

EDA-TECH HUBS PHASE 2-2023

PRBio Tech Hub Phase 2: Overarching Narrative

I. Executive Summary

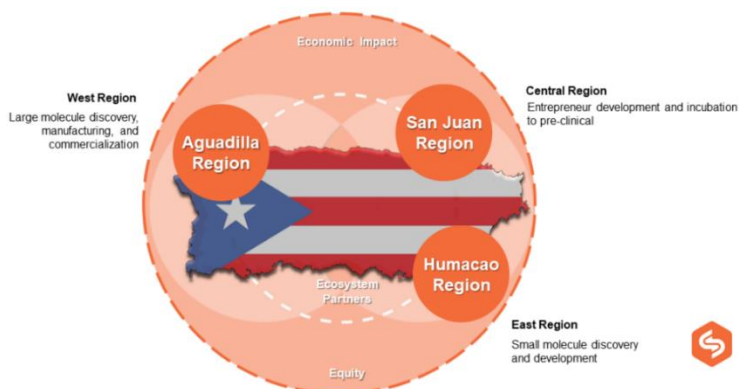
PRBio Tech Hub's includes the full region of Puerto Rico (PR), an unincorporated, commonwealth territory of the United States (US) with a population of ~3.3 million (2022) American citizens, 98% Hispanic¹. Nearly the entire region of PR is defined within the EDA's definition as a Metro/Micropolitan Statistical Area with a concentration of assets, capital, R&D, labor market, and infrastructure strongly relevant to the EDA Tech Hub biotechnology key technology focus areas. Since PR's bioscience landscape incorporates employees from most of the 78 municipalities, the full region of PR will constitute the PRBio Tech Hub's region for purposes of the Tech Hub Competition.

The **overall goal** of the PRBio Tech Hub (Hub) is to retain, grow, and attract innovative companies in biotechnology, enabling the consortium to drive regional growth and capacity to accelerate development, manufacturing, and distribution of 1st generation pharmaceutical and medical products and disruptive technology platforms. The Hub will enable the established

ecosystem, including the coordination with the NSF Engine Development Award 2305699 *Advancing Biopharmaceutical Technologies and Manufacturing Practices PR*, to boldly leverage the EDA's key technology focus area (KTFAs) #7 including bio and medical technology, genomics, and synthetic biology. The Hub will also intersect with KTFAs #1 & #9 for advancements in medical devices and wearable technology: artificial intelligence (AI), machine learning, and industrial efficiency technologies. The Hub's commitment to the EDA KTFAs ensures a resilient domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs capable of meeting national security requirements for responding to threats arising from chemical, biological, radiological, nuclear threats, and public health emergencies.

II. Vision for Regional Economic Development

The key question for the Hub's visionary path is *Why Puerto Rico?* For more than six decades, PR has been a global leader in the FDA regulated biotechnology sector, earning the reputation as the *Medicine Cabinet of the US*. Beginning with the electronics and pharmaceutical industries and then growing into medical devices, the biosciences industry reaches 75% of the FDA Class III device manufacturers shares in 30 medical device facilities, demonstrating PR's leadership in the biosciences. The industry has been the anchor of PR's economy representing 32.2% of its GDP, 33% of all manufacturing jobs, and employing over 83,500 of its total population representing 15.8% of total jobs in PR². With a rich history of expertise and state-of-the-art infrastructure ready to be utilized for the next generation of technology innovation, PR's biotechnology industry offers a solid foundation for innovation and growth. We believe that this moonshot opportunity will create generational change for all of PR, while creating lasting benefits for the US and globally. According to the BIO National Industry Report, PR stands out as the only US jurisdiction specialized in four of the five bioscience sub-sectors including distribution, pharmaceuticals,



¹ <https://www.census.gov/quickfacts/PR>

² Biopharma industry creates 87K jobs, May 2022, <https://newsismybusiness.com/biopharma-industry-pumps-3b-into-economy-creates-87k-jobs/>

medical devices, and research³. White House Executive Order 13944 supports the US’s need to have a strong Public Health Industrial Base with a resilient domestic supply chain and states that these chains must be capable of meeting national security requirements. This proposal seeks to further strengthen this important Order for the national security and well-being of all US citizens. As a Designated Hub, PR will continue to make bold impacts on the EDA’s KTFAs of biotechnology, medical technology, genomics, and synthetic biology, strengthening PR’s pharmaceutical industry as an asset to national security. The Hub’s vision is to develop the necessary strategies, activities, and workforce to further strengthen PR’s focus on Technology Readiness Levels 6 & 7 (commercialization), 8 (deployment), and 9 (manufacturing) to support PR as a global leader in the rapid development of new products to address unmet medical needs of patients worldwide. The **Hub members listed below** will strengthen PR’s capacity to manufacture, commercialize, and deploy critical technologies to support PR’s position as a global, leading biopharmaceutical tech hub for decades to come.

