

Effectively Transition Your Team to Open-Source

Yingshan You, Janssen Research & Development
yyou@its.jnj.com

Abstract

The poster outlines the necessary ingredients to successfully transition the clinical study team to R. It is crucial to discuss why it is important to the organization and/or to those individuals endorsing the adoption of this emerging trend and landscape change across pharma, how individuals can equip themselves with the must-have skills to thrive in today's workforce, how leaders can approach developing the organization, building the community culture, and more.

Several strategic focus areas will be touched upon and shared as follow.

- Change management
- Infrastructure and package development
- The community of practice and talent
- External partnership and engagement.

Change Management

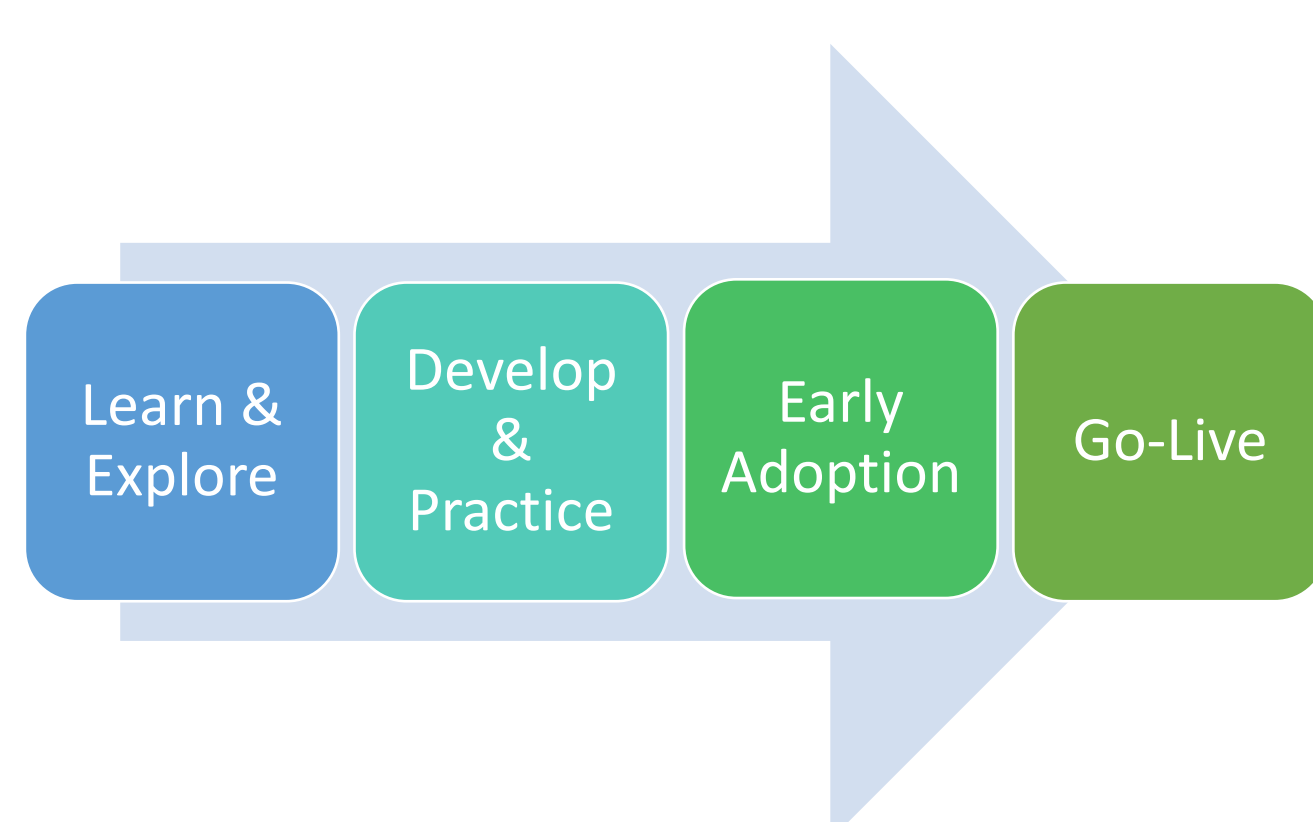
Change management and leadership is the key to foster and thrive in success. Illustrate key elements brought to achieve the desired outcome, and the strategy for the communication.

