Survey Time

Change management practice is increasingly important to clinical research, as both the industry and regulators work to adopt new clinical trial methodologies aimed at improving quality and efficiency. Conducting surveys among clinical staff is one way to help drive this approach forward

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For drug developers, the transition from traditional, 100% source document verification (SDV) to risk-based monitoring (RBM) strategies requires a sweeping transformation in clinical trial operations. RBM impacts everything – from trial design and data management platforms to the roles and skillsets of clinical project teams. Effective change management can identify barriers to implementing RBM, inform the development of training programmes and guide interventions to overcome obstacles among operations teams.

It has been found that incorporating surveys of clinical trial managers (CTMs) and clinical research associates (CRAs) is an effective way to gauge adoption progress and to refine change management processes.

New Mindset

PPD has conducted more than 150 RBM trials since late 2013. Early experience has shown that implementing risk-based approaches necessitates new ways of thinking and executing trials.

Recognising the scope of the adoption task ahead, an adaptive and intelligent monitoring (AIM) working group was established in 2012. AIM provides expertise and services supporting RBM approaches – including risk assessment, identification of key risk indicators (KRIs), source document review and SDV sampling methods, and site-level risk assessments focused on quality performance. Remote monitoring and RBM are introduced using clinical trial management systems and real time data platforms.

Pervasive and complex operational changes also demanded deeper collaboration among investigators, CROs and client research teams. To manage alignment of processes, a cross-functional RBM working group was set up to agree on custom client specifications and RBM implementation practices (1).

Adoption Strategy

In 2013, as the RBM regulation was finalised, we took the first step towards a comprehensive change management programme aimed at increasing RBM knowledge and expertise. The Prosci® ADKAR® model provided an easy-to-use framework of five, goal-focused steps – namely awareness, desire, knowledge, ability and reinforcement – to facilitate descriptions and guide discussions of the change management process among our managers and clinical research teams (2).

Module 1. Overview of AIM training
Module 2. Introduction to risk assessment and bidding
Module 3. Finalising protocol and writing monitoring plan
Module 4. Remote and on-site monitoring
Module 5. Site health assessment
Module 6. Real time in-house review

Table 1: Six operations training modules

This programme created a general training module to build an understanding of RBM across a broad segment of the company. Six individual training modules followed to arm project teams with the knowledge of specific RBM components pertaining to sampling, KRIs and site performance evaluation. To oversee study execution, a cadre of experts was fielded to help each project group. The change management team then measured progress in adoption using two surveys in February 2015 and March 2016.

An eTraining module was required for all clinical and project management personnel. Content included an overview of the FDA; the EMA and the Medicines and Healthcare products Regulatory Agency guidance on RBM; the goals and anticipated outcome of RBM pertaining to time, cost and quality; and an introduction to how AIM's strategy was expected to support this methodology.

We identified the knowledge and skills needed by operations teams and built six eTraining modules specific to the monitoring tasks required (see Table 1). The CTMs took all six courses, while the CRAs took the modules related to their specific roles just prior to implementing an RBM study. By March 2016, this training had been completed by nearly 80% of clinical personnel.

To guide teams as they implemented the new risk-based approaches, we deployed a special group of experienced CTMs with extensive training in RBM strategy, implementation and technology. A specialist was dedicated to each individual RBM study to mentor the project team and navigate challenges as they arose.

	CRA	CTM
Understand industry guidance	X	X
Understand PPD's RBM methods	X	X
Understand timing of IMVs	X	X
Understand appropriate IMV method (on-site or remote)	X	X
Understand which subject visits need to be monitored	X	X
Comfort with use of technology to manage work	X	X
Understand remote IMV tasks	X	X
Understand real time review of subject data tasks	X	X
Understand impact of site performance assessment	X	X
Feel training is adequate	X	X
Comfort with site performance assessment override process		X
Comfort with answering client questions		X
Comfort in assuming RBM oversight responsibilities		X
Comfort in using less than 100% SDV	X	
Comfort in training sites on remote IMVs	X	
Have more time to focus on process improvement with sites	X	
How much reliance on RBM specialist mentoring and oversight	X	

Table 2: Summary of RBM survey questions

Assessment: Taking Our Pulse on Adoption

Approximately 3.5% of PPD-conducted studies were using RBM strategies in 2014, when data showed that project teams were still performing the majority of monitoring visits on-site rather than remotely. It became apparent that teams needed greater confidence in remote monitoring. To help build that confidence, clinical management required the first site visit of every RBM-based study to be conducted externally. After just nine months, a 50% increase in visits being performed remotely was observed.

