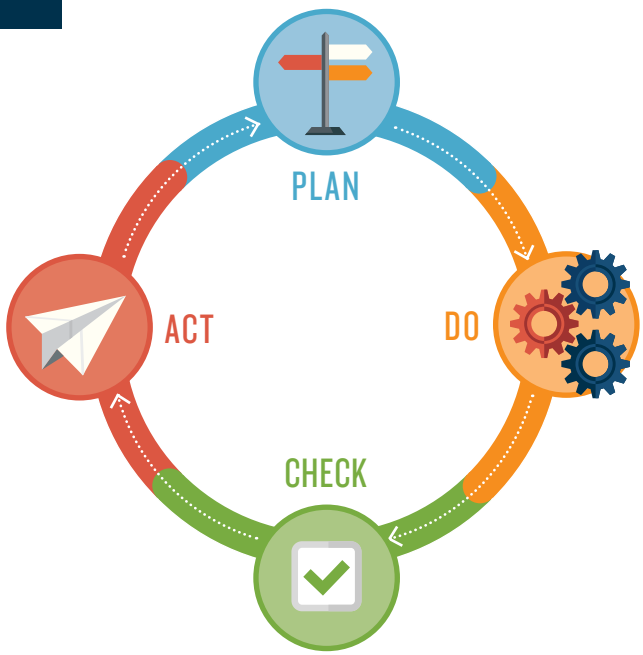
ACRO

RBQM SYSTEM

FOR CLINICAL TRIALS

Quality by Design (QbD)



RISK CONTROL MECHANISMS

Risk Based Monitoring (RBM)

Centralized Monitoring
is where document review, data review and analysis can all be performed at a remote site

Onsite Monitoring
is the basic fact-checking process of clinical trial monitoring quality tolerance limits

REDUCED ONSITE SDV/SDR

October 2019

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RBM TRIAL EVALUATION

EXAMPLES REPORTED BY ACRO SURVEY RESPONDENTS

QUALITY IN RBM TRIALS

Enhanced ability to identify and manage patient eligibility issues, unreported adverse events and protocol deviations, **helping to monitor safety risks**

Central data reviews enabled **early detection of quality issues**, allowing sites to identify data issues and make early corrections

16% reduction in critical and major findings in site audits

17% better detection of significant deviations

4x LOWER error rate in critical data in a head-to-head comparison of RBM to traditional 100% SDV approach

45% reduction in the number of missing pages in RBM trials versus traditional trials

EFFICIENCY AND SPEED IN RBM TRIALS

10 DAY reduction in **data management cycle time** for a large sponsor implementing a new RBM technology

A smaller biotech has seen database locks go from **30-60 days** from Last Patient Visit (LPV) to **about 5 days**

40% faster database lock timeline compared to non-RBM trials

20% reduction in SDV, resulting in more than $1M savings for a mid-sized sponsor in the first year

3-15% savings over traditional monitoring, depending upon the level of SDR/SDV included

21% reduction in subject visit data entry lag

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