Bring the awareness of the need for change. People ask why we adopt open-source tools. Several of reasons below have given the inspiring vision.

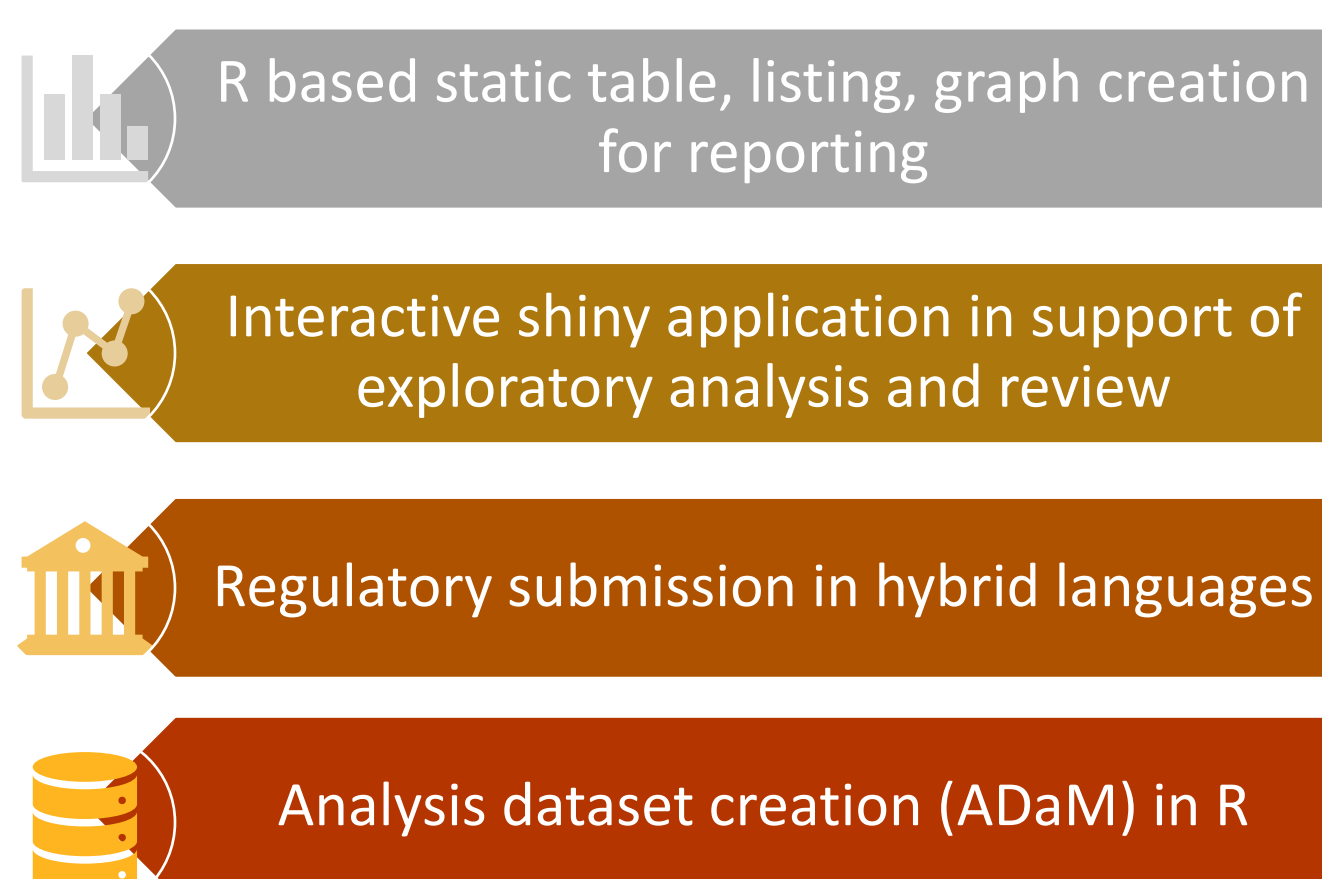
- Open-source tools have been grown in the adoption in recent years, which extend the analysis by using hybrid languages and methods.
- Open-source tools provide the interactivity and visualization with the productive communication in conducting of clinical trial research and data science.
- FDA has been open on the software choice to be used for statistical analysis and submission. Explore the chance in align of external landscape from cross pharma and Health Authority.
- Any other more like to attract new graduated talent.

