Paper PM12

SAIL.R: Navigating Change Together in Clinical Analytics!

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ABSTRACT

SAIL.R is a cross-functional initiative at Johnson & Johnson dedicated to implementing R for the development of both static and interactive analysis output in clinical data exploration and reporting. The initiative revolves around key streams such as regulatory submissions, the R reporting framework, interactive visualizations, and effective change management. This paper emphasizes the importance of people-centric approaches during this transition for statistical programmers and statisticians from SAS to R. Engaging employees throughout the change process allowed for valuable feedback and promoted a sense of ownership. One fundamental principle was to show the tangible benefits of the change to the team. We prioritized providing robust support through training, access to subject matter experts, and a safe environment for questions. We will also cover strategies for stakeholder management, effective communication, overcoming resistance, and evaluating success metrics. Overall, the SAIL.R initiative aims to enhance analytical capabilities while fostering a collaborative and supportive atmosphere for all team members involved.

THE SAIL.R INITIATIVE

At J&J, we embarked on a journey in 2020 to implement R [1] software for the development of both static and interactive analyses in clinical data exploration and the delivery of production outputs. This is a major change in our day-to-day way of working, as previously, all programming in our statistical programming department was done in SAS®. To navigate through this change, we established a comprehensive cross-functional initiative called SAIL.R. This initiative revolves around 4 key streams:

- **Reporting framework and standards:** this team has developed a reporting framework based on the pharmaverse packages [2]: rtables, tern and teal. The team wrote additional functions (in a package called JUNCO) in order for the pharmaverse packages to work on our J&J statistical computing environment and create outputs that are matching our new J&J Connected standards. These new J&J standards are in alignment with the FDA newest standards, and are taking into consideration other global regulatory standards. An open-source version of this JUNCO package was recently published on CRAN. The team also takes care of the necessary validation to ensure our system is in accordance with the rules for Good Clinical Practice and creates the documentation. In addition, they provided a script catalog in R for standard Tables, Listings and Graphs (TLGs) for safety, and template scripts for efficacy are currently under development in collaboration with the Therapeutic Area statisticians.
- **Submission:** the Submission stream is vital for ensuring the seamless and successful submission of programs and outputs developed in R. It employs targeted testing methods to identify necessary adjustments or enhancements to current submission tools, programs, and guidelines. These insights are then discussed with stakeholders to explore practical solutions for improving the process. Additionally, the stream offers both technical and strategic support for select early-adopter studies utilizing R-developed outputs. This includes providing briefing book assistance, facilitating pre-submission communications with regulatory authorities (such as mock submissions to gather early feedback), independently reviewing submission packages in the role of a regulatory reviewer and provide instructions for R setup. J&J has recently completed several successful Hybrid R submission to the FDA [3].
- **Interactive visualization and reports**: the Interactive visualization and reports stream focuses on developing and enhancing interactive visualization applications for exploratory use, as well as for the production of outputs for clinical study reports or interactive safety analyses. At the beginning of the project, the team was developing J&J home grown Shiny applications. However, after the publication of the open-source teal package, we decided to join the collaborative effort and we switched strategies. Integrating the new concept of interactivity into our existing processes is an important piece of the puzzle.
- **Change management:** this overarching stream drives the adoption and implementation of R within the organization. The rest of this paper will elaborate on how we handled the change management for our SAIL.R initiative.

THE HUMAN DIMENSION OF CHANGE [4]

People are central to the success of organizational changes, emphasizing the importance of placing individuals at the core of change initiatives. Effective change leadership necessitates a deep understanding of and sensitivity to the emotional responses experienced by individuals throughout the change process. It is critical to recognize that people are not mere resources to be managed; rather, they are the primary agents responsible for adopting and sustaining change. During periods of change, individuals may encounter a spectrum of emotions—including excitement, optimism, anxiety, resistance, and anger—and change leaders must develop appropriate strategies to manage these

emotional states effectively.
Key principles of people-centered change management include:

- **Change as a Human Process:** Change extends beyond technological or procedural adjustments; it fundamentally involves people. Leaders must comprehend the human aspects of change and formulate strategies that support individuals throughout the transition.
- **Active Involvement:** Engagement of personnel in planning and implementation enhances their likelihood of embracing change. Creating opportunities for participation and feedback fosters a sense of ownership and commitment.
- **Clear Communication of Benefits:** Communicating the advantages of change in a transparent and concise manner increases acceptance and motivation among stakeholders.
- **Support Mechanisms:** Given the challenges associated with change, ongoing support—such as training, coaching, and mentoring—is essential to facilitate adaptation.

Given that people form the foundation of successful change, building strong relationships and cultivating a culture of trust are vital. When individuals feel trusted and respected by change leaders, their tendency to accept and support change increases. Empowering individuals to take ownership of the change process further enhances engagement. Moreover, change should be viewed as a continuous journey rather than a destination. It requires patience and perseverance from leadership. Not all individuals will readily embrace change; resistance may persist despite clear benefits. Consequently, change leaders must be equipped to manage resistance and develop strategies to overcome it. Importantly, change also presents opportunities for growth and development, enabling individuals to acquire new skills and capabilities. Effective change leadership involves highlighting these positive prospects and assisting individuals in perceiving change as a pathway toward personal and professional evolution.

