

Implemented with PLATO e1ns

The approval of medical products in Europe is subject to numerous regulations. To comply with these regulations, medical technology companies already start planning compliance during the development process and work according to the required standards and directives.

Reducing Damage to People and the Environment

One of the main standards is risk management according to DIN EN ISO 14971. The purpose of this standard is to verify that the benefits of a medical device are greater than its risks. The standard focuses in this case on the reduction of damage to people and the environment, and actions derived from the risk analysis are usually implemented in the form of warnings on the product and training medical personnel so they can react properly. The opportunity to apply technical product optimizations to reduce the frequency with which the causes of such damage arise is often neglected.

Lowering Technical Risks

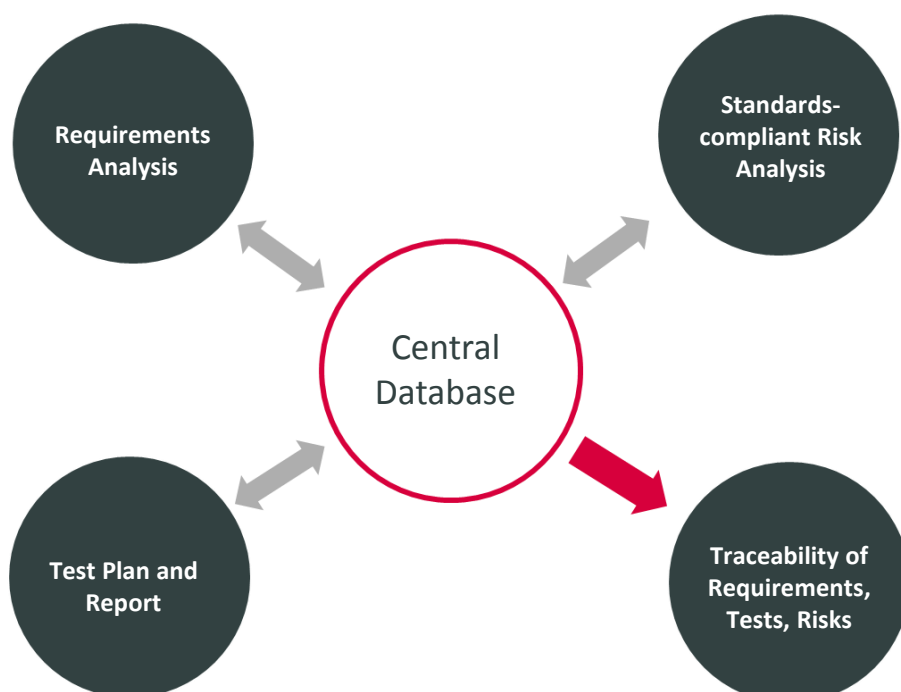
Medical products are becoming more and more complex, and the recall campaigns carried out in recent years show that the "technical risks" factor is becoming more and more important. For this reason, we have also integrated technical risk management into the PLATO e1ns DIN EN ISO 14971 risk management solution in addition to implementing the corresponding standards.

Implementation with PLATO e1ns

PLATO e1ns provides the methods for managing risks during the development phase using a shared data concept (database). Everyone involved in the project therefore has access at all times to the latest data and are also able to edit the data.

PLATO e1ns links the methods and data so that redundant data is eliminated and the time and expense required to propagate changes to the data are a thing of the past.

The Concept



DIN EN ISO 14971 Risk Management

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Your Benefits

- **The integration of risk management** into the development process promotes acceptance in the development team
- **Add/change data** quickly through central administration of the data and analyses
- **Compliance with standards** due to the use of standardized methods
- **Faster approvals** due to the use of standardized layouts for printouts and circulating approvals
- **Effect knowledge management** through evaluations using database queries
- **Certainty** due to the central monitoring of actions

Scope of Delivery

With the PLATO e1ns solution for implementing risk management according to DIN EN ISO 14971, you have a portfolio of networked methods forms on a single platform.

Method forms

- Questionnaire according to DIN EN ISO 14971, Appendix C
- Requirements analysis
- Test plan and report
- Risk analysis
- Traceability

Supplemental Methods and Modules

As an option, you can also expand your DIN EN ISO 14971 Risk Management solution package by adding the following methods and modules, and thus obtain new functions.

Methods

- HACCP
- Control Plan

Modules

- e1ns.actions
- e1ns.documents