



# ***PROACTIVE*** **New York State**

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# Disclosures

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Research support:

- PROACTIVE NYS: Funded by NICHD Task Order 75N94021D00018
- LINCATS Network Mentored Clinical Research Development Award

- Long-term follow-up study of cCMV screen-positive newborns
- Goal: Systematically follow all children through 2 years of life
- Enrollment estimate: 500-1,000 children (0.25 – 0.5% cCMV rate)
- Periodic assessments of:
  - Clinical findings
  - Antiviral treatment status
  - Neurodevelopmental outcomes
  - Audiological outcomes
  - Ophthalmological outcomes

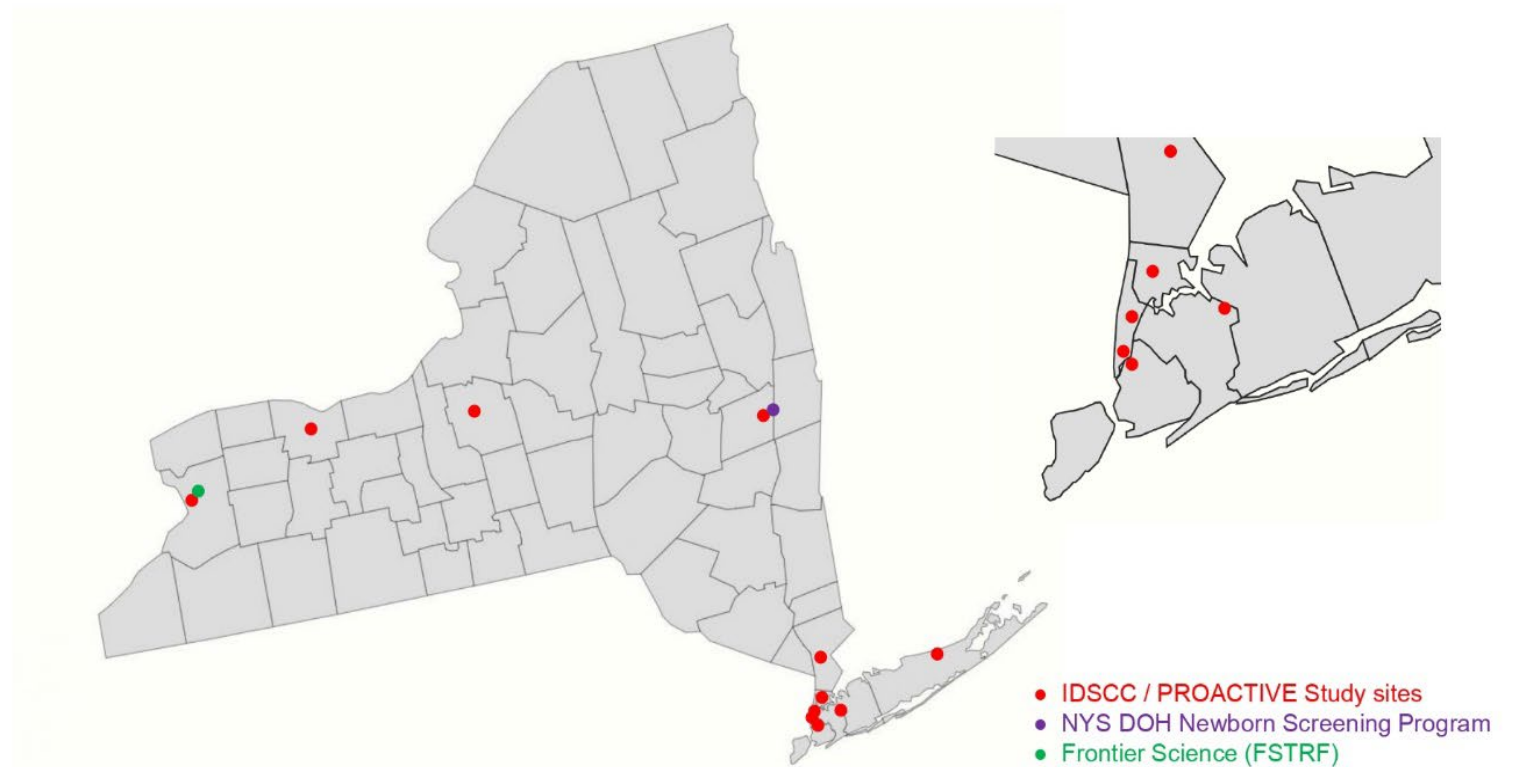
# Study Objectives

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- To enroll at least 90% of all cCMV screen-positive infants across NYS
- To determine the rate of confirmed cCMV in a statewide cohort
- To describe the distribution of neonatal features among children with confirmed cCMV
- To describe trends in antiviral and non-pharmaceutical treatments, adverse effects, and impact on long-term outcomes
- To assess the long-term audiologic, neurologic, and developmental outcomes
- To describe the impact of a positive cCMV screen on the quality of life (QoL) of infants and families