PLANNING FOR CHANGE

A comprehensive and well-structured change plan is fundamental to achieving successful transformation. Effective planning serves multiple purposes, including clarifying the objectives of the change, identifying key stakeholders, assessing potential impacts, developing resistance management strategies, and establishing an implementation timeline. Such a plan functions as a strategic roadmap, delineating the trajectory and defining key milestones throughout the change process. In the absence of a clear plan, organizations and individuals risk losing direction, encountering avoidable challenges, and unnecessary costs. Conversely, a detailed change plan ensures alignment among stakeholders, reduces ambiguity, and provides clarity regarding objectives and execution methods. Additionally, it facilitates progress monitoring and enables timely intervention should deviations occur. In essence, possessing a robust change plan is analogous to having a GPS during a journey—it guides, informs, and ensures the efficient achievement of desired outcomes.
The following steps outline a systematic approach to effective change planning:

1. **Define the Change:** Clearly articulate the nature, purpose, and scope of the proposed change, including the current state, the envisioned future state, and the rationale behind the transition.
2. **Identify Key Stakeholders:** Recognize and categorize all individuals or groups impacted by or influencing the change, utilizing tools such as stakeholder analysis matrices to prioritize based on influence and interest.
3. **Assess Impact:** Analyze how the change will affect each stakeholder group—considering potential risks, benefits, and areas of resistance.
4. **Develop Resistance Management Strategies:** Anticipate sources of resistance and design targeted strategies, including open communication, stakeholder involvement, training, and feedback mechanisms.
5. **Create an Implementation Timeline:** Establish a realistic schedule, identifying key milestones and deadlines, to facilitate coordinated execution and monitor progress.

DEFINE THE CHANGE

Defining the change involves articulating its specific nature, scope, and implications. This process encompasses outlining the current state, envisioned future state, and the underlying reasons for the transformation. Clarity at this stage provides a strategic blueprint, enabling stakeholders to visualize the journey and its endpoint, fostering shared understanding and alignment. Moreover, a well-defined change mitigates ambiguity, reducing the likelihood of resistance and resource misallocation. Importantly, it also enhances stakeholder buy-in, as understanding the "why" behind the change encourages commitment and active participation. Ultimately, precise definition establishes the foundation for successful transformation.

IDENTIFY KEY STAKEHOLDERS [5]

Identifying key stakeholders entails recognizing all individuals, groups, or entities that will be affected by, able to influence, or interested in the change. This involves mapping stakeholder influence and impact, often through stakeholder analysis matrices, to prioritize engagement efforts. Recognizing stakeholders early ensures that their perspectives and concerns are incorporated into planning, promoting inclusivity and collaboration. Additionally, understanding stakeholder interests and motivations allows for tailored communication strategies, addressing potential resistance proactively. For effective stakeholder analysis, it is valuable to categorize individuals or groups into four primary categories:

- Change initiators “above” the change
- Change partners “on” the change

- Change recipients “in” the change (those directly involved)
- Interested onlookers “around” the change

In evaluating each group, it is essential to consider their desires in relation to the change—what they stand to gain or avoid—and tailor engagement strategies accordingly. Continual stakeholder assessment is an ongoing process that adapts as the change progresses.

ASSESS THE IMPACT OF CHANGE [6] [7]

Impact assessment acts as a navigational compass, providing insights into how different stakeholders—ranging from frontline employees to senior management—will be affected by the change. Recognizing these diverse impacts is crucial for anticipating resistance and customizing communication and support strategies. This assessment also highlights potential risks and opportunities, enabling proactive measures to amplify benefits and minimize adverse effects.

A critical component of impact assessment pertains to elucidating the "what’s in it for me" (WIIFM) for each stakeholder group. Clearly articulated WIIFM statements inspire commitment by demonstrating tangible benefits and addressing concerns. These statements should reflect the emotional and practical gains for stakeholders, effectively framing the change as an opportunity for growth and positive outcomes. Emphasizing these elements fosters autonomy, trust, and internal motivation, which are essential for lasting change.

Business Readiness

Assessing organizational readiness for change involves evaluating whether the organization is equipped—both practically and culturally—to support the transition. This comprehensive evaluation includes baseline assessments of current processes, resources, skills, and organizational culture; resource and infrastructure audits; and risk analysis. It also considers the availability of feedback channels and the presence of change champions within the organization. This holistic approach ensures that the organization is not only prepared on paper but also capable of effectively implementing and sustaining the change in practice.

DEVELOP RESISTANCE MANAGING STRATEGIES

Resistance is a natural human response rooted in fear of the unknown, job security concerns, or disruption of established routines. Managing resistance requires tailored strategies such as transparent communication, early stakeholder engagement, and skill development initiatives. Training sessions, workshops, and open forums provide platforms for dialogue, increasing understanding and ownership. Proactively addressing resistance not only smooths the transition but also builds trust and fosters an environment conductive to sustainable change.

