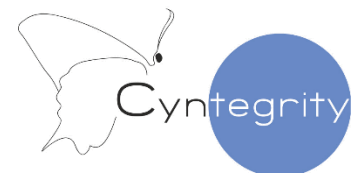


Why Pharmaceutical Clinical Trials Struggle to Succeed?

Cyntegrity's Presentation for Potential Investors

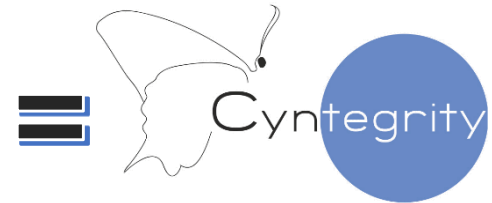
Artem Andrianov, PhD, MBA

Cyntegrity, 2015



WHO ARE WE?

WHO ARE WE?



- Team with 10+ years of experience in clinical data analysis
- 20+ analyzed clinical trials
- Over 100+ supported clinical trials for big pharma
- OverRead(Central Lab) and Data Cleaning services
- Scientific research together with academia
- Partnerships with local and global CROs

OUR STRATEGY



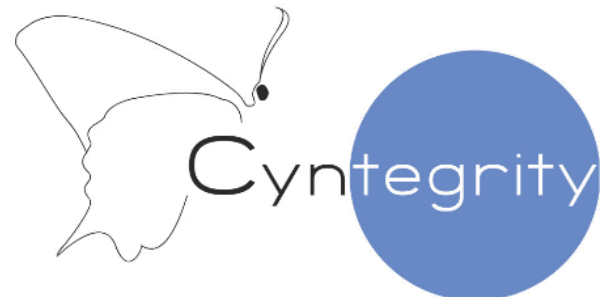
Our Partners and Customers in RbM already



German Government Research Funding

Cyntegrity - winner of the Hessen Model-Project
Funding with the Project
“Process Innovation in Clinical Trial Monitoring”

