PharmaSUG 2026 - Paper LS-173

From Programmer to Influencer: Strategic Leadership for Statistical Programmers in Clinical Development

Xiaohan Zou, Wei Shao, and Yi Yan, Bristol Myers Squibb

ABSTRACT

The role of statistical programmers is evolving—from technical executors to strategic influencers shaping clinical development. Building on strategies for bridging functional gaps discussed at PharmaSUG 2025—where strengthening collaboration between programming, biostatistics, and regulatory teams proved critical for delivering high-quality, compliant outputs—this paper takes the next step. We explore how programmers can leverage these collaborative foundations to transition from technical contributors to influential leaders, shaping processes, driving innovation, and guiding organizational change in an increasingly complex regulatory environment.

We showcase a recent initiative led by statistical programmers to design an end-to-end FDA Bioresearch Monitoring (BIMO) submission process. Acting as strategic leaders, programmers influenced cross-functional alignment with biostatistics, regulatory, and clinical operations, driving proactive adherence to the FDA BIMO Technical Conformance Guide (TCG). By championing automation through metadata-driven SAS macros and Python integration, they transformed fragmented workflows into a streamlined, compliant process—eliminating manual effort and accelerating timelines.

A practical framework—Initiation, Engagement, Influence, Leadership—will be presented to guide attendees toward leadership development and process harmonization, illustrated through this real-world case. The session concludes with a look at future-ready competencies, including AI-enabled workflows, open-source integration, and strategies for driving innovation in clinical programming.

INTRODUCTION

The landscape of clinical development is undergoing rapid transformation. In this evolving environment, the role of the statistical programmer is also changing. Once viewed primarily as a technical executor responsible for producing analysis outputs, the modern statistical programmer is increasingly positioned at the intersection of data, technology, and regulatory compliance, with the potential to influence decisions well beyond code delivery.

This evolution matters in day-to-day practice. Fragmented workflows, manual processes, and limited process harmonization not only slow delivery timelines but also increase compliance risk. At the same time, programming teams often have deep visibility into end-to-end data flows, submission requirements, and technical inefficiencies—insights that uniquely position them to drive innovation and organizational change. Realizing this potential requires a mindset shift, from viewing programming as a support function to recognizing it as a strategic partner in clinical development.

This paper builds on the foundation established in the 2025 paper “Bridging the Gap: Leadership of Statistical Programmers in Clinical Trials,” which focused on strengthening cross-functional engagement and collaboration. Moving a step further, the current work explores how statistical programmers can transition from collaborative contributors to strategic influencers and leaders within clinical development organizations. Specifically, this paper aims to provide a practical roadmap for programmers seeking to expand their impact beyond technical execution. Through a real-world case study centered on the design of an end-to-end FDA Bioresearch Monitoring (BIMO) submission process, we demonstrate how statistical programmers can shape processes, drive automation, and influence cross-functional alignment. Drawing from this experience, we introduce a four-step leadership framework—Initiation, Engagement, Influence, and Leadership—to guide professional growth and process harmonization.

By illustrating how technical expertise, regulatory awareness, and leadership behaviors intersect, this paper underscores a central message: leadership in statistical programming is not defined by title, but by mindset, action, and the ability to drive meaningful, sustainable change.

BACKGROUND

PHARMASUG 2025 RECAP: FROM SILOED FUNCTIONS TO COLLABORATIVE FOUNDATIONS

Recent years have seen growing recognition across the pharmaceutical industry that effective clinical development depends on strong collaboration across functions. The paper “Bridging the Gap: Leadership of Statistical Programmers in Clinical Trials”, presented at PharmaSUG 2025, focused on this collaborative dimension by emphasizing the need to break down traditional functional silos. It demonstrates how intentional engagement and communication among statistical programming, biostatistics, data management, clinical, and regulatory teams can improve efficiency and meet rising expectations for quality, speed, and regulatory compliance.

This work highlighted the evolving role of statistical programmers as key enablers of collaboration. Positioned at the intersection of data standards, analysis outputs, and regulatory deliverables, programmers often serve as the connective tissue across functions. When engaged early and meaningfully, they can help align assumptions, surface downstream implications of design decisions, and reduce rework later in the development lifecycle.

However, collaboration alone is not sufficient. While improved cross functional engagement helps reduce misunderstandings and inefficiencies, it does not automatically resolve deeper structural challenges related to fragmented processes, manual workflows, and inconsistent governance.

