Organizing for Economic Development: Lessons from Leading Life Sciences Regions

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Executive Summary

This report addresses how successful life sciences regions have organized their life sciences development efforts, with an emphasis on how medical, education and research institutions can combine effectively to support growth in this sector. The objective is to provide Detroit's leaders with a framework for considering opportunities to enhance cooperation to expand the region's life sciences sector.

The life sciences are broadly interpreted here to include biosciences, biotechnologies, and healthcare, as well as research and pharmaceutical or medical device manufacturing. Through brief case studies, this report addresses strengths, weaknesses, key initiatives and lessons learned in ten leading biotechnology and life sciences regions, as ranked by their research capacity, business base, clinical and education assets, and the ability commercialize new products. These regions are:

- Baltimore-Washington, DC
- Boston
- Cleveland
- Los Angeles
- New York

- Philadelphia
- Raleigh-Durham
- San Diego
- San Francisco
- Seattle

These case studies reveal several inter-related themes:

Successful life sciences clusters have strong leadership from multiple sources

- The state and business community are typically the primary leaders in pursuing and organizing efforts, but university and hospital leaders must commit their institutions to the effort.
 - State government can provide high profile leadership, attention grabbing resources and funding, and funding to support organizational capacity.
 - The business community often pushes for initiatives to take place. It also plays an important advocacy role either through large firms or industry associations.
 - Universities and hospitals rarely lead region-wide initiatives, but they are the critical participants and must be involved in high-profile roles in the organizational stages.
 - Local economic development organizations are often participants, but rarely lead due to their lack of resources and specialized knowledge.
- An important first step is for the leadership group to define the region's life sciences assets and advantages, quantify the sector's importance to the economy, and build consensus for a wider intervention.
 - If the consensus states that the region is heading in the right direction, then the focus should be on tactical leadership to address specific issues.

 If the consensus states that the region is heading in the wrong direction, then the region may require strategic leadership to address broader issues.

Perceptions of a regional life sciences cluster can affect its continued development

- If the importance of the life sciences cluster is neither well-defined nor quantified, the lack of visibility in both the business community and public sector will affect the amount of support and resources it receives.
 - Both legislators and the public must view the industry as an important activity.
 - Promoting successes and specializations attracts the attention of the risk capital community.
 - High profile research initiatives help attract world-class researchers and talent.
 - Information about quality employment opportunities attracts workers into technical occupations.
- Several key issues should be addressed:
 - The case must be made for the importance of the industry to the overall economy in terms of direct jobs and spending, economic impact, and linkages to other sectors.
 - Hospitals and universities offer real opportunities for economic development – in particular, the healthcare sector is not just the product of population growth.
 - o These institutions generate employment opportunities at all levels.
 - The life sciences sector can and should be defined broadly to identify the important region-specific linkages that can be used to identify competitive advantages.

Opportunities exist at the intersection of different technologies and industry sectors

- Successful regions connect the life sciences to other technological areas. Examples include bio-informatics and bio-defense. Whether it is plastics manufacturing expertise, a strong finance and insurance sector, or an agricultural base, it is important to think about how a region's strengths can be linked to life sciences initiatives.
- Similarly, successful life sciences clusters develop niches or unique areas of competitive advantage; areas that do not find niches will always play catch up and never get ahead.
- Creating opportunity at the intersection of technologies, requires engaging a wider set of stakeholders, even if those stakeholders do not appear to be immediately relevant to the life sciences.

Improving technology commercialization efforts is a core activity

- Commercialization is problematic for many regions because it is a function that is often outside of the core mission of hospitals and universities.
- The region's stakeholders much reach a consensus that these activities are important.
- Successful commercialization efforts require strong, high profile leadership that can work across silos and overcome the difficulties presented when working on activities outside of an institution's core mission. Low profile programs fail because their activities are viewed as bureaucratic work.

A centralized source of information to support the unique operational needs of life sciences businesses is valuable

- The high degree of regulation associated with life sciences activities makes business development relatively more complicated for the life sciences than for other industries.
- Many places have sought to create a "One Stop Shop" for all information regarding permitting, regulation and the availability of sites, buildings, funding and technical assistance.
- Financial, management, and professional and business services firms that specialize in assisting life sciences companies should also be included.
- The best organizations also offer connections to the university and healthcare community.
- The creation of centralized data sources often occur at the urging of the business community and are often structured as a public-private partnership.

All regions have a strategy for attracting risk capital

- Strategies often depend on the maturity and diversity of the regions respective industry.
 - Established clusters may focus primarily on facilitating connections between venture capital and regional businesses or entrepreneurs.
 - Less established places may focus on establishing regional angel investment networks and promoting the region to venture capital firms.
- Deal flow will often change the perception of the region in the eyes of the marketplace.

Addressing unique real estate and facilities needs is also typically an element of regional life sciences initiatives

• There are many benefits to be gained by the co-location of research assets and technology users. Accordingly, several regions have embarked on ambitious real estate development projects in order to facilitate this co-location in cooperation with universities.

- Putting flexible, yet specialized, facilities (e.g. wet labs) in place can be expensive and a barrier to small firm development.
- It is important to recognize that a life sciences cluster's facility needs will change as the cluster matures and develops.
- The real estate community could prove to be an important part of the stakeholder community.

In sum, medical, research and education institutions are critical players in regional life sciences initiatives, but, unexpectedly, they generally do not play primary leadership roles in structuring the overall effort. Exceptions are in smaller regions in which they *are* the leading institutions and/or employers. Instead, state government and the business community typically provide the initial push, with hospitals and universities holding a prominent place at the table.

The role of these institutions can be enhanced by quantifying and promoting their important role in the regional economy, establishing organizations that connect these institutions to the broader business community (not necessarily limited to the traditional life sciences businesses), providing strong, high profile leadership for their commercialization programs and measuring their results, and evaluating the viability of real estate developments on or near their campus to support both technology cooperation and business development.

Introduction

To many, the life sciences are the "Next Big Thing." They represent one set of knowledge-intensive activities with seemingly limitless potential for growth. It is also an industry capable of creating many good-paying jobs. The average worker in the life sciences (also frequently referred to interchangeably as biosciences and biotechnologies) earns an average of \$65,775 annually, as compared to all private sector workers who earn an average of \$39,003 annually.¹ Moreover, the industry provides employment opportunities for people of varying levels of educational attainment ranging from Ph.D. scientists to technicians with associates degrees. It should therefore come as no surprise that harnessing the potential offered by the life sciences forms an important plank of many regional economic development strategies, and many states and metro areas allocate substantial funds to support the further development of these activities.

Before proceeding it is important to define what exactly is meant by the life sciences or the biosciences. In a 2006 study, the Biotechnology Industry Organization (BIO) offered its perspective:

The biosciences are a diverse group of industries and activities with a common link— they apply knowledge of the way in which plants, animals, and humans function. The sector spans different markets and includes manufacturing, services, and research activities. By definition, the biosciences are a unique industry cluster and are constantly changing to incorporate the latest research and scientific discoveries.

In describing the sector in general terms, BIO recognizes five major elements of the sector: (1) Agricultural Feedstock & Chemicals; (2) Drugs & Pharmaceuticals; (3) Medical Devices & Equipment; (4) Research, Testing, & Medical Laboratories, and (5) Health Care Clinical Research.

In order for a region to develop a successful biosciences cluster, several factors must be in place. These factors include: (a) the region's Research and Development capacity. (b) a skilled life sciences workforce; and (c) the capability to finance and commercialize life sciences innovations. R&D capacity has become more widely dispersed across the country, but the development of these clusters has been limited in some cases by the availability of capital. Large venture capital pools, which are particularly important to sustain the long development time required for new life sciences products, have become more concentrated in a relatively limited number of locations. Whereas many places have the necessary R&D capacity and workforce, they lack the risk capital required to sustain and translate the research into a commercialized product. An important corollary to the issue of available capital is an apparent overlap between capital access and workforce talent issues. Venture capitalists bring much more than money to the table when they make investments. Frequently, they also bring entrepreneurial management talent. Rather than being single-mindedly focused on continuously improving the technological attributes of the research—as a researcher might often be, the venture capital management team brings a different kind of focus. The venture capital team typically has a single-minded goal of generating economic value from the research:

¹ Battelle Technology Partnership Practice and SSTI, "Growing the Nation's Biosciences Sector: State Biosciences Initiatives 2006," prepared for BIO—Biotechnology Industry Organization, April 2006, http://bio.org/local/battelle2006/battelle2006.pdf.

taking the product to market and identifying new market opportunities or identifying existing firms that might wish to buy the product idea for their own economic ends.

This concentration of patient capital has helped to establish a limited number of regions as globally competitive life sciences clusters. According to a 2002 report from the Brookings Institution,² 75 percent of new biotechnology firms created during the 1990s were established in just nine major metropolitan regions. In Boston and San Francisco, the availability of venture capital drove much of this growth; the Philadelphia and New York regions benefited from the presence of the country's major pharmaceutical companies and their internal resources; well recognized and well funded medical research establishments led to growth in start-up firms in San Diego, Seattle and Raleigh-Durham; and a large supply of federal research grant funds supported growth in Los Angeles and the Baltimore-Washington corridor.

This is not to say that future growth will be limited to just these regions. A number of cities—Chicago, Houston, St. Louis, Detroit—can safely be called centers of life sciences research, but they are not in the top tier of US life sciences centers due to their relatively low level of commercialization activity. What the Brookings report made clear is that regional research capacity is a necessary, but not sufficient, condition for supporting the development of a truly competitive biosciences cluster.

Nevertheless, established life sciences clusters and aspiring life sciences clusters across the nation continue to face a number of similar challenges. First, many firms find securing sufficient risk capital. A common response to this challenge is offering tax credits to firms involved in life sciences research. Of course, tax credits are not very valuable to research enterprises that are not-for-profit or they may not be earning a profit. This is recognized by offering the credits to potential investors in research and development. Second, many places focus on the technology transfer process, with particular attention to the recognized systemic gaps in the life sciences sector. For instance, few places have specific strategies to link basic research and clinical research so that basic research discoveries can be turned into real world treatments. This issue was highlighted as a more general concern in Michigan and other states.³ Third, critical workforce shortages exist almost everywhere. There is a nationwide need for more people with science, technology, engineering, and math (STEM) educational backgrounds. The National Governors Association spent the past year identifying statelevel responses to this issue at the K-12 level, recognizing that it is foundational for the nation's future.⁴ The Commission on the Future of Higher Education has also raised the alarm for post-secondary institutions.⁵

² Joseph Cortright and Heike Mayer, "Signs of Life: The Growth of Biotechnology Centers in the U.S." Brookings Institution, June 2002, http://www.brookings.edu/es/urban/publications/biotech.pdf.

³ Lt. Governor's Commission on Higher Education and Economic Growth, "A Final Report of the Lt. Governor's Commission on Higher Education and Economic Growth," December 2004, http://www.cherrycommission.org/docs/finalReport/CherryReportFULL.pdf.

⁴ National Governors Association Center for Best Practices, "Building a Science, Technology, Engineering and Math Agenda," July 2007, http://www.nga.org/Files/pdf/0702INNOVATIONSTEM.PDF.

⁵ Secretary of Education's Commission on the Future of Higher Education, "A Test of Leadership: Charting the Future of U.S. Higher Education." US Department of Education, September 2006,

Industry Overview

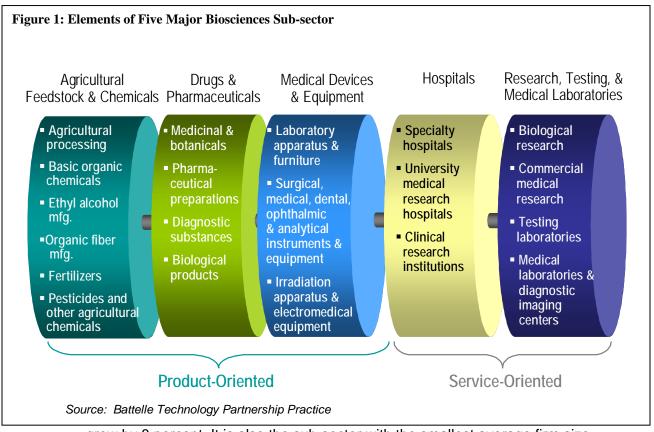
The biosciences industry represents an emerging sector, but its employment growth is not as rapid as many might expect. The April 2006 BIO report⁶ provides a national overview of this sector and an important benchmark for state and regional efforts in defining the sector. The Biosciences sector employed roughly 1.24 million workers in 2004, up one percent from 1.23 million in 2001. This estimate excludes hospital-related clinical research or any other segment that is fully integrated into the health care sector. Battelle specifically indicates that it excluded health care in this analysis because it is not possible to separate out the research activities. While the study found that most states have some kind of biosciences sector, not surprisingly the size and scope of those activities varies greatly from place to place.

The BIO report describes the size, composition and geographic distribution of the US biosciences sector. A more recent report describes the make-up of biosciences in the metropolitan areas with the largest cluster of biosciences activity.⁷ It specifically focuses on the data and trends from four of the five key sub-sectors. A summary of the key findings include:

- (1) The agricultural livestock and chemicals sub-sector includes technologies involved in the processing of agricultural goods and the production of organic and agricultural chemicals. In 2004, this was the smallest sub-sector with almost 105,000 workers or 8 percent of all biosciences-related employment. The Houston metropolitan area has the largest number of employees in the subsector.
- (2) The drugs and pharmaceuticals sub-sector involves the production of commercially available medicinal and diagnostic substances. It was the third largest sub-sector, employing 313,000 workers and representing 25 percent of the total. This sub-sector has the largest average firm size, with an average establishment employing approximately 120 people. New York, Philadelphia and Chicago have the largest number of employees in the sub-sector in an absolute sense. Relative to the overall economy's size, Indianapolis and Raleigh-Durham have the largest concentration of drugs and pharmaceuticals activity.
- (3) The medical devices and equipment sub-sector consists of the production of equipment, products and supplies for diagnostics, surgery, patient care and laboratories. It is the second largest sub-sector, and the firms in this sub-sector employ 411,000 workers—almost one-third of total employment. The largest employment is found in New York and Minneapolis, with 28,000 and 23,000 workers respectively. It should also be noted that it accounts for 81 percent of Minneapolis's total biosciences employment.
- (4) Research, testing and medical laboratories account for the largest share of biosciences employment, with 413,000 workers and one-third of total employment. Between 2001 and 2004, it was the fastest growing sub-sector, as it

⁶ Battelle Technology Partnership Practice and SSTI, "Growing the Nation's Biosciences Sector: State Biosciences Initiatives 2006," prepared for BIO—Biotechnology Industry Organization, April 2006, http://bio.org/local/battelle2006/battelle2006.pdf.

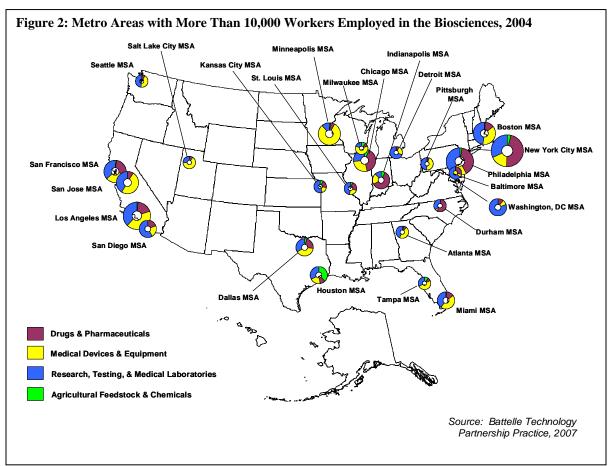
⁷ Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.



grew by 8 percent. It is also the sub-sector with the smallest average firm size, with approximately 20 workers per establishment. The largest employment for this sub-sector found in New York, Los Angeles, Philadelphia and Boston. Research, testing and medical laboratories account for a high relative percentage of total biosciences employment in places like Baltimore-Washington, San Diego, Detroit and Kansas City.

(5) Hospitals represent another sub-sector, but the data are not included here. Research hospitals and academic health services are invaluable to the biosciences industry, but they are not included in the BIO study due to limitations in available data assigned in the North American Industrial Classification System (NAICS) codes in which hospital research activities are not distinguished from more general healthcare activities.

Total employment in the biosciences sector is highly concentrated in metropolitan areas in the Boston-Washington megalopolis. The New York-Philadelphia corridor is particularly important, with a dominant biopharmaceutical sub-sector. Detroit's particular strengths appear to be in research, testing, and medical laboratories. The key competitors in this sub-sector include those same northeastern cities as well as the major California urban centers. Figure 2 provides a quick benchmark of the relative size and concentrations of the biosciences cluster and its key sub-sectors.



In short, the national biosciences cluster network is particularly relevant to Detroit as it seeks to better understand and take advantage of its existing assets as well as build new ones. In better understanding its assets, Detroit should consider its role in the larger context of the biosciences cluster of activities and the likely competitors in attracting future investment in those activities.

Purpose of the Report

The 2002 Brookings study, the 2006 and 2007 BIO studies represent major efforts to quantitatively assess and compare the biosciences industry at the national, state and metropolitan level. As such, they provide useful resources for benchmarking the performance of one life sciences cluster against others. The purpose of this report is to supplement that information by examining more specifically the context for development of clusters in the leading life sciences regions.

Through an examination of key reports and strategy documents as well as other secondary research, this report highlights the key issues affecting the life sciences industry in those regions as a way to help Detroit's leaders to begin thinking about ways to strengthen their own region's life sciences industry. This report summarizes the key assets and challenges identified in each of 10 metropolitan regions. The report also highlights key initiatives launched to take advantage of opportunities and address weaknesses in each region's biosciences industry.

Selection of the Case Study Regions

In consultation with Detroit Renaissance, we opted to examine activities in ten key metropolitan areas. These regions have all shown leadership in biotechnology and the life sciences, both in terms of their research capacity and the ability to commercialize new product innovations. They also demonstrate strength in the cluster of industries that could offer lessons for Detroit. These benchmark metropolitan areas are:

- Baltimore-Washington, DC
- Boston
- Cleveland

- Philadelphia
- Raleigh-Durham
- San Diego

- Los Angeles
- New York

- San Francisco
- Seattle

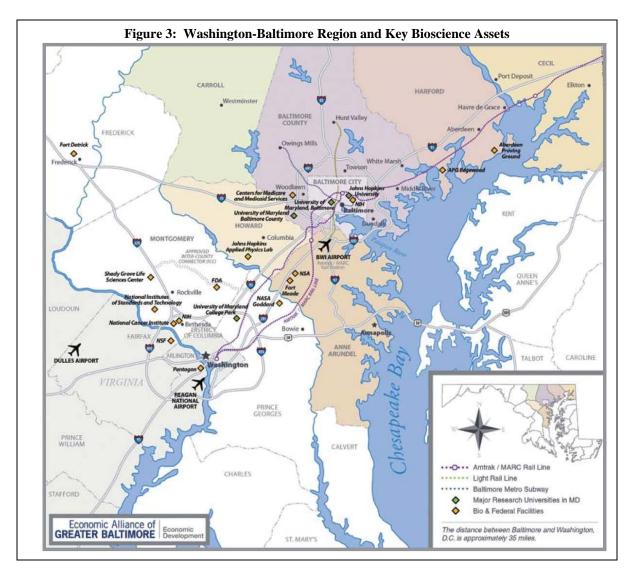
For each of these regions, we develop a case study that describes the partners involved in the major initiatives with a particular emphasis on the role of key actors in the private sector, government, higher education and hospitals.