HESSEN

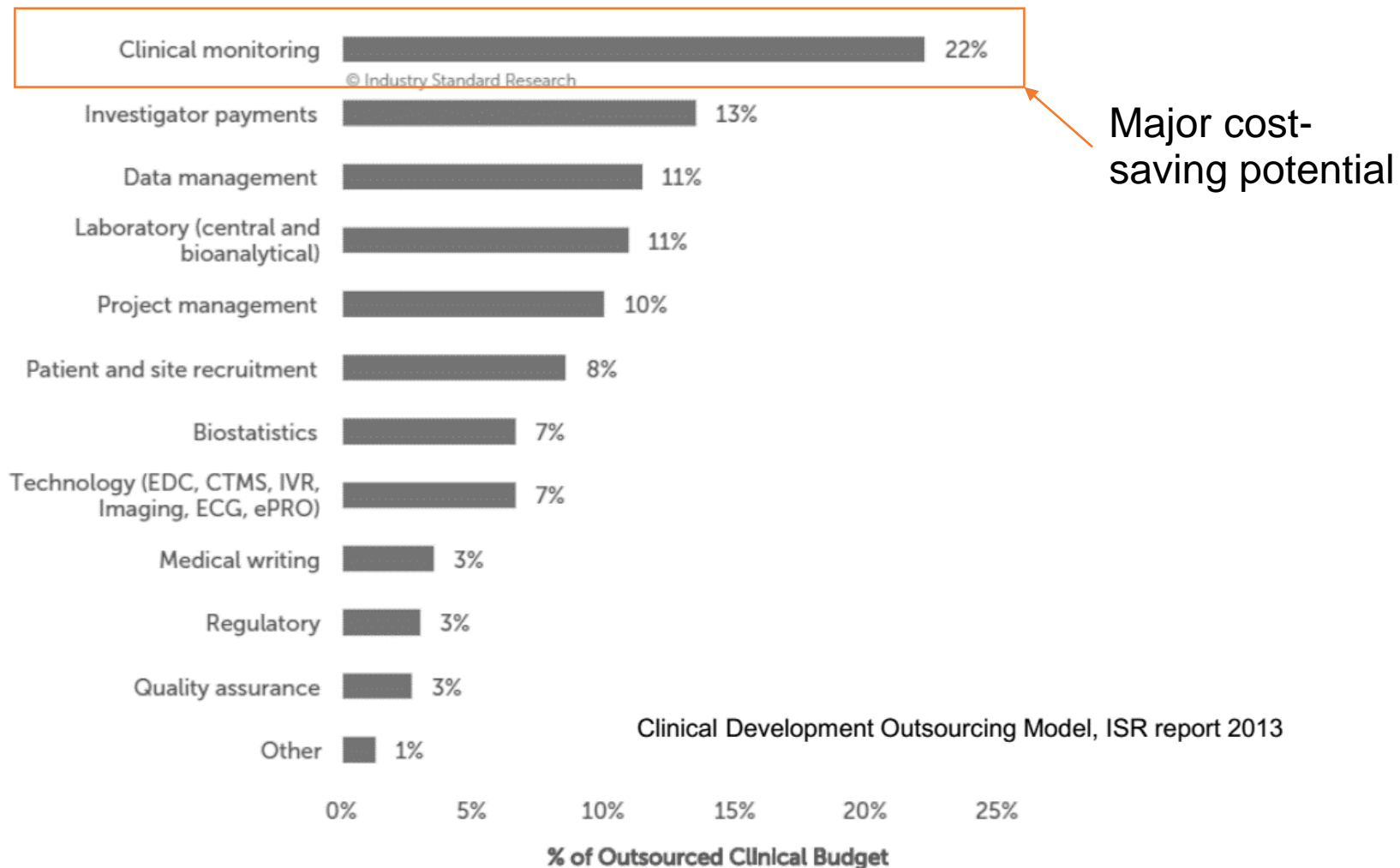


LOEWE

Exzellente Forschung für
Hessens Zukunft

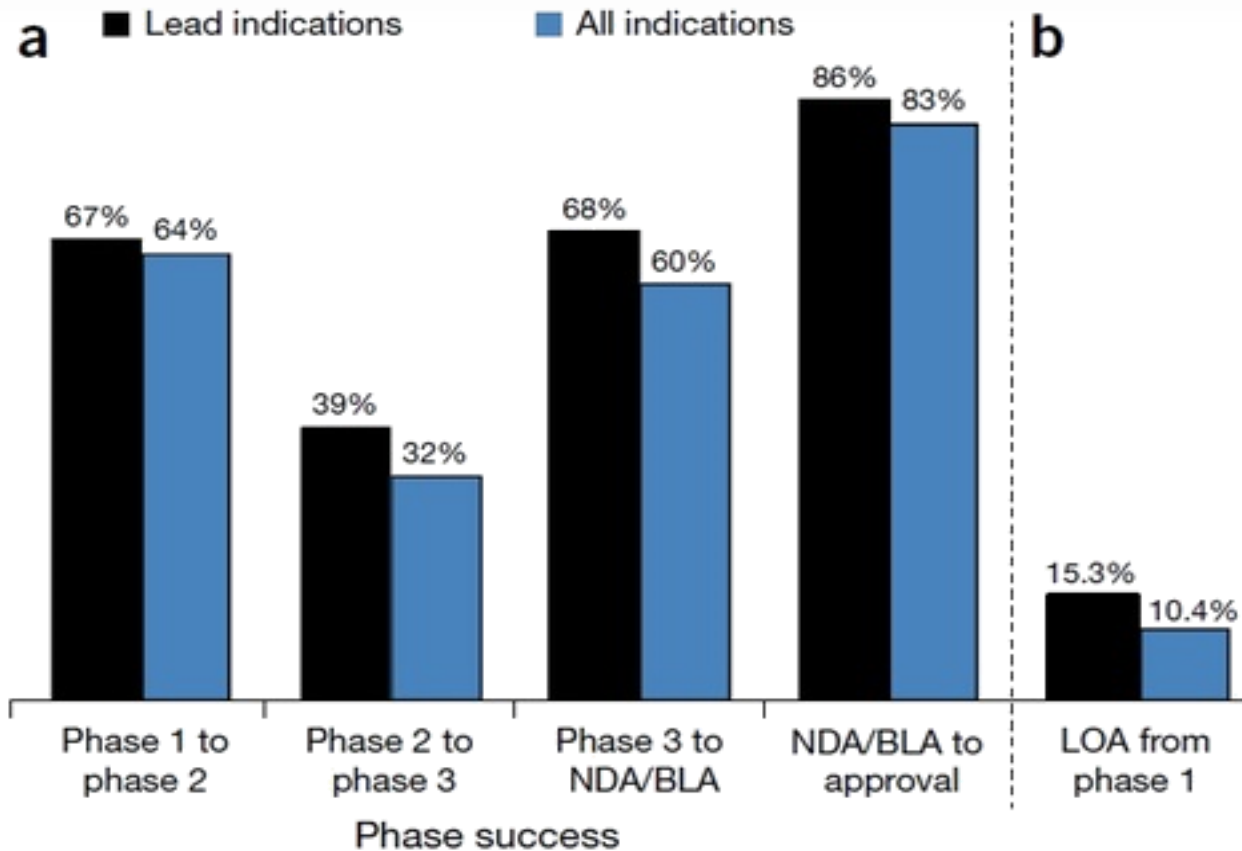
WHAT PROBLEM WE TACKLE?

Cost of Outsourcing by Function In Clinical Research



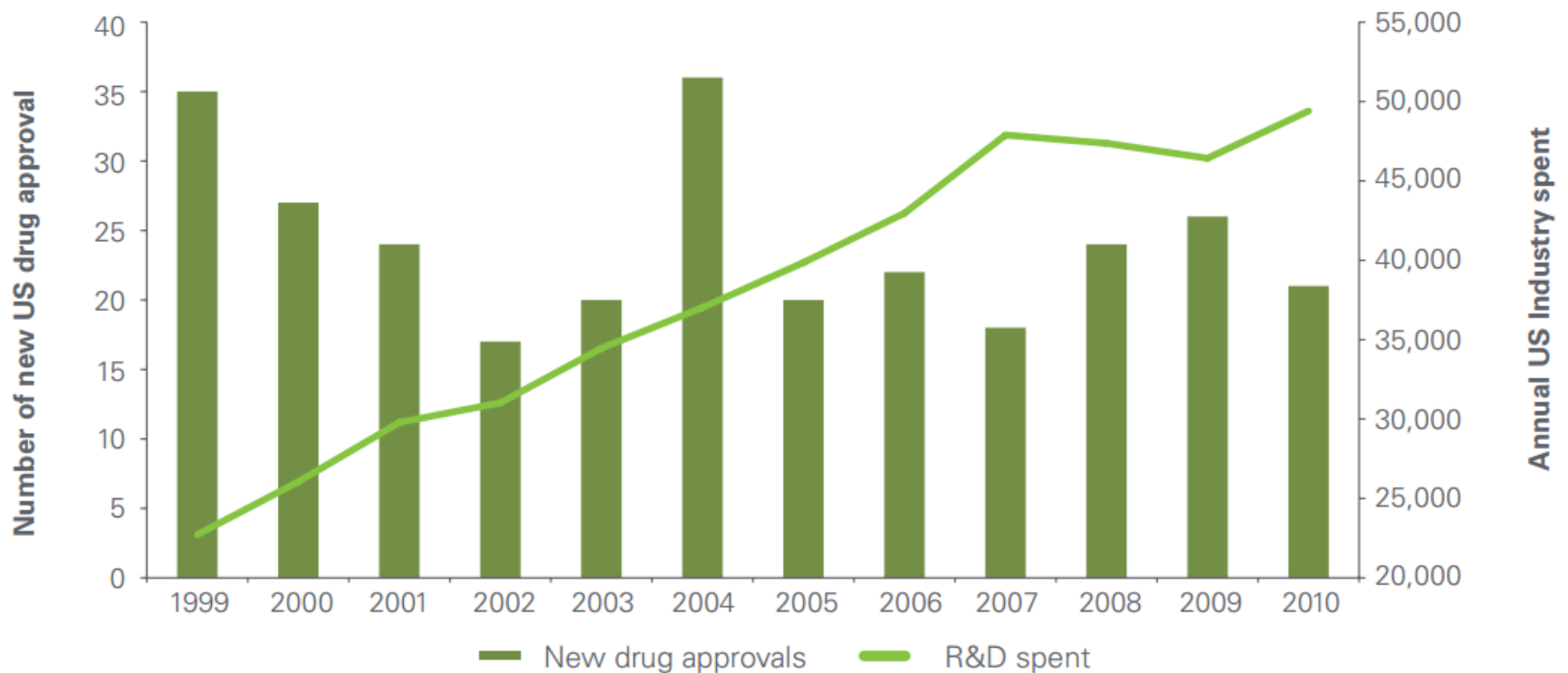
FDA Success by Phase

(LOA=Likelihood Of Approval)



Consequence: Budget and regulatory pressure
Cost optimization is needed!