PRBio Tech Hub Consortium Members & Additional Partners	
Consortium Lead – EDA Tech Hub Lead Applicant: Puerto Rico Science, Technology & Research Trust (PR Trust)	
Component Project Leads	
<u>PRBio Tech Hub Governance</u> ; <u>Access to Capital for Entrepreneurship</u> ; <u>Advancing NextGen Workforce</u> – PR Trust	
<u>Next-Generation Therapeutics & AI Drug Discovery</u> – Bright Path Laboratories (BPL)	
<u>Acceleration of New Drug and Precision Medicine Laboratories</u> – University of Puerto Rico Medical Sciences Campus	
<u>Entrepreneurship: Lab to Market</u> – Molecular Sciences Research Center (MSRC)	
<u>Advanced Technologies Center (ATC): Pharmaceutical Manufacturing and Enabling Technologies</u> – OcyonBio	
Consortium Members	
<u>Institutions of Higher Education (all Minority Serving Institutes):</u> University of Puerto Rico (UPR), UPR Medical Sciences Campus, School of Pharmacy (UPR MSC SoP), UPR at Mayagüez, UPR at Aguadilla, UPR at Humacao, MSRC	
<u>Government:</u> Puerto Rico Department of Economic Development and Commerce (DDEC)	
<u>Industry/Private Sector:</u> OcyonBio, Dsquare Analytics, LLC, Galephar Pharmaceutical Research, Inc., CytoImmune Therapeutics Puerto Rico, LLC, Bright Path Laboratories (BPL, venture development), PR5GZone (nonprofit), Industry University Research Center Bioscience Cluster (INDUNIV, nonprofit)	
<u>Economic Development/Science Organizations:</u> Invest Puerto Rico, PR Trust’s Parallel18 (venture development)	
<u>Workforce/Labor:</u> DDEC (WIOA/Apprenticeship), PR Ready (Workforce Training Program of PR Trust), Coursera, Inc.	
Committed Key Partners and Additional Partners: Pharmaceutical Industry Association, Johnson & Johnson, Bristol Myers Squibb, Biotechnology Innovation Organization, Avara Pharmaceutical Contract Manufacturing Company, Bayer Healthcare Pharmaceuticals LLC, North Carolina State University Biomufacturing Training and Education Center, Lilly del Caribe, Department of Biomedical Engineering at Georgia Tech and Emory University, Amgen Manufacturing Limited, Organon, Sartorius, Principia, BLDM, PRO Quality Strategic, VOCES: Vaccine Coalitions, Viatris, BD Biosciences, GCM Medical Group, SanaClis, AbbVie Biologics Ltd, 323 Family Trust, LLC.	

The Hub members have developed **six (6) component projects** aligned with the PR Trust’s Governance Project and supported by the overall Risk Mitigation Plan. Brief details of the Projects and how each reinforces one another in the overall success of the Hub are listed below. The Hub synergy briefly defines how the Projects will **complementarily lead to the Hub’s global competitiveness** over the next decade. Each individual Project has detailed the constraints that its activities and initiatives will enable the Hub to overcome (see full Component Projects).

Component Project Short Descriptions	Complementary Hub Synergy
PRBio Tech Hub Governance	
Outlines the PR Trust’s comprehensive strategy for managing the consortium, ensuring oversight, workflow management, evaluation, reporting, communications, and sustainability, including the role of the RIO. Aims to establish a robust framework that supports transparent decision-making, accountability, efficient project execution, and long-term sustainability.	Builds consensus with Hub consortium members/partners for goal-driven strategies for Phase 2 implementation by ensuring that the Component Projects are aligned with the Hub’s overarching mission and vision and through the leadership of the RIO and the overarching Risk Mitigation Plan.
Access To Capital For Entrepreneurs	
Seeks to solve PR’s biotechnology funding gap through the creation of the PR Biotechnology Capital Network (PRBCN) through two	Industry sector attraction and retention plan for Hub to determine the best strategy to attract, retain, and fund