From these case studies, we draw out the key themes about the points of emphasis in the various regions and the critical concerns from each sub-sector. The goal is to identify those themes that have particular relevance to Detroit in its efforts to foster the region's own life sciences cluster. These themes include the need for planning and organization; leadership at all levels; the need to attract talent and investment capital; the need to avoid complacency; and establishing a cluster-wide commitment to commercialization, even among stakeholders who may not see those activities as part of their core mission. These issues arise repeatedly in each of the nation's leading life sciences clusters.

Case Profile: Baltimore-Washington, DC

The life sciences cluster in the Baltimore-Washington area is very much influenced by the region's position as the nation's capital. As a result, large multinational companies play a more minor role in the cluster than in other regions. Instead, large federal agencies drive much of the region's life sciences research and development activity. These agencies attract not only significant amounts of funding for life sciences research, but also some of the nation's top talent. The region also benefits from the presence of several major research institutions. Most notably, the region has Johns Hopkins University—and its research hospital—and the University of Maryland and its biotechnology research centers. Within the region, many of these activities are concentrated along the I-270 corridor that runs northwest from Washington, DC into suburban Maryland and along the I-95 Corridor between Baltimore and Washington, DC.

In spite of this impressive collection of assets, there is a sentiment that these assets have not yielded a commensurate level of commercialization. As will be shown, regional leaders have focused on ways to better exploit the commercial potential of the ongoing research in the I-270/I-95 corridors. This has required efforts to make commercialization a higher priority among all the stakeholders within the region's life sciences cluster.



Cluster Strengths

The presence of large federal agencies draws many researchers and scientists to the region as well significant amounts of funding for basic research. The region is home to such key institutions as the National Institute of Standards and Technology (NIST), the National Science Foundation (NSF), the Food and Drug Administration (FDA), the Defense Advanced Research Projects Agency (DARPA), the US Army's Medical Research Institute of Infectious Diseases at Fort Detrick, and perhaps most importantly, the National Institutes of Health (NIH).

The NIH represents one of the region's greatest strengths. Located in Montgomery County in suburban Washington, the NIH is the US government's focal point for health research. It has 20 institutes and seven centers and in 2006 had a budget of \$28.5 billion dollars.⁸ In the Baltimore-Washington area alone, NIH awards approximately \$1 billion annually to the region's researchers. A 2002 report by the Johns Hopkins Institute for Policy Studies showed that the NIH was the region's primary source of entrepreneurs in the life sciences.⁹

In addition to the federal agencies, laboratories and research centers, the Baltimore-Washington area is also home to several major research universities. The Greater Washington area has more than 50 colleges and universities and one of the country's greatest concentration of adults with advanced degrees. In no small part due to the NIH and Johns Hopkins University, the region also attracts a significant share of research money. JHU ranks first for all US universities in overall R&D expenditures, first in NIH awards among universities (\$607 million in 2005), third in biotechnology patents, and seventh in biotechnology publications. It should also be noted the University of Maryland-Baltimore received an additional \$181 million in NIH funding, and the University of Maryland (UMD) at College Park, UMD-Biotech Institute and UMD-Baltimore County received an additional \$46 million combined.

The region has created a number of different agencies and organizations that provide early stage funding. For instance, the state-sponsored Maryland Technology Development Corporation (TEDCO) has several programs providing pre-seed and seed capital, as does the Maryland Department of Business and Economic Development (DBED). More locally, Montgomery County (home of the I-270 corridor and NIH), provides gap financing for emerging tech-companies. Private sources are available as well. For instance, MdBio (an operating division of the Technology Council of Maryland) has programs for near-term commercialization.

The region is also well connected by road, rail and air to other clusters, especially those immediately to the north in Philadelphia, New York, and Boston. This is an important asset in attracting risk capital because it puts the area in close proximity (in terms of travel time) to some of the country's largest concentrations of venture capitalists.

Cluster Weaknesses

One of the region's biggest identified challenges¹⁰ is that it has not achieved a level of commercial activity that is commensurate with the amount of research currently being undertaken in the region. This is due in part to the fact that much of the talent in the

⁸ <u>http://www.greaterwashington.org/business/biotech/</u>

⁹ M. Schachtel and S. Heacock, "Founders of Maryland Bioscience and Medical Instrument Companies", Johns Hopkins Institute for Policy Studies, August 2002.

¹⁰ Economic Alliance of Greater Baltimore, "Biosciences in Greater Baltimore," June 2007.

region is in large government agencies and research institutions whose primary mission is focused on basic research and discovery. In many of these research institutes, their mission does not include the commercialization of new technologies and in fact these organizations often have cultures that embrace their public purpose and shun the potential private benefits that could be gained from commercialization. When researchers or academics do leave these agencies to pursue more commercial ventures, they run into many of the same problems faced by entrepreneurs everywhere -- a lack of business knowledge and experience necessary to create a sustainable enterprise.

The region has focused on understanding how it can better encourage more commercialization activities from the research underway in area institutions. According to an Economic Alliance of Greater Baltimore report on the region's biosciences industry, some of this frustration pertains to one of the region's most prominent assets—Johns Hopkins University, Johns Hopkins School of Medicine and Johns Hopkins Hospital. Critics contend that the Johns Hopkins Hospital drives the university's agenda with regards to biosciences. As a result, the JHU focus has been on research, healthcare services and philanthropy, rather than technology transfer and commercialization.

Key Initiatives

The focus on teaching, research, patient care and philanthropy means that technology transfer and commercialization are not part of JHU's core mission. However, this academic environment has also hindered JHU's ability to translate breakthroughs in medical research into tools for treating patients. This is one of the motivating factors causing Johns Hopkins University to rethink its technology transfer efforts. The Economic Alliance of Greater Baltimore's report identifies several signs that show that Johns Hopkins will be more active in this arena in the future.

- The construction of the Science and Technology Park at Johns Hopkins is a tangible sign that the university is becoming more interested in public-private partnerships.
- JHU recently hired the former Maryland Economic Development Secretary to serve as a "czar" to oversee and energize the university's tech transfer and commercialization office.
- The successes of some JHU scientists in starting their own companies has served as an example for other researchers by showing that prestige and funding can be garnered through private sector initiatives.
- The prospect of declining NIH funding will force more researchers to seek out private sector partnerships to compensate for the diminished funds.
- There is a growing awareness at the university that the private sector plays a vital role in bringing medical discoveries to patients.

The extent to which these efforts and issues will push commercialization to the forefront of JHU's mission remains to be seen. However the appointment of a czar to invigorate the university and hospital's commercialization activities appears to be a tacit admission that the university must play a greater role in supporting the region's life sciences cluster.

Just as JHU is moving to become more actively involved in the life sciences clusters, so too is the University of Maryland system. It is currently in the process of making

significant efforts to expand the role played by its multiple institutions. For instance, in 1985, the state created the University of Maryland's Biotechnology Institute (UMBI). In FY 2005, the UMBI received about \$15 million from the state and \$35 million in sponsored research.¹¹ UMBI has five centers focused on different types of biotechnology research.¹² These centers include:

- Center for Advanced Research in Biotechnology (CARB) which is a cooperative venture between UMBI, NIST and Montgomery County. Its research focuses on protein structure and engineering as well as other molecular studies.
- Center for Biosystems Research (CBNR) which promotes research and training about the applications used to study complex biological systems. Its facilities include the UMBI system's primary DNA sequencing facility.
- Center for Marine Biotechnology (COMB) which includes an aquaculture facility designed to conduct advanced research on developing and improving fin-fish and shellfish production and hatchery technology.
- Medical Biotechnology Center (MBC) which focuses on molecular medicine and seeks to provide new innovations for companies to develop and commercialize new products and technologies.
- Institute for Human Virology (IHV) which focuses on discovering new ways to diagnose and treat human viral diseases and cancers.

In order for these research assets to truly make a difference, the state has launched initiatives not only to encourage greater interaction between academics and industry, but also to support the commercialization of these technologies.

The Maryland Industrial Partnerships (MIPS) program at UMD-College Park is designed to help encourage greater interaction between industry and academics. It provides matching funds for research projects that assist companies develop new projects. These are competitive awards and startup companies can receive as much as \$70,000, while small medium and large companies can receive up to \$100,000. The company match depends on the size of the company. Grant proposals however must be co-written by a private company and faculty members from any of the University of Maryland's 13 institutions.¹³ To date the state has contributed \$27.8 million and Maryland private industry has contributed \$115.6 million to support joint research between Maryland Businesses and the University of Maryland.¹⁴

Maryland's Technology Development Corporation (TEDCO) offers several programs to support greater commercialization of technology. For instance, its University Technology Development Fund helps universities conduct pre-commercial feasibility studies on university intellectual property. The Fort Detrick Technology Transfer Initiative includes a partnership with US Army Medical and Materiel Command and the Frederick County Office of Economic Development to support the commercialization of technologies that

¹¹ BIO, "Maryland Biosciences Initiatives", April 2006. Available at <u>http://www.bio.org/local/battelle2006/Maryland.pdf</u>

¹² BIO, "Maryland Biosciences Initiatives", April 2006. Available at <u>http://www.bio.org/local/battelle2006/Maryland.pdf</u>

¹³ <u>http://www.mips.umd.edu/overview.html</u> and BIO, "Maryland Biosciences Initiatives", April 2006. Available at <u>http://www.bio.org/local/battelle2006/Maryland.pdf</u>

¹⁴ National Governors Association Center for Best Practices, "Investing in Innovation," July 2007, www.nga.org/Files/pdf/0707INNOVATIONINVEST.PDF.

meet the needs of the Army. TEDCO will also manage Maryland's newly established Stem Cell Research Fund, which is expected to receive \$23 million in state funding annually.¹⁵

It should also be noted that the first two technology/biotechnology platforms of the Tech Council of Maryland's 2007 Policy Platform¹⁶ focus on capital formation, particularly for early stage companies, and innovation, with a focus on providing sufficient space in research parks and business incubators. The four other issues that appear in their 2007 policy platform include: (1) creating a tax climate that makes Maryland competitive with other states, (2) continuing to attract the kind of workers needed to support technology-related fields, (3) increasing support for higher education to produce technology-related workers, and (4) improving the transportation infrastructure.

Lessons Learned

The Baltimore-Washington biosciences cluster illustrates that a strong workforce and ample supply of innovation assets are not enough for a biosciences cluster to maximize its full potential. The region does not lack skilled workers or research facilities or research funding. Yet, the region has still not been able to exploit these assets fully in support of technology transfer and commercialization.

Attracting talent is a necessary but not sufficient step. A 2002 study showed that most of Maryland's biotechnology entrepreneurs were researchers or scientists that lived in Maryland but were not from Maryland¹⁷. Moreover, they were more likely to come out of institutions such as universities or large federal agencies like the NIH than from the private sector. While these researchers may have good product ideas, they often lack the business acumen necessary to move those ideas into the market place. These business skills are important components to the commercialization process and must be combined with good ideas. Venture capitalists provide not only money, but they also play an invaluable role in evaluating the quality of a start-up firm's business plan and its management capabilities.

The Baltimore-Washington case study also shows that in addition to supporting entrepreneurs, the region's institutions must make commercialization a greater focus of their mission. Hospitals, and particularly large research hospitals, are vital stakeholders in any life sciences cluster. They represent an important place for research and testing, especially in performing clinical trials. However, to maximize the value of these regional assets, the hospitals must truly see technology transfer and commercialization as part of their core mission. These activities play an important role in translating new treatment possibilities to applications that can be useful for their patients. Similar issues exist for universities, where academic researchers do not view commercialization as a vitally important outcome. If universities want to increase their tech transfer activities, then they will need to make a concerted effort to include commercialization as an explicit part of the academic incentive structure in which faculty are rewarded as much for their commercial endeavors as for the academic research.

¹⁵National Governors Association Center for Best Practices, "Investing in Innovation," July 2007, <u>www.nga.org/Files/pdf/0707INNOVATIONINVEST.PDF</u>.

¹⁶ Tech Council Maryland, 2007 Policy Platform for the Technology and Biotechnology Industries

¹⁷ M. Schachtel and S. Heacock, "Founders of Maryland Bioscience and Medical Instrument Companies", Johns Hopkins Institute for Policy Studies, August 2002.

Case Profile: Boston

The greater Boston area, and Massachusetts more generally, is one of the country's most innovative regions. It is known worldwide for institutions like Harvard University and the Massachusetts Institute of Technology (MIT), national hospitals like Massachusetts General, and its culture of high-tech firm creation along the Route 128 corridor. The region has over 42,000 workers in the life sciences industry and is particularly strong in the Medical Device & Equipment and Research, Testing & Medical Laboratories subsectors.¹⁸ Combined, these two sub-sectors account for 85 percent of the region's biosciences employment. The region is also one of the country's leading destinations for venture capital.

In spite of its strengths, the Boston region illustrates the necessity of leadership and organization. It is a region with many assets and a track record of success, but it is facing growing challenges from life sciences clusters elsewhere. Without strategic direction and leadership, many of the region's key stakeholders will adhere closely to their core mission and functions, even if those core missions do not allow the region's life sciences sector to maximize its potential.

Cluster Strengths

Perhaps the greatest strength of the Massachusetts life sciences cluster can be found in its sheer depth and diversity of activity. Massachusetts has an extraordinary number of world class hospitals, universities, research facilities, and companies of all types, sizes and stage of development. Two of the world's first biotech companies -- Biogen and Genzyme -- were founded in the Boston region. In addition to a history of creating homegrown companies, the region is also attracting the research activities of many major multinational firms. For instance, Novartis relocated much of its biosciences-related research from northwest Switzerland and the United Kingdom to Cambridge.¹⁹

Harvard and MIT are not the only academic stories to be told in the region, Boston University, Boston College, Tufts University and Northeastern University also add to the research prowess of the region. Further northward and westward are the University of Massachusetts (UMass) at Amherst, UMass-Lowell and Worcester Polytechnic Institute. The region also has strong tradition in medical research with institutes at Massachusetts General Hospital, the New England Medical Center, the University of Massachusetts Medical School, the Dana-Farber Cancer Institute, Beth-Israel Deaconess Medical Center, and the Whitehead Institute for Biomedical Research.

Combined, these universities and research institutes play vital roles not only in producing one of the nation's most skilled workforces, but also in attracting large numbers of research talent to the region. In 1999, Boston had the nation's second highest number of PhDs granted and second highest number of workers employed in the life sciences-related industries, behind only New York.²⁰

¹⁸ Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.

¹⁹ Economic Alliance of Greater Baltimore, "BioSciences in Greater Baltimore," June 2007.

²⁰ Massachusetts Technology Collaborative/John Adams Innovation Institute, "Taking Stock Of Progress And Challenges: Massachusetts Life Sciences Supercluster," Prepared for the Boston Foundation, October 2006. <u>http://www.masslsc.org/taking_stock_3_07.pdf</u>

Figure 4: An Example of the Life sciences-related organizations clustered in one of Boston



Source: PriceWaterhouseCoopers, "Super Cluster: Ideas, perspectives and updates from the Massachusetts life sciences industry," prepared for the New England Health Care Institute and the Massachusetts Technology Collaborative

The region's research capacity is one of the reasons why the Boston metro area attracted more than \$2.3 billion in NIH funding in 2003. This figure led the nation and was almost \$400 million more than New York. The region's history of new company formation and advanced research has also made it one of the country's leading destinations for venture capital. Between 2002 and 2006, the region attracted \$3.6 billion in biotechnology-related venture capital. This figure was over 18 percent of the total and second only to the San Francisco Bay area²¹.

Cluster Weaknesses

The 2006 Boston Foundation Report noted that Massachusetts has several areas of concern and competitive disadvantages. As more and more states and regions get involved in the life sciences, Massachusetts has seen increased competition for life sciences employment and research funding. The Bay Area, Silicon Valley, Research Triangle, and Minneapolis are adding workers in life sciences industries at a faster rate while other areas like Baltimore, New York, Raleigh-Durham, and Cleveland attract increased research dollars at a faster growth rate than Boston.²²

The high cost of doing business in Massachusetts is also perceived as a real weakness. Not only are the state's taxes on life sciences cluster activity in the state high relative to other regions, but the permitting process for developing new facilities is viewed as expensive and complicated. Moreover the high cost of housing has made it difficult for the state to attract and retain the talent needed to retain its life sciences workforce. This is particularly true for many of the mid-level employees and technicians.

These factors all contribute to another identified weakness in the Massachusetts life sciences cluster. The state has been unable to capture many of the downstream activities associated with the array of life sciences research activities. Traditionally, the

²² Michael E. Porter, "Massachusetts' Competitive Position in Life Sciences:

²¹ Economic Alliance of Greater Baltimore, "BioSciences in Greater Baltimore," June 2007.

Where Do We Stand?" Institute for Strategy and Competitiveness, Harvard Business School, prepared for the Massachusetts Life Sciences Summit, 12 September 2003.

state has succeeded in attracting and developing companies in their early stage activities such as initial development and prototype manufacturing. These activities benefit from having a close proximity to research facilities and talent. However the state has witnessed a declining number of downstream production and commercialization activities, and more mature companies now have a smaller percentage of their workforce in the state than is the case in competitor regions. The 2006 Boston Foundation report indicated that in a survey of life sciences executives, wages were not to blame for the lack of downstream activity, but rather the unpredictability of the local regulatory and permitting environment.

There is also a perceived bottleneck in getting new products fully through their clinical trials. Massachusetts is second only to California in terms of the number of products requiring clinical trials. However, Massachusetts hospitals lag behind a number of states in terms of the number of clinical trials actually performed. There are several national trends that create inefficiencies in carrying out clinical trials. These trends include the rising costs in recruiting participants and the high degree of regulation that can act to slow the process so much that roughly a quarter of those enrolled drop out before the trial is completed.²³ For the region as a whole, conducting clinical trials at institutions such as Mass General near major research institutions provides a cost effective approach, and it contributes to the regional cluster's innovative capacity. However, there is widespread concern that these hospitals do not place a high enough priority on performing clinical trials relative to their core mission. Even though increasing the quantity and efficiency of these trials benefits both the hospitals and the region's competitive position, area hospitals are more focused on day-to-day patient care. For the hospital, clinical trials may provide an important source of revenue and can improve both their image and the quality of health care delivery, but these do not have as great an impact on the hospital's bottom line as managing on-going patient care services efficiently.