Clinical Trial Challenges

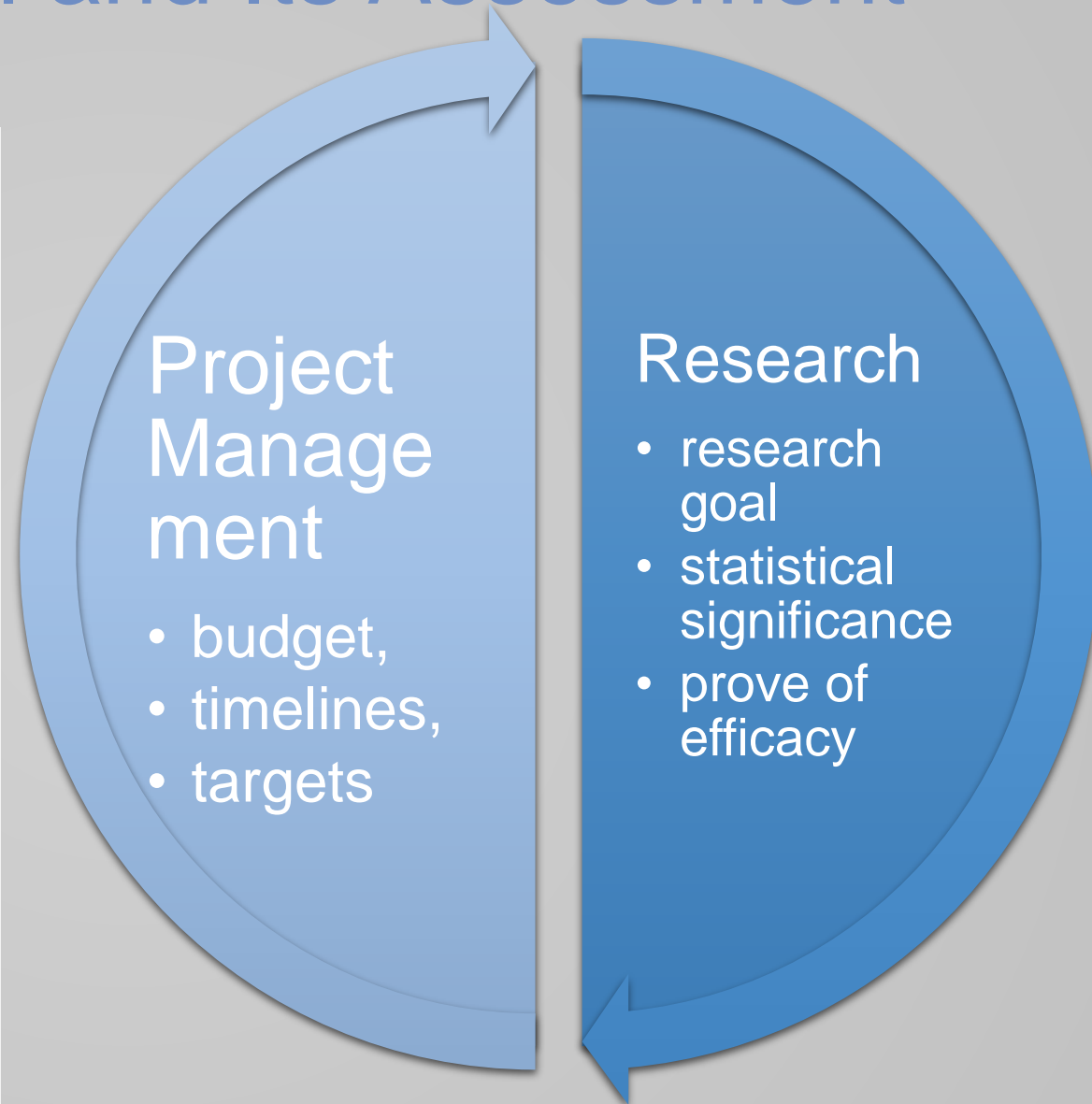


⁵Linda Martin KMR, Bernstein R&D Conference 2011, cited in Roche 1H2011 results presentation

