



ANGLE Technology Group

**Health Enterprises Network
Health Economic Research Study**

Draft Final Report

Health Enterprises Network

Louisville, Kentucky

Prepared by ANGLE Technology Group

May 20, 2006



ANGLE Technology Group

May 20, 2006

Mr. Tom McMahon
Executive Director
Health Enterprises Network
614 West Main Street, Suite 6000
Louisville, KY 40202

Dear Mr. McMahon:

Re: Louisville Health Economic Research Study

We are pleased to submit the Draft Final Report on our Louisville Health Economic Research Study, conducted in collaboration with Dr Paul Coomes of the University of Louisville.

We appreciate the time and participative efforts you and your staff have provided to us during this project.

Yours sincerely,

Alyson Onstad
Senior Consultant

Health Enterprises Network

Health Economic Research Study

Contents	Page
1. Executive Summary	3
2. Introduction	7
3. Context for Assessment	9
<i>Research Base</i>	9
<i>Technology Companies</i>	9
<i>Entrepreneurial Environment</i>	10
<i>Physical Infrastructure</i>	10
<i>Workforce Development</i>	11
<i>Leadership and Networks</i>	11
4. Methodology	12
<i>Interviewee Selection Process</i>	13
5. Louisville's Health-related Economic Base	14
6. Analysis of the Innovation System	16
6.1 <i>Research Base</i>	16
6.2 <i>Technology Companies</i>	17
6.3 <i>Entrepreneurial Environment</i>	19
6.4 <i>Physical Infrastructure</i>	20
6.5 <i>Workforce Development</i>	20
6.6 <i>Leadership and Networks</i>	21

7. Additional Findings: Research and Development.....	22
7.1 Research strengths, focus areas	22
7.2 Clinical trials and industry funding	22
8. Summary and Recommendations	24
8.1 Summary	24
8.2 Recommendations – Healthcare Services	25
8.3 Recommendations – Life Sciences	27

APPENDIX I: Economic Base data

APPENDIX II: Interviewee List

1. Executive Summary

The Health Enterprises Network mission is to champion and foster the growth of the region's health-related economy, and support a vision to be recognized as a "location of choice" for health related business, researchers, educators, investors, and consumers.

In 2001 an initial economic study was conducted for the Health Enterprises Network, providing a baseline of health-related economic data for the entire health-related industry in the Louisville area as well as comparative city data. In 2006, the Health Enterprises Network now seeks a progress update to the report, as well as supplementary research to help define business growth opportunities and help guide the development of a strategic business plan.

The Health Enterprises Network has contracted with ANGLE Technology to:

- ◆ Assess Louisville's health-related economic base
- ◆ Evaluate the level of innovation and collaboration within two health-related market sectors: Healthcare Services and Life Sciences
- ◆ Define Louisville's strengths and weaknesses in life sciences research and development
- ◆ Compare economic activity in the Louisville metro area to other selected metro areas
- ◆ Suggest general steps to take that will help to grow the region's health-related economy
- ◆ Provide a basis for development of a strategic business plan

Methodology

Several factors were reviewed to assess Louisville's five year progress toward the stated vision and to identify opportunities for growth. Dr. Paul Coomes of the University of Louisville provided a five-year update on a wide array of economic data on the health-related economy. To supplement this data a thorough qualitative assessment was conducted by interviewing 30 key stakeholders. The study findings in this report represent the insights and opinions voiced during the interviews.

The theme of the interviews centered on innovation and collaboration, with the intent to identify the region's strengths, weaknesses, needs, and opportunities. Using both the quantitative and qualitative data, an "innovation system" analysis was conducted.

General Findings

Our interviews identified both near-term and longer-term business growth opportunities for the healthcare services and life sciences market sectors.

- ◆ Louisville’s healthcare services sector is much more established and recognized than its life sciences sector. Louisville has a healthy range and size of existing companies, including the headquarters of two Fortune 500 firms, Humana and Kindred Healthcare.
- ◆ Dr Coome’s study indicates Louisville ranking third among 16 metro areas in headquarters of privately held, publicly traded and not for profit healthcare services firms. Louisville also ranks third among 16 metro areas in nursing home and long term care companies.
- ◆ Regarding the near-term, we concluded there are untapped opportunities for Louisville to further leverage existing healthcare services key assets. While much activity has occurred in the healthcare services sector, we believe Louisville should place more emphasis on leveraging these assets.
- ◆ In comparison, Louisville’s life sciences sector is less mature with many fewer establishments. Additionally, this sector inherently requires a longer time-to-market business model than healthcare services. We found strong support to further the growth in life sciences research, which has gained significant momentum over the last five years.
- ◆ Several key assets and visible public sector programs have been put in place to position Louisville for longer-term economic growth in the life sciences and to refine commercialization efforts for these longer-term growth opportunities. These assets include the University of Louisville’s “Bucks for Brains” program which recruited key scientists to help drive the National Institute of Health funded research rankings from 204th to 103rd in the last eight years.
- ◆ In the past five years significant efforts and funding have been allocated to building a physical and entrepreneurial infrastructure for life sciences, including more than \$400 million worth of research space, the formation of 14 start-ups, and the establishment of venture and seed capital funds.

Below is a summary of some of the key improvement areas identified in this study, along with their corresponding recommendations.

Leveraging assets: Louisville is not fully leveraging the existing healthcare services assets, including strong company presence, management talent, and relationships.

- ◆ Address the need to leverage existing assets in Louisville for additional healthcare technology and healthcare service outsourcing opportunities. Arrange meetings among university leadership and healthcare organizations to identify opportunities for joint research and company creation. Collaborate on grant proposals to facilitate leveraging opportunities.
- ◆ Consider developing a healthcare services concentration within the university’s entrepreneurship program; include internship opportunities with the local healthcare service companies.

