

# Overview of Clinical Research and the Clinical Trials Infrastructure

Howard S. Hochster, MD

April 26, 2023



**RUTGERS**  
Cancer Institute  
of New Jersey  
**RUTGERS HEALTH**

**NCI** Comprehensive  
Cancer Center  
A Cancer Center Designated by the  
National Cancer Institute



**RWJ Barnabas**  
**HEALTH**

# Associate Director for Clinical Research



## Howard S. Hochster, MD

Associate Director for Clinical Research

Director of Oncology Research,  
RWJBarnabas Health

Distinguished Professor of Medicine,  
Rutgers RWJMS

## Mission

Conduct state-of-the-art trials:

- Translating CINJ science
- Creating new standards of care

Deliver these state-of-the-art trials  
to the people of New Jersey

Train and mentor new generations  
of clinical investigators

## Specific Aims

AIM  
1

**Unify clinical trial operations** at Rutgers and the RWJBH system to facilitate the conduct of clinical trials (institutional and multicenter) within the State of New Jersey

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- AIM 1 **Unify clinical trial operations** at Rutgers and the RWJBH system to facilitate the conduct of clinical trials (institutional and multicenter) within the State of New Jersey.
- AIM 2 Promote and simplify **access to and implementation of clinical trials** to increase accrual and engagement at RWJBH sites.
- AIM 3 Work with Community Outreach and Engagement (COE) to foster interventional accruals from **underrepresented populations** within our catchment area

## Specific Aims


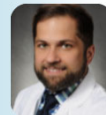
- AIM 1** **Unify clinical trial operations** at Rutgers and the RWJBH system to facilitate the conduct of clinical trials (institutional and multicenter) within the State of New Jersey.
- AIM 2** Promote and simplify **access to and implementation of clinical trials** to increase accrual and engagement at RWJBH sites.
- AIM 3** Work with Community Outreach and Engagement (COE) to foster interventional accruals from **underrepresented populations** within our catchment area.
- AIM 4** Train and mentor faculty, fellows, and staff on the conduct of clinical cancer research, with particular attention on investigator-initiated trials (IITs)

# Clinical Research Leadership

## CPDM (OHRs)

	<b>Associate Director for Clinical Research</b>	Howard Hochster, MD
	<b>Associate Director for Translational Research</b>	Shridar Ganesan, MD, PhD
	<b>Medical Co-Director OHRs (CPDM) ★</b>	Biren Saraiya, MD
	<b>Medical Co-Director OHRs (CPDM) ★</b>	Neil Palmisiano, MD
	<b>OHRs (CPDM) Executive Director</b>	Tracie Saunders, RN, MS
	<b>Director, System Research Operations ★</b>	Renee Kurz, RN, DNP

## PRMS (SRB)








	<b>Scientific Review Board (PRMS) Chair ★</b>	Salma Jabbour, MD
	<b>Scientific Review Board (PRMS) Chair ★</b>	Neil Palmisiano, MD








## DSMC (HROC)

	<b>Human Research Oversight Committee (DSM) Chair</b>	Dirk Moore, PhD
	<b>Human Research Oversight Committee (DSM) Chair ★</b>	Patrick Boland, MD

★ Newly Created Position  
 ★ New Incumbent

# ≡ Disease Specific Group Leaders

	<b>Breast Cancer</b>	Deborah Toppmeyer
	<b>Cancer Prevention</b> ★	Katie Devine
	<b>Cellular Therapies</b> ★	Christian Hinrichs
	<b>Gastrointestinal Cancers</b>	Howard Hochster
	<b>Genitourinary Cancers</b>	Biren Saraiya
	<b>Gynecologic Malignancies</b>	Aliza Leiser
	<b>Hematologic Malignancies</b>	Matthew Matasar

	<b>Lung and SCCHN Cancers</b>	Missak Haigentz
	<b>Melanoma/Sarcoma</b>	Sarah Weiss
	<b>Neuro-Oncology</b>	Michael Salacz
	<b>Pediatric Oncology</b>	Peter Cole
	<b>Phase I</b>	Sanjay Goel
	<b>Precision Medicine</b>	Shridar Ganesan
	<b>Radiation Oncology</b> ★	Salma Jabbour

★ New DSGs





# Clinical Protocol and Data Management (CPDM)

CINJ Office of Human Research Services (OHRS)

# Response to Prior Critique

## **CPDM - Exceptional to Outstanding**

- Dramatic increase in enrollment
- DSG-based review
- Robust educational program
- Rapid activation process
- Increased breadth and depth of services

## **PRMS - Acceptable**


- Leadership noted as a strength
- Robust portfolio noted as a strength
- Infrastructure/processes noted as strengths
- Addressed low quorum requirement

## **DSM - Acceptable**

- External DSMC noted as a strength
- Structure for Adverse Event review noted as a strength
- Overlap with CPDM addressed

## **Women, Children, Minorities - Acceptable**

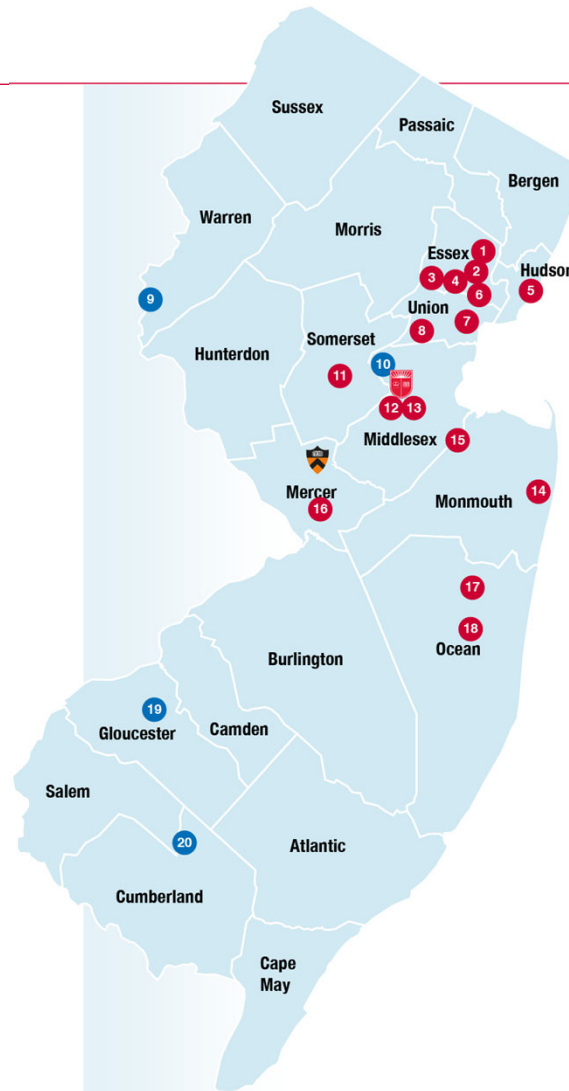
- Strong record of enrolling women (greater than 50% for treatment and non-treatment trials)

























# Unified Clinical Trial Infrastructure Across CINJ System

# CINJ System

- 12 adult hospitals across NJ
- One Oncology Service Line
- Clinical trials open and actively accruing at 10 (RWJBH) and 2 (CINJ) sites
- All System Sites with open trials
- New Affiliates



-  Rutgers Cancer Institute of New Jersey
-  Clara Maass Medical Center
-  University Hospital
-  Cooperman Barnabas Medical Center
-  Children's Hospital of New Jersey at Newark Beth Israel Medical Center
-  Jersey City Medical Center
-  Newark Beth Israel Medical Center
-  Trinitas Regional Medical Center
-  Robert Wood Johnson University Hospital Rahway
-  St. Luke's Hospital – Warren Campus
-  Saint Peter's University Hospital
-  Robert Wood Johnson University Hospital Somerset
-  Robert Wood Johnson University Hospital
-  Briston Myers Squibb Children's Hospital at RWJUH
-  Monmouth Medical Center
-  Unterberg Children's Hospital at Monmouth Medical Center
-  Robert Wood Johnson University Hospital Hamilton
-  Monmouth Medical Center Southern Campus
-  Community Medical Center
-  Leading-Edge Cancer Center at Inspira Medical Center
-  The Frank and Edith Scarpa Regional Cancer Pavillion at Inspira Medical Center
-  Princeton University

