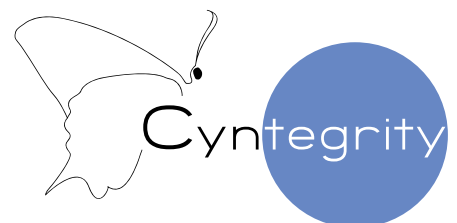
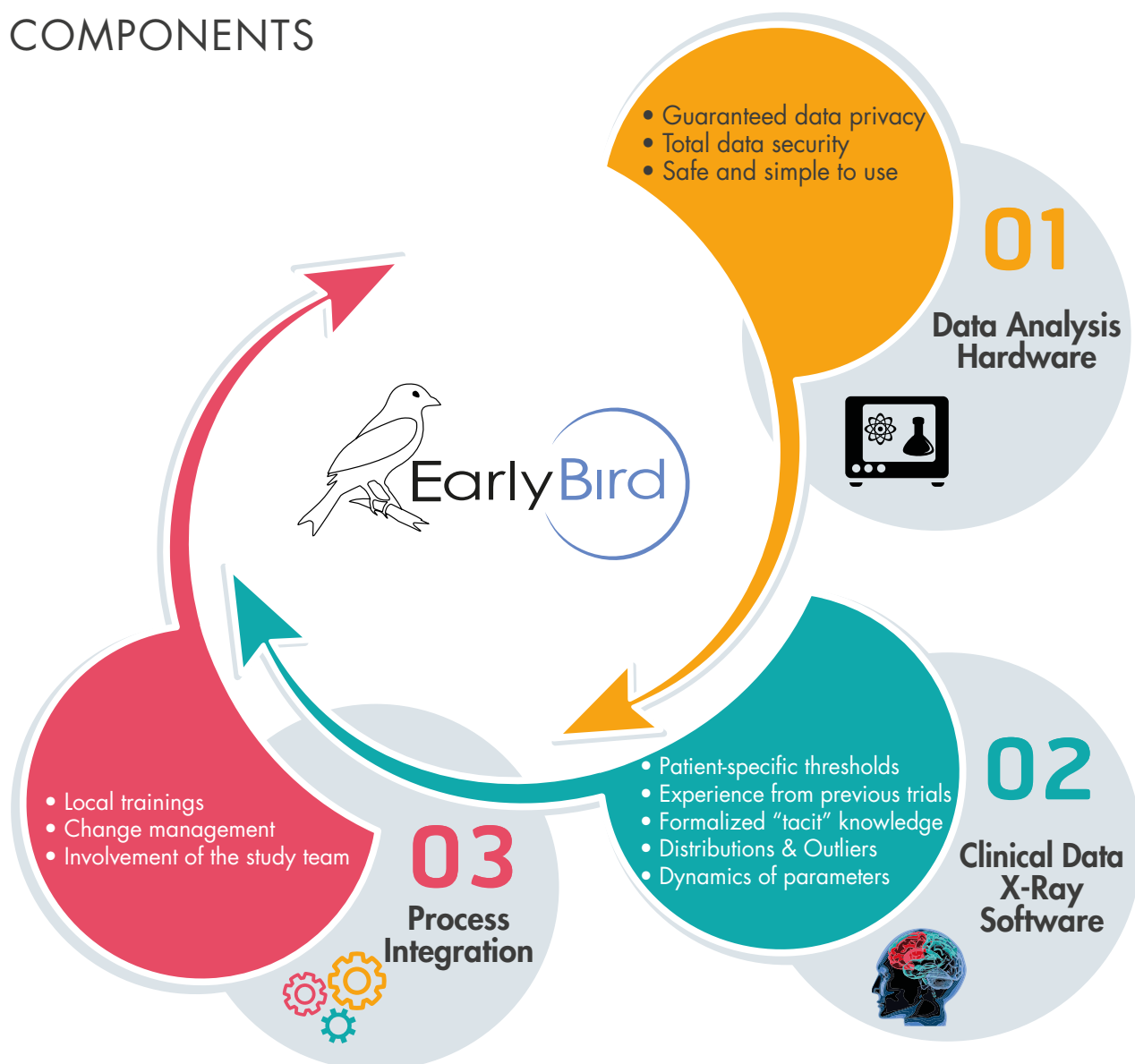


EarlyBird® Solution for Risk-based Monitoring



COMPONENTS



ADVANTAGES FOR YOUR TRIAL

Risk Profile of Clinical Sites. Based on accumulated parameters from previous clinical trials, EarlyBird® categorizes sites into low, medium and high risk sites.

Dynamics of Risks in Your Trial. How has a risk developed since last month? You can see the risk dynamics on EarlyBird® interactive charts and react fast on approaching issues.

Improved Statistical Significance. Continuous data quality control reduces "data noise" in a clinical trial, makes confidence intervals narrow and improves chances to reach statistical significance.

