

# FON Registry

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*Michael Di Maria, MD*

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**National Pediatric Cardiology**  
*Quality Improvement Collaborative*





# The FON Registry:

# Foundational Data

# Structure/Overview of Database

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*Quality Improvement Collaborative*





- Secure web-based platform used by >7000 institutions for electronic data capture and management
- HIPAA compliant

Fontan Outcomes Network Registry (PRODUCTION) PID 11354

The Codebook is a human-readable, read-only version of the project's Data Dictionary and serves as a quick reference for viewing the attributes of any given field. Checkbox fields have their coded values displayed both in the format defined by users in the Online Designer/Data Dictionary as well as in the extended format.













Print page

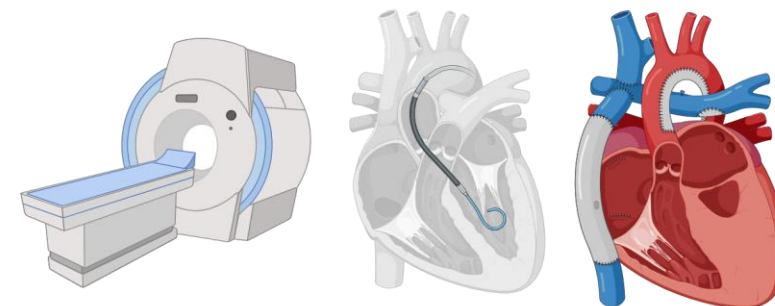
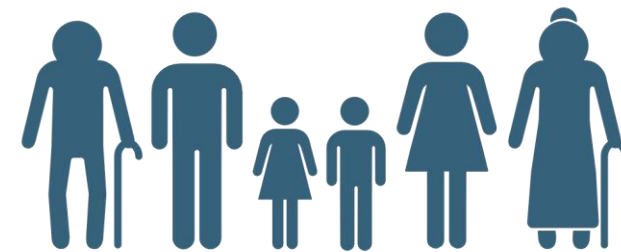
Data Dictionary Codebook

Field finder:

#	Variable / Field Name	Field Label <i>Field Note</i>
<b>Instrument: Registration/ Patient Profile</b> (registration_patient_profile)		
1	[subjid]	FON Registry ID: (Site # - ID #) ###-####
2	[enrollcenter]	Section Header: <i>Patient Information</i> Enrolling Center: Hidden and read-only for launch
3	[currentcenter]	Current Center providing Primary Cardiology Care: Hidden and read-only for launch
4	[firstnamelast]	Patient's First Name

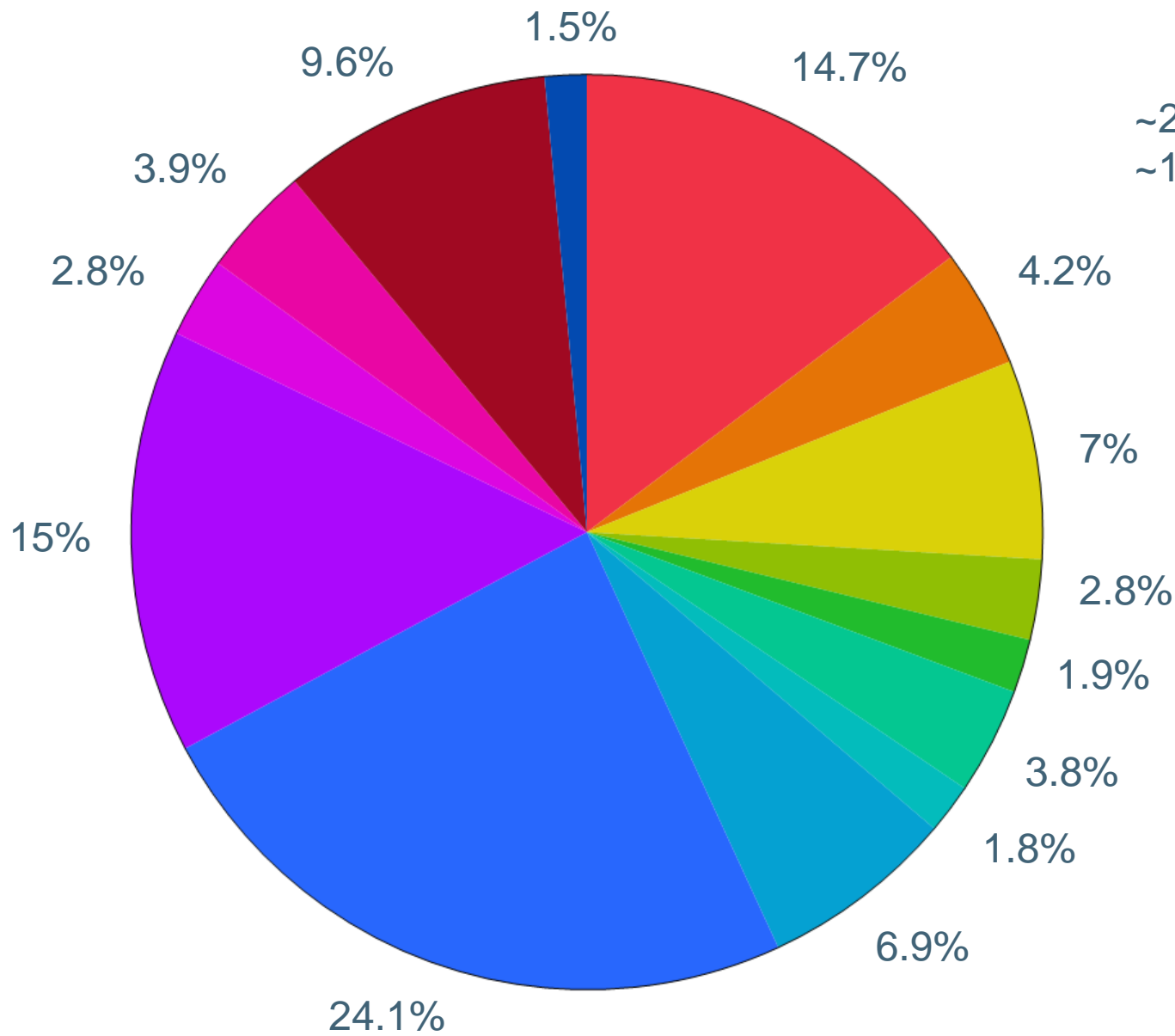
# Data Modules in Redcap

	Registration
	Demographics
	Medical History
	Surgical History
	Laboratories
	Echo
	Exercise Test
	Cardiac MRI
	Cardiac CT
	Cardiac Cath
	Emotional Health + Neurodevelopment
	Medication Log
	Surgical Log



# Percentage of Data Fields in Each Form













~200 questions  
~1000 data fields



- ★ Cardiac Catheterization
- Cardiac CT
- ★ Cardiac MRI
- Demographics
- Diagnosis
- Echocardiogram
- Emotional Health and Neurodevelopment
- ★ Exercise Test
- ★ Labs
- ★ Medical History
- Medication Log
- Registration
- ★ Surgical History
- Surgical Log

