



**Ohio Third Frontier Technology Commercialization Center
Letter of Intent**

Lead Applicant: University Hospitals Health Systems, Inc.
Harrington Discovery Institute
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Project Collaborators: University Hospitals Case Medical Center, BioMotiv, Ohio Based
Pharmaceutical Development Partners

Project Title: Harrington Discovery Institute - Innovation Support Center

State Funds Requested: \$25 million

Total Project Cash Cost: \$75 million

Project Term: 4 years

Project Summary

University Hospitals Health Systems, Inc. (“UHHS”) seeks to partner with the State of Ohio in the Harrington Project for Discovery and Development (“Harrington Project”), a \$250M national initiative, anchored in Ohio, to accelerate the development and commercialization of breakthrough therapeutics by physician scientists.

The commercialization acceleration engine of the Harrington Project is its Innovation Support Center (“ISC”). To selected projects, the ISC offers both funding and expert guidance and mentorship to position drug technologies for commercialization. Specifically, the ISC assists projects in creating detailed development plans, conducts business and market assessments, strengthens intellectual property positions, and provides support for pursuing additional funding. In doing these things, the ISC helps forge powerful relationships among inventors and industry experts and serves as a translation link between inventors, their institutions and commercialization partners.

Through this project, the ISC:

- Serves as the hub of support and accelerates the nation’s most promising pharmaceutical developments
- With its primary commercial partner, BioMotiv, develops new companies based on the nation’s most promising pharmaceutical products in the State of Ohio; and

- Connects, develops and coordinates pharmaceutical commercialization resources throughout the State of Ohio to support the selected projects, and thereby supports the growth of those Ohio pharmaceutical service companies and resources
- Serves as a platform to attract near-term partnerships with and investments by the world's leading pharmaceutical companies

The ISC, and The Harrington Project, are an opportunity for Ohio to become a leading center of pharmaceutical development, resulting in significant economic impact in the State.

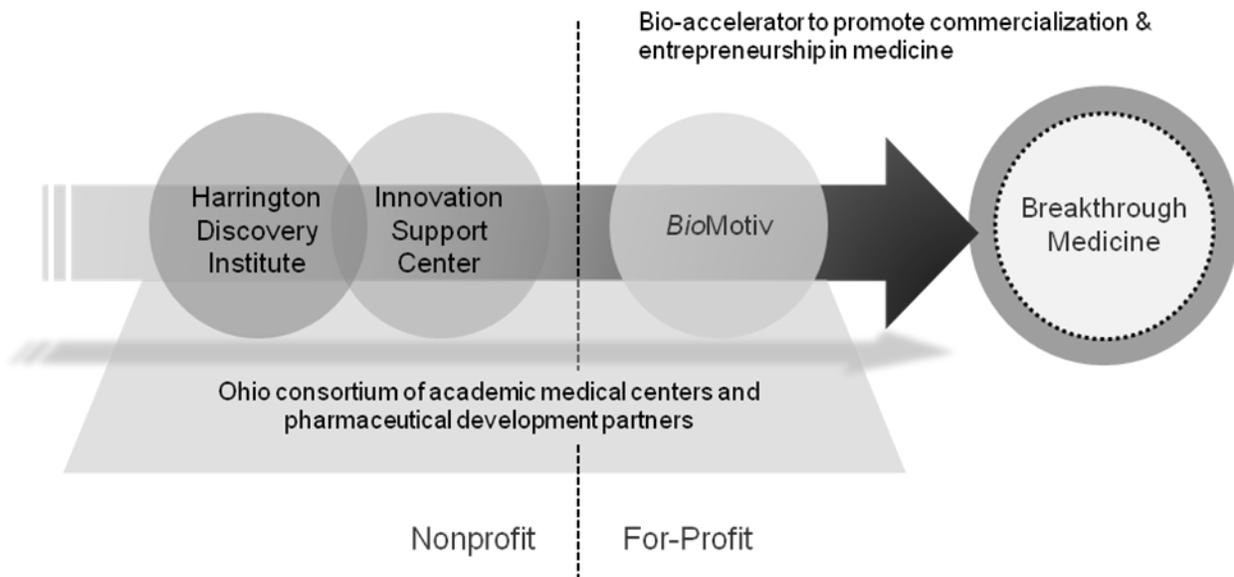
The Harrington Project

The Harrington Project, based at University Hospitals Case Medical Center in Cleveland, is a \$250 million national initiative that promises to dramatically change how quickly new drugs advance from initial research discoveries to commercial products, with a particular focus on eliminating barriers that physician-scientists face when developing a new therapy.

