

# Successful Collaboration Profiles



*Underwritten by:*  
Cincinnati USA Partnership for Economic Development  
and Wood Herron & Evans LLP

## CTI CLINICAL TRIAL AND CONSULTING SERVICES

Stromedix, Inc., a Cambridge, Massachusetts biotechnology company, wanted to conduct a Phase 1 first-in-man Clinical Study for its novel drug STX-100 in order to initiate a clinical development program for patients with fibrosis. A Food and Drug (FDA) approved treatment for hepatic and renal fibrosis does not yet exist, and the disease is responsible for many deaths in the developed world.

Although Stromedix had preclinical data, it needed outside expertise to facilitate their first human trial. The company selected CTI Clinical Trial and Consulting Services to provide that expertise.

Headquartered in Cincinnati, CTI is a full service provider of drug development, regulatory consulting, healthcare communications, and continuing education services to more than 50 pharmaceutical, biotechnology and medical device companies in the United States and across the world. CTI has a track record of success and understands the challenges that are faced during each stage of the drug and commercialization process.

### COLLABORATION STRATEGY

CTI brought much more than its own expertise to the study. It combined the expertise of numerous life science organizations in Greater Cincinnati including Community Research and Camargo Pharmaceuticals, to create an all-inclusive solution.

CTI was responsible for facilitating all aspects of the study with its partners. The comprehensive services included developing the study protocol, negotiating the study design with the FDA, selecting the clinical research site, monitoring all activities, collecting and analyzing data, and preparing the clinical study report for submission to the FDA.

### RESULTS AND BENEFITS

This collaborative effort is an excellent example of how the collective expertise of life science organizations can result in a complete solution for clinical studies. It also shows that the Greater Cincinnati area has this proven infrastructure in place.

The STX-100 study was very successful. Not only did the drug demonstrate an attractive safety and tolerability profile, the study paved the way for future clinical studies. Biogen Idec, the biotechnology company that originally developed STX-100, recently acquired Stromedix and is launching a Phase 2 Clinical Program in patients with idiopathic pulmonary fibrosis. The company's continued work in advancing STX-100 through clinical trials increases the likelihood of bringing a much needed life saving therapy to patients.

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## HealthBridge

Since 1997, Cincinnati-based HealthBridge, one of the nation's leading health information exchanges, has been dedicated to helping improve the quality and efficiency of health care for Tri-State residents.

HealthBridge combines its uniquely connected, secure technology with innovative process improvement to electronically send the right health information, at the right time, to hospitals, physicians and other health care organizations. Since patients move from one health care setting to another, access to the appropriate information enables providers to make informed and timely decisions about the care they deliver. In addition, patients benefit from higher quality and more cost-effective health care solutions. Currently, HealthBridge serves more than 50 hospitals, 800 physician practices and 7500 physicians through its services.

### COLLABORATION STRATEGY

Collaboration has always been a part of HealthBridge's business model, and its involvement in The Greater Cincinnati Beacon Collaboration (GCBC) is a prime example of this.

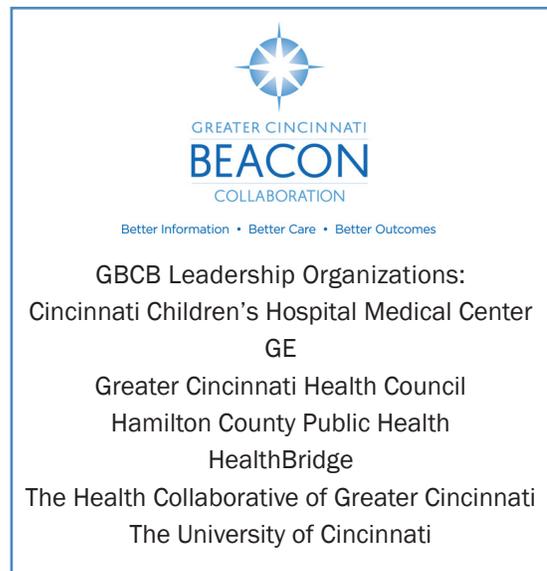
In 2010, the GCBC was awarded a \$13.75 million Beacon Community cooperative agreement from the U.S. Department of Health and Human Services. The goal is to implement advanced health information technology, health information exchange, and proven clinical interventions to improve health care cost, quality, and outcomes in the Greater Cincinnati area.

HealthBridge serves as the lead organization and is implementing an enhanced community IT infrastructure to improve information flow across the health care system, providing real-time data and connectivity between hospital, practice and home. HealthBridge is working with the Greater Cincinnati Health Council, The Christ Hospital and Mercy Anderson Hospital on a Transitions of Care Demonstration that will improve information flow between hospitals, nursing homes, home health and other post-acute care providers. Txt4Health, a mobile health program implemented in collaboration with Hamilton County Public Health, was recently launched and delivers personalized text messages to help people understand their risk for Type 2 diabetes and how to prevent it. In addition, HealthBridge, Cincinnati Children's Hospital Medical Center and the Health Collaborative are working together to help more than 80 practices and clinics in the region to enhance their patient information and work flows to provide exceptional care for childhood asthma and adult diabetes.

