UCI 趙 Chao Family Comprehensive Cancer Center

Clinical Research

WARREN CHOW, MD

EAB 2025

MARCH 14, 2025

Leadership

Warren Chow, MD
Associate Director for Clinical Science

EXPERTISE
- 3 years as AD for Clinical Sciences
- 4 years as PRMC Chair (at another institution)

ROLES
- Oversee cancer clinical research across the UCI Health enterprise

Farshid Dayyani, MD, PhD
Medical Director & AD for Translational Science

EXPERTISE
- 4 years as Medical Director of the Stern Center Clinical Trials Office
- 3 years UCI IRB Vice Chair

ROLES
- Lead strategic planning and provide clinical direction; ensure quality of services

Arash Rezazadeh, MD
Chair, Protocol Review & Monitoring Committee

EXPERTISE
- 3 years as PRMC Chair
- 5 years as PRMC member

ROLES
- Ensure the scientific feasibility and progress review of all cancer-related clinical research

John Fruehauf, MD, PhD
Chair, Data & Safety Monitoring Board

EXPERTISE
- 15 years as DSMB Chair
- 20 years as DSMB member

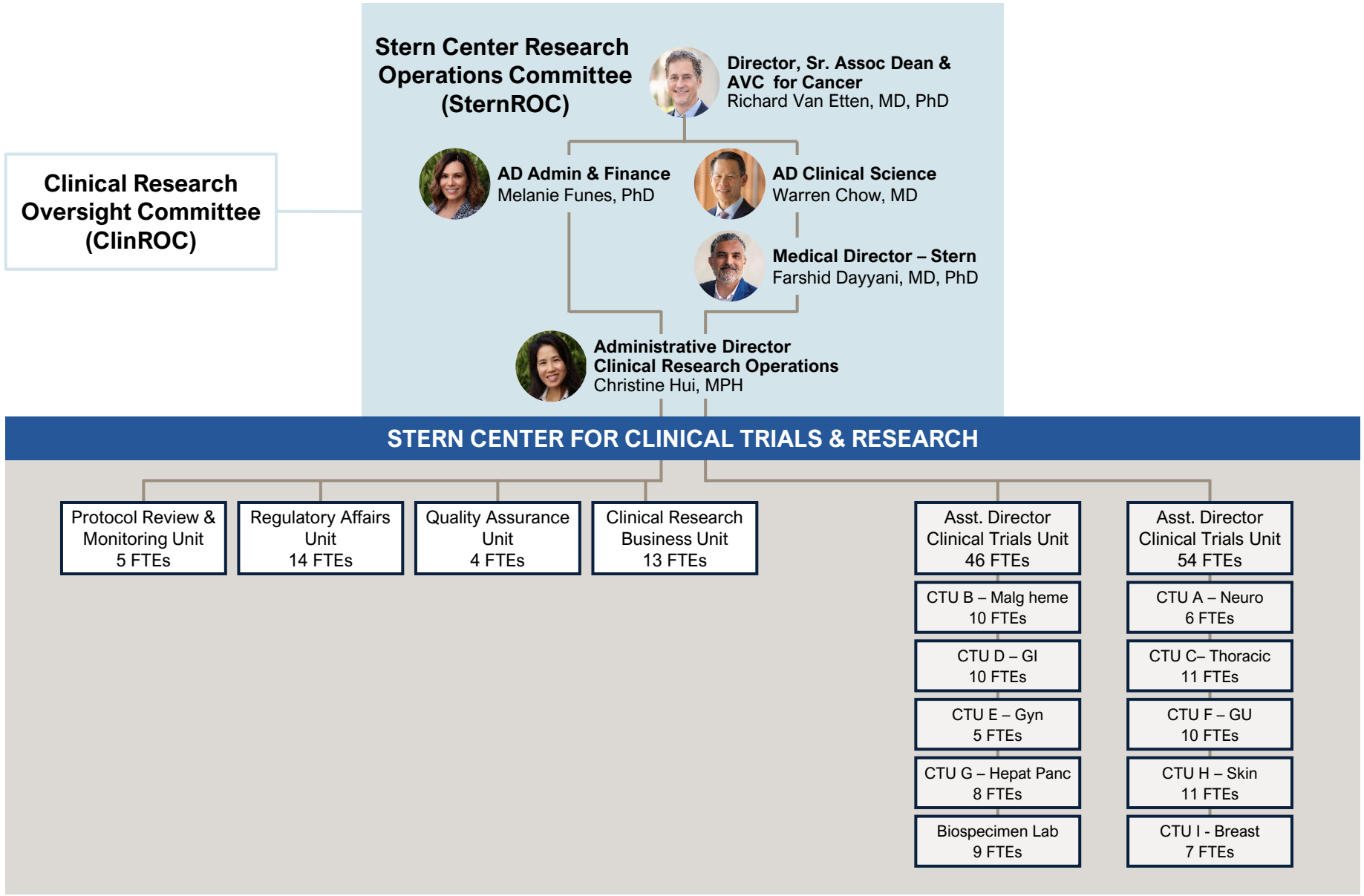
ROLES
- Ensure the safety of subjects and the validity and integrity of data for interventional institutional trials

Christine Hui, MPH
Administrative Director for Clinical Research Operations

EXPERTISE
- 20 years experience in regulatory, research administration and clinical research operations

ROLES
- Leadership and oversight for operations for the CFCCC clinical research enterprise

Stern Center for Cancer Clinical Trials & Research: Organizational Structure



UCI 趙 Chao Family Comprehensive Cancer Center

01

Clinical Protocol & Data Management (CPDM)

Objective & Specific Aims

OBJECTIVE

The Stern Center for Cancer Clinical Trials & Research (Stern Center) aims to enhance clinical trial management by improving trial activation processes, research patient accrual, ensure quality control through education and training activities and trial auditing and monitoring.

AIMS

1. **Personnel**

   To ensure the readiness of highly-qualified and trained clinical research personnel committed to managing and coordinating cancer clinical trials in an innovative, methodical and efficient manner

2. **Clinical Trial Management System**

   To provide an accurate, reliable and central location for cancer protocols and reporting, and a centralized database of protocol-specific data for use by investigators

3. **Research Study Management**

   To ensure the safety of subjects and the validity and integrity of data from clinical trials

4. **Catchment Area Inclusion**

   To provide all patients in the Catchment Area with the option of participating in a clinical trials through the inclusive, robust and thoughtful management of the CFCCC trial portfolio in coordination and partnership with the Disease-Oriented Teams and the Office of Community Outreach and Engagement

Accomplishments in 2024

Significant Increase in Clinical Trials Accrual

- 30% overall increase in interventional treatment accrual
- Doubled institutional interventional treatment accruals
- Doubled national interventional treatment accruals

Major Reduction in Study Time to Activation

- 29% decrease in time to study activation
- 50% increase in activating institutional trials

Opening of Chao Family Comprehensive Cancer Center – Irvine

- Opened for research in September 2024
- >100 trials open at the Chao Irvine facility
- Enrolled 22 patients in 2024

Updated MOU with SOM & UCI Health

Efficient Stern Center Operations

- Broad utilization of AE documentation in Epic across active trials
- Utilization of source documentation in Epic
- Templated Clinical Research Source Log Epic Smartphrases (e.g. medical history logs, concomitant medication logs, etc.)
- Screening Progress Notes for audit defensible visits
- Auto-notification of research patient emergency department visits for potential SAE reporting
- Full utilization of Complion, e-Regulatory Binder platform for all trials
- Initiated Clinical Research Training Program for New Clinical Research Coordinators

Response to EAB Review

2021 NIH Merit Rating
OUTSTANDING

STRENGTHS (2021 NIH Summary Statement)

> “….the centralized office for clinical trials operations has undergone a dramatic transformation since the last CCSG site review with several notable accomplishments…

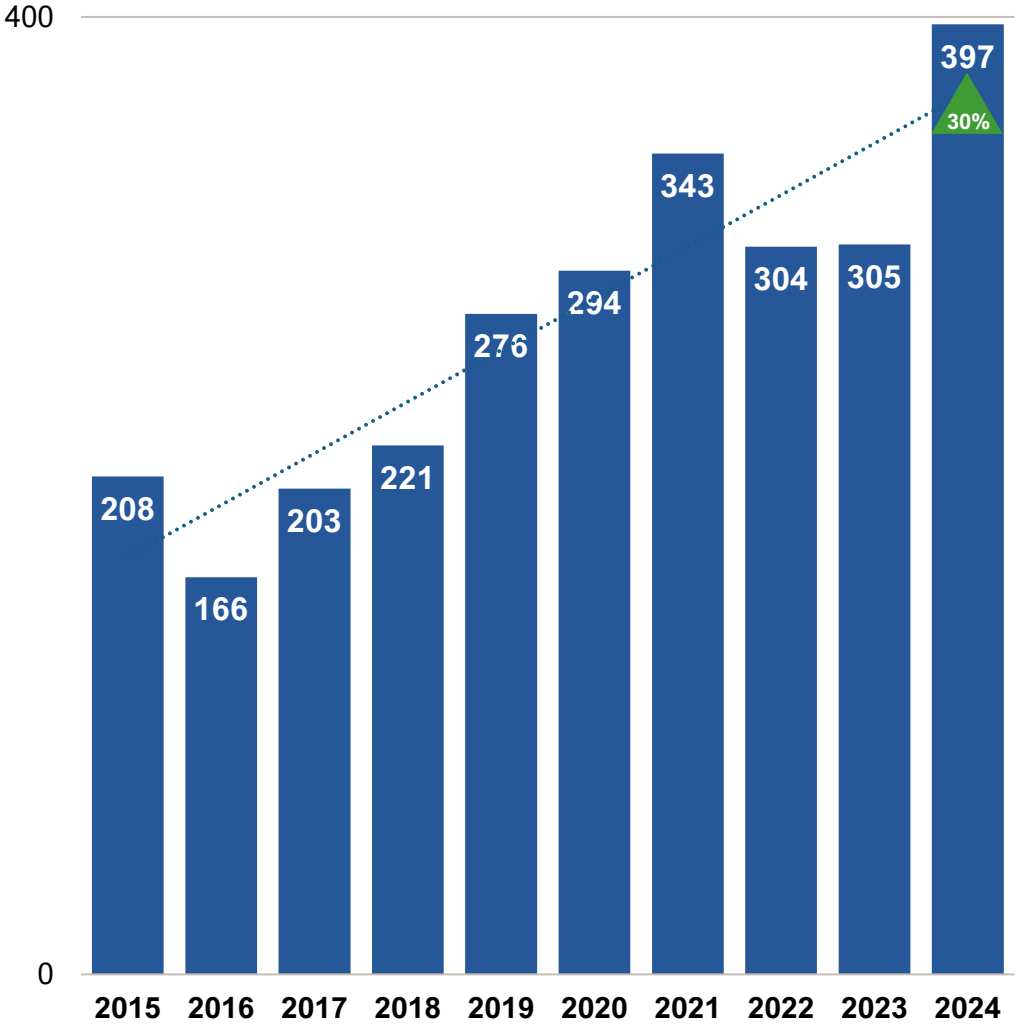
CRITIQUE	RESPONSE
“…static and low accrual into interventional treatment trials during this funding period…”	• 30% increase in the interventional treatment accrual to 397 patients in 2024 • 15% increase in the interventional accrual to 764 patients in 2024
“…apparent disconnect between the impressive clinician scientist funds flow support and accrual…”	• Modified Memorandum of Understanding with School of Medicine and UCI Health effective 7/1/24 • Criteria focused on consenting, accrual, and investigator-initiated trial activation
“…despite a recent increase in the number of radiation oncology faculty and clinical trial activations of RT-trials, this has not yet resulted in an increase in accrual.” “…no specific portfolio was presented. This needs to be developed (with accrual goals)...”	• Focused effort to open multidisciplinary RT-trials (e.g. via ETCTN) • Will utilize the ETCTN LOI platform to write protocols with RT faculty • AD Dayyani will participate in hands-on mentoring for IITs with Radiation Oncology faculty
”CFCCC has made it clear that it supports a genomics platform and has an EPIC based access to genomics. This is critical and needs to be done ASAP as it will strengthen the clinical science effort.”	• AD Chow serves on the UCI Epics Genomics Working Group for implementation • Implementation slated for 12/6/25, with UCI’s own instance of Epic (no longer shared with UCSD) • For patients with a genomic alteration, clinical trials will be screened by Epic AI
“…precision oncology aspects of the programs need to be integrated throughout the DOTs and strengthened by interaction between the DOTs as well as with the SPT and BIDD programs.”	• Disease-Oriented Team (DOT) flowcharts highlight molecular-driven biomarker trials for all disease sites • Epic ordering integrated for Caris, other companies integrating in December 2025 • Translational IITs in start up [e.g. methionine depletion for immune resistant cancers (PI Arter), statins to overcome gemcitabine resistance (PI Valerin)], • AD Dayyani co-chairs Discover work group (w. Shared Resource Director Sandmeyer)