- ◆ Discuss a strategy and plan with UPS to develop niche market opportunities. For example, approach medical technology/biologics companies nationwide to identify shipping, distribution, and inventory needs.

Healthcare services incentives: Public sector support and initiatives are focused more heavily on life sciences. The healthcare services sector can apply “lessons learned” from life sciences by creating business attraction incentives.

- ◆ Work with the Louisville investment community to establish an Angel Investor Network for healthcare services investors to review and qualify deals, support business plan development, and act as investor liaison.
- ◆ Create an incentive package to attract existing healthcare service executives of mature organizations from other locations to establish and build new healthcare service companies in Louisville. Interview executives to determine incentive requirements and methods to encourage adoption.
- ◆ Advocate for tax incentives to attract headquarters operations, especially those with high payrolls but lower employees counts (specifically address the requirement of 15 jobs within two years to access Kentucky incentives).

Life science infrastructure: Existing life science commercialization gaps include a lack of high-risk/early stage capital, a lack of available serial entrepreneurs, and a “thin” pool of manufacturing establishments and expertise.

- ◆ Explore the creation of a “u-angel” investment fund comprised of university alumni, a model under development at George Washington University in Washington DC. Work with partners like the Kauffman Foundation and National Association of Seed Venture Funds (NASVF).
- ◆ Develop a mentoring program for young entrepreneurs/CEOs of start-ups. The Health Enterprises Network should consider visiting the Greater Cincinnati Venture Association to evaluate their model for Louisville. Develop an incentive package to draw experienced start-up CEO’s to the region.
- ◆ Work with the state to develop a state tax incentives package for out-of-state corporate recruits that addresses challenges with inventory taxes.

A common vision: Louisville needs a united vision on economic development initiatives. A general lack of awareness exists on health-related business growth strengths, opportunities, and the “Louisville story”.

- ◆ HEN should engage with innovation participants, including representatives from the state, healthcare business leaders, and the university. HEN can build on the

results of this study to help define the target sub-sectors, articulate the vision and develop a system to measure progress.

- ◆ Engage Louisville's top 30 healthcare services executives in business attraction. Seek their support in further raising the profile of health services sector by providing testimonials and making presentations to companies they can influence via their service as a director, participation as an investor, etc.

Through the study interview process, many excellent suggestions were received, such as headquarters tax incentives and personal income tax reform strategies. Many of these suggestions, along with their implementation details could be used as specific elements in a comprehensive business plan to grow the health-related economy in Louisville; this is the next strategic step after the completion of this assessment of the health-related economy.

2. Introduction

The Health Enterprises Network is an economic development-focused business network formed by the leadership of Louisville's health-related economy. Examples of health-related businesses include hospitals, health services providers, health-related information technology companies, medical device manufacturers, and professional service providers. The Health Enterprises Network mission is to champion and foster the growth of the region's health-related economy, and support a vision to be recognized as a "location of choice" for health related business, researchers, educators, investors, and consumers.

In 2001 an initial economic study was conducted for the Health Enterprises Network by Dr. Paul Coomes, providing a baseline of economic data for the health-related economy in the Louisville region. The report also included comparative data for Louisville and its traditional 15 competitor cities. In 2006, the Health Enterprises Network now seeks an update to the report, as well as supplementary research to support and guide the development of a strategic business plan.

The goals of this health economic research study which are addressed by this report, are to:

- ◆ Assess Louisville's health-related economic base
 - Provide an update to the 2001 economic data report
 - Include new comparative indicators for the economic base
- ◆ Evaluate the level of innovation and collaboration within two primary areas of interest: Healthcare Services and Life Sciences
- ◆ Define Louisville's strengths and weaknesses in life sciences research and development
- ◆ Compare economic activity in the Louisville metro area to other selected metro areas
- ◆ Suggest next steps to take in areas that will help to grow the region's health-related economy
- ◆ Provide a basis for development of a strategic business plan

There were two key tasks to this study. The first task was to provide an update to the 2001 economic study conducted by Dr. Paul Coomes, and to highlight key aspects and outcomes of the data which convey five-year progress. The key findings from this first task are described in Section 5 of this report. The entire set of economic data from Dr Coomes study is included in Appendix I of this report.

The second task was to conduct qualitative research by conducting interviews with executives from healthcare and life science companies, economic development organizations, university administration and research, and the entrepreneurial and investment community. The goal of the interviews was to capture insights on the level of innovative activity and commercialization capability, identify existing gaps and

issues impacting growth, and highlight unique business attraction opportunities for Louisville. It was requested to use innovation and collaboration as an overall theme when analyzing issues and comparing Louisville to other cities.

Throughout the study we articulated and analyzed two healthcare focus areas: life sciences and healthcare services. Life sciences refers to technologies which produce medical devices, medical instrumentation, pharmaceuticals, and diagnostics. Healthcare services is a large field that includes a wide range of specialties such as hospital management, regulatory and reimbursement consulting, and software development. In this study, we placed much more emphasis on “technology-based” services, as these solutions will generate higher paying jobs and have brighter prospects in the future. Therefore, throughout this report healthcare services and its associated observations and opportunities refers to technologies and initiatives such as e-health, health management systems, and electronic medical records. In reference to the innovation system, both life sciences and healthcare services technologies are relevant in our discussion of the subsystems listed above.

3. Context for Assessment

The idea of innovation systems is in many respects simply a specific view of how industry clusters function - the essential idea being that within a given geography the different cluster participants collectively function as an organized system that can effectively identify market opportunities, develop products or services to address those opportunities and successfully deliver them to the market. As with the broader concept of clusters, the definition and analysis of innovation systems can take many different forms and involve differing levels of complexity. However, there are a number of common core elements, and they are discussed briefly in the following paragraphs.

