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Children's Mercy leads juvenile drug study

Hospital will analyze proper dosages for kids

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For the next seven years, **Children's Mercy Hospitals and Clinics** will play a key role in a \$95 million federal contract to improve drug label dosing instructions for children.

The contract, which could bring upward of \$10 million into the hospital alone, will enhance the area's goal of establishing a corridor for human biosciences, said Dr. Gregory Kearns, chairman of the department of medical research at Children's Mercy and co-principal investigator on the contract.

"This is truly a national and potentially international effort that's going to shine even more light here," Kearns said. "It's going to create opportunities in the region that the region perhaps hasn't seen before."

The contract is worth a potential \$95 million from the National Institutes of Health and combines the expertise of six institutions to create the Pediatric Trials Network. The goal: provide more information about child dosing to improve drug labels.

"It doesn't just work for children and Children's Mercy or children in Kansas City," Kearns said. "When we make drugs available with complete knowledge to let them be used safely and effectively, it brings value to children in the country and beyond."

Children's Mercy will serve as the clinical pharmacology core, making it responsible for evaluating and analyzing the selected drug compounds and how they react in children. The team at Children's Mercy also will work to develop new formulations for older drugs and help design trials for the network.

Kearns said he thinks Children's Mercy will earn between \$5 million and \$10 million of the contract financing.

Currently, between 50 percent and 75 percent of the medications prescribed to children are done so off-label — with dosing instructions lacking approval from the Food and Drug Administration and complete information, said Dr. David Siegel, representative with the **Eunice Kennedy Shriver National Institute of Child Health and Human Development**, the department within NIH overseeing the contract.

“This contract will contribute significantly to putting a dent in this incredible gap,” he said.

Peter Joiner, president and CEO of **Madeira Therapeutics LLC**, a Leawood-based company working to establish formulations for adult drugs used in children, said about 400 compounds are used to treat children but haven’t been tested completely.

“For too long, I think our children have been treated as second-class citizens,” he said.

“Large drug companies have no interest in going back and doing pediatric drug trials on products that have already gone off patent. That’s exactly what the Pediatric Trials Network is doing.”

Madeira’s work in pediatric formulations positions the company as a potential partner within the network, Joiner said.

Kearns agreed, adding that the contract will enhance partnerships throughout the region, such as with the **University of Kansas Medical Center** and **Quintiles Transnational Corp.**