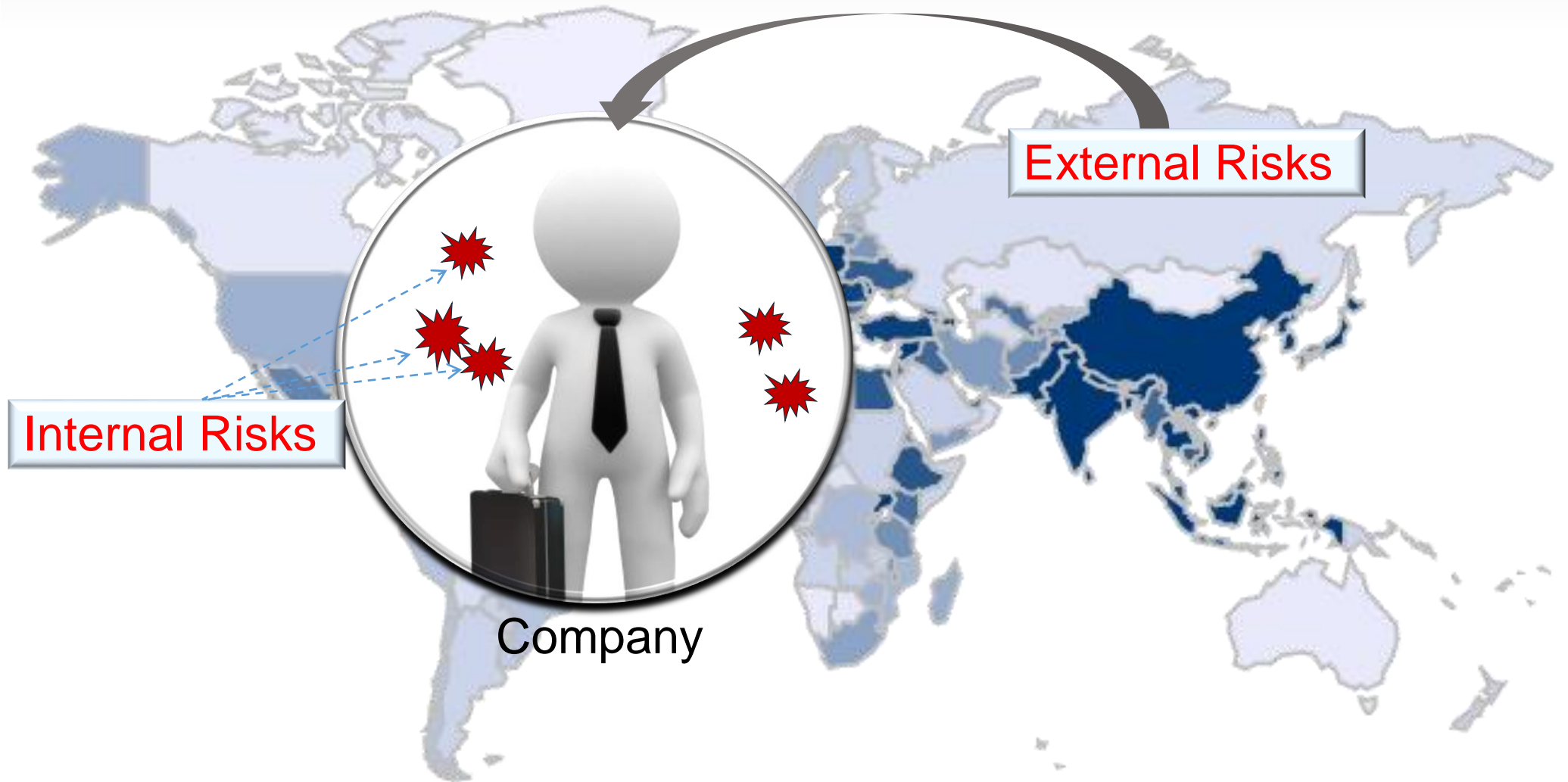
R&D returns have nearly halved over the last 10 years.

Risk Potential and Its Assessment

- Potential risk may arise from the budget, milestones and activities
- The probability of occurrence can be estimated
- Usually an incoming risk affects the time course and thus to the costs



Internal and External Risks



Clinical Trials Challenges

Unskilled Project Manager

Unproductive Team

Complexity of Protocol

Dilemma 'Project completion targets' vs. 'Eligibility of the volunteers'