³ https://go.bio.org/rs/490-EHZ-999/images/TEconomy_BIO_2022_Report.pdf

Component Project Short Descriptions	Complementary Hub Synergy
principal initiatives: <i>i. PR Biotechnology Grant Fund</i> ; and <i>ii. PR Biotech Emerging Managers Program</i> to overcome the challenges of capital funding that local private equity & venture capital firms encounter when investing in the PR bioscience entrepreneurs.	biopharma manufacturing businesses through leveraging regional assets and synergistically support within Hub component projects as the bridge to capital.
Advancing NextGen Workforce	
The Hub’s Workforce Plan will harness collective learnings and scale existing, proven approaches to education and workforce development that are essential for biotechnology innovation focusing on lifelong learning programs, STEM engagements, apprenticeships, and programs that support the “cradle to career” workforce pipeline development through various initiatives.	Industry sector workforce plan to guide the Hub to launch and strengthen PR life sciences workforce by working closely with a cross-section of life science employers, academia, labor organizations, and workforce curriculum leaders to understand industry workforce needs.
Entrepreneurship: Lab To Market	
Complete the build-out of the MSRC’s EDA ASTRE project to provide state-of-the art laboratories and pilot scale infrastructure for small and large molecule development technologies, viral, DNA and RNA derived immunotherapies, and gene and cell therapies for future workforce development to accelerate benchtop to commercialization.	Will complement the activities of the Hub’s component projects and goals and strengthen MSRC’s multidisciplinary ecosystem by educating new biotechnology professionals and startups that will bolster the biotechnology sector resulting in a more stable pharmaceutical supply chain.
Next-Generation Therapeutics & AI Drug Discovery	
Advances beyond drug manufacturing to drug development and the go-to-market leader for biotechnology through an enabling tech-to-chemistry capability (STT [®]) that allows therapeutics produced through AI drug-discovery, repurposed, or reformulated drugs to be synthesized using computer-aided synthesis, optimization, and analysis to produce APIs.	Enables the Hub shared, tech-to-chemistry capabilities produced through AI drug-discovery and acts as a conduit to additional assets that include workforce talent, industrial space, intellectual property, and access to capital investments in AI drug discovery across the Hub.
Acceleration Of New Drug And Precision Medicine Laboratories	
To catalyze the development and scale-up of new drugs and PMs with the use of advanced manufacturing and enabling technologies, provided by <i>state-of-the-art</i> equipment and instrumentation to support existing infrastructure to close technology gaps to produce innovative biopharma products and drive Enabling Technologies.	Identify Hub desired academic curriculum advancement needs within pharmaceutical degree programs to support regulatory professional development to strengthen the knowledge transfer to the biopharmaceutical and medical device ecosystem.
Advanced Technologies Center (ATC): Pharmaceutical Manufacturing & Enabling Technologies	
Empower disadvantaged and limited educational backgrounds through hands-on job training experience as support mechanism for emerging biotech startups by providing critical, shared equipment, facilities, resources, and expertise to enhance manufacturing capabilities within the PR pharmaceutical sector to advance gene and cell therapy, viral vectors, biologics, and small molecules.	Provide the Hub with shared facilities and equipment for the development and utilization of advanced pharmaceutical manufacturing technologies and provide non-traditional students with hands-on job training enabling them to qualify for high-demand jobs in emerging technologies, addressing gaps in workforce readiness.

Puerto Rico provides a unique **investment and policy commitment** to the EDA’s funding for the overall Hub’s sustainability for the 10-year expectation and beyond. While the PR Government is supporting the Hub’s application through various commitments from DDEC and to specific component projects, PR’s Act 60 and 73 are part of the economic incentive laws designed to attract investment and promote various sectors, including research and development (R&D). Act 60 offers tax credits to businesses that engage in eligible R&D activities in PR. The goal is to promote innovation, technological advancement, and the development of a knowledge-based economy, making PR a competitive jurisdiction for investment in these industries. Key benefits under Act 60 for R&D include a tax credit of up to 50% for investments in R&D activities, an additional 25% tax credit for payments made to the PR Trust, and favorable tax rates on income generated from intellectual property developed through R&D activities. These tax credit incentives, coupled with the Hub’s commitments (See Section V.) act as a viable source of long-term, sustainable funding for the Hub.

In the Hub’s Governance Project, the consortium has focused on the deliverables necessary for Phase 2 implementation, ensuring PR’s biotechnology industry moves towards achieving its net-zero goals and contributing to a greener, more sustainable future. PR’s industry also maintains the highest EPA environmental standards, protecting water resources; minimizing air emissions; and preventing land contamination including solvent elimination from chemical processing and

efficient use of water and energy, in coordination with government and regulatory agencies. The quality of the products, protection of the environment, and preservation of life are intrinsic elements of PR's bioscience industry and are at the forefront of the Hub's activities and outcomes. The Hub will utilize the **Climate and Economic Justice Screen Tool (CEJST)** when accounting for environmental and climate-related impacts and risk as activities are implemented throughout Phase 2 and beyond. The PRBio Tech Hub and its biosciences industry is dedicated to improving the nation's health, food supply, and the environment through responsible biotechnological or chemical applications meeting the highest regulatory standards. Since these products are sensitive to environmental conditions such as temperature, humidity, and other conditions and contaminants, redundant and resiliency protocols are established to maintain the business continuity during atmospheric events that can cause power outages. The Hub will utilize the PR Trust's disaster preparedness plans including the Emergency Management Plan and Cyber Security Policy & Framework of IT (see Overarching Risk Mitigation Plan) to account for weather and climate related risks and security protections.

The Hub's region is comprised of ~3.3 million American citizens of which, 98% are Hispanic. The region's communities and groups are inclusive to the definition of a SEDI (**Socially and Economically Disadvantaged Individuals**) and comply with the characteristics of SEDI-owned businesses within a Community Development Financial Institution Investment Area and Opportunity Zone. The Hub initiatives were developed with **equity** in their approach to benefit the underserved populations and communities of PR from high school and undergraduate level on-the-job training; to apprenticeships, mentorship, and scholarship opportunities; to graduate and post-graduate level advanced degree programs; to engaging and collaborating with STEM underserved, minority serving institutions (MSI); to providing access to capital to Opportunity Zone entrepreneurs. Each component project's KPIs include measurements related to serving the full population of the Hub and the economic growth associated with these initiatives.