While Massachusetts remains one of the country's strongest life sciences center, there has been a widely held perception that the region is not maximizing its potential. In an era where economic development is seen as a collaborative process, the lack of an overarching strategy or mechanism to put that strategy in place is seen as impeding the life sciences cluster's long-term development. This leadership vacuum has caused many stakeholders, such as the region's teaching hospitals, to overlook opportunities that might be beneficial to the long-term potential for the life sciences industry.

Key Initiatives

A number of initiatives have been underway to strengthen the regions. The Boston Foundation released a report in October 2006 that identified a number of the key initiatives underway.²⁴ These efforts are aimed at improving technology transfer, strengthening the life sciences workforce, increasing the number and efficiency of clinical trials and attracting more downstream activities related to life sciences research.

²³Michael E. Porter, "Massachusetts' Competitive Position in Life Sciences:

Where Do We Stand?" Institute for Strategy and Competitiveness, Harvard Business School, prepared for the Massachusetts Life Sciences Summit, 12 September 2003.

²⁴ Massachusetts Technology Collaborative/John Adams Innovation Institute, "Taking Stock Of Progress And Challenges: Massachusetts Life Sciences Supercluster," Prepared for the Boston Foundation, October 2006. <u>http://www.masslsc.org/taking_stock_3_07.pdf</u>

Several efforts have been made to strengthen the region's technology transfer initiatives. For example, in 2004 the state established the Massachusetts Technology Transfer Center to better organize the activities of the tech transfer offices at the state's various universities and research centers. The university tech transfer offices play a major role in commercializing innovations originating in university labs. Within the state, MIT's Technology Licensing Office has been particularly active in managing intellectual property and granting licenses for new companies. It has also been active in building partnerships with other regions, particularly Cambridge in the UK.

The Massachusetts Biotechnology Council has a Biotechnology Education Foundation (MassBioEd) that has programs designed to strengthen the region's workforce range all the way from the K-12 system to its most skilled participants. For instance, the BioTeach program provides lab equipment and professional development resources to the state's high schools so that they can all provide life sciences curriculum by 2010.

Several efforts are also underway to expand clinical trials in state. MassBioEd offers courses in biotechnology project management and clinical research. As part of these programs they specifically offer seminars for physicians, providing up to date information on the status of relevant clinical research and drug development activities. This latter program is designed to get more physicians involved in clinical trials. Similar initiatives are ongoing in other places as well. Mass General runs a clinical research program that helps clinical investigators and study coordinators with their career development. This program seeks to improve the quantity and quality of the clinical research undertaken there. It also attempts to create partnerships with industry, Partners HealthCare System and the Harvard Medical School. Another effort led by Partners HealthCare System is the Research Study Volunteer Program (RSVP) that keeps a registry of people interested in participating in clinical trials.

The state is also attempting to develop and attract more downstream activities such as manufacturing. These efforts have focused on two primary areas, providing more financial tools and making information more readily available. As an example of increasing the financial tools available, the Massachusetts Development Finance Agency (MassDevelopment) offers loans for facilities and equipment, tax exempt bonds to purchase or renovate equipment and facilities, and real estate loans up to \$3 million for facility acquisition, renovation, construction or financing the permitting process. These programs exist in a number of states, but Massachusetts has managed to link these traditional economic development tools with the unique facility needs of the life sciences industry.

In terms of making information more available, a number of key stakeholders including the Massachusetts Department of Economic Development, the Massachusetts Alliance for Economic Development (MAED), MassDevelopment and the Massachusetts Technology Collaborative created the "Mass Means Business" partnership. This partnership will create an online database of sites, permitting issues, and a listing of life sciences companies and teaching hospitals.²⁵

The Massachusetts Life Sciences Initiative

In spite of these initiatives and efforts, the lack of an overarching structure for organizing the state's life sciences industry has left many stakeholders with a sense that Massachusetts could lose some of its competitive advantage. This actually became an

²⁵ www.massmeansbusiness.com

issue during the last gubernatorial election cycle. As noted above, Massachusetts has for a long time had no overarching strategy to develop and support the life sciences, and it lacks the structure to develop that strategy.²⁶ As a result, many stakeholders have looked to state government to fill that void by taking a more active role in leading and committing to the development of the Massachusetts life sciences cluster.

In response to these calls for greater state leadership and commitment, in May 2007, Massachusetts Governor Deval Patrick announced a \$1 billion plan to invest in the state's life sciences industry over the next decade. Half of this proposed funding will go toward public higher education for facilities and equipment used in collaboration with the life sciences industry. One quarter will be directed toward research grants, fellowships and sector-wide workforce training initiatives. The remaining \$250 million will be used for tax credits to support job creation in the life sciences. It should also be noted that the plan calls for an additional \$250 million of private sector matching funds to be leveraged from this state investment. Those private dollars would be used to provide capital, match research grants, fund fellowships and support workforce training initiatives.

Planning represents one of the key components of this initiative. The need for some kind of comprehensive strategy has emerged as a common theme in several key assessments of the Boston and Massachusetts life sciences industry. In the Governor's proposed initiative, a reformed and strengthened Massachusetts Life Sciences Innovation Center would serve as the main organizing agent for the state's life sciences industry. This will involve working closely with the private sector, public and private higher education institutes, academic medical centers and the Mass Life Science Collaborative.

Another focus of the Governor's initiative will be research. This mainly involves directing research funds toward filling gaps in the current funding pool. For instance, the initiative calls for efforts to support researchers prior to the receipt of their NIH grants. The state is also looking to provide research funding for stem cell research, recognizing that federal restrictions could limit the region's strengths in this area. The initiative also seeks to direct these funds to support leading researchers, as well as retaining researchers who might otherwise leave the state.

The initiative will also focus on building a stronger innovation infrastructure in the region. A key aspect involves developing stronger collaboration and funding partnerships between the private sector, higher education and academic medical centers. A lack of interaction between these vital partners has led to weaknesses in certain areas of the applied research and development process. For instance, insufficient quantity and efficiency of clinical trials can be traced to inadequate partnerships. Funding will also be used to support the purchase of instrumentation and equipment for both public and private entities. These resources will create regional facilities or life science innovation centers that will enable collaboration while also defraying the costs associated with research through space and equipment sharing. Through the state funding, Massachusetts also plans to create a stem cell bank, intended to become one of the largest such repositories in the world.

The Governor's initiative will also support efforts to commercialize more of the region's life sciences technology discoveries in state. These efforts are in large part geared directly toward employment creation, most notably in providing funding to support the

²⁶ Michael E. Porter, "Massachusetts' Competitive Position in Life Sciences: Where Do We Stand?" Institute for Strategy and Competitiveness, Harvard Business School, prepared for the Massachusetts Life Sciences Summit, 12 September 2003.

small businesses and non-profits that traditionally provide much of the state's innovative strength. It will also fund workforce training for specific skills needed in the life sciences. The state will also support efforts to develop related economic activities, such as manufacturing, by providing tax incentives specific to job creation or grants to the medical-device and drug-development firms requiring production capabilities to bring their product to market. This, too, responds to one of the state's long standing weaknesses of not capturing the downstream activities that emerge from the innovation taking place in Massachusetts.

Lessons Learned

The greater Boston area has long been at the top echelon of the nation's biosciences industry. It is facing a challenge from new centers of cluster development. A key lesson learned is that life sciences leadership is dynamic. One reason that the region has felt greater competition is that Boston has not had the state or regional leadership that could bring the various organizations together. In his first year in office, Governor Deval Patrick appears to be making an effort to assume a larger leadership role and is beginning to make a difference in building consensus and developing a cohesive vision for the region.

Boston remains a global player in the research arena, but regional leaders have not been satisfied with the region's ability to convert that research into applied products. In particular, area hospitals are viewed as a key impediment because they are focused on their core mission of patient care, leaving resources available for clinical trials as more of an afterthought than a core priority. For some treatments and products, this issue has created bottlenecks, slowing the product commercialization process. Clearly, engaging hospitals as key partners and addressing their concerns is a critical lesson learned in moving forward.

The state has worked at great lengths to develop unique initiatives that reflect the Massachusetts experience, serving as a benchmark in some of their tactical approaches to addressing regulatory reform, building "on-the-ground" operational collaborations, and designing new models for fostering the life sciences industry. Ultimately, this effort has worked to expand the stakeholder community involved and recognized the important role that traditional economic development organizations can play to support emerging life sciences industry-specific intermediaries as well as partners.

Case Profile: Cleveland

The Cleveland region's life sciences sector is based on its strong clinical base and medical device manufacturing industry. Its major clinical assets are the Cleveland Clinic, University Hospitals Health Systems, and Summa Health System. Leading device manufacturers include Invacare, Steris, Philips, Hitachi, and General Electric – the latter three specializing in medical imaging equipment. The regional economic development organization reports that the region has over 400 bioscience companies, 62 hospitals, and 7 educational institutions, including Case Western Reserve University, that offer bio PhD programs.

The state, region, and the healthcare industry itself all emphasize the importance of the broad healthcare sector to the economy, pointedly contrasting its growth with manufacturing sector employment trends. In 2004, the regional hospital association released an economic impact study stating that Greater Cleveland hospitals alone employed 70,400 and had direct spending of \$7.2 billion, with a total estimated economic impact of \$15.5 billion and an additional 137,000 jobs. Bioscience companies are reported to employ an additional 20,000 people.

Cluster Strengths

Multiple institutions are involved in life sciences initiatives at the regional level. The core institutions—and Cleveland's main strength—for most efforts are the Cleveland Clinic, Case Western Reserve University, University Hospitals, and Summa Health System. The Center for Health Affairs (CHA) is also an important healthcare player. CHA is a hospital trade association representing 35 Northeast Ohio hospitals and providing a variety of advocacy and business management services. CHA also promotes healthcare's contributions to the regional economy.

The region's other life sciences strengths are its medical equipment manufacturers, including leading diagnostic imaging equipment, and health insurance. However, the private sector does not appear to provide overall leadership for the region's healthcare/biosciences initiatives, though it is involved in the major organizations and funding efforts.

The Cleveland Clinic deserves particular attention as it drives much of the region's life sciences activities. A not-for-profit, multi-specialty academic medical center that integrates clinical and hospital care with research and education, the Cleveland Clinic is perennially on the list of the best hospitals in America and is a leading hospital for several clinical specialties. Among these, the Heart and Vascular Institute and the Digestive Disease Center are ranked one and two in their respective specialty areas. All laboratory-based research at the Cleveland Clinic is conducted through the Lerner Research Institute, which is the fifth largest institute in the country with total annual research expenditures exceeding \$150 million. The Cleveland Clinic reports that it sponsors one of the nation's largest physician-graduate training programs. The Cleveland Clinic also runs thousands of clinical trials.

Cleveland Clinic Foundation Innovations (CCFI) is the Cleveland Clinic's technology commercialization arm with a mission to "benefit the sick through the broad and rapid deployment of Cleveland Clinic technology." CCFI facilitates innovation, creates spin-off companies, licenses technology, secures resources and establishes strategic collaborations with corporate partners.

Case Western Reserve University represents another major regional asset. Case Western offers a medical school (actually two programs: Cleveland Clinic College of Medicine at CWRU and the Case School of Medicine), life sciences research, a leading biomedical engineering program, and an "empowered" Technology Transfer Office through the University's Office of Research and Technology Management. The mission of the Technology Transfer Office is "to assist and lead the successful commercialization of ideas created by people at CWRU". Case Technology Ventures is a pre-seed stage venture capital fund at Case Western Reserve University.

The region also has two other notable health systems. University Hospitals (UH) is a community-based health care system serving patients at more than 150 locations throughout Northern Ohio, including seven wholly owned and four affiliated hospitals. UH provides healthcare services and education and has a separate center for research purposes. The Center for Clinical Research focuses on translational research, taking fundamental advances in biomedical research and applying them to improvements in healthcare by combining federal-funded research, sponsored research agreements with the pharmaceutical, biotechnology and medical device industries, and a partnership with Case Western Reserve University

Summa Health System is another network of hospitals, community health centers, a health plan, a physician-hospital organization, an entrepreneurial entity, research and a foundation. The Summa Enterprise Group (SEG) is a 100-percent, fully owned subsidiary of Summa Health System created to provide an entrepreneurial outlet for the system by launching products and services in the market and creating additional revenue streams for the health system.

Cluster Weaknesses

Unlike the other case studies described in this report, Cleveland is not one of the country's largest and most successful life sciences clusters. It is a region that has a large healthcare industry, but a relatively small life sciences industry. The Cleveland region's small market creates several difficulties for the future development of its life sciences cluster.

Like many places, the region has not achieved a high degree of success in commercializing the technologies being developed in its research institutions. This limited success is partly due to a lack of risk capital. This however presents a chicken and egg problem. Risk capital will follow deal flow so until the region becomes more successful in commercializing technology and growing new companies it will continue to have this problem. Several initiatives summarized below describe the region's efforts to improve these weaknesses to support growth in the overall life sciences sector.

Key Initiatives

Life sciences initiatives in Ohio and Northeast Ohio are focused on commercializing technologies and creating companies. The traditional economic development organizations, such as Team NEO/Cleveland Plus and Greater Cleveland Partnership, appear to be minor players. However, there are several biosciences organizations that are attempting to better leverage the region's clinical and education assets in support of the life sciences industry. These organizations include the Third Frontier program, BioOhio, and BioEnterprise.

Created in 2003, The Third Frontier Commission administers the Third Frontier Project and its respective funding programs. The Third Frontier Commission consists of the

Director of the Ohio Department of Development, the Chancellor of the Ohio Board of Regents, the Governor's science and technology advisor, and six regional commissioners appointed by the Governor. The 10-year, \$1.6 billion initiative is designed to build world-class research capacity, support early stage capital formation and the development of new products, and finance advanced manufacturing technologies to help existing industries become more productive

Ohio's biosciences strategy is grounded in the Third Frontier funding program. Key elements of the strategy are to use its RFP and funding process for the following activities:

- Focus funding on opportunities for rapid commercialization: Encourage technology-based, collaborative projects managed by the private sector and designed to result in rapidly commercialized technologies.
- Support and leverage academic partnerships: Support academic and private research initiatives that are aggressively translational in nature and linked to a private-sector partner
- Establish privately managed funds to spur commercialization: Establish privately managed funds to provide early stage money and management advice.
- Create a comprehensive biosciences support network: Focus on projects that create privately managed enablement functions, especially projects that create services for new company formation, infrastructure coordination, incubation, networking, recruiting and asset visibility.

Within the Third Frontier effort, there are two programs that directly support the biosciences—The Biomedical Research and Commercialization Program (BRCP) and the Wright Centers of Innovation in Biosciences (WCIB). The BRCP provides grants which support biomedical and biotechnology research leading to Ohio commercialization and long-term improvements to the health of Ohioans. Projects are to be collaborations among Ohio higher education institutions, non-profit research organizations, and Ohio companies in the areas of human genetics and genomics, structural biology, biomedical engineering, computational biology, plant biology and environmental biology. Five organizations, including Case Western, have been awarded a total of \$105,578,565 and 16 grants through this program.

The WCIB provides grants to support large-scale world-class research and technology development platforms designed to accelerate the pace of Ohio commercialization. Wright Centers are to be collaborations among Ohio higher education institutions, non-profit research organizations, and Ohio companies in the biosciences. Four organizations have been awarded a total of \$87,303,003 and 4 grants through this program.

BioOhio is a non-profit organization designed to build and accelerate bioscience industry, research, and education in Ohio. It is also an industry membership organization. The Thomas Edison Program of the Ohio Department of Development and member contributions support BioOhio's activities. The current mission of BioOhio is to accelerate bioscience discovery, innovation, and commercialization of global value, driving economic growth and improved quality of life in Ohio. BioOhio regional business development affiliates are located in Athens (Edison Biotechnology Institute), Cincinnati (BIO/START), Cleveland (BioEnterprise), and Columbus (TechColumbus). BioOhio has four primary strategy areas that include company and capital formation, asset-based company and partnership attraction, workforce development and deployment, and community and awareness development.

The third organization supporting the development of the Cleveland region's life sciences industry is BioEnterprise. BioEnterprise is the lead biosciences organization in Northeast Ohio. BioEnterprise is a business formation, recruitment, and acceleration initiative designed to grow health care companies and commercialize bioscience technologies. BioEnterprise assists qualified companies by offering:

- Experienced bioscience management guidance.
- Privileged relationships with world-class research and clinical institutions.
- Access to bioscience venture capital and private equity firms as well as knowledge of grant funding opportunities.
- Business development and alliance support for strategic partnerships.
- Network of regional business capabilities including technical services, equipment, professional service providers, and flexible development space.

BioEnterprise works closely with the following commercialization offices: the Case Office of Technology Transfer, Cleveland Clinic Innovations, University Hospitals Case Medical Center - Center for Clinical Research and Summa Enterprise Group. BioEnterprise also maintains an incubator for housing emerging bioscience companies, which has 25,000 square feet of wet and dry lab and office space.

BioEnterprise reports that since July 2002, it has achieved the following results:

- More than 60 companies created, recruited, and accelerated
- More than \$515 million in new funding attracted by these companies
- Over \$65 million in revenues collected by technology offices
- Over 160 technology transfer deals concluded with industry partners
- Evaluated over 850 company opportunities and 1,200 invention disclosures

While these organizations support the development of life sciences companies, JumpStart is an organization attempting to further develop the region's risk capital pool. JumpStart was formed to help accelerate the growth of early-stage ideas and business into venture-ready companies. JumpStart is a venture development organization that advises, invests in, assists, and accelerates Northeast Ohio's early-stage ideas and companies. Founding partners were Case Western Reserve University and NorTech, the Northeast Ohio Technology Coalition (a group of fifty regional business and institutional leaders). Other funders include the Greater Cleveland Partnership, Fund for Our Economic Future, Ohio Third Frontier Project, Ohio Department of Development, and several foundations.

Lessons Learned

The Cleveland case study illustrates many of the problems faced by relatively less developed life sciences industry. It has limited sources of risk capital and new business formation, but until the region creates more companies it will not attract the attention of venture capitalists. Through several programs, the State of Ohio has directed resources toward supporting entrepreneurial ventures in the life sciences. Relative to the other case studies presented in this report, Cleveland remains a small life sciences cluster.

The region does however benefit from having one of its primary research assets—the Cleveland Clinic—takes an active role in technology transfer and commercialization. Through the Cleveland Clinic Foundation Innovations, it places a high priority on activities like creating spin-off companies, licensing new technologies and forming strategic partnerships with the private sector. The fact that the Cleveland Clinic places such a high priority on these activities makes it unique among many major research hospitals.