Response to EAB Review

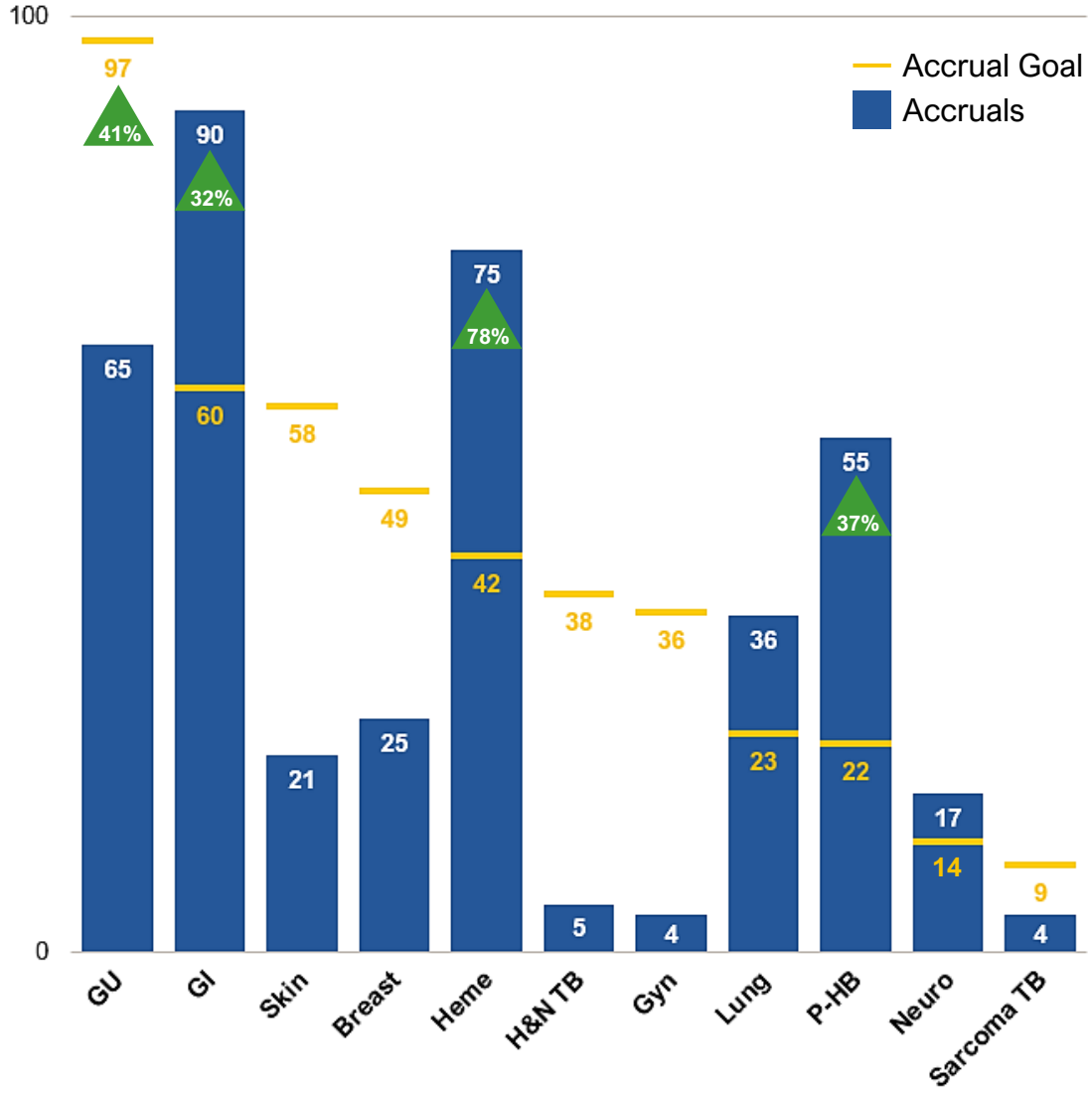
CRITIQUE	RESPONSE
CFCCC proposed using IIT trials to increase accruals. EAB supports IITs as they are necessary for the CCSG renewals but remain concerned this strategy is not sufficient. Should include large Phase 3 trials from NCTN/industry that will be open for substantial period of time with ability to readily accrue patients.	• Doubled institutional trial accrual in 2024 to 76 accruals • Doubled national trial accrual in 2024 to 101 accruals • 30% increase in accrual in Phase III trials
"Focus carefully on selected underperforming disease sites especially including breast, GYN, H&N. GYN should have a greatly expanded portfolio as soon as possible. It was suggested that a medical oncologist with gyn interests would be a reasonable approach…"	• UCI-21-173 Head & Neck investigator-initiated trial opened in November 2024 • UCI-24-05 breast investigator-initiated trial opened in December 2024, with 4 patients accrued • Management of gynecologic oncology trials will move from Department of Obstetrics/Gynecology to Division of Hematology/Oncology • Gyn medical oncologist slated for July 2025 hire
Expand the Phase I operation, in part, by recruiting an early drug development expert, have dedicated infusion chairs, and inpatient beds	• Center for Innovative Health Therapies is converting to Site of Service 22 (allows billing of both standard of care and research activities) with dedicated chairs and staffing • Director, Early Phase Clinical Trials and Precision Therapeutics, faculty recruitment ongoing
Fellows should be required to screen patients for trial as part of their training and encouraged to assist in writing IITs with the PI	• Multiple fellows have written IIT protocols: ▪ UCI-23-173, IIT, written by Dr. Jeffrey Ahn – 3rd year fellow (at the time) ▪ UCI-18-120, IIT, writing assisted by Dr. Sami Dwabe – 3rd year fellow, Gyn/Onc Phase 1/1b trial with Dr. Tseng (letrozole/everolimus/Lenvatinib) ▪ UCI-24-87, IIT, written by Dr. Ann Arter – 3rd year fellow, methionine depleted diet in solid tumors ▪ Dr. Omid Yazdanpanah [Sub-I on GU trials (UCI-20-123/20-179), PI for IIT with Dr Rezazadeh as 3rd year fellow (UCI-21-131)]

Accrual to Interventional Treatment Trials

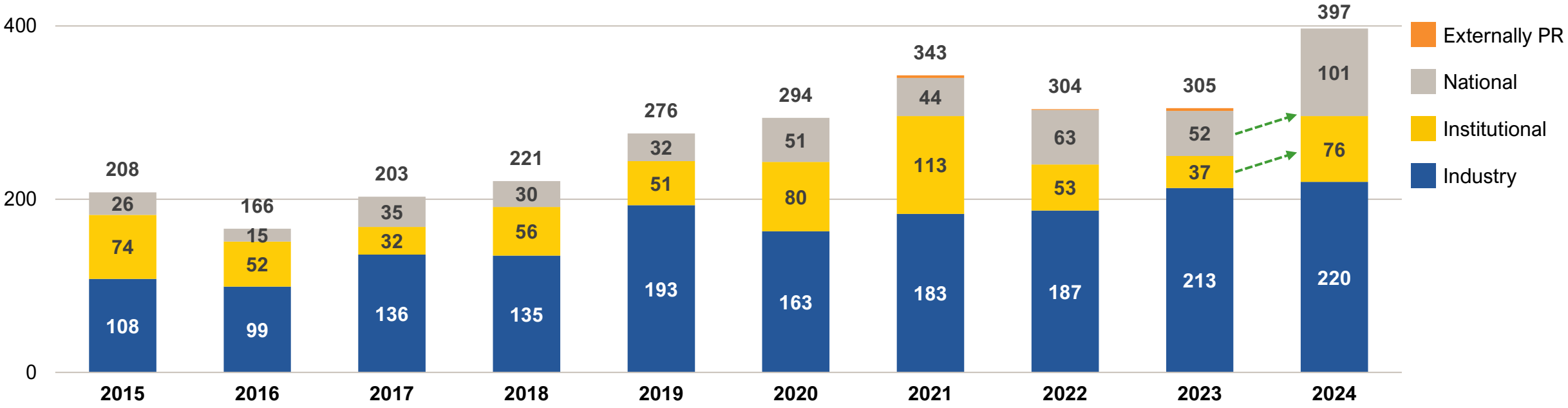
Patient Accruals to Overall Interventional Treatment Trials



Patient Accruals to 2024 DOT Interventional Treatment Trials

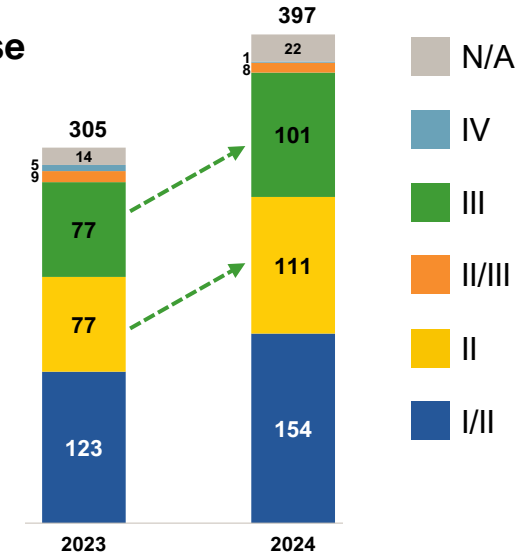


Accrual to Interventional Treatment Trials by Sponsor



- **Doubled** National accrual from 52 to 101 in 2024
- **Doubled** Institutional accrual from 37 to 76 in 2024
- **31% increase** in Phase III accruals in 2024
- **44% increase** in Phase II accruals in 2024

Accrual by Phase



Strategies to Increase Accrual of UCI Investigator-Initiated Trials

Prostate

- UCI-23-137, PI David Lee, Investigator Initiated Trial: Impact of Intraoperative ICG Use During Robotic-Assisted Radical Prostatectomy on Functional Outcomes, opened in July 2024, accrued **24** patients, n=400

Skin

- UCI-22-49, PI Warren Chow, Investigator Initiated Trial: Metronomic Cyclophosphamide with Pembrolizumab in Checkpoint Inhibitor Refractory Melanoma, opened December 2024, accrued **1** patient, n=14

Breast

- UCI-24-05, PI Alexandre Chan, Investigator Initiated Trial, Repurposing Riluzole for Augmenting Brain-Derived Neuropathic Factor (BDNF) Levels and Cognitive Function in Breast Cancer Patients Experiencing Cancer-Related Cognitive Impairment: An Interventional Pilot Clinical Trial, opened in December 2024, accrued **4** patients, n=26

Head & Neck

- UCI-21-173, PI Rupali Nabar, Investigator Initiated Trial, Single-Center Evaluation of the Clinical and Radiological Benefit of AHCC® in Combination with Standard of Care Treatment for HPV-Positive Patients with Head and Neck Squamous Cell Carcinoma (HNSCC), opened in December 2024, accrued **0** patients, n=34