CREATING A TIMELINE FOR IMPLEMENTATION

Developing a detailed implementation timeline is essential for maintaining control and alignment during change initiatives. This timeline delineates sequential tasks, milestones, and responsibilities, enabling stakeholders to coordinate efforts and resources effectively. It also provides a basis for monitoring progress, identifying bottlenecks, and making necessary adjustments. A clear, realistic schedule ensures the transition occurs systematically, reducing chaos and uncertainty.

HOW WE DID IT AT J&J

Define the change

The senior leadership team defines the goals and objectives related to R. A core team is put together to lead the SAIL.R initiative and define the overall roadmap. A few study teams will conduct pilot studies using R and R shiny to create TLGs using R and Shiny. Lessons learned meetings will be organized to gather feedback and refine the path forward for all studies using R for TLG. In the meanwhile, subteams are put together. One team will develop fully validated functions and packages to generate TLGs in line with the standards. A second team works on interactive visualisation tools. Another team will focus on regulatory submission strategy. A change management team is created to overview how the change will be implemented and manage the human side. Each team has at least one representative in the core team meetings to make sure all streams are aligned.

Identify Key Stakeholders

A change this big involves more departments than only the Clinical and Statistical Programming (C&SP). A careful stakeholder analysis was done to make sure the right people from other departments, like Statistics & Decision Sciences and IT were involved. It was evaluated what the appropriate meetings and means of communication were with all the stakeholders. A communication plan was written.

Assess the Impact of Change and Business Readiness

The training team conducted a survey to assess the level of familiarity of our programmers with the R programming language and mapping skill gaps. A small percentage of the group were R experts, most people had no experience with R at all, and the rest of the group had an intermediate level. We realized training would be an important part of the preparation for the new programming language. An R training strategy team was put together to identify the trainers and topics we would cover, as well as the strategy on how to deliver the trainings.

A technical analysis of our Statistical Computing Environment (SCE) was done to evaluate the current status and the required changes to sustain programming in new languages and interactive apps. A plan, including detailed timelines, was worked out to make sure the technical requirements were met at the right times.

Develop Resistance Managing Strategies

Training
The first step in the training plan was to train the trainers, not only in knowledge about R, but also improving teaching skills. All candidates were trained by R Studio (now Posit) and were given the chance to go for certification as R studio trainer. The team spent a lot of time on developing the content of the trainings on the topics deemed necessary as basic R skills required for all statistical programmers. At first, the plan was to have live in-person classroom trainings at different locations across the globe, requiring the trainers to travel. However, at that moment the COVID pandemic hit, and we had to change the strategy (even in change management, change is the only constant). We switched to virtual training. This had several advantages: the trainers did not need to travel, the sessions could be cut into more bite sized sessions, more options across the week and across time zones could be offered.

The audience
Approximately 300 programmers (across US, EU, APAC) responsible for programming ADaM datasets and TLGs in support of regulatory submissions. They are experienced in clinical trial work and programming concepts, primarily experienced in SAS, but in most cases limited to no experience in R. We noticed some people were eager to learn and implement the new programming language, while others, who spend decades with SAS, showed a lot of resistance. The recent switch of SCE [8] and other tools supporting the programmers are certainly an advantage from technological point of view. On the downside, it increased a feeling of change saturation. Another challenge was that during the period the training sessions run, the programmers also need to continue the day job and make sure trial deadlines are met.

The content

- **2020 - An Introduction to R:** Designed to introduce R to the Janssen SAS Programmer. Emphasis placed on building the skillset required to accomplish basic tasks commonly performed by a SAS Programmer (e.g., reading, manipulating, and summarizing data). The goals of this course were to understand and use R Studio, import data into R using the haven package, perform data manipulation using the dplyr and tidyr packages, produce basic statistical summaries using the dplyr package, produce basic formatted Tables and Listings using the huxtable package, produce basic formatted Figures using the ggplot2 package.
- **2021 - Janssen Statistical Reporting Package:** Uses the Tidyverse suite of packages to generate highly formatted, statistical summary Tables, Listings, and Graphs (TLG) for regulatory submission.
- **2022 – present: Building on the Foundation:** Continue to add tools to the R "toolbox." Emphasis placed on strengthening the foundational understanding of data manipulation and summary in R. Here we focused on more data manipulation tools (e.g., dates, string manipulation, working with factors), statistical testing (e.g., Chi-square, ANOVA) and creating functions.
- **2024 – Cross Pharma Statistical Reporting Package**: This new R reporting ecosystem is based on rtables [9], tern [10] and junco [11] to generate TLGs according to the Johnson and Johnson Connected standards, provides extended statistical analysis capabilities for safety and efficacy tables, an rtf exporter and support for spanning column headers and risk difference columns in tables.

The approach
For our initial trainings, we adopted a traditional “classroom” approach, leveraging modern technology. Lessons were kept as interactive as possible:

- Class polls
- R vs SAS: show people what they know already and how they can reuse it in a new context
- Guided exercises: step by step approach clearly explaining what is expected, and provide starting code where only a few blanks need to be completed. This is less scary than a completely blank page!
- Full exercises with relatable content: show people the new knowledge can be useful in situations they are familiar with, e.g. derive age groups based on age variable

A nice trick to help overcome resistance is to give people a quick win for starters, e.g. put some “building blocks” of code in the right order, run the code and you already created your first graph! One of the most heard comments after the training sessions was that the R programming language was “not as scary as they thought it would be”. This was proof for us that training was a very important step in the change manage process and in lowering the resistance.