Case Profile: Los Angeles

Los Angeles remains one of the nation's largest centers for life sciences. It is the country's second largest cluster for life sciences employment and one of the ten largest recipients of venture capital funding in the life sciences. Between 2002 and 2006, the Los Angeles Metro received \$516 million in biotech-related venture capital²⁷. With over 66,000 life sciences workers, it is large than either the San Francisco-San Jose industry or the San Diego industry²⁸. However, between 2002 and 2006 the Bay Area and San Diego ranked first and third respectively in terms of biotechnology venture capital received, while the Los Angeles area ranked ninth²⁹.

The Los Angeles region has world-class research facilities, strong anchor companies in both biotechnology and medical devices, prominent scientists and executives, and a deep labor pool within its colleges and universities. The region's basic assets include over a dozen public and private universities and four major medical schools. Leading regional hospitals are City of Hope, UCLA Medical Center, and Cedars-Sinai Medical Center. Major companies include Abbott (Diagnostics Division), Allergen, Amgen, Baxter, Genzyme, and St. Jude Medical.

In spite of these many assets, Los Angeles appears to lack a lead organization to pursue an overarching strategy. This lack of strategic direction opens up the possibility for key gaps and wasteful redundancies to emerge. It also prevents the region's life sciences industry from maximizing its commercial potential.

Cluster Strengths

The region's baseline life sciences report, the 2004 "Los Angeles Region Life Sciences Action Plan"³⁰ states that the region's primary strength is its "intellectual infrastructure." The region is home to a number of major research universities including UCLA, USC, UC Irvine, Caltech, UC Riverside, and UC Santa Barbara. Key strengths are the availability of qualified scientists and engineers and the availability of specialized facilities for research.

The region also possesses several leading regional research hospitals such as City of Hope. City of Hope is a biomedical research and treatment center dedicated to the prevention, treatment and cure of cancer and other life-threatening diseases. It has approximately 300 scientists conducting basic and translational research. The region also has several organizations advocating on behalf of its life sciences industry. For instance, the California Healthcare Institute (CHI) is an independent organization devoted to researching and advocating policy to forward the interests of California's biomedical community. Another supporting organization is the Southern California Biomedical Council (SCBC). The SCBC is the trade association of the Greater Los Angeles Life Sciences industry.

²⁷ Economic Alliance of Greater Baltimore, "Biosciences in Greater Baltimore," June 2007.

²⁸ Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.

²⁹ Economic Alliance of Greater Baltimore, "Biosciences in Greater Baltimore," June 2007.

³⁰ The Monitor Group, "Taking Action for Tomorrow: Los Angeles Region Life Sciences Strategic Action Plan", May 2004.

Cluster Weaknesses

The Los Angeles region consistently focuses on its relative lack of commercialization or new business formation in the life sciences sector, especially compared to San Francisco and San Diego, despite its strong business and research base. The 2004 Los Angeles Region Life Sciences Action Plan stated, "For all of our region's leading companies and world-class research, the most prominent feature in our local landscape may be its wealth of untapped Life Sciences opportunities."

Weaknesses identified in that report were technology commercialization efforts, the high cost of doing business, lack of access to capital, the government's lack of responsiveness to the needs of doing business, and a dispersed and unconnected life sciences business base that does not provide the critical mass necessary to promote strong business formation. Companies surveyed for the report also cited that the lack of affordable and available land around the universities as a primary barrier to expanding the life sciences industry in the Los Angeles region.

In terms of research commercialization, the report noted that the number of life sciences spinout companies per research dollar is much lower in Los Angeles than in the Bay Area or San Diego. The technology transfer and licensing process within the UC system was singled out as a significant problem. The report stated that the UC technology licensing function was overly centralized, limiting flexibility at the Los Angeles regional universities, and under-staffed. For example at the time of the report, UCLA had 17 technology transfer staff (up from 5), compared to 25 at Stanford and 45 at MIT.

A 2006 presentation on the life sciences cluster in Los Angeles listed several of the same weaknesses: lack of multi-tenant space and the need for stronger linkages with universities, especially on sharing technology. It also noted a lack of lack of venture financing in the region.

Key Initiatives

The "Los Angeles Region Life Sciences Action Plan" listed four major areas for improvement -- enhancing technology commercialization, lowering the cost and difficulty of doing business, developing and improving workforce efficiency, and strengthening the regional life sciences community. These priorities were first laid out in 2003, and they remain the priorities in 2007. There does not appear to be a single organization that provides overall leadership in the Los Angeles region for efforts to expand the life sciences sector. Instead, several organizations pursue initiatives relevant to their main missions, and occasional meetings or summits are held to discuss activities. Accordingly, there has not been a comprehensive update to the Los Angeles Region Life Sciences Action Plan, nor has any group prepared a "report card" on progress made on the key issues. Nevertheless, a number of initiatives are underway in each of these areas.

Technology Commercialization

The Larta Institute (formerly the Los Angeles Regional Technology Alliance) provides entrepreneur training, commercialization, and technology transfer services for governments, companies, and universities. Larta Institute's mission is to increase economic development through the improved transition of scientific and technological breakthroughs from the laboratory to the marketplace, where they can solve problems, enhance economic opportunities, advance medical care, and better people's lives. The Institute was originally formed in 1993 through legislation enacted by the State of California to assist small companies developing innovative technologies. Today it has a national client base and is not focused exclusively on Los Angeles. It reports that it assists over 200 companies per year spinning out from the federal government, top research universities, and a global network of 18 nations.

The Industry-University Cooperative Research Program (IUCRP) at the University of California system provides funding and cooperation on research projects. IUCRP awards Discovery Grants in several fields, including biotechnology. The program allows UC researchers and California R&D companies to jointly conduct commercializable research at laboratories in the UC system. The state provides research funds and tax credits, UC contributes scientists, students, and laboratory access, and participating companies provide matching funds. IUCRP reports that the effort has reached \$281 million in investment with a research portfolio "that now has the capacity to grow at a rate of \$60 million annually."

The Alfred E. Mann Institute at the University of Southern California (AMI) is a non-profit organization that supports research, development and commercialization of biomedical devices and other technologies. AMI is a development center devoted to accelerating the commercialization of biomedical devices by nurturing promising biomedical technologies. One of AMI's priorities is to assist USC faculty in navigating the transition of medical device development from the academic to the commercial environment by providing funds and services.

The New Business Ventures, Technology Management and Facilities group within the Los Angeles BioMedical Research Institute (LA BioMed) develops agreements with industry to support entrepreneurial projects and the transfer of technology developed at LABioMed. The group also assists in providing funding for LABioMed research programs, manages intellectual property program, coordinates capital building projects and laboratory issues. LABioMed conducts biomedical research, provides education and training of scientists, and provides a variety of community services such as nutritional assistance, childhood immunization, anti-violence programs and various disease education initiatives. It is a freestanding, not-for-profit biomedical research, training and service organization and is an affiliate of both the UCLA School of Medicine and the Harbor-UCLA Medical Center.

The Center for Applied Technology Development Office of Technology Licensing oversees licensing opportunities at the City of Hope (Duarte, CA). The CATD's Center for Biomedicine & Genetics (CBG) works to ensure that technological innovations are translated from the research lab to the clinical setting. The CBG facilitates the development of innovative biologics created by City of Hope investigators, colleagues and partners and establishes working relationships with regional biopharmaceutical and academic organizations.

The USC Stevens Institute is a university-wide, centralized organization within the Office of the Provost designed to consolidate innovation transfer operations, educational and co-curricular programming, and "innovator development". The Institute focuses on transferring the innovations that are discovered at USC into society, as well as cultivating researchers and students as future innovators. Services include intellectual property development and licensing, patent processing, and IP protection; a central connection for industry seeking cutting-edge innovations in which to invest; promotion of educational programs, courses, student groups, and resources in innovation; development of new interdisciplinary partnerships to advance innovation across campus; information on volunteer, investment; and sponsored research opportunities at USC; and

community-building events to connect the innovators and investors. Medicine and life sciences is one area of focus. USC is also developing the BioMedTech Park adjacent to its Health Sciences Campus. The space will be used for researchers and biotech start-ups.

At the UCLA Office of Intellectual Property, 23 professionals are engaged in support of the research enterprise and technology transfer. OIP handles patenting, marketing, licensing and material transfers and provides assistance to faculty start-ups. In FY06, UCLA had 264 new invention disclosures, 39 new license or option agreements, 156 active license agreements, active equity holdings in 20 companies, and \$22 million in licensing revenue.

Cost of Doing Business

The California Healthcare Institute (CHI) is an independent organization devoted to researching and advocating policy to forward the interests of California's biomedical community. Founded in 1993, its mission is to research, develop, and advocate policies and actions that promote biomedical science, biotechnology, pharmaceutical and medical device innovation in California. Tax policy and economic incentives as well as efforts to increase state science, education and training funding remain priority objectives on its state policy agenda.

Workforce Programs

The California Community Colleges run the Applied Biological Technologies Initiative statewide. The program has six grant-funded centers serving different regions of the state. The mission is to provide life sciences companies with appropriately educated and trained workers. In FY2005-2006, more than 1,800 people participated in ABTI center activities. Donations of equipment, supplies, time and cash in FY 2005-2006 to ABTI centers totaled more than \$1.6 million. The centers rely on partnerships with local companies; among the program's company partners are Edwards Lifesciences, Inamed, Raven Biotechnology, Amgen, Genentech, Biosource, Ceres, Invitrogen, Biogen-Idec and Novartis AG.

Strengthening the Community

The Southern California Biomedical Council (SCBC) is the trade association of the Greater Los Angeles Life Sciences industry. The mission of the SCBC is to promote and support the life sciences industry in the region for job creation and economic growth. One of its priorities is to "build on local assets to create a self-sustaining critical mass in biocommerce." The SCBC was spun out from Rebuild LA (RLA) in mid-1997 to give the industry a unifying voice and a source of identity.

Lessons Learned

Most of the region's major institutions have launched some kind of significant technology transfer initiative or have an office dedicated to support these activities. As a result, it is clear the region's many institutions and key stakeholders see the value of tech transfer and commercialization. However, it appears that these activities are all occurring in isolation of one another. The region does not have any kind of overarching organization or strategy to effectively support the industry. This lack of regional coordination creates the potential for gaps and redundancies. It also limits the potential for collaborative initiatives that might help the region overall.

Case Profile: New York

The New York metropolitan region has the nation's largest life sciences cluster. The New York Metro area had 110,000 people employed in the sector in 2004—more than any other area of the country³¹. This estimate excludes the health care sector (e.g., ambulatory and hospital care), which had another 664,000 workers in 2004. Outside health care, the largest share of New York's biosciences workers are employed in the drugs and pharmaceuticals sub-sector, representing 52,000 people and nearly one in six of the nation's workers in this sub-sector.

New York provides an example of how some regions have developed economic specializations in the biosciences industry – with its focus on drugs and pharmaceuticals as well as in research and teaching. It also demonstrates that cost factors strongly influence the location of certain activities. However, there remains a need for direct linkages between innovative research, product development, and production activities, especially during the clinical trials phase of drug testing. The region has focused much of its efforts on addressing some of the core challenges facing the region's industry – traversing the wide array of opportunities, overcoming the high cost of doing business, and fostering private capital investment in a still-risky industry.

Cluster Strengths

The New York metropolitan area has one of the largest concentrations of academic assets in the nation. In addition to drugs and pharmaceuticals, the region also has a large concentration of research and testing activities. The corridor between Manhattan and Philadelphia represents the core of the nation's biopharmaceutical industry. While the research and teaching assets appear to concentrate in the City, the industry's headquarters firms are somewhat more widely dispersed. For instance, the region boasts the headquarters of Bristol Myers Squibb, ImClone Systems, and Pfizer (located in the city) and OSI Pharmaceuticals and Regeneron (located in the inner suburbs). These companies also have a number of testing and production labs in locations around the metropolitan area as well as around the world. The region is also generating new companies in the field as well. For instance, New York City-based Eyetech Pharmaceuticals raised \$157 million in 2004, representing the nation's largest initial public offering before it was acquired in 2005 by OSI Pharmaceuticals.

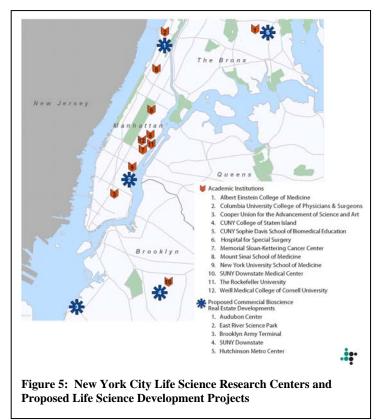
The region has been successful in attracting real estate investment to support the unique needs of the biosciences industry. With several large development projects, nearly 2 million square feet of new space is under development to house headquarters of growing manufacturing operations, divisions of multi-national companies, and facilities for institutional research.

At the institutional level, the New York City metro region has more than a dozen worldclass life sciences research institutions. Figure 5 illustrates that the city alone boasts of 12 major academic research institutions. In addition, the city has 26 other research institutions and medical centers and 175 hospitals, research centers and laboratories. These serve as a significant source of idea generation, new product development, and early product adoption. The scientific, clinical and entrepreneurial talent available at

³¹ Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.

these institutions is relatively near a large concentration of investment capital and professional services with expertise in the life sciences. The region also offers access to the East Coast's "pharmaceutical corridor," representing 60 percent of the U.S. industry.

In 2005, the New York City Partnership convened these assets in the form of the NYC Bioscience Initiative, a "real-estateoriented" effort designed to leverage the network of state-ofthe-art facilities in support of commercial and research activities. The goal is to build on the unique set of talent available. The participating institutions represent the nation's second largest metropolitan concentration of National Institutes of Health (NIH) funding between 1999 and 2006 as well as the second largest



concentration of Howard Hughes Medical Institute Investigators. The NY metro region also has the largest concentration of National Medal of Science recipients of any US metro area. During the past decade, area institutions also have developed more patents (6,800) than another metro area and almost as many as San Francisco (3,991) and Boston combined (3,007). The region has also ranked in the top four metro areas in attracting venture capital to biotechnology and medical device companies.

Cluster Weaknesses

The city's commercial bioscience industry is small relative to its academic assets as well as to its competitor regions. For example, the New York Metro area has only 140 biotechnology companies compared with approximately 600 in San Francisco and over 250 in Boston. Thus, the region's industry is dominated by a few large employers with many very small companies making up the balance of the economic activity.

Access to capital is viewed as a concern and the State of New York has been an active investor in biomedical research, designed to help the state to develop the academic research and create venture management firms. A number of companies, including Amgen, Amicus, Memory Pharmaceutical, Pharmacopeia, and Sugen initially started with technology from New York City academic institutions, but ultimately moved elsewhere when they entered their growth stage. One company, Regeneron Pharmaceuticals, which employs 565 people, provides an exception to this story. Started by a researcher at Weill Cornell Medical Center in New York City, the company eventually moved to the Landmark at Eastview Research Park in Westchester County and started manufacturing in Rensselaer.

A key concern for state and local policy makers is that the cost of commercial real estate makes operating a business in the New York metro region very difficult. That is why

much of the economic development incentives have focused on bringing these costs into line. The region has been successful in launching new ventures and developing new products, only to see them leave the region for lower cost areas or accessible facilities when the projects reach the production phase.

Key Initiatives

At the heart of the region's life sciences cluster is a network of state-of-the-art facilities to accommodate commercial bioscience businesses and related research activities throughout New York City and the surrounding region. In addition, the city is developing East River Science Park, its first major bioscience office park, which will offer 4.7 acres of space near NYU/Bellevue Hospital medical campus to build 872,000 square feet of flexible office and laboratory space in two phases, with the first completed by 2008. In addition, the NY City Economic Development Corporation has invested \$10 million through the New York City Investment Fund and the New York City Partnership to finance the redevelopment of the city-owned, 300,000 square-foot Brooklyn Army Terminal for bio-manufacturing. Furthermore, Columbia University Medical Center is developing the Audubon Biomedical Science and Technology Park on its campus in upper Manhattan, and SUNY Downstate Medical Center in Brooklyn is planning a fourbuilding complex , the Downstate Biotechnology Park, that would offer wet-lab incubator and single-tenant space. Regional efforts include a 275-acre technology park at Eastview in Westchester County.

To supplement the science park, New York has several incubators, including the 100,000-square-foot multi-tenant wet-lab at Columbia University's Audubon Business and Technology Center and the 50,000-square-foot Downstate Advanced Biotechnology Incubator planned for SUNY Downstate in Brooklyn. Long Island also has a 72,000 square-foot High Technology Incubator at SUNY Stony Brook.

The state Senate instituted a \$225 million state program called Gen*NY*sis (Generating Employment through New York State Science) in 2002-2003. This program has helped to develop life science facilities in the City as well as across the state. So far, the Long Island Cold Spring Harbor Laboratory (a private non-profit research laboratory), the City University of New York (CUNY) College of Staten Island, Hofstra University, and Yeshiva University-Albert Einstein College of Medicine are all regional institutions that have benefited from the program's investments in capital facility projects.

The Gen*NY*sis program offers two levels of funding. First are the large-scale Strategically Targeted Academic Research (STAR) Centers, which received \$15 million and provide a significant funding source for major building programs. The second level of funding is for Academic Research Centers (ARCs). ARCs receive up to \$4 million for construction and fit-out of laboratory suites provided for targeted projects. The most recent of these STAR Centers is the New York Structural Biology Center. The Center represents a consortium of 10 large universities and institutions that came together to build a high-field nuclear magnetic resonance spectroscopy center at CUNY City College. Two large STAR Centers already were located at Stony Brook University, which received funding for a biomolecular diagnostics and therapeutics facility and Columbia University, which supports an integrated imaging facility. Smaller ARC grants were awarded to Mt. Sinai School of Medicine for neuronal plasticity.

The State of New York funds Centers of Advanced Technology to work closely with companies. Each Center receives a \$1 million per year to provide grants to faculty that are working with industry. At Stony Brook, the Center for Biotechnology is focused on

biomedical research. The Center has a separate outreach function, the Long Island Life Sciences Initiative, designed to encourage and support the industry on Long Island. The CUNY Center for Photonic Applications is investing in photonic sensing projects with multiple medical applications. Columbia University's Center for Advanced Information Management has three focus areas, one of which is medical informatics.

The state also provides technology commercialization grants up to \$750,000 to support the transfer of university-owned technology, matched 1:1 by companies in the state. The program has been used to support the start-up of university-affiliated business incubators. In addition, New York University (NYU) has created an Applied Research Support Fund for pre-commercialization projects up to \$50,000 managed by the Office of Industrial Liaison and Technology Transfer.

