NEW YORK STATE OF OPPORTUNITY.

Empire State Development

Life Science Initiative

The Next Phase

2023

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Empire State Development

Empire State Development
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The Life Science Initiative: The Next Phase 2023

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Introduction

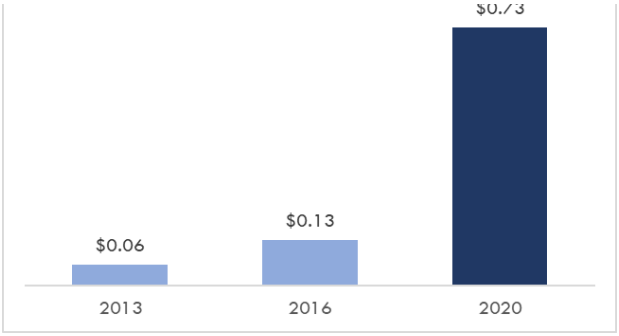
New York State has always been a place where new industries emerge, and growing businesses thrive. That long-standing legacy is no less true today than it was during previous eras of national economic expansion. Under Governor Kathy Hochul's leadership, New York is reinforcing its preeminence as place of economic opportunity.

Life Science is a rapidly growing area of societal interest and importance. Over the coming years, New York stands not just at the epicenter of expected consequential discoveries within the life sciences field, but also as the preeminent location where those breakthroughs can be commercialized. While New York's support for the life sciences industry pre-dates the COVID-19 global pandemic, under Governor Hochul, Empire State Development is doubling down on the opportunities that exist in this critically important sector.

ESD's first-ever Life Science Initiative (LS Initiative) is investing more than a half-billion dollars to catalyze the long-anticipated promise of a commercial life science sector in the state. This historic initiative, launched in 2017, was warranted because of both the enormous value it would generate for the state and the wealth of New York's academic medicine assets to be leveraged.

The LS Initiative has focused on making New York competitive with more mature life science markets in attracting companies, talent, and investments. ESD has followed a diversified portfolio strategy to fill investment gaps, lay the foundation for budding regional clusters, and revitalize New York's life science ecosystem. These strategies have been highly successful. With ESD's support we are seeing New York emerge as a global leader in the field. For example, the ratio of venture capital (VC) funding to National Institutes of Health (NIH) grant dollar has substantially increased, from $0.06 in 2013 to $0.73 in 2020[i] (Figure 1).

Figure 1: NY VC Funds per NIH Grant Dollar[i]



The global life science sector continues to innovate at a rapid pace. From lifesaving cell and gene therapies to highly affordable whole-genome sequencing platforms, advances in this sector will enable the LS Initiative to envision and implement projects that were unimaginable even a few years ago. Governor Hochul and her administration are ensuring New York State fully captures these new opportunities by broadening and updating its statewide Life Science strategic plan to support breakthroughs in technology and science and build complementary resources and capabilities across the state. At the same time, the plan recognizes the need to retain or expand programs anchoring the state's life science ecosystem.

Strategic Vision 2030

By connecting regional life science clusters across the state,
New York will become the leading destination for innovation and commercialization in Life Science,
providing a long-term economic benefit to the state and its residents.

Industry Focus: Past and Future

Since its inception, ESD's LS Initiative has been successful in seeding a robust life science cluster in New York State. In its first five years, ESD has made great progress in overcoming many of the impediments to attracting life science investments and nurturing a locally grown cluster, which has raised the state's profile as a national life science hub. As of December 2022, ESD has committed $181.5 million of investments through the LS Initiative to a number of programs, including a preclinical drug development lab using advanced Artificial Intelligence (AI) and Machine Learning (ML) technology, a collaborative, multi-partner institute to accelerate development of discovery research, an incubator, an accelerator, and a life science entrepreneurship development program, among others[ii].

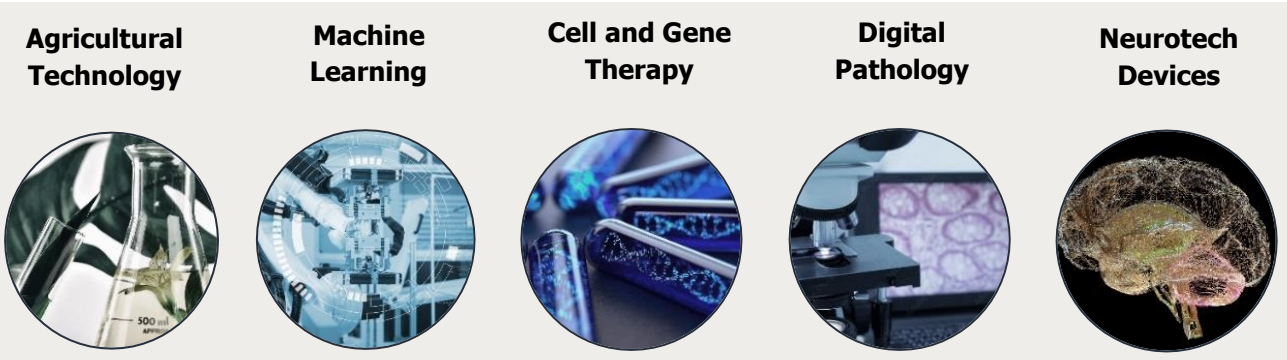
ESD has played a pivotal role in the growth of the life science ecosystem and in elevating the state's profile as a leading life science investment destination, and that commitment is paying off. New York State's LS Initiative has directly contributed to building the sector in several ways:

- Generated an additional $1.48 billion of leveraged investment by private and other public entities, in conjunction with the grants and contracts funded by the LS Initiative
- Incentivized 17 new life science companies to locate in New York
- Created more than 540 direct jobs
- Seeded subclusters in several areas of the state

The tremendous growth in New York's life science sector in key economic development indicators – such as new companies, jobs, new lab space, talent and investment dollars – has been driven by the more than $1.5 billion combined investment by New York City and New York State. Overall, there has been a nearly 20% growth in the number of life science companies, an over 10% increase in the number of life science jobs in the state between 2017 and 2021[iii], and New York City now has more than 3.1 million square feet of laboratory space[iv].

The LS Initiative is strengthening the support and resources needed to feed the life science value chain and removing barriers to continue the innovation maturity cycle. These accomplishments have primed the state's life science ecosystem to continue an upward trajectory, strengthening and defining New York as a life science center where innovative companies can thrive. (See ESD Life Science Initiative Annual Report 2022 for additional details.)

