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R Adoption and Change Management – A Large CRO Perspective

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ABSTRACT

Organizations are increasingly leveraging open-source tools to enhance their statistical analysis, reporting, competitiveness and agility. For CROs, this transition can be challenging, as much of the current work is traditionally conducted in SAS, supported by well-established processes. This presentation will address the complexities and resource constraints associated with such a transition. Attendees will gain valuable insights into best practices for implementing change management strategies, enriched by a detailed case study of how change management is being implemented in a large CRO Biostatistics and Programming department. This case study will demonstrate how R and other open-source tools can drive efficiency and foster innovation right now while moving as fast as possible towards a future state. By incorporating key change management aspects—leadership, vision, training, competency, support and communication—viewed through a large CRO context, this presentation will equip you with essential knowledge and considerations for seamless and effective change management within your organization.

INTRODUCTION

In today's fast-evolving technological environment, the adoption of open-source tools such as R has become essential for enhancing flexibility, competitiveness, and innovation in statistical programming. However, for Contract Research Organizations (CROs), where SAS-based systems have long been the standard, transitioning to R requires significant planning and coordinated change management.

Running the Open-Source Marathon!

"Like a marathon, the change to using R and other open-source languages is a challenge that requires preparation, pacing and perseverance."

This marathon metaphor captures the journey of open-source adoption in a regulated industry. Just as marathon runners must train systematically, develop endurance, and maintain mental fortitude to reach the finish line, organizations must approach R adoption with similar discipline and commitment.

The marathon of open-source adoption is not a sprint to quick results but rather a strategic long-distance journey that transforms how we work. It requires:

- **Preparation:** Building the right foundation with infrastructure, goals, and leadership
- **Pacing:** Implementing changes at a sustainable rate with appropriate training and communication
- **Perseverance:** Overcoming inevitable obstacles through collaboration and adaptability

We will explore each of these critical phases, providing practical insights from our experience as a large CRO navigating this transformative journey.

PREPARATION

Just as marathon runners must assess their fitness level, acquire proper equipment, and develop a training plan before race day, organizations must thoroughly prepare for the R adoption journey. This preparation phase encompasses three critical elements: infrastructure assessment, goal setting, and leadership development.

Pause! – Where are you starting from?

When beginning our R adoption journey, we needed to honestly assess our starting point. Are you starting from "the couch" with minimal R infrastructure and R skills, or are you already an "Olympic Triathlon Gold Medalist" with infrastructure and skills in place?

When we first assessed our R capabilities, we discovered we had no RStudio installation, no defined processes for using R in study work, and limited expertise scattered across the organization.

So ask yourself honestly:

What infrastructure do we have available?

What is my Shared Computing Environment (SCE) like?

What are our processes?

Assess:

What do we have already?

What do we need?

What do we need to repurpose?

What do we need to create?

Goal Setting

Equally important is establishing clear objectives for your context. Using the SMART framework (Specific, Measurable, Achievable, Relevant, Time-bound), teams should set individual, team-based, and organizational goals. These may include training goals (e.g., proficiency in tidyverse), output goals (e.g., producing clinical tables with R Markdown), or strategic goals (e.g., reducing dependency on proprietary software by a specific percentage).

Just as marathon runners need to know their target distance and time, organizations need clear goals for R adoption.

Here are some examples of R goals at different levels:

Individual level goals:

- "Within 8 weeks, I will learn how to perform an MMRM analysis in R and contribute my learning to our internal knowledge base"
- "By next quarter, I will be proficient in using the tidyverse packages for data manipulation"
- "This month, I will complete an R training module"

Team level goals:

- "X% of department will be familiar with the tidyverse and admiral packages by year-end"
- "Our team will develop capacity to respond to client requests for R deliverables by Q3"
- "We will create a repository of 10 validated R functions for common analyses by Q4"

Organizational level goals:

- "Establish standard operating procedures for R validation by end of fiscal year"
- "Reduce dependency on proprietary software licenses by 15% within 18 months"
- "Develop capability to offer R-based solutions to clients in three therapeutic areas"

When setting these goals, here are some helpful key principles:

1. **Focus on what you can control:** Channel efforts into areas of biggest impact
2. **Identify low-hanging fruit:** Early wins build momentum and demonstrate value
3. **Align with interests:** Connect R adoption to topics that excite you and your team members
4. **Set realistic horizons:** Balance short-term achievements with long-term vision
5. **Learn and do together:** Combine training with practical application

Leadership

Effective change always requires strong leadership to drive the process, motivate employees and address resistance. We have found it particularly crucial to have clear support from management and building a particularly set of experts and champions that can support and push the change.

Leaders of successful R adoption should demonstrate key characteristics:

- **Visibility:** They demonstrate their commitment through active participation
- **Accessibility:** They remain available to address concerns and provide guidance
- **Commitment:** They consistently reinforce the importance of the transition
- **Inclusivity:** They bring people on board rather than leaving them behind

PACING

Just as marathon runners must find their sustainable rhythm—neither sprinting too quickly nor moving too slowly—organizations must establish the right pace for R adoption. The key to successful pacing lies in recognizing the abundance of opportunities, immersing yourself strategically, training smartly, and communicating effectively throughout the journey.

Find Your Pace! Multiple adoption pathways

Introduce R in as many different ways as you can. There are many different possibilities to use R as a driver for new innovative solutions. Look to drive different areas if possible through working groups.