Gynecologic Oncology

- Proposed UCI-18-120, PI Jill Tseng, Investigator Initiated Trial, Phase I Dose-Escalating and Phase II Dose-Expansion Study of N-Acetyl-Cysteine (NAC) Administration to Ovarian Cancer Patients Receiving Platinum-Based Therapy (PBT) for the mitigation of Chemotherapy-Related Cognitive Impairment (CRCI), scheduled to open by 6/1/25, n=87

Malignant Heme

- UCI-21-90, PI Stefan Ciurea, Investigator Initiated Trial: Risk-ADAPTed Conditioning Regimen for Allogeneic Hematopoietic Stem Cell Transplantation (ADAPT)

Strategies to Increase Accrual

Opening of Chao Family Comprehensive Cancer Center – Irvine

- All Phase III, NCTN, and Institutional trials are open: 100+ trials are open at the facility
- Will open Phase II trials by March 2025: ~50 additional trials
- Phase I trials will open after July 2025
- Hospital will open in December 2025, additional cellular therapy trials will be able to open

Radiation Oncology

- Early Therapeutics Clinical Trials Network (ETCTN) Letter of Intent (LOI) submissions
- AD Chow to meet with the faculty in March to further engage them

New Faculty Hires

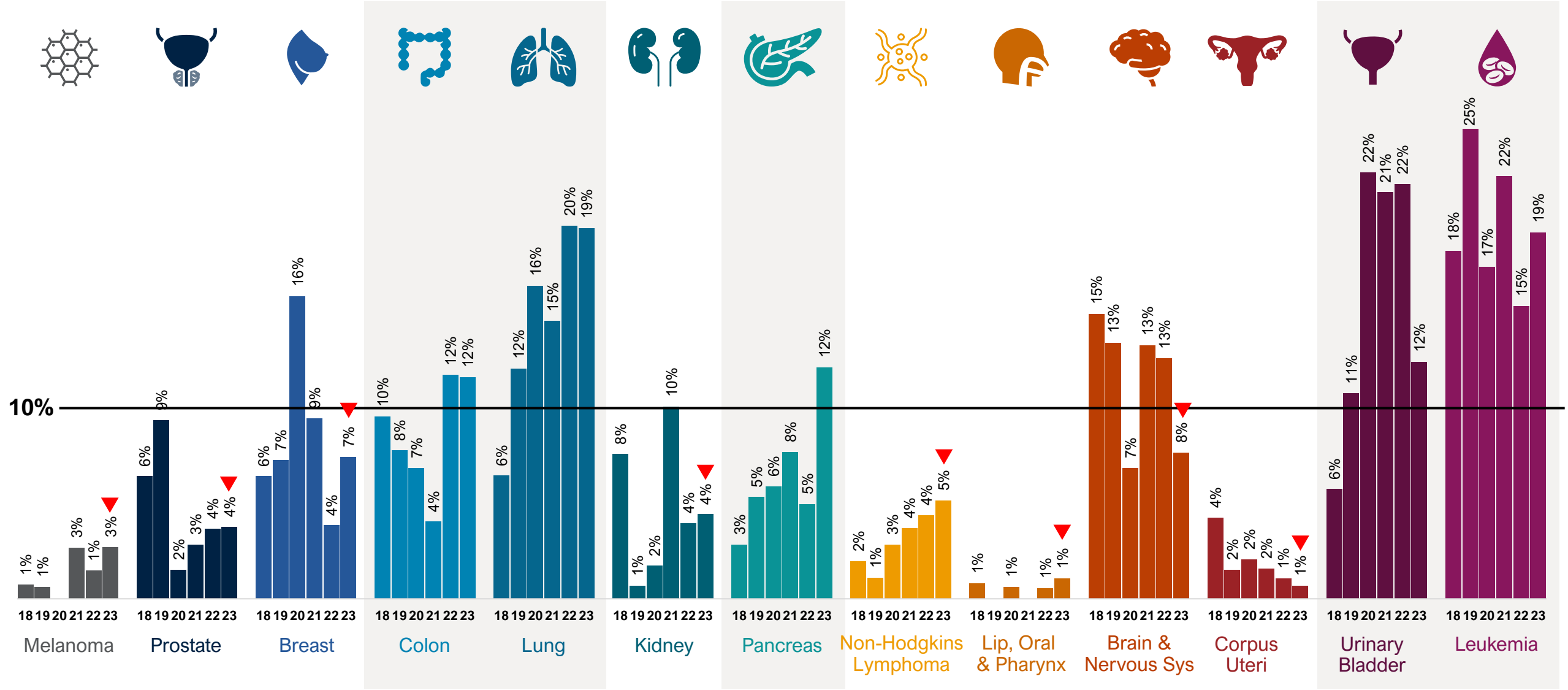
- Senior Head & Neck Medical Oncologist
- Gyn Medical Oncologist
- Director, Early Phase Clinical Trials and Precision Therapeutics

Top Catchment Area Disease Sites at CFCCC: 2023 Data Table 3

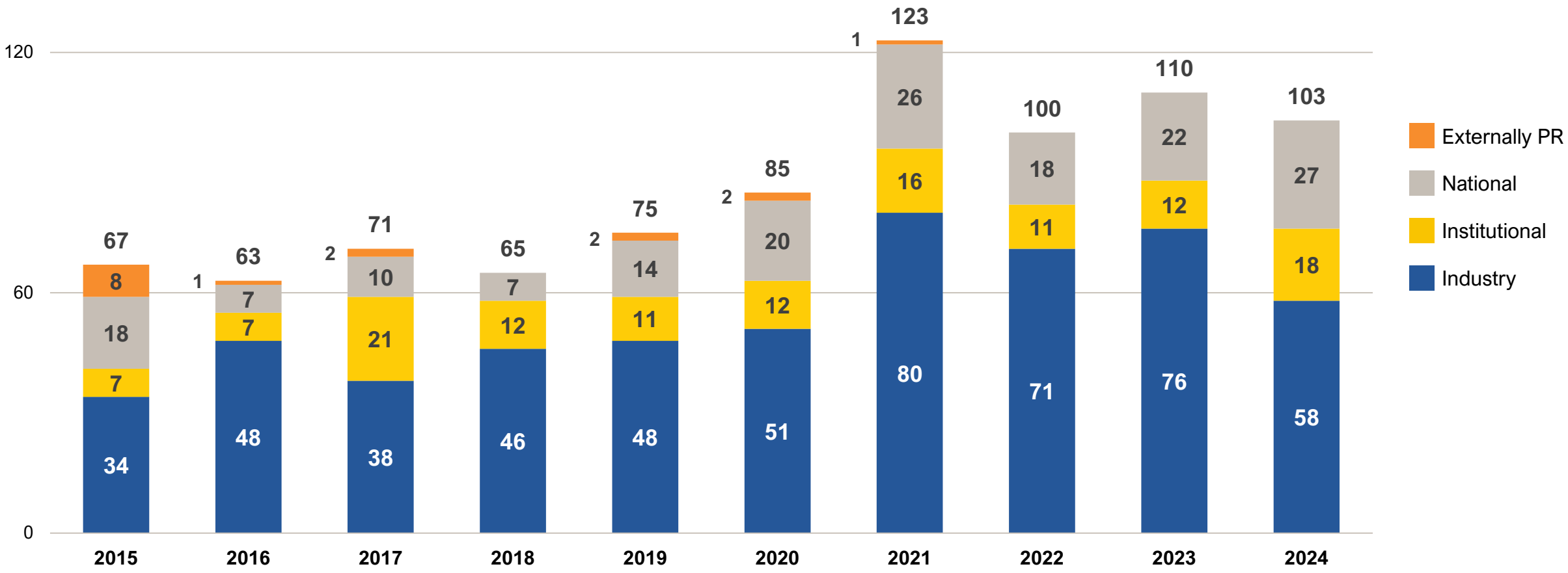
Primary Site	New Patients
Lip, Oral Cavity and Pharynx	187
Esophagus	66
Stomach	128
Small Intestine	22
Colon	241
Rectum	105
Anus	29
Liver	87
Pancreas	198
Other Digestive Organ	114
Larynx	28
Lung	211
Other Respiratory & Intrathoracic Organs	22
Bones and Joints	18
Soft Tissue	86
Melanoma, Skin	625
Kaposi's Sarcoma	8
Mycosis Fungoides	26
Other Skin	32
Breast	363
Cervix	56

Primary Site	New Patients
Corpus Uteri	147
Ovary	66
Other Female Genital	36
Prostate	505
Other Male Genital	29
Urinary Bladder	137
Kidney	203
Other Urinary	11
Eye and Orbit	15
Brain and Nervous System	183
Thyroid	154
Other Endocrine System	58
Non-Hodgkin Lymphoma	194
Hodgkin Lymphoma	20
Multiple Myeloma	68
Lymphoid Leukemia	2
Myeloid & Monocytic Leukemia	54
Leukemia, other	69
Other Hematopoietic	27
Unknown Sites	60
Ill-Defined Sites	24
TOTAL:	**4714**

Top Catchment Area Disease Sites: Data Table 3 and 4 Comparison



Number of Trials Activated



Strategies for Reducing the Activation Timeline

Concurrent study calendar creation & Medicare Coverage Analysis

- Vendor WCG
- Reduces time frame for all trials by two full weeks
- Piloted in June 2024 and implemented in October 2024

Stern Center support of Dept of Urology Portfolio Pipeline

- Initiated March 2024
- Decrease of timeline activation by >100+ days
- Doubled the number of trials activated in 2024

Decrease in volume of protocols through the pipeline

- Due to judicious DOT review with a 41% disapproval rate

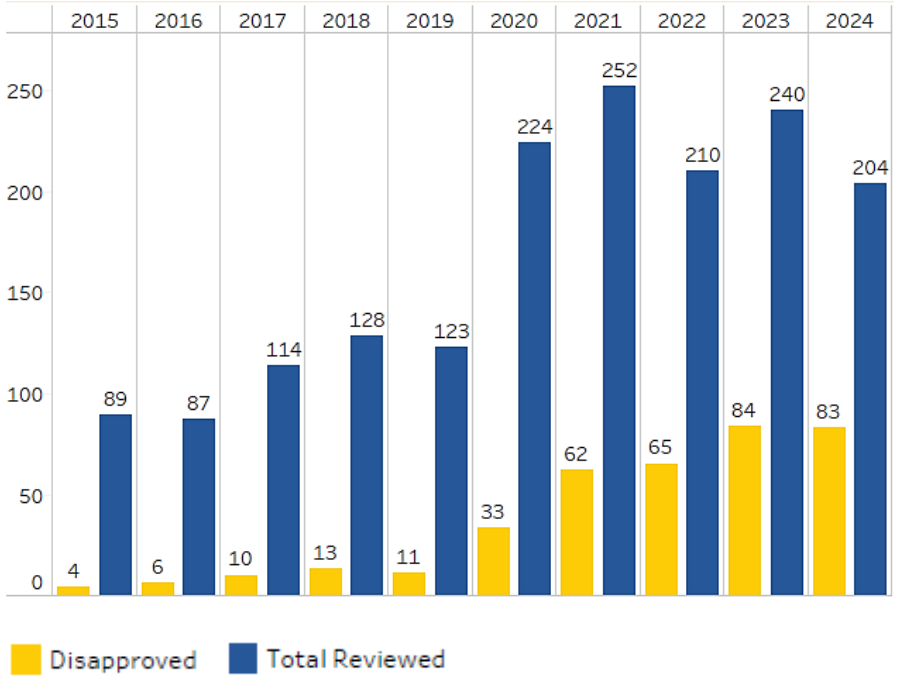
Review of each disease team's time to activation metrics and work

