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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 |