Create an Implementation Timeline
Each substream has its own detailed roadmap. The core team also creates a high-level Roadmap to bring all streams together and visualize how the different milestones interact with each other.

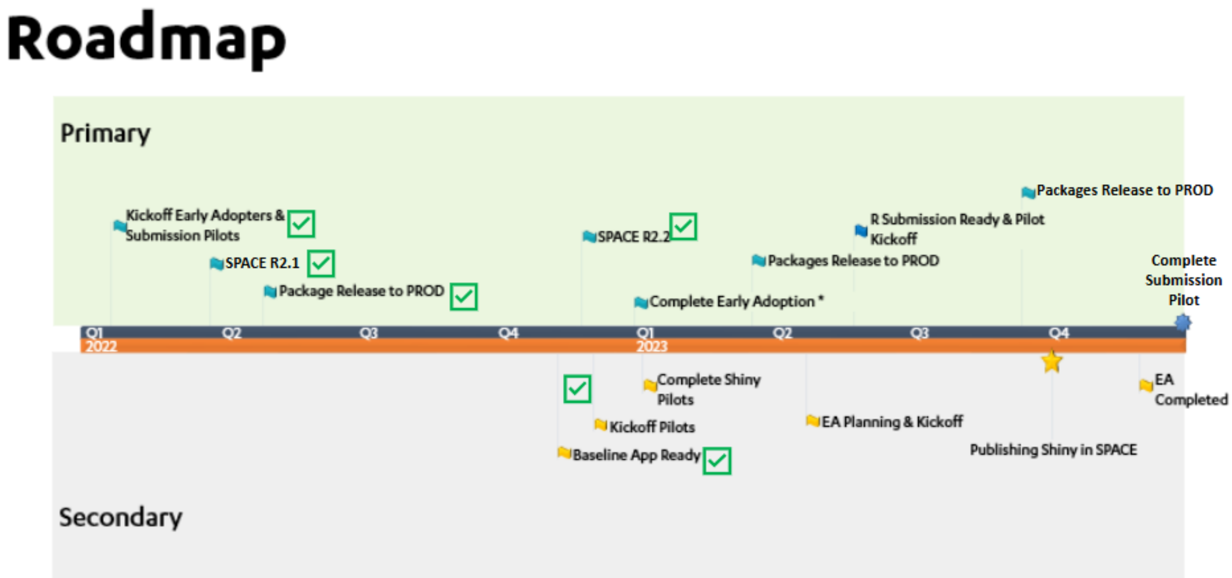

Figure 1: Example of the high-level roadmap

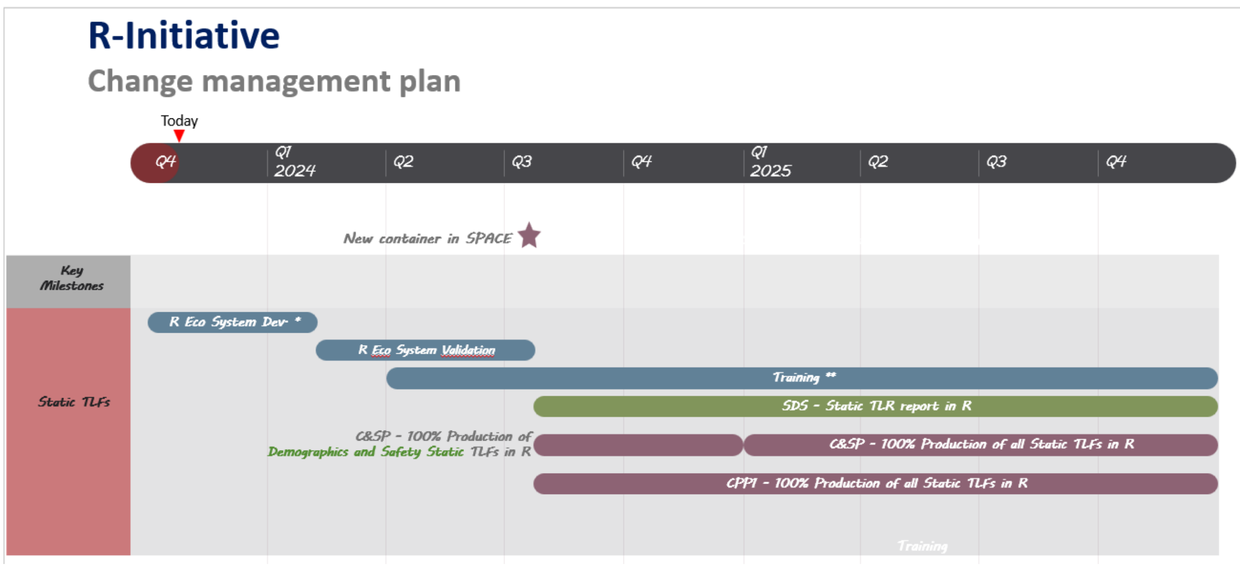

Figure 2: Example of the “Change management stream” roadmap

IMPLEMENTING CHANGE

While meticulous planning lays the foundation for successful transformation, the true measure of a change initiative’s viability lies in its execution. Effective implementation ensures that the strategic blueprint materializes into tangible results, aligning organizational efforts with the overarching objectives. Any lapse or deviation during this phase can undermine the entire initiative, rendering even the most comprehensive plans ineffective. Therefore, precise and conscientious execution is paramount, emphasizing not only the completion of prescribed steps but also their alignment with stakeholder needs and strategic goals. Ultimately, successful implementation transforms the theoretical aspects of planning into operational realities, bringing the vision of change to fruition.