In a first-of-its-kind and culturally transformative approach, the project aligns nonprofit and for-profit components to accelerate the translation of the most promising drug discoveries into patient medicines that will save lives. The result will be a series of new therapies advanced to market, providing hope for patients – locally and internationally – with cancer, Alzheimer's, and other devastating health conditions.

The Harrington Project includes the non-profit Harrington Discovery Institute (“HDI”) at University Hospitals Case Medical Center, the non-profit Innovation Support Center (“ISC”), and the for-profit accelerator, BioMotiv, all of which are based in Cleveland. The Harrington Project's strength lies in the alignment of those three components:

- HDI identifies the most promising discoveries from the nation's leading physician scientists who are designated and supported as Harrington Scholars
- ISC provides both funding and pharmaceutical development expertise to support Harrington Scholars to productize their discoveries and launch the products into commercialization
- BioMotiv, as the mission-aligned, early-stage investment and development partner, launches new start-up companies to commercialize each product and also as serves as a critical interface among research institutions, financial investors, and the pharmaceutical industry



The Harrington Project has achieved significant momentum and external validation during its first eighteen months of existence. As the success and stature of the Project accelerates, the Harrington Discovery Institute seeks to partner with the State of Ohio to ensure that the biopharmaceutical commercialization resources, companies and economic benefit gained through the Project are anchored in and most fully benefit the State of Ohio. Through this initiative, the State of Ohio will be recognized as a national leader in the pharmaceutical industry by serving as a base for leading pharmaceutical partners to access the nation’s most sought after drug discoveries, and by creating a pipeline of products around which pharmaceutical companies can both invest and develop operations.

Stature and Resources

Although the program is developed and run by University Hospitals Case Medical Center, the final selection of Harrington scholars is determined by a national panel of leading innovators and industry experts. The panel of experts, with a track record of successful drug discovery and development, selects the most promising projects without bias. Once projects are selected institutions and other funders receive true external validation to provide additional funding and acceleration support.

Combined, the Harrington Discovery Institute, the ISC and BioMotiv will support over 50 projects during the grant period, generating significant activity and visibility for the State of Ohio:

- While selected projects originate from institutions throughout the country, the ISC connects them to the State of Ohio as a hub of support and expertise for their development
- The commercialization resources and infrastructure of the State of Ohio will be accessed to support the development of the identified projects
- All supported physician scientists and members of the HDI, ISC and BioMotiv leadership boards, as well as national policy makers join in Cleveland annually to showcase their discoveries and advance their work

- As BioMotiv identifies the most promising early stage commercial opportunities through the Harrington Discovery Institute and other mechanisms, those opportunities are supported through the establishment of Ohio-based start-up companies

HDI is clearly “best in class” as it defines a model that is superior to the traditional road to commercialization, where promising innovations often languish in the Valley of Death. This model focuses on creating solutions rather than supporting isolated projects, eliminates the barriers of location and individual institutional limitations, and focuses on selecting, supporting and commercializing the most promising opportunities. A Technology Commercialization Center award from the State of Ohio to HDI will establish Ohio as a leader in pharmaceutical commercialization.

Scale and Opportunity to Develop Ohio’s Pharmaceutical Infrastructure

Ohio’s biomedical industry stands as one of the State’s key assets with its robust base for highly skilled and compensated employment, company formation, company attraction and workforce development at all levels, serving all geographies within the State.