specifically to reduce activation timelines

Continued engagement in key Sponsor Partnerships platforms

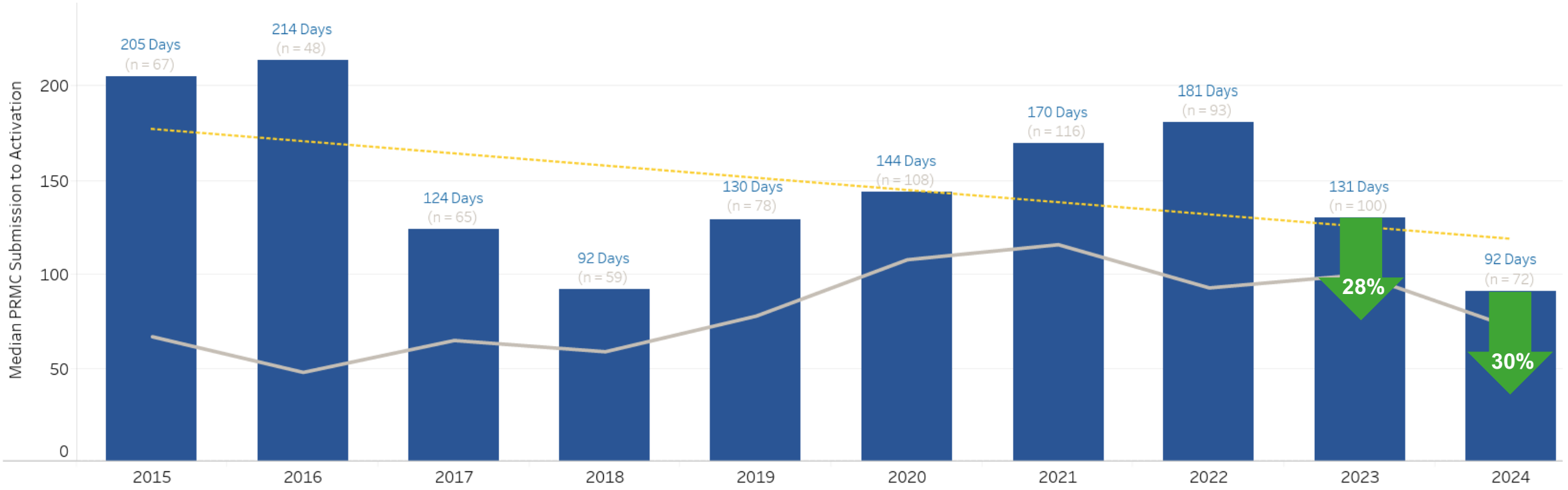
- Pfizer
- Genentech/Roche
- AstraZeneca
- Amgen
- Novartis
- Merck
- Bristol Meyers Squib

Overall DOT Disapprovals



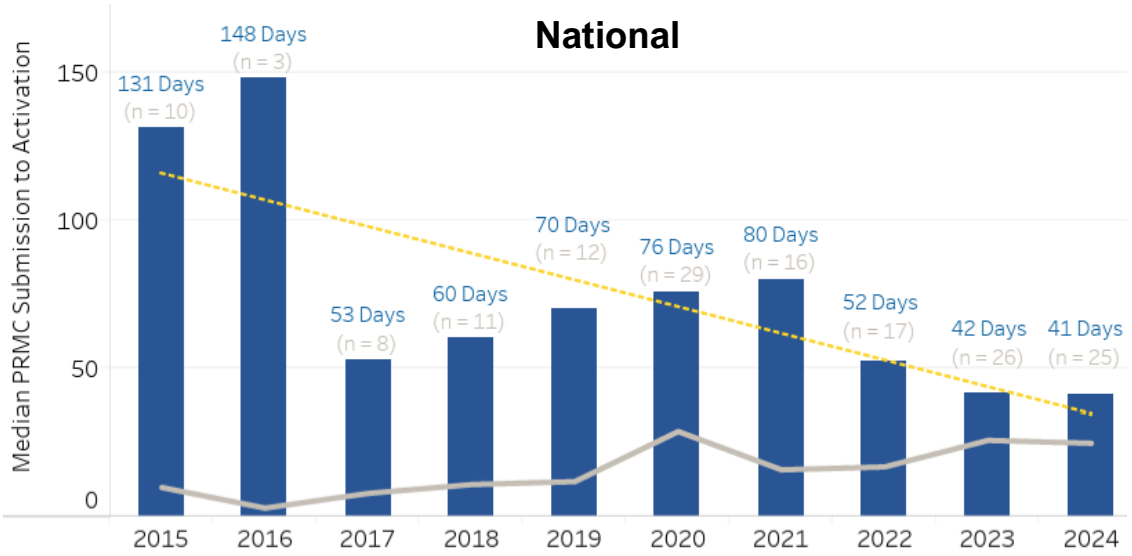
Overall Activation Timeline

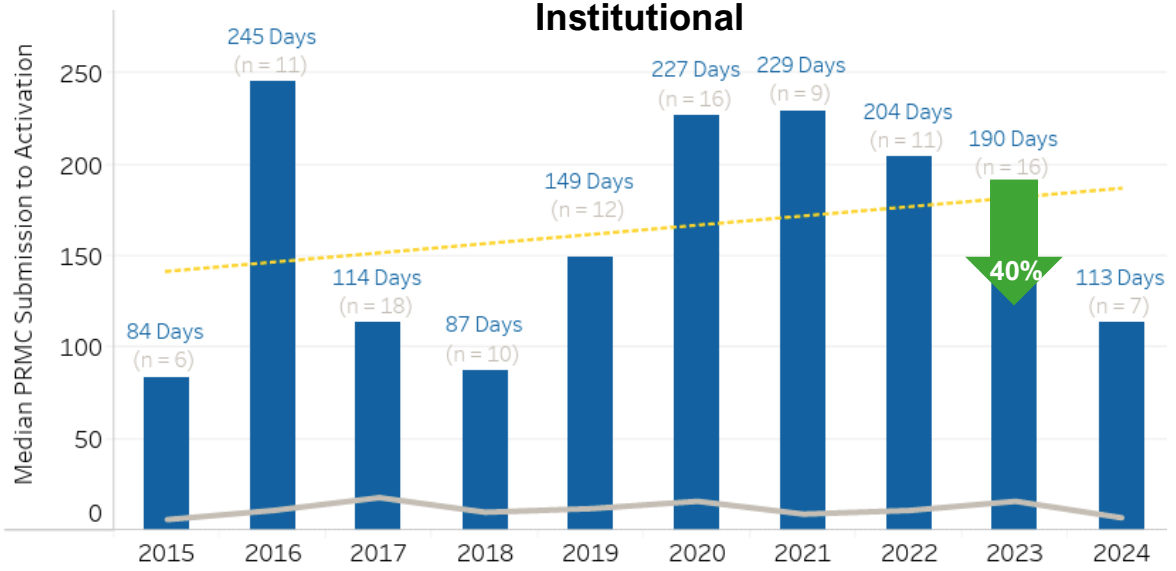
PRMC Submission to Study Activation

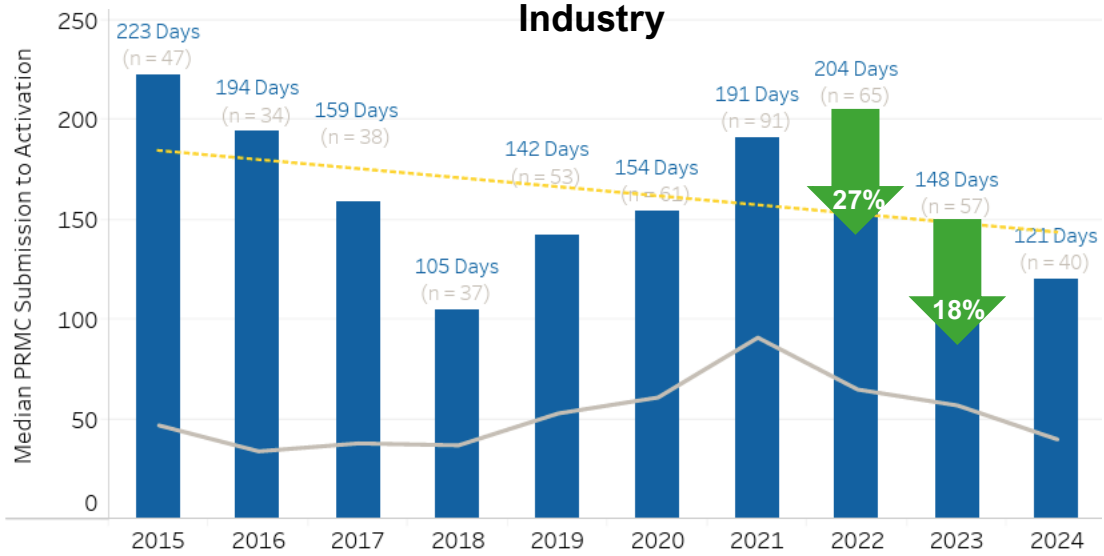


Activation Timeline by Sponsor Type

PRMC Submission to Study Activation







MOU with SOM & UCI Health for Clinical Investigator Support

ORIGINAL CLINICAL PI MOU (FY21)	FY25 CHANGES	Rationale
CLINICAL TRIAL ACCRUAL	**CLINICAL TRIAL ACCRUAL**	**CLINICAL TRIAL ACCRUAL**
In year 1, must accrue 5 patients annually to achieve 20 points. Year 2, increase to 7; Year 3, increase to 10, w/increases in subsequent years (at least 15). Accrual over the annual benchmark generates 4 points for each patient accrued.	1 interventional treatment trial patient = 5 points 1 multi-Investigator interventional treatment trial patient = 3 points to each Investigator 1 INT non-TRE patient = 1 point *Sub-I enrollment on IIT/ETCTN INT TRE credited to PI of IIT/ETCTN = 2 points* *Sub-I enrollment on NCTN/Industry INT TRE credited to PI = 1 point*	Incentivized to interventional treatment accrual. *Team Accrual Approach: Points are awarded to credit PIs opening trials that ALL DOT members enroll into not just PI preferred trials*
PI ON A TRIAL	**CONSENTING**	**CONSENTING**
Conduct/lead industry developed clinical trials as Principal Investigator for UCI (Site PI) = 5 points per trial	1 screen fail interventional treatment trial consent = 1.25 points Inpatient setting only, if consenting physician is not the treating physician and patient is consented and accrued = 2 points	Points awarded for consenting patients which should convert to greater accrual.
INVESTIGATOR INITIATED TRIAL	**INVESTIGATOR INITIATED TRIAL**	**INVESTIGATOR INITIATED TRIAL**
- Investigator-initiated treatment trial (e.g. national PI on National Clinical Trial Network study) = 15 points - Investigator-initiated interventional non-treatment trial (e.g. national PI on National Clinical Trial Network study) = 10 points	Activating NCTN Trial or multisite IIT INT TRE = 15 pts Activating IIT INT TRE as PI = 10 pts Activating IIT INT non-TRE as PI = 1.25 points	Incentivize writing and activating investigator-initiated trials at both the local and national level.
DOT/TB ATTENDANCE	**DOT/TB ATTENDANCE**	**DOT/TB ATTENDANCE**
Attend and participate in >70% of DOT or Tumor board (TB) meetings = 10 points.	-5 points for DOT/TB attendance that is < 70% (utilize highest attendance for multi-attenders)	Attendance is required, points are deducted for not reaching an attendance threshold.

