Clinical Trials in Medical Devices: Life Cycle Risk Management

PEER REVIEWED

Abstract:
Risk planning is a crucial aspect for clinical trials, yet is often omitted because clinical teams are hurried or in demand, but they must meet as needed with staff and other stakeholders to be together in the plan. Device designers can take precautions to make items safer through their innovative designs. Evaluating a control after its introduction has to be analysed and addressed accordingly, with risk analysis. This device can be recommended if it has been demonstrated to have benefits that outweigh its residual risks. This leads to the surveillance of post-market aspects of a product for a number of years. Survey results indicate that risk management's (RM's) impact or effectiveness on a medical device is mainly affected by the type of device and its life cycle stage (i.e., pre-market versus post-market). Risk management is necessary for meeting the goals of medical devices projects.

Keywords: Risk Management, Clinical trials, Life Cycle stage

Introduction
Risk refers to the chance of suffering loss or injury, or anyone proposing a hazard. The process of risk management identifies, evaluates and prioritises potential hazards, then applies initiatives and resources to minimise, coordinate and manage the possibility of hazards occurring, and to lessen the effect of any concerns.

This paper describes the fundamental principles of project risk management, and how clinical information can be used to manage risks of medical device projects.

The clinical study drug development programme is a vital operation that can help the regulators to believe the quality data of the drug. Clinical trials are the most important drivers of research and development costs, as compared to the past. Drug manufacturers are searching to improve the efficiency of clinical trials due to economic and efficiency considerations.

Risk Management Procedure
Risk management conceptions can be taken from the **"ISO 14971: Risk Management for Medical Devices and ICH Q9: Quality Risk Management".** The initial phase is based on describing the method for leading this action. The simple phases of risk management include: recognise and evaluate risks, lessen risks, and evaluate risks. Supplementary phases that are necessary during the process contain statements of threats, and records of actions.

General Risk Management Process
- Step 1 – Plan – plan risk management effort.
- Step 2 – Identify – Identify potential hazards and sources.
- Step 3 – Estimate and Analyse – Estimate / analyse risks for likelihood of occurrence and potential effect.
- Step 4 – Respond and verify – Develop responses / actions to reduce likelihood of negative risks occurring and verifying implemented controls have reduced or eliminated risks, and not introduced new risks.
- Step 5 – Monitor and control – Monitor and control identified risks and any changes, adding new risks or information.
- Step 6 – Report – Summarise risk management effort and outcome.

Risk management is an important fragment of the lifecycle of a medical device invention or project, and is stranded in the context as above.

Lifecycle Risk Management for Projects and Medical Device Products
Project Life Cycle: Initiating to Closing

Risks
Risks to project objectives (scope, quality, resources, budget, schedule) can be either:
- Negative (threats or harms)
- Positive (benefits or opportunities)

Product Life Cycle: Conception to obsolescence (total product life cycle) or TPLC.

Risks
- Unlike project risks, product risks are negative only; that is, have the potential for harm to the health of people or the environment.
- Risks must be managed to ensure the device operates within its safety or risk profile throughout its TPLC.

Project Risk Management Process
Besides, the certified Project Management Institute (PMI) provides guidelines for project control. The life cycle process includes five sub-processes:

- Initiating
- Planning
- Executing
- Monitoring
- Controlling &
- Closing

The project risk management procedure and actions are detailed in the project's life cycle. "Monitoring & controlling" can be equated to the "monitor & control" in the risk management.

The Following Provide Additional Strategic Factors for Managing Risk to Clinical Trial Project Goals

- Therefore, both project manager and safety should understand and talk with other to achieve project objectives together.
- Risk management groups a solid basis for the trial, but is never started or completely finished due to external schedule requirements. Plan to organise a team session to discuss the topic.
- Understand both in-scope and out-of-scope to manage both types of risk, for compliance and facilitation.
- Provide correct details of requested changes.
- Allow everyone to obtain knowledge of relevant information, following issuance of escalation.

