THE NEW PARADIGMS IN CLINICAL TRIALS

Quality Risk Assessment (RBM) &
electronic Informed Consent (eIC)

EXOM GROUP

DEFINITION OF RISK

"The combination of the probability of occurrence of harm and the severity of that harm"

(ICH Q9 and ISO/IEC Guide 51)

ASSESSMENT OF RISK

What can go wrong?
The risk

How bad are the consequences?
The severity

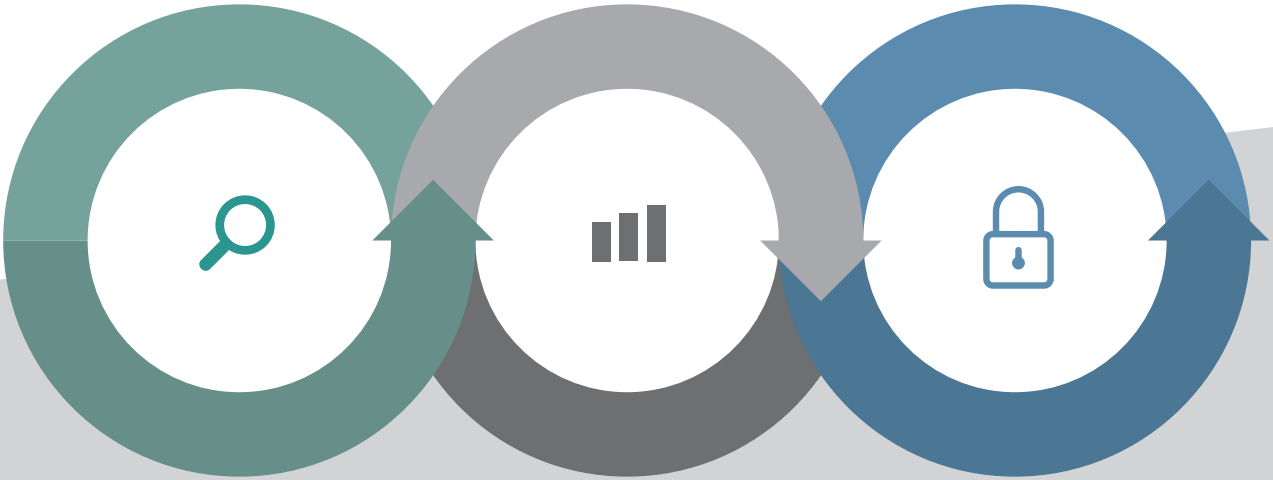
How often does/will it happen?
The probability of occurrence