Currently PR's biopharmaceutical sector is essential for biopharmaceutical manufacturing, distribution, and development, and contributes 35% to PR's GDP, accounts for 45% of manufacturing jobs, and employs over 88,000 people throughout the region. The Hub is laser focused on the pace of change and the scale of labor market fluctuations affecting the US and the global pharmaceutical industry. The Hub's Projects will provide significant advancements in the biopharmaceutical industry workforce pipeline as a global leader in advanced drug discovery and development using emerging technologies such as generative AI, expanding production capabilities, increasing investments, and creating new high-salary job opportunities **impacting PR's GDP** at a greater scale. While each Project has specific SMART goals and KPIs related to the timeline of their respective activities (see Section IX), the Hub's **overarching outcomes** expect to impact PR on a larger socio-economic scale. With the Hub prioritizing closing PR's gap in biopharmaceutical access to capital, the project expects to impact over 10,000 individuals from the sector, directly and indirectly, while serving entrepreneurs and R&D focused organizations. While access to capital will provide a financial launching pad for entrepreneurs, this capital allows companies to open and expand resulting in job creation, R&D opportunities, and indirectly fueling the market with higher salary opportunities. During the EDA's expected 10-year time period, the Hub is expected to attract over 100 companies through the enrollment in the Access to Capital Project initiatives with over \$100M of raised capital, expecting to create 250+ direct jobs and ~75 new investors in PR.

The Hub has been extremely conscience of the need to make an **impact** starting on Day 1 to ensure the resources necessary for biopharma companies in PR to advance globally are readily available. With this in mind, the Hub concentrated its construction project within the Molecular Sciences Research Center (MSRC) to complement the current EDA funded Advancing Science

and Technology Research and Entrepreneurship (ASTRE) project (EDA #01-79-14873) to incubate and develop both new and established companies that can translate scientific discoveries into commercial and intellectual property that can bolster PR's economy. In addition, the Hub plans to upskill ~2,000 PR residents through online short-form credentials provided by Coursera, Inc. By engaging Coursera on Day 1, the Project will develop a pipeline of workers to support the Hub activities immediately. For those completing online courses through a massive online open course provider, 87% reported a general or tangible career benefit, ensuring increased wage growth opportunities throughout the Hub.

III. Need for HUB

Puerto Rico's ecosystem has been nurtured by expertise that has emanated from major pharmaceutical companies such as Eli Lilly, Bristol Myers Squibb, Amgen, Johnson & Johnson, and others. These companies provide many of the services needed to start a new manufacturing operation or validate processes and complement the services offered by contract manufacturing organizations and facilitate the implementation of a new manufacturing process. The Hub provides a unique opportunity for new pharmaceutical companies to grow the region's ecosystem with over 60 years of pharmaceutical manufacturing experience. With the designation of Puerto Rico's R&D tax credits, multiple drug development companies have begun operating within PR to expand the ecosystem from advanced manufacturing to pharmaceutical drug development. However, these new drug products must be approved by FDA and other regulatory agencies before they can be available globally. Ensuring that all avenues of both advanced manufacturing and drug development are readily available and supported by available talent, is vital to these company's success and PR knows that no single company or organization can ensure all elements of the biopharmaceutical ecosystem alone. The Hub has built a growing consortium with the input and activities of industry, private, public, academia, nonprofit, and government entities to ensure full, wrap-around services from workforce development and on-the-job training, to regulatory and start-up support services, to academia curriculum expansions and short-form credentialing, to access to capital and R&D tax credits, to governance and management oversight to ensure a sustainable ecosystem over the next 10-years.

Puerto Rico has experienced lessons learned through the cyclical closure of multiple manufacturing plants, the Hub has used these lessons to build its goals and outcomes for the advancement of biopharmaceutical industry, both large and small, to prevent their closure and migration from the region. This Hub's ecosystem will provide the foundation through matched consortium commitments and long-term sustainability plans to ensure the longevity of the Hub as a globally competitive powerhouse to retain, grow, and attract innovative companies in biotechnology. The Hub has already seen a successful impact in companies such as Galephar, Dsquare, and OcyonBio (Consortium Members), among others, as new, small pharmaceutical companies located in the region providing new jobs opportunities.