### RESULTS AND BENEFITS

This collaboration illustrates how the combined efforts of organizations can ultimately improve the quality, efficiency and cost-effectiveness of health care.

GCBC partners estimate that care for 32,000 patients with diabetes and asthma in Greater Cincinnati will be transformed through its numerous initiatives. Solution planning, development and testing among selected providers have been completed, and a roll-out to a larger group is underway.



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## Schulman Associates IRB

Institutional Review Boards (IRBs) play the important role of protecting the rights and welfare of people who participate in clinical research. IRBs are empowered by Federal regulations to approve, monitor and review biomedical and behavioral research studies that are conducted by pharmaceutical companies, organizations and institutions.

For over 25 years Schulman Associates IRB has been one of the leading accredited independent IRBs in the nation. Based in Cincinnati, the company provides IRB services for single and multi-center clinical trials in the United States, Puerto Rico and Canada and reviews nearly 500 research protocols and 7000 investigative sites each year.

### COLLABORATION STRATEGY

Schulman has developed an effective collaboration strategy with its long-standing client, CTI Clinical Trial and Consulting Services (CTI), which is a full service provider of drug development services to the pharmaceutical, biotechnology and medical device industries.

Schulman provides IRB services for clinical trials that are sponsored by CTI's clients. An experienced team of Schulman professionals facilitates the IRB process and works closely with CTI throughout each trial. After Schulman conducts a formal review of the research protocol, related safety information and the investigator's credentials, the companies continue to work together on other aspects of clinical trials.

They develop Informed Consent documents (ICs) which advise potential participants of the procedures, risks and benefits involved in a clinical trial. In addition, Schulman trains the research sites and inspects the medical licenses of clinical investigators, while both companies collaborate to confirm that the sites are adequately prepared for each trial. They make certain that research sites have the appropriate training and experience, and understand their responsibility to inform subjects of any new information that may affect their participation. Furthermore, Schulman and CTI discuss how to report and manage unanticipated safety issues that may arise during a trial.

Since both companies have offices in Cincinnati, frequent face-to-face meetings enhance their collaborative efforts; however technology also plays an important role. Schulman's proprietary WebPortal 3D™ provides CTI with immediate feedback about the status of various activities between Schulman and the research sites. This dynamic tool can be customized to further meet the needs of CTI, as well as other clients.

### RESULTS AND BENEFITS

This collaboration demonstrates how organizations can work together to provide high quality, comprehensive oversight of the conduct of clinical trials, which in turn helps protect the rights and welfare of people who participate in them. It also demonstrates how process, people and technology can be successfully combined to accomplish this goal.

In addition to making clinical trials safer for participants, both companies benefit from their collaborative efforts. Schulman gains greater insight into the specific needs and concerns of CTI, its sponsor clients and research sites, and CTI is able to enhance its service offerings to clients through Schulman's IRB expertise.

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**SCHULMAN**  
ASSOCIATES IRB

## Spineform, LLC

Progressive Adolescent Idiopathic Scoliosis, also known as curvature of the spine, can lead to serious complications later in life if left untreated, and the current treatment, Spinal Fusion Surgery, has a number of draw backs. It is a long and invasive procedure that requires blood transfusions and lengthy hospitalization. In addition, children often experience a high degree of post operative pain, have a slow rehabilitation process, are left with limited spine mobility, and can have complications that require further surgery.

Thanks to the collaborative efforts of SpineForm LLC, The Cincinnati Children's Hospital Medical Center (CCHMC), and several other partners, a revolutionary new treatment for progressive scoliosis in children is on the horizon. The HemiBridge™ System is designed to help patients avoid fusion surgery, stop spine curvature progression and spare spine mobility through a minimally invasive surgical procedure and spinal implant system that is intended to redirect the growing spine.

SpineForm received an Investigational Device Exemption (IDE) from the Food and Drug Administration (FDA) which allows the device to be used in clinical studies in order to collect safety and effectiveness data. As a result, clinical trials at CCHMC and Rainbow Babies and Children's Hospital in Cleveland are currently underway.

### COLLABORATION STRATEGY

The collaboration began in 2004, when E-Prime LLC, a Cincinnati-based medical technology development company, secured an exclusive licensing agreement with CCHMC to commercialize the HemiBridge™ System and then created SpineForm LLC. Since a number of steps need to occur before market clearance from the FDA can be obtained, several other collaborators play important roles. These include clinical research sites, physicians, scientists, consultants, contract manufacturers, and testing laboratories to name a few.

SpineForm leads ongoing meetings and communications between the partners, and involves new collaborators as interest in the commercial advancement of the HemiBridge™ System continues to grow. SpineForm also collaboratively manages the intellectual property, including issued patents and patent applications in the US and foreign equivalents.

### RESULTS AND BENEFITS

This success story provides an outstanding example of how collaboration may lead to a revolutionary new treatment and promise for an improved quality of life for children with progressive scoliosis. It also demonstrates how, Cincinnati-based SpineForm, a new company with high growth potential, continues to involve a vast majority of support and supply chain resources in Ohio and the region to help accomplish the objectives of providing much needed pediatric medical technology advancements and addressing a treatment gap of a progressive childhood onset disease.

