

Recommendations for workforce development in regenerative medicine biomanufacturing

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Abstract

In its 2019 report, *The Skilled Technical Workforce: Crafting America's Science and Engineering Enterprise*, the National Science Board recommended a national charge to create a skilled technical workforce (STW) driven by science and engineering. The RegenMed Development Organization (ReMDO), through its RegeneratOR Workforce Development Initiative, has taken on this challenge beginning with an assessment of regenerative medicine (RM) biomanufacturing knowledge, skills, and abilities (KSAs) needed for successful employment. While STW often refers only to associate degree or other prebaccalaureate prepared technicians, the RM biomanufacturing survey included responses related to baccalaureate prepared technicians. Three levels of preparation were articulated in the research: basic employability skills, core bioscience skills, and RM biomanufacturing technical skills. The first two of these skill levels have been defined by previous research and are generally accepted as foundational—the Common Employability Skills developed by the National Network of Business and Industry Associations and the Core Skill Standards for Bioscience Technicians developed by the National Center for the Biotechnology Workforce. Fifteen skill sets addressing the specialized needs of RM and related biotechnology sectors were identified in the ReMDO survey, defining a third level of KSAs needed for entry-level employment in RM biomanufacturing. The purpose of the article is to outline the KSAs necessary for RM biomanufacturing, quantify the skills gap that currently exists between skills required by employers and those acquired by employees and available in the labor market, and make recommendations for the application of these findings.

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Significance statement

This Perspective article addresses workforce development in regenerative medicine, providing an overview of the skills needed for the technical workforce and an assessment of the current skills gap between the skills needed and those present in the incumbent workforce or available in the labor market. The article will inform faculty development, curriculum development and alignment, RM work-based learning, and efforts to develop a diverse and inclusive workforce. It will also provide rationale for federal and state workforce development policy and investments.

1 | INTRODUCTION

In its 2019 report, *The Skilled Technical Workforce: Crafting America's Science and Engineering Enterprise*, the National Science Board lays down a national charge to create the skilled technical workforce (STW) for a workplace driven by science and engineering—"We must 'step-up' our game and nurture and expand our domestic talent along the entire S&E (science and engineering) worker-value chain from the STW to the Ph.D. if our workforce is to remain competitive."¹ The report reflects a recurring theme in technology-based workforce development. The World Economic Forum in its 2020 research and commentary reinforces the international scale of the skilled workforce challenge across technology-driven economic sectors.²

The emergence of the COVID-19 pandemic in 2020 and its disruption of the economy has expanded the workforce development challenge of developing or acquiring the needed knowledge, skills, and abilities (KSAs) for regenerative medicine (RM) biomanufacturing, increasing the competition for a skilled workforce, and accelerating technological change in the field. While the pandemic has dramatically increased unemployment worldwide, the focus on vaccines and therapies associated with the virus has increased the demand for the STW to support R&D, clinical translation, and the scaling up of operations across biomanufacturing and biopharmaceutical enterprises, including the RM sector. Some of the immediate applications for RM in developing therapies and the emerging technologies that make development and scaling possible were recently articulated.³ The response of academic institutions to COVID has by necessity dramatically accelerated online and hybrid learning models.

RM biomanufacturing represents one of the emerging technology-driven growth sectors. With recent and projected future growth in RM, the availability of a knowledgeable and skilled workforce is increasingly a critical success factor for business and academic organizations. As the field progresses from research to clinical translation and from translation to biomanufacturing, the skill requirements are evolving. The RegeneratOR initiative of the RegenMed Development Organization (ReMDO) has undertaken a necessary early step in addressing the challenge with the articulation of the KSAs needed to align education and workforce development programs with employer needs. The purpose of the article is

to outline the KSAs necessary for RM biomanufacturing, to quantify the skills gap that currently exists between skills required by employers and skills acquired by employees and available in the labor market and make recommendations for the application of these findings.

2 | BACKGROUND

Over the past decade, significant work has been done to address the need for highly skilled technicians for advanced manufacturing, including biomanufacturing. Defining the basic employability skills (soft skills) and core sector skills (eg, core bioscience technician skills) are essential to addressing the skill needs and skills gap. The National Network of Business and Industry Associations (NNBIA) Common Employability Skills (CES) has defined the foundational skills needed by employers across the economic spectrum. The CES is organized around four categories—personal skills, people skills, applied knowledge, and workplace skills—with 20 specific KSAs further defined by behaviors and actions.⁴ The assessment and statement of these skills provide a common language for employers, educators and workforce developers, and students/employees to articulate what is needed for employment and workplace success for all economic sectors.