MOU with SOM & UCI Health for Clinical Investigator Support

UCI Chao Family Comprehensive Cancer Center **FY 2025 Faculty Metric Performance Summary - Heme Onc**

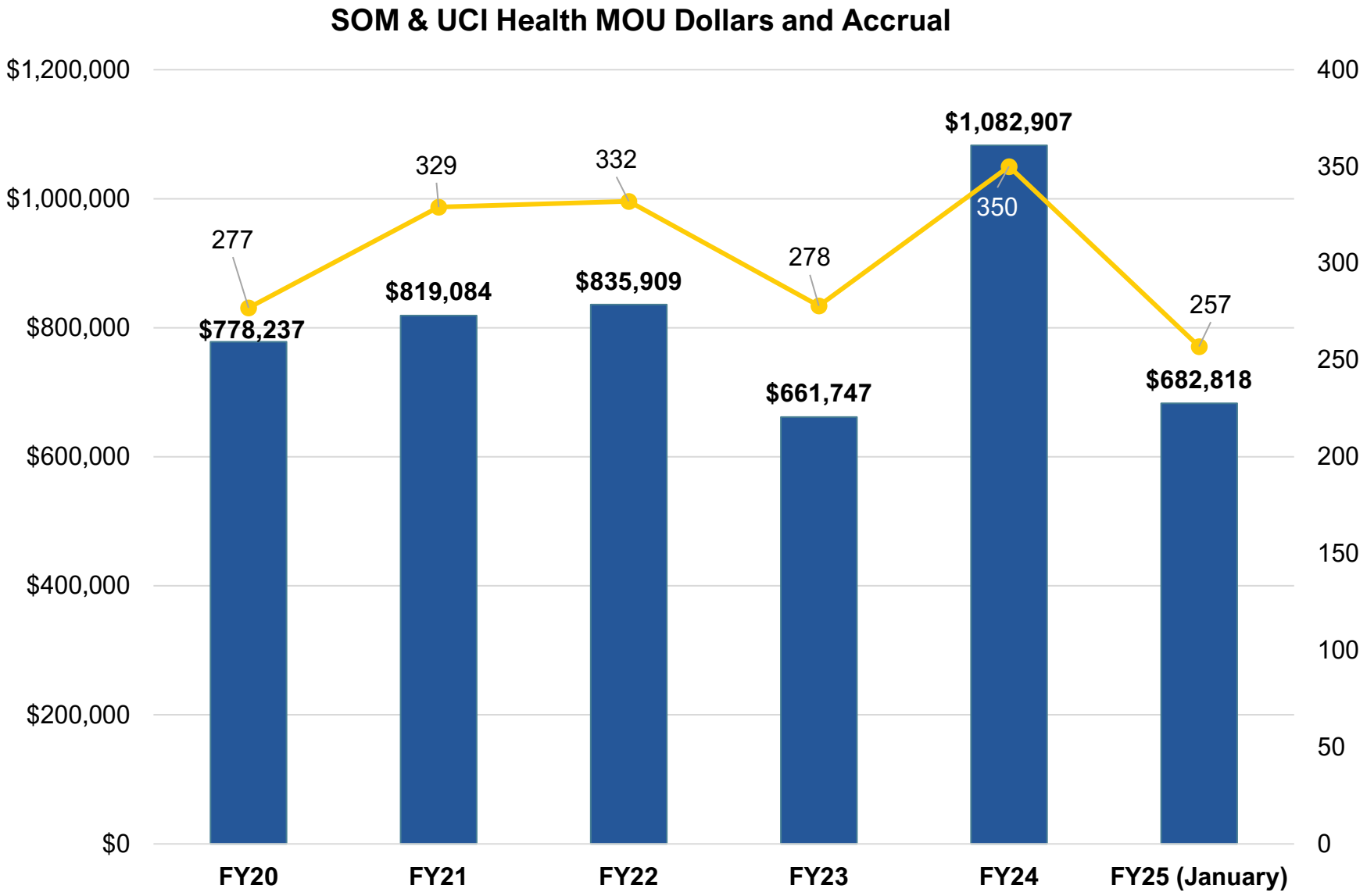
Heme Onc | Neuro Onc | Others | MOU | Prior MOU

Overall Summary Point Table (Jul. 2024 - Dec. 2024) (Select a faculty name to view individual scorecard)

Faculty Name	Clinical Trial Accrual	Consenting*	IIT	DOT-TB Attendance	Total Points**
Dr. Dayyani, Farshid	193	21.75	0.00	0	215
Dr. Mar, Nataliya	86	8.75	10.00	0	105
Dr. Valerin, Jennifer Brooke	79	18.75	0.00	-5	93
Dr. Kongtim, Piyanuch	73	6.50	0.00	0	80
Dr. Nagasaka, Misako	62	5.00	0.00	-5	62
Dr. Mehta, Rita	49	11.25	0.00	0	60

- Faculty performance dashboards were created to manage the progress for both Hematology/Oncology and Neuro Oncology
- Faculty from other Departments may be included for faculty who can hit clinical research performance metrics
- Dashboards are updated quarterly to see progress

MOU with SOM & UCI Health for Clinical Investigator Support*



- Total of **$4.8M in institutional support** provided to Division of Hematology/Oncology since FY20 through January FY25 from UCI Health & SOM
- New MOU started FY25

*** Div of Hem/Onc Only**

Contribution to Educations, Training & Mentoring

Early-Career Faculty

- ADs Chow, Dayyani and Administrative Director Hui provide seminars to the annual CFCCC Clinical Research Bootcamp (CRTEC) and work with attendees on IIT protocols
- ADs Chow and Dayyani participate in Mentoring, Education and Training (MET) for clinical investigators

Graduate Students

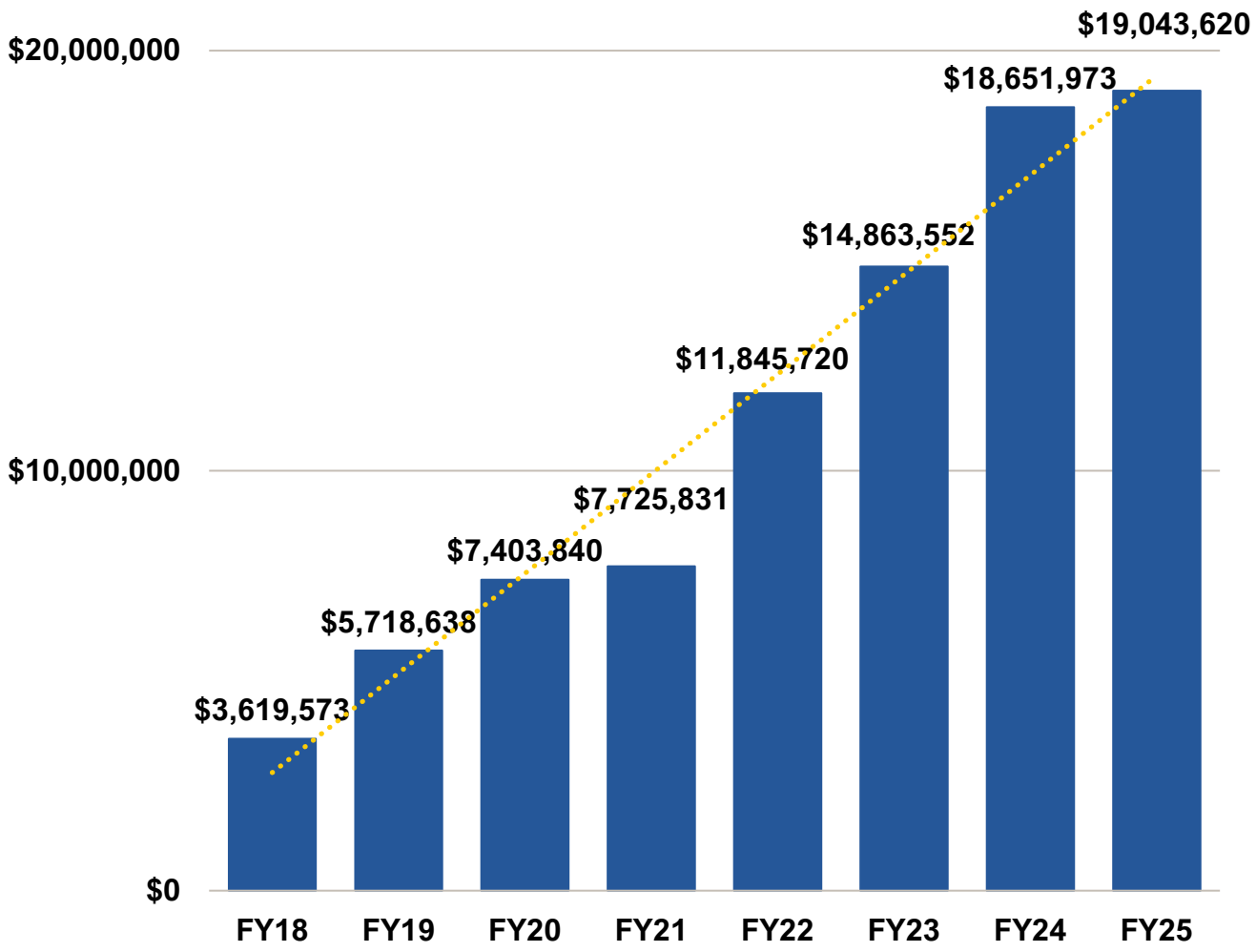
- Stern Center partners with Joe C Wen School of Public Health providing Master's level research practicum internships
- Several students have been hired into the Stern Center

Undergraduate Students

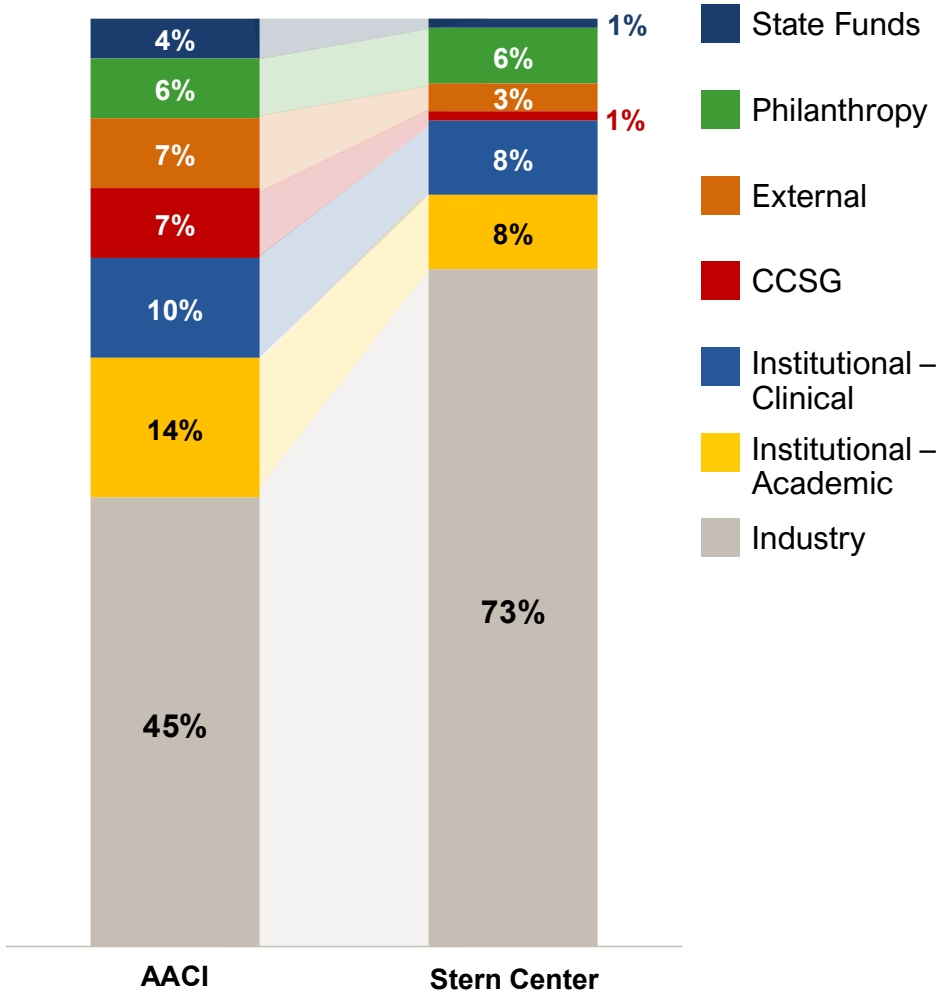
- Stern Center partners with School of Biological Sciences enrolling Bio 199 (upper division course) students into AD Dayyani's lab
- Several students have been hired into the Stern Center

Stern Center Financials FY24

Stern Center Fiscal Year Budgets



2023 AACI Benchmark and Stern Center Funding Sources



Future Plans

AIMS

1 Personnel

- Hire Stern Center staff as appropriate and per stated metrics benchmarks with School of Medicine