# Unified Clinical Trials Infrastructure

## Our Vision (2018)

- One IRB**
- One Contract/Budget process**
- One EMR**
- One CTMS**
- One Pharmacy**
- One Clinical Trials and Quality Assurance Office**

Accomplished  
2018-  
2022

# Unified Clinical Trials Infrastructure

## Our Concept:

### Centralized

- Operations
- Data Management



### Sites Contribute

- Ideas
- Protocols
- Principal Investigators
- Patient Enrollment
- Data Management



# Innovations in Clinical Trials Infrastructure

## Creating a Single Research Operation

- Statewide Research Office – established and staffed to manage trials at RWJBH sites
- OnCore® Everywhere
- Consolidated CTSU family (all NJ066) – single system-wide PI per protocol
- Legal: Master IRB and Clinical Trials Agreements signed
- Investigational Pharmacy management (Vestigo)
- Clinical Trial Lab (jointly with BRHS)
- Revised all SOPs to cover Oncology Service Line integrated model
- Tools: Intranet Website; => Real time, web-based RECIST (and other) readings

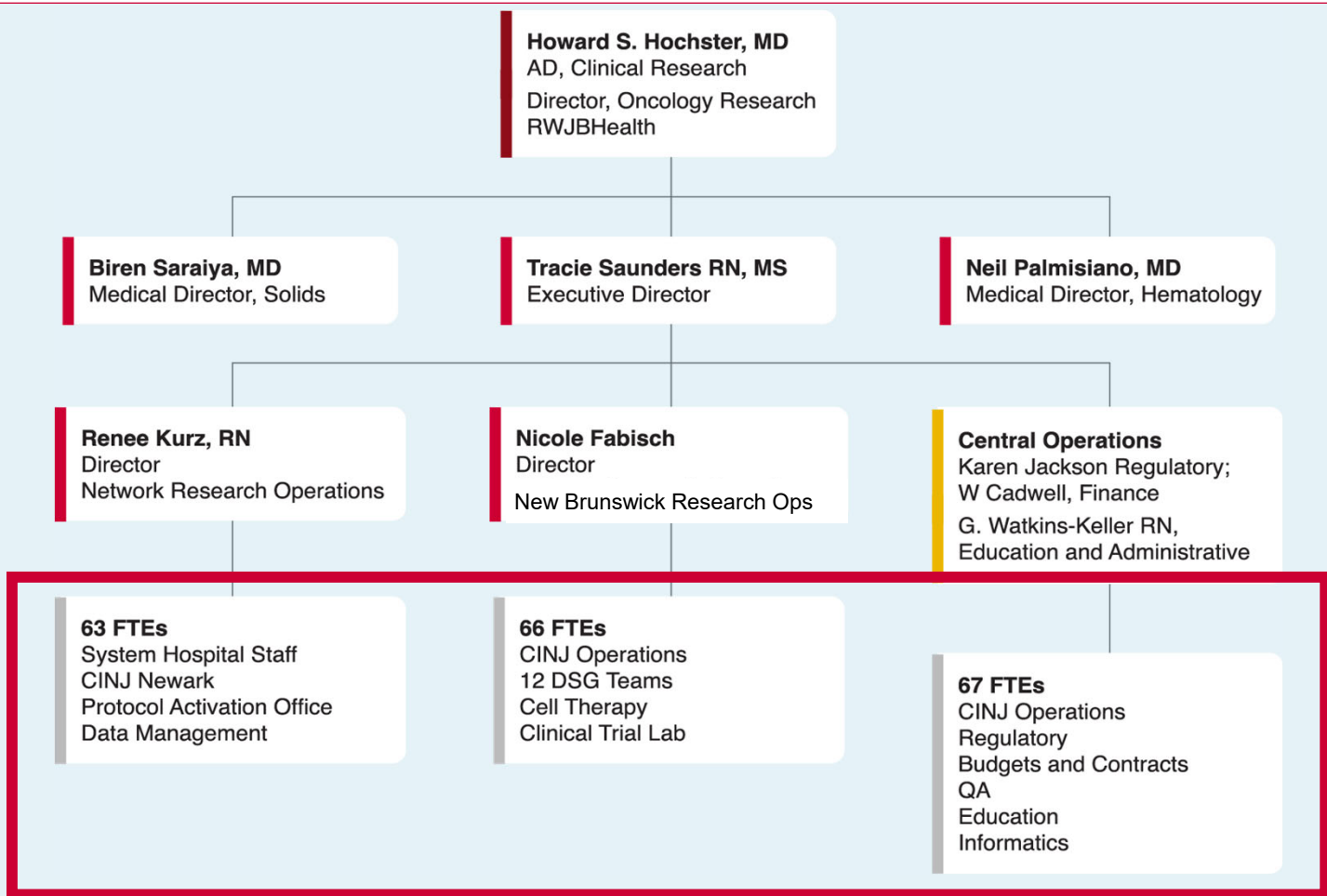
Clinical Trials Imaging Network Assessments PACS Login PROPRIETARY RECIST WEBSITE

Procedure	Protocol	Examination Type	Clinician	Radiologist	MRN	Patient												
RECIST	071910	FDG PET/CT	Howard S. Hochster	Sokol, Levi														
2020-10-06																		
2020-12-14 H.J.																		
2021-02-05																		
2021-04-09																		
Target Lesions																		
#	Location	Type	LDI (mm)	SDI (mm)	S/I #	Image	LDI (mm)	SDI (mm)	S/I #	Image	LDI (mm)	SDI (mm)	S/I #	Image	LDI (mm)	SDI (mm)	S/I #	Image
1	Left lower lobe subpleural lung nodule	E	23	16		Image	9	7	2/31	Image	9	7	2/31	Image	10	9	3/78	Image
2	Right basilar subpleural lung nodule	E	21	19		Image	5	5	2/41	Image	5	5	2/43	Image	7	7	3/84	Image
3	Left perisigmoid adenopathy	E	38	32		Image	23	16	2/113	Image	23	17	2/114	Image	24	18	3/173	Image
Sum of Diameters			82				37				37				41			
% Increase Since Nadir			0				0				0				11			
% Change Since Baseline			0				-85				-55				-50			
Response			Baseline				PR				PR				PR			
Non-Target Lesions																		
#	Location	Type	Presence/Absence	S/I #	Image	Presence/Absence	S/I #	Image	Presence/Absence	S/I #	Image	Presence/Absence	S/I #	Image	Presence/Absence	S/I #	Image	
1	Sigmoid mass	E	Present		Image	Present	2/116	Image	Present	2/117	Image	Present	3/175	Image	Present			
Response			Baseline				SD				SD				SD			
New Lesions																		
#	Location	Type	LDI (mm)	SDI (mm)	S/I #	Image	LDI (mm)	SDI (mm)	S/I #	Image	LDI (mm)	SDI (mm)	S/I #	Image	LDI (mm)	SDI (mm)	S/I #	Image
Response			Baseline				N/A				N/A				N/A			
Evaluation of Best Overall Response																		
Acceptance			Accept				Accept				Accept				Accept			

## Engaging Physicians and Staff

- Monthly research/staffing meetings and monthly accrual updates
- DSG based participation for patient monitoring
- Virtual DSG meetings
- Monthly Nursing/Staff Collaborative meetings
- Protocol Activation Office – unified SIVs across system

