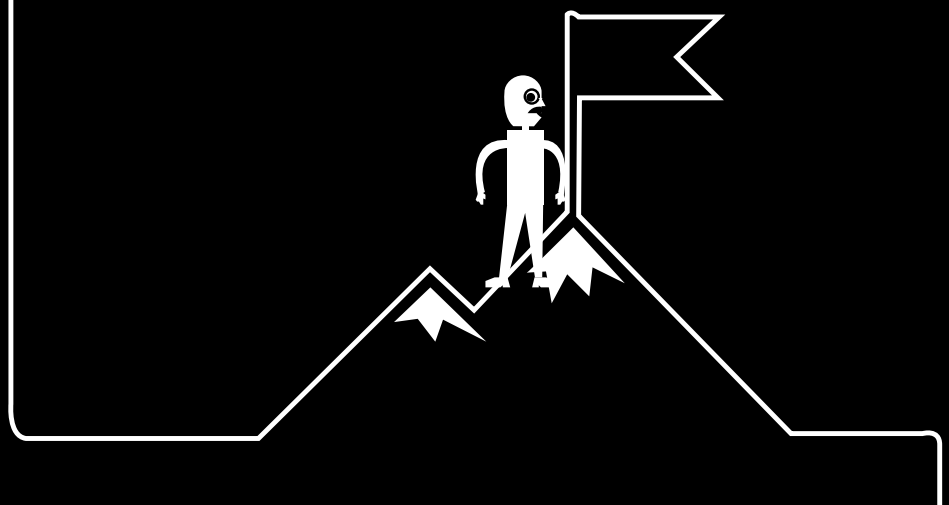
THE EVOLUTION

OF RISK-BASED MONITORING

Increasingly sophisticated EDC capabilities, declining R&D productivity, and new regulatory guidance combined to create the ideal time to implement Risk-Based Monitoring. In this infographic, ISR explores the events that have shaped the adoption of RBM.

1 FIRST USE.

The increased use of electronic data capture, combined with the patent cliff and declining R&D productivity forces pharma to look at ways to cut costs and increase efficiency. As early as 2010, pharma companies and CROs begin to use risk-based monitoring approaches to clinical trials.



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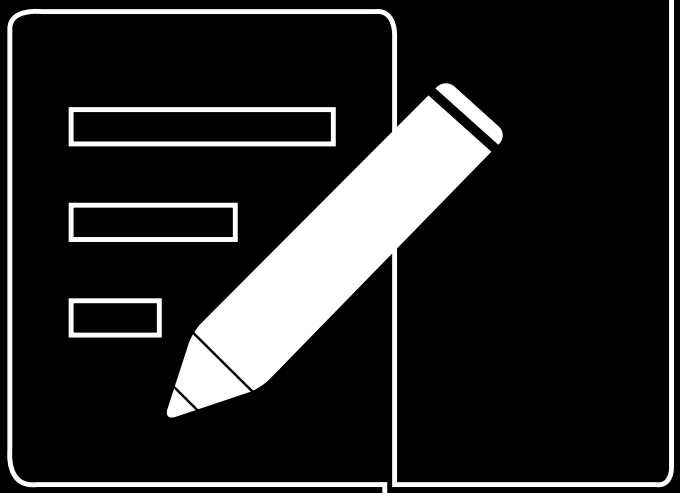
REGULATORY DRAFT GUIDANCE.

In response to the increased use of RBM, the FDA issues draft guidance on alternative drug development models and processes. The 2011 draft acknowledges that one size doesn't fit all when it comes to clinical trials. Instead, the FDA recommends a tailored approach that combines both on-site and centralized monitoring along with real-time access to data.

Also in 2011, the EMA releases a reflection paper on RBM. The paper opens a discussion on the new standard of RBM and favors a preventative approach to trial management rather than a reactive one.



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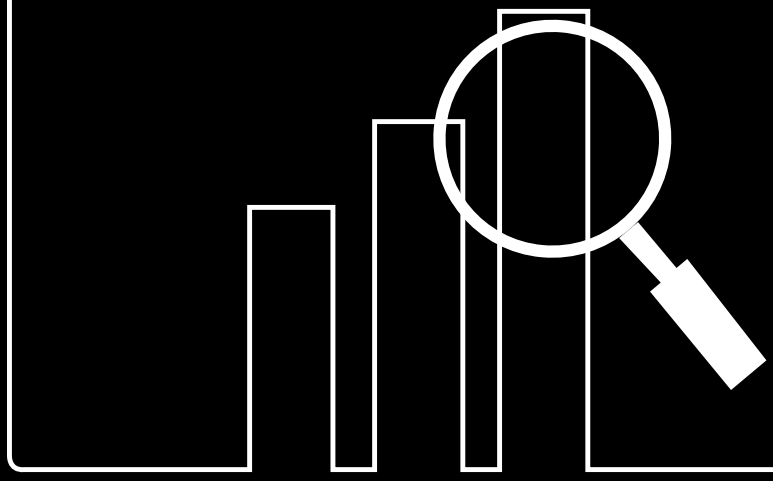
ISR'S RESEARCH REPORT.