A key enabler of effective implementation is active stakeholder engagement. Involving stakeholders—whether employees, customers, or partners—during execution fosters a sense of ownership and collective responsibility. Their unique insights and perspectives can enrich the process, providing valuable feedback that refines implementation tactics. Engaged stakeholders are more inclined to support the change, as their concerns and contributions are acknowledged, reinforcing their commitment and reducing resistance. This collaborative approach serves as a vital bridge connecting strategic intent with practical, collective action, thereby enhancing the sustainability and impact of the change.

COMMUNICATION DURING IMPLEMENTATION

Communication serves as the lifeblood of the implementation process. Continuous, open dialogue with stakeholders

fosters transparency, builds trust, and cultivates a sense of inclusion. Keeping all involved parties informed about progress, upcoming milestones, and challenges sustains engagement, motivation, and alignment toward shared goals. Furthermore, effective communication provides a platform for stakeholders to voice concerns, ask questions, and offer insights. Addressing feedback in real-time helps prevent potential issues and demonstrates organizational responsiveness, reinforcing collective commitment.
Different stages of communication are crucial throughout implementation:

- **Announcing the Change:** Introduce the change to stakeholders, outlining its purpose, scope, and anticipated impact.
- **Explaining the Change:** Provide detailed information concerning the rationale, benefits, and associated risks.
- **Responding to Questions:** Answer inquiries transparently, acknowledging uncertainties and committing to follow-up where necessary.
- **Listening to Feedback:** Actively solicit and incorporate stakeholder input to refine implementation strategies.
- **Sharing Progress:** Regularly update stakeholders on milestones, successes, and obstacles to maintain transparency and trust.

Addressing Difficult Conversations
Handling difficult news candidly is critical to maintaining trust and credibility. The guiding principle is clarity: address issues directly, promptly, and without equivocation. Avoiding or delaying tough conversations can erode trust and exacerbate uncertainties. Instead, confront challenges head-on, articulating the facts plainly, and emphasizing potential positive outcomes arising from the resolution of these issues. Authenticity and transparency foster respect and strengthen relationships, demonstrating organizational integrity.
Effective communication tips during change include:

- Using clear, simple language devoid of jargon.
- Being honest and transparent about all aspects of change, including setbacks.
- Encouraging open feedback and adapting strategies accordingly.
- Leveraging multiple communication channels to reach diverse audiences.
- Maintaining consistency through regular updates.

MANAGING RESISTANCE TO CHANGE
Resistance is an inherent response to transformative initiatives, often rooted in apprehensions about the unknown, potential disruptions, or perceived threats to existing routines. While resistance can seem like a barrier, it also provides valuable insights into concerns that may otherwise remain unarticulated. Addressing resistance proactively is essential for fostering an environment of understanding and shared ownership.
Strategies for managing resistance include:

- Identifying the root causes behind resistance behaviors.
- Acknowledging and validating stakeholders' concerns.
- Approaching resistance with empathy and understanding.
- Engaging in open dialogue to explore mutually acceptable solutions.
- Maintaining flexibility and willingness to adapt plans to alleviate concerns.

FOSTERING A MINDSET FOR CHANGE
Successful implementation also requires cultivating a positive mindset toward change. Recognizing that mindset shifts are gradual and necessitate patience and persistence is vital. Leaders must create opportunities for individuals to internalize the benefits, share success stories, and experiment in low-risk environments. Celebrating early adopters and emphasizing personal and organizational gains reinforce positive attitudes.
Additional tips for fostering a mindset shift include:

- Ensuring leadership fully understands and embodies the change vision.
- Sharing compelling narratives that resonate emotionally.
- Providing ample opportunities for experiential learning.
- Maintaining focus, confidence, and consistency throughout the process.

HOW WE DID IT AT J&J

Communication
We learned from the successful deployment of our SCE SPACE. An extensive, multi-channel communication plan was worked out.

- **Town hall meetings and the newsletter** were used as primary channels to communicate broad updates on expected change early on, with a focus on "what's in it for you" and benefits, while at the same time acknowledging risks and emotions associated with the change. We avoided multiple e-mails as we learned from feedback, most programmers felt that they received too many e-mails and people might miss important communications.

