

Kayentis

Dedicated to eCOA and patient engagement

Improve your Risk-based Monitoring with eCOA solutions!

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High-frequency on-site monitoring with 100% source data verification does not necessarily improve data quality. New solutions are available to improve data quality efficiently.

What about FDA and EMA recommendations?

Since 2013, FDA and EMA have proposed considerations for a new monitoring approach, namely risk-based monitoring (RBM). The main objective is to increase data quality by increasing monitoring efficiency. Although on-site monitoring remains relevant, the importance of off-site and centralized monitoring has grown.

These new methods of monitoring are facilitated by the use of electronic case report forms and by democratization.

The role of eCOA providers in risk-based monitoring

While all stakeholders in a clinical study can contribute to the Sponsor's risk-based monitoring, eCOA providers have a particularly important role due to the variety of information sources at their disposal as outlined below:

- Sharing of information to improve the quality of data collected through devices (e.g. ePROs, ClinPROs, eDiaries) and the quality of the monitoring of these data. In particular, the sharing of metrics and other data management (DM) data.
- Sharing of information to limit potential problems at critical points of a study (e.g. at baseline, randomization).
- Sharing of information relating to support activities and logistics.
- Sharing of information to limit potential problems linked to mis-use of eCOA solutions (e.g. education of study site personnel, CRAs, and sponsors).
- Sharing of information that is relevant for the users.

'Sharing is improving, sharing to increase success'

This information is all the more valuable since it can be combined by the eCOA provider into a single tool that allows it to be shared between the different

stakeholders and sponsors in real time.

As a member of the Metrics Champion Consortium (MCC) and with an extensive experience in eCOA studies, Kayentis can offer a well-designed interface according to sponsors' requirements. In this way Kayentis can help sponsors develop a risk-based monitoring policy.

[Click here to know more about our solution allowing risk-based monitoring strategy](#)

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