

# Pediatric and Adult Clinical Research Centers

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## *RWJMS Clinical Research Centers(Adult and Pediatric)*

Facilitating investigator-initiated and externally sponsored phase I-IV clinical trials and translational research

### ADULT CRC

- 11,000 SF research facility
- 4 Examination, 2 infusion rooms
- 4 Long stay rooms
- Phlebotomy/laboratory
- Comprehensive Pulmonary Laboratory
- Robotic Echocardiogram
- Investigational Drug Pharmacy
- Staff trained in clinical research



### PEDIATRIC CRC

- 5000 SF research facility, adjacent to the children's campus
- Child friendly space
- Examination rooms and long stay beds
- Phlebotomy station
- Laboratory
- Staff trained in pediatric research



## *RWJMS CRC Services for Investigator Initiated Studies and NIH grants (Inpatient, Outpatient, Community)*

### **Protocol development**

Work with investigators to provide guidance and input

### **Regulatory Assistance**

Guidance for IRB application and regulatory requirements, CT.gov submission consultation

### **Budgetary/Financial Assistance**

Protocol review and budget development

### **Study Management**

Operational support of study specific needs.(e.g. consenting and study coordination, phlebotomy, EKG, infusions, point of care testing)

### **Data Management**

REDCap database development for simple studies, data entry and data quality support

### **Laboratory services**

Sample Preparation, storage (-80F, -20F) , shipping and point of care testing (e.g. Preg test, HbA1C, glucose)

### **Investigational Drug Pharmacy Services**

IND consultation, Study drug and placebo preparation, Randomization

### **Comprehensive Pulmonary Laboratory**

Spirometry, Full PFT, CPET, Metabolic cart

#### **Service models**

- Services on an hourly basis per fee and study schedule
- Partial or full salary support for a particular staff member

# CRC TEAM

## Pediatric CRC

**Assistant Director: Dr. Maya Ramagopal**

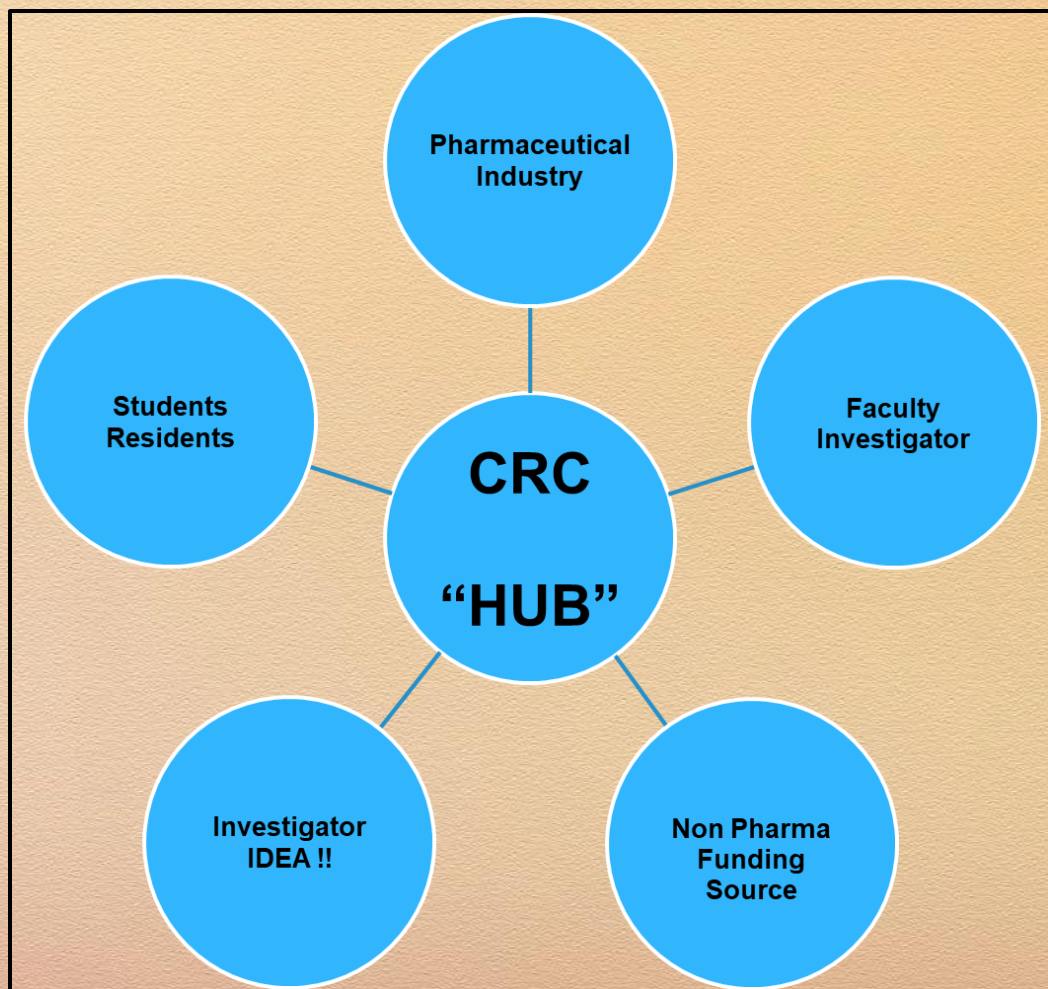
- **Lisa Cerracchio, Nurse Manager**
- Christina Varghese, Research Coordinator
- Bibiana Vargas, Research Coordinator
- Christian Suarez, Research Coordinator
- Akhil Patel, Research Assistant
- **Yue Hao, MBS Regulatory Coordinator**
- Damaris Soto, Administrative Assistant
- Harsh Sharma, Research Assistant
- Claudio Mendes, Research Assistant

