**Study/Product:** [Name of your study/product]

**Storyboard:** [Title of issue (ensure that title clearly reflects the topic for ease of identification during inspection)] *Example:* Six Monitoring Visit Reports Written in Pencil

The following top-level information is provided to ensure consistent internal understanding and communication of a GxP issue that [your company name] self-identified and the actions taken to resolve and document both the issue and its resolution. See attached additional detailed information, if required.

|  |  |
| --- | --- |
| **Issue Identification:**  [Include a high-level positive message on how the company self-identified the issue and acted. Ensure that the issue is clearly stated; focus on the root cause issue. Include known dates or timeframes.]  *Example:*  On 27 April 2020, ABC Pharma self-identified that monitoring visit reports (6) for Protocol 123 had been completed using pencil. Following manager review of the submitted reports, the potential trend was escalated, and ABC Pharma took immediate action to ensure comprehensive mitigation. | **Key Background Information:**  [Provide the highest-level background information available that clearly relays information and/or events that led to or contributed to the issue, with key focus on root cause. This should be limited to three to five points and can be bulleted or in paragraph format.]  *Example:*   * During review on 24 Jan 2020, a clinical operations manager (COM) identified that a monitoring visit report dated 10 Dec 2019 had been completed using a pencil. The COM immediately notified the responsible monitor. * The monitoring visit report was resubmitted on 27 Jan 2020. The manager reviewed the report on 27 Jan 2020 and confirmed that it was compliant with SOP 502. A certified copy of the original handwritten report was created for preservation purposes. * On 27 April 2020, it was identified that five additional monitors had submitted five (one each) monitoring visit reports completed using a pencil. |
| **High Level Impact Analysis Statement:**  [Include a high-level statement regarding the impact that this issue had, could have, or will have on data integrity and/or patient safety.]  *Example:*  The use of pencil for completing clinical trial documentation is strictly prohibited by ABC Pharma Policy 100: Good Documentation Practices. It is also prohibited by SOP 502 (V1). A trend of completing monitoring visit reports with a pencil introduces a high level of risk to data integrity as well as risk to patient safety. There is a high probability that the use of a pencil for documenting monitoring visits will result in an inspection observation. | |
| **Overview of Corrective and/or Preventative Action(s):**  [List key high-level actions taken in the past, recently, or are planned to clarify, address, or prevent the issue, focusing on root cause. If available, include date/quarter/year when actions were completed or a target date for completion. For actions still in progress, review and update just prior to inspection. This information can be presented in a bulleted list or in a table indicting the date and action(s).]  *Example:*   * 27 Apr 2020: An internal CAPA was initiated, which included a root cause analysis. It was determined that the monitors completed reports using pencil while experiencing computer issues so that they could meet timelines required by the monitoring plan. None of the six monitors had access to a pen during the computer downtime due to a state-wide ink pen shortage between 25 Nov and 15 Dec 2020. * 28 Apr 2020: It was confirmed that as of 25 Nov 2020 all six monitors involved had completed the required annual GCP refresher training, which includes Good Documentation Practices (GDPs). * 3 May 2020: A review of all monitoring reports awaiting COM confirmed that no additional reports were written in pencil. * 4 May 2020: The six monitors involved participated in a decision-making coaching session led by Jane Doe, PH.D., Make Good Decisions, Inc. The session included retraining on the following SOPs and topics:   + SOP 302 (V1) Quality Event and CAPA Management   + How to contact the IT help desk via phone   + GCPs and GDPs * 7 May 2020: All employees living or working in the state received a corporate communication regarding the use of pencils during the ink pen shortage. In addition, ABC Pharma initiated the Can’t Find a Pen? Task Force. * 1 July 2020: It was confirmed that zero monitoring visit reports, nor any other clinical trial documentation completed between 27 April and 1 July 2020, involved the use of a pencil. * 15 July 2020: The scenario of a complete loss of pens during computer downtime was added to the annual 2020 disaster recovery and business continuity testing plan. The testing will take place on 1 Nov 2020. | |
| **Available Supportive Documents, if Requested by Inspector(s):**  List the key supporting documents that are ready and available to potentially satisfy a document request related to the issue. Be as specific as possible. Review this list and update just prior to audit. If possible, insert hyperlink directly to each document.  *Example:*   * Documentation that COM (John Brown) notified monitor of issue via email on 24 Jan 2020 and provided an overview of actions taken regarding the initial instance identified * No Pencil Confirmation Review Report dated 3 May 2020 * Current training records of six monitors confirming that the training noted above was completed on the dates indicated * Copies of the monitoring visit reports completed in pencil * Documentation that certified copies were made to preserve original hardcopy documentation * Copies of the six monitoring visit reports that were submitted properly, all showing the date submitted * ABC Pharma communication to all employees living and/or working in the state dated 7 May 2020 * Documentation dated 1 July 2020 confirming that no monitoring visit reports submitted between 27 April and 1 July 2020 involved the use of pencil. * 2020 Annual Disaster Recovery and Business Continuity Plan dated 15 July 2020 * The “Can’t Find a Pen in the State of Confusion” Task Force Charter * Protocol 123 Monitoring Plan * Also list all related SOPs or Policies … | |