Under Governor Hochul's leadership, the next phase of the LS Initiative will continue to support emerging life science communities while capturing new opportunities from breakthrough technologies and novel capabilities, such as cell and gene therapies, application of machine learning to preclinical and clinical decision-making, food technology, neurotechnology devices and nano and organoid technologies. This diversity provides more opportunities for long-term growth by capitalizing on a broader range of innovations. It will also focus on expanding the benefits of life science activities to New York's highly diverse population and establish the life sciences as one of the state's key economic growth engines.



Updated Sector Strategy

Given the rapid, remarkable advances within the life science industry over the past several years, this updated strategy identifies new opportunities and builds on the program's successes to date. To accomplish this, a data-driven process was employed to identify and understand the most current and emerging life science technology trends, investment opportunities, and data on cluster development. New York State's life science landscape was assessed to identify gaps and opportunities for future strategic investments. Interviews with potential key partners, as well as ESD stakeholders, helped deepen this analysis.

This updated strategy also describes a **more fully realized set of investment opportunities at a regional and state level designed to make New York the leading destination for life science development**. These investments include anchoring two developing regional clusters in Western New York and Long Island and connecting them through technology and collaboration while leveraging New York's diverse population. This "networked" cluster strategy would be unique even among multi-cluster state strategies such as those underway in Massachusetts, Pennsylvania, and California.

THE UPDATED LIFE SCIENCE STRATEGY

A. Bet On New York

Concentrate the largest investments in New York's leading research institutions and medical centers

B. Connect the State

Link regional investments that complement each other through data integration and clinical specialization

C. Support Emerging Technology

Leave room for early bets on breakthrough technologies to build a pipeline of future investment opportunities

D. Continue to Invest in Winners

Continue to support existing programs that have achieved their goals and consider using them as blueprints for new initiatives

A. Bet on New York

Successful life science markets like California, Massachusetts, and Pennsylvania are concentrating their investments in a few select subsectors with high growth potential and forming public-private partnerships with prestigious institutions and major corporations. Additionally, investors are placing more bets on fewer select markets, reinforcing the preeminence of top-performing regions. This investment trend clearly favors regional clusters with depth, not breadth, where the greatest resources are allocated only to the most likely winners.

As the LS Initiative and New York's ecosystem have matured, a focused approach to cluster development is now both preferred and being pursued. By concentrating on specific strengths and assets and capitalizing on technologies that leverage the state's competitive advantages, New York will take a giant step forward to further enhance its position as a global life science hub.

This comprehensive opportunity assessment included evaluations of various therapeutic areas, key trends in life science technology development, and risk-reward assessments, and how these areas could leverage New York's strengths and the successes already achieved by the LS Initiative. For example, New York State is a national leader in the number of National Cancer Institute (NCI)-Designated Cancer Centers per capita and advanced research institutions focused on clinical breakthroughs. These institutions are generating intellectual property in areas such as cell and gene therapy, which attracts some of the largest private investments today.

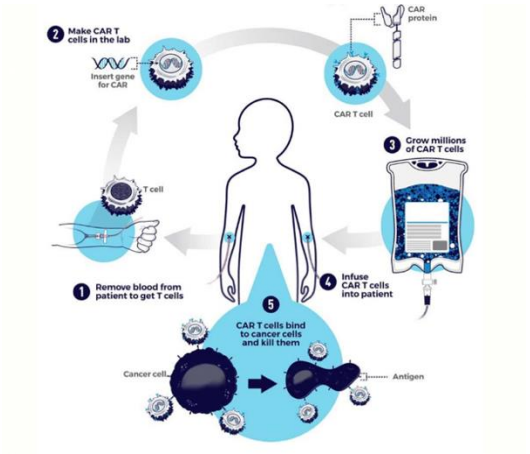
Out of this research, we identified the following major investment opportunities [v, vi].

Cell and Gene Therapy in Oncology	Neurology	Diversity in Clinical Research
$90B	**$175B**	**150**
2030E Global Market[v]	2028E Global Market[vi]	Languages Spoken in NYC

Opportunity I: Cell & Gene Therapy

Therapeutic technologies that hold the promise of either shortening the drug development process or lowering the risk of failure are the most highly valued, and oncology continues to receive the majority of life science investments, especially since the successful launch of checkpoint inhibitors and chimeric antigen receptor (CAR) T-cell therapies[vii] (Figure 2). This is one of the most promising technologies in medicine today, and New York State is uniquely positioned to become a world leader in this field, with strategic support from the LS Initiative.

Figure 2: CAR T-Cell Therapy[vii]



According to the National Cancer Institute, cancer continues to be the second leading cause of death in the U.S., after heart disease. Approximately 1.9 million new cancer cases and 610,000 deaths a year were expected to occur in the U.S. in 2022. By 2028, worldwide sales of cancer drugs are projected to reach $370 billion, accounting for over 20% of total

prescription drug sales and more than double the next therapy area. Industry analysts assume oncology will remain the dominant therapy area for the foreseeable future[vii].

With a large addressable market and the prospect for faster approval and cheaper off-the-shelf alternatives, cell and gene therapy (CGTx) holds the potential to radically alter the biopharmaceutical business model. Currently, there are more than 2,000 ongoing clinical trials globally[viii], and the FDA estimates 10 to 20 new approvals per year[ix]. Analysts estimate that the CGTx market could grow from $16 billion in 2022 to $90 billion in 2030 at a compounded annual growth rate of 25%, making it one of the fastest growing sectors in life science[v].