Establish the roadmap in the desire to support the change. The leaders must know about the nature of leading change and paint a clear and simple vision of a desire future state that the change bring about. In Janssen we evoked four skillset development phases on four focused areas for thriving in future.

Four skillset development phases:



Four focused areas for R development:



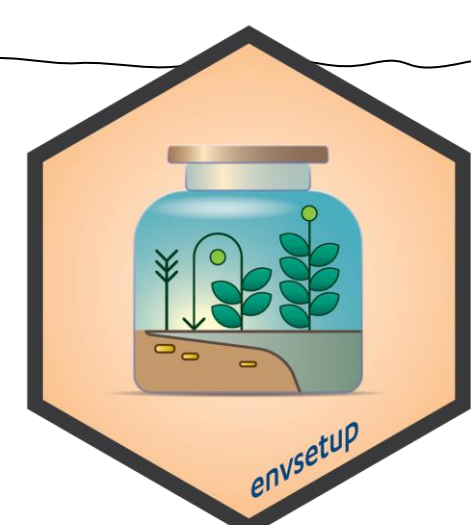
Infrastructure and Package Development

The method to establish the robust environment is essential to the effectiveness and quality of deliverable milestones. The strategical development has been implemented in support of the production at Janssen as follows.

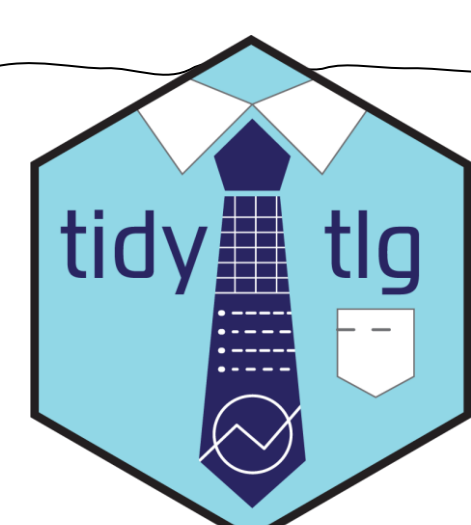
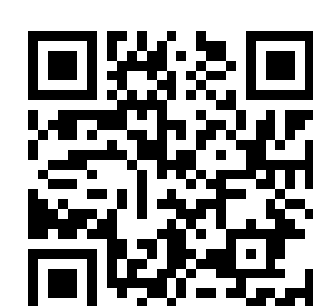
- Built a strong R eco-system with robust CICD pipeline in computing environment.
- Established R package governance committee to review and approve package requests.
- Established the process to develop and validate R packages for production and submission uses.
- Developed R packages & tools for user development.
- Established the process and communication for hot fix on bugs and feature requests.

With the note from recent releases Janssen brought two opensource R packages to the pharmaverse community as tool stack for usage. Hope audiences find benefits by checking pharmaverse github repository (QR code below) for detail or refer to presentations from Open Source Technologies stream talks shared in PHUSE US Connect 2023.

{envsetup} Tool for setting up environment
OS03 Extending your .Rprofile with {envsetup}
& {renv}