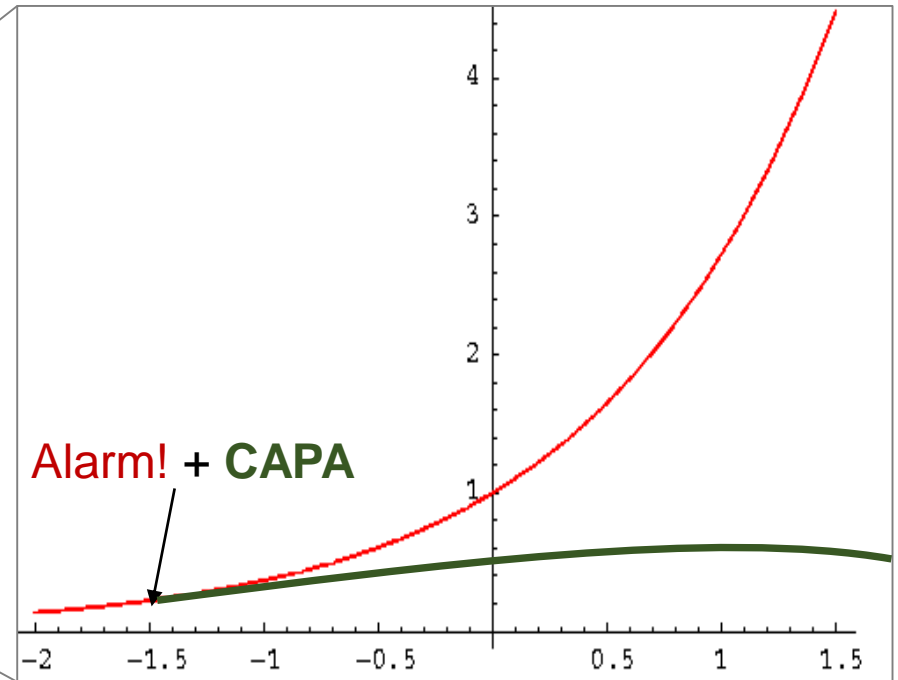
Poor training & poor verification

Ethical Issues

Data Quality



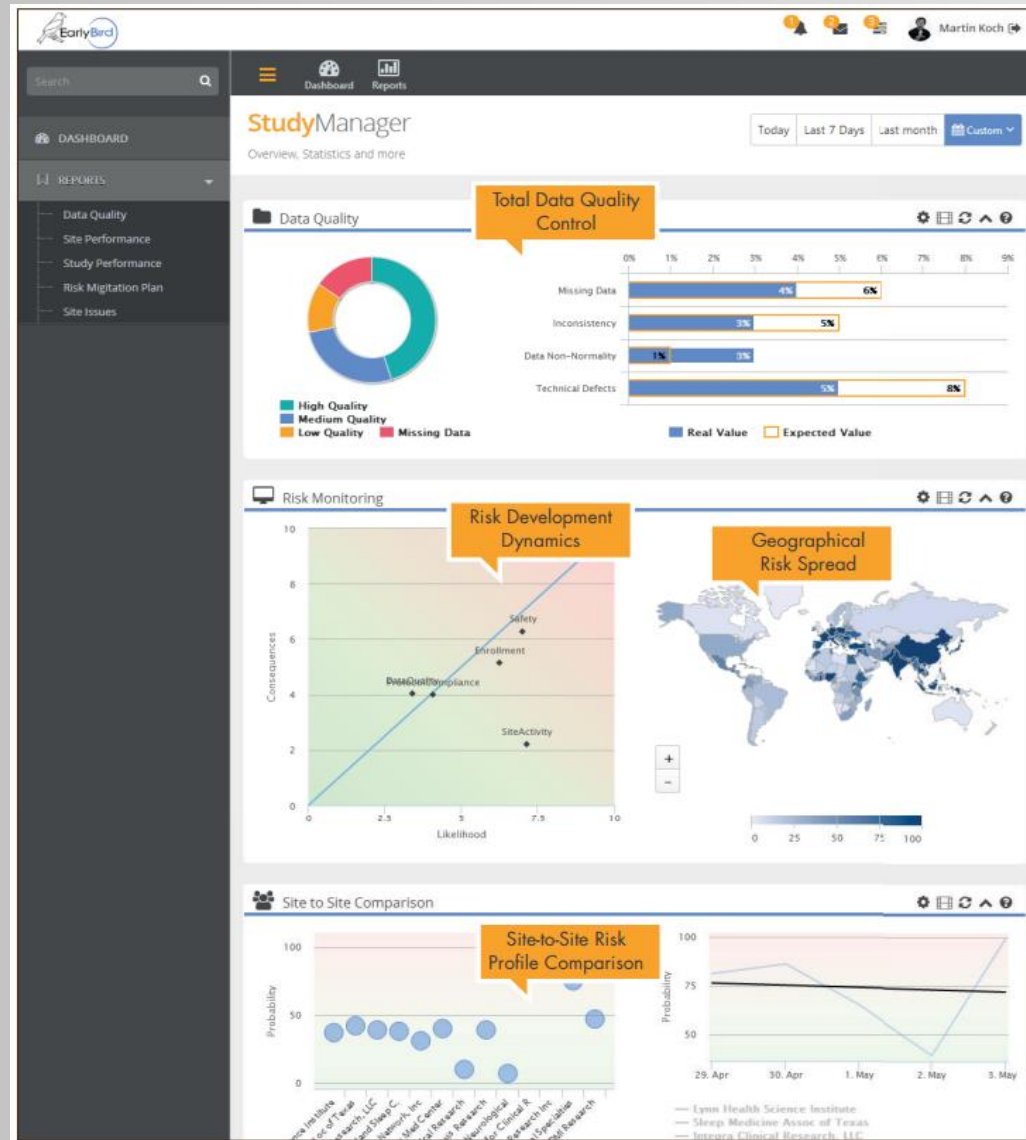
Right Actions in Right Time



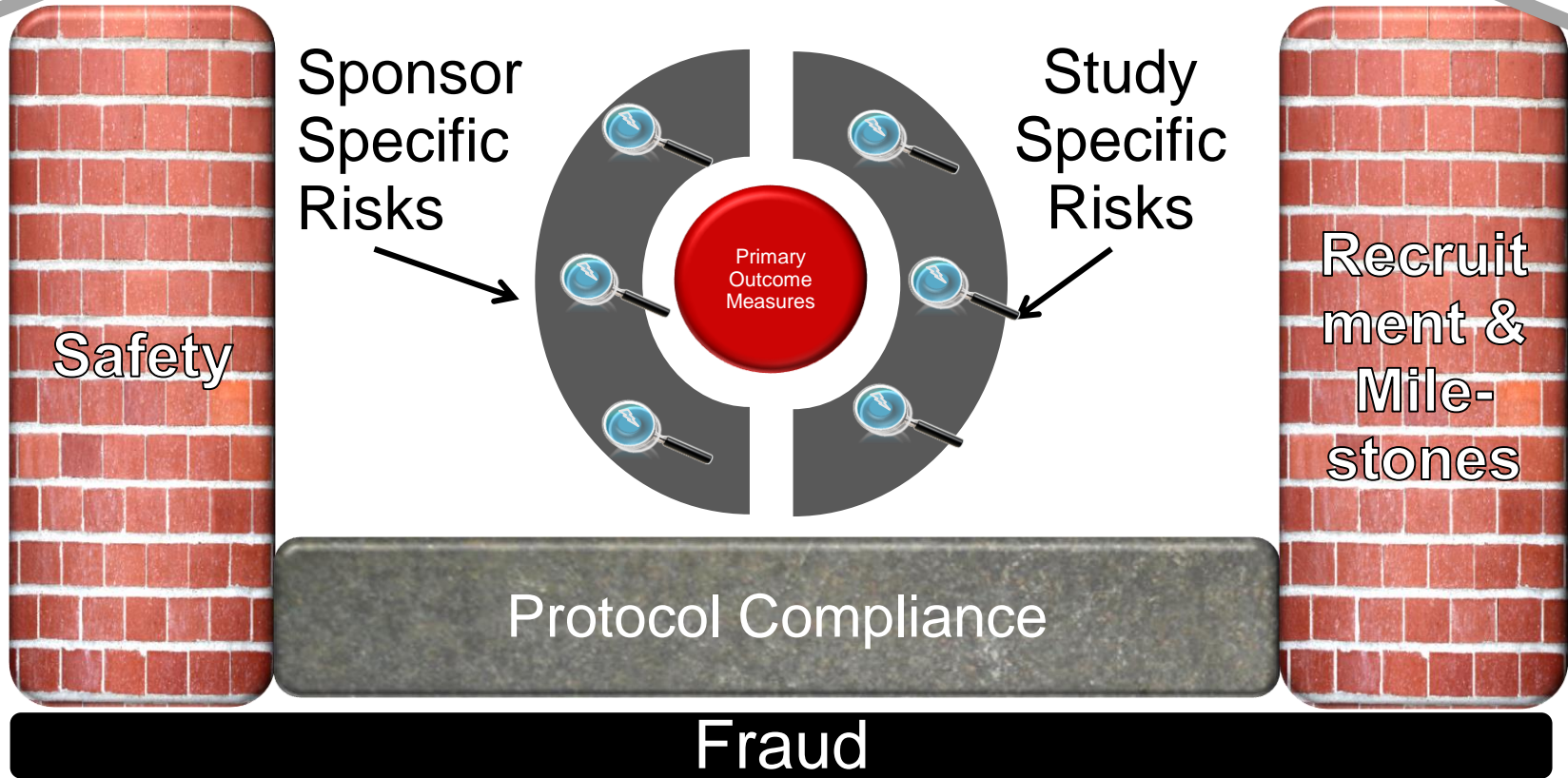
WHAT SOLUTION WE PROVIDE?