If it happened, how would we know?
The likelihood of detection

Is the risk acceptable?
The risk evaluation and remediation

Genius RIBAM™

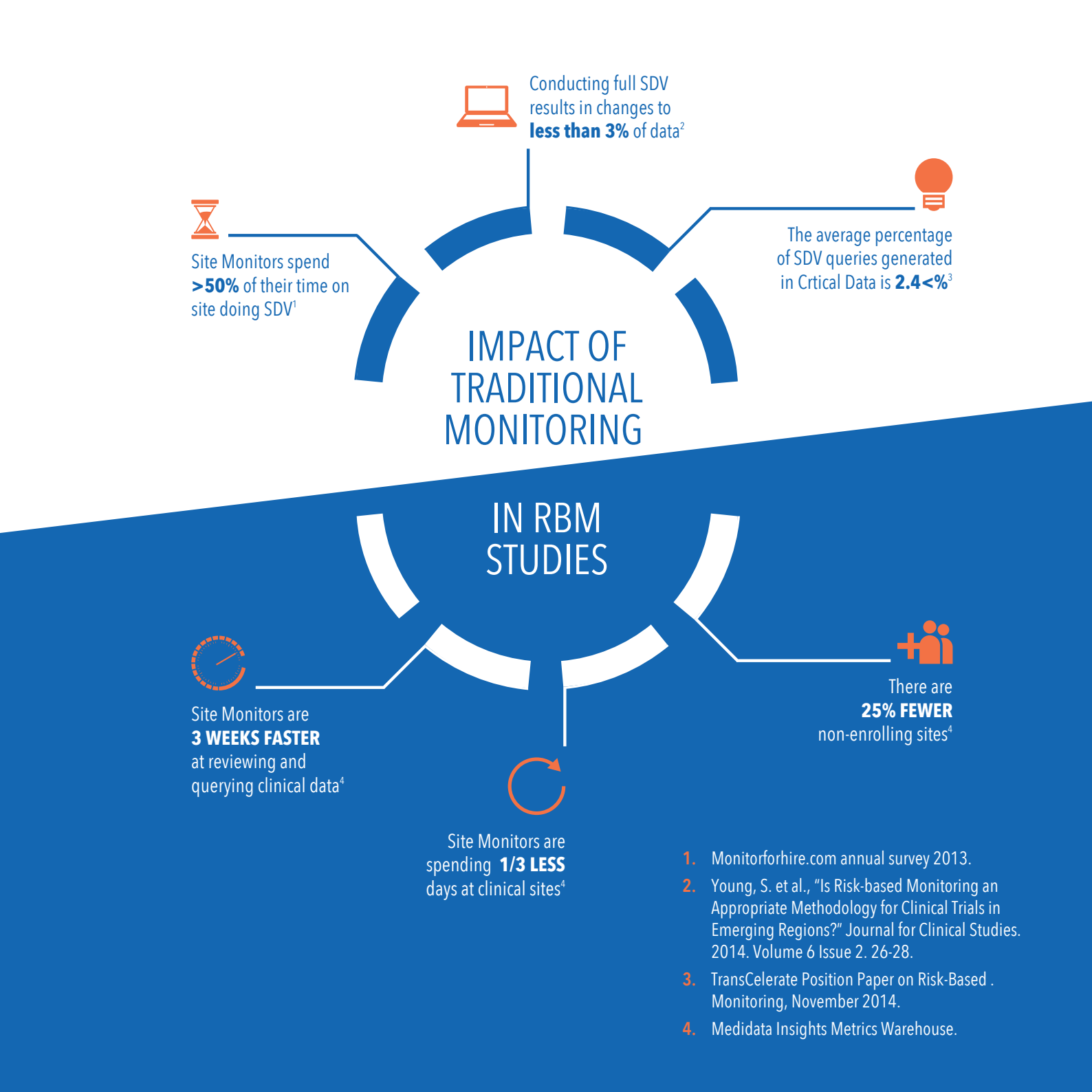
The Quality Risk Management & Monitoring Solution



Analyzes essential risks for patient's safety and data integrity and adjust monitoring strategy accordingly

Expands the concepts of risk-based monitoring to optimize your trial execution

Assures the full compliance of your trials with the new GCP E6 (R2)



1. Monitorforhire.com annual survey 2013.
2. Young, S. et al., "Is Risk-based Monitoring an Appropriate Methodology for Clinical Trials in Emerging Regions?" Journal for Clinical Studies. 2014. Volume 6 Issue 2. 26-28.
3. TransCelerate Position Paper on Risk-Based . Monitoring, November 2014.
4. Medidata Insights Metrics Warehouse.

The electronic Informed Consent

INFORMED CONSENT PROCESS
RETENTION IMPACT

	OVERALL	DROPPED OUT, N=260	COMPLETED, N=1,326
It was "Somewhat/Very Difficult" to understand the ICF	19%	35%	16%
After reading the ICF, the purpose of the study was "Not Very/Not at all Clear"*	5%	14%	2%
"Not Very/Not at all Satisfied" questions were answered during IC review*	4%	12%	1%
I did not understand parts of the stydy after ICF review*	12%	21%	11%

* Dropped Out vs. Completed significantly different at $P<0.05$

The results of a CISCRP study measuring the effects of dissatisfaction with the informed consent process on patient retention.

