“RBQM is the next RBM” (Abstract)

“Risk-Based Quality Management concept is the whole system not just the last component of monitoring” began his speech on July 17, 2019, the FDA’s Director David Burrow in the Robert J. Margolis Center for Health Policy at Duke University. His main points were:

- Risk assessment is the foundation of an effective RBM plan.
- The goal of RBM is “To avoid errors that matter”

Poor clinical trial data can be a reason for issuing a request for additional information from FDA or recommendation of a third-party audit. There are two categories of FDA’s recommendations: passive (acknowledging the reliability of the submitted data) and active (requiring an enhanced review).

EMA Scientific Administrator Camelia Mihaescu explains, “How do we build quality into a clinical trial”? It could be implemented using the approach of Quality by Design (QbD):

- Quality is designed into the study protocol and processes at the very beginning
- Focus on critical to quality factors to ensure the protection of study subjects and data reliability
- Correct management of the risks related to the critical to quality factors (e.g. implementing an RBQM system).

Camelia Mihaescu pointed out that risks in a clinical trial should always be considered at two levels:

- trial level (investigational medicinal products, trial design, etc.)
- system level (facilities, SOP, computer system, etc.)

Summing up, FDA and EMA point to the concept of quality in clinical trials and implementation of this concept in RBM. They stress that focus must be put on the overall Risk-based approach to quality management rather than just Risk-based Monitoring. The proactive approach of RBQM ensures the predictive success of clinical trials.