THE NEW PARADIGMS IN CLINICAL TRIALS

Quality Risk Assessment (RBM) & electronic Informed Consent (eIC)
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)
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)
Site Monitors spend >50% of their time on site doing SDV\(^1\)

Conducting full SDV results in changes to **less than 3%** of data\(^2\)

The average percentage of SDV queries generated in Critical Data is **2.4<%**\(^3\)

Site Monitors spend >50% of their time on site doing SDV\(^1\)

Site Monitors are **3 WEEKS FASTER** at reviewing and querying clinical data\(^4\)

There are **25% FEWER** non-enrolling sites\(^4\)

The electronic Informed Consent
**INFORMED CONSENT PROCESS RETENTION IMPACT**

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Dropped Out, N=260</th>
<th>Completed, N=1,326</th>
</tr>
</thead>
<tbody>
<tr>
<td>It was “Somewhat/Very Difficult” to understand the ICF</td>
<td>19%</td>
<td>35%</td>
<td>16%</td>
</tr>
<tr>
<td>After reading the ICF, the purpose of the study was “Not Very/Not at all Clear”*</td>
<td>5%</td>
<td>14%</td>
<td>2%</td>
</tr>
<tr>
<td>“Not Very/Not at all Satisfied” questions were answered during IC review*</td>
<td>4%</td>
<td>12%</td>
<td>1%</td>
</tr>
<tr>
<td>I did not understand parts of the study after ICF review*</td>
<td>12%</td>
<td>21%</td>
<td>11%</td>
</tr>
</tbody>
</table>

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

The results of a CISCRRP study measuring the effects of dissatisfaction with the informed consent process on patient retention.
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
We provide cloud technological solutions & value-added services for clinical development of drugs & medical devices.

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 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 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 processes
- 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)