Creating and maintaining an effective and robust innovation system depends on the presence, strength and balance among these subsystems.

Research Base

It is intuitively apparent, and there is a substantial body of evidence to indicate that for any location to be successful in fostering technical innovation, an academic and / or industry research base is a vital requirement. The technical research base provides the raw material for the innovation process in the form of the essential intellectual property (IP) -- whether or not this is formally protected-- from which new products and services can be created.

It can in some circumstances be argued that innovation can occur with new business models that do not involve technology innovation per se, while still relating to industries that are essentially technology-based. These models can provide new energy to an existing industry base, but they do not represent the same kind of barriers to entry that are more widely applicable in technology-based industries that arise from core technical intellectual property. As such, they are more likely to offer a degree of first mover advantage which is more easily eroded by competitors. It may be the case that some forms of IP protection are available for business methods even in the absence of technical innovation, but there is little evidence to suggest that this somewhat unusual situation would be relevant to a robust innovation system.

Technology Companies

Technology companies are clearly an essential component of the innovation infrastructure within a region. It is the population of companies that will primarily drive the commercialization of the research base. Not all companies are innovative or engage in product development directly, but those companies that are major users of technology-based products also form an important part of the innovation system by providing a local market for products and services that can drive the development of new solutions.

Entrepreneurial Environment

The nature of the environment within a region with regard to fostering and supporting entrepreneurial activity is a critical element in the overall innovation system. This applies both to the creation of new companies to commercialize technology and to established companies to the extent to which their management is receptive to the use of new technologies as a source of competitive advantage and has the ability to act entrepreneurially to create new products and services.

The relationship between more established companies and start-ups is also an important one. Being dedicated to the commercialization of a specific technology, early stage companies generally provide an efficient mechanism for the commercialization process, provided they are competently managed and have adequate resources. They are often more agile and able to more rapidly redefine their plans in response to changes in the market or technical challenges than are large companies. It is the large companies however that generally have (and control) market access through established marketing, distribution and supply channels. It is therefore perhaps not surprising that it is considerably more common for early stage companies to be acquired by larger ones once they have achieved a certain level of success, than for them to go down the route of a public offering.

Both early stage companies and larger more established ones are therefore important in the overall innovation system, but it is the former that generally have the greatest risk of failure and, in many respects, form the weakest link in the chain. Initiatives such as business incubators and mentoring services are potentially valuable tools for increasing the likelihood of success of early stage companies through the provision of a range of services designed to support their entrepreneurial management teams.

There are, however, other elements that contribute to the overall entrepreneurial environment such as the availability of management education, networking groups for entrepreneurs, and seed and later stage venture capital. An assessment of the overall entrepreneurial environment must therefore consider all of these elements.

Physical Infrastructure

Although often overlooked in analyses of innovation systems, the physical infrastructure of a given location forms an important part of the overall system. The availability of flexible space with the appropriate characteristics for research and product development to be undertaken is a vital component, as is a similar flexibility in the management of this space. The established models and management processes for real estate development are not generally conducive to fostering the growth of technology-based companies which can exhibit very rapid growth and changes in the nature of the physical space that they require. Early stage companies in particular also cannot provide the financial guarantees that property managers generally seek. This is a role that business incubators can fulfill in part, although the special demands

of technology-based companies can extend beyond the point where companies have outgrown typical incubator space.

It is in this post-incubation phase where research parks then often play a role, providing larger but still highly flexible specialist space for technology-based companies.

The transportation infrastructure can also play an important role in the overall innovation system. Technology-based companies, by the nature, often access partners and customers across the globe and require easy access to transport links regionally, nationally and internationally. Similarly, they often draw their workforce from a wide geography and need either to have the necessary transport links to make access to the workplace simple and efficient or to be able to locate staff in close proximity to their workplace. In this latter respect, quality of life is particularly important – the typical employee in technology-based businesses has both educational qualifications and income that enable them to be highly mobile. They therefore have the benefit of being able to choose where to work to a greater extent than many other members of the workforce and typically look for locations with high levels of amenities for social activity and education for their families. These factors are often somewhat intangible, although some efforts have been made to quantify them into quality of life ‘indices’.

Workforce Development

The availability of a suitably-qualified workforce is a critical element in the overall innovation system of any region, and yet it is often overlooked or given a relatively low level of importance. It is sometimes feasible to develop workforce strategies that incorporate an element of attracting workers from other locations, but it is generally the development of the indigenous workforce that is the cornerstone of such strategies. The extent to which post-high school education is available in relevant skills areas, including management education, is a vital factor in assessing the viability of regional innovation systems, and often requires significant attention.

Leadership and Networks

The leadership of the community engaged in innovation in all of its forms and many aspects is a further vital component in the overall innovation system. Leadership in this context relates to the development of shared agendas and consensus relating to the kinds of factors and issues discussed earlier – defining priorities developing appropriate action plans, and where relevant, voicing them to the political community.

Providing appropriate formal networking organizations and venues for informal networking is also important in supporting the development of leadership within the innovation community and for fostering the kind of unstructured interactions that are often cited as being characteristic of the innovation process.

4. Methodology

The project was initiated at a kick-off meeting of representatives from key stakeholders in the Health Enterprises Network. The purpose of the meeting was to compare the Request for Proposal they drafted in late 2005 with the ANGLE project plan in order to gain an understanding of the key issues and desired outcomes from the study. A list of resource organizations and individuals to be interviewed was developed by representatives of the Health Enterprises Network, and was reviewed during the kick-off meeting.

The economic data was collected and analyzed in parallel with conducting 30 one-on-one interviews with leaders from: healthcare business, life science business, economic development, university administration and research, and the entrepreneurial and investment community. The majority of these interviews were conducted in-person by ANGLE and attended by the executive director of the Health Enterprises Network. The theme of the interviews centered on innovation and collaboration, with the intent to identify the region's strengths, weaknesses, needs, and opportunities.