IV. Nexus

How does the Hub fulfil this moonshot opportunity? Puerto Rico has committed to transforming the region into a bio-manufacturing and product development hub where ideas can flourish, and bioscience products can efficiently reach customers while creating a more resilient supply chain to enable national security. This transformation is strongly supported by initiatives driven by the PR Department of Economic Development and Commerce (DDEC, Consortium Member), who in May of 2022 unveiled the strategic framework of sustainable economic development or PR's Comprehensive Economic Development Strategy, the *PRoposito*. The strategy supports the Hub's initiative to transform PR's pharmaceutical manufacturing sites with smaller, more flexible, cost-effective operations. The Hub's directed activities within its committed academic institutions will have students and researchers readily available to help

transform these manufacturing sites through modern manufacturing approaches. The nexus of the Hub members is united in its collaboration with emerging, local pharmaceutical companies to incorporate advanced pharmaceutical manufacturing and drug development based on industry-led guidance and training within the Hub’s universities and workforce development plans. These approaches have been presented to and accepted by the local pharmaceutical industry through INDUNIV (Consortium Member) and PIA (Partner). The Hub already has real-time examples that indicate a future PR-based pharmaceutical industry is a possibility through emerging companies such as MBQ Pharma, a local company that licensed its intellectual property from UPR (Component Lead), currently developing two drug candidates for the effective removal of pre-existing metastases to lead to the removal of solid tumor cancer. However, companies still require substantial financial, talent, and programmatic support, all represented in the Phase 2 Hub activities to meet the overall Hub goal to retain, grow, and attract innovative companies in biotechnology, enabling the consortium to drive regional growth and capacity to accelerate development, manufacturing, and distribution of 1st generation products and disruptive technology platforms. In addition, the Hub provides a governance structure and overall risk mitigation plan aligned with the industry’s highest national and economic security at the forefront.

V. Partnership Commitments

The **role of the private sector** in PR’s bioscience industry plays a crucial role in its development. PR currently hosts 12 of the world’s top 20 pharmaceutical companies including Amgen, AbbVie, Bristol Myers Squibb, Sartorius, Boston Scientific, among others. According to the Bureau of Labor Statistics, PR led US exports of pharmaceutical and medicine manufacturing in 2020, accounting for 19.3% of total US exports. Therefore, the PR biopharmaceutical, medical device, and supporting technology manufacturing sectors are a cornerstone of the US bioscience industry and the Hub. The biotech industry encompasses a wide range of activities, and the Hub has aligned multiple private sector entities to contribute to the Hub as Project Leads and members, through investments, job creation, and as R&D sites to contribute to PR’s overall economic growth while establishing PR as a global leader in biopharma advancement. The industry’s growth, driven by private sector innovation, contributes to economic diversification making PR less reliant on traditional industries and creating a knowledge-based economy. A full list of the Hub’s **commitments** is listed below.

Commitment	Entity Type	Entity Name	Associated Component Project(s)	Value	Delivery
Cash Match	Government	DDEC	Advancing NextGen Workforce	\$1,000,000	12/31/2027
Cash, In-Kind	Industry	Dsquare	Advancing NextGen Workforce	\$680,000	12/31/2028
Cash Match	Industry	323 Family Trust	Next-Gen Therapeutics & AI Drug	\$254,087	12/31/2028
Cash, In-Kind	Industry	OcyonBio	Advanced Technology Center (ATC)	\$1,900,000	03/31/2028
Cash, In-Kind	Higher Ed	UPR MSC SoP	Acceleration of New Drug & PM Lab	\$728,905	08/31/2029
Cash Match	EDO	PR Trust	PRBio Tech Hub Governance	\$626,968.15	08/31/2029
Cash Match	EDO	PR Trust	Access to Capital for Entrepreneurs	\$870,000	08/31/2029
Cash Match	Higher Ed	MSRC	Entrepreneurship: Lab to Market	\$750,000	08/31/2029
Cash Match	Industry	BPL	Advanced Technology Center (ATC)	\$90,000	12/31/2025
In-Kind, Policy	Higher Ed	UPR MSC SoP	Advancing NextGen Workforce	\$310K/\$1.5M	12/31/2028
In-Kind Match	Higher Ed	UPR – Mayaguez	Advanced Technology Center (ATC)	\$360,000	12/31/2028
In-Kind Match	Industry	INDUNIV	Advancing NextGen Workforce, Acceleration of New Drug & PM Lab	\$640,500	08/31/2029
In-Kind Match	Industry	INDUNIV	Advancing NextGen Workforce	Invaluable	08/31/2029
In-Kind Match	Industry	BPL	Next-Gen Therapeutics & AI Drug	\$572,160	08/31/2025
In-Kind Invest	Industry	BPL	Advanced Technology Center (ATC)	\$2,910,000	12/31/2025
Investment	Industry	BPL	Advancing NextGen Workforce	\$500,000	10/15/2025
Policy Match	Government	DDEC	All Component Projects	\$4,500,000	12/31/2027
In-Kind, Invest	Workforce	Coursera, Inc.	Advancing NextGen Workforce	\$300,000	12/31/2027
In-Kind Match	EDO	Invest PR	PRBio Tech Hub Governance	\$100,000	08/31/2029
In-Kind Match	Nonprofit	PR5GZone	PRBio Tech Hub Governance	\$250,000	08/31/2029