Thus, what makes CGTx a compelling opportunity is the combination of:

- Cancer's high unmet need —The lion's share of R&D efforts in the CGTx sector go to cancer, with an overwhelming number of CGTx clinical trials focused on cancer[x] (Figure 3)
- Viable therapeutic modalities
- Expedited regulatory process
- Advances in genomic diagnostic tools, and
- Decentralized manufacturing

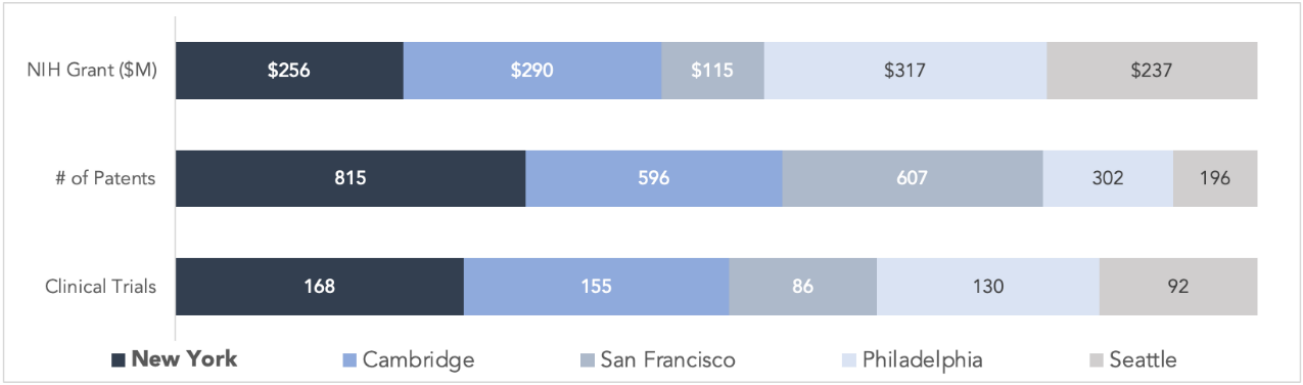
Figure 3: Top 5 Areas of CGTx Clinical Trials[x]

Additionally, CGTx requires the integration of several enabling technologies provided by a range of companies poised to grow as CGTx grows. The ability of ESD to lead that integration translates into additional opportunities for expanded cluster development and job growth.

Within the CGTx market, New York State holds a natural advantage[x] (Figure 4), with:

- Top academic and medical institutions, in terms of NIH grants for CGTx, and
- Largest numbers of patents and clinical trials in CGTx.

Figure 4: NY vs. Top CGTx Clusters, 2018-Aug 2022[x]



In her 2023 State of the State, Governor Hochul announced plans to establish two Cell and Gene Therapy (CGT) centers, including one Upstate and one Downstate. With these two centers, New York can help partners potentially leapfrog competitors in cell therapy research, development, and manufacturing.

The largest opportunity in CGTx is in developing therapeutics that target solid tumors, which constitute approximately 90%[vii] of all cancers and New York State offers several unique advantages that make it and the Western New York region the ideal location to establish a CGTx hub. For one, Roswell Park Comprehensive Cancer Center (RPCCC), the only NCI-designated Comprehensive Cancer Center in the region and world-renowned for its cancer care and research, is expanding its CGTx manufacturing and research capability. RPCCC has tapped Renier Brentjens, M.D., Ph.D., a cellular therapy pioneer whose research helped to establish CAR T-Cell Therapy as a major step forward in cancer treatment, to lead its efforts in CGTx. Dr. Brentjens, a founder of the highly successful cell therapy company Juno Therapeutics, has assembled an outstanding team of solid tumor researchers with world-class CGTx research experience to work with him in continuing this groundbreaking research and development.

Downstate, Long Island offers an unmatched combination of assets, including under-utilized real estate readily available to house the desired companies and technologies needed to support the hub, in addition to the presence of several top research and clinical care institutions, including Cold Spring Harbor Laboratory (CSHL), the Feinstein Institutes, Northwell Health, and Stony Brook University. In addition, with its proximity to New York City and the high population density and diversity of its boroughs – Queens, in particular, where 150 languages are spoken – Long Island offers unparalleled access to a uniquely diverse population to participate in clinical trials.

Northwell, for instance, has the largest clinical footprint in the state, providing care to two million patients annually, including 19,000 new cancer patients[xi]. Northwell is applying to become an NCI-designated cancer center and has partnered with CSHL, which is already an NCI-designated cancer research center. With NCI accreditation, advanced genomics capabilities, and a partnership with RPCCC, Northwell could deliver the most advanced cancer care in the region to the world's most diverse patient population.

To turn Governor Hochul's vision into a reality, ESD is well positioned to partner with leaders across New York State to build CGTx hubs in Western New York and on Long Island. We envision a multipart initiative that includes:

- Expansion of a cGMP (current Good Manufacturing Practice) facility for CGTx research and manufacturing in Western New York
- Leveraging of infrastructure already established through the ESD-funded Empire Discovery Institute (EDI)[xii]
- Creation of another CGTx hub downstate on Long Island and linked to the RPCCC CGT cGMP facility, which will provide direct access to CGTx for large patient populations as well as house companies with technologies required for CGTx development
- Establishment of satellite CGTx hubs in key regions of the state over the longer term

