Including risk as a component in clinical trial monitoring efforts is encouraged by the FDA & EMA since 2013. Between 25 and 30% of trial total budget is spent on monitoring, leading more and more sponsors and CROs to considering the potential in decreasing monitoring costs and hours spent significantly by applying a risk-based approach to study monitoring. However, which data items should be monitored under which conditions is a difficult decision to make and its reasoning needs to be sound and done carefully.

According to the FDA, RBM is a combination of strategies and plans for monitoring, including the risk evaluation in clinical trial management. Different strategies include and are not mutually exclusive:

1. Centralized monitoring
2. Remote monitoring
3. Reduced monitoring
4. Triggered monitoring

For each part of this, tools can enable and empower the stakeholders in the trial. In some cases, the tools available can even determine how worthwhile it is to apply specific RBM approaches. We’ve found that there is a correlation between how comfortable trial management feels with working with and analyzing data, and how much trial stakeholders rely on the tool providers to provide RBM strategies.

Regardless of where stakeholders for different trials fall on that scale, we’ve found that it is essential that the RBM strategies are (1) clearly defined and (2) a shared understanding is created between the sponsor, trial management, and providers. Without this, it is very likely that several issues will happen, threatening the viability of RBM strategies – and in some cases, result in abandonment of the application of most risk-based strategies, usually in the face of impending deadlines.

In this talk, we will discuss what Risk Based Monitoring means in reality, which critical values we’ve found essential in stakeholders to be successful, and what the potential pitfalls are which seem to impede the process to apply Risk Based Monitoring – from a provider’s perspective.

Furthermore, we will show how at Clincase we’re empowering our users supporting RBM and where we see further improvement can have a great impact on RBM, and therefore trial success.