Industry Standard Research releases its "Risk-based Monitoring: Industry Guidance on Adoption, Use, and Outsourcing" report, which provides peer-based guidance from 78 industry experts. 72% of these respondents say their companies saved money using RBM.



TRANSCELERATE POSITION PAPER.

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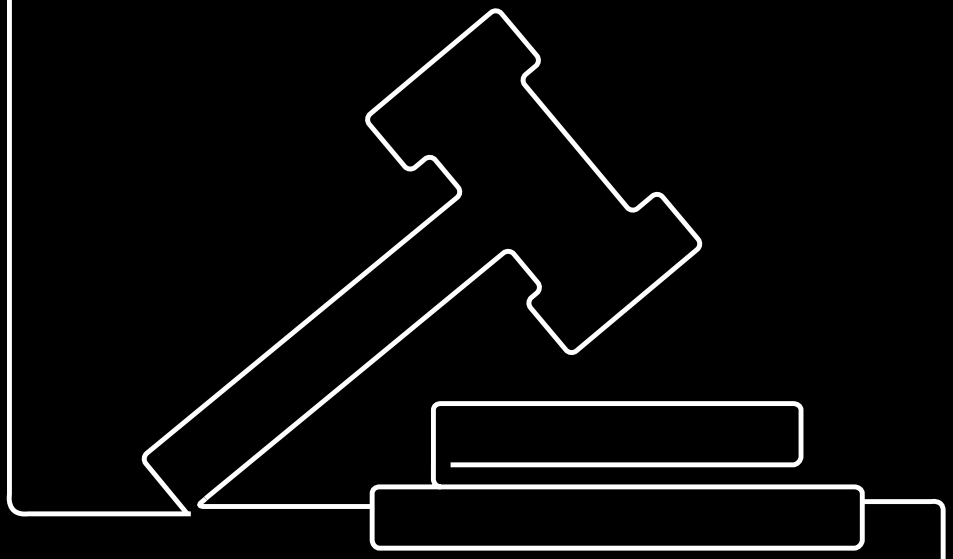
TransCelerate BioPharma, a non-profit organization comprised of R&D executives, releases an original position paper outlining a methodology for risk-based site monitoring in June 2013.

5

FINAL REGULATORY GUIDANCE.

In August 2013, the FDA releases final guidance on RBM. The document encourages sponsors to take a more proactive approach to clinical development to ensure compliance and mitigate risks.

In November 2013, the EMA publishes guidance on RBM. The paper claims that the goal of RBM is to protect trial participants' safety and well-being, as well as to ensure the quality of data.



MORE TRANSCELERATE GUIDANCE.

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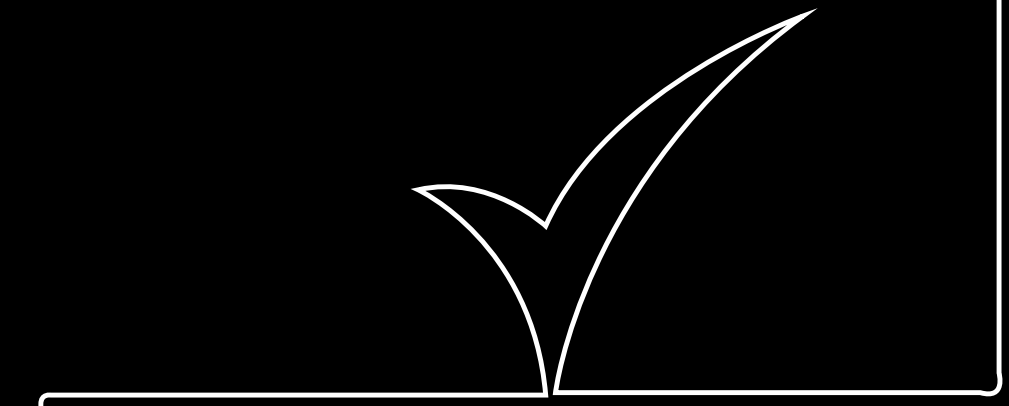
In two new papers published in September 2014, TransCelerate provides in-depth insights into central monitoring and technology enablement, and provides lessons learned from ongoing clinical studies using RBM methodology.



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WHAT WILL 2015 BRING?

ISR will release two new reports on RBM in 2015 which will cover industry trends and changing RBM implementation and methodology. Join our mailing list to be the first to access these reports.

Sources: ISR Reports, Applied Clinical Trials, TransCelerate Biopharma, Inc, FDA

ISR reports

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