

Building High-Performing Biometrics Teams: The SELF-REINFORCING LOOP and Leadership in Clinical Trials

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ABSTRACT

In the evolving field of biometrics teams within pharma, effective leadership is crucial for driving innovation, maintaining compliance, and achieving outcomes. This article explores essential leadership practises that elevate biometric teams into high-performing units capable of overcoming complex challenges. Key leadership skills include technical expertise, clear communication, and strong project management. A significant focus is on the SELF-REINFORCING LOOP, which integrates management and training by interviewing trainees, providing managers with feedback to address skill gaps, assigning relevant tasks, and conducting follow-up interviews to assess progress. This continuous loop fosters growth, development, and the cultivation of highly skilled and industry-ready biometric professionals. Through examples and case studies, the article illustrates how these practices and the SELF-REINFORCING LOOP enhance team performance, streamline workflows, and contribute to successful clinical trials. It offers practical guidance for current and aspiring leaders, equipping them with actionable strategies to cultivate effective leadership within biometric teams.

INTRODUCTION

Building and sustaining high-performing biometric teams is essential in clinical trials, where precision, teamwork, and continuous development drive success. Effective leadership goes beyond managing tasks—it involves fostering a culture of learning and structured development.

As the team expanded, balancing leadership responsibilities with technical work underscored the need for a structured, scalable system. This realization led to the development of the SELF-REINFORCING LOOP—a process integrating training, evaluation, feedback, and mentorship to facilitate continuous team development while ensuring productivity.

FROM CHALLENGE TO SOLUTION: THE ORIGIN OF THE SCHEME

Managing a growing team is both an opportunity and a challenge. Initially, I worked with a small team of four members. This setup allowed me to dedicate focused attention to each individual, mentoring and guiding their growth. While it required significant effort, this personal engagement allowed them to develop rapidly. These four members not only improved their technical skills but also built confidence and began taking ownership of their tasks.

However, as the months passed, the team began to grow. Within a short span, it expanded to eight members, and the challenge of scalability became apparent. Balancing the increasing demands of team management with my own responsibilities highlighted the need for a structured approach. The team's growth continued, reaching ten members and eventually thirteen by the end of the year (Figure 1). This rapid expansion illustrated the importance of finding a sustainable method to manage the team while ensuring consistent development for each member.

Faced with these challenges, I turned to the first four members of my team—those I had mentored closely from the beginning. They had developed significant expertise and were ready to take on leadership roles within the team. Together, we began brainstorming ways to address the growing complexity and identified the need for a structured, iterative process to manage the team effectively.

This collaborative effort led to the creation of the SELF-REINFORCING LOOP, a system designed to integrate training, evaluation, feedback, and mentorship into a seamless and scalable process. This loop ensured that the team could grow sustainably while maintaining high standards of performance and productivity.

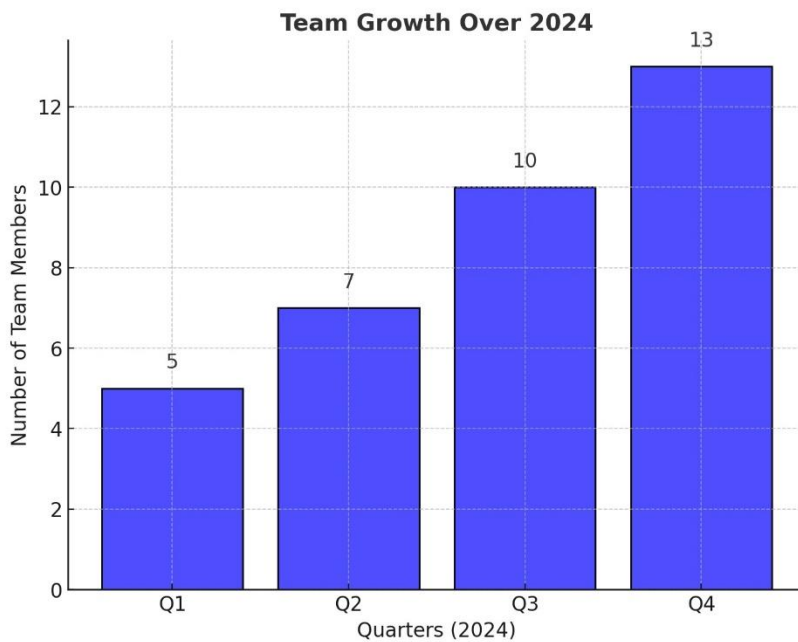


Figure 1.Graphical Representation of Team Growth Over Four Quarters

THE CORE OF THE TEAM DEVELOPMENT PROCESS

The SELF-REINFORCING LOOP is a continuous process designed to ensure the consistent growth and development of our team. This system integrates four interconnected components—**Training, Mentorship, Interviews, and Feedback**—that work seamlessly together to create a cycle of improvement. Once the process is completed, it begins again, reinforcing skills, addressing gaps, and elevating the team's overall performance.