The effectiveness of this intervention led to the design of a survey to identify factors that might enhance the adoption rate. The survey asked task-related questions of CTMs and CRAs. Most were the same for both groups, but several applied to CTM- or CRA-specific roles (see Table 2). Respondents were required to describe their 'understanding and confidence' level in performing tasks using a five-point scale from 'very much' to 'not at all'. Responses of 'very much' and 'somewhat' were scored as positive; 'neutral' was considered neutral; and 'not really' and 'not at all' were taken as negative. The goal was to obtain a baseline reflecting current adoption and to define target areas for intervention to improve project teams' skill and confidence in using RBM systems.

Thirty-five CTMs and 113 CRAs responded to the first survey in February 2015. Results are shown in Figure 1.

The CTMs responded more positively overall. Roughly 60% said they felt very or somewhat confident in answer to all questions. CTMs responded most positively to: understanding industry guidance and PPD's RBM strategy; understanding which subject visits need to be monitored as directed by RBM strategy; and understanding how site performance assessments impact RBM strategy.

CRAs were less positive overall. Half said they felt very or somewhat confident in response to 8 of the 14 questions. CRAs responded most positively to: understanding industry

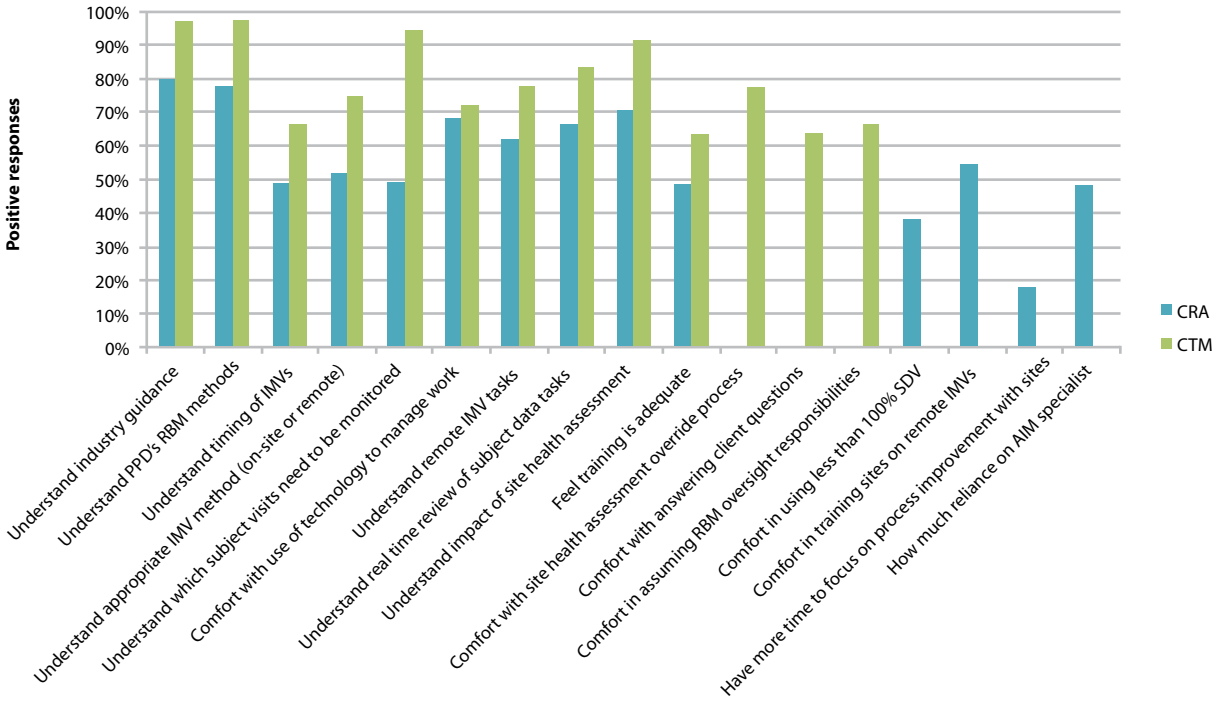

Figure 1: 2015 survey results: Positive CRA and CTM responses

Visit Preparation (CRA, Part 1)
Conducting Visits and Visit Report Completion (CRA, Part 2)
Project Oversight (CTM and Project Director/Associate Director)
Targeted Monitoring and KRI Review (CTM and CRA)
Visit Forecasting and Workload Planning (CTM and D/AD)
Remote Monitoring (CRA and Regional Site Manager)

Table 3: RBM clinical topics and content

guidance and PPD's RBM strategy; confidence in using the technology to manage workloads; and understanding the impact of site health assessment.