VI. Sustainability

PR's existing assets are included as part of the Hub's plan towards ensuring sustainability for both its Component Projects and the Overarching 10-year EDA timeframe. Existing assets include but are not limited to expertise in advanced manufacturing, partnerships in PR's universities and industry, research and laboratory facilities, talent in pharmaceutical science and engineering to advance manufacturing, biopharmaceutical incubators, initiatives to enhance workforce development, and efforts and implementation of advanced concepts such as Industry 4.0, 5G, and IoT. Furthermore, the Hub has aligned its goals and outcomes with the PR Trust's awarded NSF Engine Development Award (2305699 *Advancing Biopharmaceutical Technologies and Manufacturing Practices PR*) and through its EDA funded *Forward Center* for incubation and acceleration capabilities for up to 60 technology-driven start-ups and early-stage companies. The Hub will continue to leverage the PR Trust's Technology Transfer Office (TTO) which enables academic inventors in disclosing new discoveries by providing best-in-class technology transfer support for PR's scientists and researchers.

The Hub's ecosystem has shown its ability to continue and transform within the biopharmaceutical sector including developing the first Industrial Biotechnology program in PR, proving the ability to transform from small molecule tablet-based manufacturing to successfully implementing biologic products in collaboration with Amgen, AbbVie, and Eli Lilly. These assets have opened the door to biotechnology job development for many large pharma and small start-ups companies providing top industry positions throughout PR. The Hub's assets also include the MSRC (Component Lead), funded by both EDA and NIH awards, a Ph.D. in Pharmaceutical Sciences at the UPR MSC (Component Lead), and the collaboration of the Engineering Research for Cell Manufacturing Technologies through the NSF Center for Structured Organic Particulate System. The ecosystem's sustainability is further strengthened with the mission to drive entrepreneurship, beginning with the development of companies such as PACIV providing computer validation services and PharmaBioServ serving multiple world-wide locations. The ecosystem has developed logistics companies, providing indirect job opportunities, and is adapting to contract manufacturing to focus large pharmaceutical companies on developing new products while contracting their manufacturing with in-region companies such as ThermoFisher, Avara, among others. Finally, the UPR-Mayagüez (Consortium Member) was recently awarded an NSF Phase 1 EPIIC grant, ensuring best practice models and training to enhance partnership capacity-building providing a foundation for the management of the Hub's ecosystem. Under the EDA Phase 2 funding, the Hub's ability for self-sustainability increases greatly with its consortium commitments (see Section V.). In addition, many Hub Projects are self-sustained by PY 3-5 due to generated revenue, PR's R&D Act 60/73 tax credits, and access to capital initiatives.

VII. Labor Union Engagement

The Hub's Entrepreneurship: Lab To Market Project includes the MSRC construction to complete the previously EDA-grant funded Advancing Science and Technology Research and Entrepreneurship (ASTRE) Center. The MSRC will pursue project labor agreements (PLAs) with bid awarded contracting entities in PR. This construction will require soliciting electricians, plumbers, engineers, and a host of specialized trade workers. The MSRC will pursue contracts with PLA to ensure economic benefits of this construction are equitable and local residents are closest to their impact. And although the MSRC doesn't have a community benefits agreement in place, all wages for this effort will be at or above the minimum wage and comply with all construction wages under the PLA. In addition, the Hub's workforce plan includes supporting existing, registered apprenticeship programs which support good quality jobs. Lastly, the Hub will incorporate promising practices such as the AFL-CIO Technology Center which has partnered with Microsoft to support the voice of Labor in AI development.

VIII. Equity

The Hub’s distributed manufacturing concept allows for *diverse* distribution of jobs, *equitable* economic, and *inclusive* workforce development, while raising the existing footprint of the industry in PR. Included Letters of Commitment demonstrate the Hub’s commitment to ensuring the representation of underserved communities, businesses, and the PR workforce as they serve the full region of PR including underserved, rural, and socioeconomically disadvantaged populations. In addition, the PR Trust’s TTO manages a portfolio of 96 technologies from its partner universities and diversity in inventorship is exceptional, as 42% of the inventors (76 of 179 total) are female compared to the US average of 13% female inventor-patentees. The Hub’s workforce development commitments will also ensure that Hub benefits are equitably shared across PR since its bioscience landscape encompasses nearly a third of PR’s cities, incorporating employees from nearly all 78 municipalities. Expanding the technology and innovation beyond advanced manufacturing to drug discovery will only further expand the Hub’s reach, positively impacting economic development across a historically disadvantaged region. The Hub’s focus to expand the pharmaceutical landscape positions the Hub’s academic institutions and workforce labor organizations to expand industry-specific course certifications and degree programs, providing direct benefits to Minority/Hispanic Serving institutes, workplaces, and communities.

IX. Expected Outcomes

The worldwide competition in manufacturing and commercialization has been dominated by the maturation, commoditization, and widespread application of computation in production equipment and logistics, effectively leveling the global technological playing field. The next generation of biotechnological competition will be dictated by inventions of new materials, chemicals, devices, processes, and methods, among others. The Hub Component Projects have considered bold investments to fulfil this moonshot opportunity with the fundamental R&D required in AI, biotech, materials science, sustainability, education, and workforce development for PR to lead globally. Upon award, the Hub will continue enhancing its leadership in biomanufacturing, drug development, and commercialization through the joint impact its Projects’ Key Performance Indicators (KPI) per Project Year (PY) (primary KPIs represented below).