CURRENT CHALLENGES IN CLINICAL PROGRAMMING ORGANIZATIONS

Even with improved cross-functional collaboration, gaps can remain at the process and system level. Workflows are frequently distributed across teams and supported by a combination of legacy tools, manual handoffs, and locally developed solutions. When workflows are implemented on a studybystudy basis, variability across submissions can emerge, process standardization may be limited, and adapting or scaling workflows as requirements change can be challenging.

Manual effort is frequently concentrated in late stage preparation and quality activities, formatting, validation, and quality checks. When these steps rely on manual coordination and postprocessing, transparency and traceability across submission artifacts can be difficult to maintain, and consistency depends heavily on individual experience rather than defined, repeatable processes. In this context, supporting technical conformance, data traceability, and inspection readiness becomes increasingly dependent on how well processes are designed and governed.

At the same time, statistical programming teams are closely involved in the generation of datasets, listings, and other regulated clinical deliverables and typically have end-to-end visibility into how these components are produced. However, this visibility does not always translate into ownership of workflow design, standardization, or automation. When programming expertise is applied primarily during execution rather than upstream in defining end-to-end processes, opportunities to reduce variability, embed automation, and establish scalable, sustainable workflows may not be fully realized.

Together, these conditions highlight the need to complement collaboration with a more deliberate focus on process leadership—where statistical programmers help shape how end-to-end workflows are designed, governed, and sustained. These challenges require statistical programmers not only to collaborate within existing workflows, but to actively influence how those workflows are constructed to support consistency, scalability, and long term inspection readiness.

TRANSITIONING TO STRATEGIC LEADERSHIP

DEFINING STRATEGIC LEADERSHIP FOR STATISTICAL PROGRAMMERS

Strategic leadership in statistical programming extends beyond simply delivering programming deliverables. It encompasses the ability to shape processes, anticipate regulatory needs, drive innovation and automation, and influence how work is performed across functions. Rather than focusing solely on what is produced, strategic leaders focus on how and why it is produced. In day today programming, success is often defined by questions such as, Did the output run? or Was the deliverable submitted on time? Strategic leadership reframes these measures of success by asking different questions: Is this the right way to produce the output? Will this approach scale and remain sustainable? Does this approach improve organizational effectiveness and long term resilience? Through this shift, leaders ensure that end-to-end workflows are efficient, compliant, scalable, and aligned with organizational goals.

For statistical programmers, this represents a fundamental mindset shift—from task execution to change leadership. Rather than responding solely to specifications and requests, strategic leaders act as change agents who proactively identify gaps, inefficiencies, and risks, propose solutions, and help the organization move toward better ways of working. Leadership, in this context, is defined not by title or formal authority, but by initiative, influence, and impact.

CORE COMPETENCIES FOR STRATEGIC LEADERSHIP

Transitioning into a strategic leadership role requires the development of competencies that extend beyond programming skills alone.

- **Communication and cross functional collaboration** are foundational. Strategic leaders must be able to translate technical concepts into language that resonate with diverse stakeholders, including biostatisticians, clinicians, and regulatory partners. Clear communication builds trust, enables alignment, and allows programmers to meaningfully participate in upstream discussions.
- **Regulatory awareness and proactive compliance** are equally critical. As regulatory expectations become more detailed and technically prescriptive, programmers who understand submission guidance, technical conformance requirements, and inspection priorities are well positioned to influence process design. Rather than reacting to regulatory findings, strategic leaders anticipate requirements and embed compliance into workflows from the outset.
- **Technical adaptability and innovation** form the third pillar. Embracing automation, metadata driven approaches, and opensource integration allows programmers to move beyond incremental efficiency gains toward transformative change. Strategic leaders leverage technology not as an end in itself, but as a means to reduce risk, improve consistency, and enable sustainable scalability, and transform fragmented or undefined activities into cohesive, governed, end-to-end processes.

FROM COLLABORATION TO INFLUENCE

While collaboration establishes strong working relationships, influence determines whether ideas translate into action. Strategic leadership requires the ability to actively and deliberately push for a better way of working by raising the right questions, making the case for change, and helping others see why and how that change should happen—whether that involves adopting new tools, redefining workflows, or establishing governance structures. This often means articulating value in terms that matter to stakeholders, such as reduced compliance risk, improved inspection readiness, or accelerated timelines.

Influence also involves persistence and credibility. By demonstrating quick wins through pilot initiatives, presenting data driven outcomes, and consistently delivering high quality results, programmers can build confidence in their recommendations. Over time, this credibility enables programmers to move from being consulted on solutions to being trusted partners in shaping strategy.