Monitoring Cost Reduction. Tailoring monitoring to identified risks reduces the number of costly on-site monitoring visits and saves you 25-28% of monitoring budget while keeping the same quality. A structured monitoring approach allows a CRA to skip repetitive tasks, which makes her/his work more efficient. [Source: PWC 2013, Risk-based monitoring: Reduce clinical trial costs while protecting safety and quality]

Better Clinical Results. EarlyBird® equips you with corrective and preventive actions (CAPA principle). Your team has the whole information to react on pain zones. All activities are tracked automatically and can be used as a great support during audits.

EarlyBird® RBM Dashboard

NEW: Private *Cloud* Solution



HOW YOU GET IT?

EarlyBird® is available in two options:

- SaaS Product: that requires no IT infrastructure, is accessible from any browser and is cost effective and scalable for any number of clinical trials
- On-premise software: installed on your server(s) and guarantees ultimate data security

KEY DIFFERENTIATORS

Intuitive. Quick Learning Curve. Simplified Presentation.

EarlyBird® is a Risk-based Monitoring system that was designed for non-statisticians. You do not need to read manuals to learn it. It is self-explaining. Its user-friendly design hides the complexity behind the scenes.

Flexible. Customizable. Fast Deployment.

Thanks to data abstraction layer EarlyBird® can be customized and deployed just in a few days. EarlyBird® can integrate all your information: starting from clinical databases up to Excel spreadsheet.

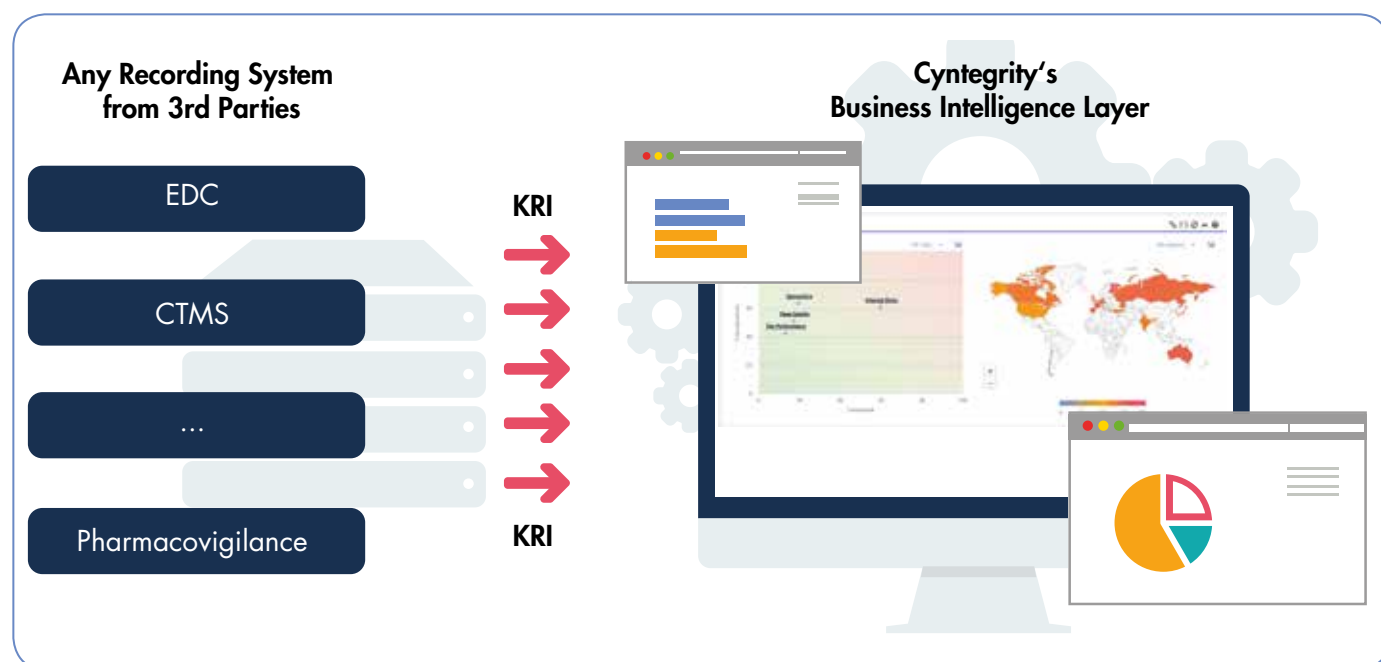
Proven. Based on Real Clinical Data.

EarlyBird® was developed based on the long years of experience in electronic data capture and clinical data quality. The system is compliant with CFR 21 part 11.

Innovative. New Approach in Risk-based Monitoring.

EarlyBird® provides you with the most advanced approach of constant statistical data surveillance and offers an evidence based methodology in Risk-based Monitoring.