2 CTMS

- Push for trial activation to 90 days or less for industry trials

3 Research Study Mgmt

- Ensure audit defensible charts

4 Catchment Area

- Enroll >450-500+ patients into interventional treatment clinical trials

UCI 趙 Chao Family Comprehensive Cancer Center

02

Data & Safety Monitoring

Response to EAB Review

2021 NIH Merit Rating

ACCEPTABLE

STRENGTHS (2021 NIH Summary Statement)

> The Quality Assurance Unit has also been restructured, and a new Monitoring and Auditing Plan was approved and implemented in 2019

CRITIQUE	RESPONSE
None	

Updates & Accomplishments

Initiated Clinical Trial Bootcamp Training (October 2024)

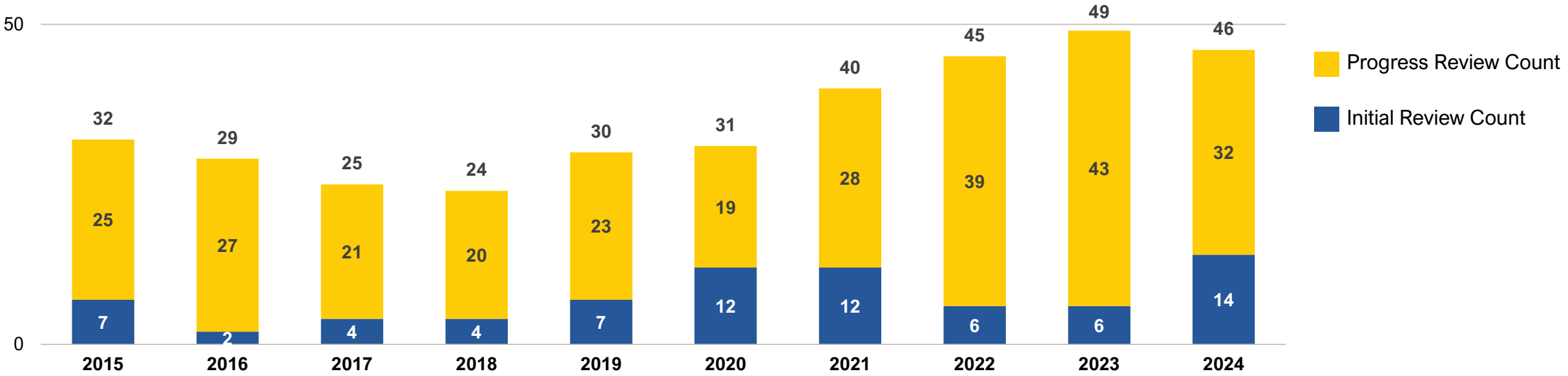
- Week-long program training with baseline competency exams and training on Stern Center Standard Operating Procedures, Guidelines, informed consent, screening, etc.
- Monthly training for newly hired Clinical Research and Research Data Coordinators
- 29 participants

Submitted Data Safety Monitoring Plan to NCI in March 2025

Hired a Second Quality Assurance Coordinator for Monitoring Institutional Trials (June 2024)

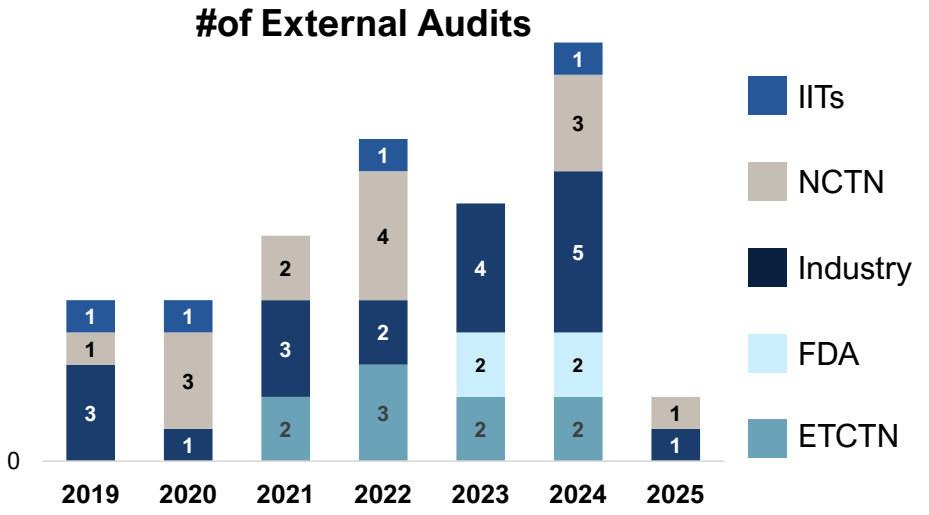
Carmencita Recto, BSN, RN

Audits & Monitoring



Audits

- Record number of external audits, from all Sponsor types (e.g. Industry, NCTN, ETCTN, FDA, IITs, etc.) with 13 audits in 2024
- One FDA inspection of two separate trials in January 2024
- Resulted in an FDA Form 483 issued with three observations
- FDA acknowledged Stern Center's response to the observations and corrective action plans



Future Plans

- Ensure NCI Data Safety Monitoring Plan Approval in 2025
- Create a Biospecimen Training Boot Camp for newly hired Biospecimen Coordinators
- Create an Investigator Training Boot Camp for junior Investigators

UCI 趙 Chao Family Comprehensive Cancer Center

03

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Response to EAB Review

2021 NIH Merit Rating
ACCEPTABLE

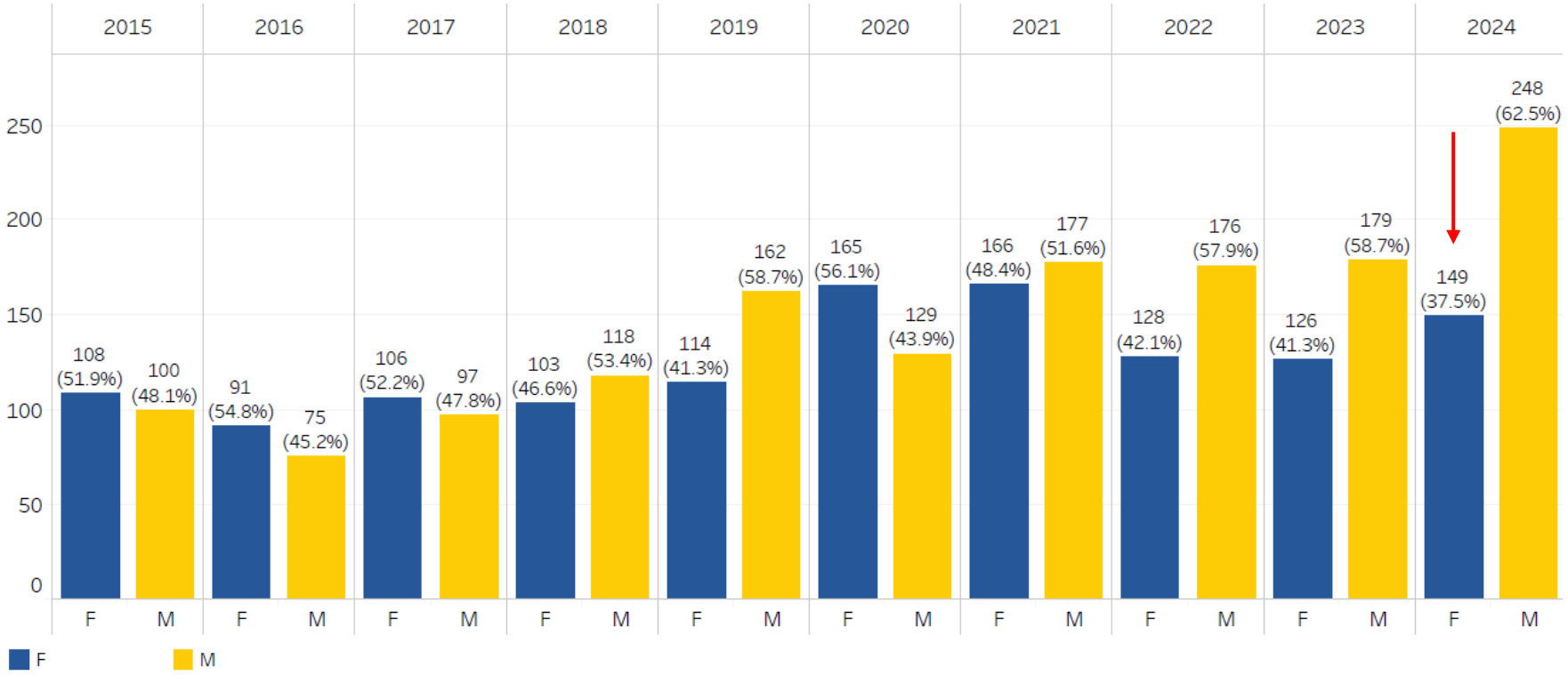
STRENGTHS (2021 NIH Summary Statement)

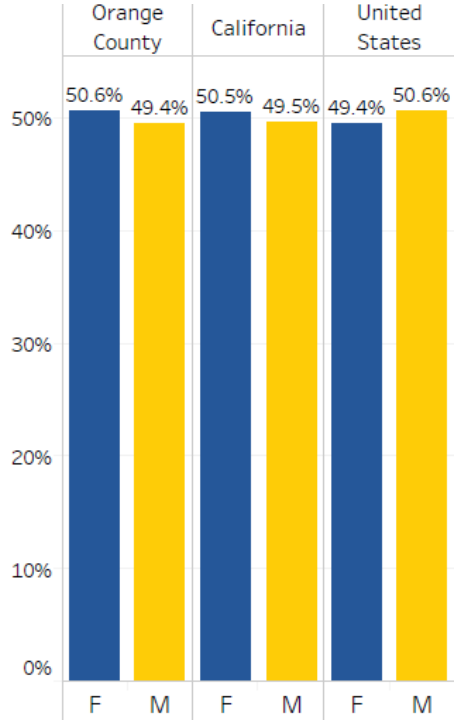
> …accrual alignment to the racial diversity of the catchment area (23% Asian and 22% Hispanic treatment trial accrual) as well as a balanced gender accrual