LEADERSHIP AS SUSTAINABLE CHANGE

Ultimately, leadership is realized when change becomes embedded and sustainable. For statistical programmers, this may include defining standards and best practices, establishing governance for automated or metadata driven processes, and creating mechanisms for ongoing review and improvement. Rather than building one-off tools, strategic leaders focus on creating frameworks that can evolve alongside regulatory guidance and organizational needs.

This transition—from collaboration to influence to leadership—sets the stage for the real-world case presented in the next section. Through the design of an end-to-end FDA Bioresearch Monitoring (BIMO) submission process, we illustrate how statistical programmers can operationalize these leadership principles to drive meaningful, organization wide impact.

REAL WORLD CASE: END-TO-END FDA BIMO SUBMISSION PROCESS

CONTEXT AND INITIATIVE TRIGGER

Prior to this initiative, FDA Bioresearch Monitoring (BIMO) submissions were prepared without a standardized, end-to-end process. Submission components—including subject level data line listings by clinical site, summary level clinical site datasets, and supporting documentation—were developed independently on a studybystudy basis. As a result, teams frequently relied on repeated programming from scratch and extensive manual postprocessing to assemble submission packages. These practices increased variability across submissions, extended timelines, and placed heavy reliance on individual experience rather than defined, reusable processes.

In response to these practical challenges, an initiative led by statistical programmers was launched to establish a standardized, automated, and scalable end-to-end BIMO submission process aligned with the FDA Bioresearch Monitoring Technical Conformance Guide. The objective was not only to improve efficiency, but also to create a more consistent and sustainable approach to generating inspection ready submission artifacts through clearly defined processes, standardized components, and automation.

STAKEHOLDER ENGAGEMENT AND DECISION STRUCTURE

The initiative began with early engagement across regulatory and clinical operations teams. Statistical programmers worked with stakeholders to clarify submission scope, interpret FDA BIMO Technical Conformance Guide expectations, and identify gaps in existing practices. Regular discussions were used to align assumptions, resolve interpretation questions, and confirm expectations before implementation.

As the initiative progressed, coordination and decision responsibilities became more structured. Statistical programmers acted as central points of coordination, proactively raising questions and facilitating discussions related to scope, regulatory interpretation, and implementation standards. Decision pathways were defined to ensure that key determinations—such as inclusion criteria, data presentation approaches, and submission structure—were discussed transparently and resolved collaboratively. These practices supported consistency across studies and reduced reliance on ad hoc decision making.

END-TO-END PROCESS AND SCOPE DEFINITION

The initiative scope encompassed the full set of BIMO submission deliverables, including subject level data line listings by clinical site in a submission compliant format, the summary level clinical site dataset (clinsite.xpt), and define.xml.

An end-to-end process was established to clarify how these components were generated, assembled, and finalized for submission. Automation was incorporated to reduce programming from scratch, eliminate manual postprocessing, and minimize repeated effort across studies. Outputs were produced through repeatable, parameterized scripts instead of ad hoc programming and manual postprocessing, supporting consistency across submissions while reducing variability introduced by study specific redevelopment.

Process design also addressed standardized file locations and directory structures within the submission environment, supporting both single study and integrated clinsite implementations. By defining consistent locations for datasets, programs, and outputs, the initiative improved traceability and supported inspection readiness.

STANDARDIZATION OF SUBMISSION COMPONENTS

As part of the initiative, multiple submission components were standardized to promote consistency and reuse across studies. This included the development of standardized templates for BIMO Data Presentation Plans to support subject level listings, as well as standardized summary level clinical site dataset specifications—covering both content and structure—that could be used to generate define.xml directly.

These standards were designed to address common elements applicable across studies, such as study population, treatment assignment, discontinuations, inclusion and exclusion criteria, adverse events, and protocol deviations, while allowing flexibility for study specific aspects, including efficacy endpoints and safety monitoring. This approach enabled individual studies to focus primarily on study specific components rather than redefining common content and structural elements.

Instructional text was incorporated into the templates to promote consistent interpretation and application across studies. Standardization also extended beyond individual templates to include consistent formatting conventions and documentation practices, supporting reproducibility and reducing study specific variation.

TECHNICAL IMPLEMENTATION AND AUTOMATION

Technical implementation focused on enabling consistent generation and assembly of BIMO submission outputs. Macros and template SAS programs were developed to support standardized generation of subject level site listings and site level datasets, enabling reuse across studies and reducing variability across submissions.

