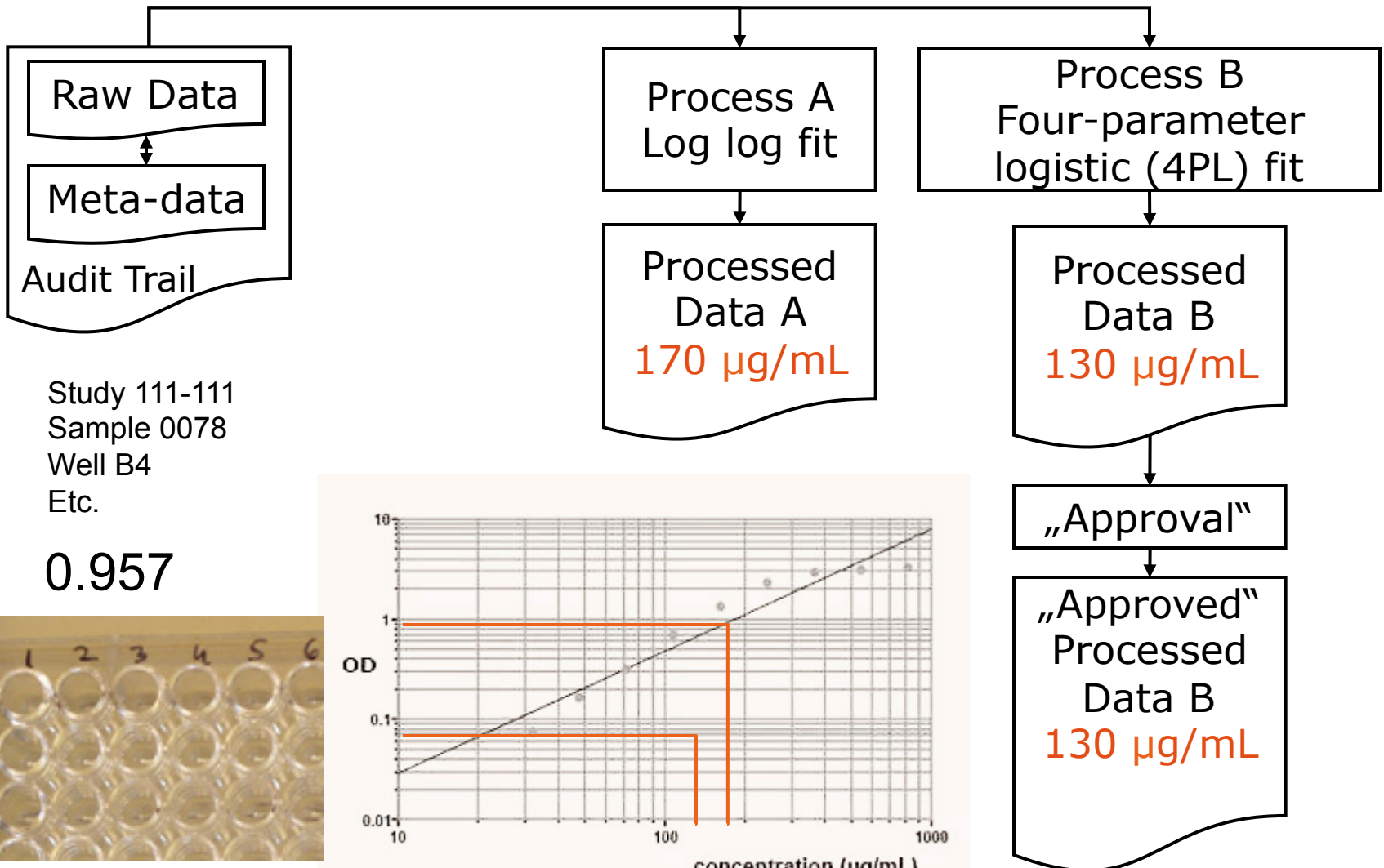
- Each element of the cluster needs to be audit trailed in case of a change
- Loss of an element may invalidate the cluster
- Relationship should be maintained during the life cycle of the electronic raw data (acquisition, processing, and archiving)