The state also provides three Qualified Emerging Technology Company (QETC) tax credits. One provides a \$1,000 credit for creating jobs in technology companies. A second provides tax credits for investments in qualified projects that are held for a period of time. The investor credit is 10 percent for investments held for four years (with a cap of \$150,000) and a 20 percent credit for those held up to nine years (with a cap of \$300,000). A third credit encourages companies to invest their own facilities, operations, or training. Companies investing in research and development facilities can receive up to an 18 percent credit for these costs. Companies can also receive credits up to 9 percent on "qualified research expenses (including the cost of in-house research activities, research results dissemination, and the cost of protecting intellectual property)". Employers can also receive a credit for training expenses totaling as much as \$4,000 per employee per year. All of these direct business credits are capped at \$250,000 per company per year.

The New York City Investment Fund (managed by the Partnership for New York city) has a \$110 million seed capital fund. It has also invested in the Academic Medicine Development Co. (AMDeC), which will mobilize the resources of the region's academic community to further promote the expansion of the bioscience community. The AMDeC Foundation, Inc. brings together 28 of New York's medical schools, academic health centers, and major medical research institutions to encourage institutional collaboration aimed at building and developing:

- Large-scale basic, clinical and translational research projects (particularly in high need areas such as cancer, diabetes, alzheimer's);
- Genomics and other state-of-the-art core facilities for biomedical research;
- A world class hub for biotechnology; and
- A collaborative and pioneering research environment in New York.

One project of AMDeC is the BioResource Network, which provides a comprehensive guide to biomedical research currently underway at regional academic institutions. Its website provides a one-stop-shop for biomedical research and an overview of the institutional research capabilities. The data included on the site include the major activities of each participating institution's basic science and clinical departments as well as information about interdepartmental research centers. In addition information about shared core facilities, on-going and recent clinical trials, and technology transfer contacts are provided. The goal is to provide a mechanism for rapidly identifying relevant research and accessing web links with up-to-date information. Researchers can look at specific institutions and find out more about their expertise as well as do a broad

Departments	Research Centers	Core Facilities
Anatomy and Structural Biology	<u>Aging</u>	DNA Sequencing
Biochemistry	AIDS/HIV	Flow Cytometry
Cell Biology	<u>Cancer</u>	<u>Library</u>
Dev. and Molecular Biology	Clinical Research	Microarray
Genetics	Computational Biology	Monoclonal Antibody
Microbiology and Immunology	Heart and Vascular	Spectroscopy
Neuroscience	Mental Health	Transgenic Mouse
Pharmacology	Neuroscience	

regional search aimed at identifying where expertise can be found in a variety of areas by department, research center, or core facility (see Figure 6).

AMDeC's shared core research facilities program is particularly unique. It has developed several programs aimed at advancing genomics research, including the InTraGen, the Bioinformatics Core Facility, and the Microarray Resource Center. Initially, this program was designed to increase efficiencies in sharing information across the affiliated institutions and preclude the institutions from investment in costly technologies. As the program has evolved, the partners have recognized an increased need for data standardization, and AMDeC responded by becoming a central repository for standard microarray data (including the single largest collection of microarrays in the country), new bioinformatics software and tools and general platforms for cross-institutional collaboration.

Under the auspices of the New York City Bioscience Initiative, a Bioscience Metro Inventory Website was developed that provides an extensive listing of the region's scientific and healthcare-related assets. The Inventory also provides information about the City's award-winning scientists and provides a portal to the City's bioscience-related institutions.

Lessons Learned

New York has built on its sizable academic community and its historic role as a headquarters city to support the global biopharmaceutical industry. It has retained this role despite its high cost of doing business and the globalization of the industry by remaining at the forefront of research and development and at the crossroads of innovation and capital. With the traditional concentration of activities in Manhattan and Brooklyn (see Figure 7), the City remains concerned that it may lose its competitive edge because it does not have the physical facilities to conduct new research or support new small firms.

The region's efforts have not been driven by a cohesive strategy based on an assessment of needs, but more based on the highly visible role that real estate development has played in the city's economy and economic development efforts. The State of New York has invested in other aspects of the business development process – especially in research and development as well as capital formation. Ironically, much of this state investment has focused on expanding the geography of the bioscience industry to other parts of the state, but the state investment has also served to strengthen the New York metropolitan area's role as a source of innovation.



Case Profile: Philadelphia

As one of the oldest cities in the United States, the greater Philadelphia region has built on its long and rich history to position itself as one of the nation's largest life sciences clusters. America's first hospital (the Pennsylvania Hospital), the first private psychiatric hospital (Friends Hospital), and the first college of pharmacy (the Philadelphia College of Pharmacy) are all found in Philadelphia. In addition to this long tradition, the development of the region's life sciences cluster has also been greatly influenced by the presence of some of the world's largest pharmaceutical and biotechnology companies in combination with premier universities, hospitals, and other medical research institutes. The University of Pennsylvania, Thomas Jefferson University, and Abramson Cancer Center are among some of those institutions that contribute to on-going academic research in the field.

This tradition has led to the region's biosciences cluster specializing in the areas of pharmaceuticals and drugs as well as research development and testing, and medical devices and equipment manufacturing. In 2004, the Greater Philadelphia region had more than 53,000 workers in the biosciences, third only to the New York and Los Angeles.³² This concentration of life sciences activities help to supports more than 310,000 workers in other related industries. Eight of the world's largest pharmaceutical companies are located within 50 miles of downtown Philadelphia, including GlaxoSmithKline, Merck, Johnson & Johnson, and Wyeth. Several of the largest firms trace their history back to the 19th century.

Although the Philadelphia region has a long history in the development of pharmaceuticals and biotechnology, increasing global competition in transforming life science innovations into an economic growth engine has propelled state and local policymakers and stakeholders to take aggressive action. The focus has been on maintaining and enhancing the region's competitive advantages in research expertise and industrial capacity. Several renowned technology development initiatives and models can be found in the region, including the state's Ben Franklin Technology Partnership (with a specialized regional program targeted to southeastern Pennsylvania), the Life Science Greenhouse Initiative, Keystone Innovation Zones, Delaware Valley Innovation Network, BioAdvance and Innovation Philadelphia. Together and individually, these initiatives are providing life science companies with seed-stage investment, entrepreneurial support, networking, and collaborative partnership opportunities. Through these initiatives and technology development activity, the life sciences industry continues to be a pivotal part of the region's economic growth.

Cluster Strengths

The rich legacy of many established pharmaceutical companies in the Philadelphia region has been an important asset for the region's economic development for more than a century. Approximately 40 percent of them worked directly in the pharmaceutical

³² Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.

industry.³³ In terms of the concentration of its employment in pharmaceuticals, Philadelphia ranks first compared with other large metro areas in the nation. The long history of the pharmaceutical industry in Philadelphia has helped to create the necessary institutional infrastructure to support the development of life science clusters in the region.

Another regional strength that drives the development of the life science clusters in the Philadelphia region is the considerable amount of biomedical research activity. The Milken Institute report also shows that, in 2003, 27 percent of life science employment in the Philadelphia region was in R&D, the second largest life sciences sub-sector. Between 1997 and 2003, the region's employment growth in the R&D sub-sector of life science industry outpaced any other metro areas.

The significance of R&D activity in life sciences is evidenced by the presence of the region's highly prestigious medical schools and research hospitals. The region's four medical schools and their affiliated research institutes and teaching hospitals include the University of Pennsylvania, Thomas Jefferson University Hospital, Temple University and Drexel University. These facilities are not only key contributors to the local economy but they also serve as a focal point in attracting substantial private investment and federal grants, especially the R&D funding from the National Institutes of Health, in support of medical research and training.

In addition, the city of Philadelphia alone has four NCI-designated cancer centers, including Abramson Cancer Center, Fox Chase Cancer Center, Kimmel Cancer Center, and the Wistar Institute, more than any other metro area in the nation. In all, the region's concentrated and leading medical/bioscience research institutions have provided both the quality of medical and technological research and the availability of specially trained research scientists and technicians to propel the life sciences cluster.

Adding to the strength of the region's biomedical research activity is the collaboration underway among academic, entrepreneurial, corporate, financial, and government partners. Those strong regional partnerships – led by BioAdvance, Pennsylvania Bio, Innovation Philadelphia, Greater Philadelphia Chamber of Commerce, Ben Franklin Technology Partners of Southeastern Pennsylvania, the University City Science Center, Greater Philadelphia Bioinformatics Alliance, the Delaware BioScience Association, and the Delaware Biotechnology Institute – are critical players in establishing and reinforcing the region's bioscience capability through policy advocacy, capital access, and networking³⁴.

³³ Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.

³⁴ Battelle, *Growing the Nation's Bioscience Sector: A Regional Perspective*, January 2007 http://www.bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf

Figure 8: Aerial View of University City Science Center (foreground) and downtown Philadelphia (background)



The greater Philadelphia region has long shown public policy leadership in developing this cluster. For instance, one of the earliest development models was initiated by the region's universities in the form of the University City Science Center

(<u>http://www.sciencecenter.org</u>).

Started in 1963, the Science Center is a 40-year-old research and technology park located between the University of Pennsylvania and Drexel University just outside downtown Philadelphia that provides earlystage life sciences and high-tech entrepreneurs with business development services, capital and

the infrastructure needed to succeed. The Science Center also provides the private sector with access to the region's educational and health-related institutions in order to encourage commercialization of new technology and innovation. Throughout its history, the Science Center has created more than 26,000 jobs and raised more than \$150 million funding from government and private ventures.³⁵ Currently, the Science Center is planning to double its existing facilities by 2010 as part of a \$600 million development investment plan. Once completed, the Science Center will be established as a premier urban research park on the East Coast.³⁶

Ben Franklin Technology Partners of Southeastern Pennsylvania (BFTP Southeast) is another well recognized model for innovation in technology-based economic development. Established in 1982, BFTP Southeast is one of four regional Ben Franklin Technology Partners in the state whose mission is to diversify and strengthen Pennsylvania's economy through innovation, entrepreneurship and the development and adoption of new technology. To achieve its goals, the organization has provided funding to support a variety of R&D, technology transfer, and joint research activities. The Philadelphia region's biosciences companies have benefited significantly from this public-private partnership as it offers seed-stage investment and entrepreneurial support to ensure their competitiveness and success in the global marketplace.

Pennsylvania Bio is a statewide biosciences industry association dedicated to help Pennsylvania become a global leader in the life sciences industry. It creates a cohesive community that allows biosciences companies to network and interact in order to attract a talented workforce and grow and partner for advancement. Another important regional collaborator is Innovation Philadelphia, a public and private partnership created to grow the wealth and workforce of the region's technology and knowledge industry sectors. It has focused its efforts on attracting and retaining young professional workers as well as

 ³⁵ See information from the history of the Science Center at <u>http://www.sciencecenter.org/history.asp</u>
³⁶ Natalie Kostelni, "Science Center Doubling", *Philadelphia Business Journal*, February 10, 2006
<u>http://philadelphia.bizjournals.com/philadelphia/stories/2006/02/13/story1.html</u>

generating innovative ideas that will define the region's future as a global destination for technology and knowledge industry businesses.

Cluster Weaknesses

The Philadelphia region holds a lot of strengths to foster and develop the life sciences cluster; however, retaining the locally developed and trained workforce in order to provide a deeper pool of workforce talent has been an issue. The region does a better job at graduating degree holders in important specialties but lags behind in employing them in related professional fields³⁷. In particular, the region has not been able to utilize students graduating with a degree in bioengineering and biomedical engineering and placing them efficiently in local biotech and medical device sectors.

The region's success in attracting large pharmaceutical companies may have discouraged some employees in the region from creating new firms or trying entrepreneurial ventures. As a result, talented workers produced by the region's outstanding universities have frequently out-migrated because the large, mature firms are generating low levels of new employment opportunities in biotech and medical devices.

Philadelphia has not been as successful at winning an equitable proportion of federal discretionary research, development, and commercialization funding through programs like the Small Business Technology Transfer (STTR) and the Small Business Innovation Research (SBIR) grants³⁸. Despite the region's outstanding research ability among its educational and research institutions, area companies seem to need specialized technical assistance in applying for this federally competitive funding if they are to be successful in competing.

Key Initiatives

The development of life sciences clusters in the Philadelphia region cannot become successful without the support of state and local leadership. In the case of Pennsylvania, the state is particularly committed and invests substantial public resources and works closely with regional academic and industry leaders to build bioscience R&D capacity, encourage academic and industrial interaction, provide space for bioscience companies, and support entrepreneurs and emerging life science companies with pre-seed and seed capital.³⁹

In 2001, the state legislature created the Ben Franklin Technology Development Authority (BFTDA) and since then it has provided more than \$32 million into state venture funds. BFTDA provides direct investments and leverages private investment to support technology-oriented businesses through its university research funds, technology development grants and venture investment program. In addition, the BFTDA provides funding to the state's four Ben Franklin Technology Partners for preseed and seed capital investments, ranging from \$100,000 to \$500,000 in technology

³⁷ The Milken Institute, *The Greater Philadelphia Life Sciences Cluster: An Economic and Comparative Assessment*, June 2005. <u>http://www.milkeninstitute.org/pdf/philadelphia sciences 0605.pdf</u>

³⁸ The Milken Institute, *The Greater Philadelphia Life Sciences Cluster: An Economic and Comparative Assessment*, June 2005. <u>http://www.milkeninstitute.org/pdf/philadelphia_sciences_0605.pdf</u>

³⁹ Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.

start-ups (including those in the biosciences). One recent initiative supported by the BFTDA – the Nanotechnology Initiative – is a good example of demonstrating collaboration between regional universities and Ben Franklin Technology Partners of Southeastern Pennsylvania. The Nanotechnology Initiative provides capital for biomedical applications using nanotechnologies. The success of BFTDA in leveraging the creation of new venture funds further led to the launch of the Health Venture Investment Account and the Commonwealth Universal Research Enhancement (CURE) Program. These two programs help extend financial resource to startups and emerging life sciences companies and support the commercialization of new innovation.

In 2002, Pennsylvania's \$2 billion plus Life Sciences Enterprise program combined with Governor Rendell's \$2.3 billion Economic Stimulus Package served as the foundation upon which the state designed a roadmap for continued growth in the life sciences industry. The Life Sciences Enterprise program is funded through the state's tobacco settlement revenues (one-fifth of the projected \$11.3 billion tobacco settlement monies). It supports the life sciences industry through capital funding, R&D support, and regional hubs for growing life sciences companies. This particular program is divided into four major components: (1) \$1.6 billion for the state's research institutes engaged in life sciences and biomedical research; (2) \$100 million for three Life Sciences Greenhouses (including \$33.8 million designated for BioAdvance – the Biotechnology Greenhouse of Southeastern Pennsylvania); (3) \$60 million for venture capital funding in commercialization, and (4) \$140 million in projected matching funds for the venture capital fund.⁴⁰ The Life Sciences Greenhouse Initiative is a particularly innovative regional model designed to commercialize new technology with seed and pre-seed stage funding designed to enhance regional collaboration between academic, entrepreneur, corporate, and government partners. In the Philadelphia region, BioAdvance has launched several initiatives, including the \$20 million Greenhouse Fund to support start-up companies and academic research institution projects. BioAdvance has also provided \$2.5 million to support the Greater Philadelphia Bioinformatics Alliance, a consortium of regional academic and research organizations dedicated to advancing the field of bioinformatics.

The Governor's 2002 Economic Stimulus Package sought to leverage at least \$5 billion from private investments in economic and community development projects. Its goals included encouraging research & development, attracting venture capital, producing an appropriately educated and skilled workforce, and creating an infrastructure that would stimulate innovation activity across the state.⁴¹ The Keystone Innovation Zones program, a cornerstone of the Economic Stimulus Package, is particularly important for academic and industrial interaction by providing grants ranging as high as \$250,000 to build infrastructure for partnership collaboration and technology transfer.

Furthermore, two recent regional initiatives—the Delaware Valley Innovation Network and Life Science Career Alliance—address the specific issue of workforce development in the life sciences industry. Formed in 2005, the Delaware Valley Innovation Network is a 13-county initiative that has been endorsed by the governors of Pennsylvania, New Jersey and Delaware and is dedicated to transforming the region's life sciences industry into a global center for excellence in life sciences research, industry and human capital development. The Life Sciences Career Alliance, created by the Southeastern

⁴⁰ See PA Life Science Initiative at <u>http://www.bioadvance.com/life-sciences.asp</u>

⁴¹ PA Department of Community and Economic Development, *Pennsylvania Life Science Enterprise*, 2003 http://www.pambdc.com/mti/Life_Sciences_Booklet.pdf

Pennsylvania Regional Workforce Investment Board and the Delaware Valley Healthcare Council, is a five-county regional skill development partnership dedicated to ensuring the continued growth of the life science industry in Southeastern Pennsylvania. It is supported by regional workforce investment boards, hospitals and foundations. Its board consists of representatives from health care industry, workforce organizations, labor groups, and academia. To maintain and improve the region's life sciences workforce, the Alliance tracks health care-related educational training and internship opportunities and provides training assistance to local biotech employers. These two initiatives may demonstrate that the region has increasingly recognized that maintaining a stronger and deeper life sciences workforce will be a critical component of developing life sciences clusters.

Another related workforce initiative has involved Innovation Philadelphia through the Knowledge Industry Partnership (KIP) initiative, a broad-based coalition of Greater Philadelphia's civic, business, government, and higher education leaders working together to maximize the impact of the region's "knowledge industry" of colleges and universities on Philadelphia's competitive position. KIP aims to tap the talent being developed at the region's colleges and universities, to get them engaged with the community, and ultimately convince them stay in the region once they graduate. This is an important element of the region's talent attraction and retention strategy and involves cross-academic institution collaboration in developing appropriate regional amenities as well as in career-opportunity development through internships with local companies. The goal is to help college students connect with their careers while they are still in the greater Philadelphia region in an intentional way rather than leaving their "first-job-after-college" opportunities to chance.

Lessons Learned

The Philadelphia case in the development of the life sciences cluster provides several key lessons for other regions that intend to foster this particular industry. Despite the region's long historical industrial strength in pharmaceuticals and fine-chemistry, the strong commitment from state and local leaders is one of the key elements that has helped to guarantee the life sciences industry's long-term successful development in Philadelphia. The state government and its local partners have provided strong leadership and tremendous public investment in order to leverage sufficient private venture funding to make the needed seed and pre-seed capital accessible for startups and emerging life science companies. Public investment has also been used to encourage and enhance the region's R&D capacity, to build a strong collaboration between academic and industrial partners, as well as to accelerate the commercialization of new innovation from the laboratories to the marketplace.

The other important lesson learned from Philadelphia is to build the needed support infrastructure for networking and collaboration among all key stakeholders. The examples of Pennsylvania Bio, BioAdvance, Innovation Philadelphia, and Delaware Innovation Network illustrate the importance of collective efforts. These organizations not only provide networking opportunities for research institutions and life sciences companies to build relationship and obtain the necessary services and resources, but together these specialized entities also serve an important role in providing a more effective force in advocating for and promoting the growth of the life sciences industry because they are concentrated on the issues of greatest concern to this important sector of the economy.