The National Center for the Biotechnology Workforce (NCBW), in a project funded by the US Department of Labor, published the *Core Skills Standards for Bioscience Technicians*⁵ in 2016. These core bioscience technical skills are organized around six "critical work functions"—maintaining a safe and productive work environment, providing routine facility support, performing measurements/tests/assays, complying with applicable regulations and standards, managing, and communicating information, and performing mathematical manipulations—and form the foundational technical skills for RM biomanufacturing. These bioscience skill standards have been confirmed by NCBW with the recent work of the National Science Foundation-sponsored Biomedical Emerging Technology Application Skills (BETA Skills) project.⁶ Subsequent work in skills standards, including the RegeneratOR skills survey has been grounded in these seminal efforts and they continue to provide an accepted definition of foundational skills required in the workplace generally and biotechnology/biomanufacturing in particular.

2.1 | RegeneratOR RegenMed biomanufacturing KSAs

In January 2020, the RegeneratOR Workforce Development Initiative was launched by the ReMDO at the annual meeting of the Regenerative Medicine Manufacturing Society (RMMS). The initiative was created to develop a national workforce development ecosystem in RM biomanufacturing by developing, leveraging, and brokering educational and training resources grounded in the unique, world-class R&D and translational science of ReMDO and its partners. The initiative recognizes that the development of the scientific and engineering talent driving knowledge and discovery of RM, including RM biomanufacturing process and product development, is national and international in scope, but the STW is regionally centered and developed around hubs of RM research, clinical translation, and emerging RM biomanufacturing.

While research and clinical translation with their inherent rewards of scientific challenge and discovery provide intrinsic motivation for career development, the scaled RM biomanufacturing environment relies on routinized, repetitious processes where problem solving and excellence in execution are defined by lack of variability in the process.⁷ Thus, the starting point for developing the STW for RM biomanufacturing workforce is the definition of the skills and competencies needed for highly regulated production processes and current Good Manufacturing Practices. The appropriate academic preparation for the entry-level STW will likely be the technical associate degree, with immersive preparation in a lab or bioproduction setting mirroring the workplace. The associate degree will be articulated with an appropriate baccalaureate degree that will provide the employed, early career technician with development opportunities, strengthening the theoretical grounding in bioscience or bioengineering needed for career advancement.

Drawing on the work of NNIA CES and NCBW Core Skills, ReMDO surveyed academic and private sector enterprises in RM regarding the skills needed for the emerging RM biomanufacturing workforce. The survey development began with a review of the previous skill standards work noted above by a select group of academic and business leaders. This review confirmed the current validity of the NNIA CES and the NCBW Core Skill Standards. A list of 36 technical skill items was compiled from technical skill items generated by the BETA Skills project; associate degree and baccalaureate curricula in biotechnology, applied biology, bioprocessing, or bioengineering at selected community colleges and universities with recognized programs; and expert review. To facilitate the survey, these skill items were clustered into 15 skill sets.

Survey participants were asked to assess each of the skill sets along two dimensions—importance of the skill set (skill need) and, if important, whether the skill set was available in their workforce or the labor market (skills gap). Three response choices were included to determine the skill needs and the skills gap for each skill set. Possible responses were: (1) skill set is not important for my technical workforce; (2) skill set is important for my technical workforce, and I currently have it or can acquire it; or (3) skill set is important for my technical workforce, but I do not have it or have difficulty acquiring it. The skill need dimension addresses current status of the workforce;

the skills gap dimension articulates where attention is needed for the current and near-future workforce.

Previous efforts by practitioners and researchers to survey representative participants in the field to specify the skill needs and skill gaps for the RM biomanufacturing STW were challenged by small numbers of responses with some response numbers barely above single digits. The response number issue was addressed with the ReMDO survey by including a large population of research, translation, and biomanufacturing practitioners in the RM field. The survey was administered using Survey Monkey and was broadly distributed to members and contacts of the RMMS, the industry-led Regenerative Manufacturing Innovation Consortium, and the members of ReMDO. The initial distribution of the survey was followed by a reminder 10 days later. Of the 3792 recipients who opened the survey, 149 individuals responded (4%).