Moving the Needle

The survey results drove the next refinements in change management. They provided three important insights:

- CRAs needed more focused training in several areas compared to CTMs
- CTMs were capable of assisting in reinforcing RBM concepts to project teams
- CTMs could begin to assume more oversight responsibilities from the RBM specialists

While 60% of CTMs responded positively to the question assessing confidence in assuming RBM oversight responsibilities, their overall positive feedback to questions pertaining to the majority of individual RBM tasks showed that they possessed the needed skills and confidence for successful conduct of RBM-based studies.

Negative response rates indicated the areas where more intense training was required. RBM clinics were used to focus training on the most critical areas of skill and competency (see Table 3). Clinics were by invitation only to avoid overburdening busy project teams and were presented in live sessions and via the web. They began in October 2014 – initially with four sessions per month – but then, during the following year, survey results directed the addition of specific topics and, as a result, clinic sessions scaled up to 15 per month, each with between 20 and 40 participants.

Survey-Directed Interventions

CTM responses indicated the need for more training, and support clinics in three critical tasks: determining the timing of interim monitoring visits (IMVs); deciding if an IMV should be conducted on-site or remote; and assuming oversight responsibilities independent of the RBM specialist. In addition, we created clinics on project oversight and a project review form to train all managers of CTMs on project review necessary for compliance and to help guide them through a thorough review process.

CRA responses suggested the need for more training and support in: determining the timing of IMVs; using less than 100% SDV; and having more time available to focus on site processes and workflow improvement. CRA clinics included additional training to improve knowledge and skills in IMV timing and methodology.

To increase confidence in conducting less than 100% SDV, we shared video success stories showing how remote monitoring