# PROACTIVE Study Sites

- Study referral & enrollment
- 11 study sites
- Study partners
  - NYS DOH NBS
  - Frontier Science



# Participant enrollment categories

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- **Category 1:** Confirmed cCMV identified by NBS
- **Category 2:** Confirmed cCMV **not** identified by NBS (False-negative cCMV screen)
- **Category 3:** False-positive cCMV screen
- **Category 4:** Premature infants with confirmed cCMV on late positive NBS

# Study Entry Visit (Birth – 1 month old)

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## **Newborn diagnostic evaluation**

- Maternal CMV history
- Confirmatory CMV PCR results
- Physical exam findings
- Lab results
- Imaging
- Neonatal hearing screen results
- Ophthalmologic screening

## **Treatment decisions**

- Treatment provided
- Toxicities

# Long-Term Outcomes: Neurodevelopment

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## Neurodevelopmental Assessment Screening

- ASQ-3
- ASQ:SE-2
- MCHAT-R/F

## Children with developmental delays identified

- Early Intervention referral
- Neuropsychology assessment
  - Bayley-III
  - Vineland Adaptive Behavior Scales



# Long-Term Outcomes: Hearing and Vision

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## **Audiological monitoring**

- Every 3-6 months (or more frequent)
- Interventions provided

## **Ophthalmologic monitoring**

- High-risk infants
- Every 6-12 months, per Ophtho recommendations

# Quality of Life

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## QoL Assessment

- Cross-sectional QoL assessment at 1 year from study start date
- Second QoL assessment when each child reaches 2 years of life

Prospective Observational study of Asymptomatic cCMV Transmission to Infants for Virological Evaluation in New York State

# Working **Together** to Improve Outcomes

While cytomegalovirus (CMV) is the most common congenital infection, the vast majority of newborns show minimal or no symptoms at birth and go undiagnosed.

One fifth of children known to have cCMV will develop long-term issues such as hearing loss and cognitive impairment, but there is little known about the treatment and long-term outcomes for those newborns without symptoms.

There is now an unprecedented opportunity to leverage New York State's new universal screening program to gain in-depth insight into the symptoms shown at birth and medical care provided for all newborns across a diverse state and work toward better outcomes for everyone.

[Learn More](#)

Period  
Entry

Visit Date  
2/3/2022 5/9/2023

Site Name  
 (All)  
 Albany  
 Rochester  
 Stony Brook  
 Syracuse

Congenital CMV  
 (All)  
 Negative  
 Positive

Symptomatic  
 (All)  
 No  
 Unknown  
 Yes

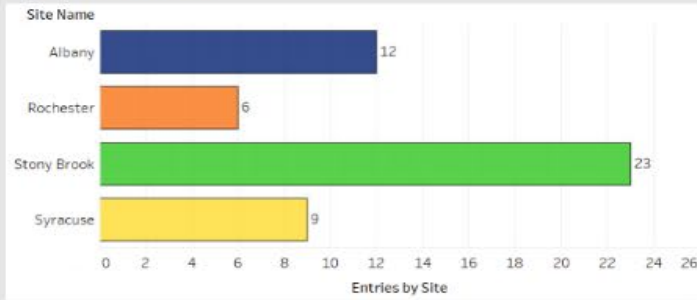
Prenatal abnormalities  
 (All)  
 Head  
 Liver  
 None  
 Spleen

Gestational age at birth  
29.30 41.90

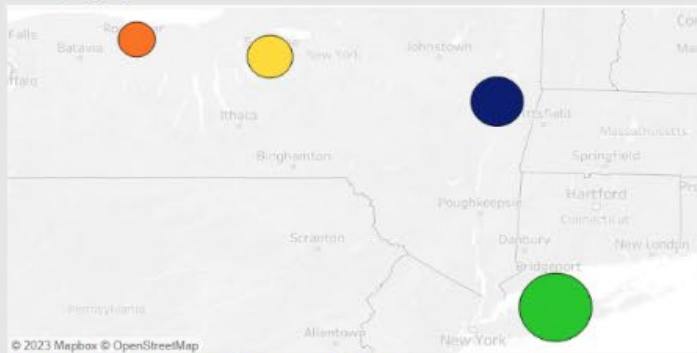
Birth weight  
4 000 9 940

Prenatal Abnormalities  
 Head  
 Liver  
 Spleen  
 None  
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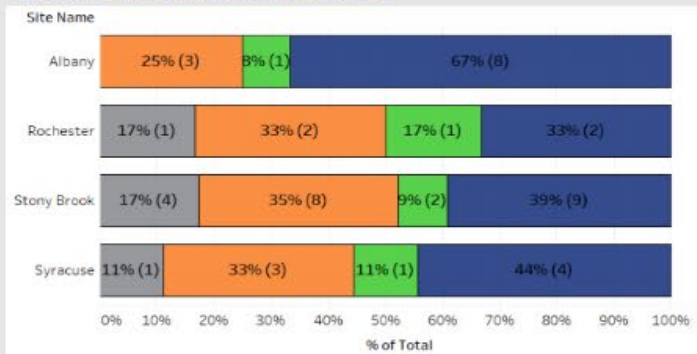
### Enrollment by Site