TRAINING: BUILDING A STRONG FOUNDATION

The first step in the loop is **Training**, which is led by one of the four core team members responsible for onboarding and educating new staff. Using a well-structured **Training Agenda Plan**, she ensures that every junior team member is equipped with the knowledge and skills necessary to excel in the clinical programming sphere.

The training agenda, meticulously designed based on her extensive experience, outlines a comprehensive two-to-three-week program that covers both theoretical knowledge and practical application. This agenda ensures that new hires are not only introduced to the fundamentals of clinical trials but also gain hands-on experience in industry standards and programming techniques.

- **Week 1: Introduction and Fundamentals**
During the first week, trainees are immersed in the basics of clinical trials. They learn about study phases, cohort information, trial designs, and the essential terminology required to navigate the clinical programming industry. This phase focuses on theoretical and verbal knowledge to build a strong foundation.
- **Week 2: Industry Standards and Practical Work**
The second week introduces trainees to critical standards such as SDTM, ADaM, and other CDISC guidelines. They are guided through the process of creating Tables, Listings, and Figures (TLFs). Trainees also develop an understanding of the importance of the protocol and Statistical Analysis Plan (SAP), learning how these documents define study objectives, design, and statistical methods. Practical work becomes the focus here, with trainees beginning to understand the applications of these standards in real-world scenarios.
- **Week 3: Programming Practice**
In the final week, trainees dive into programming tasks. They work on creating and validating SDTM and ADaM datasets and practice generating TLFs. This week is designed to consolidate their learning and provide them with hands-on experience that mirrors real project work.

Supporting Materials: The training agenda is supplemented with a wealth of resources, including presentation slides, video tutorials, and practical exercises. These materials are carefully curated to simplify complex topics, making it easier for trainees to quickly adapt to industry standards and workflows.

THE KEY ROLE OF INTERVIEWS

Once the training phase is complete, the **Interview** stage begins. This critical step is led by the second core team member, who organizes structured interviews to evaluate the progress and competency of the trainees. The process ensures that team members are equipped with the necessary skills and knowledge to excel in their roles.

THE INTERVIEW AGENDA AND AUTOMATION TOOL

To streamline this process, the interviewer has developed an exceptional **Interview Agenda** and an **automation tool**—a system meticulously designed based on the collective experience of the team. This tool revolutionizes the interview process by introducing structure, flexibility, and efficiency, making the evaluation phase highly effective.

Database of Questions:

The tool incorporates a comprehensive database of questions, each paired with sample answers. The questions are carefully categorized according to the experience level of the interviewee—ranging from junior to senior-level programmers. This ensures that the interviews are tailored to the specific skill set and experience of the candidate being assessed.

Customization for the Interviewer:

The automation tool empowers the interviewer to customize the interview process based on their preferences. Users can specify:

- The number of questions they wish to ask
- The experience level of the interviewee

Once these parameters are set, the tool dynamically generates a customized set of questions. It then creates a structured sheet that includes the questions, their sample answers, and a separate column for the interviewer to record grades based on the responses provided by the interviewee.

Dynamic Evaluation System:

At the conclusion of the interview, the tool calculates the results dynamically. It:

- Computes the maximum possible score based on the selected questions
- Sums up the grades awarded by the interviewer
- Calculates a percentage to evaluate the interviewee's overall performance

Pass/Fail Assessment:

Based on the percentage score, the tool provides an objective pass/fail evaluation. This system ensures a consistent and unbiased evaluation process, enabling the team to accurately assess the readiness of trainees for the next phase of development.

Continuous Improvement Through Interviews:

The interviews serve as a critical checkpoint in the **SELF-REINFORCING LOOP**. They provide valuable insights into the strengths and areas for improvement for each team member, which are then shared with mentors and trainers. This feedback ensures that the development process is both iterative and targeted, addressing the unique needs of every individual.