Technical Solution

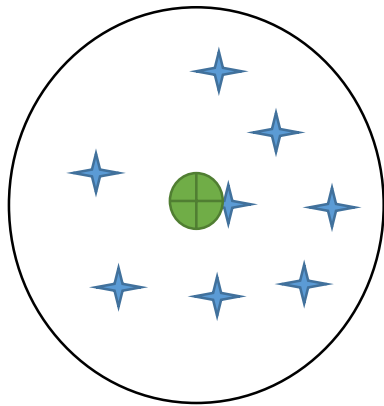
EarlyBird®



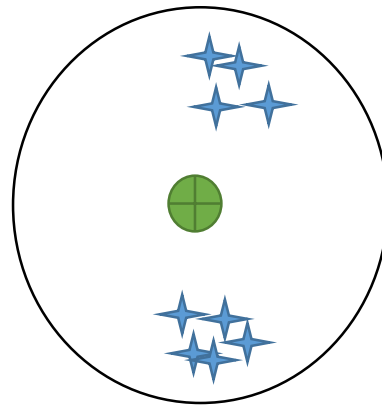
Key Risk Defense Strategy



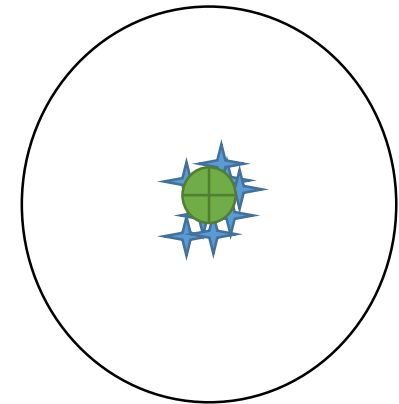
Control of Clinical “Data Noise”



Random Error



Systematic Error



Precision



Equality



Equality

Technology plays a critical role in effective risk-based monitoring. However, the **monitoring team** is equally important.