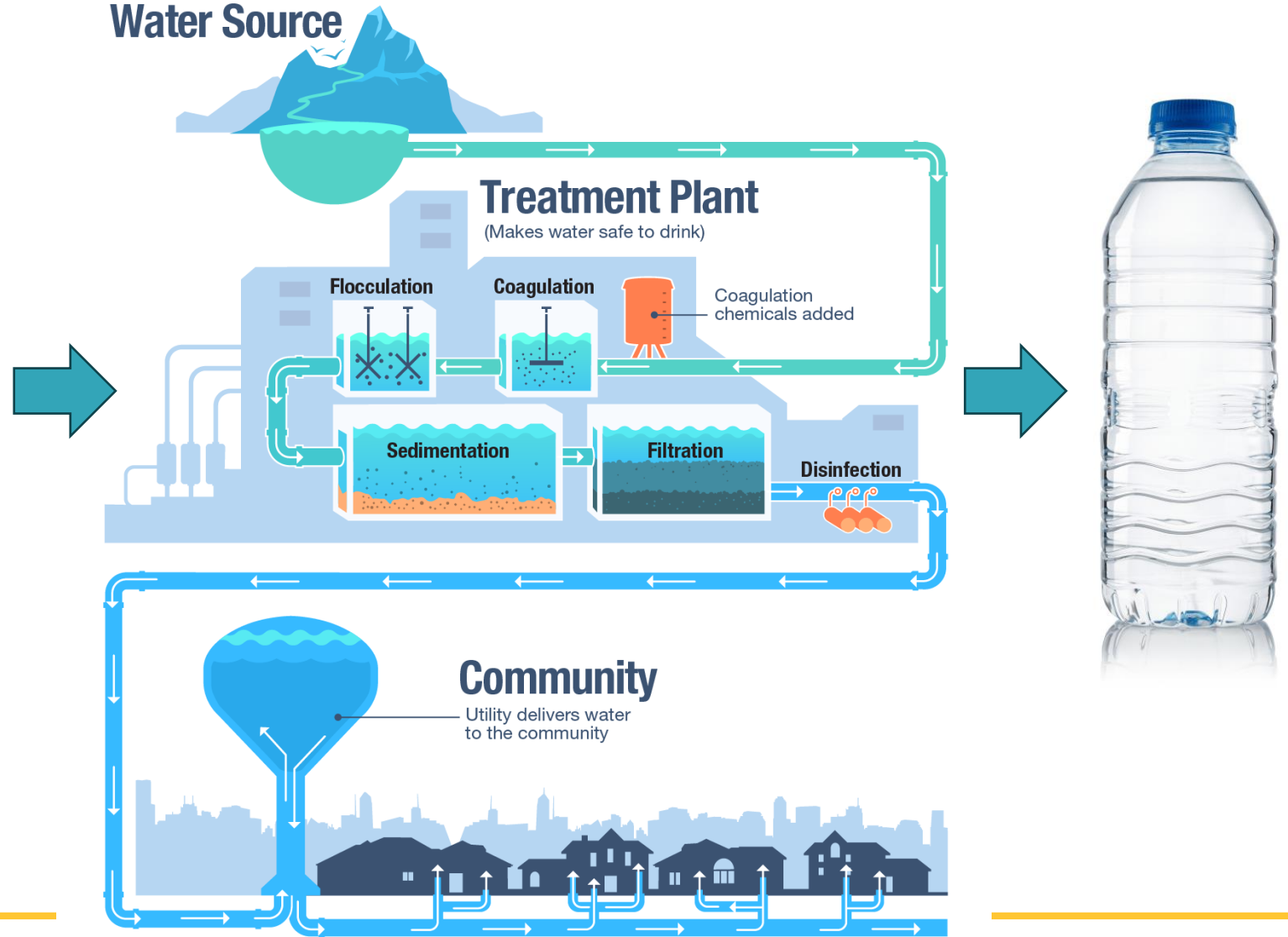
# Data Modules in Redcap

## Current

	<b>Registration</b>
	<b>Demographics</b>
	<b>Medical History</b>
	<b>Surgical History</b>
	<b>Laboratories</b>
	<b>Echo</b>
	<b>Exercise Test</b>
	<b>Cardiac MRI</b>
	<b>Cardiac CT</b>
	<b>Cardiac Cath</b>
	<b>Emotional Health + Neurodevelopment</b>
	<b>Medication Log</b>
	<b>Surgical Log</b>

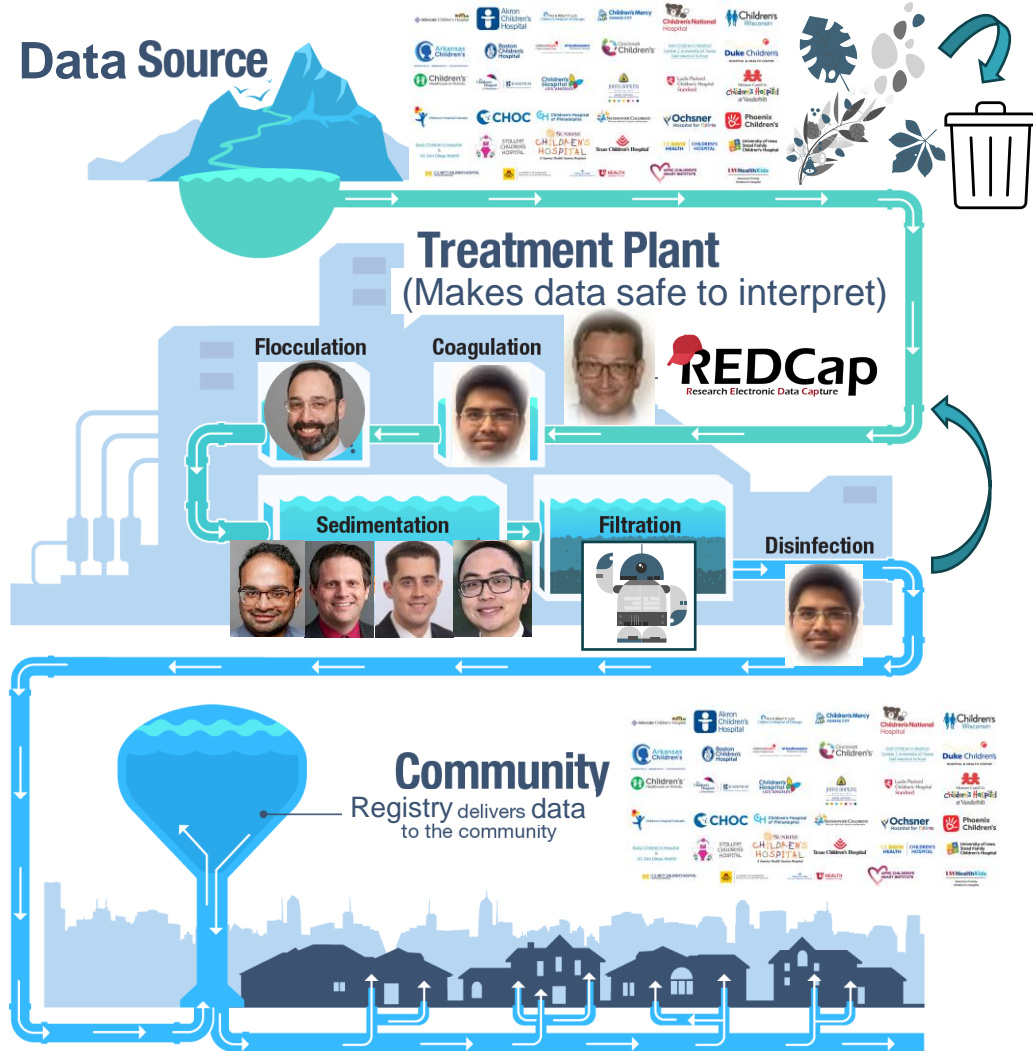
# Water Treatment Steps

Water Source

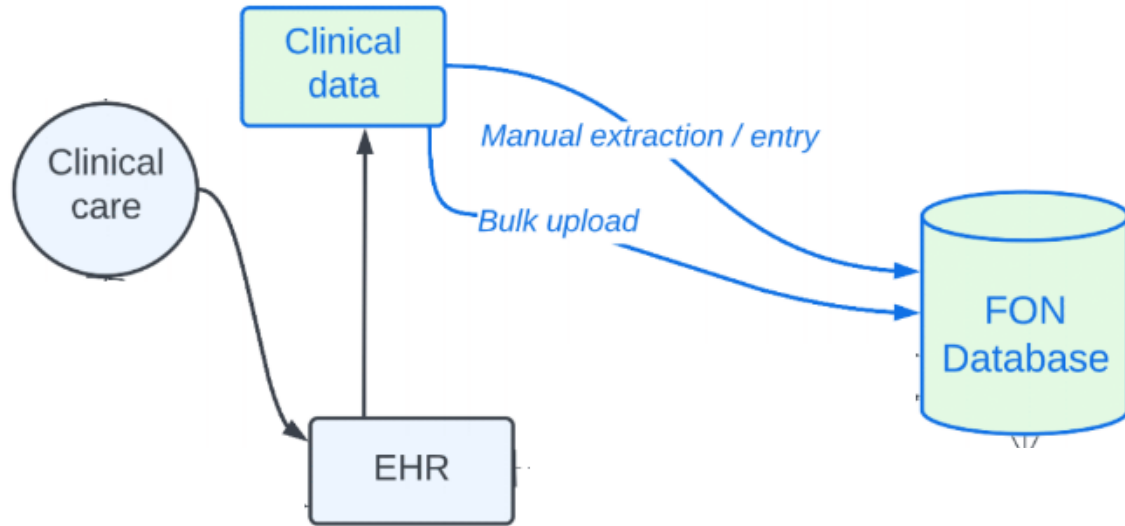




# FON Data Treatment Steps



1. Local human review at FON centers
2. REDCap validation rules
3. First-line automated validation rules
4. Limited human review by Data and Analytics Workgroup
5. Second-line automated validation rules
6. Clarification of flagged data with FON centers
7. (Iterative learning as data accumulates)
8. Data safe to consume!



## Current Flow of FON Data

# Example of Realtime Data Query

“Is ventricular morphology associated with exercise capacity?”