KEY RISK INDICATOR SOURCES



PRODUCT FEATURES

Interactive user interface for a variety of capabilities such as clinical data quality check, data driven risk management, overview of risk development, geographical risk spread and site-to-site comparison.

- Continuous clinical data quality check
- Risk development and geographical spread
- Site-to-site comparison by risk type
- Actionable risk mitigation to-do plan for a CRA
- Consolidated actions in "tickets"
- Site rank with report and search possibility
- Detailed site risk profiles

The Simplest Solution for Efficient Risk-based Monitoring

WHO USES IT?

Sponsors, CROs, and service providers aiming to deliver highest data quality and manage a trial in the most efficient way. Managers, regardless of their location or organization. EarlyBird® provides in-stream data intelligence to:

- Site and Central Monitors and Central CRAs
- Project Managers
- Project Directors
- Tech Support



HessenAgentur

HA Hessen Agentur GmbH

Winner of "Model Project" award of the German region Hessen with the project "Process Innovation in Clinical Trials Monitoring" (2014)

OUR RESEARCH PARTNERS:



ANY TIME AND ANYWHERE

Effective Communication and Knowledge Sharing within Team and among Trial Groups



STAY MOBILE

Tablet and Smartphone ready - MAC OS and Android



KEY FEATURES

Easy “Plug and Play”. Data abstraction layer makes EarlyBird® independent from a variety of your internal data standards.

Constant Data Quality Control. EarlyBird® constantly monitors: data normality, distributions, outliers and inliers analysis.

Control Risk Dynamics. Follow the risk development over the recent time period with EarlyBird®’s dynamic charts.

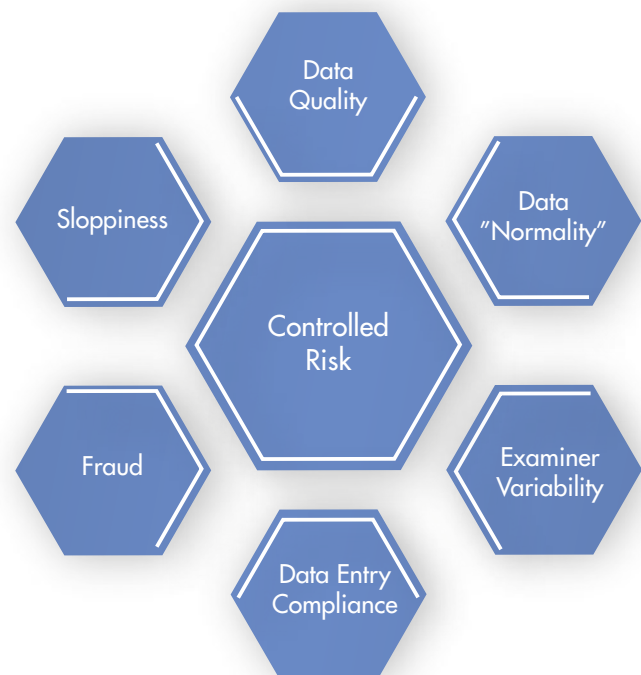
Geographic Risk Spread Localization. Plan next trainings or visits considering a geographic localization of the high risks centers.

Extend Your Capabilities. We help you to customize your own indicators for risk monitoring to control your specific parameters.

Full Control Over Your Trial. The EarlyBird® data quality module provides tools that control the operational activity of your trial.

Comply with Fast-Evolving Regulatory Environment. Add the efficient Risk-based Monitoring process and be compliant with FDA and EMA guidance.

Ad-hoc Clinical Data Reports. EarlyBird® offers you a number of ad-hoc risk and quality reports.



“Risk varies inversely with knowledge.”

Irving Fisher (1867-1947)

Cyntegrity Insights

WHY "EARLY BIRD"?

The inspiration we got from the canary birds, which were regularly used in coal mining as an "early warning system". Historically, numerous industries have used a variety of methods to obtain early warning signs of potential future problems. One of the most well known of these is the canary that miners would bring into the mine with them. The idea was that an ailing canary was an early warning signal of the invisible, but deadly, poisonous fumes. Only at their peril did miners ignore a sick or dead canary.

Today, the system EarlyBird®, like a canary bird in older times, can detect early warning signs and save clinical trial integrity.



CYNTEGRITY = CLINICAL + INTEGRITY

We are a team with expertise in data analysis and software, driven by the idea of clean medical data.

We believe that only a standardized data care approach can guarantee a valid scientific evidence for regulatory approval.

We believe that people's trust in approved medicines is the foundation for a new drug discovery.

We believe that any medicine that we use for ourselves or our relatives must be clinically proven in the most genuine scientific way.

VISION AND MISSION

Our mission is to apply innovative approach to drive quality improvements in clinical research.

Our vision of clinical data monitoring consists of three main aspects:

- Control of the data quality
- Application of the latest data mining methods to gain new knowledge
- Development of a risk-based strategy for trial cost reduction



Scan the QR code to add
Cyntegrity to your contacts

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