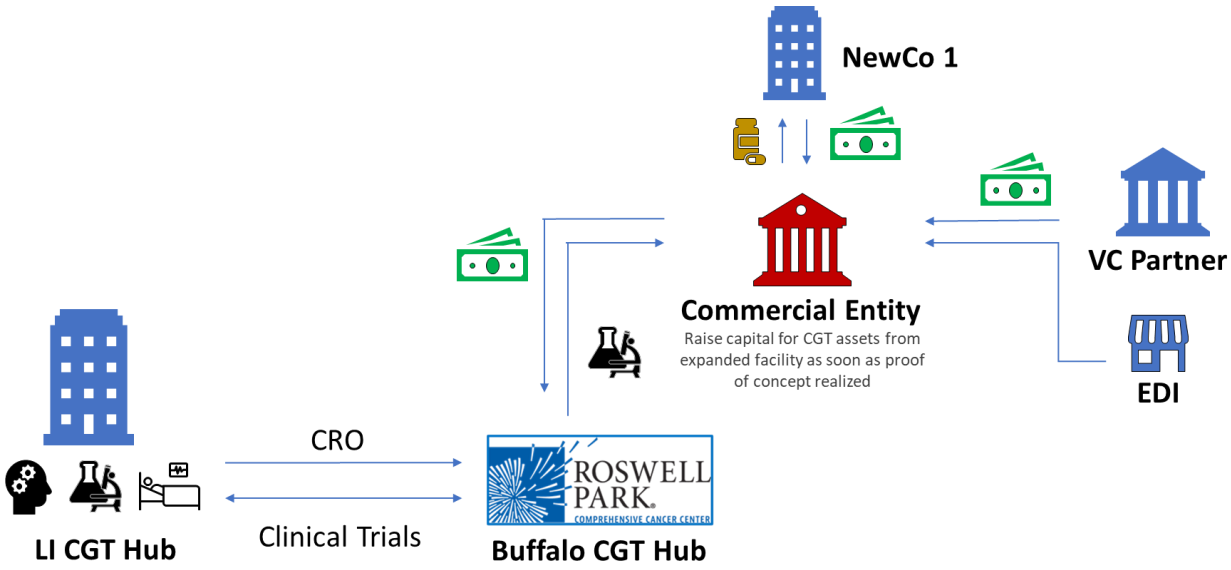
Western New York Hub

ESD has already planned its first regional investment in CGTx with $30 million of capital assistance to RPCCC. This funding will allow them to greatly expand their existing cGMP facility and supply New York State west of the Capital District with therapeutic cells to treat blood, and eventually solid tumors. As the explosive growth in CGTx R&D has caused a shortage in cGMP capacity, creating significant delays across the development value chain[xiii], ESD's investment in Western New York's RPCCC can both accelerate innovation in CGTx and increase access to CGTx treatment, as proximity to patients is key to safe and effective CGTx. Two other major research institutions, the University of Rochester (UR) and the University at Buffalo (UB), will further enhance the area's research capabilities and access to patients, as will the Empire Discovery Institute (EDI), created by a partnership of RPCCC, UR, and UB, to fast-track development of promising research from these institutions.

As research progresses, it is critical that cell and gene therapies are commercialized and made available to patients across New York. To facilitate this, ESD and RPCCC are planning to create a commercial entity that will efficiently advance these therapeutics toward commercialization. This entity will not only take cell and gene therapies through clinical testing, but also raise capital for RPCCC's CGTx assets that will result from the facility expansion. This expansion of RPCCC's CGTx manufacturing facility also will enable other New York State research institutions developing CGTx, as well as industry partners, to use the cGMP facility for their cellular therapies in development.

EDI can be a conduit for these therapies, ensuring their efficient development through its cost-effective approach to facilitating the creation of new therapeutics. By evaluating every potential development project through a strict set of criteria, EDI provides a highly efficient path to commercial development. The cGMP facility also will attract to the region CGTx companies in need of manufacturing services (Figure 5).

Figure 5: CGTx Network with Complementary Capabilities



This program to expand RPCCC's cGMP facility could deliver multiple benefits that meet many of the underlying goals of the LS Initiative, including:

- Attracting industry and investment partners
- Creating jobs
- Increasing IP and talent pipeline
- Creating spinoffs
- Significantly increasing the volume of cellular therapy clinical trials at RPCCC, and
- Promoting equitable access to advanced therapeutics through ESD's Clinical Research Diversity Network, leading to growth and expansion of life science clusters in the Western New York and Long Island regions

ESD investments in this project would target the goal of sparking regional economic growth through the development and manufacture of cell therapies while creating a network of local institutions across the state to ensure access to advanced therapies in what are underserved communities. For example, the structured commercial entity will connect the CGTx initiative at Roswell with the Long Island hub, participating in a clinical trial consortium being developed by RPCCC that will connect with cancer centers like Northwell, Columbia University Medical Center, and Weill-Cornell. This will accelerate patient recruitment and ensure access by underserved patient groups.

The commercial entity also could partner with New York State-based vendors and tenants at the Long Island hub, including advanced contract development and manufacturing organizations (CDMO), next-

generation sequencing (NGS), and clinical genomics. This strategy will help repatriate these industries to the U.S. and to New York State. The new entity also will attract and incubate new therapeutic technologies such as mRNA cancer vaccines, which will be an important adjuvant technology to CGTx.

With multi-partner EDI as an investor in this entity, it could also serve as a template for other public/private initiatives and partners, such as biopharmaceutical partners and private equity investors. This approach has been highly successful in the Cambridge biotech cluster, as observed with MIT's Koch Institute collaborating with the Dana-Farber Cancer Institute, Mass Bio, Polaris Ventures, and Landmark Bio (CGTx facility). These relationships reinforce the success of each participant and are imitated in many states with much smaller life science industries than New York State.

As these collaborations grow in complexity, they will drive powerful network effects for economic development. If successful, the commercial entity can act as an economic engine the way Moderna, in its use of CRISPR technology, has for the Koch Institute and Cambridge.

Long Island Hub

To tap into Long Island's tremendous potential and ensure that cell and gene therapies are available to patients Downstate, ESD will work with a developer to ensure the vision for the Long Island hub is fully realized. By establishing hubs in Buffalo and in Long Island, New York will be the first state to employ a coordinated strategy in CGTx to attract a diverse array of innovative companies and drive large economic growth while addressing healthcare disparities in underserved communities (Figure 6).

Figure 6: Illustrative Long Island Companies and Services for CGTx Capabilities

- cGMP Biomanufacturing of Cell and Gene Therapies by a CDMO
- Advanced Clinical Genomic Sequencing and Clinical Decision Support
- Cross-Institutional Clinical Data Integration and Analytics
- Other (e.g., Immune Monitoring, Viral Vector Processing, Binder Development, Protein / Oligo / Organoid Manufacturing, and other emerging technologies)
- Clinical Trial Services

The Western New York and Long Island hubs represent just the first phase of a larger and longer-term statewide strategy to connect the singular resources available in these two regions, making New York the leading destination for CGTx. Companies resident in the hub will be called upon not only by RPCCC and Northwell, but by all institutions in the greater New York metropolitan region that are developing CGTx, as they also will require the technologies supportive of CGTx.