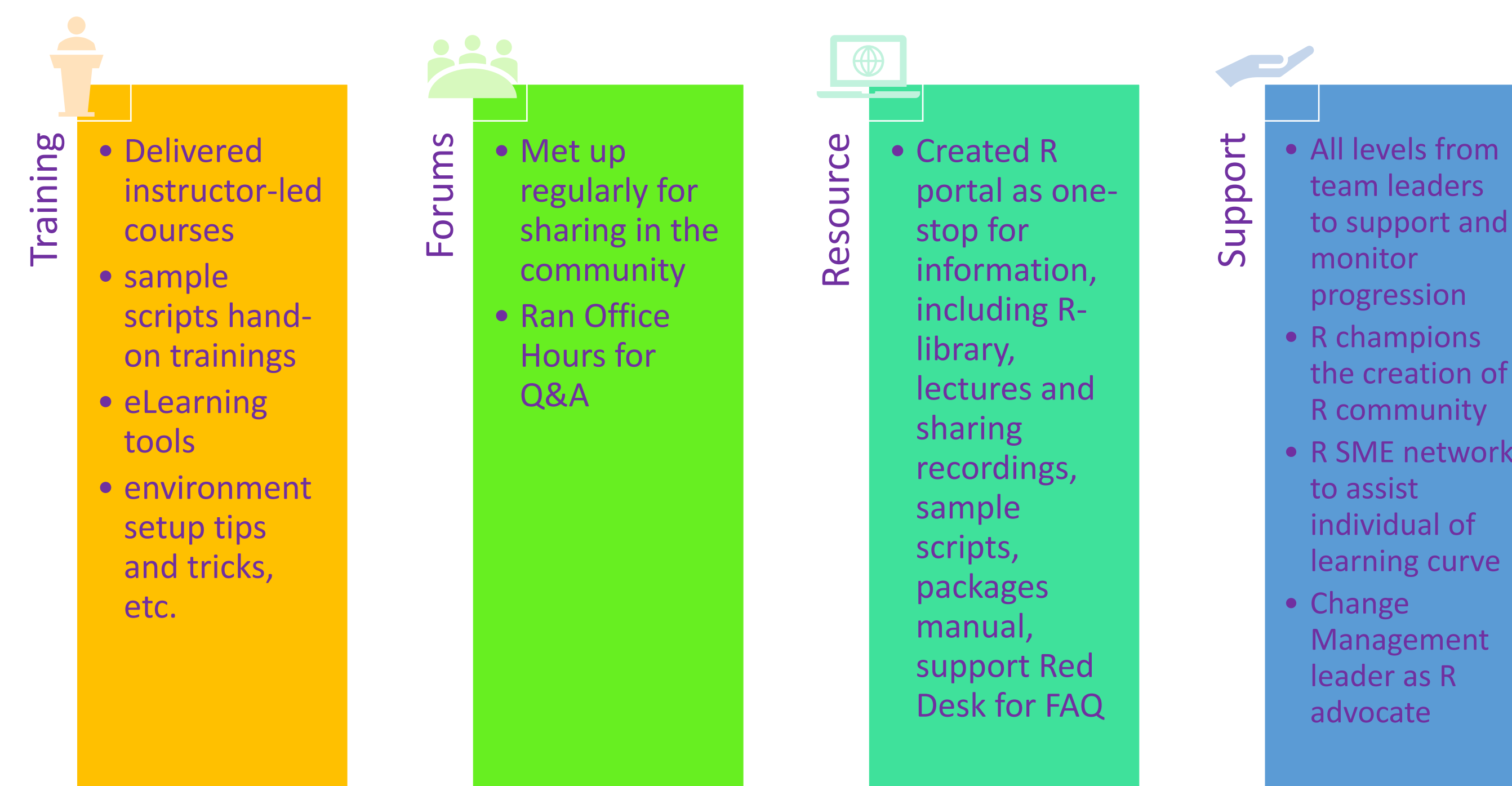


{tidytlg} Tool for creating tables, listings, graphics
OS02 tidytlg: An R package for clinical reporting
using Tidyverse



The Community of Practice and Talent.

The growth of community in learning and practicing R takes part in change and moves employees to commitment. In Janssen we built dynamic flagship initiative and different sub streams in support of knowledge know-how as follows.



External Partnership and Engagement

In align of envision and practice from cross pharma industry and the insight of regulatory filing from agencies, Janssen has been extended the connection to explore external landscape for shaping internal environment in several different ways. Engaging R consortium submission working group and the review of pilot projects is one of examples to translate R-based clinical trial regulatory submission experience for internal implementation.

Janssen also passionately engaged in the network of pharmaverse community with the aim of connecting individuals and organizations in pharma to shape the collective collaboration culture for enabling efficiency on end-to-end clinical reporting ability.

In addition to above dedicated endeavors, several different opportunities and resources listed below are good to explore and get involved the strength in the transition to R.



Summary

The successful outcome of driving the organization change is leading from individual level to inherit new skills and behaviors, so consequently measure how individual shows the ability to implement and to make the effort as essential. In Janssen we developed the framework to address as follows.

- Developed deliverable matrix and communication plan to track milestones.
- Established the forum to voice concern, routinely conduct the user survey.
- Created the metric report in the measurement of achievement.
- Communicated lessons learned of challenges and solution, the potential barriers to be overcome.

In overall the transition takes times. After the significant investment in helping people makes a change, we expect the enthusiasm is sustained and the results are delivered over time. The focus on the reinforcement needs to remain strong after go-live.

Acknowledges

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