

Appendix A
Good Documentation Practice Job Aid

Effective Date: 03/23/21

Document No.: **APP-A15-OPC-007.00**

1.0 PURPOSE

- 1.1 The DAIDS Good Documentation Practice Tool is a companion to the DAIDS Good Documentation Practice Policy and will provide more detailed information to guide our external stakeholders.

2.0 SCOPE

- 2.1 Good Documentation Practice has been described in the form of ALCOA+ - attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available (known as ALCOA+). The European Medicines Agency has also included additional qualities (credible and corroborated) to describe good electronic source documentation. These attributes apply to both paper and electronic records and represent the foundation of data integrity (ICH E6 R2).

3.0 DEFINITIONS

For additional definitions, see [DAIDS glossary](#).

- 3.1 Attributable: Is it traceable to a person and date?
- When documenting data on paper, every written element needs to be traced back to the authorized individual who is responsible for recording it. This requires a signature, initials, and date.
- 3.2 Legible: Is it clear enough to read?
- On paper, everything that's written must be easy to read and recorded in a blue ink, permanent medium (not pencil).
- 3.3 Contemporaneous: Was it recorded as it happened?
- Record, sign, and date the data at the time the study is being conducted. On paper, data needs to be documented in real-time and dated with the current date (no predating or postdating).
- 3.4 Original: Is it the first-place data is recorded?
- The source is the earliest record – the first place that data is documented.
- 3.5 Accurate: Are all the details correct?
- The data must be an accurate representation of the conduct of the study.
- 3.6 Complete: Is the data whole?

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- All information that would be critical to recreating a study is important when trying to understand the study. All the data needs to be available and nothing deleted.

3.7 Consistent: Is data repeatable and traceable?

- Good documentation practices should be applied throughout any process, without exception, including deviations that may occur during the process.

3.8 Enduring: Will the data last over time?

- Part of ensuring records are available is making sure they are long-lasting and durable, lasting throughout the life of the study.

3.9 Available: Is the data easily accessible? Will it remain easily accessible over time?

- Records must be available for review, audit and inspections.

3.10 Credible: Is the data trustworthy?

- The data must be real and based on reliable facts.

3.11 Corroborated: Can you confirm the data?

- The data must be supported by evidence.

4.0 RESPONSIBILITIES

4.1 Making Handwritten Entries on Documents

- All entries will be made with BLUE indelible ink only. Any color besides BLUE or BLACK ink can be utilized for reviewing. Pencils are not permitted for any documentation.
- Sign or initial and date entries at the time the work is performed to ensure the accuracy of the information.
- Critical entries must be independently checked (second person verified).
- Ditto marks or continuation lines are not acceptable.
- Date entries will be made with the following date format dd/mm/yy unless the procedure or form specifically indicates a different format.

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- F. Enter your signature or initials (according to what the procedure requires).
- G. Use a diagonal line and N/A to indicate no entry is required, then initial, and date across any blank space on a document where late entries could occur. No spaces for handwritten entries are to be left blank.
- H. Sign and date across the edge of every affixed entry, such as labels.
- I. Never sign your name to work performed by someone else.
- J. All entries will be legible.

4.2 Making Handwritten Corrections or Adding Additional Information

- A. Draw one line through an error. Ensure that the previous entry has not been obscured.
- B. Document the correct information, initial, and date beside the information. If additional information is needed to justify the change, please note it. If space is limited, an * (asterisk) can be utilized and the note can be placed in a different location on the document.
- C. All corrections will be clear and legible.
- D. Abbreviations will be utilized to explain data changes such as " EE" for entry error.
- E. Do not write over an entry to correct or change it.
- F. Whiteout is not permitted.

4.3 Electronic Documents

- A. Each data element in an electronic record needs to be associated with an originator type, otherwise known as an authorized data originator. An authorized data originator could be a person, a computer system, a device, or an instrument that is authorized to enter, change, or transmit data into the electronic record. Examples of data originators include, but are not limited to:
 - a. Clinical investigator(s) and delegated clinical study staff
 - b. Participants or their legally authorized representatives

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- c. Consulting services (e.g., a radiologist reporting on a computed tomography (CT) scan)
- d. Medical devices (e.g., electrocardiograph (EKG) machine and other medical instruments such as a blood pressure machine)
- e. Electronic health records (EHRs)/ Electronic Medical Records (EMRs)
- f. Automated laboratory reporting systems (e.g., from central laboratories)
- g. Other technology

- B. Develop and maintain a list of all authorized data originators. This list must be made available for study-related monitoring, audits, IRB/EC review, and regulatory inspection by authorized individuals at each clinical research site.
- C. Access to electronic documents must be password protected.
- D. A history (audit trail) must be maintained of all changes and deletions to electronic versions of documents.

5.0 REFERENCES

- 5.1 [E6 \(R2\) Good Clinical Practice: Integrated Addendum to International Conference of Harmonization \(ICH\) E6 \(R1\)](#)

6.0 REVISION HISTORY

- 6.1 APP-A15-OPC-007.00 is the original version of this Appendix.