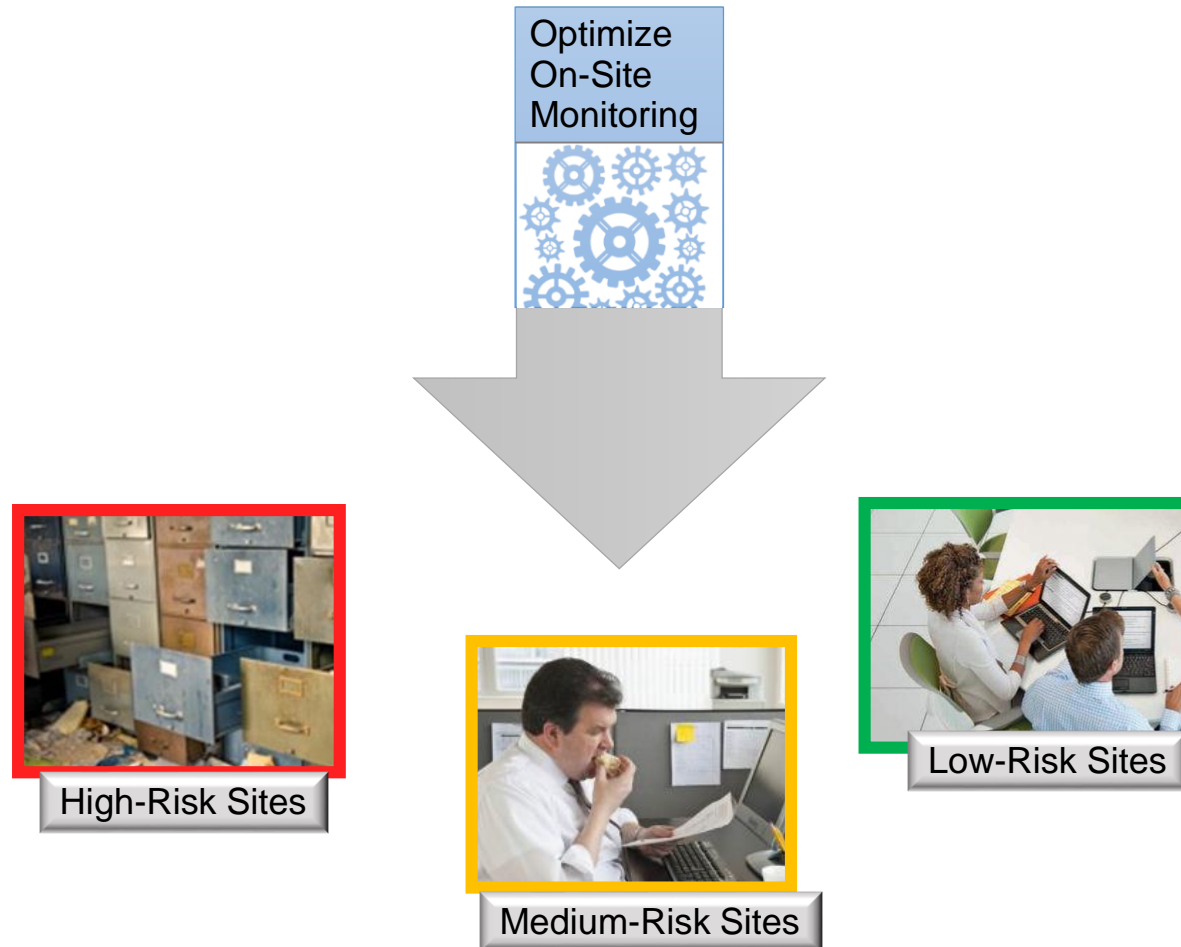


HessenAgentur

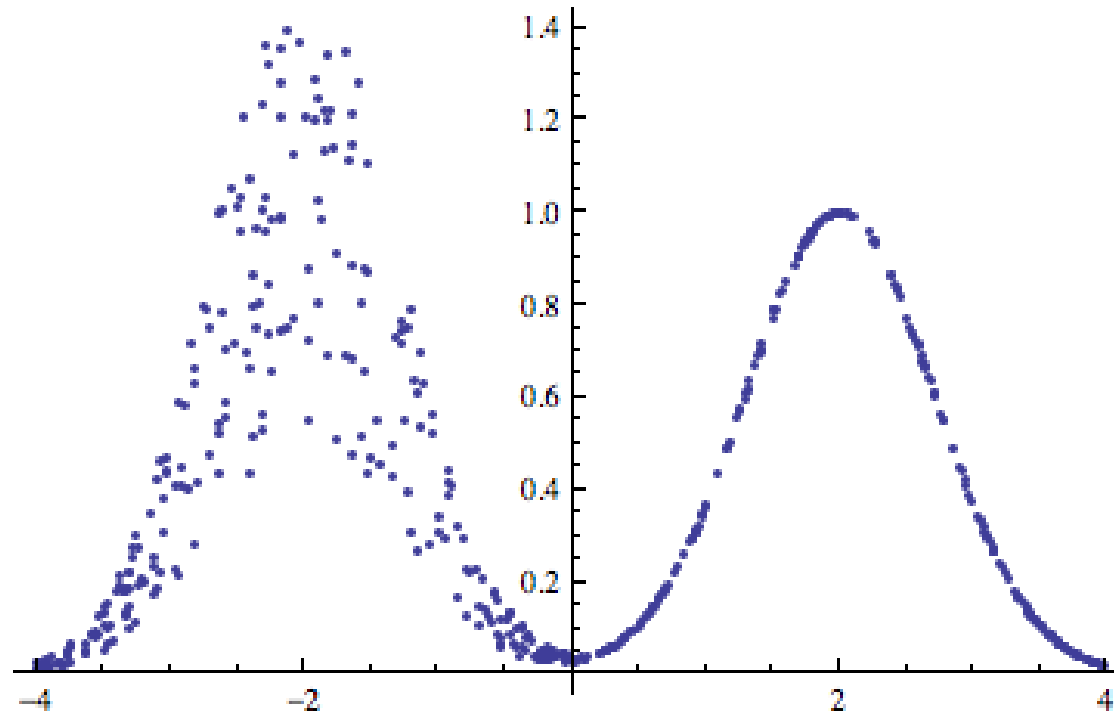
HA Hessen Agentur GmbH

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

Result 1: Site Visits Optimization



Result 2: Absolute Data Quality



Equality



Equality

Result 3: Continuous Improvement



Result 3: Effective Communication and Knowledge Sharing within Team and among Trial Groups

Internal Risk-Chat

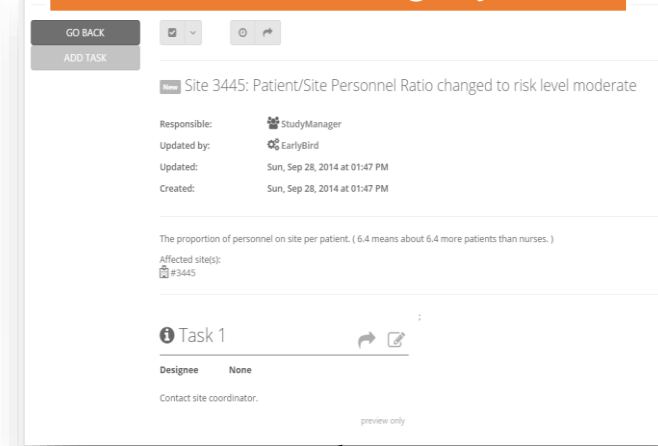


Risk Mitigation To-Do plan

MessageId	Subject	Priority	AssignedTo	CreatedAt	Actions
343	Check a patient signature in patient agreement is different to handwriting in the CRFs.	3	Ms. Mandy M. Young	5/6/2014 1:30 PM	Details
344	Check if patient agreement form is available.	3	Ms. Courtney E. Payne	5/6/2014 1:30 PM	Details
345	Check if returned investigational drug is very clean for all patients and has no signs of use.	3	Ms. Wendy G. Cox	5/6/2014 1:30 PM	Details
346	Known correlation between age and blood pressure could not be detected.	3	Mr. Kevin J. Salazar	5/6/2014 1:30 PM	Details
347	No free text and no comments found in questionnaires.	2	Ms. Debra D. Kaplan	5/6/2014 1:30 PM	Details

Showing 1 to 5 of 14 entries

Internal Ticketing System



Applied Statistical Methods



- ✓ Distributions and Properties Variables
- ✓ Proportion of missing values
- ✓ Means
- ✓ Global variances within patient variances
- ✓ Proportion of week days
- ✓ Proportions of Outliers
- ✓ Correlation between variables
- ✓ Event counts