Project life cycle process		Corresponding risk management process	Activities
Monitoring & Controlling	Initiating	Authorisation	Risk management effort and kick off project, and assign project manager
	Planning	Plan risk management	Define how project risks will be managed and change control pathway process
		Identify risks and sources	To define either negative and positive causes
		Perform risk analysis	To determine potential impact either positive or negative, to categorize, evaluate and prioritize risks. Estimate likelihood risks occurring to prioritize the plans
		Plan risk responses	Determine actions to address the Risks • Negative – avoid, reduce potential negative impacts • Positive – exploit potential beneficial opportunities • Both – it needs time and budget • Approval risk plans to be gain • Monitor the risks, status, triggers regularly
	Executing	Control and monitor risks	• Introduction of previously unidentified risks to evaluate new risks or any changes with risk analysis process • Have risk plans ready to execute with a change control process
	Closing	Report or close outcomes	• Complete documentation has required • Summarize the outcome of risk effort

Source: MED DEVICE ONLINE (Guest Column | September 12, 2018) Managing Risk For Medical Device Clinical Trials

- We tend to focus on the negative impact of various events, so we cannot make good use of opportunities to improve the project schedule, apply more solutions, and leverage resources.
- We have to understand the ways of communicating to provide an important update for stakeholders.
- Have you ever performed risk analysis for the first time? Create a small table with a few categories at a critical crossroads. Tier 1 first, then Tier 2, then Tier 3. All of the risks should be quantified into ranges of cost increases, schedule delays, and quality impacts.

Probability	Impact risk ranking		
High	Medium	High	High
Medium	Low	Medium	High
Low	Low	Low	Medium

Clinical Study Plan Risk Management

When you are an individual doing a clinical study for development of a new virus diagnostic instrument under the leadership of a project leader at the IVD firm, the purpose of this research is to collect data that could be used to submit an application to the Food and Drug Administration (FDA). So, we are identifying risks to minimise them.

Pre-market

Clinical studies information plays a crucial role in the design validation, verification and implementation of risk mitigation measures. With respect to the medical device type, intended use, and risk classification, and with the aim of supporting device risk analyses, acceptability determinations and post-market surveillance activities.

Post-market

Clinical research/data/evidence is part of monitoring and risk management activities after a drug has been approved for sale. Regulatory expert decisions include clinical evidence, risk benefit analysis, and licensing circumstances.

A key point of medical device clinical studies is the inclusion of this trial information with your evaluation of the risk for product rejection and safety assessment. This tip provided in this article can help clinical trial managers more precisely organise a procedure to meet pre-market and post-market requirements.

The Clinical Trial Manager and Medical Device Product Risk Management

ISO 149714 shows the process of consumer product risk management. Project risk management has the basic components

Clinical Trial Risk Management Considerations

Objective	Managing	Clinical trial examples
Scope	The work requirements and deliverables of the project	Definition of in-scope and out-scope should be documented
Quality	The outcomes and deliverables of project should meet acceptance criteria	Trail outcome and data should not meet acceptance criteria. Analysis handling methods, adequacy of protocols & tools to obtain, manage and verify the data
Time	Schedule	Data willingness to meet 510k submission date. Achieving patient enrollment timings and site engagement
Cost	Budget	Product development or trial risks that could impact on budget.
Resources	People & more	The resources are available at the right time. Not only people but also skill sets like materials, equipment, services and supply chain.

of plan, identify, analyse, control, monitor, and report. ISO focuses on preventing medical accidents caused by product defects.

Example 1: Non-standard of Care Testing with Clinical Study
Sample concludes an experimental study focused on a project end about one of those types of tests.

Identify and Assess:
There are misused assessments, since the places are not used to gathering these assessments and / or outcomes for this category of topic.

Mitigate:
To alleviate this risk, the traditional method is to guarantee personnel involved are educated and qualified properly. Study workers will be qualified on the procedure; however, the prolonged workers of the core laboratory or central laboratory may also have to be qualified. Another option would be to conduct primary on-site observing appointments that include exact attention to the non-standard testing; these appointments would guarantee correct procedure steps were being tracked to collect this data.

Review:
At each site, examinations have to be assessed for the duration of the study for the risk of unused examinations. Some of the projects may not have any problem and if some sites do have problems, additional training and visits may be necessary to address the issues. The sponsor should identify what further competency actions will be required.

In the example given above, we will indeed start by assessing the desired use and potential risks from a variety of sources: performance, and much more.

Possible harm is evaluated in terms of severity and probability (likelihood of occurrence).

Detection accuracy of hazards, situation or events may be introduced to provide crucial information to the risk analysis.