The RM biomanufacturing STW skill sets generally align with the needs of the survey participants, reflecting the current capabilities required of the STW. Seventy percent or more of respondents indicating a need for 14 of the 15 skill sets (only half of the respondents needed chromatography skills) (Figure 1).

Skill sets in highest demand are focused on manufacturing operations management and cell science. The manufacturing operations management KSAs needed by skilled technicians such as documentation (needed by 93.9%), validation (91.8%), standards (88.4%), and regulation (85.7%) make up a cluster of skills identified as being the most critically important skills for the RM biomanufacturing workforce. These skill sets exhibit the greatest unmet need with 30% to 40% of respondents reporting that they are unavailable in their current workforce or in the labor market.

Not surprisingly, technical skills related to basic cell biology are also essential to RM biomanufacturing with 92% of respondents indicating that cell biology related skills—the ability to prepare cell cultures, perform tissue culture and or cell-based assays, confocal microscopy, and flow cytometry—were important skills to their operations. However, employers responding report that these basic cell biology skills are generally available in their workforce or in the labor market, indicating that the preparation of technicians in cell science in community college associate degree programs and university baccalaureate programs are providing the technical skills that are needed. Only 10% of respondents report an unmet need. The molecular biology KSAs (eg, the ability to perform basic recombinant DNA techniques, including analysis and purification, protein and enzyme assays, polymerase chain reaction (PCR), polyacrylamide gel electrophoresis (PGE), Western Blot, enzyme-linked immunosorbent assay (ELISA), mass spectrometry and immunological assays) are viewed as important by a strong majority of respondents in RM biomanufacturing (87%), but 72% indicate that the KSAs needed are available, while less than 15% have an unmet need. Just over half of employers responding indicate a need for biochemistry skills, chromatography specifically (the lowest stated need of the 15 skill sets); however, those respondents who do need chromatography skills report that the skills are often unavailable with 24% of all respondents having an unmet need. Understanding stem cell concepts and applications (a knowledge of adult stem cells, induced pluripotent stem cells (iPSC)

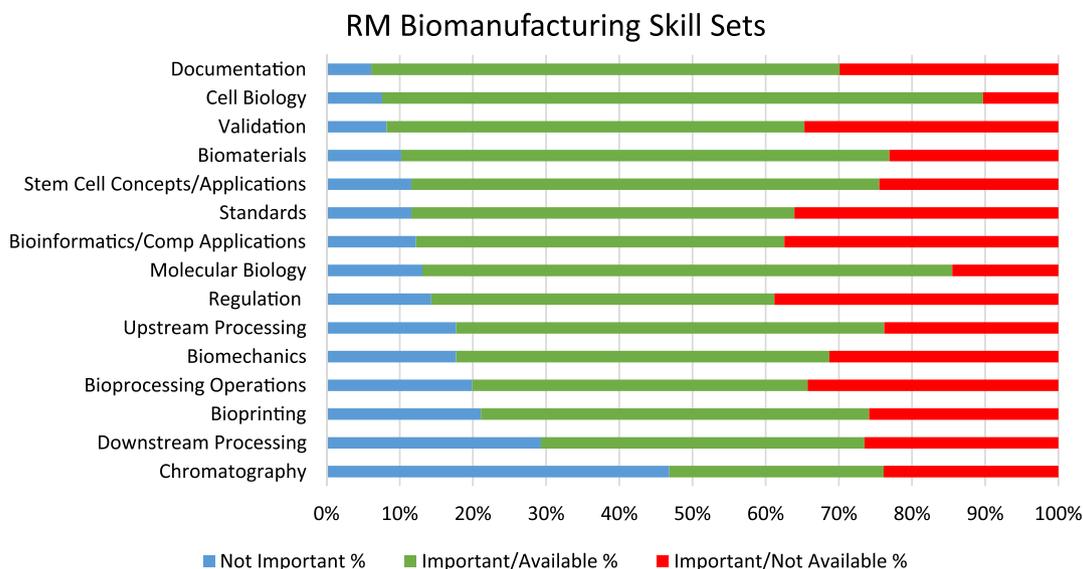


FIGURE 1 Illustrates the ReMDO survey results that address skills needs (green and red) and skill gaps (red only) for the 15 identified skill sets for the regenerative medicine skilled technical workforce

technologies, cell signaling pathways, and cell differentiation and differentiating human embryonic stem cells (hESC) are needed by 88% of the employers surveyed—a high need within the cell science cluster—and a quarter of all respondents indicate that needed stem cell KSAs are unavailable in their current technician workforce and the labor market.