Opportunity II: Neurology

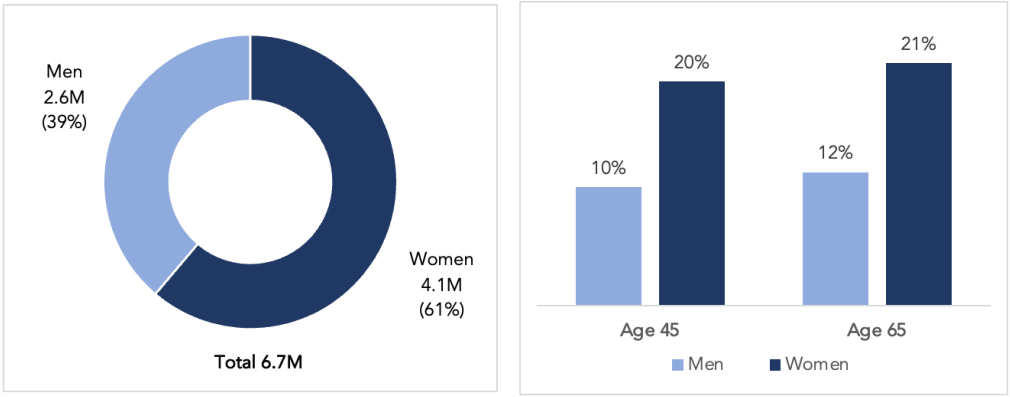
New York is a national leader in neurology and neurosciences research - with five of the top 20 NIH funded schools of neurology, and four of the top 20 in neuroscience located in the state[xiv]. NIH grants awarded in neurology and neurosciences to New York institutions in 2022 total approximately $275 million, which is 17% of the grants awarded nationwide. The state also has the second largest number of institutions with undergraduate neuroscience programs in the U.S.[xv] Given New York's strength and the significant unmet need in neurological diagnostics and treatment modalities, ESD's strategic focus in this area will enhance the state's profile as a life science cluster. By partnering with leading research

institutions and companies and by supporting startups, ESD can help de-risk some of the challenges in neuroscience while attracting meaningful outside capital to accelerate the growth of its ecosystem.

Between 2020 and the second quarter of 2022, neurologic biotech ventures in the U.S. raised a total of $2.2 billion in Seed and Series A funding[xvi]. During 2021 and the third quarter of 2022, biopharmaceutical companies announced an aggregate of $51 billion in licensing deals in neurology[xvii]. By 2028, worldwide sales of treatments for neurological diseases are projected to reach $175 billion, making it the second largest therapeutic area after oncology[vi]. From Alzheimer's and Parkinson's disease at one end of the life cycle, to Autism Spectrum Disorder (ASD) and the concurrent mental health issues at the earliest stage of life, to less common Amyotrophic Lateral Sclerosis (ALS) and Huntington's disease, neurodegenerative diseases have an increasingly high incidence rate, and their impact is often devastating.

Among the most common neurodegenerative diseases is Alzheimer's and related dementia. An estimated 6.7 million Americans aged 65 or older today are living with Alzheimer's, and that number is projected to rise to 12.7 million by 2050 as the U.S. population age 65 and older continues to grow. Almost two-thirds of Americans with Alzheimer's are women and the estimated lifetime risk at age 45 is approximately 1 in 5 (20%) for women versus 1 in 10 (10%) for men (Figure 7). One in three seniors dies of Alzheimer's or another dementia, a mortality rate greater than that for breast cancer and prostate cancer combined[xviii].

Figure 7: Prevalence (left) and Estimated Lifetime Risk (right) of Alzheimer's Dementia[xviii]



Alzheimer's patients currently have limited options for treatment, which offers modest clinical benefits but potentially causes serious side effects such as brain swelling and bleeding. It was only at the end of 2022 that the Centers for Medicare & Medicaid Services (CMS) implemented coverage for FDA-approved monoclonal antibodies directed against amyloid[xix].

For the past 40 years, the National Institute on Aging (NIA) at the NIH has funded more than 30 Alzheimer's Disease Research Centers (ADRCs) at medical institutions across the country. New York State alone has three ADRCs at Columbia University, Icahn School of Medicine at Mount Sinai, and NYU Langone. The goal of the ADRC network is to enhance clinical research, outreach and education and data sharing. In collaboration with these leading New York State institutions, ESD can further drive the translation of breakthrough discoveries into commercial opportunities in neurodegenerative diseases.

Equally devastating and growing in numbers are the estimated 5.4 million adults in the U.S. with Autism Spectrum Disorder (ASD)[xx]. Moreover, approximately one in 36 children in the U.S. were diagnosed with ASD in 2020, up from one in 150 children in 2000, an increase of 478%[xxi]. Autism affects all ethnic and socioeconomic groups, but minority groups tend to be diagnosed later and less often. The increase in the prevalence of ASD and the rise in the diagnosis rate are driving market growth for diagnostic and treatment modalities. The global ASD market is projected to reach $43.2 billion by 2031[xxii] and the cost of caring for people with ASD is predicted to reach $461 billion by 2025[xxiii].

Early diagnosis of ASD plays a vital role in understanding and managing the disorder. Various studies have found the average age of diagnosis to be between three and six years, with significant differences across

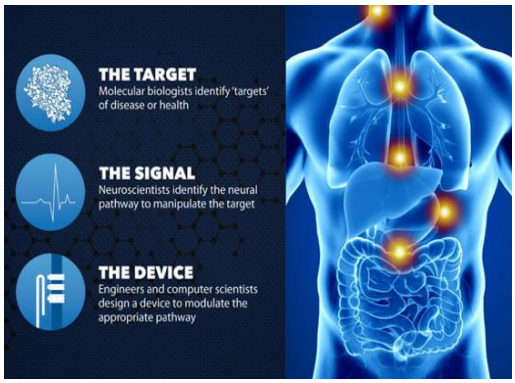
ethnicities and socio-economic statuses. This, despite the fact that a delay in diagnosis can have a profound cascading effect across development and that early intervention improves outcomes in young children[xxiv]. Accordingly, there are a number of efforts underway in conjunction with the NIH to pave the way for earlier, simpler and more affordable tools to diagnose ASD. One example is the funding by NIH for a project to develop a screening tool using infrared light to follow a baby's eye movement. The tool has successfully helped diagnose children with autism at just 12 months of age and in only minutes instead of hours. Also in 2021, the first FDA-authorized AI-based diagnosis aid was approved to diagnose autism in a primary care setting.

New York State already has an established ASD research community with Columbia University as one of the nine NIH funded Autism Centers of Excellence (ACE)[xxv], the Seaver Autism Center for Research and Treatment at the Icahn School of Medicine at Mount Sinai and the Center for Autism and the Developing Brain (CADB), a collaborative program between New York-Presbyterian, Columbia University College of Physicians and Surgeons, and Weill Cornell Medical College, in partnership with New York Collaborates for Autism, among others throughout the state.

Given that advances in technology are proving essential to improve both early diagnosis and management of ASD in children, combined with New York's strengths in ongoing ASD research, diverse breakthrough technologies and novel capabilities emerging across the state, as well as the growth of investment in early-stage companies, ESD could accelerate commercialization of early diagnostic innovations and strengthen New York's ASD life science cluster.