## Adult CRC

**Assistant Director: Dr. Marc Sturgill**

- **Fei Chen, Nurse Manager**
- Therese Pagulayan, Research Nurse Coordinator
- Barbara Tsounis, Research Nurse Coordinator
- Sheila Redding, Research Coordinator
- Sarah McCracken, Research Assistant
- Galina Solodkin, Lab Assistant
- **Anoja Warusawithana, MS Regulatory Coordinator**
- Sylvia Rodrigo, Program Support Specialist
- Sherri Gzemski, Business Manager
- **Elizabeth George, RPh – Lead Research Pharmacist**
- **Mark Rusay, PharmD- Research Pharmacist**
- **Kathy George, RPh, Research Pharmacist**
- **Chetram Nauth - Pharmacy Tech.**
- William Russel, Research Coordinator/Respiratory Therapist

## RWJMS CRCs : Core Resource Units



- Industry Sponsored studies: Interface with sponsor, Connect with interested PI, IRB preparation and submission, launch and manage studies (full support or partial support )
- Investigator Initiated funded studies: Protocol development, budget input, IRB submission assistance if needed, launch and manage studies as needed
- Resident /student project: Serves as a resource for Protocol guidance, IRB guidance
- Investigator idea: Protocol guidance, help with seeking pharma sponsor. IND submission as needed.

# CRC Interface with the CTSA(NJACTS) Clinical Trials Office

- Assess for **recruitment potential** with Deep6 AI Cohort Builder
- If feasible, study moves forward

**Feasibility Review**

**Regulatory Affairs**

- **Scientific Review Board** for Investigator Initiated studies
- Provides consultation to investigators during protocol preparation