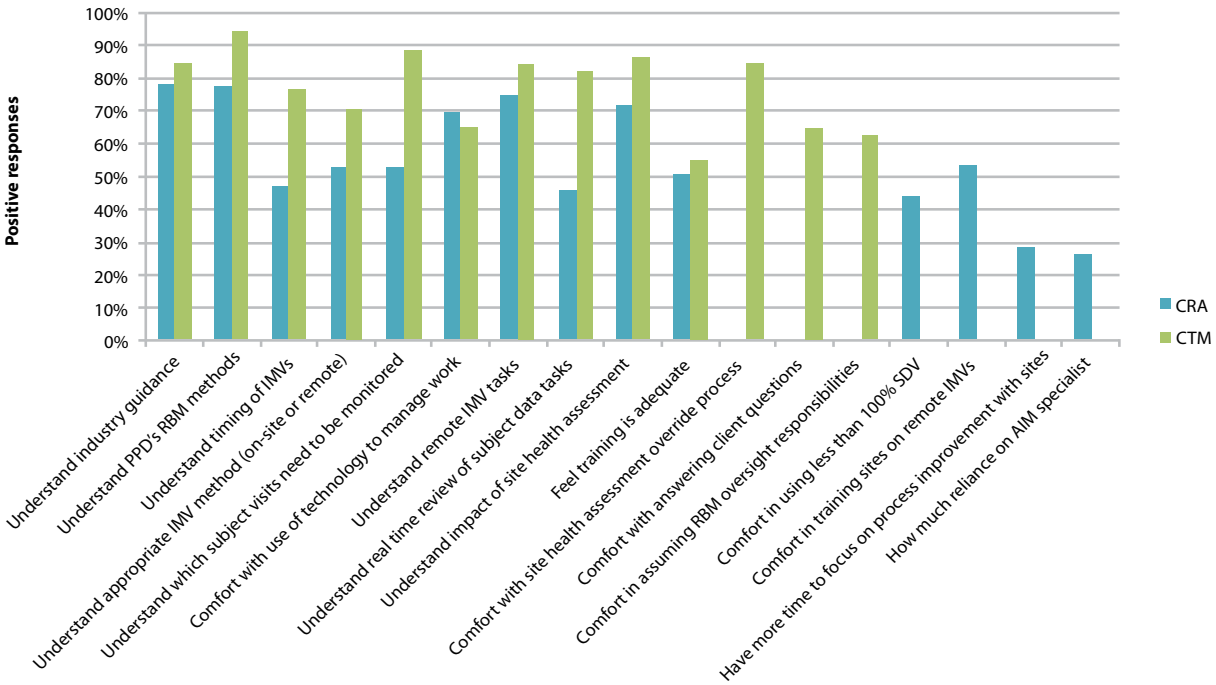

Figure 2: 2016 survey results: Positive CRA and CTM responses

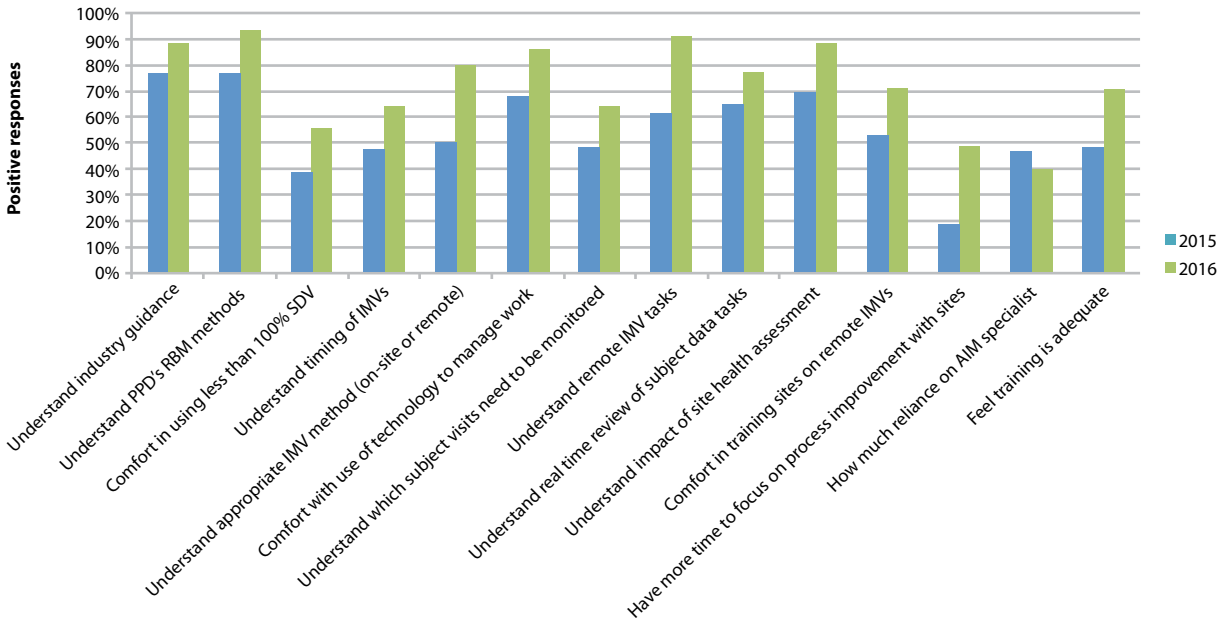

Figure 3: Positive responses from CRAs who now have experience with RBM

was employed to identify critical factors in site performance, and shared metrics on improvements in audit findings when RBM monitoring methods were used, compared to traditionally monitored trials. We also created a task matrix to help CRAs understand the role of remote monitoring to support subject data review – so they could focus more time on site process development – and fielded external site monitors to assume some remote tasks. To support process improvement, guidance on KRIs was implemented.

Survey 2 in March 2016 measured progress following the targeted clinic interventions and another 12 months of experience for our project teams. Survey 2 asked the same questions; 51 CTMs and 207 CRAs responded. Results are shown in Figure 2 (see page 28).

Overall, 2016's survey results showed that CTMs maintained positive response rates above 70% on 9 out of 13 questions, and increased positive response for four questions. CRAs kept positive response rates on 12 of the 14 questions. Positive feedback above 70% increased from two questions in 2015 to four questions in 2016. Negative responses decreased for 12 of the 14 questions, indicating growing confidence in RBM knowledge and skills.

Additionally, we assessed responders' levels of RBM experience, assuming that it would significantly influence confidence levels. When Survey 2 was conducted, 58% of CRAs and 22% of CTMs had six months or fewer experience using RBM. This may have accounted for some increase in negative responses.

Progress in Targeted Areas

On questions that measured progress in areas targeted by clinic interventions, CRAs exceeded a 70% positive response rate in understanding their role in performing remote IMVs. Overall, CRAs were somewhat more positive about reviewing less than 100% SDV, and more positive in being able to devote more time to process improvements with sites.

The most impressive developments in 2016 were among the cohort of CRAs who had been using RBM methods for more than 12 months. Their positive responses are shown in Figure 3. In this subgroup, CRAs exceeded 70% positive rates for 9 of the 14 questions. For the remaining five questions, responses showed significant movement in the direction of greater knowledge and confidence.

These findings from the 2016 survey are guiding PPD's additional change management efforts to further spur RBM adoption.

Beyond Benchmarks

The 2015 and 2016 surveys are considered instrumental to the progress achieved by PPD's change management strategy to advance RBM adoption. More than a means to gauge the state of adoption among clinical project teams, the surveys proved to be invaluable in refining training efforts, modifying processes and enhancing communication. Now an important tool in our ongoing change management programme, future surveys will guide us in adapting change management strategies to meet specific needs of the organisation.

References

1. Stansbury N, Worth the effort, *International Clinical Trials*, August 2015. Visit: www.samedanltd.com
2. Visit: www.prosci.com/adkar/adkar-model

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