The interview guide used for the project addressed the following topics, reflecting the elements of the innovation system for healthcare services and life sciences.

Research and Development

- ◆ Key research strength areas and emerging areas.
- ◆ Collaborative activity within university departments, with clinics/hospitals, and with industry partners.
- ◆ Willingness, goals/objectives, and intent to commercialize mindset, partnerships/collaboration activity.
- ◆ Strengths and limitations of the commercialization process.
- ◆ Needs and actions required to address gaps/shortcomings. Actions being pursued.
- ◆ Measurements or metrics in place to measure quality of commercialization.
- ◆ Specific examples of research that have been commercialized; key success factors and lessons learned.
- ◆ Progress made in the last 5 years regarding innovation capability.

Enterprise Needs

- ◆ Workforce (skills, availability)
- ◆ Education and training requirements
- ◆ Facilities (space, equipment, infrastructure – expanding or declining)
- ◆ Intellectual property (sources)

- ◆ Product/service development (R&D, prototype and testing facilities)
- ◆ Financing (debt, equity)
- ◆ Partners
- ◆ Access to markets

Entrepreneurial Environment

- ◆ Innovative companies (large, small, start-ups, and their relationships)
- ◆ Business incubator availability
- ◆ Equity capital availability
- ◆ Management education availability
- ◆ Mentoring

Leadership and Networks

- ◆ Community leadership promoting innovation
- ◆ Formal action plans
- ◆ Formal networking organizations
- ◆ Informal networking venues

Interviewee Selection Process

The interviewee selection process was organized by obtaining a balanced representation of healthcare executives and experts across the following five categories: business leaders, university administration & academics, university research, investors and entrepreneurs, and economic development. It was our aim to include a mix of long-time Louisville residents and newcomers to the area, as well as a compilation of representatives from healthcare delivery, insurance, medical device development and manufacturing, biotechnology development, and healthcare services.

The interviewee list is included in Appendix II of this report.

5. Louisville's Health-related Economic Base

The entire results of Dr. Paul Coomes updated economic data report is included in Appendix I of this report. The sections below highlight the most interesting and important findings of the latest research. Within Section 6 of this report we reference additional data points from the economic data that are relevant to the innovation system in Louisville.

- ◆ We have identified nearly 2,500 health-related establishments in the Louisville area (in 2001 we tracked 2,100). Collectively they employ about 85,000 persons, with an annual payroll of \$3.5 billion. In 2001 those numbers were 72,000 and \$2.3 billion, respectively. The establishments generate over \$430 million annually in state and local taxes. All major components of the industry posted growth over the last five years, particularly hospitals and ambulatory care facilities. Also, we have been able to document much more educational, nonprofit, and governmental activity than in our previous study.
- ◆ Health care remains one of the largest employers in the Louisville area, accounting for 10 percent of all jobs and compensation. Employee compensation grew by over 7 percent per year during the last two years for which data are available. On a per capita basis, most health care economic measures indicate that Louisville ranks in the middle or above compared to other similar metro areas, and is consistently above the national average in terms of revenues, payrolls, and jobs.
- ◆ Louisville is home to two of the fourteen *Fortune 1000* headquarters of health-related companies located in the sixteen comparison metros: Humana and Kindred. Only the Nashville (7) and Indianapolis (3) metros have more major headquarters. Nashville continues to rise in national prominence, gaining the most headquarters since our last study. In another headquarters listing, by *Reference USA*, Louisville stands out in the health insurance, nursing home, and home health industries.
- ◆ The University of Louisville continues to soar up in the rankings of federally-funded research. It jumped from 204th to 103rd among all institutions in funding from the National Institutes of Health in the last eight years, by far the greatest growth among any of the institutions among the competitor metros. UL now brings in over \$50 million annually in federal research funds in health-related fields, a growth of tenfold over the last decade.
- ◆ Louisville continues to rank near the bottom in private research and development activity and, as we observed in our last study, has no pharmaceutical companies.

- ◆ Louisville ranks higher in health-related patent activity than in our last study (10th rather than 14th), posting the third highest growth rate this decade – behind only Birmingham and Raleigh.

6. Analysis of the Innovation System

Strengths and weaknesses found from our interviews are assessed in each element of the innovation system in the following sections.

6.1 Research Base

For any location to be successful in fostering innovation, an academic or industry research base is a vital requirement. With regard to life sciences research activity, Louisville has gained significant momentum over the last five years, with progressive funding programs in place to recruit key scientists and further research at the University of Louisville. The “Bucks for Brains” program which is designed to recruit key scientists has had a significant impact on the federally-funded research rankings success, as highlighted in Section 5. Additional initiatives include building a new 10,000 sq ft class 100 clean room on the University of Louisville campus which will be dedicated to medical device and sensor development. A new Bioengineering department has recently been formed, and corporate internships are being proposed.

University of Louisville collaborative activity with industry and local hospital researchers has been initiated and is growing, leveraging world-class practitioner expertise for technology development. Representatives from the University acknowledged that working relationships are forming with Jewish Hospital, Jewish/Frazier Rehabilitation Institute, and Norton Healthcare to further the development of life sciences research. Commercialization infrastructure is building in areas such as neuroscience, where partnerships with Jewish/Frazier Rehabilitation Institute are forming to provide a continuum from basic research through rehabilitation therapy.

The University of Louisville’s Office of Technology Transfer recently located their offices in the MetaCyte building, one of the business incubators primarily focused on life science research. Five key research strength areas were highlighted: oncology, neurology, cardiology, ophthalmology, and bioengineering. Approximately 14 startups have been formed over the past 5 years, with 3 of those formed in 2005. In comparison to other regions we researched, Nashville’s Vanderbilt University had 10 active startups in 2003 with no new startups that year. Purdue Research Foundation in Indianapolis created 3 new startups in 2003 and had 26 existing operational startups at that time. Biostart in Cincinnati currently has 9 startup tenants, with one known startup from University of Cincinnati licensing.