# Office of Human Research Services (CPDM): Organization



**Total =  
196 FTEs**

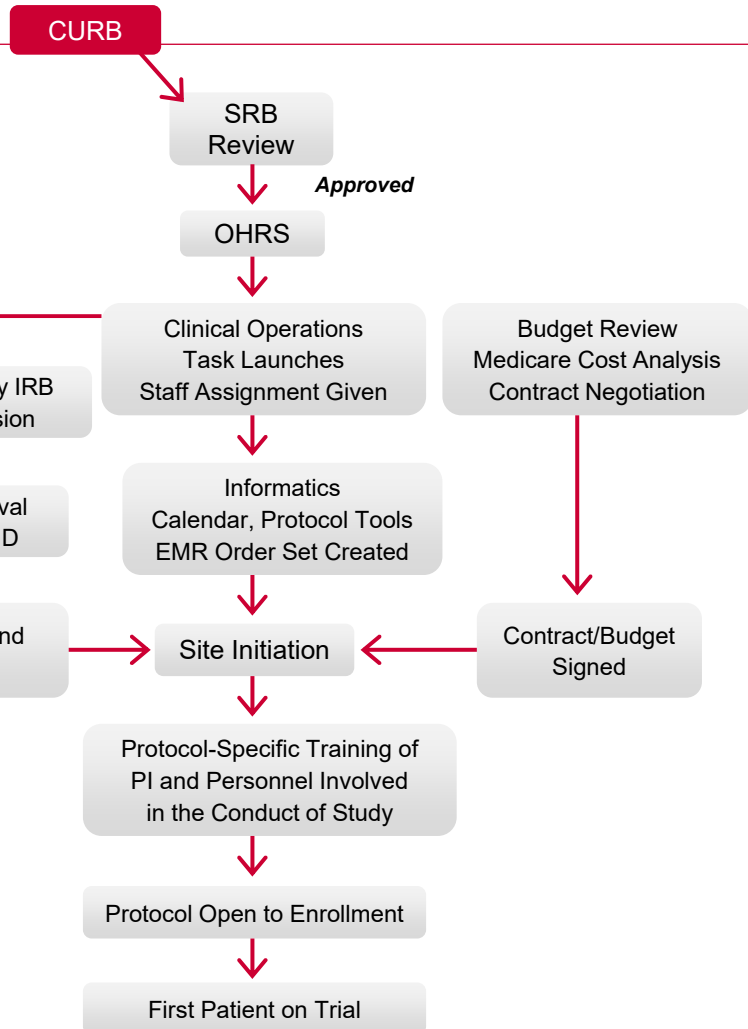


# Major Improvement in Trial Activation

## Activation Metrics

Metric	DAYS (MEDIAN)				Improve- ment*
	2018	2020	2021	2022	
IRB Submission to IRB Approval	45	18	30	<b>21</b>	30%
Contract Turnaround	Not Tracked	86	80	<b>60</b>	25%
Budget Turnaround	Not Tracked	79	86	<b>60</b>	30%
SRB Submission to Open to Accrual	136	152	167	<b>72</b>	232%

\* improvement 2022 vs 2021 with Protocol Activation Office

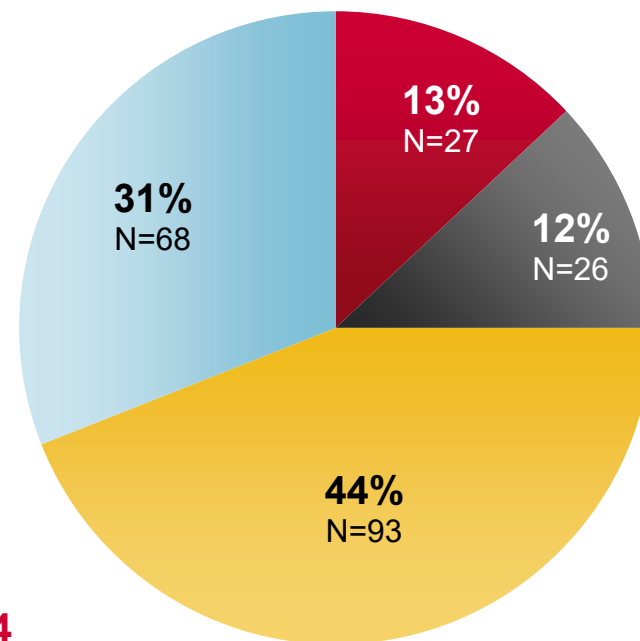


# Clinical Trial Portfolio 2022

Treatment protocols 214  
Interventional non-treatment + 25

**Total  
Interventional  
Trials** **239**

## Interventional Treatment Protocols

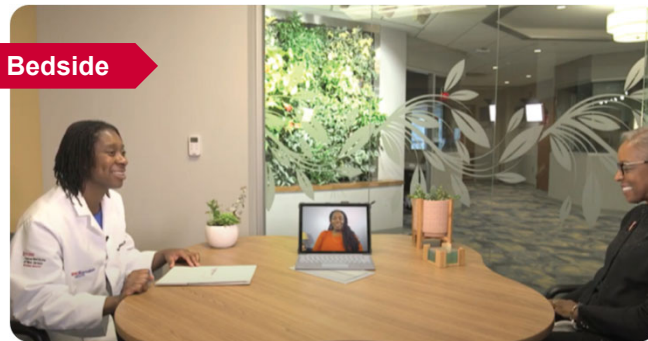


■ Institutional ■ Externally Peer Reviewed ■ Industry ■ National

# CPDM Supports Investigator Initiated Trials and Education

## RFA for Investigator Initiated Trials: November 2021

- Criteria: science, feasibility, system applicability, catchment area responsiveness
- 6 studies funded and CINJ sponsored (breast, GI, lung, H&N, RT)
- RFA issued again December 2022
  - Funded 2 trials with 3 more under revision
- **Fellow and junior faculty education**
  - Working together with CRTEC
  - Twice monthly Research In Progress seminars
  - Clinical Trials Course (offered yearly)
  - One-to-one mentoring research projects and protocol development
  - Fellow programs – ASCO, FDA, Vail course