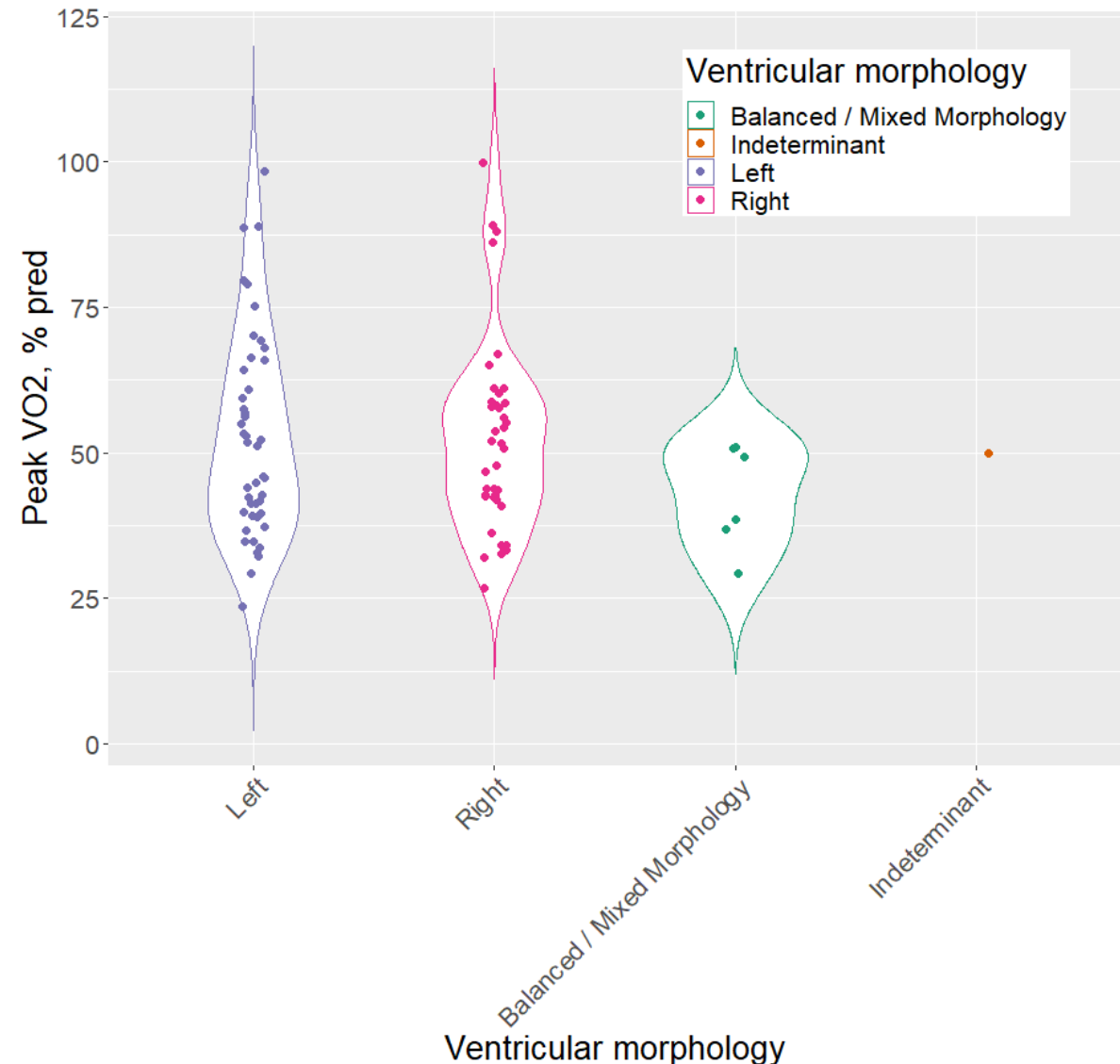
N=91 exercise tests with peak RER>1.05 and with data on age, sex, height, peak VO<sub>2</sub>, and ventricular morphology

Small sample size, but...

**N=135** Dhauna J, *et al.* Cardiopulmonary Exercise Test Outcomes in Fontan Patients With Right Versus Left Single Ventricle Morphology (2022)

**N=50** Padalino MA, *et al.* The impact of dominant ventricle morphology and additional ventricular chamber size on clinical outcomes in patients with Fontan circulation (2022)

**N=166**, max (n=411 total) Paridon, *et al.* A Cross-Sectional Study of Exercise Performance During the First 2 Decades of Life After the Fontan Operation (2008) [Didn't explore relationship of ventricular morphology to peak VO<sub>2</sub>]

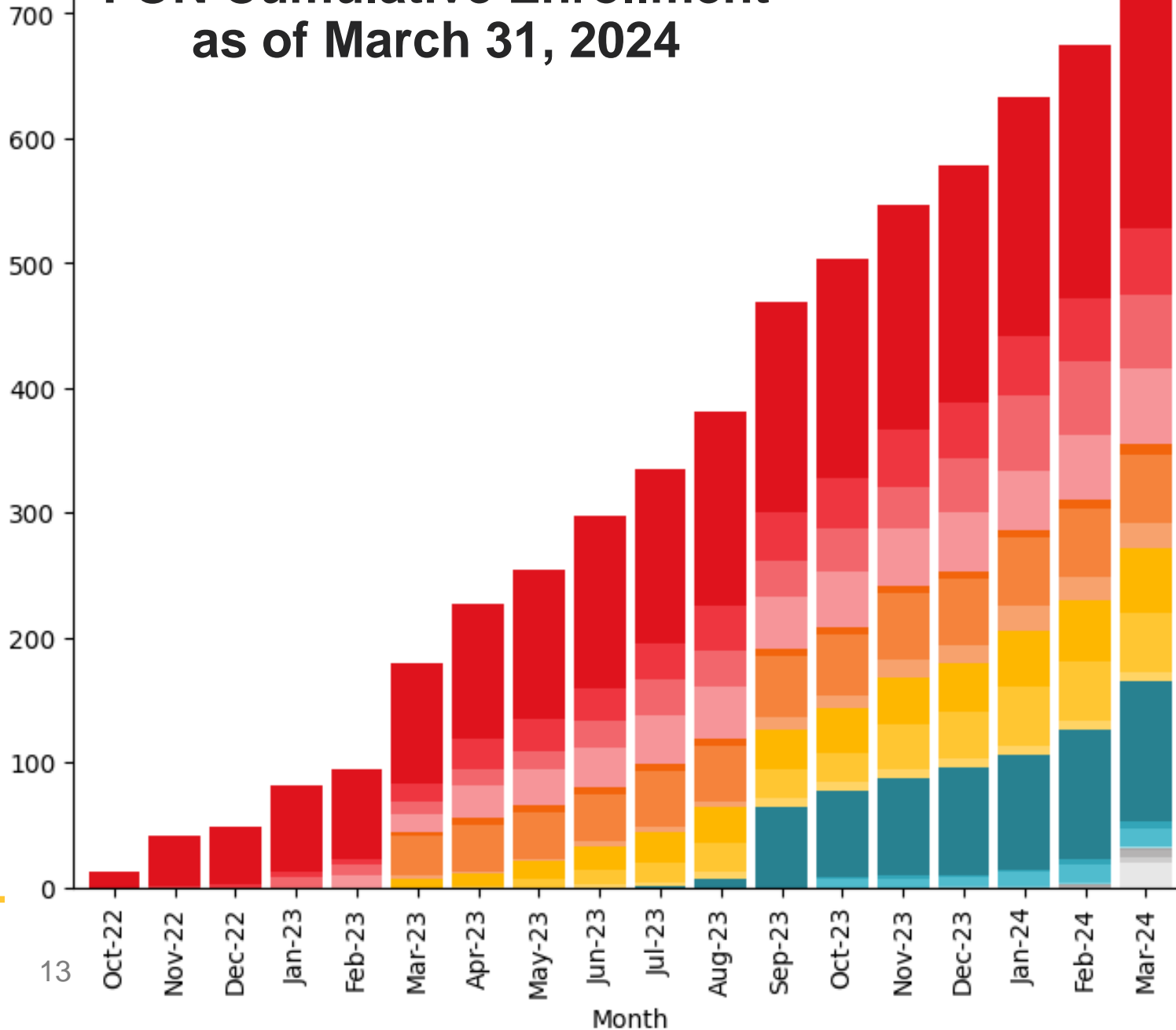


# Data Collection Progress

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*Jeff Theobald, FON Data Manager*