The Office of Technology Transfer at the University of Louisville identified 2 key gaps or weaknesses they are challenged with: the lack of seed stage capital, and availability of serial entrepreneurs. Similar to the “Bucks for Brains” program, a “Brains for Business” program is being proposed to attract management talent.

Great efforts have been applied via the public sector and community support for a life sciences research base. Throughout the interviews there was evidence that would suggest some level of support or activity has been allocated to healthcare services research and technology commercialization, but to a much lesser degree than life sciences. It was noted that 3 NSF information technology-related grants enabled strengths in healthcare information technology, however the applications mentioned were focused on life sciences research as opposed to healthcare services. There was no mention throughout the interviews with University representatives that working relationships were forming with industry partners to develop healthcare service solutions, however it was acknowledged there is untapped potential to work with Kindred and healthcare service organizations on information technology related healthcare service needs.

The level of networking activity between university researchers and the private sector for startup creation is more pronounced and visible for life sciences. The following comments were noted: “there is an untapped relationship with Humana”; “the University of Louisville is not an aggressive suitor to working with Humana”. It was our observation the life science research community and associated activities are completely separate from healthcare services research.

There is a stated commitment for Louisville to become a life science research community. Fortunately, there is much to be learned by Louisville from its own efforts in supporting life sciences research activity. That said, some life science commercialization challenges remain at the University, which include encouraging faculty to disclose inventions, and developing expertise in technology valuation.

The healthcare services sector – clearly the largest and most active health-related industry cluster in Louisville – offers great opportunity for Louisville through more focus and commitment to leveraging existing assets and fostering entrepreneurial activity, especially from larger organizations.

6.2 Technology Companies

The number of technology companies is clearly an essential component of the innovation infrastructure within a region. It is this population of companies that will primarily drive the commercialization of the research base.

Looking to Louisville’s life science cluster, there has been good, steady progress of support mechanisms for early-stage startups. Five commercialization support centers were found to be active in life science technology and business development. The level of formality ranges within the five centers in terms of access, services, and ownership terms. Examples include: MetaCyte, The Cardiovascular Innovation Institute and iACT. MetaCyte, a business incubator for life sciences and information technology, currently has 12 companies (11 of which are technologies from the University of Louisville) with a goal of forming 3 companies per year. The Cardiovascular Institute, a joint venture among the University of Louisville, Jewish

Hospital, and the State, is devoted to bringing new medical devices to the marketplace. iACT, a technology incubator under development within the Brown Cancer Center, will develop and launch successful drug technologies.

While there is a good source of life science technology users in the Louisville area (hospitals, nursing homes, physician offices, etc), there are relatively few (approx 40) established medical manufacturing and equipment companies in the area, with only 11 of those companies having more than 20 employees. There has been essentially no growth in the number of these established life science technology companies in the past 5 years, although the number of employees within these establishments has grown approximately 35%. It is important to mention that the impact from the progress made in life science research noted above takes time, and may not be realized in the near-term. Providing the young life science start-up incubator tenants are successful and graduate from the incubator, we would expect the number of establishments to increase over the next several years.

In the healthcare services cluster, there are also technology-based opportunities. However, the public sector support infrastructure for developing these opportunities appears to lag the life science cluster. The large nationally-recognized healthcare service companies that exist in Louisville (Humana, Kindred, others) have a variety of technology needs, however there was little evidence to suggest the same level of industry collaboration occurs between the University of Louisville and these companies.

During the interviews, executives from the large healthcare service companies acknowledged they have not been approached by University representatives to discuss partnership opportunities. With appropriate focus and attention there may be opportunities to generate technology companies in Louisville that can meet their needs. For example, while no economic data was available on “e-Health” businesses, there is anecdotal evidence of some limited entrepreneurial success in this field. While Louisville was noted as one of the first regions to implement progressive e-health records and clinical information systems technologies back in the mid-90’s, the pioneering spirit, critical thinking, and skilled healthcare IT workforce has not been fully leveraged to create an entrepreneurial environment for fostering new companies. Several interviewees suggested e-health initiatives as a promising area to form new companies in Louisville and get the community “on the map”, however they were not aware of activity focused on such initiatives. It was acknowledged Humana has one of the most sophisticated health information systems in the nation, but this asset is not getting fully leveraged.

Profitable private healthcare service companies exist in Louisville, but somewhat under the radar screen and not widely recognized. One executive made mention of 4-6 healthcare services companies he is aware of that are private-equity backed, including Trilogy, SHPS, and Trover Solutions. Acquiring additional capital is a key need to generate more of these types of companies.

6.3 Entrepreneurial Environment

We consider the entrepreneurial environment “emerging” in Louisville. While capital is still limited in the life sciences cluster, things have significantly improved over the last five to seven years and there is an acknowledged need at the University of Louisville to align promising drug technologies with local investors to keep young companies in Louisville. The University has taken a stance that “entrepreneurship is good”, and is committed to developing the newly created doctorate program in entrepreneurship. There are plans to move the graduate business facilities downtown, closer to industry locations.

Existing life science commercialization gaps include a lack of high-risk/early stage capital, a “thin” talent pool of manufacturing expertise, and a lack of available serial entrepreneurs, primarily due to the small number of mature life science companies in the region.