In addition, a Python based application was implemented to automatically combine individual site level listing outputs into a single regulatory compliant PDF file. This approach eliminated manual postprocessing steps involved in document assembly and ensured consistent formatting of submission packages.

OUTCOMES AND OBSERVED CHANGES

The implementation of a standardized, automated end-to-end BIMO submission process resulted in measurable improvements in efficiency, consistency, and quality. Standardized templates and specifications reduced the need for study specific redevelopment, allowing study teams to focus primarily on study specific content rather than recreating common submission components. This shift reduced repeated programming effort and improved output consistency while reducing duplicated effort across studies.

Automation further enhanced efficiency and quality. SAS macros and template programs enabled consistent, repeatable generation of subject level listings and site level datasets, reducing programming from scratch and minimizing variability across submissions. The BIMO Python application enabled regulatory compliant PDF files to be generated directly from individual listing outputs, automating document assembly tasks such as adding cover and introduction pages, dynamically assigning page numbers and headers, creating multilevel bookmarks, and automatically splitting large PDFs exceeding size limits with support for cross-PDF bookmarks.

By removing manual postprocessing and document assembly, the automated approach reduced the risk of human error and improved overall submission quality. Downstream manual listing combination and postprocessing steps were eliminated, avoiding an additional publishing cycle and associated resource costs. Together, these changes improved submission timelines, reduced operational burden, and strengthened inspection readiness, demonstrating a more efficient and sustainable approach to BIMO submission preparation.

LEADERSHIP DEVELOPMENT FRAMEWORK: FROM INITIATION TO SUSTAINABLE LEADERSHIP

The real world BIMO case demonstrates that leadership in statistical programming is not a single action or role change, but a progression. Building on this experience, we propose a four-step leadership development framework—**Initiation, Engagement, Influence, and Leadership**—to guide statistical programmers as they expand their impact from technical execution to strategic, organization wide change.

This framework is not intended as a linear checklist, but as a practical model that reflects how leadership behaviors evolve over time and reinforce one another. Each step represents a distinct shift in mindset, scope, and responsibility, while remaining grounded in the core strengths of statistical programming.

INITIATION: IDENTIFYING GAPS AND PROPOSING SOLUTIONS

Leadership begins with initiation—the ability to recognize gaps, inefficiencies, or risks within existing processes and to envision a better way forward. For statistical programmers, initiation often arises from close proximity to end-to-end workflows. Daily exposure to data flows, submission artifacts, and manual handoffs provides unique insight into where processes break down or fail to scale.

In the BIMO case, initiation occurred when programmers observed that no standardized BIMO processes were in place, requiring studies to be developed from scratch. As a result, variations existed across submissions, manual handoffs were common, and significant effort was spent on repeated programming and postprocessing. These conditions led to inefficiencies, inconsistencies, and increased reliance on individual experience rather than defined standards. Rather than accepting these limitations as fixed constraints, statistical programmers framed them as solvable problems and proposed standardization and automation as viable solutions. This step required both technical insight and confidence to raise questions about established practices.

At this stage, leadership does not require formal authority. It requires curiosity, ownership, and the willingness to examine existing practices critically and challenge established ways of working. Small pilot ideas, early demonstrations, or well-defined proposals can serve as powerful entry points for broader change.

ENGAGEMENT: BUILDING TRUST AND CROSS FUNCTIONAL ALIGNMENT

Once an opportunity for improvement is identified, engagement becomes critical. Engagement focuses on building trust, fostering collaboration, and aligning stakeholders around a shared goal. For statistical programmers, this often means stepping beyond traditional functional boundaries and engaging proactively with regulatory, clinical, and operational partners.

In the BIMO initiative, engagement was achieved through regular cross functional discussions that clarified scope, aligned interpretations of regulatory guidance, and surfaced open questions early. By facilitating dialogue rather than simply responding to requests, programmers positioned themselves as partners in problem solving rather than downstream implementers.

Effective engagement requires strong communication skills and empathy for different stakeholder perspectives. Translating technical concepts into business or regulatory value, listening actively to concerns, and incorporating feedback are essential behaviors at this stage. Engagement transforms a technical idea into a shared initiative.

INFLUENCE: ADVOCATING FOR CHANGE AND DRIVING ADOPTION

While engagement builds alignment, influence determines whether change actually occurs. Influence involves advocating for new approaches, securing buy in, and encouraging adoption across teams. This step often represents the most challenging transition, as it requires programmers to move from collaboration to persuasion.