PRBio Tech Hub Component Projects: KPIs	PY1	PY2	PY3	PY4	PY5	Total
PRBio Tech Hub Governance						
Number of Advisory Board meetings	4	4	4	4	4	20
Number of Steering Committee meetings	18	12	12	12	12	66
Percentage resolution of day-to-day risk & issue resolutions	70%	70%	70%	70%	70%	70%/yr
Minimum number of marketing materials for Hub use	20	20	25	25	25	115
Access To Capital For Entrepreneurs						
Enrolled investors/entrepreneurs	10/5	15/10	20/10	20/10		65/35
Number of company/entrepreneur graduates	3	6	7	8		24
Total jobs created	5	10	15	25		55
Total Capital Raised by Investors	\$500K	\$1M	\$2M	\$5M		\$8.5M
Total Capital Closings	1	3	5	7		16
Advancing Nextgen Workforce						
Number of candidates who complete DDTC training	6	6	8	10		30
Number of participants enrolled/complete PR Integrated Biomanufacturing STEM Program	25/20	25/20	25/20	25/20		80/100
Number of mentorships supported by PR Integrated Biomanufacturing STEM Program	50	50	50	50		200
Apprenticeship: Number of participants enrolled/completed/employed	10/8/8	10/8/8	10/8/8	10/8/8		40/36/36
PR Ready: Number of candidates enrolled/complete	50/25	50/25	50/45	75/70		225/165
Coursera: Number of trainings started/completed	1000/500	1000/800				1800
Entrepreneurship: Lab To Market						
Number of underrepresented students served	100	100	100	100	100	500
Number of incubated companies within the space			6	6	6	18
Number of biotech/biosimilars in cGMP startups		10	20	20	25	75
Number of new incubation biotechnology companies			2	4	5	11

PRBio Tech Hub Component Projects: KPIs	PY1	PY2	PY3	PY4	PY5	Total
Next-Generation Therapeutics & AI Drug Discovery						
Number of molecules identified/manufactured/to market	10/2/3	10/2/3	10/3/3	20/3/3		50/10/12
Total Capital Raised (Non-dilutive and dilutive)	\$1M	\$3M	\$5M	\$9M		\$18M
Acceleration Of New Drug And Precision Medicine Laboratories						
Broader Impact: Number of Publications	2	2	3	4	4	15
Infrastructure & Staffing: Jobs Created	5	5	5	5	5	25
Infrastructure & Staffing: Investment (capital/funds)	\$5.8M	\$0.3M	\$0.4M	\$0.3M	\$0.3M	\$7.1M
Project Income: New Collaborative/Partnerships	2	2	2	2		8
Project Income: Co-working space/contract income (startups); onshoring D&D (scaleups)		1/0	1/0	1/1	1/1	4/2
Project Income: New grants (STTR/SBIR/CREST)	1	2	1	2	1	7
Number of patents granted/licensing agreements			1/1	2/2	2/2	5/5
Number of first-to-market products				2	2	4
Advanced Technologies Center: Pharmaceutical Manufacturing & Enabling Technologies						
Number of drug shortage candidates selected to support real-world process training		1	2	2	3	8
Number of sterile injectables capable of production		1	2	2	3	8
Established new startups and sponsored projects		2	3	5	5	15
Training certificates to participants		30	30	30	30	120
Number of scholarships awarded		5	10	15	20	55

These SMART PY interim goals and/or milestones will be used by the Hub to monitor the progress of Hub activities, ultimately allowing the EDA to further monitor progress of Hub outcomes. The goals will serve not only as the basis for determining the success of the consortium but also as a basis for building evidence-based policies to support which strategies and approaches work and which should be course-corrected based on the recommendations from the Hub's Steering, Advisory, and other overarching leadership committees. The PR Trust's Regional Innovation Officer (RIO) and Support Office will work with Project Leads to establish a comprehensive framework for evaluating project outcomes, reporting progress, and maintaining transparent communication with stakeholders. Upon Phase 2 funding, the RIO will provide a full overview of required EDA reporting tools and ensure comprehensive tracking practices are in place with each Lead. The evaluation plan will measure project impacts and progress towards overall Component Project's activities, goals, and objectives. The RIO will maintain open channels of communication between the consortium and the EDA to proactively identify challenges and collaborate with EDA and partners to find solutions that foster collaboration and support.