# FON Cumulative Enrollment as of March 31, 2024



**739 participants**  
**20 centers**

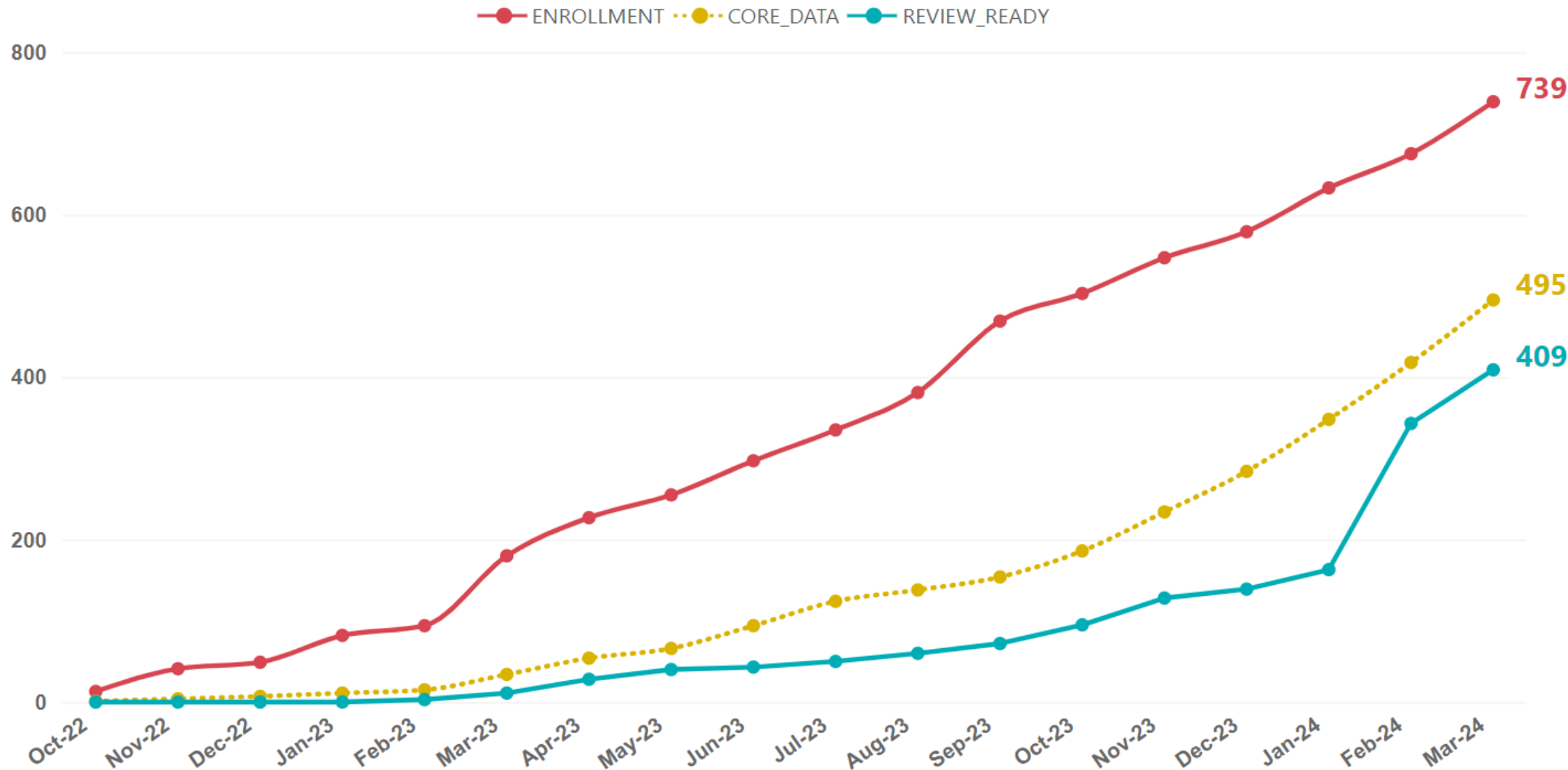
*Each distinct color  
within a bar represents  
enrollment at one center*



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# FON Registry Enrollment Progress Chart (as of March 31, 2024)



- ENROLLMENT** - record created and a unique patient ID was assigned to a consented FON participant in the FON database. (based on log activity)
- CORE\_DATA** - data entered for core enrollment forms (1. REGISTRATION / PT. PROFILE, 2. DEMOGRAPHICS, 3. DIAGNOSIS INFORMATION, 4. MEDICAL HISTORY, 5. SURGICAL HISTORY & ADDITIONAL INTERVENTIONS, 6. EMOTIONAL HEALTH & NEURODEVELOPMENT) and saved with "Complete" status. (based on log activity)
- REVIEW\_READY** - all core Enrollment forms plus additional applicable forms for available data at Enrollment (e.g., imaging, labs, medications), and the "ENROLLMENT REVIEW REQUEST" form has been submitted.

# Some context to keep in mind

Interpretation of data can be hazardous!

- Data presented here have not gone through the entire review process:
- Enrollment and data entry are still in early stages

There is no maximum number of subjects as this is intended to be a population registry. All patients who meet the eligibility criteria, will be recruited and enrolled, to the extent that CC logistics allow.

It is estimated that the overall population living with single ventricle Fontan heart disease (estimated to be ~20,000-30,000 in the United States, ~70,000 worldwide). Enrollment will continue indefinitely, as will maintenance of data in the registry database.

- Enrollment into FON is a non-random process

## 5 Selection and Recruitment of Participants



# Who is enrolled in FON?

## 5 Selection and Recruitment of Participants

### 5.1 Care Center Selection

CCs that provide care for patients with Fontan circulation are invited to apply for participation in FON. Applicants describe their practice and commit to supporting the requisite data submission and other participation requirements. CCs are then invited to join, receive training in data collection and improvement science, and are granted access to member-only information and data. Each center is responsible for obtaining IRB agreement to rely on the CCHMC IRB or provide local IRB approval if required by the institution's IRB, and each center signs a data use/sharing agreement with CCHMC.

### 5.2.1 Inclusion Criteria

Centers identify eligible participants. Participants who meet all of the following criteria will be eligible for the prospective arm of the study:

1. Has ever had a Fontan procedure, has a likely or definite single ventricle congenital heart diagnosis (e.g., unrepaired or palliated), or is otherwise anticipated likely to undergo a Fontan procedure in the future.
2. Has been cared for at a participating CC.

### 5.2.2 Exclusion Criteria

Individuals who meet any of the following criteria will be excluded from the prospective arm of the study:

1. Underwent heart transplant prior to enrollment.
2. Has never received care at a participating CC.





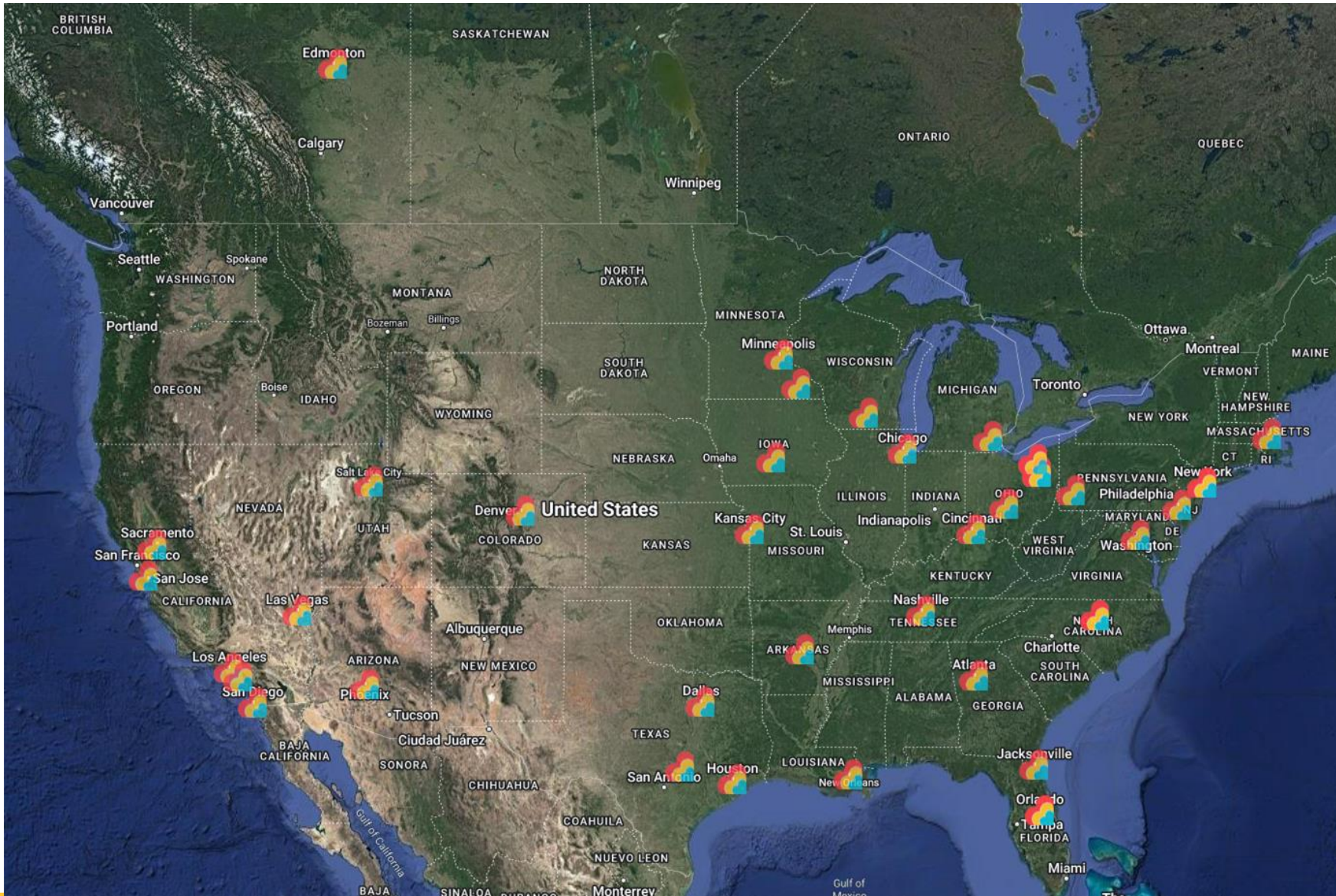


HOSPITALS • RESEARCH • FOUNDATION



**Get Involved:** Data Coordinator meeting open to CRCs, people doing the data entry or overseeing/working with the registry (reach out to [info@fontanoutcomesnetwork.org](mailto:info@fontanoutcomesnetwork.org))