Fortunately, capital is much more available in the healthcare services cluster, and Louisville’s healthcare services cluster has a wide array of companies at all stages. However throughout the interviews a common theme emerged regarding a general lack of entrepreneurial passion or drive, and a passive attitude towards fully leveraging the existing healthcare services assets in Louisville. A lack of “entropy” in Louisville was acknowledged from several of the interviewees, in comparison to Nashville and Indianapolis. Some of the interviewee comments include “the level of expectation is low for entrepreneur activity”, and “leaving a big company to start a new business is frowned upon, as there is no payoff for the big company”. Despite this, we did find entrepreneurial success stories at Rescare, one of Louisville’s nursing home corporate headquarter companies. Several novel information technology initiatives have been developed and implemented. Rescare collaborated with the University of Indiana to develop a remote monitoring system for mentally retarded group homes. They also developed the largest time/attendance system in collaboration with Kronos, and have plans to open their own pharmacy, collaborating with Rouben’s Pharmacy. Additionally Rescare has internship programs in place with University of Kentucky and Spalding University.

It is worth noting historical economic events and entrepreneurial dynamics in other comparable regions significantly impact entrepreneurial culture differences. For example, Nashville’s entrepreneurial culture was cultivated primarily due to a few key drivers: 1) the availability of private equity and plentiful workforce talent was the output of large public companies such as HCA; 2) the state’s tax incentives; and 3) the presence of Vanderbilt University. These drivers working in concert helped create the entrepreneurial mindset, high-energy level, and entropy necessary to build new companies. Total venture capital inflow in health-related sectors in Nashville was about \$1 billion from 1995-2005, with approximately \$27 million in 2005, and a peak of \$324 million in 1999. Louisville’s total deal inflow from 1995-2005 was approximately \$151 million, with approximately \$17 million in 2005, and a significant peak in 2004 of \$46 million.

Looking at the estimated number of establishments and number of jobs in Louisville versus Nashville, the two regions are relatively comparable within the “healthcare delivery” industry, which include ambulatory, hospitals, and nursing homes. Nashville had approximately 2,595 establishments employing 75,000 people in 2004, while Louisville had approximately 2,330 establishments employing 64,850 people. However within “related enterprises”, which include manufacturing, health insurance, management, nonprofit service, and support companies, Nashville figures far exceed Louisville figures. Nashville had 3,300 establishments employing 94,350 people, while Louisville had 163 establishments employing 19,600 people.

Regarding support services, Nashville’s Healthcare Council offers entrepreneurial training workshops called “Garage to Wall Street”, and a life sciences center affiliated with Vanderbilt University, “Cumberland Emerging Technology’s Life Sciences Center”, provides support and expertise for entrepreneurial companies.

Indianapolis has a fairly robust entrepreneurial infrastructure with several incubators in operation including Indiana University’s Emerging Technology Center for life sciences, Rose Hulman Institute, Purdue research park, Anderson Flagship Enterprise Center, and Innovation Center at NE Indiana.

6.4 Physical Infrastructure

The provision of flexible space with the appropriate characteristics for research and development to be undertaken is a vital component, as is a similar flexibility in the management of this space. There has been significant progress made in Louisville to provide incubator space for emerging life science technologies, as highlighted above. A 20 block research park located in downtown Louisville (having close proximity to the medical school buildings and industry) is currently under development to accommodate post-incubation phase life science technologies. The transportation infrastructure can also play an important role in the overall innovation system. Several of the interviewees acknowledged the Louisville airport to be somewhat a deterrent in terms of direct flight availability.

6.5 Workforce Development

The availability of a qualified workforce is a critical element in the overall innovation system of any region, and yet it is often overlooked or given a relatively low level of importance. Because of the number of healthcare services firms, and the relative age of this cluster in Louisville, there may be more availability of workers at all levels than in the life science cluster.

While there are some technical and management positions that can be filled by recruiting from non-life science industry, due to the complexities and specific know-how associated with commercializing a life science technology, there needs to be sufficient staffing positions filled by industry experienced personnel. Also, an experienced talent pool within a region of interest is a key factor in the decision to

locate life science start-up companies. In addition to the University of Louisville's program in entrepreneurship, Louisville's Jefferson Community and Technical College offers a wide array of educational and internship programs to develop lab technicians for biotech companies. Knowledge and skill-set gaps identified during the interviews include IP valuation analysis skills, experienced management from life science companies, and local FDA/regulatory system expertise.

Because of the importance of this issue and the breadth of issues to address, the Health Enterprises Network is planning follow-up research on human capital, both in regard to healthcare services and life sciences, in conjunction with Kentuckiana Works.

6.6 Leadership and Networks

The leadership of the community engaged in innovation in all of its forms and many aspects is a further vital component in the overall innovation system. Leadership in this context relates to the development of shared agendas and consensus relating to the kinds of factors and issues such as defining priorities, developing appropriate action plans, and where relevant, voicing them to the political community. During the interview process several themes emerged regarding innovation and the entrepreneurial culture in Louisville.

A common observation among the interviewees is that there is a general lack of entrepreneurial confidence within the community, and a culture that does not embrace risk taking and failure with regard to new company formation. There was also a general consensus that a lack of understanding and awareness exists on the Louisville "story"; on a national, local, and self-awareness level. Viewpoints on healthcare services innovation are fragmented, lacking a common vision, commitment, and course of action.

While there may be supporting elements in place within other subsystems, the existing environment will limit Louisville's success in terms of harnessing the momentum, collaboration, tenacity, and drive to build new companies. Providing formal networking organizations and venues for informal events is important in leadership development and nurturing unstructured interactions.

Many of the business leader interviewees acknowledged the value of maintaining existing formal events, and encouraged further informal venues to foster entropy and more interaction, particularly in regard to healthcare services. The Venture Club, a networking organization, facilitates monthly meetings for investors, entrepreneurs, and service providers. The meetings are well attended, and interviewees noted they are of value and should continue. The Health Enterprises Network should communicate the activities of this forum to its membership.