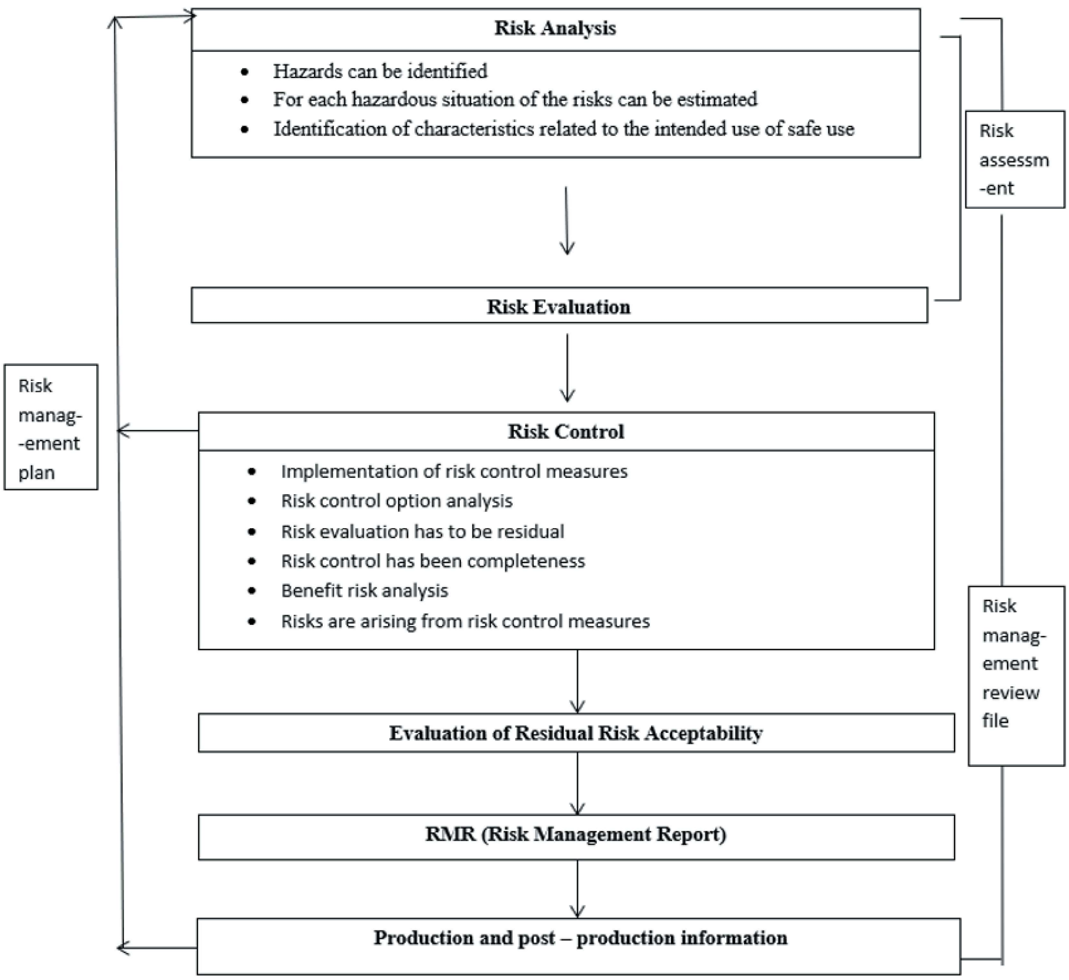
Risk mitigation by design, and preventative measures are put in place when possible within a device. Evaluating a control after its introduction has to be analysed and addressed accordingly, with the assessment of a risk.

Devices are used in diagnosis, in which accuracy must be the primary concern. Product safety management continues for the remainder of the life cycle of the product.

There are various ways the clinical trial manager can positively affect product risk management:

- A crucial part of offering any pharmaceutical product is to collaborate closely with our medical advisers and liaise with the clinical department.
- Test the device both clinically and functionally, and explain how certain user interfaces may cause harms.
- Coordinate with researchers' managers to navigate potential risks and possibilities.

ISO 14971 Medical Device Product Risk Management Process



In Summary

Clinical study managers can effectively control risk for medical device projects by taking a methodical approach. Risk management is necessary for meeting the objectives of medical devices projects. The Food and Drug Administration and European Medicine Agency released guidelines that describe the implementation of the concepts into the scientific experiment process, technique execution and closure of risk management strategies in clinical trials industry. Combining good principles, norms, and excellent behaviours has strong influence on clinical trials that will save time, cash, troubles, and difficulty.

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