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### **BPCA-PTN COVID-19 STUDIES**

Project Number Contact PI/Project Leader 275201800003I-0- ZIMMERMAN, MD, 759402000001-1 KANECIA

Awardee Organization DUKE UNIVERSITY

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#### **Abstract Text**

For the last 25 years the scientific community, including academia, the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the pharmaceutical industry have worked to improve the knowledge of medications used in children. The responsibility for the implementation and oversight for improving drug development has been delegated primarily to the FDA (for on-patent drugs) and to the NIH (for off-patent drugs). The Pediatric Trials Network (PTN) has been established and funded under the Best Pharmaceuticals for Children Act (BPCA) Clinical Program implemented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). Many PTN studies historically capitalize on standard of care (SOC) procedures, such as data and biological-sample collection from infants and children already receiving drugs of interest (DOIs), and have produced meaningful pharmacokinetic (PK) data resulting in improved dosing recommendations in infants and children. These studies do not prescribe or administer drugs to children, but rather collected samples from children who were already receiving drugs per SOC as prescribed by their treating provider. In addition, preliminary data obtained through opportunistic studies have served to design phase 1 through 3 trials in children as well as support applications for extramural research. The coronavirus disease 2019 (COVID-19) pandemic is caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The infection may range from the patient having no symptoms to causing a wide range of symptoms, such as mild cold like symptom to life-threatening pneumonias, sepsis, and multi-organ system failure. COVID-19 first emerged in December 2019 when a cluster of patients in Wuhan, China developed severe pneumonias of unknown cause. [Wiersinga et al, JAMA doi:10.1001/jama2020.12839]. As of August 11, 2020, SARS-CoV-2 has affected more than 200 countries, resulting in 20,124,437 million identified cases with over 737K confirmed deaths [https://www.cdc.gov/coronavirus/2019-ncov]. In April 2020 at the peak of the COVID-19 outbreak, there was recognized a new onset of hyperinflammatory symptoms in children who either had active disease or in children who had been previously exposed to COVID-19 with or without symptoms. This syndrome was named multisystem inflammatory syndrome in children (MIS-C) by the CDC in May 2020. As of July 29, 2020, 570 patients have met the criteria for MIS-C in the US [https://www.cdc.gov/mmwr/volumes/69/wr/mm6932e2.htm]. As the pandemic continues to spread throughout the US and the world, the scientific community anticipates that the number of children infected and affected will continue to rise. There must be an organized concerted collaborative effort between public health, patient care, and research in order for the appropriate prevention, identification and treatment of children impacted by COVID-19. Since COVID-19 has ravaged the world with inordinate high infection rates and death, the need for preventive, research and clinical data have become paramount and top priority for NIH as a research and funding institution. Furthermore, NIH, academia, clinicians, and others in the scientific community are concluding that the harmonization of all epidemiology and clinical related data as well as clinically relevant outcomes vital to identification and treatment of patients at-risk for COVID-related illnesses, such as the multi-system inflammatory syndrome in children (MIS-C), are critical to successfully managing the pandemic. These COVID-19 related studies will leverage the expertise and existing data within the PTN infrastructure of the BPCA program (BPCA PTN and Data Coordinating Center) to expand the research on SARS-CoV-2 (COVID-19) in children.

### **Public Health Relevance Statement**

Data not available.

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### **BPCA-PTN COVID-19 STUDIES**

**Project Number** Contact PI/Project Leader Awardee Organization 275201800003I-0-**DUKE UNIVERSITY** ZIMMERMAN, MD, **KANECIA** 759402000001-1

**Academia Best Pharmaceuticals for Children Act** 2019-nCoV **Affect** COVID-19 **Biological Biological Markers** COVID-19 pandemic

**Cessation of life** Centers for Disease Control and Prevention (U.S.) Child

Childhood Clinical **Clinical Data Clinical Trials Design** China

Communities Coronavirus **Data Coordinating Center** Country Data

**Disease Outbreaks Drug Industry Drug Kinetics Diagnosis** Disease Dose

**Effectiveness Epidemiology Exposure to Extramural Activities Failure** 

**Funding Future** Infant Infection Inflammatory Institution

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# **Details**

**Other Pls Contact PI/ Project Program Official** 

Leader Not Applicable

Name Contact **ZIMMERMAN, MD, Email not available** KANECIA

Title

Contact

**Email not available** 

**Organization** 

Name Department Type State Code Unavailable **DUKE UNIVERSITY** NC

City **Organization Type Congressional District** 

**DURHAM Domestic Higher Education** 

Country **UNITED STATES (US)** 

**Other Information** 

2020

FOA Administering Institutes or 21-**Project Start** 

Centers Study Section Date

**EUNICE KENNEDY SHRIVER** Award Notice NATIONAL INSTITUTE OF Fiscal Year CHILD HEALTH & HUMAN

Date **DEVELOPMENT** 

**DUNS Number** 

044387793 CFDA Code **Project End** 20-

Date September-

2023

September-

**Budget Start** Date

Name

04

**Budget End** Date

Thank you for your feedback!

### **Project Funding Information for 2020**

**Total Funding Direct Costs Indirect Costs** ĊΩ \$5,000,000 \$0

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**Project Number** 

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Contact PI/Project Leader ZIMMERMAN, MD, KANECIA

Awardee Organization **DUKE UNIVERSITY** 

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# **品 Sub Projects**

No Sub Projects information available for 275201800003I-0-759402000001-1

### **Publications**

No Publications available for 275201800003I-0-759402000001-1

# **'d'** Patents

No Patents information available for 275201800003I-0-759402000001-1

### Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 275201800003I-0-759402000001-1

### **Clinical Studies**

No Clinical Studies information available for 275201800003I-0-759402000001-1

# News and More

**Related News Releases** 

Thank you for your feedback!

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No Historical information available for 275201800003I-0-759402000001-1

# **Similar Projects**

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