In the BIMO case, influence was demonstrated by articulating the value of standardization and automation in terms that mattered to stakeholders— faster submission package generation, increased consistency, improved quality, reduced compliance risk, improved inspection readiness, and decreased manual effort. Early wins and tangible outputs helped build credibility, reinforcing confidence in the proposed approach.

Influence is strengthened through evidence and consistency—by delivering the consistently high quality results repeatedly across studies and showing that the approach works reliably in practice. Over time, influence enables programmers to shape not only how work is done, but how decisions are made.

LEADERSHIP: EMBEDDING CHANGE AND ENSURING SUSTAINABILITY

Leadership encompasses proactively leading the development of new standards and processes and ensuring that those improvements and changes are embedded, governed, sustainable, and able to evolve over time. For statistical programmers, leadership is demonstrated by taking ownership of how work should be done—designing standardized workflows, defining expectations, and guiding others toward a more consistent, efficient, and compliant approach. At this stage, programmers move beyond contributing individual solutions to shaping the way of working.

In the BIMO initiative, leadership was demonstrated when statistical programmers identified gaps and led the definition of standardized submission components and the design of an end-to-end BIMO submission process. This included establishing standards, developing supporting tools, and guiding cross functional teams toward adopting a consistent approach. Beyond developing these standards and processes, programmers also led their implementation — ensuring they were applied across studies, supported by automation, and integrated into routine submission activities rather than treated as one-off solutions.

Leadership at this level is less about individual contribution and more about enabling others. By championing adoption, supporting training, and planning for continuous improvement, statistical programmers help institutionalize new ways of working and prepare the organization for future regulatory and technological change.

APPLYING THE FRAMEWORK IN PRACTICE

The Initiation–Engagement–Influence–Leadership framework provides a practical roadmap for statistical programmers seeking to expand their role and impact. While the BIMO case offers one concrete example, the framework is broadly applicable to other areas of clinical development, including data standards, submission readiness, and automation initiatives.

Importantly, progression through these stages does not require a change in job title. Leadership emerges through mindset, behavior, and sustained action. By intentionally developing these capabilities, statistical programmers can move from supporting projects to shaping strategy—driving meaningful, lasting change within their organizations.

BUILDING FUTURE READY COMPETENCIES

The leadership framework defines how statistical programmers progress from execution to influence; the future ready competencies described below enable that progression to scale, persist, and remain effective over time. As clinical development continues to evolve, sustaining strategic leadership requires not only mindset and behavior, but also the ability to adapt skills to emerging regulatory, technological, and organizational demands. This section highlights key competency areas that enable statistical programmers to sustain leadership impact in an increasingly complex and dynamic environment.

The competencies in this section are intentionally ordered to reflect how leadership capacity is sustained over time, moving from responding to external technological change, to building adaptable technical and process foundations, and ultimately to strengthening enduring leadership and influence.

EMBRACING AI ENABLED AND AUTOMATED WORKFLOWS

Automation has long been a strength of statistical programming, but the next phase of transformation extends beyond task automation to intelligent, AI enabled workflows. As organizations explore machine learning, natural language processing, and generative AI capabilities, statistical programmers are well positioned to act as informed leaders in evaluating where these technologies add value—such as improving efficiency, consistency, and quality—and where they may introduce risk related to regulatory compliance, inspection readiness, and traceability.

Future ready leaders focus on responsible adoption. This includes understanding how AI tools can support activities such as data review, document generation, and quality checks, while maintaining transparency, traceability, and regulatory compliance. Rather than treating AI as a replacement for human expertise, strategic leaders position it as an enabler that augments decision making, reduces manual burden, and allows teams to focus on higher value analytical and oversight activities.

OPEN-SOURCE INTEGRATION AND TECHNICAL ADAPTABILITY

The growing adoption of open-source tools within regulated environments requires both technical adaptability and strong governance. Future ready statistical programmers develop fluency across multiple programming languages and platforms, enabling them to integrate open-source solutions thoughtfully into established clinical workflows.

Strategic leadership in this area involves more than technical proficiency. It requires an understanding of validation considerations, documentation expectations, and long-term maintainability. By defining standards for how open-source tools are evaluated, implemented, and supported, statistical programmers help organizations balance innovation with compliance. This adaptability ensures that teams can respond quickly to new requirements without sacrificing quality or inspection readiness.

DIGITAL TRANSFORMATION AND PROCESS THINKING

Digital transformation in clinical development is fundamentally about process—not just technology. Future ready leaders adopt an end-to-end process mindset, viewing workflows holistically rather than as isolated tasks. This perspective allows statistical programmers to identify upstream and downstream impacts of design decisions, anticipate bottlenecks, and propose solutions that scale across studies and programs.