# Investigator-Initiated Treatment Trials

## Surgical Oncology

### 6 Investigator-Initiated Trials

- Ghodoussipour (4) – GU
- Imanguli – H&N Cancer
- Alexander – GI cancer

## Radiation Oncology

### 13 Investigator-Initiated Trials

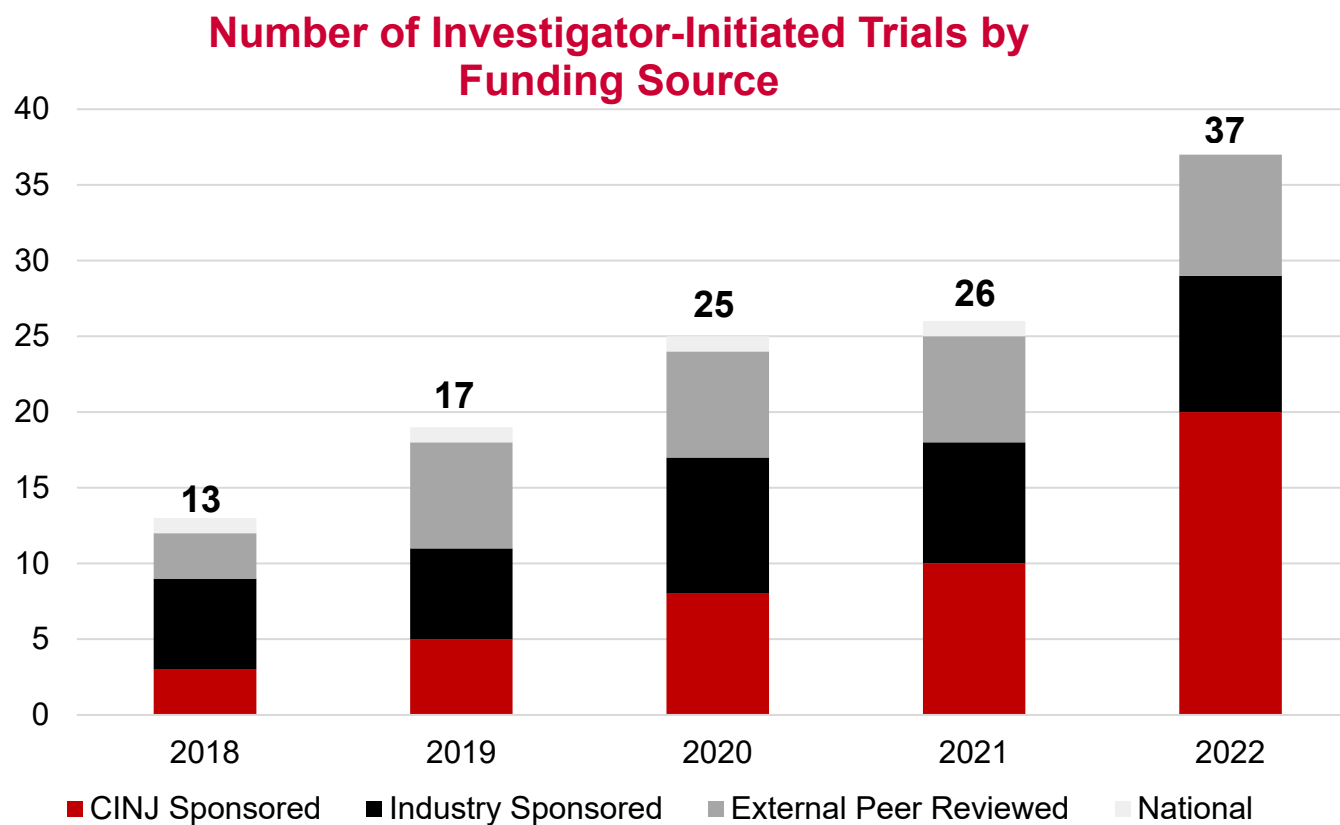
- Jabbour (7) – NSCLC, SCLC, Gastric, Rectal, HCC, **Hepatobiliary\* (CTEP)**, **Breast\* (CTEP)**
- Haffty (2) – Breast
- Hathout – Prostate
- Mattes (2) – H&N, Services Delivery, **H&N\* (CTEP)**

## Hematology/Medical Oncology

### 18 Investigator-Initiated Trials

- Strair (2) – BMT, MDS
- M. Shah – Myeloma
- Omene – Breast
- M. George (2) – Breast
- Boland (3) – Gastric, Colon, **Pancreatic\* (CTEP)**
- Berim – Pancreatic
- Gulhati – Pancreatic adjuvant
- Hochster (4) – Colon, HCC
- Haigentz – NSCLC
- Girda – solid tumors (IO)
- Hinrichs (2) – Cell therapy – solid tumors, HPV

# Investigator-Initiated Trials



\*38% (n=221) of enrollments in 2022 were to IITs

# System-Wide Focus on Clinical Research

## Expanded DSG participation across sites

- Weekly meeting with research physicians and staff
- Focus on system site needs, especially IITs
- Virtual DSG and in-person research meetings
- Biannual research conferences in New Brunswick



2nd Annual Research and Practice Summit, November 2022

## Minority-focused efforts with COE

- Across the System
- Nurse Navigators
- Community Science Impact Council

## Education and Training

- Universal training and competencies
- Courses for nursing and non-nursing research staff
- Micro-credentialing process with CTSA
- Training: Rutgers Schools of Public Health, Nursing

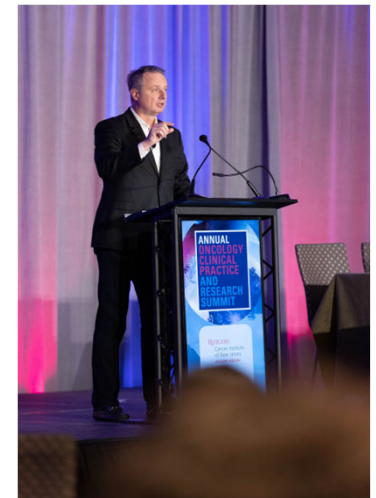
# ≡ Oncology Service Line Research Summits – 2021, 2022



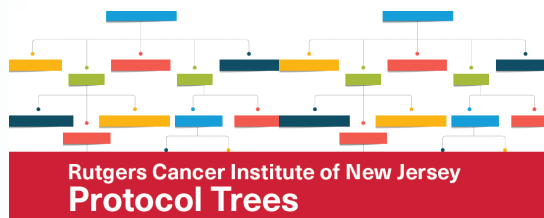
In-person meeting with **DSG lunch breakout** groups to promote interactions between CINJ and System physicians in developing clinical trials

First Annual Summit  
**11/13/21**

Second Annual Summit  
**11/5/22**



# Strong Physician and Patient Engagement Efforts



## Rutgers Cancer Institute of New Jersey Protocol Trees

Please visit this link or scan this QR code to view the current protocol trees:

<https://go.rutgers.edu/t0gi9pb2>



There are protocol trees for the following groups:

- Breast
- GI
- GU
- Gyn
- Heme
- Lung Head&Neck
- Melanoma/Sarcoma
- Pediatrics
- Phase 1
- Rad Onc

### Questions about Protocol Trees?

Please contact the Research Study Managers to be connected to a Clinical Trials Specialist at Rutgers Cancer Institute:

Research Study Manager	Disease Group	Phone	Email Address
Christian Misidary	Manager (Lung HN - GI - GU - Rad Onc)	732-735-3626	cm1344@cinj.rutgers.edu
Serban Morolanu	Manager (Peds)	732-235-8865	morolasa@cinj.rutgers.edu
Elayne Wesolowsky	Manager (Neuro - MelSarc - Heme)	732-235-3253	wesoloel@cinj.rutgers.edu
Laura Sullivan	Manager (Phase I - Cell Tx - Breast Gyn)	732-434-8522	ls1067@cinj.rutgers.edu



## A Clinical Trial For COLORECTAL CANCER

### WHAT IS THE PURPOSE?

The purpose of this research study is to learn whether a high-fiber nutritional drink will bring about good changes in the bacteria of the gut called microbiome in patients undergoing chemotherapy treatment.

### WHO CAN TAKE PART?

- 18 years or older
- You have colon or rectal cancer
- You can be treated with chemotherapy
- Other criteria also must be met

### WHAT ARE SOME BENEFITS?

If you take part in this study, the new drug plan and combination may make your cancer treatment better. However, this is not for sure. Taking part will help other patients in the future.

### WHERE WILL THIS STUDY TAKE PLACE?

This study is available through Rutgers Cancer Institute of New Jersey in New Brunswick and hospitals that are part of RWJBarnabas Health.

### WHERE CAN I GET MORE INFORMATION?

Please contact:

Christian Misidary  
at 732-735-3626 or [cm1344@cinj.rutgers.edu](mailto:cm1344@cinj.rutgers.edu)  
Research Study Manager, Rutgers Cancer Institute of New Jersey  
195 Little Albany St, New Brunswick, NJ 08901

PI: Howard Huchler, MD, FACP  
Title: Randomized Trial of Microbiotic Product (MBT-NM108) to Reduce Chemotherapy-Induced Diarrhea and Improve Chemotherapy Delivery  
Study #072201  
v1.03.16.2022



**Fewer than 10% of minority patients are enrolled in clinical trials.**

Ask your cancer doctor about a clinical trial treatment option.