Technological
Innovation

Science
Orientation

WHAT MAKES US **UNIQUE?**

Umbrella
Principle

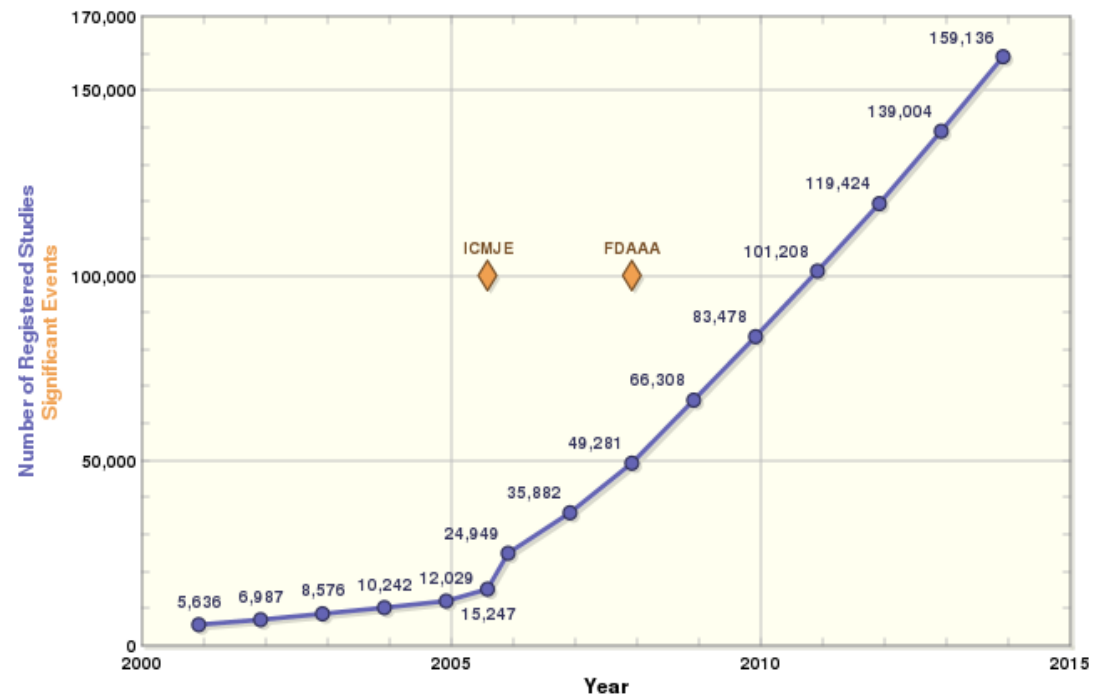
Undependability

Willingness
to share

Market Potential

Cyntegrity operates on the Healthcare Information Services, with the market capitalization **\$40 Bn**, with the forecast of CAGR 22.5% only in U.S. during 2012-2014.

Sector:	<u>Technology</u>
Industry:	<u>Healthcare Information Services</u>
Industry Statistics	
Price / Earnings:	55.3
Price / Book:	20.7
Net Profit Margin (mrq):	8.8%
Price To Free Cash Flow (mrq):	62.9
Return on Equity:	10.6%
Total Debt / Equity:	63.6



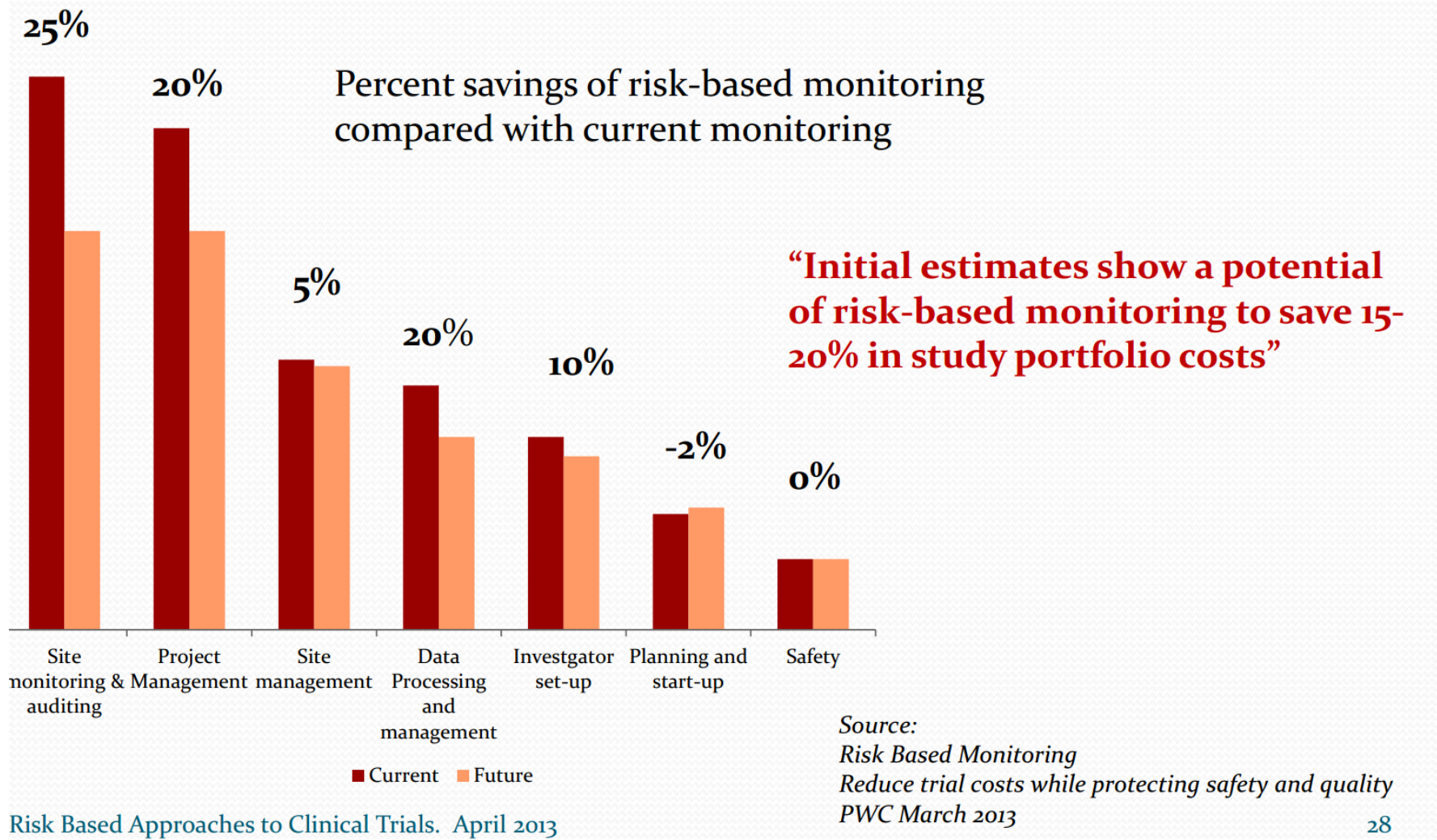
Number of registered Studies over time. Source: ClinicalTrials.gov

CAGR – Compound annual growth rate
 Source: U.S. Healthcare IT Market Analysis (Oct, 2011)
http://www.rncos.com/Report/IM321_fig.htm
 Source: yahoo finance 24. Nov 2013 (<http://biz.yahoo.com/ic/825.html>)


Who is our Customer?

Client	Value Proposition
Contract research organization (CROs)	<p>Competitive advantage on the market in offering advanced quality assurance as an additional service for pharmaceutical corporations.</p> <p>Additionally optimisation & reduction of the costs of clinical monitoring.</p>
Pharmaceutical Organizations	<p>Reduction of the dirty data risks, i.e. risk of damaging reputation, new quality standard within industry.</p> <p>Service of sanity checks can become required in the preparation to FDA audits, minimizing the risks of audit findings.</p>
Biotech Companies	<p>Optimization of clinical monitoring costs, mitigating the risks with later identification of problem zones.</p>

Proven Value for Customer



Risk varies inversely with **Knowledge**



Irving Fisher (1867-1947)