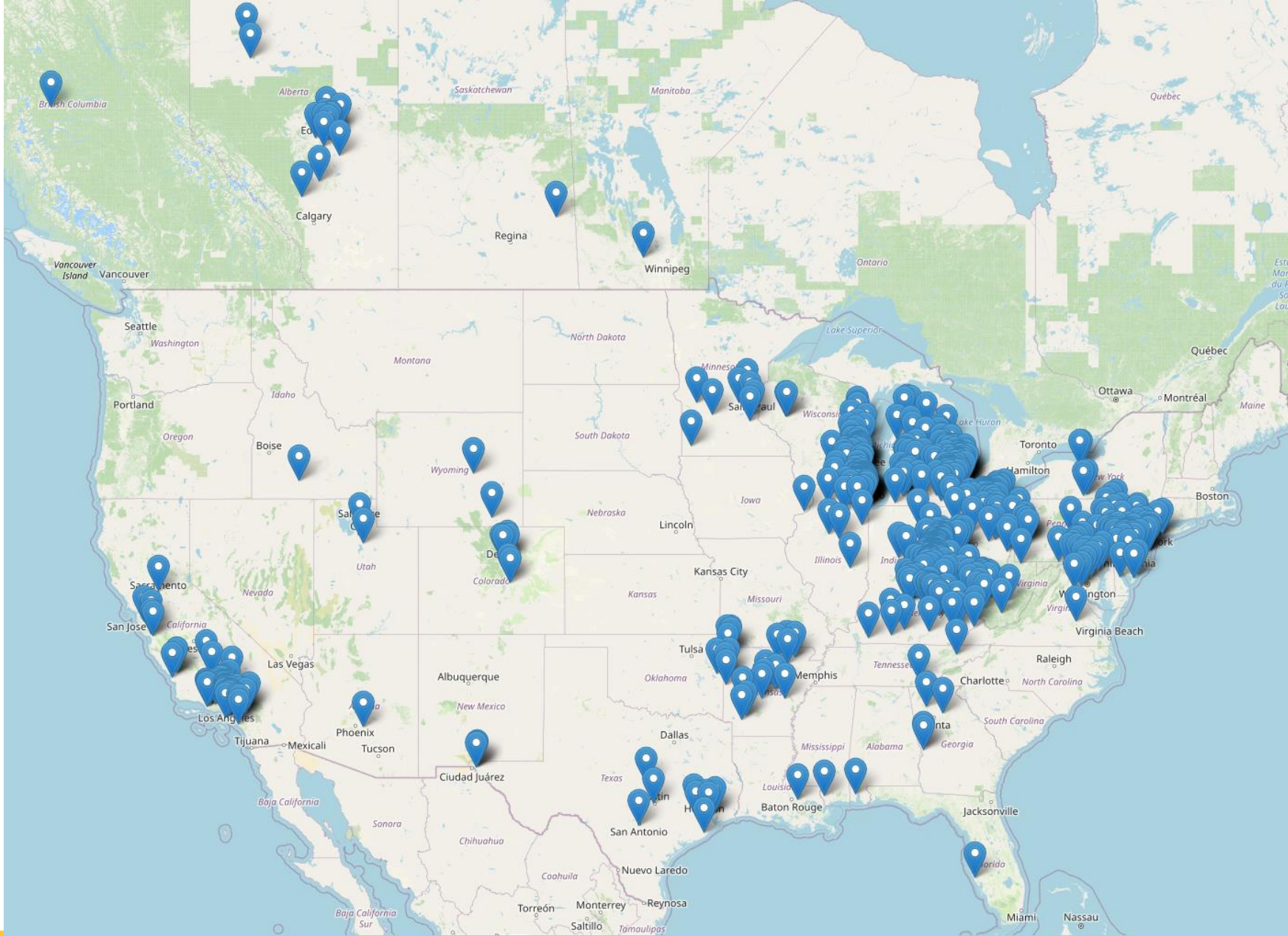
## 36 centers in 2 countries

739 patients from 20 centers, living in:

31 states

4 provinces

 = 1 FON Care Center




**36 centers in 2 countries**

739 patients from 20 centers, living in:

31 states

4 provinces

 = 1 *FON Enrollee*

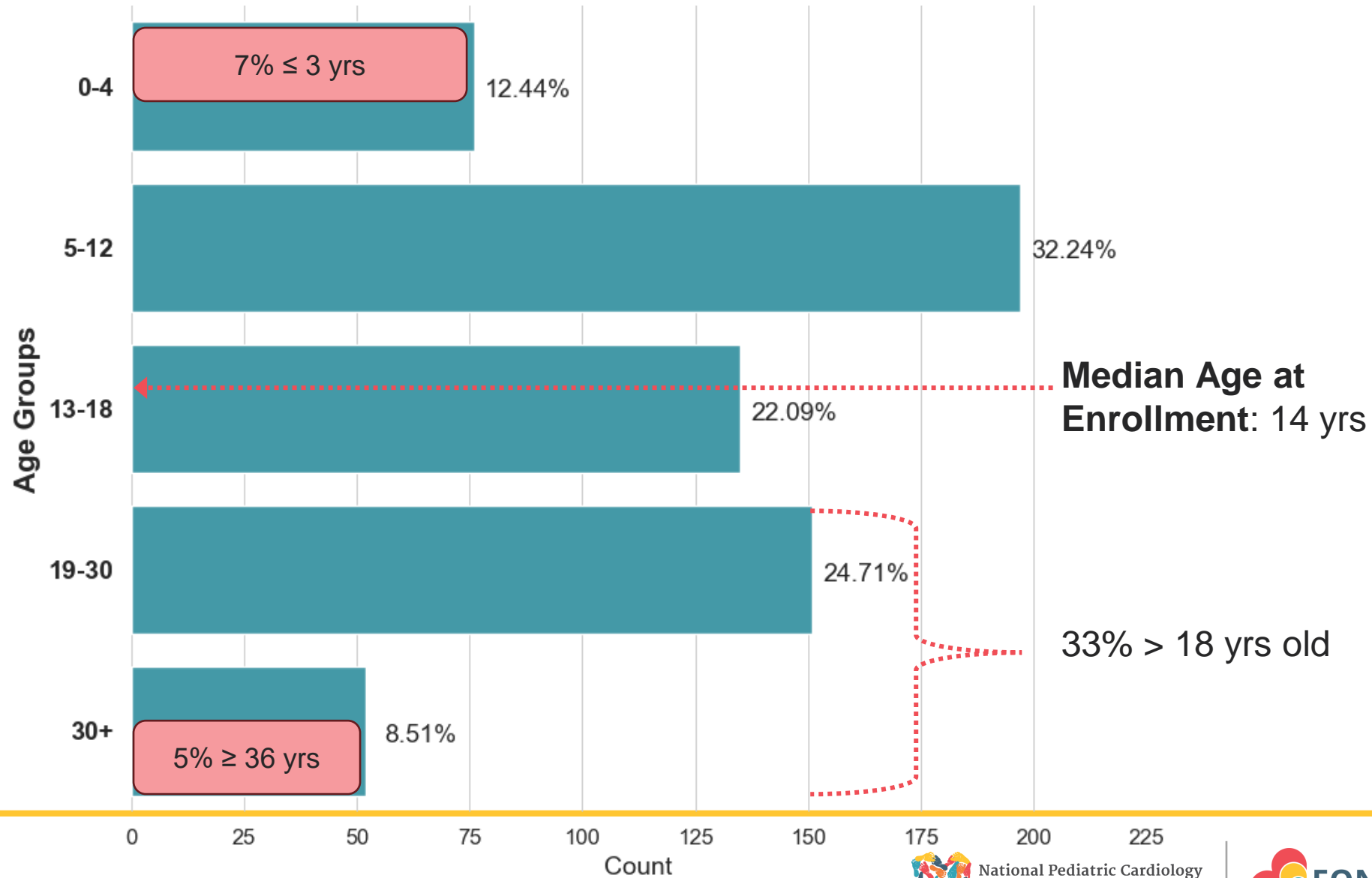
# Who is enrolled in FON? Age



Children are not little adults



Adults are not big children



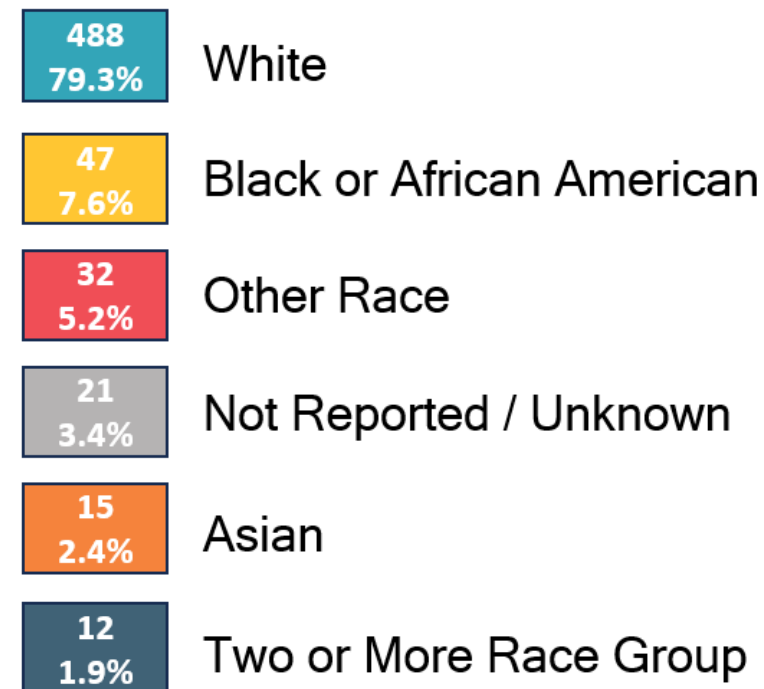
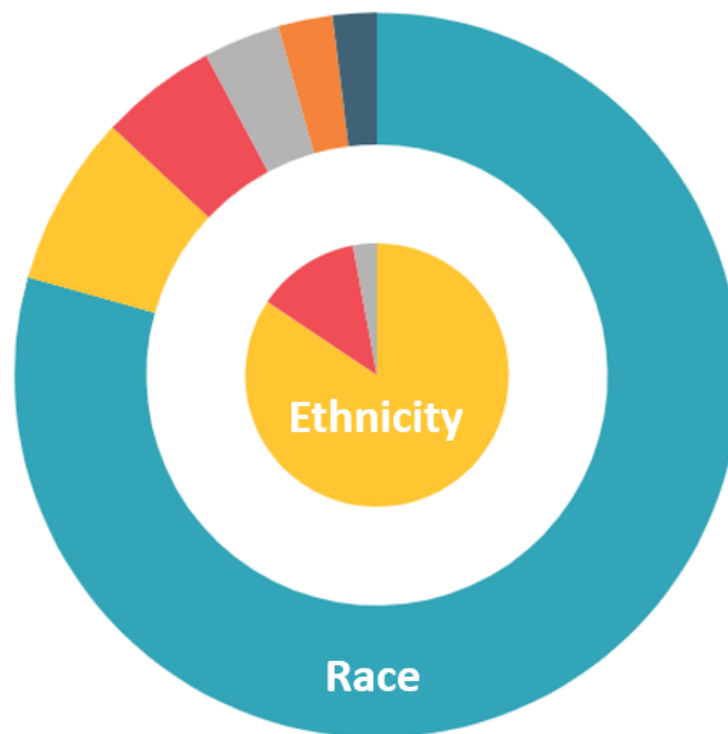
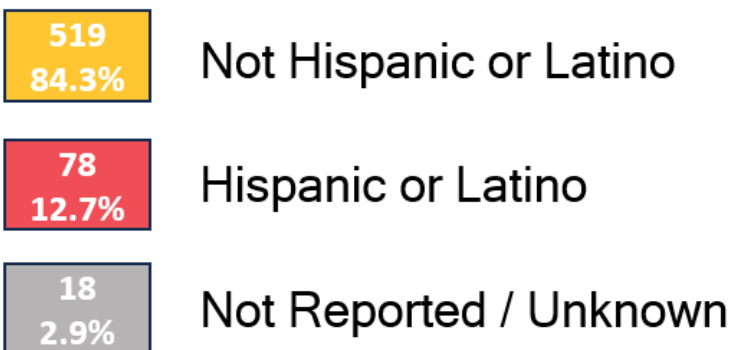
\*Cartoon from European Society of Cardiology, Davos Cardiology Update 2013:  
<https://assets.escardio.org/assets/Presentations/OTHER2013/Davos/Day%202/22-What-new-in-CHD-2013.pdf>



# Who is enrolled in FON? *Demographics*



## RACE & ETHNICITY



Data as of March 31, 2024



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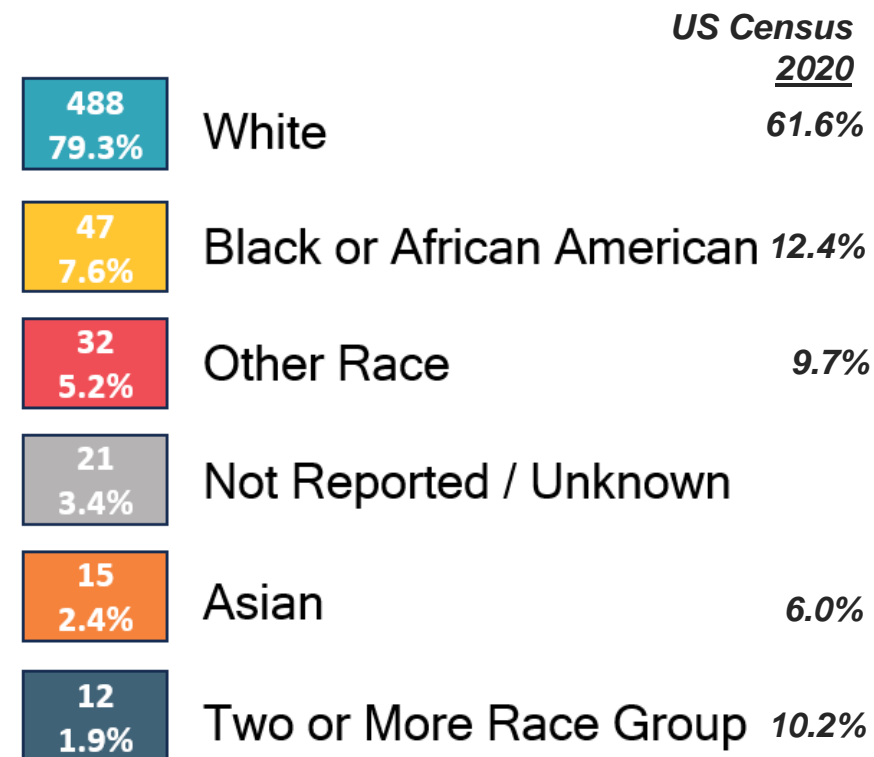
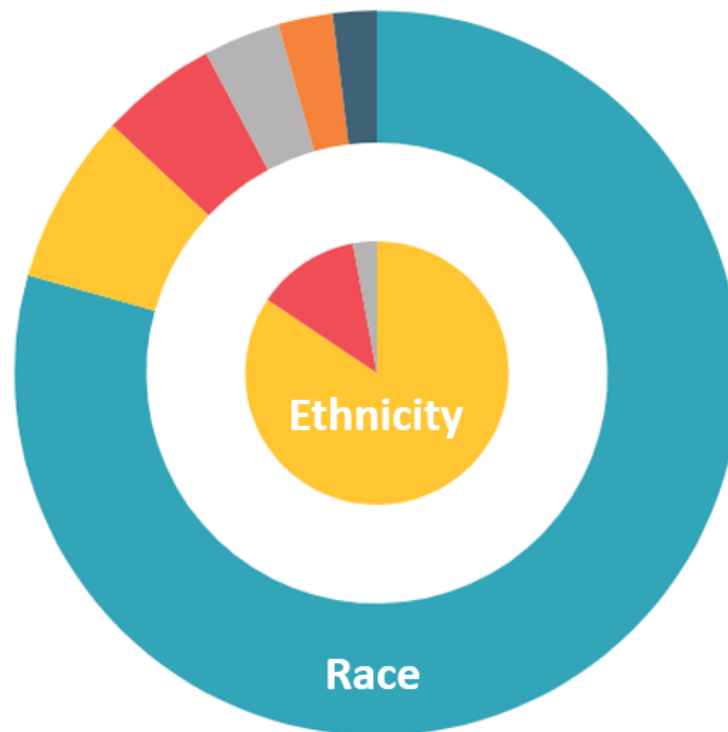
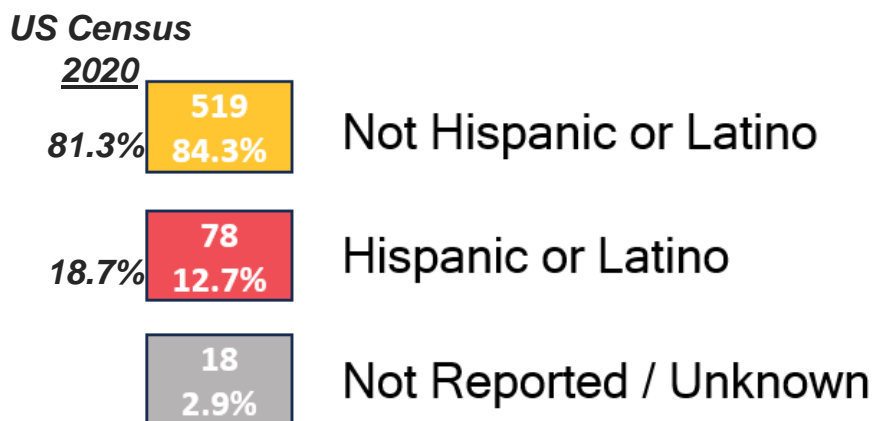