A third cluster of RM biomanufacturing KSAs—bioprocessing (the application and scaling of processes and production techniques, including bioreactor operations, to produce cell-based products) was divided on the survey into upstream bioprocess technology, bioprocess operations (bioreactors), and downstream bioprocess technology to ensure that these operations were adequately captured as a central biomanufacturing process. Upstream processing skills, from cell isolation and cultivation to cell banking and culture expansion of the cells to harvesting, including inoculum development, were identified as needed by over 80% of the respondents. Bioreactor operations were a need for a similar number of survey participants. However, fewer respondents viewed KSAs related to downstream processes—cell disruption, purification, and polishing—as important to their operations than upstream/bioreactor processes with 71% indicating a need for downstream processing skills. This finding makes sense as the RM industry does not generally try to capture and purify active pharmaceutical ingredients (APIs) from genetically engineered cell platforms but instead uses cells as therapeutics.

The multidisciplinary nature of RM as a field and the convergence of technologies needed for successful RM biomanufacturing creates complexity in the development of the highly skilled RM biomanufacturing worker. In addition to the KSAs needed in biomanufacturing operations management, cell science, and bioprocessing, several technologies converge with biotechnology to define needed KSAs. Four such skill sets were identified in the survey—biomaterials, biomechanics, bioinformatics/computer applications, and bioprinting. Biomaterials—the convergence of cell biology, bioengineering/tissue engineering, and materials science—is among

the skills sets most in demand for RM biomanufacturing. Ninety percent of respondents need employees who have KSAs associated with biomaterials (eg, can perform biomaterial synthesis and analysis, have knowledge of biochemical composition, degradation, density, thickness, leachables, residuals and stability; can assess mechanical strength and perform burst tests; and can apply nanotechnology tools and methods). The intersection of bioscience and mechanics requires the application the principles of biomechanics to RM processes and products and application of biofluid dynamics in RM biomanufacturing. Of the respondents, 82% had a need for these skills, and more than 30% find that skills in biomechanics are missing in the current workforce and labor market.

In today's manufacturing environment, all manufacturing is digital and RM biomanufacturing is no different. A workforce is needed that can collect data and perform data analysis, use numerical analysis (including modeling, computer simulation, and experimental measurements), perform digital image capture and analysis, and maintain cyberbiosecurity standards and practices. Eighty-eight percent of survey respondents expressed a need for biotech/IT convergent skills and almost 40% say that they do not have and cannot acquire the bioinformatics and IT skills needed. Bioprinting, with its origins in digital text and image printing, is an increasingly important RM digital technology in biomanufacturing and technical staff in the emerging biomanufacturing space will be required to have a knowledge base in these processes. It is no surprise that 80% of employers responding indicate a need for bioprinting skills and that many—almost 30%—find the skills lacking in the workforce.

Overall survey results indicate that, while RM biomanufacturing is experiencing rapid growth, a pronounced skill gap exists wherein 20% to 40% of employers in RM are reporting a lack of needed skills sets in their workforce and an inability to hire for those skills in the labor market (in all skill sets except cell biology and molecular biology where needed skills are more likely to be met). Clearly more and better education and training is need in regulatory processes, standards, and

validation where a third of employers do not have and cannot hire for the skills needed. Also, the survey puts educators and trainers on notice that digital and data skills are increasingly part of the convergent technologies with RM.

2.2 | Recommendations for developing RM biomanufacturing KSAs

According to a May 2020 report published by McKinsey Global Institute, “Demand for people with expertise in genetics, bioinformatics, biochemistry, bioengineering, machine learning, and data analytics skill will rise as talent starts to drive commercialization. A key question is how to ensure that these skills are available to organizations that can develop beneficial applications.”⁸ While the PhD/MD preparation for researchers and clinicians is international in scale and scope, the development of the technical skill workforce is centered regionally. Efforts to ensure the availability of the workforce KSAs that are important to RM biomanufacturing begin with the educational and workforce development ecosystem.

