Corrective Action Plans (CAP)

How To Move Forward When the Unexpected Occurs

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Objectives

- Definition
- Steps Taken When The Unexpected Occurs
- Developing the Corrective Action Plan
- How to Move Forward
- Evaluation
- Case Studies

Definition

The FDA indicates that corrective action plans are absolutely necessary to resolve problems and noncompliance in clinical investigations. Corrective actions are those taken to resolve a problem and preventive actions are those actions that keep the problem from recurring.

Corrective actions

- The first and most critical corrective action is to ensure that the immediate corrections previously taken removed any risk of harm or further harm to the subject and future subjects and that the deviation was appropriately reported to the sponsor and IRB. Because you have already assessed the **rights, welfare, and safety** of the subject and the root cause is now known, you may consider additional **reporting** to the sponsor and IRB at this time. Ensure that the report to the sponsor and IRB is accurate and thorough and that the CAP is included.

Steps Taken When the Unexpected Occurs

- The Unexpected Occurs

Step 1

- Risk Analysis and Immediate Action for Protection of the Participants
- Take a step back and look at the entire picture of what occurred
- Human error vs. procedural error
- Reportable to the IRB
- Needs assessment
- Move forward with creating the corrective action plan

Step 2

Step 3

- **S**pecific: Compliant with regulations, addresses the full observation or root cause, accountable to named individual or role
- **M**easurable: Action can be measured to demonstrate whether it is adequate to address root cause
- **A**chievable: Addresses all implicated processes and levels
- **R**ealistic: Plan can be carried out given resources, knowledge and expertise
- **T**ime-bound: Assigned to a person or role who can accomplish action in a given time period, addresses urgency and criticality

SMART

Step 4

- **What does FDA expect in Corrective Action Plans?**
- Evaluation of the extent of the problem
- Assessment of the root cause
- Any corrective actions
  - –Plan to correct
  - –Implementation details
  - –Training
  - -- Assessment of the correction
- Supporting documentation
- Preventive actions to prevent recurrence

Step 5

- Create a standard template for all Corrective Action Plans

1. Header should identify the department
2. It should be determined if this is an overall CAP or specific to the conduct of an individual study
3. The plan should indicate the occurrence and what steps were taken during that process
4. There should be a clear delineation of what steps will be taken moving forward
5. Roles and responsibilities should be clearly defined
6. Plan for future evaluation

Example

Deficiency Noted: Case Report Forms were incomplete in that the information needed to determine eligibility was missing.

Responsible for Overall Corrective Action Plan:

Research Study, Principal Investigator - _____(Signature), _____ (Date)

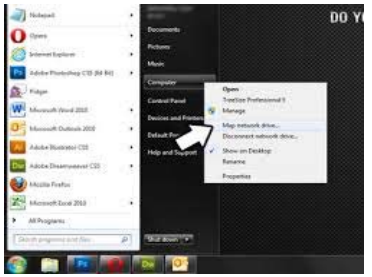
Step	Action	Due Date	Responsible Party	Status / Comments
1	A Standard Operating Procedure has been developed and implemented to assist with documentation practices for determining study eligibility. A copy of the procedure is attached.	March 3, 2008	John, CRC	Complete. See attachment
2	This SOP contains a form that will be completed by each study's primary CRC and confirmed and signed by an investigator prior to any subject enrolled in the study.	March 3, 2008	John, CRC	Complete. See attached
3	All study personnel (Investigators, CRCs, Data Coordinators, Regulatory Coordinators) have been trained on the SOP and it was implemented on March 3, 2008	March 3, 2008	Mary, Project Manager	Complete. See attached
4	After 3 months, the new eligibility documentation practices will evaluated to determine if this corrective action assists with ensuring all information is documented to determine study eligibility.	June 3, 2008	Robin, QA Manager	Evaluation and Monitoring Plan
5	A follow-up report will be submitted to the IRB and Research Director of our evaluation findings listed in step 4.	June 15, 2008	Robin, QA Manager	Evaluation and Monitoring Plan

How to Move Forward

- Train all applicable staff on the Corrective Action Plan.

How to Move Forward cont.

- Ensure that copies of the Corrective Action Plan have been distributed to the necessary parties and files.



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How to Move Forward cont.

- See the plan in action.

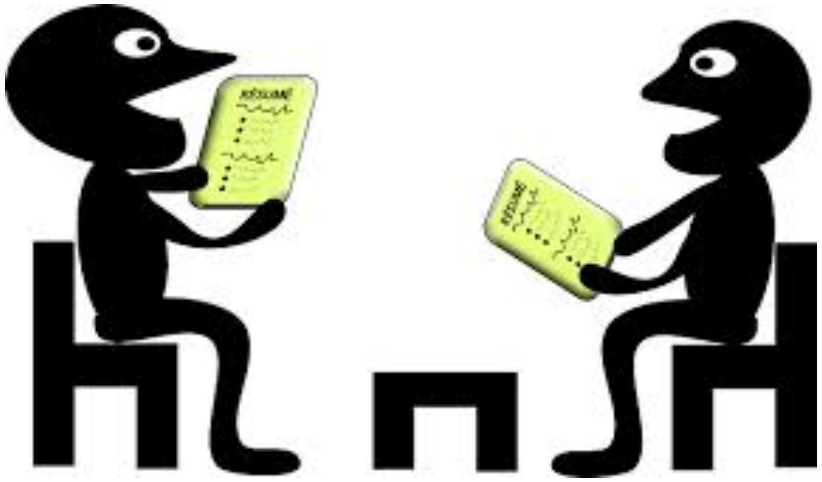
Evaluation

Evaluation cont.

- Effectiveness check is the final step of the CAP process. Ensure that the CAP has addressed the root cause and that the problem has not recurred again. If the CAP has not addressed the root cause, amend the CAP as necessary, train on the process, implement the process, and re-evaluate.

Evaluation cont.

- **Ensure that when conducting the evaluation all people responsible for implementing and following the plan have provided the necessary feedback.**



Case 1

- There have been a number of consent form irregularities seen with the study including use of the incorrect version and not re-consenting with the updated version.

1. How do you determine the root cause?
2. Is this reportable to the IRB?
3. What needs to be considered when developing the CAP?
4. Does this CAP apply to one or all studies?
5. Who is responsible for implementation?

Case 2

- At the most recent monitor visit it has been discovered that there are some inaccuracies with the study drug accountability. The coordinator has indicated bottles of study drug were handed out but they are still located with the supply.

1. How do you determine the root cause?
2. Is this reportable to the IRB?
3. What needs to be considered when developing the CAP?
4. Does this CAP apply to one or all studies?
5. Who is responsible for implementation?

Case 3

- The study coordinator has become aware that upon transfer of study participants to the provider responsible for administering the study drug injections, there have been 3 participants who received injections into the wrong joint.

1. How do you determine the root cause?
2. Is this reportable to the IRB?
3. What needs to be considered when developing the CAP?
4. Does this CAP apply to one or all studies?
5. Who is responsible for implementation?

Responsibility

- The P.I. conducting the study is solely responsible.

Contact Information

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Questions