Genius ENGAGE™

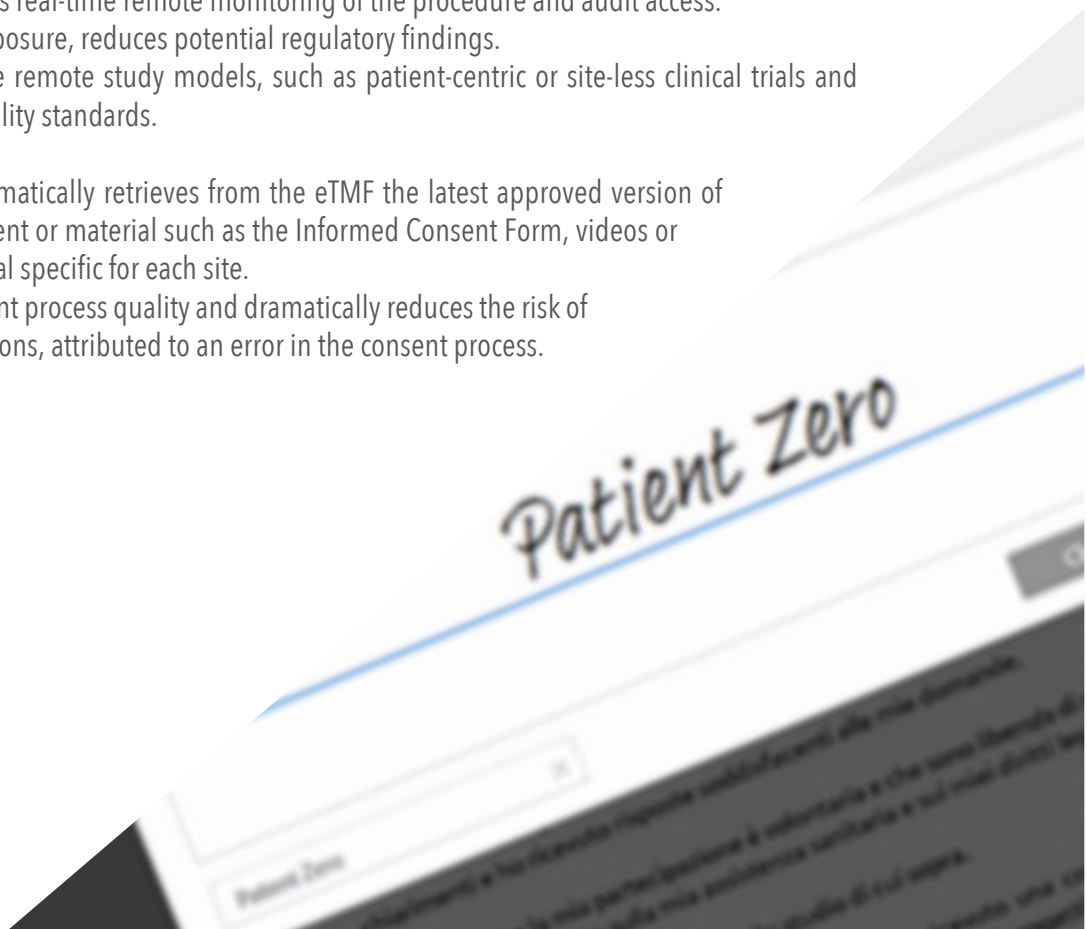
The electronic Informed Consent

Informed consent is a core prerequisite for enrolling any person in a clinical trial.

- Genius ENGAGE™ (GE) is a mobile App to support patient and investigator in the whole workflow from reviewing the content of the consent form, assessing the understanding through a questionnaire up to signing the ICF.

- Genius ENGAGE™ allows real-time remote monitoring of the procedure and audit access.
  This minimizes legal exposure, reduces potential regulatory findings.
  Ultimately it will enable remote study models, such as patient-centric or site-less clinical trials and potentially sets new quality standards.

- Genius ENGAGE™ automatically retrieves from the eTMF the latest approved version of any appropriate document or material such as the Informed Consent Form, videos or other supportive material specific for each site.
  This improves the consent process quality and dramatically reduces the risk of findings during inspections, attributed to an error in the consent process.



eCONSENT BENEFITS

Improves patient comprehension and retention by 30%

Increases patient satisfaction by 42%

Reduces dropout rates by 36%

Reduces recruitment needs by 25%

With recruitment costs 1/3 of total trial costs, 36% reduction results in astronomical savings

OUR HUMAN & DIGITAL OFFERS

We provide

cloud technological solutions & value-added services for clinical development of drugs & medical devices.

We manage

each study through a dedicated tablet and an integrated multi-modular cloud & mobile platform (Genius Suite™), to enable real-time and on-line management of any clinical trial operation.

We combine

the strong medical, regulatory and operational expertise of our staff, with the most disruptive digital cloud technological solutions to reduce costs and increase quality and performance of your Clinical Trial.

We partner

with those Life Sciences companies who recognize that implementing digital solutions is not as simple as installing new technologies but really a fundamental change in the way they do clinical drug development.