Five recommendations are proposed to develop of the workforce development ecosystem.

1. Provide faculty development opportunities in RM for K-12, community college, and universities (including 4-year colleges) that are aligned with industry needs that support grade/level appropriate learning.

Faculty development in RM for K-12 STEM teachers generally, and biology and chemistry specifically, can support the introduction of RM to students in middle and high school courses and appropriate work-based learning in the latter years of high school. Increased K-12

faculty knowledge of the RM KSAs brings exposure to the foundations of RM and RM-related products to students, strengthens middle school/high school curricula, and improves alignment with community college and undergraduate university degree programs. Community college faculty in biotechnology and RM convergent technologies, who are increasingly responsible for entry-level technician education, must be knowledgeable of RM science and processes (including rapidly changing technologies) and their application in the lab or production facility. These faculties often have limited access to hands-on professional development opportunities and state-of-the-art facilities. University faculty through their degree programs also prepare technicians and, in the ecosystem noted in Figure 2, provide greater depth of knowledge in the field and learning at the intersection of converging technologies. Faculty development aligned with the defined RM KSAs is the foundation for curriculum development and learning in RM.

2. Incorporate RM principles and applications in STEM-related academic curricula, recognizing the multidisciplinary nature of the field.

Entry-level RM biomanufacturing functions will increasingly be performed by skilled staff with the associate degree, although innovation and rapidly changing processes will require continuous learning, including additional degree or credential attainment for the incumbent workforce. The KSAs can guide an aligned, progressive approach to curricula in the ecosystem—core STEM curricula in K-12 with exposure to RM principles and applications; technical curricula in community college including didactic and significant hands-on laboratory and work-based learning; and in-depth didactic as well as hands-on lab and multidisciplinary learning in university curricula. This aligned, progressive ecosystem is supported by dual enrollment and Early College initiatives between K-12 institutions and systems and higher

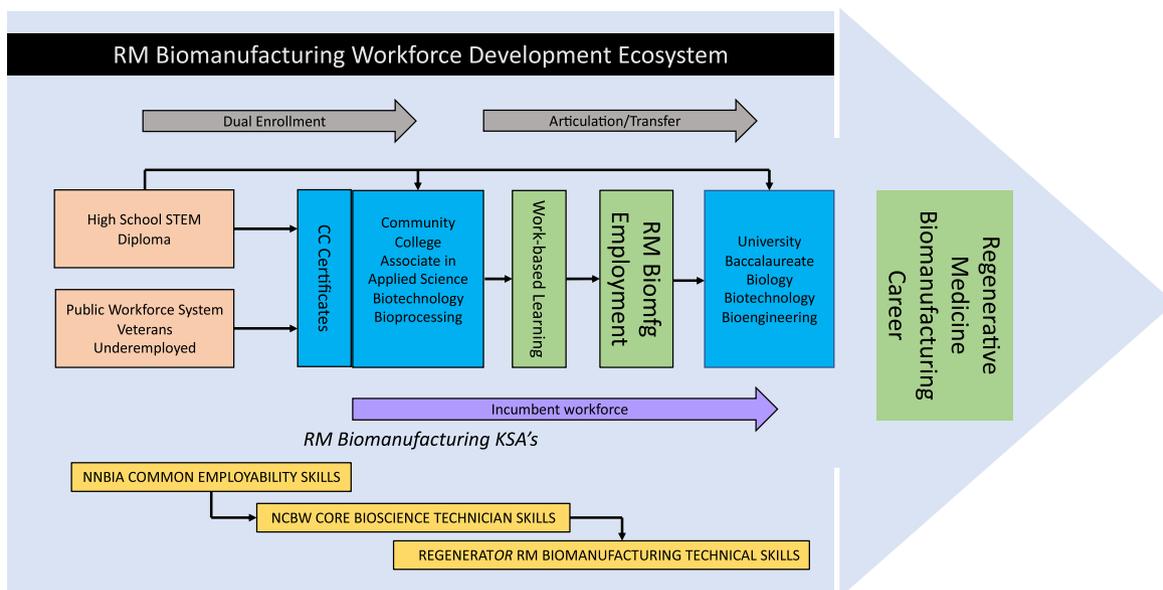


FIGURE 2 Depicts a model of the educational ecosystem for the skilled technical workforce for regenerative medicine biomanufacturing including the educational continuum from K-12 to university, the connectors that close the seams in the educational pathway (dual enrollment and articulation), and the defined KSAs that guide curricula

education institutions and bilateral transfer and articulation agreements between community colleges and universities, initiatives that accelerate STW preparation and support continuous learning for technical careers in RM.