THE ROLE OF FEEDBACK IN TEAM DEVELOPMENT

The third stage in the cycle is Feedback, a pivotal step that connects the results of the interviews to actionable plans for improvement. Once the training and interview stages are complete, the interviewer provides detailed feedback and evaluations to the mentors. This ensures that mentors are equipped with the necessary insights to work effectively with the junior staff and guide their growth.

Insights from the Interview Tool:

The interview tool plays a vital role in the feedback process. It not only provides detailed grading for each interviewee but also highlights their performance strengths and gaps in a structured manner. This clarity allows mentors to quickly understand the weaknesses and strengths of their team members, making it easier to plan targeted developmental actions.

Providing Actionable Feedback:

Feedback is tailored to each individual, focusing on specific areas where improvements are needed while reinforcing their strengths. This actionable insight helps mentors prioritize their efforts and ensures that junior staff receive the support they need to succeed.

Collaborative Planning with Mentors:

Armed with the feedback, mentors begin devising personalized strategies to address gaps in the skillsets of junior staff. This collaborative planning ensures that the transition from evaluation to mentorship is seamless and focused.

Accelerating Growth and Productivity:

Feedback acts as a powerful accelerator for team development. By addressing gaps early and effectively, mentors can help junior staff adapt quickly and integrate productively into the team.

Foundation for Continuous Improvement:

The feedback process is not static—it's an integral part of the SELF-REIN FORCING LOOP. The structured insights from interviews feed into mentorship and future training sessions, ensuring a continuous cycle of improvement and progress.

By leveraging the strengths of the interview tool and delivering actionable insights, the feedback stage ensures that the journey from evaluation to mentorship is data-driven, focused, and effective. It empowers mentors to build personalized development plans, fostering growth and collaboration across the team. The heatmap in Figure 2 showcases the improvement in clinical programming skills after receiving feedback, with all areas showing notable growth. This highlights the effectiveness of structured feedback in enhancing technical skills and fostering professional development.

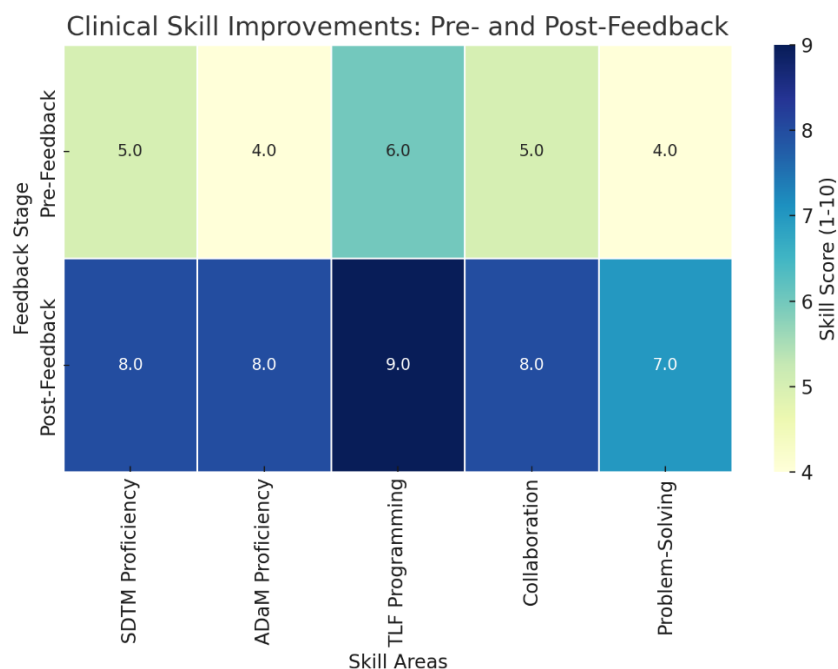


Figure 2: Clinical skill improvements: Pre- and Post-Feedback

MENTORSHIP: CULTIVATING GROWTH AND PRACTICAL EXPERIENCE

Mentorship is a key part of our system, and we have seen firsthand how effective it can be. We carefully match mentors and mentees based on work ethics, personalities, and compatibility. This strong connection has helped both sides grow, fostering technical and soft skills across our team.

Using interview feedback, we assign tasks that align with mentees' strengths and career goals. We track progress closely and adjust training plans as needed, ensuring continuous improvement.

Mentorship plays a vital role in improving key performance metrics over time, as highlighted in our findings:

Guided mentees technically:

- Improving their programming and analytical skills, which has directly contributed to higher Code Quality Improvement and Error Reduction.
- Faster project turnarounds due to optimized logic and best coding practices.