# Who is enrolled in FON? *Demographics*



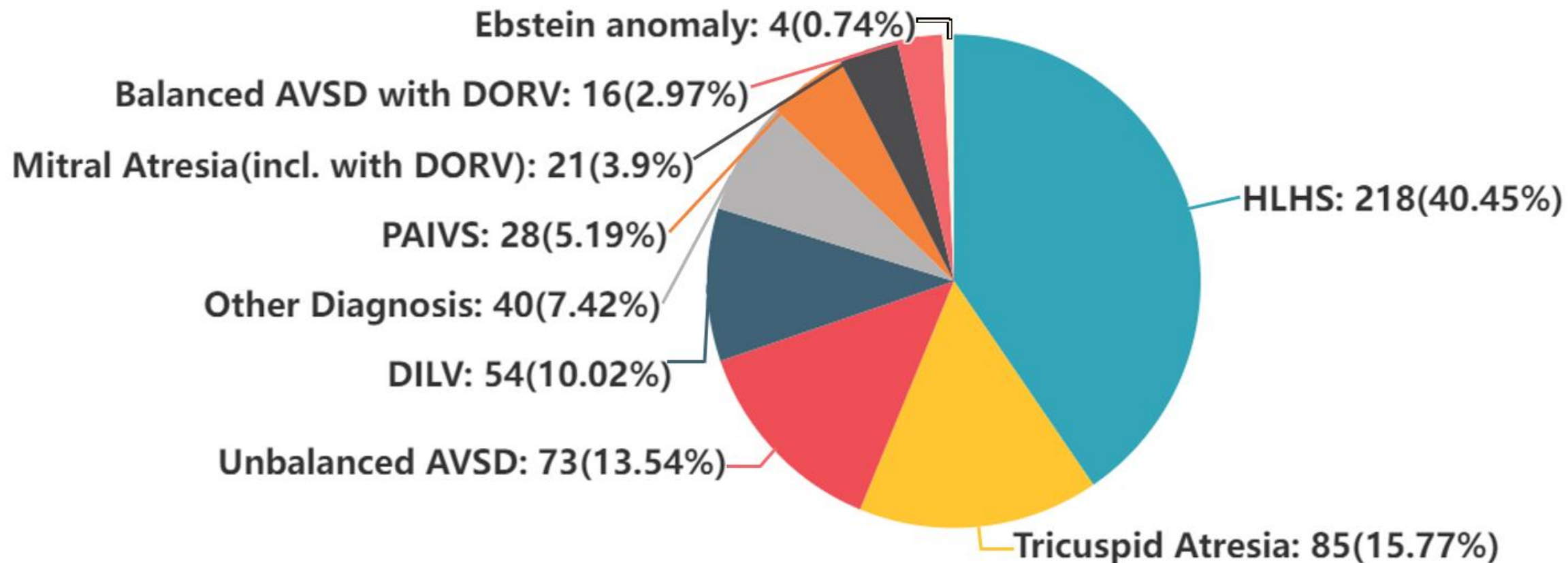
## RACE & ETHNICITY



Data as of March 31, 2024



# Who is enrolled in FON? *What type of CHD?*



Abbreviations: HLHS (*Hypoplastic Left Heart Syndrome*); AVSD (*Atrio Ventricular Septal Defect*); DILV (*Double Inlet Left Ventricle*);

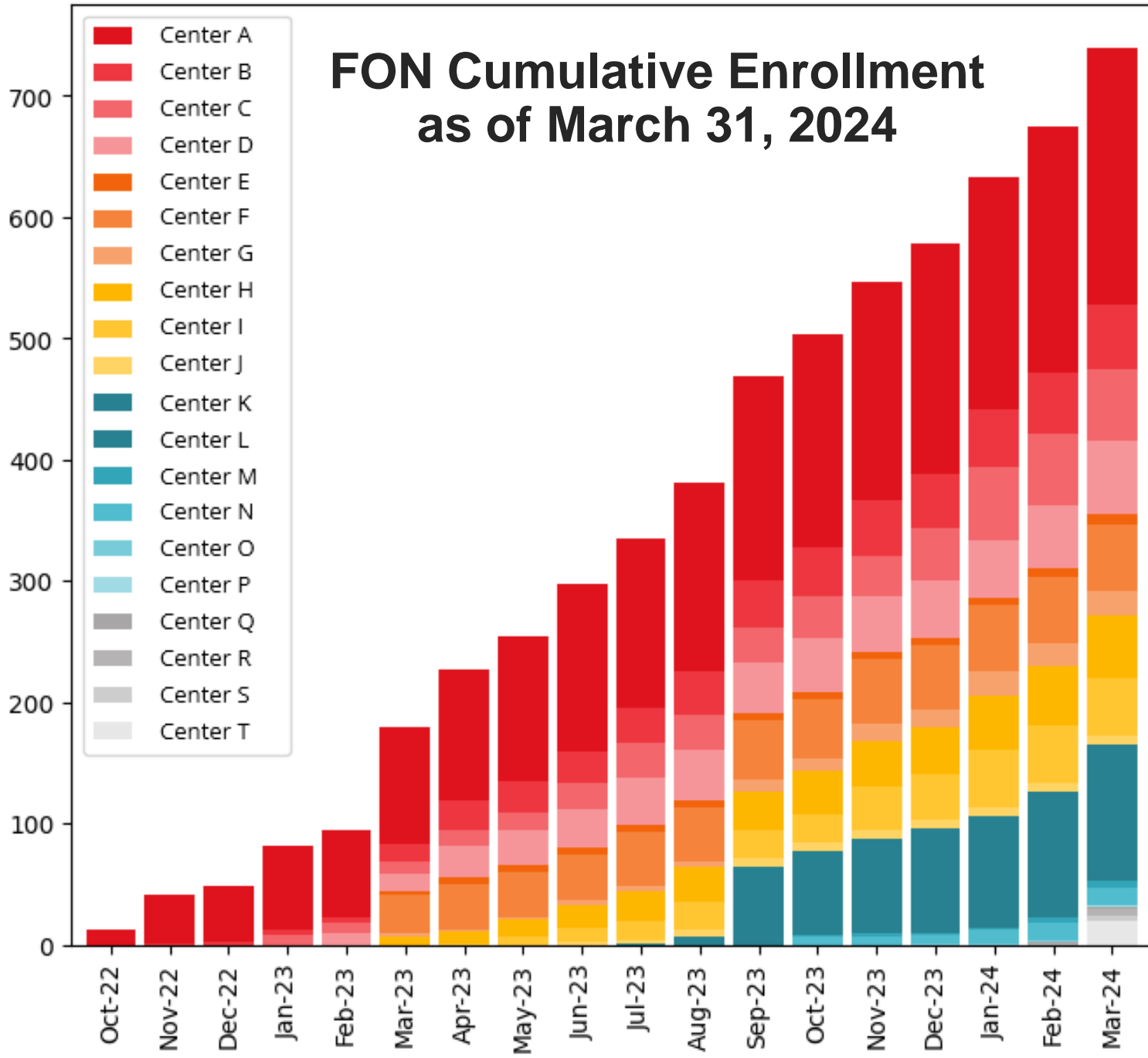
PAIVS (*Pulmonary Atresia with Intact Ventricular Septum*); DORV (*Double Outlet Right Ventricle*); TOF (*Tetralogy of Fallot*);



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# FON Cumulative Enrollment as of March 31, 2024



## Transparency is foundational

We learn and improve by sharing with each other: data, outcomes, successes, failures

*Within FON, we plan to show center names on charts like this.*

*Any concerns?*



# Mentimeter

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# POLL: In terms of patient enrollment and data entry, at what stage is your center?

