



NEWS RELEASE

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SRI International and Stanford University School of Medicine’s MISTRAL Collaborative and the Institute for Pediatric Innovation Awarded FDA Grant to Accelerate Commercialization of Pediatric Medical Devices

MENLO PARK, Calif. – July 22, 2010 – SRI International and the Stanford University School of Medicine announced today their MISTRAL Collaborative (the Multidisciplinary Initiative for Surgical Technology Research Advanced Laboratory), in conjunction with the Institute for Pediatric Innovation, was recently awarded a \$1M grant by the Food and Drug Administration (FDA) to support its work to commercialize innovative medical devices for pediatric care.

A key objective for the FDA-funded project will be to identify opportunities for new medical devices specific to the newborn intensive care unit (NICU) setting. Other focus areas for pediatric product development will include surgical tools and catheter-related products.

“Children are the ‘orphans’ of the medical device industry,” said Sanjeev Dutta, M.D., associate professor of surgery and of pediatrics at the Stanford University School of Medicine and attending surgeon at Lucile Packard Children’s Hospital at Stanford. “Market and regulatory concerns often prevent medical device companies from investing in pediatric-specific device development. Not infrequently, appropriate devices that specifically address pediatric diseases are simply not available, leaving some practitioners to use adult devices on kids or ‘jerry-rig’

their own solutions. The MISTRAL Collaborative, with this tremendous boost from the FDA, hopes to catalyze pediatric device development by performing the initial R&D, partnering with industry, and identifying paths to market for badly-needed pediatric devices.”

There are a variety of reasons to explain the lack of appropriately developed medical devices for children. In addition to design issues, there is a lack of standards for the development process, and a market size that doesn't drive investment and create sufficient data to understand efficacy and support regulatory approval. The economic challenges mean that the return on the investment required to develop and test pediatric devices usually falls below the profit goals of medical device companies.

“By applying SRI's proven methods for high-impact research together with early and ongoing involvement of pediatric clinicians, engineers, and a networked community dedicated to the successful transition of pediatric medical devices to the market, we will address a critical need in pediatric medical care,” said Pablo Garcia, an SRI principal engineer. “Although there are regulatory and economic challenges, we will work to overcome the barriers and develop medical devices intended specifically for the treatment of children.”

The work of the MISTRAL pediatric device consortium will be performed by a cross-functional team comprised of technical staff from SRI, physicians and medical staff from Stanford and Packard Children's, consultants, and industry professionals. To improve opportunities for the successful commercialization of pediatric devices, researchers will work closely with a distinguished group of advisors that will evaluate technologies and provide feedback on business plans. A venture-philanthropic program, the Pediatric Device Fund, will be established to support the development of products that do not have sufficient market pull, but that would provide significant clinical benefits if brought to the market.

“The Institute for Pediatric Innovation has pioneered a needs-driven innovation model to overcome the traditional barriers to pediatric device innovation,” said Ross Trimby, chief operating officer at IPI. “We have organized a national consortium of pediatric hospitals that

partner with us in defining needs and setting priorities, establishing product feasibility, and in detailed design and development of pediatric devices. This process has resulted in industry agreements to develop three NICU devices using this process. We are pleased that this collaboration will enable us to partner with one of the nation's leading engineering resources to address additional needs in neonatal care.”

The FDA-funded pediatric device consortium project will be led by MISTRAL co-founders Sanjeev Dutta and Pablo Garcia. Garcia leads research in medical systems and medical product development, telemedicine and robotic surgery. Dutta is a nationally recognized leader in minimal-access surgery and defined the area of stealth surgery, a “scarless” approach to pediatric operations.

About the Institute for Pediatric Innovation

The Institute for Pediatric Innovation (<http://www.pediatricinnovation.org>), a nonprofit organization, was formed to foster innovation to improve pediatric care by stimulating development of appropriate medical devices and drugs designed specifically for babies and children. Working with a Consortium of Pediatric Hospitals, IPI strives to identify the most needed products. IPI organizes public, private, nonprofit and for-profit collaborations in product innovation and licenses the resulting products to companies for commercial development. IPI is led by an experienced team of experts in licensing technology in pediatric medical care, commercializing medical technology, and marketing medical devices and pharmaceutical products. To date, IPI has received support from its consortium members along with the Ewing Marion Kauffman Foundation, Children's Medical Ventures, Inc., AGA Medical, Oxford Bioscience Partners and the World Health Organization (WHO).

About Lucile Packard Children's Hospital

Ranked as one of the nation's best pediatric hospitals by *U.S. News & World Report*, Lucile Packard Children's Hospital at Stanford is a 312-bed hospital devoted to the care of children and

expectant mothers. Providing pediatric and obstetric medical and surgical services and associated with the Stanford University School of Medicine, Packard Children's offers patients locally, regionally and nationally the full range of health care programs and services, from preventive and routine care to the diagnosis and treatment of serious illness and injury. For more information, visit www.lpch.org.

About SRI International

Silicon Valley-based [SRI International](#) is one of the world's leading independent research and technology development organizations. SRI, which was founded by Stanford University as Stanford Research Institute in 1946 and became independent in 1970, has been meeting the strategic needs of clients and partners for [more than 60 years](#). Perhaps best known for its invention of the [computer mouse and interactive computing](#), SRI has also been responsible for major advances in [networking and communications](#), [robotics](#), [drug discovery and development](#), [advanced materials](#), [atmospheric research](#), [education research](#), [economic development](#), [national security](#), and more. The nonprofit institute performs [sponsored research and development](#) for [government agencies](#), [businesses](#), and [foundations](#). SRI also [licenses its technologies](#), forms [strategic alliances](#), and creates [spin-off companies](#). In 2009, SRI's consolidated revenues, including its wholly owned for-profit subsidiary, [Sarnoff Corporation](#), were approximately \$470 million.