X. Expected Growth Plan

Accommodating the growth in housing demand resulting from the success of a technology hub, while preventing displacement and ensuring access to jobs for existing low-income residents requires a comprehensive approach that addresses supporting affordable housing development policies, preservation and renovation of existing affordable housing, direct community engagement, inclusive workforce development programs, and the promotion of transportation accessibility. While the Hub cannot tackle all these areas with the EDA funding, the Hub will actively support PR's multifaceted approach around affordable housing development such as the recent announcement of a FirstBank and CDBG-MIT jointly funded \$30M investment for the construction of Vista al Norte⁴, an affordable housing development that will benefit 102 low-income renters who earn 60% or less of the median annual household income in the metropolitan area of PR (Central Hub area). The Hub's committees will also support local community engagement efforts in the planning and decision-making processes of major economic and workforce development projects via the PR government and/or public/private interest to prevent displacement. The Hub's activities are invested in academics, training, and research activities from basic to advanced skill development to empower PR residents with the skills needed for entry to

⁴ <https://newsismybusiness.com/firstbank-grants-21-5m-in-financing-for-vista-al-norte-project-in-guaynabo/>

executive level biotechnology jobs creating a workforce that supports high wages to encourage home ownership and aligns with regional rental income levels.

XI. Relevant Activities between Phase 1 & Phase 2

During Phase 1, PR Trust secured the contracted services of Accenture to provide strategic project management for a comprehensive assessment of PR’s current biotechnology industry through documentation review and interviews of selected stakeholders resulting in a detailed work and resource plan to initiate Hub activity roles and responsibilities. Under Accenture, a two-day workshop was held to inform and receive feedback and input from industry, public and private sectors, nonprofits, government, relevant Clusters, academia, workforce industry, and others interested in Hub participation. This ecosystem building led to meetings with government, workforce, relevant industry operators, and academia, ultimately expanding the Hub’s consortium, commitments, and supporting partnerships.

From the aforementioned collaborative approach, the Hub has grown and evolved from Phase 1 Designation to the Phase 2 Implementation application to ensure the catalyzation of the Hub’s emergence over the next decade and beyond as a self-sustainable, globally competitive region. The Hub is now positioned as an established ecosystem, including the coordination with financial and policy commitments, collaborative partnerships, and other sources of funding, to support the EDA’s mission to strengthen US economic and national security through EDA KTFAs 7, 9, and 1 with PR’s assets, resources, capacity, and potential to become globally competitive, within ten years, in the biotechnology industry of the future. Over the past four months, the consortium has executed the activities presented below to prepare for Phase 2 Implementation. The Hub and its supporting structures under the PR Trust Governance, expects to evolve its capacity through its members, stakeholders, advisory board, community, and industry needs and involvement to translate innovation into equitable regional economic growth and to strengthen the overall national security by accelerating the development, manufacturing, and distribution of new products to address unmet medical needs of patients worldwide.

Phase 1 Goal 1 Relevant Activities from Phase 1-2: <u>Consensus-driven Strategies for PRBio Tech Hub</u>
<ul style="list-style-type: none"> - Component Projects selected through competitive abstract submissions, followed by full proposal submission. - Secured facilitator/consultant – Accenture project management hired for Hub assessment resulting in a detailed SOW of Hub activities through consortium agreement and a full Hub plan with roles and responsibilities. - Cross-examined NSF Engines and existing funding sources for overlapping or duplication within Hub activities.
Phase 1 Goal 2 Relevant Activities from Phase 1-2: <u>Industry Attraction, Retention, and Growth</u>
<ul style="list-style-type: none"> - Assessment of Boston Consulting Group gaps in Hub and engagement of necessary partners for Phase 2. - Assessed the most attractive industry sub-segments, key players, and drivers of site selection decisions and identified the most attractive product classes that match capabilities of existing infrastructure.
Phase 1 Goal 3 Relevant Activities from Phase 1-2: <u>Industry Future Workforce</u>
<ul style="list-style-type: none"> - Post-secondary institutions aligned and defined new pathways to workforce needs. - Planned and defined DDEC and Hub’s role in workforce development roles for the Hub. - Defined industry needs for on-the-job training, apprenticeships, and fellowship opportunities within industry.
Phase 1 Goal 4 Relevant Activities from Phase 1-2: <u>Regulatory Support Center</u>
<ul style="list-style-type: none"> -Identified the academic curriculum and workforce training needs in regulatory professional development.
Phase 1 Goal 5 Relevant Activities from Phase 1-2: <u>Contract Research Development and Manufacturing Organization</u>
<ul style="list-style-type: none"> -Developed design estimates and budget for infrastructure and equipment for state-of-the art laboratory and pilot scale infrastructure for small and large molecule development. - Identified necessary initiatives for technologies, viral, DNA and RNA derived immunotherapies, and gene and cell therapies with a parallel platform for future workforce development to complement industry capabilities.
Phase 1 Goal 6 Relevant Activities from Phase 1-2: <u>Advanced Manufacturing and Enabling Technologies Center</u>
<ul style="list-style-type: none"> -Planned a Center with platforms to deliver innovative and disruptive technologies with private industry and public university collaboration with full workforce alignment.

XII. Statement of Consortium Member Commitment: Please see Letters of Commitment within the submission package.

XIII. Key Partners – Letters of Commitment: Please see Letters of Commitment within the submission package.