Case Profile: Raleigh-Durham

The Research Triangle Region, defined as the combined North Carolina metropolitan areas of Raleigh-Cary and Durham, represents another major concentration of life sciences innovation. The name combines the traditional moniker of the "Triangle" of major universities in Raleigh, Durham and Chapel Hill combined with Research Triangle Park (RTP), which is situated in the middle of the region. RTP employs an estimated 39,000 people, of which 18,000 work in the life sciences directly. These workers generate enough economic activity to employ another 36,000 indirectly in the Research Triangle region.⁴² The Research Triangle region has more than 500 life sciences companies, and receives more than \$2 billion in new annual R&D funding through the region's multiple research universities, federal labs and contract research organizations.

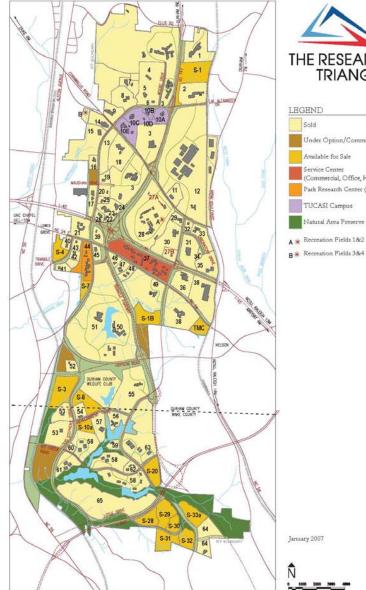
The region's success is driven in no small measure by Research Triangle Park, an economic development project that has been nearly fifty years in the making. What was once just a loblolly pine forest bisected by a two-lane blacktop between Raleigh and Chapel Hill has become an internationally recognized center for advanced research. Today, the 7,000 acre Park has only about 630 acres remaining for development. With 157 companies, the Park has 20 million square feet of space in use. Biotech and pharmaceuticals are two of the major clusters of firms located there. The Park's success has helped to position the region as a globally competitive life sciences cluster. Unlike so many other places, the Research Triangle region is not playing catch up.

However, like many leading life sciences clusters, Research Triangle is working not only to keep up with increasing global competition but also to move into the first tier of US regions with significant clusters of life sciences activities. Certainly, getting ahead in the global life sciences industry has been the core mission of the region's strategic planning efforts. This section will highlight the strategies that have emerged during these efforts, and what they have meant for sustaining the continued growth and development of life sciences in the Research Triangle area.

Cluster Strengths

Numerous multinational companies including GlaxoSmithKline, Bayer, Wyeth, Biogen and Quintiles are located in the region. The presence of so many multinational corporations involved in various aspects of the life sciences, especially biopharmaceuticals, provides numerous opportunities for collaboration and commercialization throughout the region. The region is also home to federal agencies such as the National Institute of Environmental Health Services -- a division of the National Institute of Health. These actors are all supported by the region's 12 colleges and universities and the seven community colleges that serve 130,000 degree students. Three of these universities -- the University of North Carolina at Chapel Hill, North Carolina State and Duke University -- are major research institutions. The region also has several high profile teaching hospitals in the UNC Medical Center in Chapel Hill and Duke University Hospital in Durham.

⁴² Peter Pellerito, "Innovations @ Emerging Intersections: A Strategy to Maintain the Research Triangle Region's Competitiveness in Life Sciences", prepared for Research Triangle Regional Partnership, 2006.



THE RESEARCH TRIANGLE PARK

- Under Option/Committed
 - Service Center
 - (Commercial, Office, Hotel)
 - Park Research Center (Lab/Office)
- TUCASI Campus
- B* Recreation Fields 3&4
- Microelectronics Assembly Tech. Nextreme Thermal Solutions 28 17
- Sumitomo Electric Lightwave Corporation Troxler Electronic Laboratories, Inc. 14

Biotechnology/Agricultural Biotechnology/

BASF Corporation Agricultural Product Center

Biological Agents

Bayer CropScience

Civatech Oncology

Botanics Integrated, LLC

Diosynth Biotechnology

Nufarm Americas, Inc.

Precision Bioscience, Inc

Syngenta Biotechnology, Inc.

10-B North Carolina Biotechnology Center

AlphaVax, Inc.

BioAbility, LLC

Biogen IDEC

Entegrion, Inc.

Qualyst, Inc.

Chemiceuticals

Reichhold, Inc.

Electronics/Nanotechnologies

Accurate Electronics, Inc.

Delta Products Corporation

Discover Technologies Inc.

DuPont Electronic Technologies

Southcot, Inc.

BOC Edwards

Zen-Bio

Chemicals

49

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45

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36 Humacyte

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33 47

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41

18 Cree, Inc.

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48

52

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62 Xintek, Inc.

Good Technology

IMC (USA), Inc.

- Environmental Science 42 Alion Science and Technology
- 25 General Engineering and Environmental of NC.
- Integrated Laboratory Systems, Inc. 37
- 51 National Institute of Environmental Health
- Sciences
- 51 National Toxicology Program
- 47 Tetra Tech, Inc. The Hamner Institutes 30
- 11 USDA-Forest Service-Southern Research Station
- **Financial Services** Credit Suisse
- 53 65 Fidelity Investments: Construction Site

IT/Informatics/Telecommunications/Pervasive

- Computing
- 29 Aten Inc
- 29 BrandPort, Inc
- 37 Caspian Networks 25 Chonis Systems
- 58 Cisco Systems, Inc.
- Collaborative Studio, Inc. 29
- Computer Sciences Corporation 22
- 29 Customized Technology Services Corporation
- 29 Device Solutions LLC
- 57 Ericsson, Inc.
- -48 Extreme Networks 47
- Geomagic, Inc. GretagMacbeth, LLC 25
- 29 i5inc.
- 12 International Business Machines Corporation
- (IBM) 29 Learning Machines, Inc.

 - Management Information Systems Group, Inc.
- (MISG) 29 Mi-Co

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61 Network Appliance 20

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- Network Development Group Nortel Networks
 - OC3 Entertainment
 - Pocket Science LLC
 - RadarFind Corporation

Center

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44 Bioptigen

47 Clinipace

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55 Eisai Inc.

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16

29

47 MASE, Inc.

A#

B*

S-10a Site 10a

S-1B Site 1B

S-20 Site 20

S-28 Site 28

S-29 Site 29

S-3 Site 3

BioMarck Pharmaceuticals, Ltd.

Duke Mass Spectrometry Facility

Eno Research & Development, Inc.

Cognosci, Inc. CPKD Solutions, LLC

Endacea, Inc.

GlaxoSmithKline

Howard Associates, LLC

Jenken Biosciences, Inc.

Stiefel Research Institute

Talecris Biotherapeutics

Teotten Diagnostics, Inc.

Monitors)

Biosciences Inc.)

Professional Business Services

Arneson & Associates

B W & Associates

Bank of America

Clean Design, Inc.

First Citizens Bank

First Flight Venture Center

Liggett Vector Brands, Inc.

Lineberry Research Associates

New Media Campaigns, Inc.

Parrish Brian Partners, Inc.

Practical Management, Inc.

Triangle Transit Authority (TTA)

44

Southeast TechInventures

Recreational Fields 1&2

Recreational Fields 3&4

Mechanical Specialties Contractors, Inc.

GSA Defense Logistics

Erevnion, Inc.

Services, Inc.

ICF Consulting

Spratt Financial

Teer Associates

Wachovia Bank

Wesinco, Inc.

Tricon Pharmaceuticals, Inc.

Turrett Labs (Medibeam Health

United Therapeutics Corporation

Xsira Pharmaceuticals (Formerly Norak

Carolina Group Insurance Services, Inc.

Fiducial-Comprehensive Accounting

Kucera Pharmaceuticals, Inc. Saha Pharmaceuticals

Synthon Pharmaceuticals, Inc.

- SnowFin, LLC
- Software Development Europe, Inc.
- STG, Inc. The Wireless Technology Group, Inc.
- 29 37 Triangle Research Collaborative
- Materials Science
- Bekaert Corporation
 - Bekaert Flex Circuits
- Non-Profit Organizations/Associations
- 32 American Association of Textile
- Chemists and Colorists (AATCC)
- 10-C Burroughs Wellcome Fund
- 44 International Union of Pure and
 - Applied Chemistry (IUPAC)
- 45 ISAF (International Service Assistance Fund)
- 27B Research Triangle Park Headquarters:
- Future Site 45 Kramden Institute, Inc.
- 10-E MCNC
- 34 Motor & Equipment Manufacturers
- Association
- 10-A National Humanities Center North Carolina GlaxoSmithKline 3
- Foundation 47
- North Carolina Healthcare Information and Communications Alliance
- 27A Research Triangle Foundation of North
 - Carolina **RTI International**
 - Sigma Xi, The Scientific Research
- Society 10-D Statistical and Applied Mathematical
- Sciences Institute
- 20 The Instrumentation, Systems, and Automation Society
- 27A Triangle Universities Center for Advanced Studies, Inc. (TUCASI)

Other

37 \$6

6

4

21

27.A

16

35

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19

62

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36

Medical Devices

Alnis BioSciences, Inc. BD Technologies/BD BioVenture

28

46

- Craig Davis Properties 37
- 15 EMC Corporation
- Instrumentation Associates 29 10-D National Institute of Statistical Sciences
- North Carolina State Education
- Assistance Authority 62
 - Pappas Ventures
- Radisson at RTP Sony Ericsson Mobile Communications
- (USA), Inc.
- Available Properties The Enrichment Center by Bright TMC Previous Triangle Metro Site Horizons S-1 Site 1
- The University of North Carolina
- Center for Public Television Triangle Life Science Center
- (TLS Center)
- Triangle Service Center, Inc.
- UAI Technology, Inc. Underwriters Laboratories, Inc.
- \$-30 Site 30 United States Environmental Protection S-31 Site 31 Agency
- \$-32 Site 32 United States Postal Service
 - S-33a Site 33a
- S-4 Site 4 S-7 Site 7 Pharmaceutical/Biopharmaceutical/
 - Aerie Pharmaceuticals, Inc.

The region's many assets contribute to its strengths. For instance, the region's universities and colleges not only are responsible for much of the region's innovative capacity, but they also have trained many of the workers in the high quality and diverse talent pool available locally to the industry. North Carolina's general business climate is also considered relatively more favorable than those of other life sciences clusters.⁴³

The region also has strong institutional support for entrepreneurs and life sciences entrepreneurs particularly. For instance, the Council for Entrepreneurial Development (CED) is a private non-profit program founded in 1984 with the goal of providing the Research Triangle area with the support and financing needed to grow new companies and create an entrepreneurial culture. It has over 4,000 members from over 1,000 companies in its membership.⁴⁴ To encourage those entrepreneurs, the North Carolina Technology Development Authority established a wet-lab business incubator in the Research Triangle.⁴⁵ The NCTDA morphed into the First Flight Venture Fund, managing the incubator and providing capital for start-ups and new product development activities in Research Triangle Park.

The Research Triangle Regional Partnership⁴⁶ (RTRP) is another organization that has been actively involved in supporting the region's life sciences cluster. The RTRP is a 13-county public-private partnership that promotes and facilitates cooperation between business, government and education. Initially established by the state legislature (with state funding support) as a marketing organization, the RTRP has emerged into the leadership organization for public policy making in support of the region's emerging technology clusters.

The state established another organization, the North Carolina Biotechnology Center, in the 1980s to support life sciences statewide. Headquartered in Research Triangle Park, the NC Biotechnology Center does not do any laboratory research or business incubation. Instead, the organization invests in supporting and strengthening the research capabilities within North Carolina's businesses and universities. It has a budget of \$13.1 million (FY06-07) and more than 60 staff members.⁴⁷

The region also hosts several industry associations, many of which are statewide, but focus much of their attention on the Research Triangle region. The North Carolina Biosciences Organization (NCBIO) was created in 1994 and has 60 member companies. It serves as an industry advocacy organization that lobbies the state legislature and Congress. NCBIO has 60 members and it conducts venture forums on behalf of the industry. The North Carolina Association for Biomedical Research (NCABR) promotes public understanding and support for bioscience research. NCABR, created in 1989, represents the academic research and teaching interests related to biomedical research. NCABR was one of the first organizations to develop innovative science education outreach programs designed to facilitate bioscience education and careers.

⁴³ Peter Pellerito, "A Blueprint for Life Sciences Industry Growth in the Research Triangle Region", prepared for Research Triangle Regional Partnership, 2003.

⁴⁴ <u>www.cednc.org</u>

⁴⁵ http://www.nctda.org/

⁴⁶ The RTRP is one of seven regional partnerships in North Carolina. It was created and is funded (although not entirely) by the state.

⁴⁷ <u>http://www.ncbiotech.org/about_us/index.html</u>

Cluster Weaknesses

North Carolina' economic downturn at the beginning of the decade contributed to several of the competitive challenges faced by the life sciences industry. The collapse of base industries such as textiles and furniture put a significant strain on the state's revenues. As a result, programs that supported small business development, including the University of North Carolina system and the North Carolina Biotechnology Center saw their budgets reduced. Between 2001 and 2002 the region also saw its venture capital funds decline from \$381 million to \$360 million. During that same downturn, the region's information technology sector endured dramatic downsizing, affecting the region's long-term competitive position in that industry and its competitive positioning in the bioinformatics field.

Other weaknesses that have been identified in the past include several key shortcomings with regards to the region's physical infrastructure. Not only was traditional infrastructure (e.g., roads and water) limiting development, but more notably regional leaders identified the lack of air passenger flights to Europe and the West Coast as a problem for the region in competing globally. This issue was seen as a hindrance to commercialization and new technology development activities. It also made it more difficult for the region's to attract venture capital because investors from outside the region defined it as "too far" away in terms of travel time.

Key Initiatives

Organizing Key Assets

In order to establish and grow the region's position in the global life sciences market, the regional leaders have undertaken several significant efforts to evaluate progress and identify ways to move forward. These efforts were led primarily by the RTRP along with other partners such as the NC Biotechnology Center and NCBIO. The first study in 2003, "A Blueprint for Life Sciences Industry growth in the Research Triangle Region," recommended strategies designed to ensure that the region maintained its position. The strategies that emerged out of this effort were designed to ensure that many of the region's key institutions (particularly in the public sector and higher education) were able to adapt to the changes affecting this dynamic industry. As a result, the strategies focused around four primary areas—commercialization, workforce, increasing the role of research universities and hospitals, and marketing.

The strategy recommendations relating to *greater commercialization* of life sciences innovations address several issues ranging from the availability of venture capital to ensuring the fiscal stability of many of the key partners and programs. For instance, the report recommended supporting legislation that would (a) allow the state to provide grants to new and expanding life sciences companies and (b) assist companies looking to manufacture new life sciences products. The report calls for more stable and improved funding for the North Carolina Biotechnology Center. It further recommended that the state support Golden LEAF Foundation (created from tobacco settlement money used for economic development projects) investments already being made to assist later stage life sciences companies entering the manufacturing stage of development. The study also noted the need to improve partnerships between regional and local governments to improve the efficiency of the zoning and permitting process for life sciences companies.

Furthermore, the report notes the importance of having the proper *workforce* in place to support the region's future growth in the life sciences. Higher education cannot always keep pace with the changing skill sets required in such a dynamic area like life sciences, and consequently these recommendations were designed to improve the communication and coordination between industry and higher education. The specifics of these recommendations included creating a resource that would allow regional partners to learn about what services and opportunities they make available in support of the life sciences, making access to the life sciences curriculum of the community colleges more accessible to potential students, developing life sciences curriculum for the region's K-12 system, and supporting plans for a university-based bio-manufacturing training center.

The Research Triangle region must also better engage *key partners and assets*. Specifically, the 2003 Blueprint recommended that the region energize the role of research universities and hospitals as participants in technology transfer partnerships. This involves providing financial incentives to encourage universities and teaching hospitals to take part in the commercialization process. In return for these incentives, the institutions would, in turn, establish performance standards and benchmarks. Given that universities and research centers are not structured to develop and market projects, the report identifies the need to actively engage the university and hospital leadership in taking a greater leadership role in industry-wide initiatives so they do not lose sight of the importance of technology transfer and commercialization.

The report also makes clear the need to *market and promote* the industry's growth in the region, state and nation. This marketing campaign was partially intended to attract new life sciences companies to the region. This involved creating a dedicated life sciences website for the region's economic development organizations so that they are better informed when attempting to attract companies to their locations. The marketing campaign was also designed to increase public and government awareness of current and emerging successes in the life sciences industry.

Getting ahead in the Life Sciences Industry

The recommendations that emerged from the Research Triangle's 2003 life sciences study sought to maximize the region's many assets and prepare the region for future life sciences growth. A later study conducted in 2006 -- *Innovations* @ *Emerging Intersections* -- included recommendations that were far more specific in scope and identified ways not only to enhance the region's competitiveness in the life sciences, but also to move the Research Triangle into the top tier of US life sciences clusters.

The report shows that the region's strengths within the life sciences area lie at the intersections of multiple technologies. As a result, the report recommends that the Research Triangle region focus its efforts on developing sub-sectors that draw on the region's many strengths. These areas include, Biodefense, Industrial Biotechnology, Clean Technology, and Neurotechnology. To support these sub-sectors the report recommends that the Research Triangle Regional Partnership and NCBIO convene focus groups that would identify the actions needed to grow each of these four sub-sectors. The report makes clear that succeeding in these emerging niches will require the region to actively engage new stakeholders -- such as representatives from the state's military bases -- that might not seem immediately relevant to these efforts.

Much like the earlier study, capturing a greater percentage of life sciences manufacturing activities remains a stated goal for the Research Triangle region. This is an area where the region already has a pre-existing strength, and it is also an area that

is expected to grow significantly in the future. Increasing bio-manufacturing employment also creates greater opportunity for wider segments of the region's workforce to benefit from the growth in biosciences—especially those located in the outlying rural parts of the region. In order to support this initiative, the Research Triangle Regional Partnership will monitor all new product testing and will initiate discussions with companies about their interest in manufacturing in the Research Triangle Region once new products enter preclinical testing.

As the region's life sciences activities continue to evolve and develop, engaging stakeholders remains an important activity. The 2006 report echoes this sentiment, but goes further by not only calling for broadening the level of engagement in the region, but also deepening some of these engagement activities. For instance, the report recommends that an advisory committee of industry leaders meet regularly with the region's economic developers to make the developers aware of changing industry needs and new opportunities. Extending these engagement activities also requires reaching out to stakeholders in the broader supplier community, contract research organizations and the healthcare delivery system. The goal in bringing them into the life science network's leadership positions is to open up new avenues for collaborative opportunities.

