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| ***Source Correction (i.e. ‘Late Entry’)*** | ***Note to File (NTF)*** | ***Corrective and Preventive Action (CAPA)*** |
| * Note(s) added to existing documentation
* Best uses:
	+ Typos, entry errors
	+ Minor clarifications or updates to discrepancies
	+ ‘Fill in the blanks’ to explain why something was/was not done or how decision was made
* How to:
	+ Written or electronic (EMR) addendum to applicable source documents with initial/signature of author and date reflecting when updated/changed information was documented
* Auditable document by regulatory authorities as part of the study record
 | * New document that becomes part of the permanent study record
* Best uses:
	+ Document name change or location of required documents if filed elsewhere (e.g. in a central location versus protocol specific files)
	+ Clarify source document standards
	+ Reconcile discrepancies or deviations
* How to:
	+ Written or electronic documentation of the clarification or problem, the corrective action and resolution of the issue (as applicable), with signature and date of author.
* The NTF may document the corrective action(s) taken.
* If applicable, should indicate whether a CAPA plan was needed and if not, why
* Auditable by regulatory authorities
 | * New document(s) that can be filed with permanent study records or kept as internal process document
* Best uses:
	+ Identify and address systemic issues and remedy process related deviations
	+ Should include Root-Cause Analysis
	+ Used to identify, implement, track and evaluate effectiveness of the plan
* How to:
	+ Written or electronic documentation of the problem, identification of the root cause, corrective action to be taken, preventive action to be taken, evaluation of the CAPA’s effectiveness
	+ Delegation of personnel to create, implement, track and evaluate the CAPA plan
* May be auditable by regulatory authorities if related to ongoing trial monitoring (e.g. requested by IRB)
* Central tracking at a departmental level is highly recommended
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