Held regular one-on-one check-ins:

- Addressing challenges proactively, boosting mentees' Retention Rate and overall confidence.
- Ensuring faster Time to Productivity by providing structured guidance.

Provided career advice:

- Preparing team members for internal promotions, leading to a steady increase in the Promotion Rate.

Reviewed project work and provided feedback:

- Conducting structured code reviews, ensuring adherence to best practices and enhancing Code Quality Improvement.
- Providing detailed feedback on logic, optimization, and industry standards, which accelerates mentee growth.

Encouraged knowledge sharing:

- Fostering collaboration, improving problem-solving efficiency, and reinforcing Innovation & Problem-Solving.

Offered continuous support and motivation:

- Keeping mentees engaged, ensuring commitment to their roles, and contributing to higher Retention Rate.

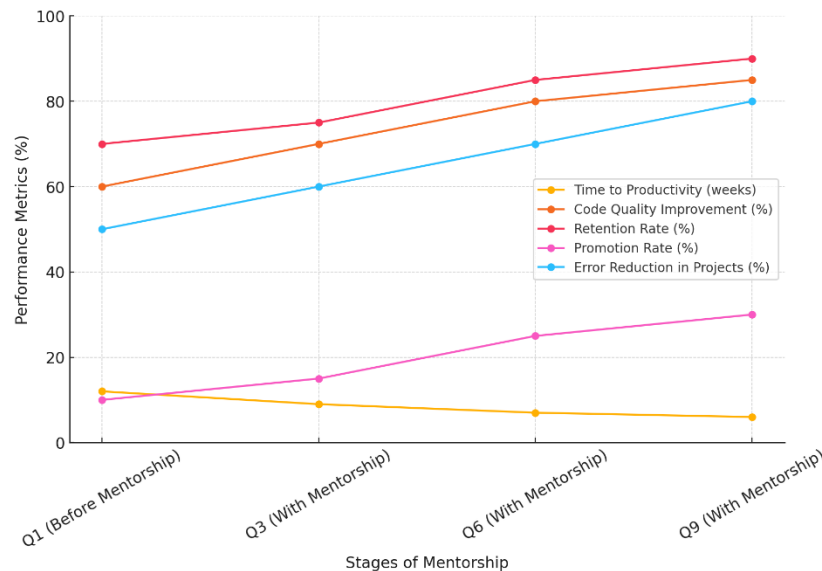


Figure 3: Impact of Mentorship over time

The cumulative benefits of our structured mentorship approach are clearly reflected in the overall growth of our team. As shown in the stacked bar chart, mentorship has contributed to continuous improvements across multiple performance metrics, including technical skills, retention, and overall productivity (Figure 3)]. By investing in mentorship, we have ensured a steady increase in team efficiency, fostering a collaborative and high-performing work environment.



Figure 4: Quantifying Team Development: Performance Improvements Through the SELF-REINFORCING LOOP

The **orange bars represent the initial state of the team before implementing the loop**, showing challenges in communication, leadership development, technical skill growth, and overall efficiency. In contrast, the **blue bars reflect improvements after applying the loop**, highlighting enhanced teamwork, faster decision-making, optimized resource utilization, and stronger clinical and technical expertise (Figure 4).

CONCLUSION

Building a high-performing biometric team requires a structured approach that integrates training, evaluation, feedback, and mentorship into an iterative process. The SELF-REINFORCING LOOP connects these elements to ensure continuous improvement, addressing individual gaps while fostering collaboration and skill development.

Although this system is adaptable for any biometric team, I developed it specifically for statistical programmers based on my experience as a manager. The process begins with comprehensive training, followed by structured interviews and actionable feedback, which guide mentors in planning targeted development strategies

Over the past year, I have closely monitored the implementation of this system within my team, actively engaging with both mentors and mentees to assess its impact. Through direct conversations, structured feedback sessions, and a carefully designed survey, I gathered insights into how the loop influenced team dynamics, professional growth, and overall efficiency. The horizontal bar chart reflects the cumulative experiences and perspectives of my team, quantifying the progress made through mentorship, structured training, and continuous feedback cycles. Moving forward, this model will continue evolving based on team feedback, ensuring long-term adaptability and success. It serves as a foundation for continuous improvement, leadership development, and high-quality contributions in the clinical research industry.

CONTACT INFORMATION

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