SpineForm is currently in the early stages of sponsoring clinical research on the HemiBridge™ System. Grant and investment funding has supported pre-clinical and clinical research and development efforts. Funding was provided by Cincinnati Children's Hospital Medical Center's Tomorrow Fund, CincyTech USA, Queen City Angels, Ohio's Third Frontier program, and private investors.

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## University of Cincinnati Blue Ash College Clinical Research

A commitment to the success of its students is the driving force behind the University of Cincinnati's Blue Ash College's Clinical Research Programs.

The college offers a number of excellent courses as well as two certificate programs that are tailored to meet the diverse needs of its students. The Professional Certificate Program requires a Bachelor's degree and is designed to develop marketable skills in students who are seeking a career in the industry. The One-Year Certificate Program enables those who are already working in clinical research to enhance their knowledge through formal, structured training. A Bachelor's degree is not required for this program.

In addition, the college helps students evaluate their career goals and find employment in the field.

### COLLABORATION STRATEGY

In 1999, the college established an advisory committee of outside organizations, including institutional review boards, contract research organizations, sponsors, and clinical research sites. The goal was to identify opportunities for partnerships that would add value to the college's clinical research programs.

The initial collaboration was so successful that the list of partners continues to grow, and so does the value that they add. Some of their contributions include providing up-to-date educational content, serving as guest lecturers, networking with students, and advertising job opportunities and internships with the college. Eleven companies currently have representatives that serve as guest lecturers.

The advisory committee meets on an ongoing basis to further enhance and update the programs.

### RESULTS AND BENEFITS

This collaboration demonstrates how industry and academia successfully work together for the mutual benefit of the students and partners.

Students benefit by having current, applicable content that enables them to develop the relevant skills that they will need in the field. In addition, interaction with professionals from outside organizations and exposure to career opportunities can help pave the way for their future success.

Partners benefit as the college provides professional development opportunities for their employees through the courses that are offered. The college also customizes courses to meet their specific needs, and courses can be made available on-line or at their locations. Additionally, partners have firsthand access to a qualified pool of trained students who will become productive employees in a short period of time.

Since its inception, more than 125 students have graduated from the program.

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## Thanks to our underwriter – **Wood Herron & Evans**

Life Sciences organizations often have a number of unique opportunities and challenges that require industry-specific experienced legal counsel. Starting a new business and forming partnerships with other organizations are two examples. In addition, protecting intellectual property through patents, trademarks and copyrights is very important because it enables a company to have exclusive use of an invention or an idea for a set period of time.

Headquartered in Cincinnati, Wood Herron & Evans understands these needs. The firm's Biotech practice is comprised of dedicated patent attorneys and support staff with in-depth experience who provide intellectual property legal counsel to Life Sciences organizations ranging in size from start-ups to large companies and institutions.

With a 140+ year legacy of superior intellectual property legal services, Wood Herron & Evans is the largest in the region.

### **Collaboration Strategy**

Collaboration with its clients enables the firm to deliver cost-effective, efficient intellectual property legal solutions that fit and enhance each organization's business objectives.

The collaboration process begins by matching each client with a lead attorney and support team that have industry-specific experience. A legal plan, which is a focused and detailed strategy, is developed to accomplish the client's objectives. This plan also enables the firm to foresee any intellectual property legal hurdles before they arise, and successfully plan around them to deliver favorable results.

In addition, the firm works with clients to identify areas of potential cost savings, which include:

- Only taking on tasks with the client's approval
- Assisting with procedures that can be completed by the client's personnel
- Educating the client's personnel to be sensitive to intellectual property potential problem areas in order to avoid issues later
- Creating form contracts for the client's use in standard situations
- Providing upfront cost estimates of planned procedures
- Preparing a detailed monthly statement of billings and costs for the client's review

### **Results And Benefits**

This success story illustrates how Wood Herron & Evans involves its Life Sciences clients throughout the entire engagement process in order to deliver targeted, cost-effective, efficient, and successful solutions.

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We assist our clients with preparing and prosecuting patent applications worldwide, as well as rendering patentability, infringement and validity opinions, negotiating licenses, and counseling a wide range of clients encompassing technologies that span the spectrum.

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**About The Cincinnati USA Partnership:**

The Cincinnati USA Partnership, directed by the Cincinnati USA Regional Chamber, has been the region's leading economic development initiative for the past 25 years. A new strategy for the Partnership is to utilize Cluster Based Economic Development. The Partnership is responsible for attracting, retaining and growing new business, jobs and investment in the three-state, 15-county region known as Cincinnati USA. A key target is the BioHealth Cluster with a mission to grow the industry sector in the region. In 2007, 2008 and 2010, the Partnership was recognized by *Site Selection Magazine* as one of the Top 10 Development Organizations in the nation. The Partnership is supported through a five-year campaign with investment from nearly 120 companies and public economic development organizations. For more information, visit [www.cincinnatiusa.org](http://www.cincinnatiusa.org).



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