

Pharmaceutical
Research Centre

STANDARD OPERATING PROCEDURE

1 DEFINITION AND RECORDING OF RAW DATA

VERSION 1

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1 INTRODUCTION

- 1.1 This Standard Operating Procedure details the procedure to be followed for the recording of all paper-based original data collected during the conduct of scientific investigations. This approach is necessary to ensure clear, consistently produced and unambiguous records as well as compliance with Regulatory Standards.
- 1.2 This SOP describes the procedure required to establish a precise audit trail to the raw data.

2 RESPONSIBILITIES

All members of staff are responsible for complying with the requirements of this procedure.

3 DEFINITION RAW DATA

- 3.1 Raw data or original data is the earliest, humanly readable record made of an observation, action or decision hence this is the first occasion that the data is recorded. Original data may manifest in several physical forms - written datasheets, photographs and computer records.
- 3.2 To ensure that any errors introduced by data processing-transcription, calculation, collation, word processing etc - are capable of elimination, it is essential that the original data is unambiguously identifiable, and totally reliable, in each and every case.
- 3.3 The majority of the data is written directly by the observer, onto a record sheet, the data is collected using the most applicable method. This sheet then contains the original data for those observations: subsequent transcription to collation sheets, log sheets etc are NOT original data.
- 3.4 Not all items on a "raw data sheet" are original data. If it is copied then this is NOT the original data. .

- 3.5 In some cases, values may be called out by an observer and written on a record sheet by a scribe. The entries made by the scribe are the original data - the verbal stage is not a RECORD.
- 3.6 Records of actions and decisions, even though they are not results, may be original data - "placed in the incubator at 14.37"; "Balance calibrated"; "Data Archived"; "This is valid or invalid".
- 3.7 Records of observations not required by the protocol are nevertheless original data - "No. 9 was omitted in error".
- 3.8 Instrument printouts - is original data so long as the data has been captured by the system - not keyed in from a paper record, and the processes between capture and printout have been verified. It is the first copy of the printout; subsequent print offs are NOT original data.
- 3.9 Statements that an observation or procedure is intended cannot be taken as evidence that the observation or procedure was done as intended. Log records must be used carefully and it must be clear whether the log is a statement of intention OR a record that an event occurred.
- 3.10 Multiple records of data should be avoided, especially where it may not be evident, by inspection of the data, which is the original. The definition establishes that there can only be one original.
- 3.11 Although it is essential for the purposes of audit and verification that the original data is recognised and defined in all cases, it is also good practice and discipline to make all entries as if they were original. This reinforces signing and dating habits, which become second nature and therefore fail-safe.
- 3.12 However the original data is defined, it must meet the requirements of original data required by the regulatory standards. Original data must be made in pen, not pencil or erasable ballpoint. Felt-tip pen should be avoided as it may continue to 'run' long after the entry is made. Original data must be legible: care must be taken with handwriting so that, years later, there is no doubt about what was

recorded. Use of dittoes should be discouraged to avoid confusion with tildes and hyphens. Decimal points should be clearly made.

- 3.13 If the original data as currently defined does not meet these criteria, procedures should be amended so that it does satisfy all these requirements: else re-definition should be considered.

4 RECORDING OF RAW DATA

- 4.1 The records of work performed and observations made consist of the original documents upon which data are recorded, and additional forms containing information generated during the conduct of the study. The record should contain sufficient information to allow someone, not connected with the work, to reconstruct the essentials of the experimental design, which are employed, and to understand, completely, the methods used and the results obtained. All portions of the record for a study are subject at any time to presentation to the client, to a regulatory authority or to introduction into a court of law as evidence. Therefore, the person recording data should review each entry, as it is generated, to make sure it is accurate, complete, legible and properly identified
- 4.2 Accuracy in recording of original data is fundamentally important and errors or obscurity must not occur through carelessness or lack of information.
- 4.3 If you have any doubts about observations, experimental results, accuracy, or operation of recording equipment or any other factor, which might affect the accuracy of data records or the validity of the work, you must ask the Study Director for assistance immediately.
- 4.4 If you notice any errors or anomalies in data, samples, identifiers etc. you must report this at once to the Study Director who will then be responsible for taking appropriate action and for recording the event in the study records where this is appropriate.
- 4.5 All hand-written data must be recorded directly, at the time of the observation, and identified with the date and time, if relevant and signature/initials of the recorder. Recording elsewhere with subsequent transcription is forbidden. Additional observations not

covered by the data sheet may be recorded on the reverse of the sheet. Instrument produced original data output must be signed and dated by the operator.

- 4.6 All data entries must be made accurately, legibly and in black ballpoint whenever practicable, not pencil. The use of felt-tipped pen is discouraged. The use of erasures, "Tippex" and other covering agents is not permitted on data records.
- 4.7 Where observations are made by one person but recorded by another, both must initial and date the record and their respective functions made clear. Where a trainee under supervision makes observations, the supervisor must also sign or initial the data as evidence of the supervision.
- 4.8 All corrections to recorded data will be made immediately the error is noted.
- 4.9 A line is drawn through the complete incorrect entry in such a manner that the original is still legible. The complete correct value is then entered together with the initials of the person making the correction and the date.
- 4.10 The need for the correction must be explained and justified. Note corrections to data made some time after the original should be subject to careful justification. Where insufficient space is available to enter this information on the data sheet, the correction should be made on the sheet and the reason for the correction may be entered on the back of the sheet or in a Data Note in such a manner that the entry to which it refers may be clearly identified.
- 4.11 Where an observation does not follow the normal pattern the value should be rechecked wherever possible and if a true value, marked to emphasise that it is a valid, accurate record.
- 4.12 Any record deemed to be invalid should be so annotated and the reason given. Any record not so annotated will be deemed to be valid.
- 4.13 The retention of data will normally be for five years, unless sponsor or regulatory requirements state otherwise.