Another key growth area of the market is neurotechnology devices - expected to grow from $11 billion in 2021 to $36 billion in 2030 at an annual compounded growth rate of 15%[xxvi]. Bioelectronic medicine, such as implantable devices, is a new approach to treating and diagnosing disease and injury, and represents a convergence of molecular medicine, neuroscience, and bioengineering[xxvii] (Figure 8). These devices monitor and decode neural signals to detect disease and control inflammation, a central phenomenon in virtually all diseases. One of the exciting aspects of bioelectronic medicine is its potential to supplement and even replace drugs, including their cost and often debilitating side effects.

Figure 8: Bioelectronic Medicine at Feinstein[xxvii]



The Institute of Bioelectronic Medicine at Northwell Health's Feinstein Institutes for Medical Research has made exciting discoveries around the central role of inflammation in many disease areas, as well as methods to modulate inflammation through the vagus nerve. The Institute's research has already attracted commercial partners, including GE Ventures and GSK-backed bioelectronics startup Setpoint Medical, to develop this technology for use in the clinic. The Institute is also partnering with MIT's Picower Institute for Learning and Memory to apply non-invasive neuroelectronic technology to diseases like Alzheimer's. Picower is part of the world's most valuable life science cluster centered around institutes like the Cambridge-based Broad Institute, which attracts billions of dollars in investment and commercial development activity every year. Breakthrough therapies in bioelectronics could help make New York's planned Long Island life science cluster similarly valuable.

Progress in applied bioelectronic therapies for neurological disorders will benefit other central nervous system (CNS) research centers across the state. In addition to the three ADRCs mentioned above, The Neurological Institute of New York at Columbia University and The Tisch MS Research Center are just a few of the many leading local clinical and research centers specializing in neurological disease.

ESD will consider a number of ways to support early-stage ventures focused on neurodegenerative diseases. Among consideration is the establishment of a Neuroscience Commercialization Fund to replicate the early success we have achieved with the New York State Biodefense Commercialization

Fund. Additionally, ESD's New York Ventures may also focus investments to advance promising therapeutics and technologies in the following areas for patients with neurological disorders:

- AI/ML-enhanced early diagnosis
- Patient care navigation
- Cell and gene therapies
- Bioelectronics, and
- Robotics / Digital therapeutics

As ESD invests in such cutting-edge technologies and companies and builds out its Clinical Research Diversity Network, New York State will be well positioned to attract greater investment for research and commercialization opportunities in neurological disorders.

Opportunity III: Promoting Diversity in Clinical Research

New York is uniquely positioned to be a leader in the growing trend towards promoting diversity in clinical research, taking advantage of immediate access to diverse populations to help achieve more equitable outcomes in treatment.

As scientists construct ever more accurate reference genomes that catalogue the genetic diversity of our humanity[xxviii], there is an increasing need to include a broader representation of the population in clinical research. However, the practical realities of securing FDA approval for a new drug while maximizing market size create strong incentives for pharmaceutical companies to design inclusion criteria and cohort profiles that will capture the largest, least specific, patient population. This means avoiding many cohort dimensions like race/ethnicity or sex that might slow trial participant recruitment or limit a drug's ultimate label. These industry dynamics contribute to one of the most persistent errors in clinical research: the so-called "reproducibility problem" or the failure of clinical trial results to reproduce in the real world. In certain diseases that disproportionately impact minority patients, the disparity in outcomes is significant.

For instance, despite advances in early detection and treatment for breast cancer, the mortality rate among Black women is 40% higher than that of white women. Among women under 50, the disparity is even greater: young Black women have double the mortality rate of young white women. The disproportionate mortality burden among Black women in part reflects the higher risk of triple-negative breast cancer and late-stage diagnosis, however they experience worse survival across all stages and subtypes[xxix].

Last year, in partnership with its Oncology Center of Excellence, the FDA released draft guidelines to recommend clinical trial sponsors to enroll individuals who reflect the racial/ethnic diversity of the population expected to use the medical product once it is approved[xxx]. Among the several sets of recommendations to improve clinical trial diversity were: a) broadening of eligibility criteria when scientifically appropriate; b) offering financial reimbursement for expenses incurred by participation in a clinical trial; c) providing language access to participants with limited English proficiency, and; d) partnering with community-based organizations to provide support to study or trial participants.

Following the release of the FDA's draft guidelines, the industry group Pharmaceutical Research and Manufacturers of America (PhRMA) announced a clinical trial diversity initiative, dubbed Equitable Breakthroughs in Medicine Development. Under the new program, PhRMA will invest $10 million to launch 10 community-based trial sites with three medical schools to address the lack of outreach, patient mistrust, and lack of available trial sites. Similarly, Novartis committed $17 million over 10 years to create clinical trial centers of excellence at three historically Black medical schools. The trial centers under Novartis' Beacon of Hope initiative will be overseen by investigators and trial managers of color and focus on participants from underrepresented populations. According to Novartis, Sanofi and Merck have signed up to conduct trials at these centers.

Given the growing interest among regulators and industry players, combined with access to one of the world's most diverse population in the boroughs of Queens, Brooklyn and The Bronx, ESD is perfectly

positioned to play a pivotal role in improving health equity and access to underserved communities. By engaging biopharmaceutical companies and clinical research organizations, ESD can support patient education, clinical trial recruitment and other outreach efforts to increase awareness and access to innovative therapeutics. ESD can also help accelerate workforce development at clinical trial centers throughout the state.