In 2011, Ohio-based institutions and companies received over \$710 million in funding from the National Institutes of Health (NIH), substantially above the US average of \$440 million. Five institutions within the State – Case Western Reserve University/University Hospitals, Ohio State University, University of Cincinnati, Cincinnati Children’s Hospital and the Cleveland Clinic – are among the nation’s top 100 NIH funding recipients. While multiple Ohio universities have participated in the Project over the past two years, Ohio based physician scientists represent less than 10% of total applications received. Despite these odds, three projects based on technologies originating from within the State of Ohio have been selected for support. Within its first eighteen months, the Project has demonstrated that scientific strength in the area of drug development resides in the State of Ohio and that the Harrington Project can attract leading scientists and their inventions to the State. The State of Ohio’s partnership with the Harrington Project will no doubt increase the visibility of the initiative to Ohio based scientists, hopefully expanding the applicant pool and increasing its competitiveness within the larger national group.

Every Ohio institution has made investments in certain research areas, but by virtue of doing so, they are strong in one area and weak in others. Through this partnership, the ISC will identify and leverage research and drug development strengths within Ohio-based institutions and seek to not only utilize and share resources but also partner with institutions across the country to enable Harrington Scholars to utilize the best resources to accelerate the projects – and leverage and increase visibility of the investments and strengths resident within our State.

In addition to leveraging institutional resources, the ISC will build a permanent team of talented drug development and experts based in Ohio and also identify and partner with pharmaceutical development resources within the State of Ohio for use by Harrington Scholars. Ohio is home to a broad range of pharmaceutical service organizations that support the development of new opportunities. These include contracted research, technical, and clinical organizations in the development of biotechnology companies such as Ricerca (Cleveland), ChanTest (Cleveland), WIL Laboratories (Ashland), Battelle (Columbus), Kendle (Cincinnati), Medpace (Cincinnati), Clinical Research Management (Cleveland), and Charles River Laboratories (Toledo), to name just a few.

The Harrington Project – the combination of the Harrington Discovery Institute, the ISC and BioMotiv – will efficiently leverage the State’s strengths while commercializing promising discoveries from across the country, thereby establishing Ohio as a drug development hub and powerhouse and formalizing the pipeline and deal flow of commercial opportunities.

Business Driven/Market Focus

The Harrington Project has assembled three teams of leadership to support its national effort:

- 1) For the Harrington Discovery Institute, a Scientific Advisory Board comprised of internationally renowned physician scientists who are leaders in the field of drug discovery select the most promising physician scientists and their projects as Harrington Scholars
- 2) For the Innovation Support Center, an Advisory Panel comprised of experts in the critical aspects of drug discovery serves as mentors to Harrington Scholars. These experts bring senior leadership experience from Bristol Myers Squibb, Glaxo SmithKline, Merck, Schering-Plough, J&J and a number of emerging biotech companies
- 3) For BioMotiv, an experienced management team and National Advisory Board - including six former heads of global pharmaceutical research & development - oversee the selection of the candidates to commercialize their discoveries through the creation and funding of start-up companies. Over their careers, the Advisory Board members have collectively overseen the development of 50 commercialized drugs which in total achieved over \$84 billion in annual peak year sales

Each of these individuals has been recruited to key roles within the Harrington Project for its national scope, and are interested in the prospective impact such an initiative can have for the industry and for society. Collectively, they represent an unparalleled resource for pharmaceutical development.

The Board for the ISC will draw upon the expertise within these three established leadership councils as well as additional representation from industry and financial experts. This Board will review technology commercialization center decisions and ensure that outcomes goals are met, most notably the commercialization of products selected for support.

Service and Technology Acceleration Orientation

Scientists and academic institutions throughout the country recognize the potential of the Harrington Project to change the biopharmaceutical landscape. The Project’s aligned components uniquely provide both the financial and technical resources required to translate a promising drug discovery into a commercialization-ready product. The ISC’s experts and network of resources provide selected projects with detailed technical guidance including product development and validation plans, intellectual property guidance, and business/market positioning support. The experts are informed by not only their industry experience, but also through the counsel provided via the ISC’s Board, which will be comprised of private-sector accelerators, investors and industry representatives that are committed to drug development.