**Business Office**

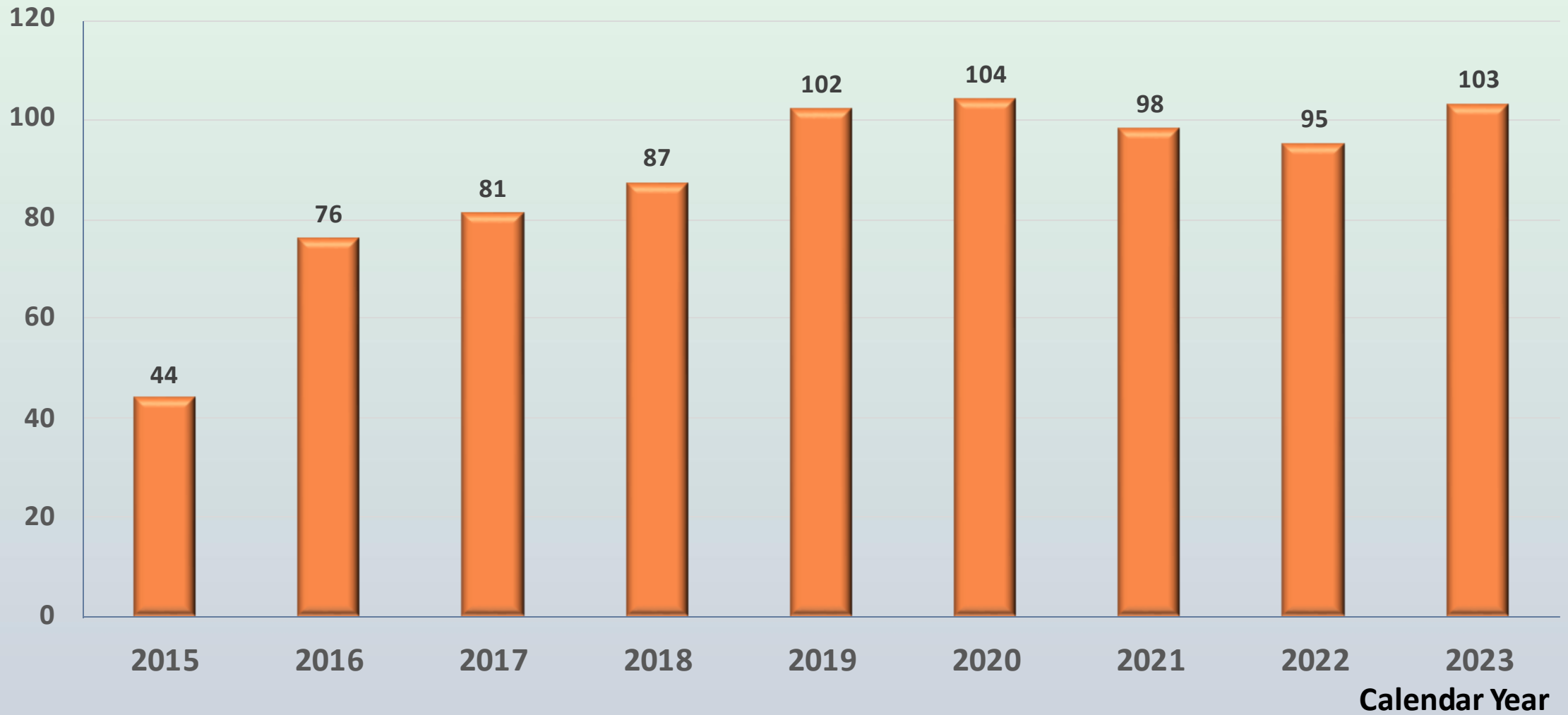
- Centralized **contract** negotiations
- Centralized **Budget** negotiations
- Post-award **financial management**
- **ClinCard** management