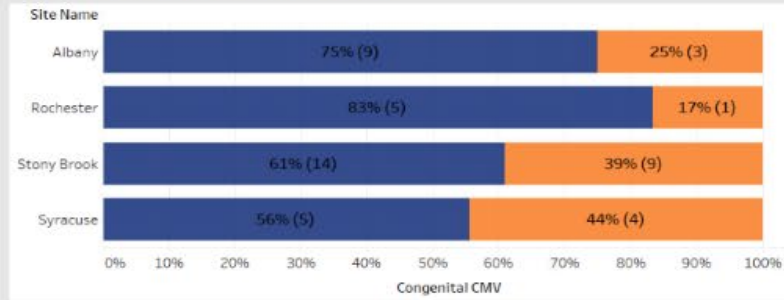
### Geography



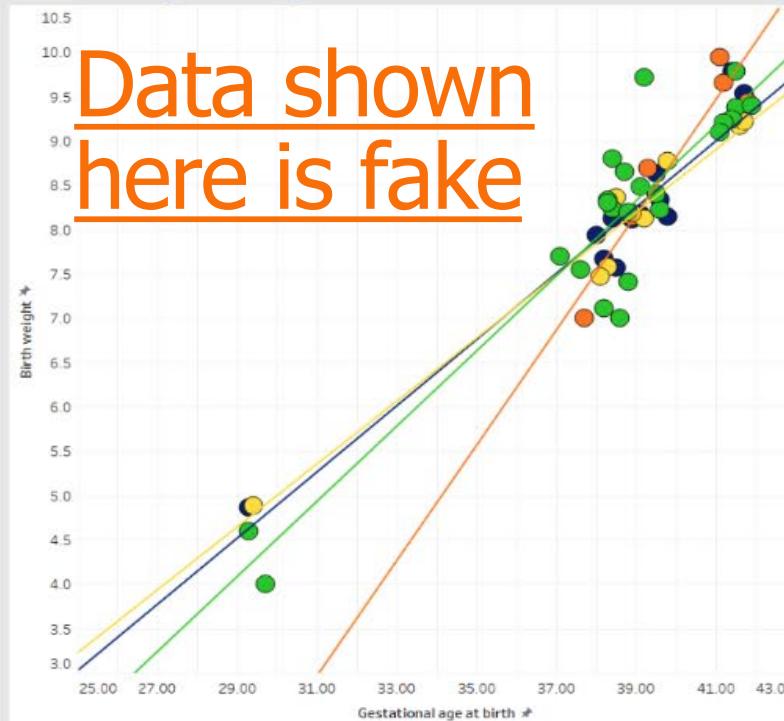
### Prenatal Ultrasound Abnormalities



### Congenital CMV Newborn Screens



### Gestational Age and Weight



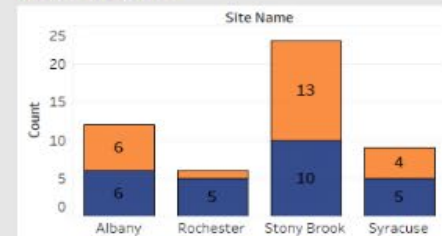
### Symptomatic

Site Name	Symptomatic		
	Yes	No	Unknown
Albany	6	4	2
Rochester	4	1	1
Stony Brook	10	9	4
Syracuse	4	4	1

### Hearing Impairment



### Missed Cases



### Quality of Life

Quality Of Life	Site Name			
	Albany	Rochester	Stony Br..	Syracuse
A. High	2	1	9	2
B. Medium prefer a..	3	1	5	4
C. Low - assistance ..	5	3	5	
D - NA	2	1	4	3

# Thank you!

## PROACTIVE Co-PIs:

- Sharon Nachman, MD (Stony Brook)
- Michele Caggana, ScD, FACMG (NYS DOH)

## NYS DOH Newborn Screening Program

Sarah Bradley, MS, CGC

Lequela Steen

Norma Tavakoli, PhD

PROACTIVE Study Site	Specialist
Albany Medical Center	Debra Tristram, MD Saul Hymes, MD Gillian Taormina, DO
New York Presbyterian - Brooklyn Methodist	Minnie John, MD
SUNY Upstate	Leonard Weiner, MD
New York Presbyterian - Weill Cornell	Christine Salvatore, MD
Stony Brook Children's	Andrew Handel, MD Sharon Nachman, MD
BCH/NY Medical College / Westchester Medical Center	Sheila Nolan, MD Patricia De La Mora, MD
NYU School of Medicine	Gail Shust, MD
Children's Hospital at Montefiore	Margaret Aldrich, MD
URMC/Strong Memorial	Geoffrey A. Weinberg, MD
Cohen Children's Medical Center / Northwell Health	Sunil Sood, MD
SUNY Buffalo	Mark Hicar, MD, PhD Karl Yu, MD, PhD

# Questions?

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