RISK-BASED MONITORING:
How to Know If It's Right for Your Study

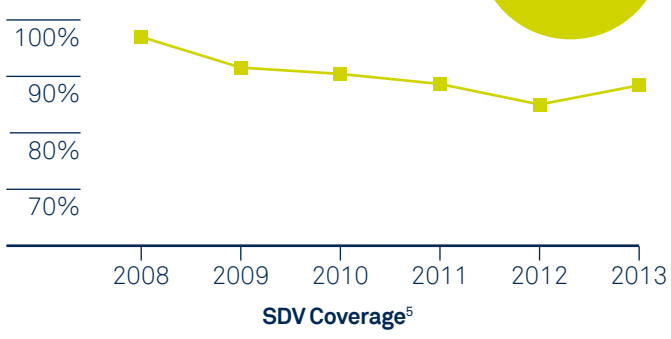
SDV Is Expensive

The life science industry will spend $7.5B on SDV in 2014

$7.5 BILLION

But, SDV Coverage Across the Industry Is Still High

In an average 2013 study, SDV coverage was 85%



SDV Coverage[5]

Is the Cost of SDV Justified?

CRAs spend

1 DAY PER MONTH
visiting **every** site in a study[1]

>50%
of their time on site doing SDV[2]

Can CRAs Use Their Time More Effectively?

Medidata and TransCelerate Find...

<3%
that conducting full SDV results in changes to **less than 3%** of data[3]

The average percentage of SDV queries generated in Critical Data is 2.4%[4]

So, Why Send Armies of CRAs out to Conduct 100% SDV at Every Investigative Site?

Medidata's Early Research Proves Risk-Based Monitoring Value

In RBM studies...

CRAs are
3 WEEKS FASTER
at reviewing and querying clinical data[5]

-33%
CRAs are spending
1/3 LESS
days at clinical sites[5]

There are 25% FEWER non-enrolling sites[5]

TransCelerate Partnered with Medidata for Robust Data Assets to Answer Important RBM Questions

7,000+
global clinical trials

120+
contributing sponsors

5+
years of data

The Important Questions to be Answered

Question 1: How many data errors do CRAs find and correct during SDV?

Question 2: How many adverse events (AEs) do CRAs uncover that are not captured in EDC?

[1] Medidata Insights™, average Phase-III trial
[2] Monitorforhire.com annual survey 2013
[3] 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
[4] TransCelerate Position Paper on Risk-Based Monitoring
[5] Medidata Insights Metrics Warehouse

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