**Execution**

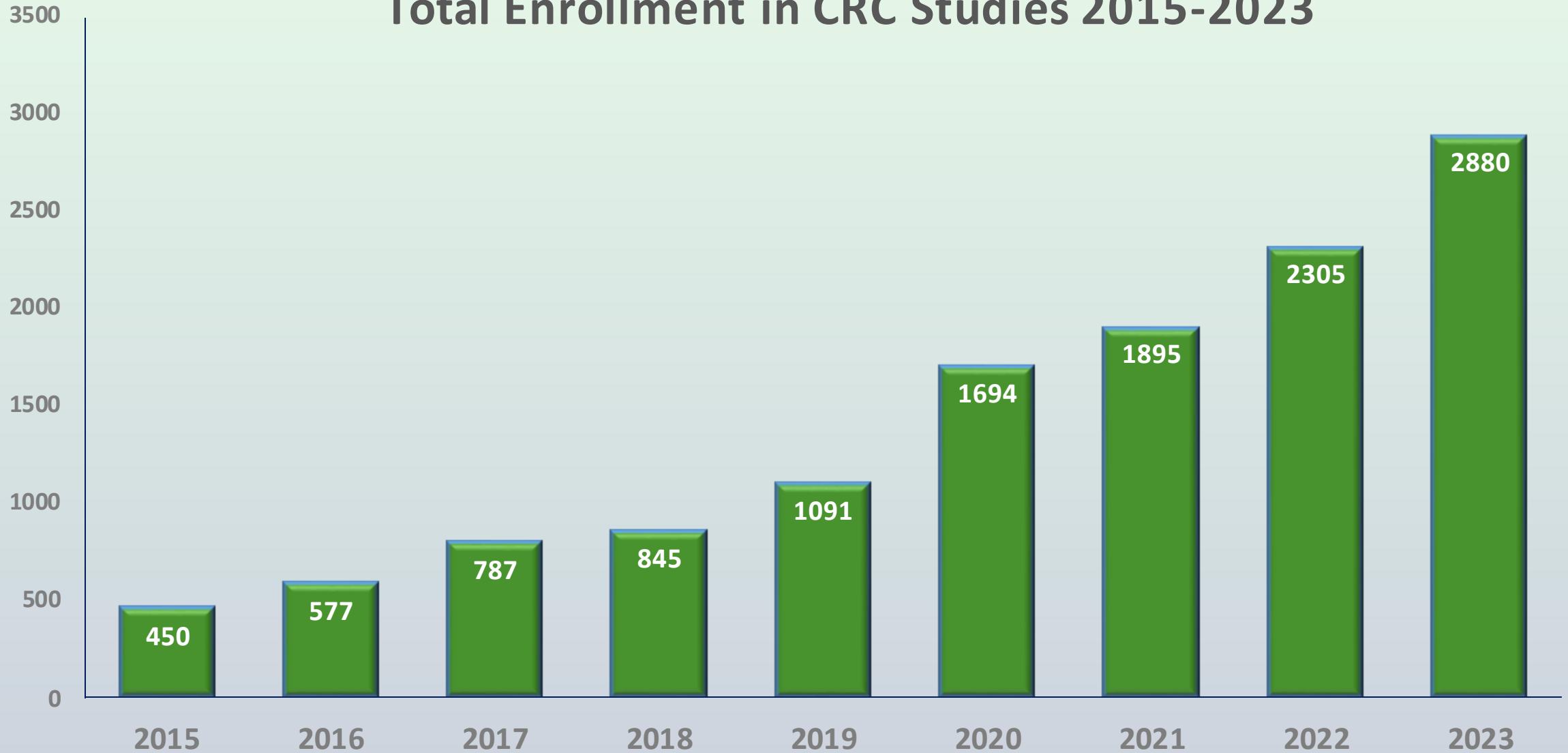
- Clinical Research Centers**
- Budget prep, negotiation, financial management
  - IRB submission, regulatory management
  - Enroll participants and conduct research and data management
  - Manage studies using **OnCore CTMS**



## RWJMS CRC Active Studies 2015-2023



## Total Enrollment in CRC Studies 2015-2023



## Major Diseases Currently Under Study

### ACRC

**Cystic Fibrosis**

**Scleroderma**

**Asthma**

**COPD**

**IBD/Ulcerative Colitis**

**Microbiome studies**

**Infectious Diseases (antifungal,  
antiviral)**

**Long COVID**

**Parkinson's Ds**

**Heart failure, Myocarditis, STEMI**

**Metabolism (glucose, exercise)**

### PCRC

**Cystic Fibrosis**

**Juvenile Arthritis**

**Multiple Sclerosis**

**Bacterial Infections**

**Endocrine (Growth Hormone,  
CAH)**

**Long COVID**

**Lyme Ds. (Vaccine)**

**Gastroenteritis (Oral Hydration)**

**NIH Maternal/child Echo Cohort**

## Highlights: Past Successes

- Major role as a Cystic Fibrosis Therapeutic Drug Network site in the pivotal studies leading to approval of CF drugs such as Trikafta that have changed the disease course of CF
- During the COVID pandemic : Vaccine and treatment studies
- Sickle cell disease: Pain management medications
- Scleroderma: New treatments
- New antibiotics (adults and children)
- New diagnostics for detection of bacteremia

# CRC Study Launch Process (Investigator Initiated Studies)

**Initial Meeting:** Early stage consultation ( preferably before budget and protocol are finalized)  
Review protocol, feasibility, feedback Nurse Manager and CRC Director

**Second meeting:** Refined protocol review  
Define CRC services needed  
Nurse manager/CRC Director  
Budget input (CRC Financial Analyst)

**Start up meeting:** Logistical planning  
Nurse manager  
Study Coordinator/other personnel as needed

All the drugs and tools we have today...



...are thanks to  
**participants**  
in clinical trials