- **R-portal** is a one stop shop website where all information related to R is grouped together. Important updates are put on the front page to draw immediate attention, as well as team members. Different tiles link to separate pages about “Training”, “R-library and scripts” which contains a catalog of standard scripts to start from, pages about the most important packages like “tern” and “junco”, guidelines on specific topics, “Submission”, …
- **SAIL.R** trips were set up, a dedicated series of meetings. These meetings are a platform for information sharing between colleagues, initially only C&SP, but later Statistics & Decision Sciences joined as well. There are three pillars for topics: small, interesting training topics, sharing of experience and process updates related to R. In every meeting there is room for questions: topic related and all R-questions. Sessions are organized in two different time zones (APAC/EU - US/EU). People are free to join whichever is most convenient. We try to align topics as much as possible, depending on the availability of the presenters and previous knowledge. Sharing information between regions is encouraged.
- **Community of practice meetings** per therapeutic area: in the beginning, we tried to have people come with their practical questions to the SAIL.R trips. This did not work well as the group was rather big (in each time zone, usually > 100 people showed up). People seemed shy to ask their questions, and thought their question was “stupid” or not important enough to bother the whole group. Therefore, community of practice meetings per therapeutic area or even sub-areas were set up. The small group sessions proved to be more interactive. In addition, gathering questions that the subject matter experts received and starting the meetings with discussion these questions proved effective in starting conversations.
- **Online platforms**: the business-focused online platform Viva Engage is used to encourage informal communication between peers. It creates a feeling of community and allows colleagues to share ideas, ask questions, have conversations, provide feedback and discuss suggestions for future improvements.

Managing resistance to change
By allowing honest feedback and listening to concerns we identified several causes of resistance. In the beginning the biggest cause of resistance was the “**fear of the unknown**”. Training was an important step to overcome this initial fear, but it is equally important to keep communicating about all of the planned steps along the way. Once people started using R, we identified a new barrier: the **need for technical support**. Programmers felt that they got stuck on technical “how to” questions, especially where practice differs from training situations. Because of their lack of experience with the new reporting packages, it took too much time, or they were unable to figure out how to use the new system. A group of experienced subject matter experts (SMEs) was identified to help answer questions quickly. At J&J, we have a knowledge sharing platform where questions can be posted, called RedDesk. Questions and answers are stored in a searchable database, building a library of knowledge. The tagline is “No problem should ever be solved twice”. Our SME group is linked to questions related to certain topics and will be immediately notified when questions are posted. As our project grew, specific SME subgroups are created per R subcategory, such as “R general”, “setup and package installation”, “tidyverse” and “R JJCS reporting packages”. The names of the SMEs are also advertised on the R-portal, so people can also get directly in contact, if preferred. It is encouraged to put a summary of the question and answer on the RedDesk afterwards, so the next person with the same question can find the answer immediately and the SME does not need to answer the same question over and over again.

Another widespread concern was if the **regulatory agencies** would accept submissions in R. Our submission substream gave regular updates about communication with regulatory authorities and provided guidelines. We paid a lot of attention in Town Hall meetings to our early adopter team who successfully completed a hybrid submission to the FDA [3]. Their presentation not only encompassed the facts but gave a nice overview of the personal journey of the programmers, their emotions during the project, the challenges and how they were overcome. This was a big boost for morale in the entire department.

Even small success stories were shared, usually in the SAIL.R trips. This gave colleagues the sense that “I can do it too”, “it is worth giving it a try”, “maybe it’s not as hard as I think it will be”. Simple stories like: “a person trying out the new reporting package, getting some errors, trying again and creating the first table” go a long way in diminishing the resistance in the team. Enthusiastic individuals from various departments were identified and trained to be ambassadors or “Change Champions” to spread the enthusiasm and lead by example.

Flexibility was crucial in our journey, and our ship had to adjust course more than once. Our initial plan was to use a J&J homegrown reporting package, but after careful consideration, the decision was taken to abandon this path and join the cross-pharma effort, using another reporting package. This created extra resistance with people, both in the group who were open to the initial change, and the ones already resisting. It took careful explanation as to WHY this decision was taken, what the advantages are and showing empathy and understanding about the resistance.

Fostering a mindset for change
Not everybody has the opportunity to immediately start to apply the new knowledge gained in the R trainings and start creating production TLGs. Most clinical trials span multiple years and there is a need for consistency between studies of the same compound. Therefore, the use of R for quality control (QC) instead of creation of production TLGs was highly encouraged. This provides a safe environment for learning and experimenting. Any number of TLGs created in R is a win, no need to immediately do the entire set at once. If no exact match with the mock was reached, but “good enough” to verify the content of the production TLG, this is ok for now and more time can be spent later to figure out the details or suggest improvement to the developers team. In addition, the comparison of TLGs created

with SAS and R helps to transfer the knowledge of the “known” programming language to the “unknown” language. Seeing that you can come to the same results, helps people believe in the new system.

Overall, our goal is to create a fundamental mindset change from “I am a SAS programmer” to “I am a programmer/developer who has a toolbox of programming languages to perform statistical analysis. I can pick the right tool for the job at hand.”

MONITORING AND EVALUATING CHANGE

Monitoring and evaluating the change process are critical components of successful change management. They provide vital insights into the progress of the transition, its effectiveness, and the level of stakeholder engagement. Continuous oversight ensures that the initiative remains aligned with its intended objectives and facilitates early identification of issues that may hinder success. Furthermore, ongoing assessment offers opportunities to adapt strategies proactively, ultimately enhancing the likelihood of achieving desired outcomes.
Monitoring and evaluation serve several key purposes:

- Confirming that the change is progressing as planned and meeting its goals.
- Detecting potential challenges or setbacks early, allowing for timely corrective actions.
- Assessing the impact on stakeholders and adjusting strategies accordingly.
- Capturing lessons learned to inform future change initiatives.