\*<https://academic.oup.com/jco/article/36/16/1784/6230107>

**Find A Clinical Trial**



<https://go.rutgers.edu/m6e2wdhc>





# Clinical Trials Brochure (global and patient-centered)

## What is informed consent?

Before a patient can participate in a clinical trial they must first give their informed consent to participate. This is done by the patient signing an informed consent document that states that they understand the purpose of the clinical trial, what will happen during the clinical trial, the benefits and risks of the clinical trial, who to contact if they have questions, and are aware of their patient rights.

## Who pays the cost of a clinical trial?

Every clinical trial is different. However, expense to the patient should be minimal the patient's health insurance will often cover any of the routine costs for participation. The costs of a clinical trial could be covered by the sponsor of the study – this could be the government, a pharmaceutical or medical technology company.

## How do I find a clinical trial?

Rutgers Cancer Institute of New Jersey and RWJBarnabas Health have an extensive list of available clinical trials for all types of cancer. Clinical trials are available at Rutgers Cancer Institute of New Jersey and RWJBarnabas Health facilities across the state. To find a clinical trial visit [cinj.org/clinical\\_trials](http://cinj.org/clinical_trials) or call **844-CANCERNJ (844-226-2376)**.

## Locations:

- Clara Maass Medical Center
- Community Medical Center
- Cooperman Barnabas Medical Center
- Jersey City Medical Center
- Monmouth Medical Center
- Monmouth Medical Center Southern Campus
- Newark Beth Israel Medical Center
- Robert Wood Johnson University Hospital
- Robert Wood Johnson University Hospital Hamilton
- Robert Wood Johnson University Hospital Rahway
- Robert Wood Johnson University Hospital Somerset
- Rutgers Cancer Institute of New Jersey
- Trinitas Regional Medical Center

## Clinical Trials



Today's treatments for tomorrow's cures

**RWJBarnabas**  
HEALTH

**RUTGERS**  
Cancer Institute  
of New Jersey  
RUTGERS HEALTH

Let's beat cancer together.

**RWJBarnabas**  
HEALTH

**RUTGERS**  
Cancer Institute  
of New Jersey  
RUTGERS HEALTH

Let's beat cancer together.

Rutgers Cancer Institute of New Jersey is the state's only NCI-designated Comprehensive Cancer Center. Together RWJBarnabas Health and Rutgers Cancer Institute offer the most advanced cancer treatment options close to home.



## Translation in 10 Languages:

<https://go.rutgers.edu/6ee1z02y>

- Spanish
- Arabic
- Chinese
- Gujarati
- Haitian Creole
- Hindi
- Korean
- Polish
- Portuguese
- Russian



# Inclusion of Women, Minorities, and Patients Across the Lifespan and Children in Clinical Research

# Interventional Treatment Trials – 2022

## Gender Characteristics

Interventional Therapeutic Trial Enrollment at CINJ

Gender	NJ %	CINJ - ALL%	2022 Accrual (n=600)	
			%	Actual
Female	50.1%	57.2%	54.2%	325
Male	49.9%	42.8%	45.8%	275

# Interventional Treatment Trials – 2022

## Race and Ethnicity Characteristics

Interventional Therapeutic Trial Enrollment at CINJ

Race/Ethnicity	NJ %	CINJ – ALL %	2022 Accrual	
			%	Actual
Asian/PI	5.1%	6.5%	10.9%	63
Black	11.6%	18.4%	16.8%	97
Hispanic/Latino	10.8%	13.1%	18.9%	109
More than one race	NA	NA	3.1%	18
Native American or Alaska Native	NA	0.1%	0.5%	3
White	79.3%	70.5%	68%	396

# Interventional Treatment Trials – 2022

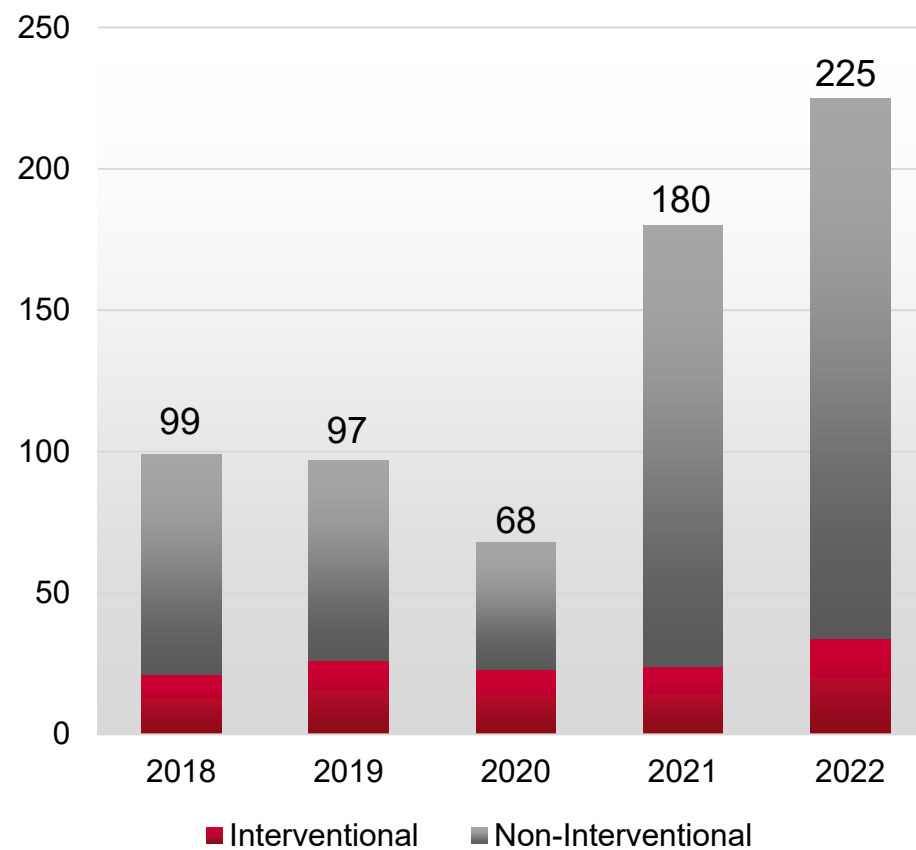
## Age Characteristics

Interventional Therapeutic Trial Enrollment at CINJ

Age Group	NJ %	CINJ - ALL%	2022 Accrual (n=600)	
			%	Actual
Under 18	0.8%	1.0%	4.2%	26
18-39	4.0%	4.9%	5.7%	35
40-64	37.8%	39.9%	54.0%	322
65 and over	57.4%	54.3%	36.1%	217