Validation and Sustainability

The Project has received significant validation since its launch:

- Over 800 opportunities from leading academic centers and industry sources have been submitted for consideration to HDI and BioMotiv, from which 17 have been selected for support to date

- The Project has structured co-funding relationships with three national disease foundations to support projects in selected areas
- BioMotiv has attracted over \$46 million in investment from investors including Nationwide Mutual Insurance Company, has formed a \$20 million co-investment relationship with Torrey Pines Investment of San Diego and has additional investment and partnership conversations currently under way

The globe's leading pharmaceutical companies are seeking approaches to identify promising new opportunities emerging from the sciences, and have shown keen interest in the Harrington Project's unique system for commercializing new drug products. Until now, an organization consisting of pharmaceutical experts that narrowed down the most promising medical discoveries from across the nation has not existed. The ISC, as an Ohio Technology Commercialization Center, will provide an Ohio-based development hub and platform for partnership among inventors, pharmaceutical companies and the State of Ohio.

The Project will provide access for the world's leading pharmaceutical partners to invest in the nation's most highly vetted, set of new drug products. The Harrington Project anticipates continued interest from global pharmaceutical companies, financial investors, and national foundations to partner with it in the quest to quickly commercialize promising pharmaceuticals. This will establish Ohio as a leader in pharmaceutical development.

The State of Ohio's partnership with the ISC will increase the Harrington Project's capability to recruit talent and resources into the State, commit the Project to recruiting, developing, and collaborating with commercialization infrastructure within the State of Ohio for the ISC and its projects—increasing throughput to those providers and increasing their national visibility and enabling the creation of new Ohio-based start-up companies with the assistance of BioMotiv and its partners.

Economic Impact to Ohio

Per the July 2013 Battelle Technology Partnership Practice report, *The Economic Impact of the U.S. Biopharmaceutical Industry*, the U.S. biopharmaceutical sector represents 20% of all domestic research and development funded by U.S. businesses, the single largest share of all U.S. business research and development. In 2011, Ohio's biopharmaceutical industry represented over 19,000 direct jobs and supported almost 58,000 indirect jobs and that same year, the nation's biopharmaceutical industry represented over 813,000 direct jobs and supported over 2.5 million indirect jobs throughout the country. These jobs represent a broad base of positions, ranging from highly skilled scientific positions to supply chain infrastructure to positions resulting from worker spending. With an average annual wage of \$110,000, the biopharmaceutical industry represents earning power greater than twice the national average across other industries.

Critical to the industry is a robust pipeline. Scientific research and development services represent 41.7% of total biopharmaceutical employment and drive the development and utilization of supply chain services such as clinical trials and regulatory support, instruments and analytical equipment, contract manufacturing and a broad base of other functions. Together, R&D and company management—the two functions under rapid development by the Harrington Project—represent over 45% of the nation's biopharmaceutical employment. These two functions occur long before the manufacturing, sales and marketing phases of pharmaceutical commercialization. A robust

foundation of inventors, institutions and companies working together to advance and commercialize drug discoveries also ultimately drives the development and growth of pharmaceutical and manufacturing, a function of keen interest to the State of Ohio, which represents one third of the nation's employment in this sector. This broad foundation of multiple players—scientists, institutions and companies—also provides a level of stability to the sector rather than the reliance on one or two large scale operations, which can be shuttered in the face of company reorganizations with significant impact to the State.

The economic impact to the State of Ohio as a national pharmaceutical commercialization destination includes the following outcomes to be achieved during the grant period:

- Creation of high-salaried jobs in Ohio in the biopharmaceutical development field
- Creation of new companies in Ohio commercializing promising pharmaceuticals
- Leading physician scientists and their research teams relocating to Ohio to be part of its burgeoning biopharmaceutical climate
- Acceleration and strengthening of Ohio's pharmaceutical development supply chain
- Serving as a base for leading pharmaceutical partners to access the nation's most sought after discoveries, and by creating assets around which pharmaceutical companies can both invest and develop operations