The change monitoring and evaluation process typically encompass the following stages:

- **Planning:** Developing a comprehensive monitoring and evaluation plan that defines key performance indicators (KPIs). These KPIs should be specific, measurable, achievable, relevant, and time-bound (SMART).
- **Data Collection:** Gathering data through various methods, including surveys, interviews, focus groups, and system metrics, aligned with the identified KPIs.
- **Data Analysis:** Examining the collected data to identify trends, patterns, and areas requiring attention.
- **Reporting:** Communicating findings to key stakeholders, highlighting successes, concerns, and recommendations for adjustments to the change plan.

Tips for Effective Monitoring and Evaluation

- Engage stakeholders actively in the process to ensure transparency and inclusiveness.
- Utilize diverse data collection methods to capture a comprehensive picture of the change process.
- Conduct regular data analysis rather than postponing until the end of the change cycle, enabling early intervention.
- Share progress reports consistently to maintain stakeholder trust and confidence.

Long-term Considerations
Monitoring should extend beyond immediate outcomes to evaluate the long-term impact of change initiatives. Some adaptations may yield short-term benefits but could be detrimental over time; hence, sustained evaluation is necessary to confirm enduring success. Patience and persistence are essential, acknowledging that change processes often unfold gradually. Furthermore, organizations should be prepared to learn from setbacks, making iterative adjustments to strategies.

HOW WE DID IT AT J&J

A metrics system was set up to monitor the adoption of R. With an interactive Shiny app, we can query our SCE for the number of registered R programs. We can dissect the data and make analysis based on Therapeutic area, per compound, who are the top users, who is not using R at all? This helps us to understand the evolution, refine engagement strategies and prompt resolution of issues.

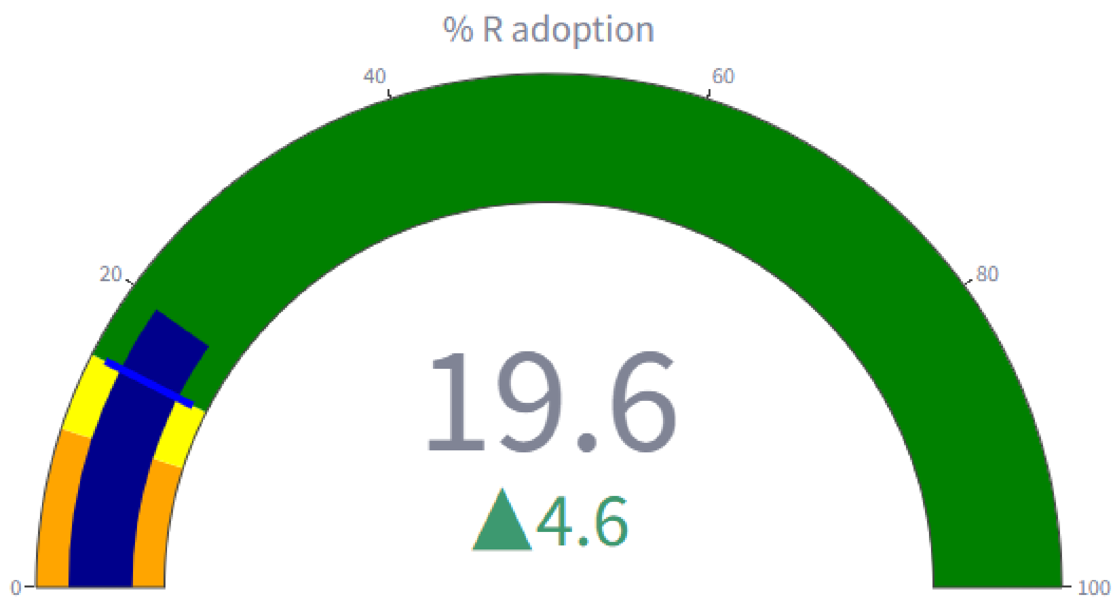

Figure 3: graph representing the R adoption and evolution in our department.

SUSTAINING CHANGE

Sustaining change extends beyond successful implementation; it involves embedding new behaviors, processes, and mindsets into the fabric of the organization. Without deliberate efforts, there is a tendency for individuals and systems to revert to old habits, undermining long-term success. Environmental changes over time can further challenge sustainability. Therefore, organizations must develop strategies that reinforce and institutionalize the change to ensure its endurance.
Key strategies for sustaining change include:

- **Engaging Leadership:** Leaders at all levels must remain committed, act as role models, and allocate resources to support continued adherence to the change.
- **Embedding in Organizational Culture:** Incorporate change into core values, rituals, and norms to reinforce its importance.
- **Ongoing Communication:** Continue to communicate the significance, benefits, and progress of the change initiatives to maintain visibility and commitment.
- **Celebrating Successes:** Recognize milestones and individual contributions, fostering motivation and reinforcing positive behaviors.
- **Leveraging Change Agents:** Identify influential individuals to champion the change and support peer adoption.
- **Supporting Structures and Systems:** Adjust organizational systems, policies, and job roles to align with the new way of working.
- **Promoting Continuous Learning:** Cultivate a culture committed to ongoing improvement, innovation, and adaptation.
- **Periodic Reviews:** Schedule regular assessments to evaluate the status of the change and make necessary adjustments.