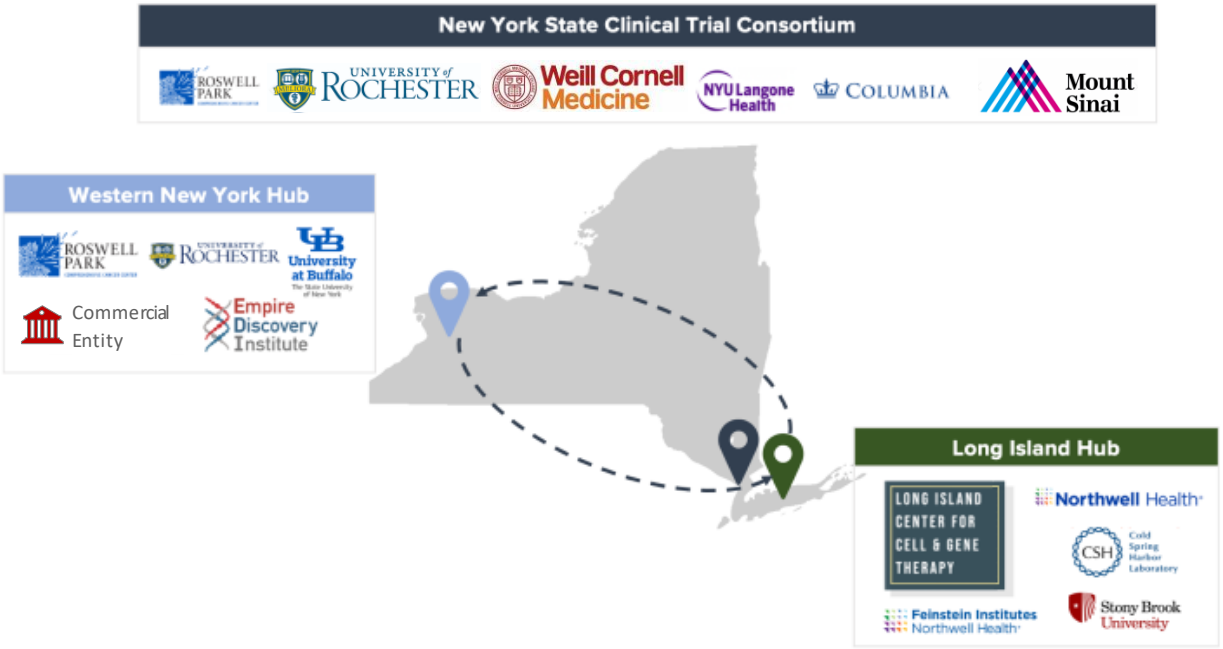
As a first step, ESD is working in partnership with the Parker Institute for Cancer Immunotherapy (PICI), a global cancer research funding organization that works with world-class research institutions like the Memorial Sloan Kettering Cancer Center and Dana-Farber Cancer Institute, as well as major companies like Bristol-Myers Squibb[xxxi], to convene a symposium of leading experts in the field. The goal of the symposium would be to uncover and explore major issues in clinical research diversity and identify possible solutions and initiatives. Based on this output, ESD will consider next steps and initiatives that New York State might undertake to address these issues.

B. Connect the State

When replicated with other areas of focus beyond CGTx, the state's multi-cluster coordinated investment strategy can reap great economic and social benefits. The comprehensive CGTx initiative offers an excellent model for how initiatives across the state can be networked and strengthened as technology matures to ultimately create a New York State Clinical Trial Consortium (Figure 9).

- Support academic and medical institutions to develop individual strategies to commercialize life science IP and occupy complementary niches in the overall CGTx value chain
- Create a Clinical Trial Network connecting major state academic medical centers (AMCs) and teaching hospitals to rapidly source and enroll eligible CGTx trial participants and exploit New York's unique patient diversity
- Link these same AMC molecular and digital pathology labs to gather data to improve the response rates for costly CGTx, a major barrier to accessing these expensive therapies
- Create regional cGMP facilities close to infusion centers and trial sites that are well equipped to minimize and manage serious side effects like cytokine release syndrome

Figure 9: Creating a Clinical Trial Consortium



Developing and networking these clusters will achieve collateral benefits that are critical to the growth of New York's life science economy:

- Create meaningful careers and well-paying jobs
- Multi-year strategic partnerships with industry leaders and a robust workforce development program can bolster the region's economy and attract further private investments.
- Create and attract a broad range of companies with complementary technologies that include genomic diagnostics, AI/ML, robotics, and contract research and manufacturing
- Enhance and expand strengths and capabilities
- Bring state-of-the-art cancer care to both Western New York and Long Island
- Improve therapeutic development for New York's uniquely diverse population.

By designing regional investments to link and complement each other through functional and clinical specialization, ESD can help regions across the state achieve significant economic development through their local academic, medical, and other institutions. This statewide design will avoid intrastate competition and redundant overhead while generating network effects that accelerate the progress of all participants.

C. Support Emerging Technology

While ESD's primary strategy focuses investments in established fields where New York State has a competitive advantage, breakthrough technologies that build a pipeline of future investment opportunities will be considered.

The new world of life science innovation goes beyond therapeutics and diagnostics and includes innovations in such fields as agriculture/veterinary, materials science, food science and marine biology. By including exciting innovations in these fields—with their typically longer lead times—in the investment strategy, we will build an investment pipeline likely to bring economic benefit for years to come.

By following this principle, prior ESD investments may also benefit. For example, several companies coming out of the IndieBio New York accelerator or the JLABS incubator, each of which received ESD support from the LS Initiative, are developing innovative alternatives to animal-based food products and toxic materials currently in widespread use.

Opportunity I: Breakthough Technologies – "Planetary Health"

"Planetary health" is an emerging research field and vital, cutting-edge industry based on recognition of the interdependent relationships between living organisms—both human and non-human—and their ecosystems. Planetary health recognizes both human health and the health of our planet are inextricably linked, and that our civilization depends on human well-being health, flourishing natural systems, and the wise stewardship of natural resources.

This concept includes areas of research and development focused on creating more sustainable products that minimize resource depletion, pollution, and toxicity that may be caused by existing products. Decreasing society's dependence on animal products for nutrition, clothing and other needs are just some of the many areas of research and development under this umbrella that may deliver economic benefits to New York State.

There is growing consumer market interest in developing alternatives to animal-based products for nutrition, and to replace materials typically used in clothing, cosmetic, personal care and industrial products that are toxic or polluting. This field offers tremendous opportunity for growth, as advances in protein science have the potential to deliver numerous industrial and consumer products more sustainably. Additionally, Artificial Intelligence (AI) and Machine Learning are being used to help researchers discover previously unknown proteins and to design entirely new ones. When fully harnessed, this capability could

help unlock the development of more efficient vaccines, speed up research for the cure to cancer or other diseases or lead to completely new materials.

Planetary health, sustainability, and the future of food each offer promising research and development opportunities. Our work with IndieBio New York has yielded several investments in these areas, helping us expand our understanding of their economic development potential and to explore further opportunities. Precision fermentation is one such opportunity. It will enable the mass-market replication of such products as milk protein, animal proteins, collagen, fish and seafood, egg whites, and others without the raising and killing of animals and sea life, as well as the development and commercialization of cost-effective solutions to reduce emissions, increase resource availability and restore environmental quality.