# ≡ Pediatric Accrual

## Interventional vs. Non-Interventional Accrual by Year



# Community Outreach and Engagement

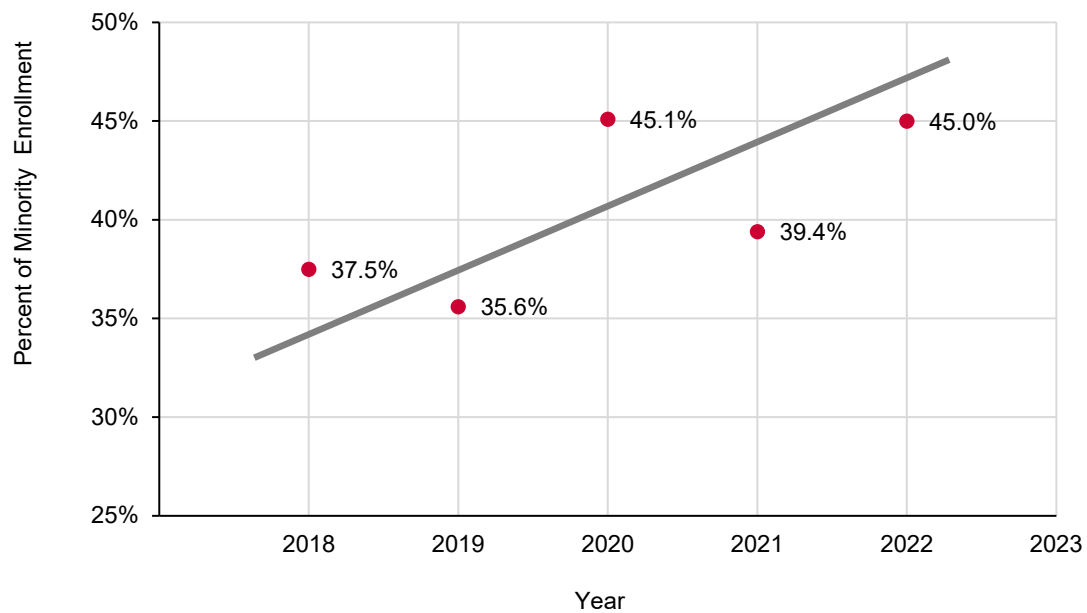


**Partner with COE to engage DSGs and address catchment area priorities**

- Participation with Community Cancer Action Board
  - Presentations and membership
- Monthly meetings to review accrual of various populations
- COE representation at SRB and HROC meetings
- SRB-approved minority/outreach plans for all protocols
- Treatment informed consents available in English and Spanish for all open trials
  - Additional short forms available in 20 translated languages
- Strategies to increase accrual in Black populations
  - Materials for recruitment
  - Outreach to community leaders
  - Bilingual Educators and Clinical Trial Navigators throughout system