Tips for Sustaining Change

- Empower employees to take ownership of the new processes, fostering intrinsic motivation.
- Provide continuous training and support to reinforce skills and attitudes.
- Maintain flexibility in the change plan, allowing adaptations in response to evolving circumstances.
- Recognize and reward contributions to reinforce commitment and sustain momentum.

Additional Considerations:

- Patience and perseverance are crucial. Sustaining change is an ongoing journey requiring time and consistent effort.

- Transparency and honesty build trust, encouraging ongoing engagement. Clearly communicate both successes and challenges to foster collective resilience.

BRANDING AND INFUSING FUN INTO CHANGE MANAGEMENT

Incorporating branding and elements of fun into change management initiatives can significantly enhance engagement, memorability, and overall effectiveness. By cultivating a positive and cohesive experience around the change, organizations can reduce anxiety and foster active participation among stakeholders. These strategies serve to transform the change process from a potentially daunting task into an inclusive and motivating journey.
Key approaches to integrating branding and fun into change management include:

- **Branded Change Campaigns:** Develop a distinctive name, logo, and visual identity for the initiative. This fosters a sense of belonging and unity, making the change more recognizable and memorable.
- **Themed Events:** Organize events aligned with the change objectives, such as "Tech Fiesta" during a system upgrade, creating an engaging environment that combines learning with entertainment.
- **Interactive Workshops:** Facilitate hands-on, participatory sessions that include games, quizzes, and prizes, enabling employees to learn about the change in an enjoyable manner.
- **Storytelling:** Construct a compelling narrative around the change through formats such as comic strips, animated videos, or short skits performed by team members, helping to humanize and contextualize the initiative.
- **Change Champions:** Identify and train enthusiastic individuals across departments to serve as ambassadors. These champions can wear branded merchandise and exemplify positive engagement, inspiring their colleagues.
- **Rewards and Recognition:** Celebrate milestones with branded merchandise, certificates, or simple public acknowledgments. Recognizing early adopters can generate motivation and reinforce positive behaviors.
- **Gamification:** Transform learning and adoption processes into game-like experiences. Implement challenges, leaderboards, badges, and rewards to motivate individuals and teams.
- **Feedback Booths:** Set up visually appealing, branded booths where employees can share opinions, concerns, or success stories, encouraging active and voluntary participation.
- **Change Journals:** Distribute branded notebooks for employees to document their experiences, record questions, or express feelings related to the change, fostering reflection and engagement.
- **Interactive Surveys and Polls:** Replace standard feedback forms with engaging surveys and polls that encourage participation and provide valuable insights.
- **Visual Communication:** Utilize infographics, flowcharts, and other visual tools to simplify complex information. Developing a consistent visual language enhances clarity and brand recognition.
- **Social Media Integration:** Create branded hashtags and encourage employees to share their experiences, photos, and stories via internal social platforms or collaboration tools, fostering a sense of community.
- **Themed Dress Days:** Organize designated days where employees dress according to the change theme, such as "Going Green" days, to promote unity and fun.

When effectively combined, branding and fun can transform perceptions of change from a burdensome obligation into an exciting opportunity for growth and participation. It is essential, however, to maintain open and transparent communication throughout, ensuring that the levity does not compromise clarity or credibility. By thoughtfully integrating these elements, organizations can foster a more positive, cohesive, and committed environment—ultimately driving the success of the change initiative.

HOW WE DID IT AT J&J

To create a positive atmosphere around the introduction of the new programming language, a brand was created in the sailor theme. The change at hand, is comparable to a sailing voyage to explore uncharted territory. The brand name SAIL.R is chosen, pronounced as "sailor" but with a wordplay on the ".R" in the scripts name. Our tag line is "Together we will sail the seas of open source". A brand launch event was organized, with a small movie created by AI about sailing ships and seas of data, we took pictures of core team members across the globe in a sailor suit and edited them all together in a group crew picture. A logo with a sailing boat was designed to be included in all related communication to make it more recognizable. Our monthly meetings are called SAIL.R trips to put the image in the mind that we go on a small trip to explore more on the R territory. By infusing fun and branding, we created a memorable experience.

Figure 4: The SAIL.R brand logo

CONCLUSION

The SAIL.R initiative exemplifies how strategic change management, combined with robust planning, active stakeholder engagement, and a people-centred approach, can successfully transform organizational practices. By thoughtfully addressing the human side of change—fostering communication, managing resistance, and cultivating a growth mindset—J&J has not only transitioned its statistical programming from SAS® to R but also built a sustainable culture of innovation and continuous improvement. The integration of branding and fun has further strengthened team cohesion and enthusiasm, turning a complex technological shift into a shared voyage of discovery. As we look ahead, the lessons learned and tools developed through SAIL.R will serve as a guiding beacon for future initiatives, ensuring that change remains a catalyst for growth rather than a challenge to overcome.

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