Growing the venture capital community also remains an important objective. While RTP has a strong venture capital community relative to other life sciences clusters, it remains in the second tier behind larger clusters located in San Francisco and Boston. For the region to truly establish itself in the first tier of the global life sciences industry, its venture capital community must continue to grow and expand. The report notes three steps necessary to support the region's continued growth. First, the Research Triangle Regional Partnership would facilitate the development and maintenance of an online inventory of the region's incubation spaces and opportunities. Second, regional leaders should continue its VC awareness and recruitment efforts through the Council for Entrepreneurial Development, but they were also encouraged to expand these efforts by including new markets and new partners. The RTRP life sciences cluster network was also encouraged to advocate for and support legislation that will improve the region's entrepreneurial environment.

The Research Triangle is also continuing to improve its marketing and promotional activities. These activities serve several purposes including better public understanding about the industry's value, engaging new stakeholders and making students and workers more aware of the opportunities available in the life sciences industry.

Lessons Learned

The Research Triangle offers several lessons for other aspiring life sciences clusters. The region shows that it is important make sure that the region has all of its basic assets in place such as universities, government support, private sector involvement, and venture capital. Venture capital and entrepreneurial support are particularly important. It is also vital that the regional leadership initiates significant marketing and information sharing efforts to let all of the region's key stakeholders know what is going on and what opportunities exist. However, what really allows a region to truly enhance its competitive edge is a high degree of coordination between all of the key stakeholders and organizations. Building these networks is an important key to regional success.

Once these regional coordinating networks are in place, the region can continue to build its basic assets such as entrepreneurial support, venture capital, workforce and the development and dissemination of its information. However, the Research Triangle example shows that moving forward requires regions to broaden their network and deepen key stakeholder engagement and interaction in that network. New stakeholders bring not only more information to the network, but also present new opportunities for development. For instance, by engaging North Carolina's military bases the Research Triangle region better positions itself to take advantage of the opportunities available in the bio-defense sub-sector. It is also important not only to bring new stakeholders into the network, but also to give them opportunities for leadership in that network. This is particularly important for stakeholders with large resources at their disposal such as research hospitals and universities, but also the supplier community which can bring new opportunities through its connections to other places outside of the region. Broadening and deepening the regional network therefore presents opportunities for previously unforeseen opportunities, as well as new information and knowledge.

Case Profile: San Diego

San Diego is one of the country's oldest life sciences clusters. Since the 1978 founding of Hybritech in the Torrey Pines Mesa area around UC-San Diego, the area has evolved from a relatively small Navy town into what is today one of the country's premier centers for life sciences research and activity. In addition to UCSD, the region is also home to universities such as San Diego State, University of San Diego, numerous community colleges and a large military and defense industry presence.

It is also one of the most organized such clusters in the United States. Through the activities of the region's life sciences industry association—BIOCOM, and the Connect program that was originally launched through the University of California at San Diego, the region has become, in many ways, the model for stakeholder collaboration and entrepreneurial support. As will be shown, these organizations and their initiatives are working to help San Diego meet the challenges of increased global competition by supporting San Diego's life sciences firms through initiatives relating to advocacy, workforce development, capital development and entrepreneurial support.

Cluster Strengths

San Diego has no shortage of innovative assets to draw upon, including a wide number of training and educational institutes. This includes UC-San Diego and its extension services, San Diego State University, the University of San Diego, San Diego Community Colleges, and the military. These institutions contribute to San Diego's deep pool of talent within the life sciences.

The region's many world-class research institutes and centers also work to attract top flight talent. At UC-San Diego, these centers include the Moores UCSD Cancer Center, the Rady School of Management, the San Diego Supercomputer Center, the Scripps Institute of Oceanography, the Skaggs School of Pharmacy and Pharmaceutical Sciences, the Sulpizio Family Cardiovascular Center and the UCSD School of Medicine. Beyond those centers at UCSD, the region is home to some of the world's most pre-eminent research institutes such as the Scripps Research Institute, the Salk Institute, the Burnham Institute, the Neurosciences Institute, the La Jolla Institute of Allergies and Immunology and the Sidney Kimmel Cancer Center. All told, San Diego has almost 40,000 researchers, 29,000 of which are located within 4 mile radius around UC-San Diego⁴⁸.

These research institutions attract and retain not only research talent, but also large amounts of research funding. In 2003 the San Diego metro area received \$1.13 billion in NIH funding, making it the nation's 4th largest recipient of NIH Funding⁴⁹. San Diego has also been able to effectively transfer technological innovations into the private sector. As of 2005, there were 120 start-up companies with UCSD licensed technology, the Scripps Institute was responsible for spinning off approximately 40 companies since the late 1980s, and 20 more companies were founded based on technologies developed at the Salk Institute⁵⁰. The success of San Diego startups gives the region a high profile for

⁴⁸ "San Diego: Ecosystem for Innovation", Presentation from Duane Roth, CEO of UCSD Connect at the 2005 ACCRA Annual Conference, June 16th, 2005.

⁴⁹ Economic Alliance of Greater Baltimore, "Biosciences in Greater Baltimore," June 2007.

⁵⁰ "San Diego: Ecosystem for Innovation", Presentation from Duane Roth, CEO of UCSD Connect at the 2005 ACCRA Annual Conference, June 16th, 2005.

venture capitalists so attracting venture capital is less of an issue for San Diego than it is for other life sciences clusters.

Beyond access to the assets, there are a number of additional reasons that San Diego has been so successful in developing its life sciences clusters. In particular, San Diego is widely perceived as having several cultural attributes that contribute to its success. For instance, San Diego is considered to be quite open to both new people and new ideas. It is also seen as having an entrepreneurial culture and being open to people taking risks. As will be described later, these cultural assets have been supported and strengthened by the work of organizations like BIOCOM and UCSD Connect which not only encourage and support industry collaboration and networking, but also provide direct entrepreneurial support.

San Diego also benefits by having a number of high-tech industries from which to draw. In addition to a vibrant life sciences cluster, San Diego also has a number of companies in telecommunications, information technology, energy and electronics. In addition, the region's large military presence has attracted a large concentration of defense contractors. These multiple industries provide many opportunities for firms to collaborate at the intersections of life sciences with defense-related uses of those technologies.

Cluster Weaknesses

Like other metropolitan regions, San Diego has new rivals for certain life sciences research activities located in other rapidly growing number of life sciences clusters. This creates heightened competition for both talent and capital. While talent often follows the best research opportunities, world-class researchers now have a wider array of places from which to choose. Even though San Diego offers numerous research opportunities and a high quality of life, it also has a very high cost of living—making housing less affordable for top talent—and a very congested transportation infrastructure. These latter factors are real impediments in attracting talent.

Greater competition also occurs in the need to secure adequate investment capital, as there are more places and more opportunities for investors than ever before. San Diego has historically been successful in attracting equity capital appropriate to all stages of company growth, but companies are continuously searching for adequate or new sources of investment capital. In the past, one identified weakness of San Diego's life sciences cluster has been an over-reliance on investors who are located outside of the region. As a result, there has been a push to develop more sources of locally controlled capital. These initiatives have been modestly successful, but growing a large pool of local investors remains one of BIOCOM's strategic priorities⁵¹.

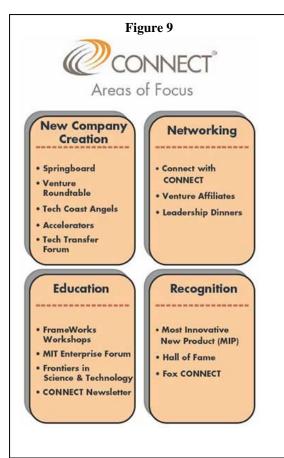
Other identified areas for improvement include simplifying the state's regulatory environment, ensuring a sufficient supply of water, increasing access to disposal sites for low-level radioactive waste, and continuing to increase the number of clinical science and laboratory programs available in the region.

Key Initiatives

In addition to the significant life sciences activity taking place in San Diego, the region is perhaps best known for its high level of organization and its successful commercialization efforts. These successes are best embodied in two organizations that

⁵¹ BIOCOM 2007-2009 strategic priorities, available at

http://www.biocom.org/Portals/0/FINAL%20PDF%202007-09%20Strat%20Plan.pdf .



have become models of stakeholder collaboration for the life sciences industry— UCSD Connect and BIOCOM.

The UCSD Connect program plays a vital networking role for the region's multiple life sciences assets. It was founded by UCSD in 1985 at the urging of the region's business community to link high-tech and life sciences entrepreneurs to the resources they need for success. It is now an entirely self-supporting organization that generates revenue through membership dues, course fees and corporate underwriting for specific programs⁵². It serves a dual role. First, Connect provides a conduit for the private sector to partner with many of the university's world-class research institutes such as School of Medicine, Jacobs School of Engineering, San Diego Super Computer Center, and Scripps and Salk Institutes. More broadly, it is one of the organizations that tries to ensure that the region's many stakeholders (i.e., research institutes, academic institutions, service providers, venture capital and investor capital community, and

government agencies) are all working together to effectively support commercialization of new ideas within the region.

Second, Connect provides services that are designed to meet the needs of entrepreneurs at all stages of growth. Connect's entrepreneurial support program has become a model for supporting and fostering entrepreneurship in the life sciences. The Connect Springboard program has become one of the most successful programs for supporting entrepreneurs at all stages of growth. It provides life sciences and high-tech entrepreneurs with free entrepreneurial assistance. Entrepreneurs accepted into the Springboard program receive three to eight weeks of coaching from one of Connect's "entrepreneurs in residence." Once completing these sessions, entrepreneurs are then invited to present their business plans to a group of experts tailored to their needs. These panels often include a venture capitalist, an accountant, a corporate and patent attorney, a marketing professional and an executive from a successful company in the same industry. The panel is designed to provide the entrepreneurs with a candid assessment of their plans. Following these discussions, the entrepreneur will meet with an entrepreneur in residence and design a strategic plan for the next 6 to 12 months⁵³.

Through 2005, 230 technology companies have graduated—of which 60 percent (or 135) are still operating. The Springboard program managers report that if a startup company can raise funding during the first 2 years after its graduation, the survival rate

⁵² <u>http://www.connect.org/about/index.htm</u>

⁵³ Connect Springboard program described on the Connect website: <u>http://www.connect.org/programs/springboard/index.htm</u>

rises to 88 percent. Overall, Springboard graduates succeed at a rate of 67 percent while, while nationally as few as 10 percent of high-tech companies survive. Overall 1,000 companies had received some kind of assistance through Connect and the companies have generated more than \$550 million in early and seed stage investment.⁵⁴ The Connect model is one of the most replicated nationally and even globally with similar programs being created in Scotland, Denmark, Norway and Taiwan among others. The State of Washington explicitly identified the Connect model as one the state would like to replicate.

In addition to supporting entrepreneurs, UCSD Connect has been involved in other areas as well. Much like BIOCOM, UCSD Connect has taken an active role in trying to attract and develop a deeper pool of venture capital and angel financing in the San Diego area. Connect has also worked to market and promote the industry by supporting an awards program and by producing a directory and regular newsletter. It has also facilitated industry advocacy for efforts for key issues such as the H1B visa program and changes in stem cell regulations.

UCSD Connect is not the only regional organization working in support of the San Diego region's life sciences cluster. BIOCOM plays an important role in advocating for San Diego's life sciences clusters and facilitating much of the region's networking activities. BIOCOM is San Diego's primary life sciences industry association. Its membership consists of over 550 companies as well as representatives from the service sector on which those companies depend. BIOCOM plays an important role in providing organization and voice to San Diego's life sciences cluster. BIOCOM has a staff of 18 full-time employees, and its funding comes from membership dues, events such as conferences and networking and educational forums. It also operates a for-profit purchasing group that allows its members to save money by using their collective purchasing power. In its 2007-2009 Strategic Plan, BIOCOM intends to focus its activities on three main areas—advocacy for the life sciences industry, capital development and workforce development.⁵⁵

In its advocacy efforts, BIOCOM plans to expand its membership reach to companies located in Orange County (immediately north of San Diego County). By adding new voices, the organization hopes to expand its influence with California state government as well as increase its engagement with the federal government. Also by diversifying its membership base, the organization gains more credibility as a spokesperson for the entire industry not just a segment of it.

In the future, BIOCOM will also continue its efforts to further develop the region's pool of investment capital. Past strategic plans called for BIOCOM to encourage more venture capitalists and institutional investors to locate in San Diego. The region has enjoyed success from these efforts, and now the organization is looking to continue working with its stakeholder community to further attract and grow this investor community in order for the region to sustain its growth.

BIOCOM has also worked on issues related to workforce development. Specifically, they have worked to connect the private sector and education providers so that they can collaboratively develop programs in support of the life sciences. They have also focused on building partnerships designed to help youth learn more about opportunities in the life

⁵⁴ "San Diego: Ecosystem for Innovation", Presentation from Duane Roth, CEO of UCSD Connect at the 2005 ACCRA Annual Conference, June 16th, 2005.

⁵⁵ BIOCOM 2007-2009 strategic priorities, available at

http://www.biocom.org/Portals/0/FINAL%20PDF%202007-09%20Strat%20Plan.pdf .

sciences. In addition, BIOCOM has helped in developing strategies aimed at attracting and retaining top talent to the industry.

Lessons Learned

Several key lessons emerge from the San Diego case study. Not only do the region's universities provide a source of talent and a place for research, but they also appear to understand that commercialization and technology transfer represent an equally important part of their core mission. As noted above, UCSD launched its Connect program in 1985 in conjunction with the private sector, and it is now widely regarded as a national 'best practice' case study for designing the university's role in supporting entrepreneurial efforts and promoting technology development, commercialization, and translation activities. UCSD Connect's high profile has helped to emphasize the importance of commercialization not only at UC-San Diego, but also at all of the region's universities and research centers.

The other key lesson from San Diego is the importance of networking and organization. Organizations like Connect and BIOCOM are actively involved in making the necessary connections between all of the region's key stakeholders. They also provide newcomers a way to become more actively involved and engaged in the cluster. Moreover, they are high profile organizations that give the region an effective voice to advocate for the region's life sciences industry.

Case Profile: San Francisco

Although the term "World-Class" is often overused, there is no denying that the San Francisco Bay Area possesses a world class life sciences cluster. San Francisco represents one of the country's most dynamic and diverse economies. It is an area that has an entrepreneurial culture and has long been held up as a model of industry and university collaboration. These assets have allowed the San Francisco Bay Area to develop perhaps the country's largest and oldest life sciences clusters.

The San Francisco case study will show that in the face of growing global competition, even leading life sciences clusters must continue to find ways to maintain and improve their competitive position. In San Francisco's case, efforts have been made to increase the number of supports for potential entrepreneurs. The Bay Area has also sought to strengthen the bridges between the region's stakeholders as a way of improving their advocacy efforts. This often involves widening the pool of relevant stakeholders.

Cluster Strengths

The Bay Area has no shortage of assets to support its regional life sciences industry. It has five major universities that are all actively engaged in life sciences research— Stanford, UC-Berkeley, UC-San Francisco, UC-Santa Cruz and UC-Davis. The Bay Area is also home to several major research institutes including the Institute for Quantitative Biomedical Research (a collaborative venture between UCSF, UC-Berkeley and UC-Santa Cruz) and national labs such as the Lawrence Livermore National Laboratory and the Lawrence-Berkeley National Laboratory.

The region is also home to three medical schools at Stanford University, UC-Davis and UC-San Francisco. The Stanford Hospitals and Clinics include the Stanford University School of Medicine, the Stanford Cancer Center and the Lucile Packard Children's Hospital. The UC-Davis School of Medicine is relatively more oriented toward treatment than basic research, particularly with regards to treating rural populations. That said, it has still attracted \$80 million in NIH funding.

Among the Bay Area medical schools, the UC-San Francisco Medical School is not only the region's largest, but it is also one of the country's largest research and teaching hospitals. It ranks third in NIH funding, and has more patents than any other unit of the University of California System. It has seven primary sites throughout San Francisco and Fresno, employs roughly 10,000 faculty and staff and has a \$1.2 billion budget⁵⁶. It is also scheduled to expand its activities as UCSF has announced that as part of its UCSF Medical Center at Mission Bay, it will construct a \$1.2 billion hospital complex that will focus on care for women, children and treatment for cancer⁵⁷. The hospital complex is scheduled to open in 2013.

The Bay Area has proven enormously successful in attracting both NIH funding for basic and early stage research as well as the venture capital needed for the successful commercialization of technological innovations. The Bay Area received over \$1 billion in NIH funding in 2003, making it the fifth largest recipient of NIH funding nationwide⁵⁸. The region is also the undisputed leader in securing venture capital in biotechnology. Between 2002 and 2006, the San Francisco-Silicon Valley received over \$5.1 billion in

⁵⁶ <u>http://medschool.ucsf.edu/</u>

⁵⁷ http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/04/02/BAG04OVSED1.DTL

⁵⁸ Economic Alliance of Greater Baltimore, "Biosciences in Greater Baltimore," June 2007.

biotechnology-related venture capital. This figure represents over 25 percent of the venture capital invested nationwide during the same period. By comparison, the Boston-New England region was the second largest recipient of venture capital funding at \$3.6 Billion⁵⁹.

Given that it is home to Silicon Valley, the Bay Area also has one of the country's most dynamic and innovative economies. Unlike other areas that have a concentration in a certain life sciences sub-sector, the Bay Area has strengths in a wide array of life sciences activities. This builds on a strong economic base in which life sciences is integrated with on-going research related to chemicals, engineering, electronics, software and the physical sciences. This creates many different opportunities for innovation to emerge at the intersection of those activities. As a result, Bay Area firms have found opportunities in a wide variety of therapeutic, diagnostic, medical device and enabling technologies. This diversity of activity insulates the region from downturns in any one given sub-sector.

The sheer volume of activity and research opportunities has allowed the region to not only produce, but also attract the talent that the life sciences industry needs to thrive. Combined the San Francisco and San Jose metropolitan areas have more than 60,000 workers in the biosciences industry, with the bulk of those workers in Research, Testing and Medical Labs, as well as in Medical Devices and Equipment firms⁶⁰.

Cluster Weaknesses

Much like the Massachusetts Life Sciences cluster, the San Francisco cluster faces difficulties arising from heightened competition. The Bay Area must compete for talent on a global scale, and as more life sciences clusters emerge worldwide, attracting this talent will become increasingly difficult. This is also due in part to the maturation of many firms in the region's life sciences industry. As these firms grow and develop, they have greater capital requirements. As a result, the region must continue to attract a disproportionate share of risk capital.

Trends in the venture capital market also create challenges for the Bay Area's less mature, startup firms. The current venture capital market prefers quick discovery over high potential (but often long term) discoveries. In the Bay Area, many small companies are finding it difficult to achieve those quick discoveries due to a lack of short-term, wet lab facilities.⁶¹ Small firms are unable to afford these facilities on their own, and more of these facilities will be required for the region to continue generating new companies.