# Processing Raw Data

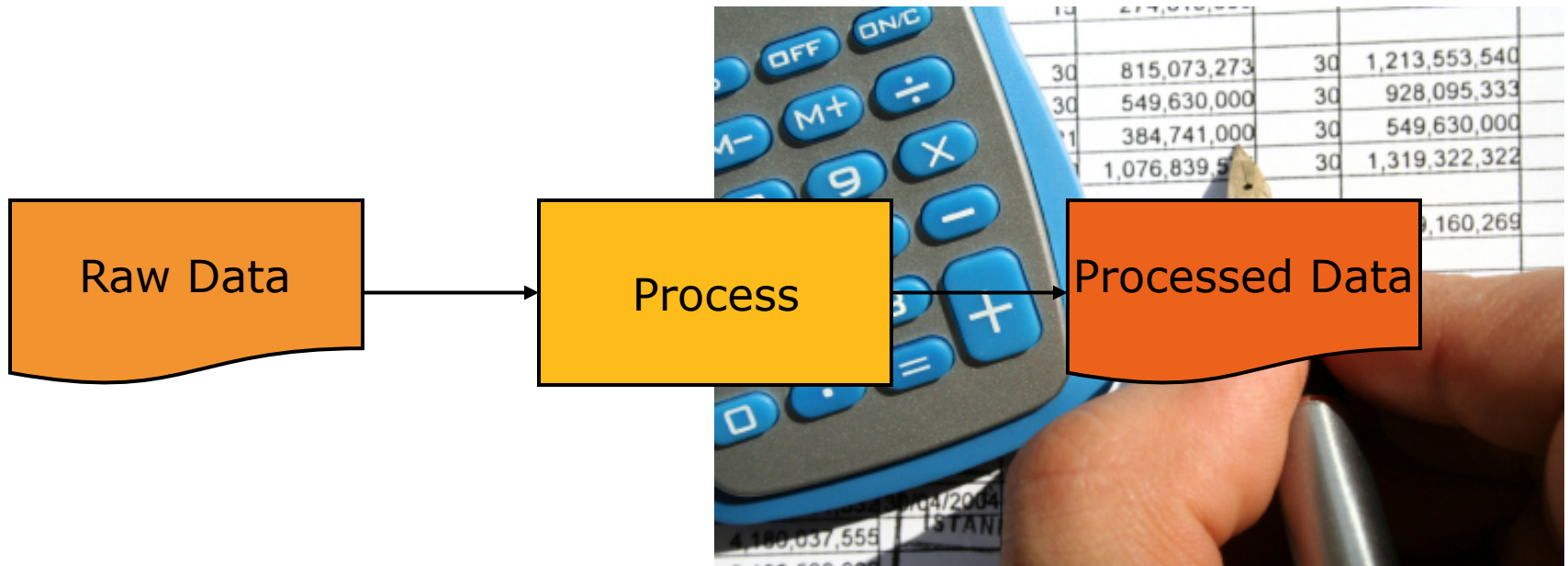


# Processing Raw Data – ELISA example



# Processed Data

- Processed Data are not raw data as such but must be retained if “approved” (described in the final report etc.).
- The process leading to the “approved” data must be described and retained





# Archiving

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- ...protection against loss, modification, and unauthorized access
- Electronic (raw) data should be stored with the same levels of access control, indexing and expedient retrieval as other types of data
- Procedures should be implemented to ensure that the long-term integrity of data is not compromised
- If long-term access might be affected, procedures for ensuring continued readability of the data should be established
  - e.g. producing hard copy printouts or transfer/migration of data

# Archiving Electronic Data

- Off-line archiving
  - Electronic (raw) data stored on read-only data media (e.g. CD-ROM, DVD)
  - Not advisable
- On-line archiving
  - Dedicated electronic archive system
  - On the productive system (flagged and logically separated, read-only)



# Issues – Retention of electronic (raw) data

- Electronic (raw) data belonging to a specific GLP study are often scattered on different systems/servers
- Exporting files to a central location is feasible but for reading and reprocessing they have to be reimported to the original system

LIMS



ELN



Analytical  
Instrument(s)



# Issues – Retention of electronic (raw) data

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It is a GLP requirement that data should be **accessible**, **readable** and potentially **even reproducible** throughout the entire record retention period

- Laboratory equipment and data systems often have shorter lifetimes than the required (regulatory) retention period
  - Software version (in)compatibility
  - Supporting strategy vendor

# Issues – Retention of electronic (raw) data

It is a GLP requirement that data should be **accessible**, **readable** and potentially **even reprocessable** throughout the entire record retention period

- Data is in most cases in a proprietary format
  - Systems (hardware and software) may have to be retained after official retirement to accomplish that data can be viewed, printed and reprocessed
  - Data migration or conversion may affect the «accurate and complete» representation of the original data
- **Standardized non-proprietary format for analytical instrument data?**
  - JCAMP, AnIML



# Thank you for your attention!

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