3. Provide progressive levels of work-based learning in RM, K-12 to university.

RM biomanufacturing also requires employers to think differently about their STW if they are to meet their business goals. For employers to have work-ready, skilled staff with minimal internal training needed at employment and to develop the incumbent STW, work-based learning is an essential component of the academic and internal learning experience. Employers, working with their regional education ecosystem—K-12 to graduate school—need to participate in a work-based learning system that ranges from “low touch” learning - the brief “career day” or facility and operations tours—to “high touch,” highly structured employer-recognized or registered apprenticeships.⁹

As the demand for STW grows greater, employers may structure technical positions to meet the varying capabilities of the entry-level and experienced workers based on education and continuing development, borrowing a concept from the clinical side of health sciences—“scope of practice”—whereby nurses, for example, can perform defined tasks that are aligned with their preparation and their positions are aligned with the standard of preparation that scope of practice represents.

4. Pursue a diverse and inclusive STW in RM.

Aligning academic curricula and positions for skilled RM technical staff with standard KSAs supports another goal and value of employers—an inclusive work environment with a diverse workforce. The traditional reliance on institutional reputation to develop the workforce makes fulfilling the goal of inclusiveness difficult for employers as higher education becomes increasingly differentiated along racial, ethnic, and class lines.¹⁰ With community colleges, historically black colleges and universities (HBCUs), (and other minority-serving institutions), and regional universities graduating a majority of students of color, immigrants, career-transitioning adults, and low-income students, RM employers will be required to look to them to provide the diverse workforce they need, including the their STW, as the labor market continue to tighten with the growth of the bioscience sector in general. The adoption of common technical skill standards by these institutions in bioscience-related programs provide employers with a level of confidence in the employment of graduates for RM biomanufacturing and a path to a diverse workforce and inclusive workplace.

5. Advocate for policy and investments in RM and convergent technology workforce development.

US government policy has recognized the need for investment in workforce development strategies associated with emerging

technology-based sectors such as RM and convergent technologies. The George W. Bush administration's President's High Growth Job Initiative and Workforce Innovations for Regional Economic Development program and the Obama administration's Trade Adjustment Act Community College and Career Training programs funded regional and sector projects that grew the national capacity for workforce development. More recently, the Department of Defense, National Science Foundation, and other agencies have articulated the projected need for the STW in bioscience, including RM, a need quantified by the skills gap assessment. The skills gap assessment provides valuable data and support for academic institutions and their educational ecosystem partners to advocate for appropriate scale federal and state investments to support the national RM ecosystem and regional sector education and training.

3 | CONCLUSION

Preparing the highly STW for RM biomanufacturing begins with defining the KSAs required to execute highly regulated, routinized production processes. The articulation of the foundational skill sets of previous workforce development efforts and the RegeneratOR skill sets provides the starting point for institutions of higher education, working with their employer partners, to adapt curricula to meet these needs and share best practices in doing so. The skill gaps in the current workforce and labor market are clear and will inform the educational process as well. Addressing the five recommendations for developing the RM STW—faculty development, curriculum development, work-based learning adoption, workforce inclusiveness, and educational ecosystem investment—will support for the ultimate goal of RM biomanufacturing—improving lives.

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CONFLICT OF INTEREST

The authors declared no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

G.M.G., R.R.: conception and design, collection and/or assembly of data, data analysis and interpretation, manuscript writing; S.L.: collection and assembly of data, manuscript review and editing; T.T.: conception and design, data analysis and interpretation; J.G.H.: conception and design, administrative support, manuscript review and editing; A.A.: conception and design, collection and/or assembly of data, final manuscript approval.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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