In practice, this competency translates into designing workflows that are modular, metadata driven, and resilient to change. Strategic leaders prioritize reuse, standardization, and clarity, ensuring that digital solutions remain adaptable as regulatory guidance evolves. By anchoring digital transformation efforts in process thinking, statistical programmers help organizations move from reactive fixes to sustainable systems.

CONTINUOUS LEARNING AND PROFESSIONAL GROWTH

Sustained leadership requires continuous learning. Regulatory expectations, data standards, and technologies are constantly evolving, and future ready statistical programmers proactively invest in expanding their knowledge beyond immediate project needs. This includes staying current with regulatory guidance, developing awareness of emerging tools, and strengthening soft skills such as communication, negotiation, and change management.

Equally important is fostering a culture of learning within teams. Strategic leaders mentor others, share knowledge, and create opportunities for skill development. By encouraging experimentation, reflection, and knowledge exchange, they help build organizational capability rather than relying on individual expertise alone.

LEADERSHIP AND INFLUENCE AS CORE COMPETENCIES

Ultimately, leadership and influence are not optional addons—they are core competencies for the future statistical programmer. Technical excellence remains essential, but impact is increasingly determined by the ability to guide decisions, align stakeholders, and sustain change over time.

Future ready leaders recognize that influence grows through credibility, consistency, and trust. By delivering high quality work, communicating clearly, and aligning initiatives with organizational priorities, statistical programmers position themselves as partners in strategy rather than solely executors of tasks. This shift ensures that programming expertise continues to shape how clinical development organizations operate and evolve.

CONCLUSION

The role of the statistical programmer in clinical development is undergoing a fundamental transformation. As regulatory expectations increase and workflows become more complex, the traditional model—where programmers operate primarily as downstream technical executors—is no longer sufficient. Instead, statistical programmers are uniquely positioned to act as strategic leaders who shape processes, influence decisions, and drive sustainable organizational change.

Through the real-world example of designing an end to end, inhouse FDA Bioresearch Monitoring (BIMO) submission process, this paper demonstrates how leadership in statistical programming can move from concept to practice. By identifying gaps, engaging cross functional partners, influencing adoption, and embedding governance and standards, programmers translated technical expertise into measurable, organization wide impact. This progression illustrates that leadership is not defined by title, but by initiative, influence, and the ability to deliver lasting change.

The proposed four-step framework—Initiation, Engagement, Influence, and Leadership—provides a practical roadmap for this transition. When paired with future ready competencies such as automation, regulatory awareness, process thinking, and continuous learning, the framework equips statistical programmers to remain relevant and impactful in an evolving clinical development landscape.

CALL TO ACTION

For statistical programmers, the call to action is clear: embrace leadership as a core part of the role. This does not require waiting for formal authority or a new title. Leadership begins with recognizing opportunities for improvement, asking the right questions, and proposing solutions grounded in technical and regulatory insight. By intentionally developing communication, influence, and process design skills, programmers can expand their impact far beyond individual deliverables.

For organizations, there is an equally important imperative. Fully realizing the value of statistical programming requires creating environments where programmers are engaged early, encouraged to challenge inefficient practices, and empowered to lead change. Investing in leadership development, governance frameworks, and future ready skills enables organizations to reduce risk, improve efficiency, and build sustainable internal capabilities.

As clinical development continues to evolve, the organizations that succeed will be those that recognize statistical programmers not only as technical experts, but as strategic partners and leaders. By adopting the mindset, framework, and competencies outlined in this paper, statistical programmers can help shape the future of clinical development—driving innovation, ensuring compliance, and delivering lasting value.

REFERENCES

Covucci, Allison; Zou, Xiaohan. 2025. "Bridging the Gap: Leadership of Statistical Programmers in Clinical Trials." *Proceedings of the PharmaSUG 2025 Conference,* San Diego, CA : PharmaSUG.

Available at https://pharmasug.org/proceedings/2025/LS/PharmaSUG-2025-LS-093.pdf

ACKNOWLEDGMENTS

The authors would like to express their gratitude to everyone who contributed to the initiative and this research, directly or indirectly. Your support and assistance have been invaluable.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Xiaohan Zou
Bristol Myers Squibb
xiaohan.zou@bms.com

Wei Shao
Bristol Myers Squibb
wei.shao2@bms.com

Yi Yan
Bristol Myers Squibb
yi.yan@bms.com