# Accrual of Minorities to Therapeutic Trials

## Minority Enrollment to Interventional Therapeutic Trials (2018-2022)



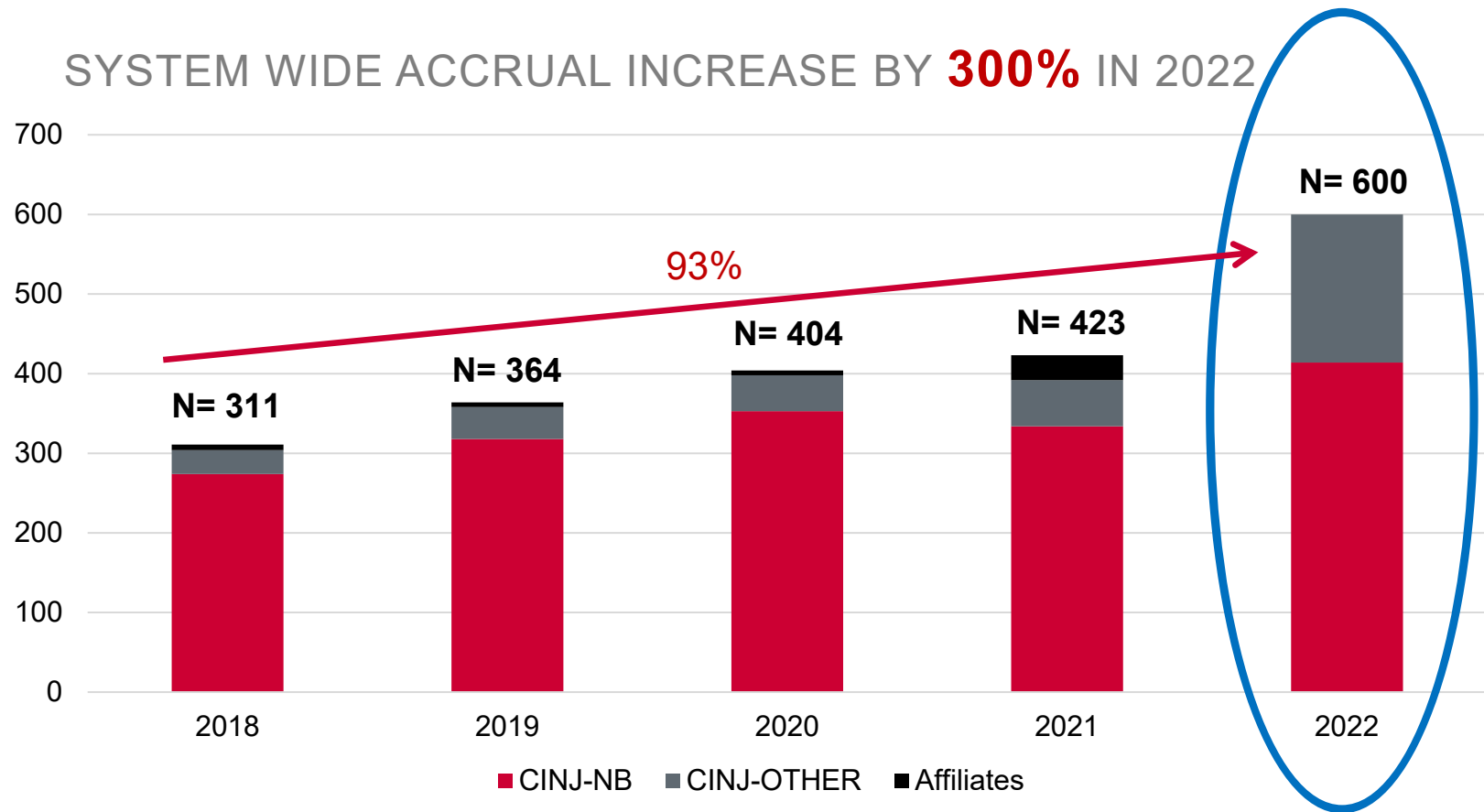


≡ Accrual

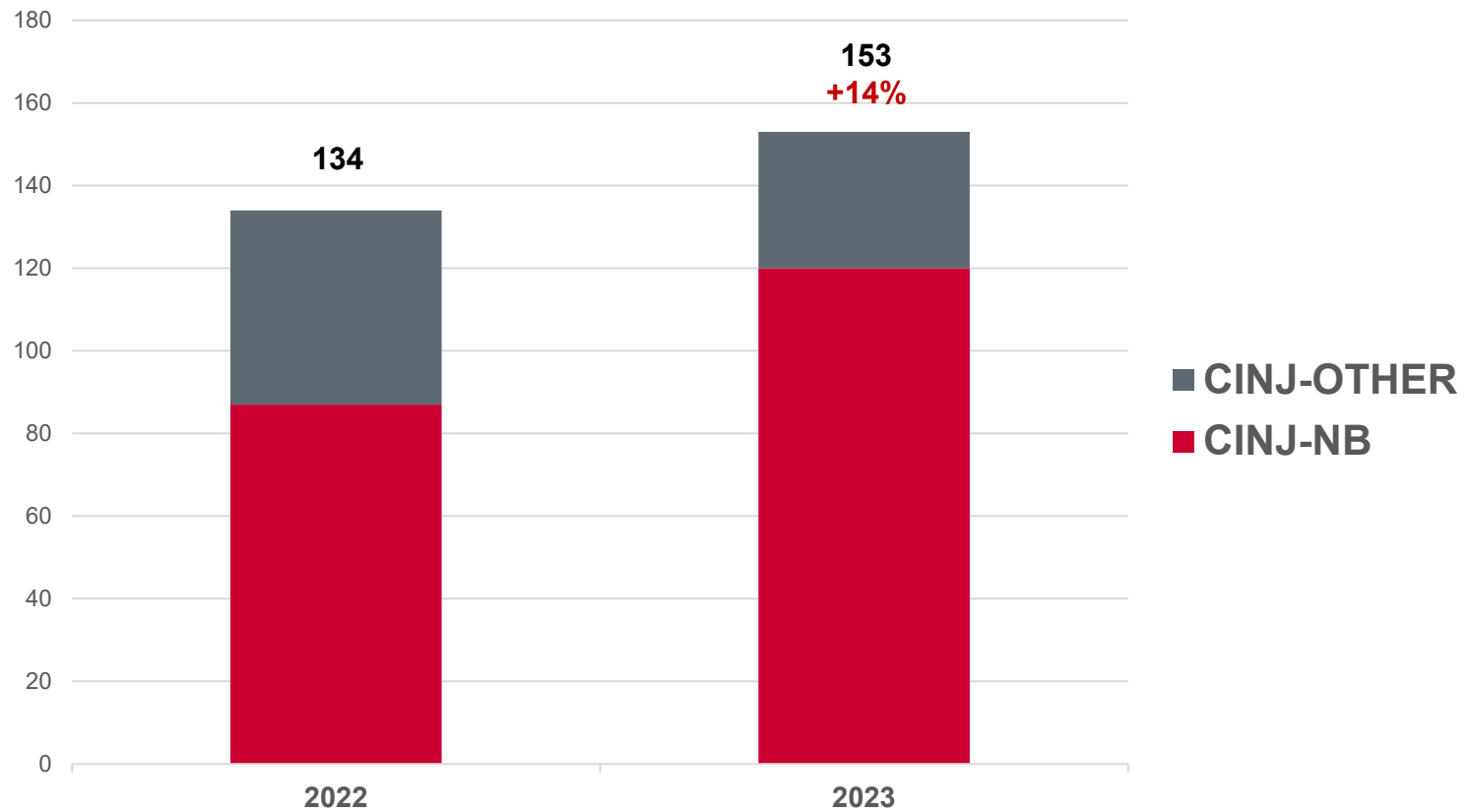
# Overall Accrual 2018-2022

<b>Accrual to Interventional Treatment Research Protocols</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>
Rutgers Cancer Institute of New Jersey	274	318	349	334	414
RWJBarnabas Health	30	40	49	58	186
Affiliates	7	6	6	31	0
<b>Total Interventional Treatment Accrual</b>	<b>311</b>	<b>364</b>	<b>404</b>	<b>423</b>	<b>600</b>
<b>Accrual to Interventional Non-Treatment Research Protocols</b>					
Rutgers Cancer Institute of New Jersey	440	2581	596	992	590
RWJBarnabas Health	1	18	2	11	1
Affiliates	18	105	14	0	0
<b>Total Interventional Non-Treatment Accrual</b>	<b>459</b>	<b>2704</b>	<b>612</b>	<b>1003</b>	<b>591</b>
<b>Total Interventional Accruals at Rutgers Cancer Institute</b>	<b>770</b>	<b>3068</b>	<b>1016</b>	<b>1426</b>	<b>1191</b>
<b>Accrual to Non-Interventional Research Protocols</b>					
Rutgers Cancer Institute of New Jersey	3371	3377	3337	2055	11812
RWJBarnabas Health	114	299	266	121	88
Affiliates	11	16	0	0	0
<b>Total Non-Interventional Accruals at Rutgers Cancer Institute</b>	<b>3496</b>	<b>3692</b>	<b>3603</b>	<b>2176</b>	<b>11900</b>
<b>Total Interventional and Non-Interventional Accrual at Rutgers Cancer Institute</b>	<b>4266</b>	<b>6760</b>	<b>4619</b>	<b>3602</b>	<b>13091</b>

# Increasing Treatment Trial Enrollment (2018-2022)



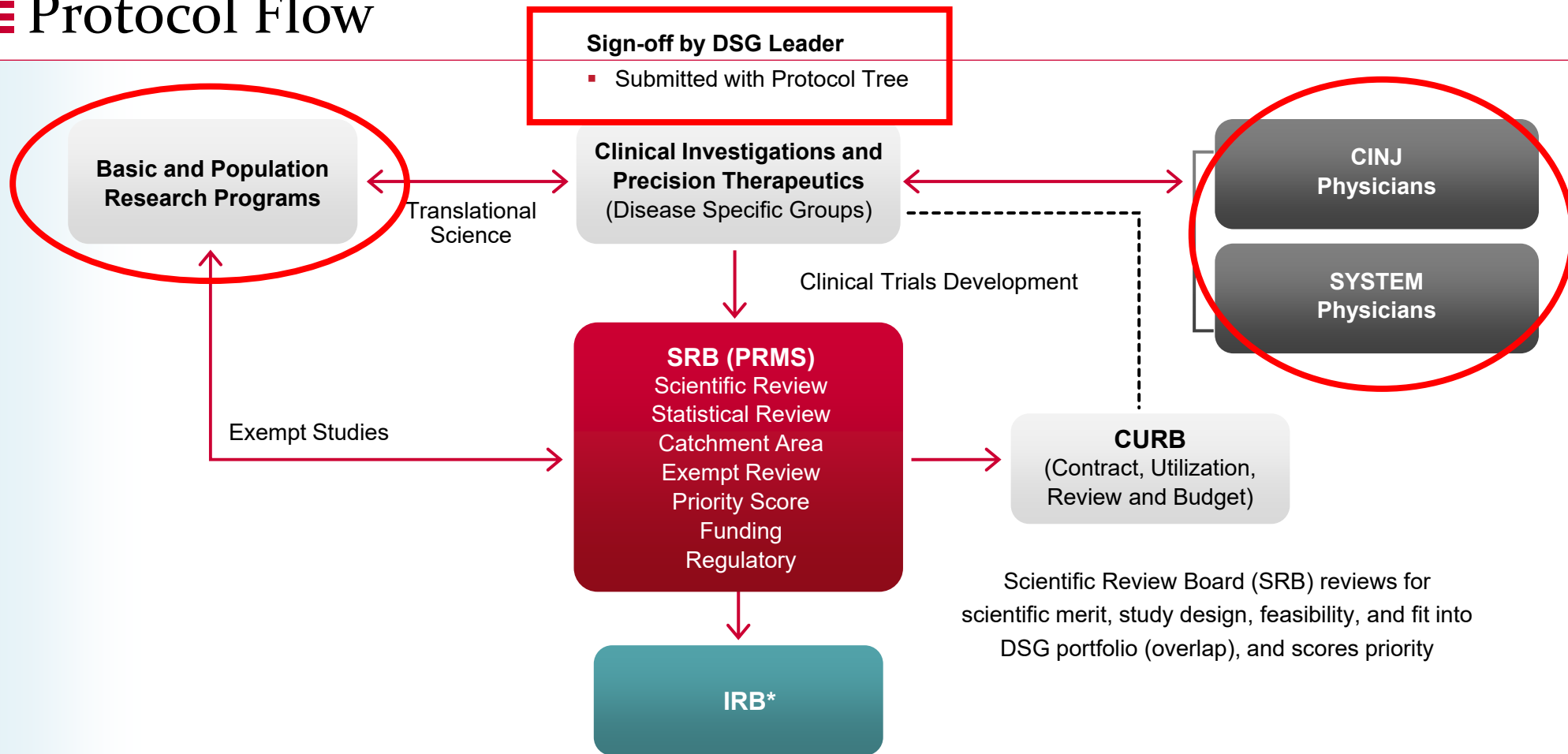
## ACCRUAL YTD (through 3/31/23): 2022 vs 2023





# Protocol Review and Monitoring System (PRMS) CINJ Scientific Review Board (SRB)

# Protocol Flow



\*All cancer protocols require SRB approval prior to IRB review

## PRMS: Scientific Review Board

Member	Area of Expertise
Chair and Co-Chair	Clinical/translational research, clinical trials, medical oncology, radiation oncology
2 Members	Population research
1 Member	Basic research
2 Members	Biostatistics
2 Members	Radiation Oncology
1 Member	Community Outreach and Engagement
1 Member	Surgical Oncology
4 Members	Medical Oncology, clinical/translational research (1 member from RWJBH)
2 Members	Patient Advocacy
1 Member	Oncology nursing; clinical research administration
<i>Ad hoc</i>	Scientist or clinician
<i>Ad hoc</i>	IRB representative