Options (select all that apply)

- Center – Enrolling patients and entering data
- Center – Enrolling patients (informed consent), but no data entered yet
- Center – Plan to enter first patient data in next 3 months
- Center – Legal and/or regulatory work in progress (DUA, IRB, etc.)
- Center – Unsure
- Center – Not participating in FON (yet)
- Patient or Family Member – I have already enrolled
- Patient or Family Member – I am at a center not participating in FON or have not enrolled



# Progress with Automation

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*Andrew Cheng, MD*

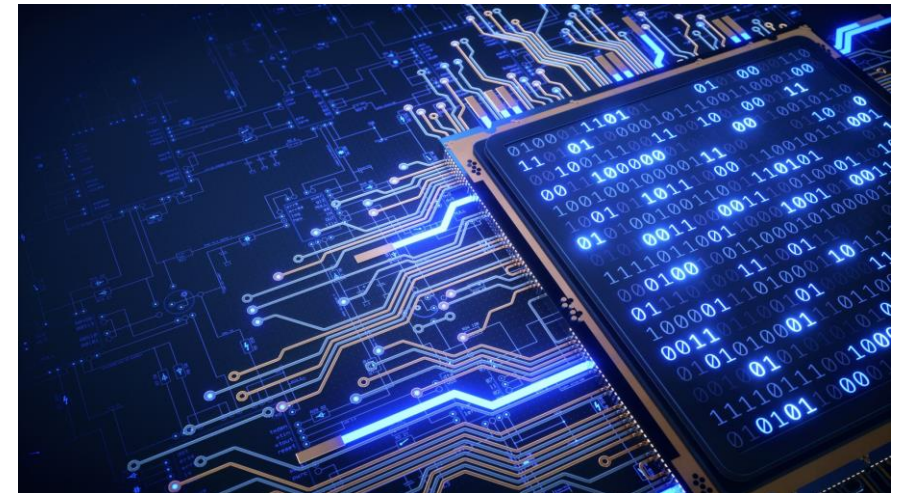


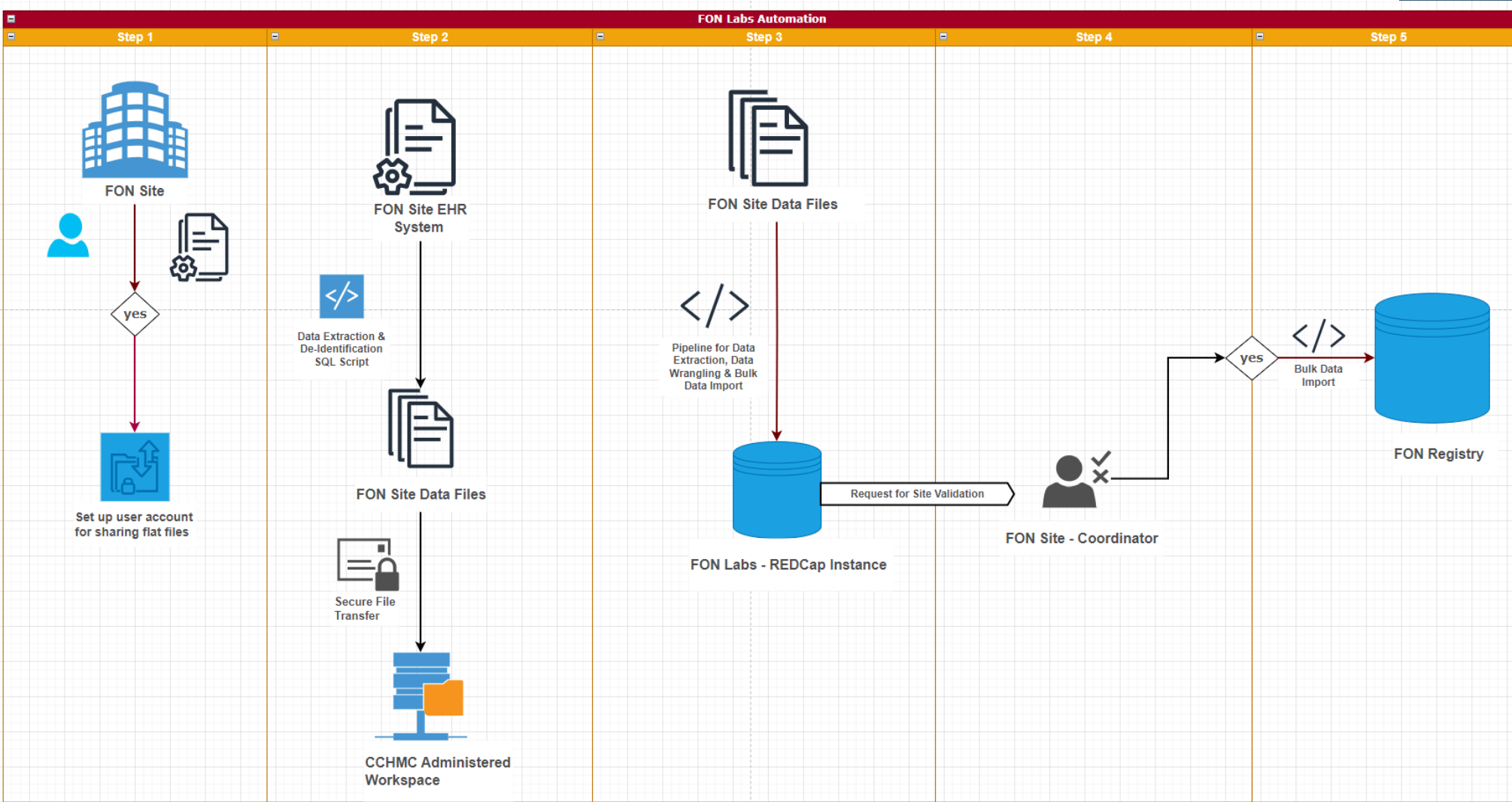
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# Overview of Automation

- Why automate?
- What can we automate?
- How do we automate?
- How can we make automation accessible to all centers?





# Lab Automation Workflow from CCHMC

# Progress & Next Steps

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*Mike DiMaria*



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# FON is On Track to Hit 1000 Subjects!

## A Cross-Sectional Study of Exercise Performance During the First 2 Decades of Life After the Fontan Operation

Stephen M. Paridon, MD,\* Paul D. Mitchell, MS,† Steven D. Colan, MD,\*\* Richard V. Williams, MD,‡ Andrew Blaufox, MD,§ Jennifer S. Li, MD,|| Renee Margossian, MD,\*\* Seema Mital, MD,¶ Jennifer Russell, MD,# Jonathan Rhodes, MD,\*\* for the Pediatric Heart Network Investigators

*Philadelphia, Pennsylvania; Watertown and Boston, Massachusetts; Salt Lake City, Utah; Charleston, South Carolina; Durham, North Carolina; New York, New York; and Toronto, Ontario, Canada*

THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Comparison of Shunt Types in the Norwood Procedure for Single-Ventricle Lesions

Richard G. Ohye, M.D., Lynn A. Sleeper, Sc.D., Lynn Mahony, M.D., Jane W. Newburger, M.D., M.P.H., Gail D. Pearson, M.D., Sc.D., Minmin Lu, M.S., Caren S. Goldberg, M.D., Sarah Tabbutt, M.D., Ph.D., Peter C. Frommelt, M.D., Nancy S. Ghanayem, M.D., Peter C. Laussen, M.B., B.S., John F. Rhodes, M.D., Alan B. Lewis, M.D., Seema Mital, M.D., Chitra Ravishankar, M.D., Ismee A. Williams, M.D., Carolyn Dunbar-Masterson, B.S.N., R.N., Andrew M. Atz, M.D., Steven Colan, M.D., L. LuAnn Minich, M.D., Christian Pizarro, M.D., Kirk R. Kanter, M.D., James Jagers, M.D., Jeffrey P. Jacobs, M.D., Catherine Dent Krawczeski, M.D., Nancy Pike, R.N., Ph.D., Brian W. McCrindle, M.D., M.P.H., Lisa Virzi, R.N., M.S., M.B.A., and J. William Gaynor, M.D., for the Pediatric Heart Network Investigators

Circulation

ORIGINAL RESEARCH ARTICLE

## Results of the FUEL Trial

Editorial, see p 652

David J. Goldberg, MD et al

**N = 411**

**N = 555**

**N = 400**



Enrollment  
payments will  
end on June 30<sup>th</sup>,  
2024



*75 days from today!*





# Muddiest & Clearest Points



Silent for 1-2 minutes - Take a moment to reflect. Reflections Questions

- What was the most confusing (muddiest) part of the information received? ,What would you want to learn in the future to provide clarity?
- What was most helpful? What would you like to see/hear more of in the future?

When you are ready, place responses in the chat.





Single Ventricle Patient Day - Fall Learning Session, 2023

*Thank you!!*