The market for food protein products is expected to grow from 587 million tons in 2020 to 745 million tons in 2030[xxxii]. By being an early-stage investor in this technology, New York State is in an ideal position to reap numerous benefits by attracting small alternative protein companies, such as those participating in IndieBio's accelerator, and ultimately by expanding the precision fermentation industry to go well beyond food and consumer products to include a broad range of industrial applications.

An investment in precision fermentation also could leverage the state's agricultural industry, with the potential to establish training and employment partnerships with Cornell University and other academic centers in the state that are focused on food science and technology. Precision fermentation also could draw on New York's agricultural products for feedstock for precision fermentation processes and will make New York more competitive with the states identified for investment by the Executive Order on the National Biotechnology and Biomanufacturing Initiative[xxxiii].

Staking a claim on the future and value of precision fermentation will further support the state's growing alternative protein industry. Collateral benefits of such an investment could include:

- Serving as a magnet for startups and other companies building equity in this field
- Attracting companies that require the services provided by precision fermentation and related technology companies
- Development of a workforce with the skills needed for food and materials biosynthesis

Opportunity II: Advanced Enabling Technologies

The real promise and potential of CGTx and the other proposed initiatives cannot be fully realized without a range of advanced enabling technologies that support the development of needed intermediaries, diagnostics, and other accessory products. Inevitably, even as a concentrated investment strategy is recommended, these investments will construct an innovation value chain that attracts and grows companies delivering the enabling technologies, such as those listed below, which are required to support the investment focused on CGTx. Each of these listed technologies offers the possibility of additional investment opportunities:

- Genomics (+omics)
- Robotics (Lab of the future)
- AI/ML
- Nano/implantables/Organoids
- Cloud & Social networks

For example, AI and Machine Learning in combination with robotics will be used to help researchers accelerate preclinical drug discovery at the Lab of the Future, a pilot laboratory supported by ESD. When harnessed fully, this capability could impact multiple industries by making the synthesis of well-designed small molecules generally available. The ability to democratize chemical synthesis will unlock more efficient development of drugs, materials, diagnostics, catalysts, and much more. Services like Lab of the Future will help reverse the decades-long off-shore outsourcing of preclinical research to India and China. Frost & Sullivan estimates the 2023 forecasting market value of preclinical research outsourcing to be

approximately $3.4 billion[xxxiv]. Lab of the Future and AI technologies have the potential to serve as the basis for a broad range of applications and development of companies in fields beyond biopharmaceutical research, such as materials science, agriculture, cosmetics and beyond.

To support the continued growth of the innovation ecosystem, including around the life science industry, ESD supports at least seven accelerators or competitions (Genius NY, 43North, HUSTLE, Luminate, New York State Business Plan Competition, NYS Commercialization Competition, and Grow-NY) and one life science accelerator program to be created in Long Island to help entrepreneurs gain the skills they need to access capital, accelerate innovation, make critical industry connections and grow their companies in New York State. Most of these programs offer comprehensive support to early-stage companies contributing technological innovation and economic growth that ultimately will bring jobs to specific regions of New York and in some cases, the entire state. These accelerators offer fertile ground from which to identify new opportunities for growth.

D. Continue to Invest in Winners

When it was first launched, the mission of the LS Initiative was to start, attract, grow, and retain life science companies in New York State. Several of the initial life science projects have achieved – and in some cases exceeded – this goal.

For example, the Biodefense Commercialization Fund has quickly demonstrated its value: Less than a year since the first awards were made, 10 patent applications have been filed and approximately $6.9 million in additional funding has been raised. Some companies awarded Biodefense Fund grants had received funding from other ESD programs, including investments from NY Ventures Fund, IndieBio, and JLABS. Additional incentive programs could be considered, such as a competition among winners, that will build even more interest in remaining in New York State.

Several ESD programs focus on talent acquisition and development:

- NYFIRST has successfully facilitated the creation of more than 100 jobs through the recruitment of translational talent from outside the state.
- The Entrepreneurship Development program is helping to develop future talent.
- IndieBio is supporting startup founders and helping to develop them to be effective leaders of innovation-driven companies.
- For programs such as the CGTx hubs in Western New York and Long Island, senior-level talent will be needed to lead the numerous spinoffs that will be created. The Life Science Division will work with the Workforce Development team at ESD to create talent development programs targeting these needs.

Intra-Agency Coordination

The LS Initiative will continue to work in close coordination with its intra-agency partners, including ESD's Small Business & Technology Development division, that complement work supported by the Initiative. These programs offer opportunities to generate synergies that can accelerate the progress and impact of the LS Initiative.

- **New York Ventures** invests in high-growth companies, including life science companies, across the state to support the growth and development of New York's innovation ecosystem. Spinouts and startups from LS Initiative could benefit from New York Ventures' funds when locating and expanding their businesses in New York State.

- **NYSTAR** (ESD's Division of Science, Technology, and Innovation) operates programs and centers to support the applied science infrastructure of New York State by accelerating new technology development and commercializing new products with better pathways to market and scale. Specifically, NYSTAR will be a valuable resource to academic institutions that are part of the LS Initiative to help secure federal funding for commercialization. Both startups and academic grantees seeking to scale up and manufacture their innovations also can benefit from NYSTAR's manufacturing resources as they implement their technologies.

- As life science programs create the infrastructure needed to strengthen New York's life science ecosystem, a strong pipeline of talent will be essential to ensure continued growth. The **Office of Strategic Workforce Development** can play a vital role in supporting industry-driven training for in-demand skills and direct job placement.

In addition, collaboration between other ESD divisions as needed will support the life science ecosystem as a one-stop shop for all necessary resources. These efforts will bolster innovation clusters, create and attract more companies and technologies, and increase wealth and job creation across the state.

Conclusion

The first five years of the LS Initiative have proved catalytic in creating the building blocks and filling gaps in the foundations of the life science sector in New York State. While many of the initial strategies will be continued, we propose a refinement in strategy to link the successful building blocks together over the next five-year period. To take advantage of the current state of this sector, major investments will be concentrated around focused areas, capturing the opportunity to become the world leader in the emerging technologies described above. In addition to economic benefits, ESD will also enable New Yorkers to be the first to benefit from the breakthroughs in both therapeutics and planet-sustaining technologies.

Endnotes

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