## PRMS (SRB) Activities 2022

	Investigator Initiated	Externally Peer-Reviewed	National	Industry	Total
Protocols Submitted and Reviewed	64	19	16	60	<b>159</b>
Approved as Submitted	38 (59%)	16 (84%)	16 (100%)	55 (92%)	<b>125 (79%)</b>
Conditionally Approved (Needs Only Admin Review)	18	0	0	4	<b>22</b>
Deferred/Disapproved	2	0	0	0	<b>2</b>
Exempt	6	3	0	1	<b>10</b>

Protocol Closures	Completed Accrual	Slow Accrual	Research Canceled	Interim Analysis	Other
<b>8</b>	<b>35</b>	<b>9</b>	<b>4</b>	<b>1</b>	<b>9</b>

\*Total closed in 2022 in response to HROC/SRB reviews = **21**

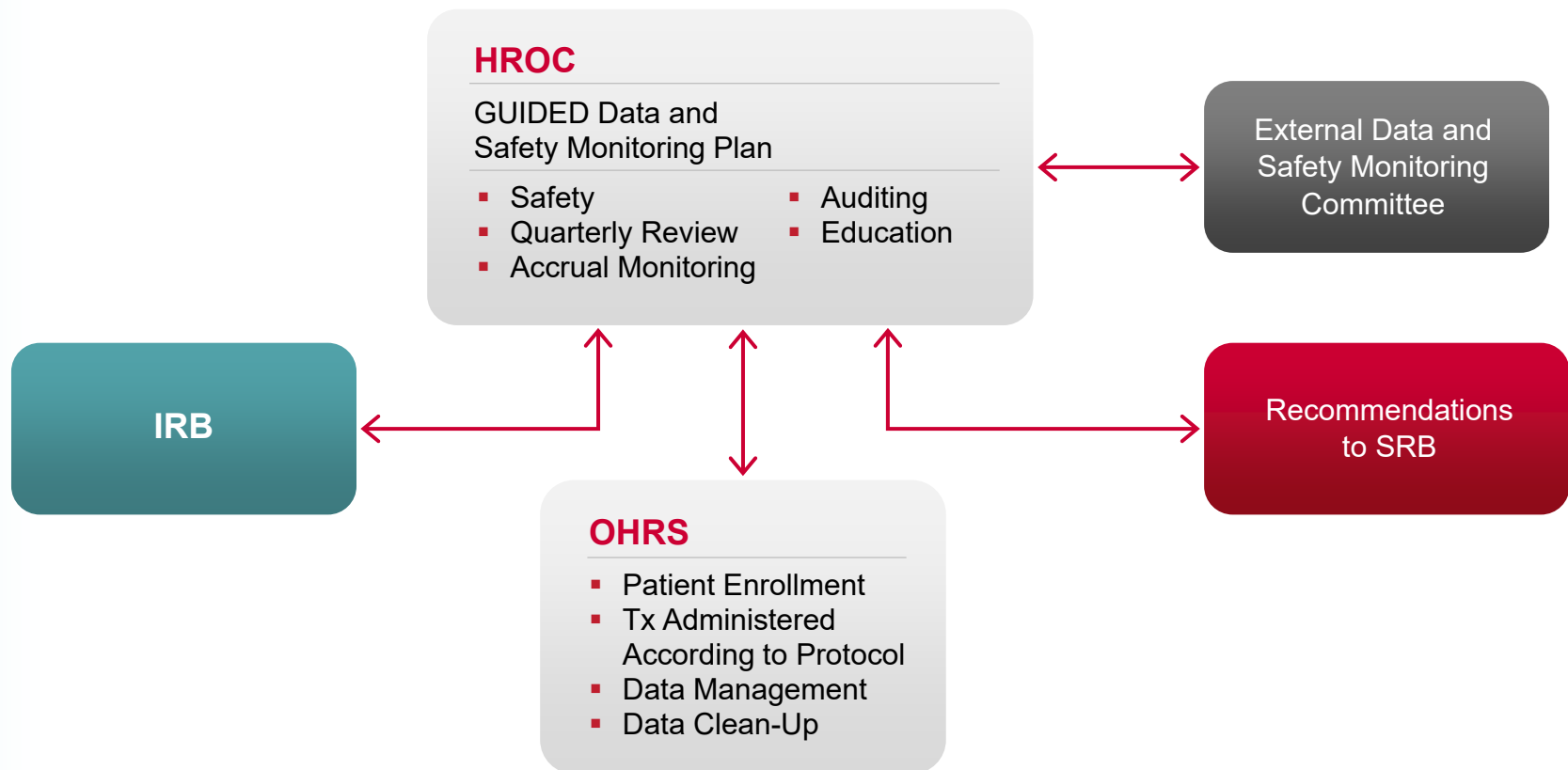




# Data and Safety Monitoring (DSM)

## CINJ Human Research Oversight Committee (HROC)

# DSM Process: Human Research Oversight Committee (HROC)



## DSM: Human Research Oversight Committee

Member	Area of Expertise
Chair	Biostatistics
Co-Chair	Clinical/translational research, clinical trials, Medical Oncology
4 Members	Medical Oncology (1 member from RWJBH)
2 Members	Surgical Oncology (1 member from RWJBH)
1 Member	Quality Assurance
1 Member	Regulatory
<i>Ad hoc</i>	Scientist or clinician
<i>Ad hoc</i>	IRB representative

# DSMC (HROC) Activities 2021, 2022

## 2021 HROC Review Activities

Protocols Audited (Quality)	CAPs	Major Findings	Minor Findings	Deviations with Resulting CAPs	Protocol Reviews (Enrollment)	Recommended for Closure (Enrollment)
13	9	5	29	317	230	6

## 2022 HROC Review Activities

Protocols Audited (Quality)	CAPs	Major Findings	Minor Findings	Deviations with Resulting CAPs	Protocol Reviews (Enrollment)	Recommended for Closure (Enrollment)
54	10	4	21	440	289	9

# Unified Clinical Trials Infrastructure: QA/Oversight

## Quality Assurance Innovations



### DSMP

Revised to include system sites



### SAEs

Global use of OnCore<sup>®</sup> for all SAEs



### Access

All meetings available via WebEx



### ↑QA




Add'l QA Specialists monitor increased enrollment activities



### Revised Site Management Plan

- PI oversight of all patients at all sites
- Investigational agent management
- QA/monitoring of accrual at all sites; focus on initial accruals

## ≡ In Summary:

- Accomplished  **One Site Model**
- Legal and Regulatory barrier superseded
- Completed  **Site Integration**
- Open trials simultaneously throughout system
  - Consolidation and Integration of all NCTN sites
  - System wide PIs – including from system sites
- Over Current Grant Period  **Accrual Gains**
- Total 600 treatment trial accruals
  - Nearly double from last renewal
  - 300% increase in system site accrual
  - “Benchmark” minority accrual = 45%

# Future Directions

## 1 Continue to **integrate** system physicians

- EPIC everywhere
- Increase DSG integration and system research meetings
- Training Center for physicians (and staff) – uniform onboarding

## 2 **Increase** recruitment – match patients to existing trials

- New recruitment office
- CRDW – joint CINJ and CTSA effort under David Foran, PhD
- Deep6 AI software and other digital efforts to aid in patient identification

## 3 Continue efforts with COE for **diversity, minority, women, and across the lifespan** accrual

- Increase in diversity, minority and URG accrual
- Focus on Black Community
- Focus on increasing older patient accrual

## 4 Continue to support and expand **Investigator-Initiated Research**

- Translational, cellular and novel therapies

## 5 Continue to **promote and develop** a “culture” of clinical research at all sites

## 6 Increase **Treatment Trial Accrual** → Toward **GOAL** of 800-1000

# Thank You

Q&A Segment



**RUTGERS**  
Cancer Institute  
of New Jersey  
**RUTGERS HEALTH**