7. Additional Findings: Research and Development

7.1 Research strengths, focus areas

The interviews with university and college representatives included a discussion on particular life science research strengths. The key focus areas for economic growth potential include spinal cord rehabilitation, where the University of Louisville and Frazier/Norton Rehabilitation Institute have forged a partnership, collaborating on progressive stem cell research for spinal cord therapies. The top research areas receiving the greatest funding include oncology, molecular medicine, cardiology, ophthalmology, logistics, and early childhood/pediatrics.

We also discussed converging research areas, in which cross-department collaboration may cultivate opportunities for unique, novel therapeutic solutions, and perhaps stimulate joint-development initiatives with industry. These converging areas include bioinformatics, structural biology, and health and wellness. Health and wellness appears to be one area in particular to explore partnership opportunities with Humana, as Humana identified health and wellness as a key focus area for future innovation projects. Bioinformatics, biosecurity, and predictive medicine were highlighted as areas targeted to strengthen.

The University of Louisville is challenged with raising the funding necessary to move the pipeline of oncology drugs into clinical trials. The University is developing an Institute for Advanced Therapeutics with funding resources split between private investors and the University. The Institute has set a goal to develop two drug compounds per year. Additional commercialization challenges include acquiring much needed valuation skills and talent (identified as an existing gap) to successfully transfer life sciences technologies.

Closely linked to health and wellness, one particular research area which potentially leverages both the life sciences research and healthcare services assets in Louisville is aging and geriatrics. This is a therapeutic market sector that appears ripe for initiating and building a nationally-recognized center of excellence in Louisville.

Bellarmino University is another university in the Louisville region that has initiated progressive growth programs. Just last month, the university announced its vision to triple enrollment and potentially add seven new schools which include pharmacy and veterinary medicine, by 2020. The University envisions this proposal will benefit the city, region and state bringing in revenue, brain power, and additional collaborative opportunities.

7.2 Clinical trials and industry funding

Performing clinical trials in a region is an important segment of the life sciences industry. The location of the clinical trials may have a positive impact on the company's decision on where to locate their operations, particularly if the center is

involved upfront in pre-clinical work. We gathered clinical trial data from both the University of Louisville and the Jewish Hospital/Frazier Rehabilitation Institute. At the Jewish Hospital/Frazier Rehabilitation Institute, the number of trials has steadily increased over the last 3 years, from approximately 150 to over 200 trials today. Most of the trials are industry sponsored versus NIH funded. The significant clinical areas include cardiology, neurology, cardiovascular surgery, orthopedics, oncology, spinal cord injury. The clinical trials representative we spoke to was not aware of any companies that had relocated to Louisville post-clinical trials.

Clinical trial activity at the University of Louisville has remained relatively stable (with the exception of FY2003) over the last 5 years. The School of Medicine's clinical trial funding has ranged from \$3 to \$4 million per year since FY2001, except in FY2003 when it dropped to approximately \$1.7 million. The majority of the Universities trials are conducted at the University of Louisville Hospital, Jewish Hospital, and Norton's Hospital. The NIH has a relatively new initiative, Clinical Translation Science Awards (CTSA), which encourages university department cross-collaboration and the associated exploration of novel converging technologies. The assumption is universities with greater collaborative activity in place will be better positioned to win this type of grant funding. It was noted during one of the interviews the University of Louisville has recently submitted a CTSA grant application. Also, the University has recently raised \$10 million of private funding to build a Clinical Trial Institute.

In addition to tracking University of Louisville NIH funding, we also collected data on industry sponsored research funding awarded to the University of Louisville Medical School. In addition to receiving \$40.1 million NIH funding in FY2004, the Medical School was awarded \$7.5 million from industry, representing over 15% of the total funding from both NIH and industry. Comparatively, in the Cincinnati area industry funded university research represents approximately 3% of the total funding.

Percent industry funding is an indicator of the researcher's familiarity with private sector markets. If research is focused primarily on government research markets it becomes more difficult to use university research programs to attract private companies. Company management can't always envision how university research could contribute to the development of products in commercial markets.

8. Summary and Recommendations

8.1 Summary

The intent of this study was to assess Louisville's five year progress and formulate a set of recommendations that address business growth opportunities by leveraging the region's key assets. We suggest these recommendations be used as an outline for future business plan development.

Our interviews revealed both near-term and longer-term business growth opportunities for the healthcare services and life sciences market sectors.

Louisville's healthcare services sector is much more established and recognized. Louisville has a healthy range and size of existing companies, including the headquarters of two Fortune 500 firms, Humana and Kindred Healthcare. Louisville ranks third among 16 metro areas in headquarters of privately held, publicly traded and not for profit healthcare services firms. Louisville also ranks third among 16 metro areas in nursing home and long term care companies. Regarding the near-term, we concluded there are untapped opportunities for Louisville to further leverage these existing healthcare services key assets. While much activity has occurred in the healthcare services sector, we believe Louisville should place more emphasis on leveraging these assets.

Louisville's life sciences sector is less mature with much fewer establishments. Additionally, this sector has inherently a longer time to market life-cycle as opposed to healthcare services. We found strong support to further the growth in life sciences research, which has gained significant momentum over the last five years. Several key assets and visible public sector programs have been put in place to position Louisville for longer-term economic growth and to refine commercialization efforts for these longer-term growth opportunities. These assets include the University of Louisville's "Bucks for Brains" program which recruited key scientists to help drive the National Institute of Health funded research rankings from 204th to 103rd in the last eight years. In the past five years significant efforts and funding have been allocated to building a physical and entrepreneurial infrastructure for life sciences, including more than \$400 million worth of research space, the formation of 14 startups, and the establishment of venture and seed capital funds.

