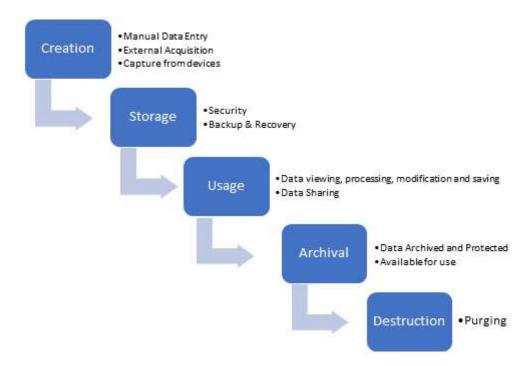


Integrity in the Data LifeCycle

If you are working with data in a Life Sciences organisation it is imperative that you can guarantee its integrity at every stage of the Data LifeCycle. Below we identify the 5 stages of Data LifeCycle Management and what you need to ensure is in place at each stage.

The 5 Stages of Data LifeCycle Management

Data LifeCycle Management is a process that helps organisations to manage the flow of data throughout its lifecycle – from initial creation through to destruction. While there are many interpretations as to the various phases of a typical data lifecycle, they can be summarised as follows:



1. Data Creation

The first phase of the data lifecycle is the creation/capture of data. This data can be in many forms e.g. PDF, image, Word document, SQL database data. Data is typically created by an organisation in one of 3 ways:

 Data Acquisition: acquiring already existing data which has been produced outside the organisation

- Data Entry: manual entry of new data by personnel within the organisation
- **Data Capture**: capture of data generated by devices used in various processes in the organisation

2. Storage

Once data has been created within the organisation, it needs to be stored and protected, with the appropriate level of security applied. A robust backup and recovery process should also be implemented to ensure retention of data during the lifecycle.

3. Usage

During the usage phase of the data lifecycle, data is used to support activities in the organisation. Data can be viewed, processed, modified and saved. An audit trail should be maintained for all critical data to ensure that all modifications to data are fully traceable. Data may also be made available to share with others outside the organisation.

4. Archival

Data Archival is the copying of data to an environment where it is stored in case it is needed again in an active production environment, and the removal of this data from all active production environments.

A data archive is simply a place where data is stored, but where no maintenance or general usage occurs. If necessary, the data can be restored to an environment where it can be used.

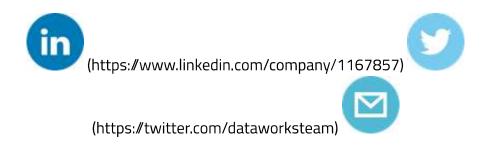
5. Destruction

The volume of archived data inevitably grows, and while you may want to save all your data forever, that's not feasible. Storage cost and compliance issues exert pressure to destroy data you no longer need. Data destruction or purging is the removal of every copy of a data item from an organisation. It is typically done from an archive storage location. The challenge of this phase of the lifecycle is to ensure that the data has been properly destroyed. It is important to ensure before destroying data that the data items have exceeded their required regulatory retention period.

Having a clearly defined and documented data lifecycle management process is key to ensuring Data Governance (http://www.dataworks.ie/Blog/Item/data_governance_life_sciences) can be carried out effectively within your organisation.

At Dataworks our highly skilled CSV & Software Engineers provide a full range of Data Integrity services as part of our offering including: Data Integrity assessments, remediation software and validation services (http://www.dataworks.ie/Validation-Software-Quality-Assurance/Software-Validation).

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