Source Data Top Tips

1. Source data refers to where data are first captured in any situation, not just on trial documents. Location of source data should be clearly documented.

2. Ensure source data is accurate and clear. If visit templates are used in medical notes to facilitate recording of visit assessments, make sure data is updated accurately for each visit.

3. Participant consent details, participation in the trial and allocated study number must be documented.

4. Review and outcome of participant eligibility should be documented. Ideally the review of each inclusion/ exclusion criteria should be documented, alternatively a conclusive statement of participant eligibility can be documented providing there is supporting evidence of the review of each criteria.

5. Document participant visits at the time of visit or immediately after. Avoid regular retrospective entries.

6. Trial visits and dates must be documented explicitly, including unscheduled visits.

7. Document all the assessments performed and the results, including labs, scans, ECGs etc

8. Document all findings pertinent to the participant's general medical well being (e.g.: medical history, physical exam, vital signs and lab results)

9. Ensure the review of investigations such as lab and ECG results are documented. This includes adding comments on the clinical significance of the results and grading where applicable, investigator's sign off and date of review in EPIC.

10. Document that concomitant medications and AEs were assessed at the visit and list details, such as relationship to IMP. AEs which have been resolved must also be documented (Lack of documentation of AE review does not mean there were no AEs to report; it suggests that AEs were not reviewed). If an AE is on-going across a number of visits but causality due to IMP changes, this should be confirmed by a clinician and noted in the source notes.

11. Record details of trial medication administration. In cases where participants are instructed to return unused oral medications, the returns should be checked and documented, and any discrepancy to expected dosage addressed. Participant diaries if used should also be copied and added to the source notes.

12. Document date of final study drug administration and when the participant completed the trial, including the reason for withdrawal if applicable.

13. Document any communication with the participant pertinent to the trial (e.g.: Participant information sheet sent for consideration, follow up phone calls), even where there are outside normal standard of care.

14. Document any other information the participant has provided or discussions that took place during the trial visit even if not immediately relevant to the trial (e.g.: pregnancy)