This study also addresses a need to develop Louisville's value proposition. There are several necessary activities a region needs to implement in order to effectively realize the desired vision of becoming a recognized "location of choice". First, a region needs to carefully define and articulate a unique value proposition. The value proposition is what informs and stimulates outside prospects to consider relocation. Without a value proposition a region potentially takes itself "out of the running".

In developing the recommendations below we focused on three key objectives: 1) leverage Louisville's existing assets, 2) seek opportunities to "build something new" in Louisville, and 3) address the gaps and weaknesses identified from the analysis of Louisville's innovation system.

Gaps and improvement areas identified through this study include:

- ◆ Few life science companies in Louisville to leverage
- ◆ Louisville is not fully leveraging existing healthcare services assets, including strong company presence, management talent, and relationships
- ◆ Louisville is not united on economic development initiatives
- ◆ Lack of awareness on healthcare initiatives and opportunities
- ◆ Public sector support and initiatives are focused more heavily on life sciences
- ◆ Healthcare executives are not incentivized to start new companies
- ◆ A shortage of high risk capital for life sciences commercialization
- ◆ A lack of entropy and entrepreneurial drive in Louisville which presents limitations for healthcare service growth
- ◆ Entrepreneurial leadership and skill-sets in technology transfer
- ◆ Aggressive business stimulation policies

8.2 Recommendations – Healthcare Services

The Health Enterprises Network should take on a leadership role to facilitate a common vision for healthcare services economic development that includes measurable objectives. HEN should engage with innovation participants, including representatives from the state, healthcare business leaders, and the university. HEN can build on the results of this study to help define the target sub-sectors, articulate the vision and develop a system to measure progress.

Here are some recommendations for consideration:

8.2.1 Overall Business Attraction

- ◆ Engage Louisville's top 30 healthcare services executives in business attraction. Seek their support in further raising the profile of health services sector by providing testimonials and making presentations to companies they can influence via their service as a director, participation as an investor, etc.

8.2.2 Apply “lessons learned” in developing public sector and community support for Louisville’s life sciences cluster to the healthcare services cluster.

- ◆ Work with the Louisville investment community to establish an Angel Investor Network for healthcare services investors to review and qualify deals, support business plan development, and act as investor liaison.
- ◆ Create an incentive package to attract existing healthcare service executives of mature organizations from other locations to establish and build new healthcare service companies in Louisville. Interview executives to determine incentive requirements and methods to encourage adoption.
- ◆ Advocate for tax incentives to attract headquarters operations, especially those with high payrolls but lower employees counts (specifically address the requirement of 15 jobs within two years to access Kentucky incentives).

8.2.3 The Health Enterprises Network should continue promoting and facilitating networking events and publicizing the sector.

- ◆ Establish a focus on healthcare services technology topics, e.g., eHealth.
- ◆ Include representatives from the business schools, healthcare service provider executives, investors, to stimulate interaction and outsourcing initiatives.

8.2.4 Address the need to leverage existing assets in Louisville for healthcare technology and healthcare service outsourcing opportunities. For example, Rescare collaborated with the University of Indiana to develop a remote monitoring system for mentally retarded group homes.

- ◆ Begin encouraging internal incentives (bonuses, training, etc.) to drive innovation in the firms.
- ◆ Promote the success of innovation at firms who have a recognized process that has led to success.
- ◆ Arrange meetings among university leadership and healthcare organizations to identify opportunities for joint research and company creation. Collaborate on grant proposals to facilitate leveraging opportunities. For example, devise a plan for an e-health “demo project” (i.e. composite of all records) which addresses a common need across all regional healthcare organizations. The potential exists to unite hospitals and make them stronger as a region. Start locally, and then build nationally.
- ◆ Consider developing a healthcare services concentration within the university’s entrepreneurship program; include internship opportunities with the local healthcare service companies.

8.3 Recommendations – Life Sciences

8.3.1 Discuss a strategy and plan with UPS to develop niche market opportunities. For example, approach medical technology/biologics companies nationwide to identify shipping, distribution, and inventory needs.

- ◆ Explore opportunities for overnight medical laboratory services facility (i.e. blood analysis, drug testing). Discuss the possibility of locating the laboratory in Louisville’s downtown research park (currently under development).
- ◆ Leverage existing UPS contracts/relationships (UPS/Toshiba) to stimulate new opportunities.

8.3.2 Connect medical technology small to midsize enterprises (SMEs) with successful, seasoned entrepreneurs.

- ◆ Develop a mentoring program for young entrepreneurs/CEOs of start-ups. The Health Enterprises Network should consider visiting the Greater Cincinnati Venture Association to evaluate their model for Louisville.
- ◆ Develop an incentive package to draw experienced start-up CEO’s to the region.

8.3.3 Devise a plan to build the SME life science sector by maintaining early-growth companies in Louisville.

- ◆ Identify the needs and determine how the public sector can potentially support, i.e. supply a strategy for acquiring venture capital resources.

8.3.4 Address the equity capital “gap” by supporting the following initiatives:

- ◆ High quality business plans for investable deals are a key component to attracting venture capital funding and generating deal flow. Engage university business school graduate students and outside experts.
- ◆ Explore the creation of a “u-angel” investment fund comprised of university alumni, a model under development at George Washington University in Washington DC. Work with partners like the Kauffman Foundation and National Association of Seed Venture Funds (NASVF).

8.3.5 Devise a plan to recruit SME life science sector companies to Louisville.

- ◆ Contact the life science research park developer to explore joint marketing program opportunities. Determine how the Health Enterprises Network can support tenant recruitment efforts, and what resources within the developer’s organization might be accessed.
- ◆ Work with the state to develop a state tax incentives package for out-of state recruits that addresses challenges with inventory taxes.

- ◆ Investigate the model used by the Omeris operations in Ohio to recruit life science companies to the state. Omeris is a non-profit organization designed to build and accelerate bioscience industry, research, and education in Ohio.