CRITIQUE	RESPONSE

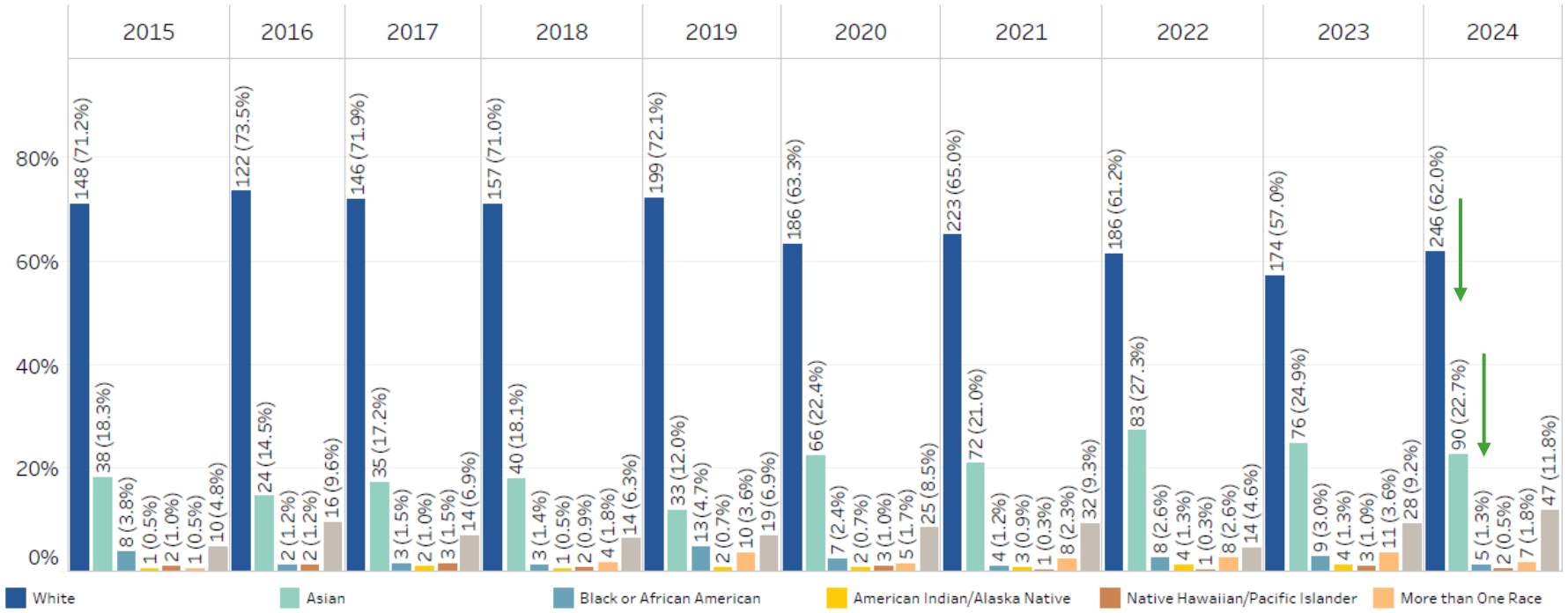
GYN should have a greatly expanded portfolio as soon as possible. It was suggested that a medical oncologist with gyn interests would be a reasonable approach, although such individuals are difficult to find. One might also consider a gyn-onc who is committed to less surgery and more clinical trials. Given the volume, they should be putting 30-50 patients per year onto clinical trials.	• Management of gynecologic oncology trials will move from Department of Obstetrics/Gynecology to Division of Hematology/Oncology
	  ▪ Gyn medical oncologist slated for July 2025 hire
	• Activating UCI-18-120: Phase I Dose-Escalating and Phase II Dose-Expansion Study of N-Acetyl-Cysteine (NAC) Administration to Ovarian Cancer Patients Receiving Platinum-Based Therapy (PBT) for the mitigation of Chemotherapy-Related Cognitive Impairment (CRCI)
	• Breast Portfolio
	  ▪ UCI-24-05 Chan, IIT, Repurposing Riluzole for Augmenting Brain-Derived Neuropathic Factor (BDNF) Levels and Cognitive Function in Breast Cancer Patients Experiencing Cancer-Related Cognitive Impairment: An Interventional Pilot Clinical Trial

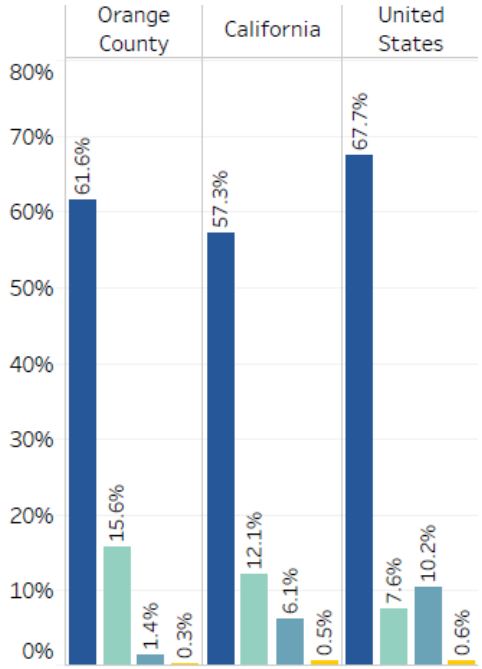
Treatment Interventional Accruals by Gender



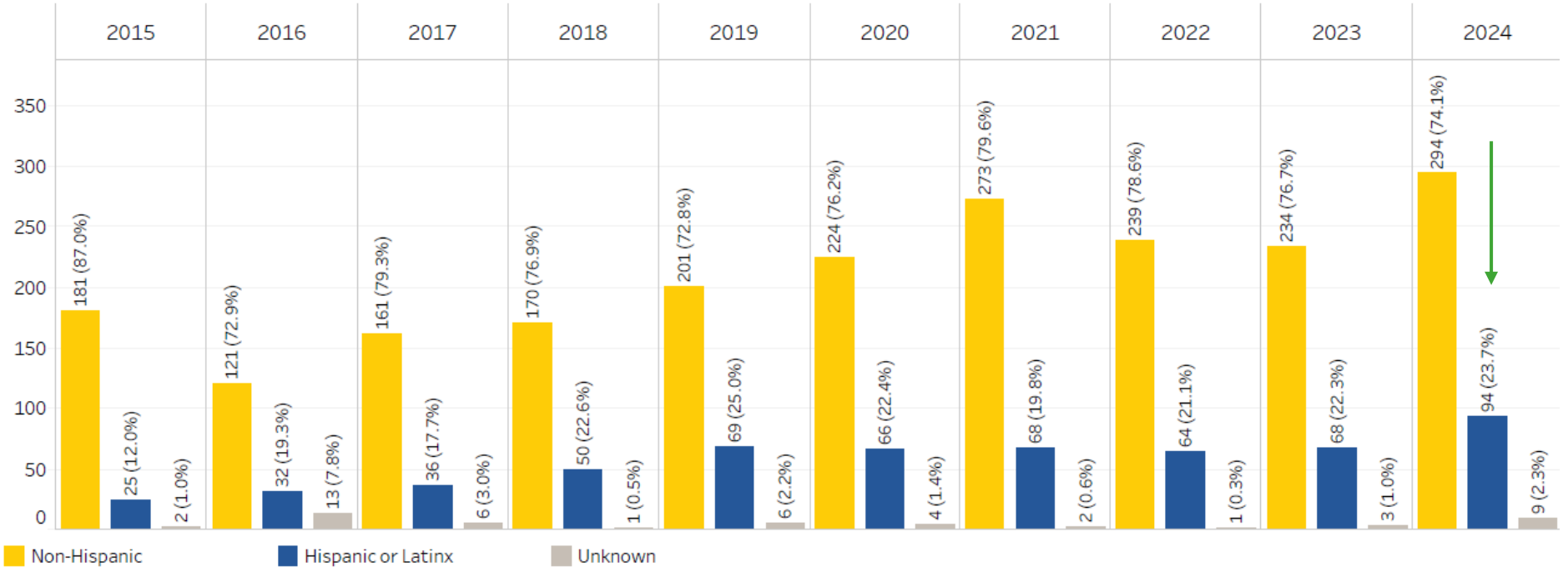


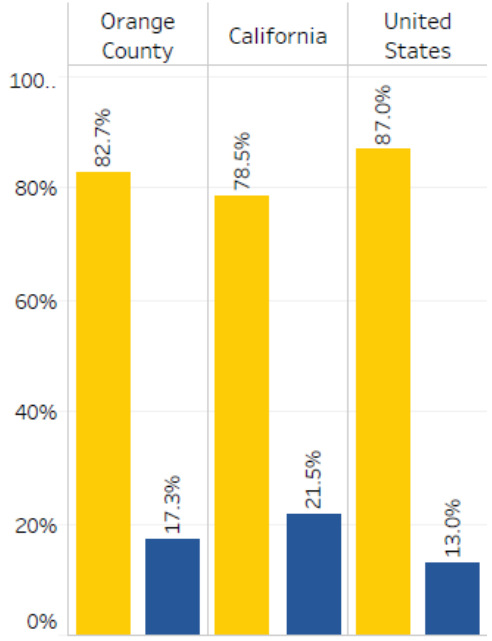
Treatment Interventional Accruals by Race





Inclusion of Diverse Ethnic Populations





Inclusion of Children

Formal affiliation with Rady Children's Health

- Children's Hospital of Orange County (CHOC) and Rady's Children's Health (RCH) entered into an agreement to merge (December 2023)
- Merger completed in January 2025
- Located two miles from the UCIMC location in Orange, RCH serves pediatric, adolescent, and young adult patients up to 24 years of age
- RCH may submit IITs to the CFCCC PRMS and DSMB for review and oversight
- Encourage co-submission for Anti-Cancer Challenge pilot grants

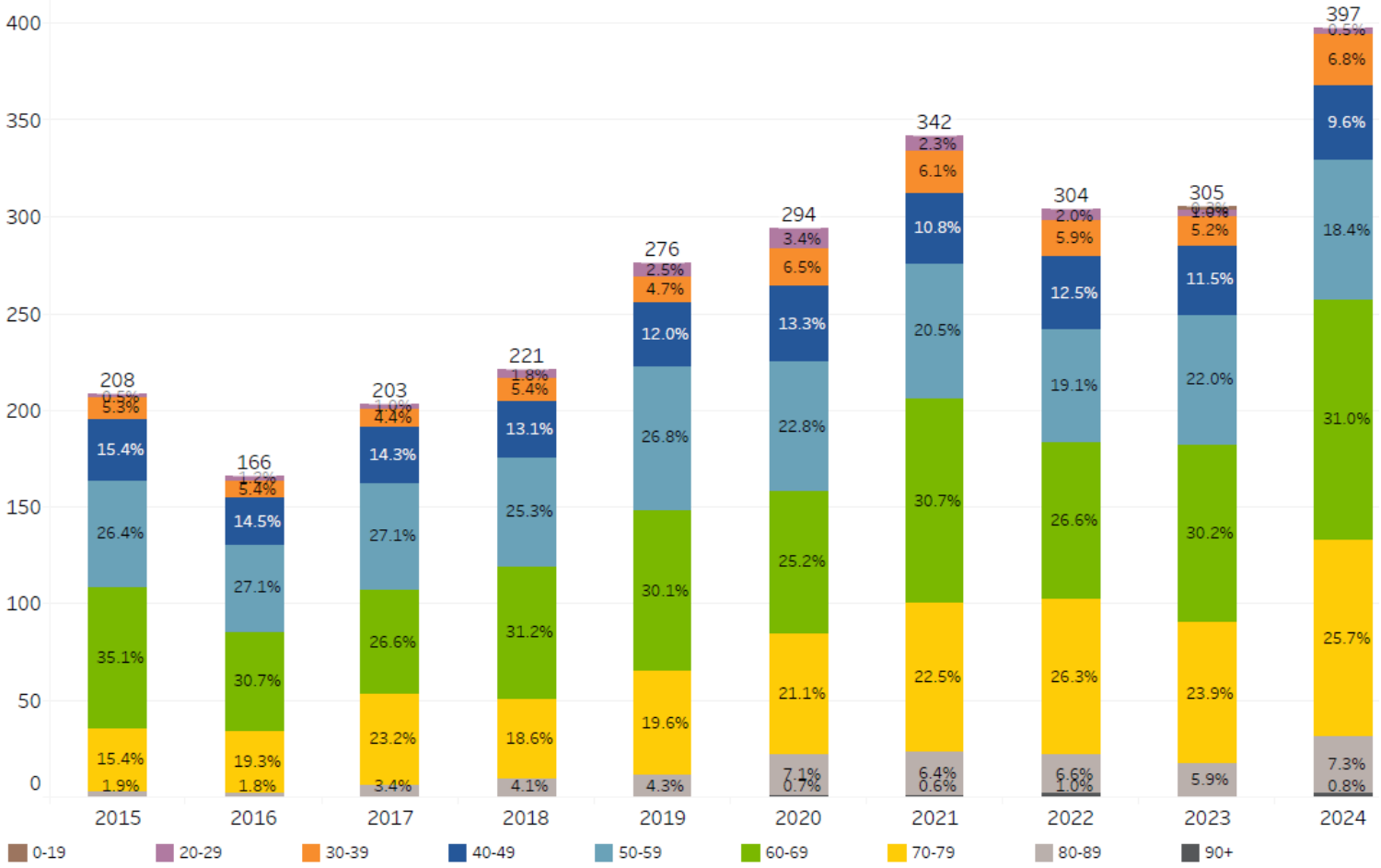
The Hyundai Cancer Institute at RCH

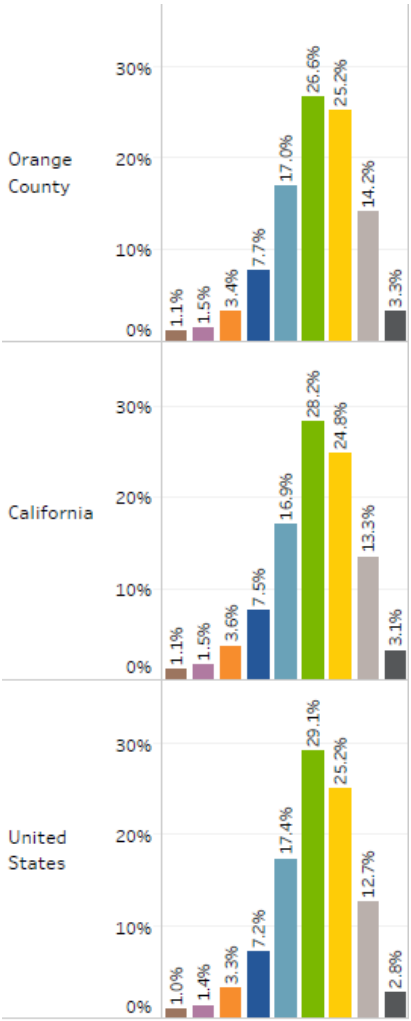
- Member of the Children's Oncology Group (COG) and COG's Pediatric Early Phase-Clinical Trial Network