The beauty of R adoption lies in its versatility—there isn't just one path forward, but many parallel opportunities to engage with the technology:

- R Markdown/Quarto: Creating reproducible reports with integrated code and outputs
- Enhanced visualizations: Developing interactive figures that bring data to life
- Simulation studies: Leveraging R's statistical capabilities for creating simulations
- R within SAS: Using PROC IML as a comfortable bridge for SAS programmers
- Interactive applications: Building Shiny dashboards for dynamic data exploration
- Specialized analyses: Implementing methods that are cumbersome or not there in other tools or languages

There are so many ways to engage with R that whether you're looking for just one particular application that speaks to you personally or multiple pathways for your entire department, you'll find suitable entry points. This flexibility is particularly valuable in diverse organizations where different teams have varying needs, technical backgrounds, and risk tolerances.

For individuals, this might mean focusing on a specific package or application that solves an immediate pain point—perhaps using ggplot2 to create publication-quality figures. For departments, it could mean strategically implementing multiple R applications across different workstreams, creating a network of interconnected innovations that collectively transform how work gets done.

We established focused working groups around specific applications—interactive data tables, enhanced visualizations, specialized analyses, and Shiny applications—creating multiple streams of innovation rather than forcing everyone down the same path.

As a CRO serving diverse clients, we found that these multiple pathways naturally aligned with different client needs, creating organic opportunities to implement R across various therapeutic areas and study types. The challenge of pleasing multiple stakeholders—often seen as a difficulty—became an advantage in our R adoption journey, as it naturally leads to explore and implement a wider range of R capabilities than we might have otherwise.

Immerse yourself!

immerse yourself in what is going on in the industry and get involved!

Immersion accelerates learning and maintains enthusiasm. Some examples include:

- **Active participation:** Contributing to working groups and package development
- **Project alignment:** Finding projects that spark genuine interest and curiosity

- **Conference engagement:** Attending events to learn from and connect with peers
- **Continuous learning:** Following webinars, tutorials, and online resources
- **Community connection:** Engaging with the R community through various platforms

This immersion strategy proved invaluable—nothing has been more helpful than connecting our internal efforts to the broader industry.

The R community's collaborative nature means that immersion delivers benefits far beyond what internal resources alone could provide. By participating in this ecosystem, you gain access to cutting-edge approaches, solve problems more efficiently, and stay motivated through connection with like-minded people.

Training as you Go

It's easy to take a course, not use the skills, and need retraining later. Generic data science courses have some value, but without immediate application they're slower and inefficient. Line up real project work to follow training, and deliver specific just-in-time modules tied to the tasks at hand (for example, admiral for ADaM). When I was a graduate statistician, SAS training was immediately applied on projects—creating tables, listings, figures, and datasets—so the learning wasn't in isolation. Apply the same model for R: train briefly, then use it right away on real deliverables.

Communicate effectively: Regularity + Effectiveness

Regular, purposeful communication turns change into progress. Focus on:

- **Sharing vision and ideas:** tie R adoption to clear outcomes.
- **Demonstrations:** show working examples and tangible wins.
- **Support:** make help easy to find and quick to respond.
- **Resources:** keep concise guides, templates, and FAQs up to date.

Make check-ins effective, not just frequent: ask what's happening in the industry, what teams are using R/open-source for, and how they're getting on. Use the answers to surface blockers, connect people to resources, and refine priorities. Consistency plus usefulness is the core of communication that sustains momentum.

PERSEVERANCE

Just as marathoners navigate the whole training process—injuries, plateaus, life interruptions, and race-day surprises—R adoption in a CRO faces legacy systems, tight deadlines, clashing priorities, and evolving client needs. Perseverance is the discipline to keep moving: collaborate widely, balance exploration with standardization, protect delivery while you innovate, and stay adaptable as evidence emerges.

Here are the CRO particular challenges and how you can start facing them:

- Multiple projects/processes in SAS; meet deadlines! stay highly utilized!
 - Make R billable; use R and SAS together during transition.
- Many clashing priorities
 - Be specific
 - Keep fighting for prioritization
- Clients developing different solutions
 - Explore
 - Stay flexible as possible
 - Ultimately you will need to make choices

But there are also challenges that everyone is going to be facing in the industry:

- Aligning diverse stakeholders; misconceptions; resistance; strong feelings.
- Cost, licensing, liability; trust-building; need for speed and quality gains.

A couple of suggestions to start facing all of these are:

- Collaborate:
 - It's hard—we need each other
 - Work cross-functionally – lots of diverse sets of people doing this
 - Pool resources: knowledge sharing, co-develop solutions/packages, internal repos

- Keep asking questions
 - Leverage PHUSE Q&A - [Open Source Technology in Clinical Data Analysis](#)
- Stay adaptable
 - Be flexible; adjust plans as evidence emerges
 - Experiment
 - Monitor and evaluate; pick standards and packages when ready

Perseverance means steady, collaborative pressure: experiment, learn, choose, and refine—without breaking what works.

CONCLUSION

Implementing R and open-source tools in a CRO is a marathon, not a sprint. Through careful preparation, realistic pacing, and collaborative perseverance, organizations can build an adaptive environment where innovation thrives. The ideas shared here illustrate how structured change management can enable transformation in even the most entrenched operational settings. We hope it provides practical insights and provokes thoughts for others whatever setting they are in embarking on this journey we all face with open-source and R!

CONTACT INFORMATION

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