Good Laboratory Practice

POSITION PAPER 1:

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)?

Release Date: 31.01.2018

Version: 2.0

1 OBJECTIVE

The aim of this document is to take position on the issue regarding the destruction of original paper raw data:

- Is it acceptable to destroy paper originals of raw data and related study documentation (excluding the final report), if the image of the paper is captured in an electronic form (e.g. scanned)?

This position paper specifies AGIT's position and its rationale, which is: **Yes, if all requirements specified in chapter 2 are fulfilled.**

The Position Paper 1 was issued as version 1.0 in October 2014. This updated version (version 2.0) is in line with the OECD Advisory Document No. 17 (replacing OECD Consensus Document No. 10) [1].

2 REQUIREMENTS

To ensure a 100% accuracy and completeness of the electronic copy the following requirements have to be fulfilled:

1. The electronic copy should preserve the **accuracy**, **completeness** and **content** of the original paper data:
   - **Accuracy**: The electronic copy should be an accurate reproduction of the original paper data. Therefore, the resolution of the electronic form should match the quality of the paper data. For pictures, plots and graphs, a higher scanning resolution may be necessary than for text. The colour balance of the electronic copy should also match the colour range of the data on paper.
   - **Completeness**: The electronic copy should be a 100% match of the data on paper. Therefore special attention should be paid to possible annotations on the margins of the paper data, hand written entries, ink colour, shaded areas, one sided or two-sided paper originals etc. The completeness may also be jeopardized by stapled slips of paper, original paper size exceeding the scanning area etc.
   - **Content**: The content of the electronic copy should be identical to that of the original paper data. Pictures in electronic form should display the same content and allow the same interpretation as the original.
2. The scanning process should be established, developed and validated; it should result in a non-editable image or reproduction of the original paper data
   - The scanning process should be validated regarding readability, resolution, contrast and colour balance, page size, counting of pages, error handling etc. The scan process should produce a read-only image file, in a non-editable form.
   - In case a search function is desirable, an additional file obtained by Optical Character Recognition (OCR) can be generated. This file is not considered as raw data.
   - The validated work-flow should be defined in an SOP which describes the responsibilities, the scanning process and its parameters, the verification process including electronic signature, the security and inventory of the electronic copies, destruction of paper originals, and the documentation of all activities.
3. Each individual scanned page should be verified
   - Each individual scanned page should be compared with the original paper and be checked for accuracy, completeness, and content. This 100% check should be documented by signing electronically the file containing the scanned paper data.
4. The electronic copies should be stored to fulfil the requirements of electronic GLP Archiving

- Archiving and storage should be operated and maintained in compliance with GLP. Therefore, data archiving/storage should fulfil requirements for electronic GLP archiving. [1, 2, 3].

5. Disposal of original paper data should be documented
   - Discarding the original data should be documented.
   - The sponsor should be informed previously about the scanning process and subsequent discarding of the paper data for his studies.

3 CRITICAL ISSUES

Legal requirements may vary from country to country. Therefore, before implementing such a process, it must be ensured that the applicable local legal regulations are met.

4 RECOMMENDATIONS

It may be appropriate to keep the paper originals until the final report has been signed.

It is recommended that raw data and study related documents generated in an electronic form, e.g. digital photos, study plan, are handled and archived as electronic data, according to the respective guidelines (see Section 2 requirement 4) and the advice given in section 3.11 of the OECD Advisory Document No. 17 (archiving, points 109 – 118 [1]).

5 REFERENCES

[1] OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 17: Advisory Document of the Working Group on Good Laboratory Practice. Application of GLP Principles to Computerised Systems. Environment Directorate, OECD, Paris, 2016. (OECD)

[2] OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 15: Advisory Document. Establishment and Control of Archives that Operate in Compliance with the Principles of GLP. Environment Directorate, OECD, Paris, 2007. (OECD)

[3] Working Group on Information Technology (AGIT); Good Laboratory Practice (GLP); Guidelines for the Archiving of Electronic Raw Data in a GLP Environment. (AGIT)

6 WORKING GROUP ON INFORMATION TECHNOLOGY

The Working Group on Information Technology (AGIT) was founded on 27 March 1998 with the objective of discussing relevant topics of Good Laboratory Practice (GLP) in the field of information technology between industry and the monitoring authorities.

The members of the AGIT are representatives of the Swiss GLP monitoring authorities and invited experts from industry.

For the convenience of users, AGIT publications are available on the Swiss GLP website (see Good Laboratory Practice (GLP)). The Swiss GLP homepage also provides links and references to guidelines, laws and regulations, definitions etc.