Study feasibility

Clinical trial applications

Global study management

Site monitoring

Data management

Statistics

Pharmacovigilance & medical monitoring

Medical writing

Quality risk management & assurance

Clinical supplies management

OUR VALUE-ADDED CRO SERVICES

OUR STAFF
& PARTNERS

- Documented and significant experience in oncology clinical trials
- Appropriate education and regular trainings on Exom's procedures and technologies
- Passion for quality and performance through digital innovation of working pocesses
- Regular assessment by KPIs of workload, performance and quality
- All study documents and data centralized on cloud server repositories

GLOBAL REACH

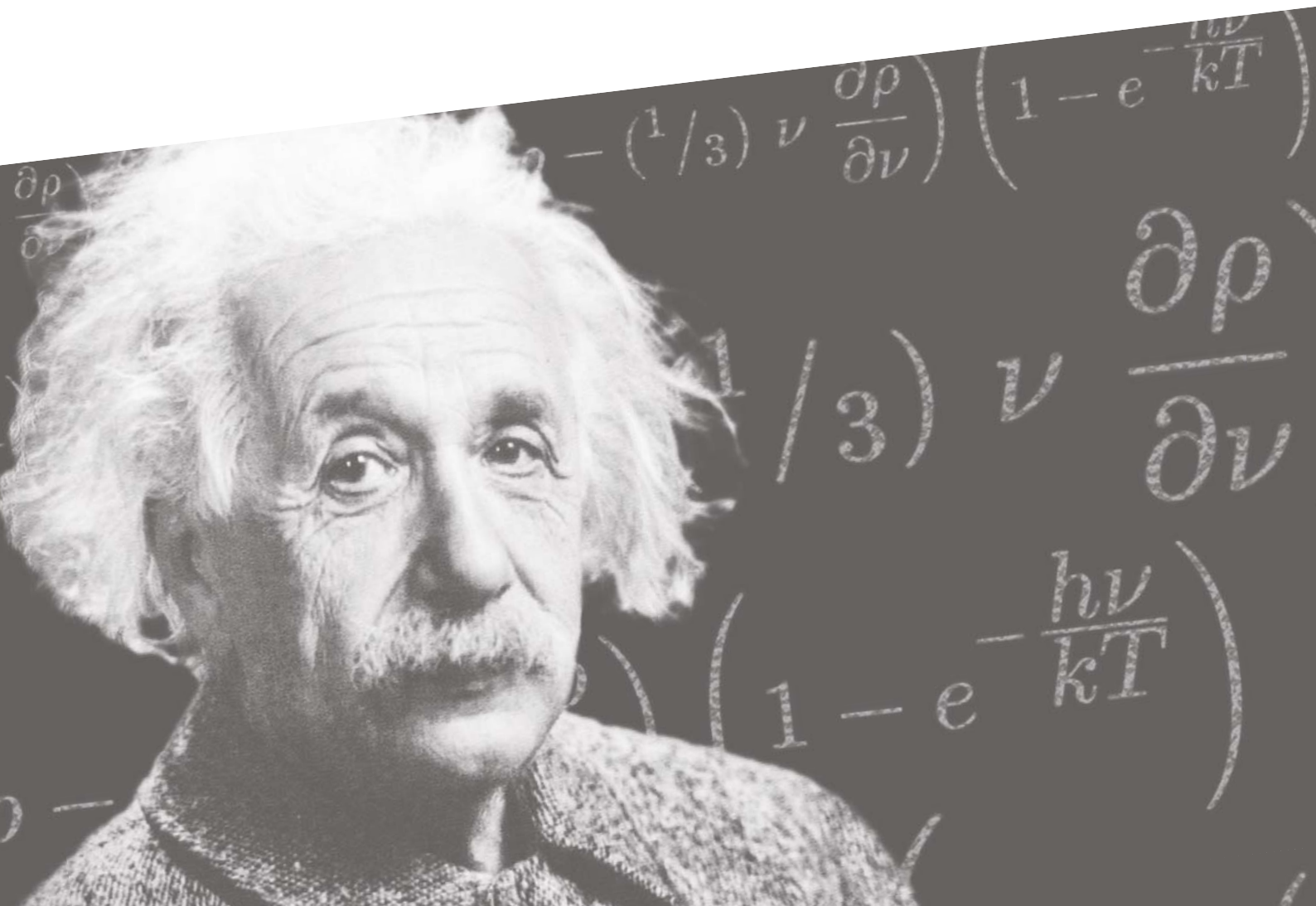
Exom Alliance provides an established organization active across the whole of **Europe and USA**

WHY WORKING WITH US?

- Medical, Regulatory & Operational expertise and experience
- Reliable people, you can count on
- Disruptive Digital Technology that enables higher quality, performance and transparency
- Flexibility and dedication of a medium-size CRO
- Clinical trials in Europe & USA
- Competitive service prices
- Risk Sharing agreement

We shall not expect that things will change...
if we keep doing the same things!

(Albert Einstein)



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