Much like other large, intensely developed areas, the region has also experienced difficulties due to the high costs, particularly with regards to property, and the chaotic zoning regulations. This is not only a potential disincentive to businesses looking to locate in the region, but it also makes it difficult to attract talent to the region. The state's business start-up and building permits systems are both considered to be quite complicated. The time to market already makes commercializing life sciences innovations difficult and expensive. Advocates maintain that making the permitting and

⁵⁹Economic Alliance of Greater Baltimore, "Biosciences in Greater Baltimore," June 2007.

⁶⁰ Battelle Technology Partnership Practice, "Growing the Nation's Biosciences Sector: A Regional Perspective, A Companion Document to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006" prepared for BIO—Biotechnology Industry Organization, January 2007, http://bio.org/local/battelle2007/BIO2007RegionalPerspective.pdf.

⁶¹ The Monitor Group, "Taking Action for Tomorrow: Bay Area Life Sciences Strategic Action Plan", May 2003.

regulatory system more streamlined would be an important step in reducing the barriers to innovation and commercialization.

Key Initiatives

The Bay Area represents one of the world's premier life sciences clusters and as a result, it has fewer issues to address than other life sciences clusters. In a 2003 report, the Monitor Group identified several areas that the region should address. For instance, it noted the need for a greater cluster voice, citing BIOCOM in San Diego as a model for organizing a regional cluster to speak with one voice.

Within the Bay Area region, BayBio—the Bay Area Bioscience Center, is one of the more active industry associations and organizers. BayBio organizes networking events for the region's key stakeholders and also facilitates regional advocacy efforts. Recently, the organization's advocacy activities have focused around improving the permitting process required for companies in the life sciences. For instance, BayBio worked to make the state's permitting and regulatory system more user friendly for life sciences companies. This involved getting more information that specifically related to the life sciences industry on CalGold. CalGold is the state website that provides information about the types of permits and regulatory approvals required to start businesses or build new facilities.

In its report, the Monitor Group report also noted the need to simplify mechanisms for cross-university course registration. In Boston, students at Harvard are allowed to take courses at MIT and other nearby universities. In the Bay Area, there are some examples of university articulation agreements, but it is not systematic. For example, since 1971, UC-Berkeley and UCSF have had a joint medical program. This 5-year M.S./M.D. program is intended to train both physicians and leaders so that in addition to the science, they are introduced to business, sociology and ethics principles related to healthcare and medicine. The program requires students to take three years of coursework at UC-Berkeley and the final two years at UCSF⁶².

In spite of the region's strong entrepreneurial climate, regional leaders still feel a need to provide more support for entrepreneurs. At the beginning of the decade, UCSF launched its Center for Bio-entrepreneurship (CBE) to encourage entrepreneurial ventures among its faculty members. The CBE is designed to enable UCSF faculty to turn their discoveries into commercial ventures by providing them with the necessary knowledge and resources. It also attempts to build cross-disciplinary expertise by connecting faculty with academic and entrepreneurial mentors. The CBE is part of the Institute for Quantitative Biomedical Research.

Lessons Learned

Many of the issues facing other places are less pressing in the Bay Area. That said, the Bay Area leaders appear to realize that their pre-eminent place on top of the world life sciences industry is not guaranteed forever. Consequently, they must continue to improve the region's competitive assets in order to stay ahead. This requires improving regional efforts to support commercial and entrepreneurial ventures.

The region's life sciences industry must also speak with a more unified voice in support of their issues. Strengthening this voice will require not only building stronger consensus on the region's needs, but also engaging new stakeholders. For instance, the

⁶² <u>http://jmp.berkeley.edu/index.htm</u>

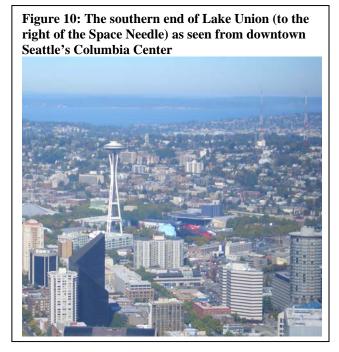
stakeholder community could be expanded to include not only more capital providers in the venture capital community, but also relevant people in professional services like real estate and law.

Case Profile: Seattle

The greater Seattle area is well known for its major corporate giants – Boeing and Microsoft – but it may be more highly regarded for its innovative and entrepreneurial culture. The region has a number of key national biotechnology and related information technology companies such as Amgen, Merck, Intel, GE Medical Systems, Siemens, Philips, Cray, Hollister-Stier and IBM Life Sciences⁶³. It also has several strong research universities and research centers that provide a foundation for the region's commercial success. Much of these activities are focused in Seattle and the South Lake Union

neighborhood specifically. The South Lake Union area, immediately north of the city's downtown, has become a de facto research park, and the sight of much of the state's life sciences activities. Overall the Seattle area has approximately 17,500 workers in 160 life sciences companies.

Like many places, Seattle is feeling the pressure that arises from growing competition both in the US and abroad. Regional leaders do not view the region's innovative assets as being used to their fullest potential. In framing the area's future vision, regional and state leaders are increasingly placing life sciences at the cornerstone of their economic development efforts. They see Seattle as being uniquely



positioned to address the convergence between information technology and the life sciences. In recent years, efforts have been made to increase competitiveness in the life sciences by laying out ways to better exploit the region's many assets. Washington's state government has been particularly active by initiating many the efforts designed to maximize the benefits derived from the state's extensive research capacity.

Cluster Strengths

As noted above Seattle, and Washington State more generally, has strengths in both the life sciences and information technology. Regarding the latter, the Seattle area is home to world's largest software company in Microsoft and Microsoft Research which is viewed as a leading computer science research organization. Much of the state's activities are focused in Seattle where there are 15 research organizations, three research hospitals and a major public research university in the University of Washington. These research organizations include among others the Fred Hutchinson Cancer Research Center, the Allen Institute for Brain Science, the Seattle Biomedical Research Institute, the Benaroya Research Institute. Seattle is also home to the Bill and Melinda Gates Foundation, the world's largest philanthropic institution.

⁶³ The Technology Alliance, "Bio 21: Washington State's Initiative in 21st Century Health", January 2004.

The region has also proven successful in attracting NIH funding. In 2004 the University of Washington attracted \$473.4 million of NIH funding, while the Fred Hutchinson Cancer Research Center attracted another \$207.3 million⁶⁴. Significant investments are also being made to increase the region's research capacity. The University of Washington Medical School is investing in expanding its capacity through the construction of a \$170 million interdisciplinary research space in the South Lake Union area in Seattle. The University of Washington has also constructed a Bioengineering-Genome Sciences Building in Seattle. This is a \$150 million building that was funded in part by a \$70 million gift from the Gates Foundation⁶⁵.

Outside of the Seattle region, Washington State has a number of other key relevant assets that contribute indirectly to the metropolitan area's growth. For instance, the US Department of Energy's Pacific Northwest National Laboratory (PNNL) in Richland undertakes advanced research related to cellular and molecular imaging. The PNNL has also collaborated with Washington State University-Tri-Cities campus to build a \$24 million dollar Bioproduct, Sciences and Engineering Laboratory.⁶⁶

One mechanism in which the state participates actively in technology commercialization activities is the Washington Technology Center, a statewide nonprofit group affiliated with the University of Washington. WTC fosters economic development and provides

valuable services to Washington companies through three program areas. More importantly, WTC provides leadership in advocating technology commercialization issues while managing a variety of applied research and commercialization programs designed to promote the economic value of life sciences and other technologies, especially nano-technology and energy.



Cluster Weaknesses

Two overarching issues have held Washington State back⁶⁷. The first is a perceived lack of commitment, financial and otherwise, on the part of the state government. The state ranked relatively low in per capita spending on R&D. Historically, this made it difficult for research institutions pursuing federal funding that required a "hard match" of state dollars as a prerequisite for federal funding. One of the consequences of this limited funding was that it made it more difficult for the state to attract the greatest research talent. Experience suggests that research talent flows to where the greatest research opportunities exist.

⁶⁴ Enterprise Seattle

⁶⁵ BIO, "Washington Biosciences Initiatives", April 2006. Available at <u>http://www.bio.org/local/battelle2006/Washington.pdf</u>

⁶⁶ BIO, "Washington Biosciences Initiatives", April 2006. Available at http://www.bio.org/local/battelle2006/Washington.pdf

⁶⁷ The Technology Alliance, "Bio 21: Washington State's Initiative in 21st Century Health", January 2004.

A second issue identified as a weakness was the lack of an organized public-private partnership. Without this infrastructure, the state has not been able to develop a coherent strategy or provide sufficient communication to relevant stakeholders. This shortcoming prevents Washington State from taking full advantage of the many innovative assets at its disposal. This also has prevented the state from fully capitalizing on the commercial potential of its available assets. As in other locations, many stakeholders feel that commercialization of life sciences has not been commensurate with the amount of research capacity.

Key Initiatives

Efforts to begin addressing those identified weaknesses in the Washington State life sciences industry began during the previous gubernatorial administration. In 2003, Governor Gary Locke provided funds to begin a planning process designed to identify ways to better exploit the state's strengthens in life sciences and information technology. The result of that effort was the 2004 Bio 21 report.

The Bio 21 recommendations sought to use the state's research capacity to improve both economic development and healthcare. Its strategies focused around five key areas—leveraging more federal research funding, further building on the state's research assets, accelerating the commercialization process, improving healthcare by moving discoveries into practice more quickly, and maintaining a research-friendly business climate. These strategies were also intended to promote increased collaboration between the state's science and technology agencies, institutions and the private sector. In particular, this includes the technology transfer offices of the state's major universities such as UW's Office of Intellectual Property and Technology Transfer and WSU's Office of Intellectual Property Administration.

More recently, Governor Christine Gregoire's office has picked up some of the ideas that emerged from that report and launched a \$350 million Life Sciences Discovery Fund. Much of the funding for this initiative is derived from tobacco settlement money. The state is also looking to generate private contributions to this fund, and has already secured contributions from Amgen, the Bill & Melinda Gates Foundation, the Paul G. Allen Family Foundation and Regence BlueShield. The current executive director is a retired President of the University of Washington and a former head of UW's bioengineering program⁶⁸.

The main objectives of the fund focus around creating successful companies, recruiting top researchers and using the Life Sciences Discovery Fund to leverage other resources. It will evaluate grants on several criteria including potential health care impact, employment creation potential and contributions to more balanced regional development.

It has also initiated the development of a new strategy—*The Future of Life Sciences in Washington*—that was released in October 2006. The Washington Biotechnology and Biomedical Association (WBBA) serves as one of the lead agencies in overseeing the implementation of the strategy's 35 recommendations. The strategy developed in *The Future of Life Sciences in Washington* report is the product of the input of over 100 of the state's key stakeholders over the course of the year. It takes into consideration the issues identified in the Bio 21 report, which was presented to the previous Governor, and

⁶⁸ BIO, "Washington Biosciences Initiatives", April 2006. Available at <u>http://www.bio.org/local/battelle2006/Washington.pdf</u>

the 2005 Life Sciences Summit. The strategy focuses its 35 recommendations around five key areas.

The first area involves building the state's research capacity. The primary purpose of these recommendations is to increase the funding of the state's primary research institutions including UW and WSU. These funds will be used for equipment and facilities, as well as to recruit and support top researchers and students. It will also fund high potential, early stage applied research. Another key recommendation is to facilitate public/private collaboration between research firms and institutions by providing places where they can be co-located so as to share equipment and instrumentation. One model that Washington seeks to replicate is the Centennial Campus at North Carolina State University in Raleigh.

The second area involves increasing the commercialization of technological innovations. Many of the relevant recommendations in this area involve adopting earlier recommendations made in the Washington Economic Development Commission's report on technology commercialization. Those recommendations focused on increasing the pace of commercialization for early stage discoveries. As a result, the report recommends using resources to encourage more institutional and industry collaboration. It also recommends enhancing and expanding the entrepreneurial support programs available to university researchers, faculty and students. In addition to the Washington EDC recommendations, the report also seeks to make the WBBA a clearinghouse for all the relevant life sciences information. The report cites the North Carolina Biotechnology Center (located in Durham) and the UC-San Francisco Center for Entrepreneurship as models. The state would also seek to encourage more mentoring opportunities for entrepreneurial mentoring programs. The WBBA will also create a networking strategy modeled after the UC-San Diego Connect program.

The third area focuses on developing more sources of investment capital. This will involve WBBA creating a dedicated staff position to coordinate all resources for life sciences entrepreneurs. It will also include working with the Washington State Investment Board and other in-state pension funds and foundations to direct more of their investments into Washington State companies.

Several recommendations are also intended to improve the state's business climate, particularly for start-up companies. To this end, the strategy includes proposals to create tax and incentive programs that help life sciences companies launch, grow, recruit and retain talent. It also seeks to improve the understanding within state government about the industry's needs and the opportunities it can create.

Finally, the report recommends ways to better meet the life sciences industry's workforce and educational needs, as well as improving public understanding of the industry. Among these recommendations include having the Workforce Development Council of Seattle-King County produce a regularly updated analysis of the life sciences industry's current and future occupational needs, as well as create a database for the public and job seekers about opportunities in the industry. In addition, the WBBA would underwrite a Life Sciences Industry-Education Council that would promote collaboration between business and educational institutions to design and promote educational programs in the life sciences and healthcare fields. There is also a recommendation for the WBBA to establish a comprehensive communications plan to support and promote the industry throughout the state.

Ultimately the goals of this statewide initiative are intended to bring together the life sciences community's resources, focus state support and optimize the state's collective strengths to maintain its competitive position.

Lessons Learned

Several key themes emerge from efforts to further develop the life sciences industry in Seattle. The first is the importance of coordination and leadership, particularly at the state level. In Washington State, it appears that the Governor's office has stepped forward to convene key stakeholders to develop a comprehensive strategy. The gravitas of the Governor's office was required to bring key regional stakeholders to the table. The commitment of a significant amount of state money is also helpful in getting people's attention and showing that the state is truly committed to making effective change. The long-term efficacy of the state strategy remains to be seen, and State leadership will not be enough. It will require the continued participation of many stakeholders from a variety of constituencies to succeed.

Conclusion

These case studies reveal several inter-related themes:

Successful life sciences clusters have strong leadership from multiple sources

- The state and business community are typically the primary leaders in pursuing and organizing efforts, but university and hospital leaders must commit their institutions to the effort.
 - State government can provide high profile leadership, attention grabbing resources and funding, and funding to support organizational capacity.
 - The business community often pushes for initiatives to take place. It also plays an important advocacy role either through large firms or industry associations.
 - Universities and hospitals rarely lead region-wide initiatives, but they are the critical participants and must be involved in high-profile roles in the organizational stages.
 - Local economic development organizations are often participants, but rarely lead due to their lack of resources and specialized knowledge.
- An important first step is for the leadership group to define the region's life sciences assets and advantages, quantify the sector's importance to the economy, and build consensus for a wider intervention.
 - If the consensus states that the region is heading in the right direction, then the focus should be on tactical leadership to address specific issues.
 - If the consensus states that the region is heading in the wrong direction, then the region may require strategic leadership to address broader issues.

Perceptions of a regional life sciences cluster can affect its continued development

- If the importance of the life sciences cluster is neither well-defined nor quantified, the lack of visibility in both the business community and public sector will affect the amount of support and resources it receives.
 - Both legislators and the public must view the industry as an important activity.
 - Promoting successes and specializations attracts the attention of the risk capital community.
 - High profile research initiatives help attract world-class researchers and talent.
 - Information about quality employment opportunities attracts workers into technical occupations.
- Several key issues should be addressed:

- The case must be made for the importance of the industry to the overall economy in terms of direct jobs and spending, economic impact, and linkages to other sectors.
- Hospitals and universities offer real opportunities for economic development – in particular, the healthcare sector is not just the product of population growth.
- These institutions generate employment opportunities at all levels.
- The life sciences sector can and should be defined broadly to identify the important region-specific linkages that can be used to identify competitive advantages.

Opportunities exist at the intersection of different technologies and industry sectors

- Successful regions connect the life sciences to other technological areas. Examples include bio-informatics and bio-defense. Whether it is plastics manufacturing expertise, a strong finance and insurance sector, or an agricultural base, it is important to think about how a region's strengths can be linked to life sciences initiatives.
- Similarly, successful life sciences clusters develop niches or unique areas of competitive advantage; areas that do not find niches will always play catch up and never get ahead.
- Creating opportunity at the intersection of technologies, requires engaging a wider set of stakeholders, even if those stakeholders do not appear to be immediately relevant to the life sciences.

Improving technology commercialization efforts is a core activity

- Commercialization is problematic for many regions because it is a function that is often outside of the core mission of hospitals and universities.
- The region's stakeholders much reach a consensus that these activities are important.
- Successful commercialization efforts require strong, high profile leadership that can work across silos and overcome the difficulties presented when working on activities outside of an institution's core mission. Low profile programs fail because their activities are viewed as bureaucratic work.

A centralized source of information to support the unique operational needs of life sciences businesses is valuable

- The high degree of regulation associated with life sciences activities makes business development relatively more complicated for the life sciences than for other industries.
- Many places have sought to create a "One Stop Shop" for all information regarding permitting, regulation and the availability of sites, buildings, funding and technical assistance.

- Financial, management, and professional and business services firms that specialize in assisting life sciences companies should also be included.
- The best organizations also offer connections to the university and healthcare community.
- The creation of centralized data sources often occur at the urging of the business community and are often structured as a public-private partnership.

All regions have a strategy for attracting risk capital

- Strategies often depend on the maturity and diversity of the regions respective industry.
 - Established clusters may focus primarily on facilitating connections between venture capital and regional businesses or entrepreneurs.
 - Less established places may focus on establishing regional angel investment networks and promoting the region to venture capital firms.
- Deal flow will often change the perception of the region in the eyes of the marketplace.

Addressing unique real estate and facilities needs is also typically an element of regional life sciences initiatives

- There are many benefits to be gained by the co-location of research assets and technology users. Accordingly, several regions have embarked on ambitious real estate development projects in order to facilitate this co-location in cooperation with universities.
- Putting flexible, yet specialized, facilities (e.g. wet labs) in place can be expensive and a barrier to small firm development.
- It is important to recognize that a life sciences cluster's facility needs will change as the cluster matures and develops.
- The real estate community could prove to be an important part of the stakeholder community.

In sum, medical, research and education institutions are critical players in regional life sciences initiatives, but, unexpectedly, they generally do not play primary leadership roles in structuring the overall effort. Exceptions are in smaller regions in which they are the leading institutions and/or employers. Instead, state government and the business community typically provide the initial push, with hospitals and universities holding a prominent place at the table.

The role of these institutions can be enhanced by quantifying and promoting their important role in the regional economy, establishing organizations that connect these institutions to the broader business community (not necessarily limited to the traditional life sciences businesses), providing strong, high profile leadership for their commercialization programs and measuring their results, and evaluating the viability of real estate developments on or near their campus to support both technology cooperation and business development.