Several Cancer Collaborations Steering Committee working groups routinely meet to collaborate

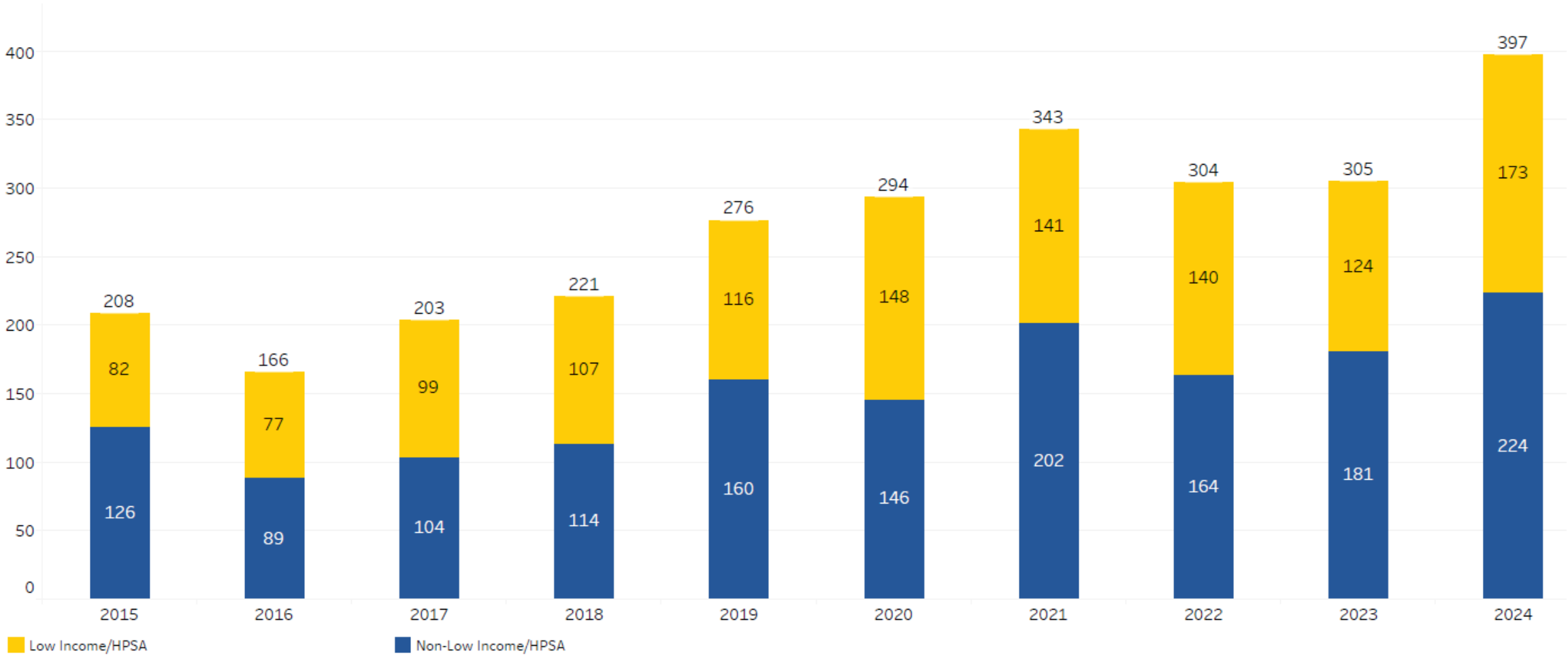
- BMT & Cellular Therapies Working Group
- Adolescent & Young Adult Population Working Group
- Research Working Group
- Education & Training Working Group

Inclusion of Individuals from Different Age Groups





Low-Income & Health Professional Shortage



Future Plans

Gynecological Oncology

- Moving management of gynecologic oncology research portfolio to the Division of Hematology/Oncology
- Recruiting a Gyn medical oncologist to start on 7/1/25

Breast Oncology

- UCI-24-05, IIT with PI Alex Chan, Repurposing Riluzole for Augmenting Brain-Derived Neuropathic Factor (BDNF) Levels and Cognitive Function in Breast Cancer Patients Experiencing Cancer-Related Cognitive Impairment: An Interventional Pilot Clinical Trial
- Hired a new Breast Medical Oncologist, Nellie Nafissi, MD

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04

Protocol Review & Monitoring System (PRMS)

Objective & Specific Aims

OBJECTIVE

Ensure rigorous oversight for scientific quality for all cancer clinical studies and maintain the highest standards of scientific merit and feasibility.

AIMS

1. **Two-Stage Review**

   Ensure a robust two stage scientific review process for cancer clinical trials

2. **Comprehensive Review**

   Employ a comprehensive set of criteria and procedures for the scientific review, prioritization, and monitoring of cancer clinical trial protocols.

3. **Ongoing Monitoring**

   Enforce a systematic approach for ongoing monitoring of active clinical trials, including assessment of accrual rates, new safety information, and continued scientific relevance.

Response to EAB Review

2021 NIH Merit Rating
SATISFACTORY

STRENGTHS (2021 NIH Summary Statement)

> "…increase in the number of Disease Oriented Teams from 6 to 7 with increased support for the DOT clinical research teams as well as alignment with basic scientific investigators to support bench to bedside trials…

CRITIQUE	RESPONSE
Poorly performing trials should be closed. DOTs should consider rejecting at least 30-40% of the trials presented to them for consideration, using a clear rubric for trial selection and prioritization.	• Overall Disease-Oriented Team (DOT) disapproval rate was highest ever in 2024 at 41% disapproved
"…DOTs should have clear performance metrics, targets, and expectations, such as a percent accrual target of all new/recurring cancer patients seen in each specific disease area (such as 30% accrual of breast patients, 10% of head and neck, 25% of lung, 30% of melanoma, etc.)."	• Performance metrics were added to the Clinical Research Performance Dashboard and are shared regularly at the DOT meetings
"…disease groups do not seem to be aligned with or integrated with bi-directional COE efforts or functioning well relative to the selection, prioritization, and opening of trials that are relevant to catchment area priorities and cancer patterns, or the predominant cancers in the patients who present to the center.	• Scorecard has a clear emphasis on COE Catchment Area disease areas
Increase the closure rate for non-accruing trials	• PRMC closures remained flat, with 25 closed trials in both 2023 and 2024, which is ~12% closure rate

Response to EAB Review

CRITIQUE	RESPONSE
It appears that the DOTs – which are responsible for clinical trial portfolio management and clinical trial accruals – may not have been sufficiently held accountable for accrual performance and for management of a growing number of activated trials that turn out to be poor accruers (since approximately 47 trials were reported to have accrued only zero to one patients in the past year). Thus, attention to the rigor and quality of DOT oversight over clinical trial endorsements/approvals or activations and their commitment to accrue to already activated trials	• Trials with zero accrual went down slightly from 31 to 30 trials from 2023 to 2024 • With a high DOT disapproval rate (41%), expect the low accruing trials to go down in 2025.

Updates and Accomplishments

Updated PRMC'S Accrual Policy

- Updated for studies undergoing full committee accrual review would receive expedited review if they met the accrual policy during the review period (August 2024)

Creation of Clinical Research Performance Dashboards

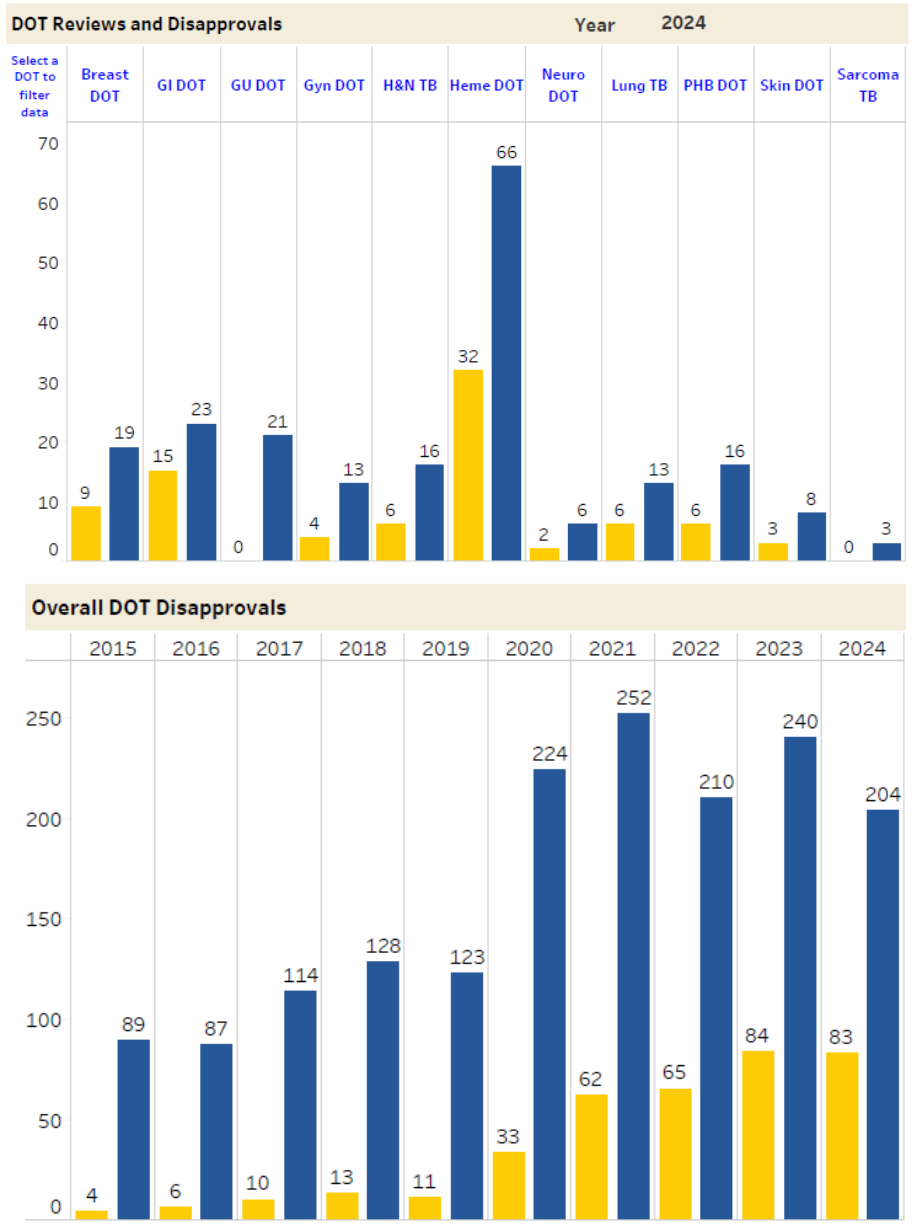
- Disease Oriented Team: Approval and disapproval rates
- Protocol Review & Monitoring Committee: Review and closure rates
- Clinical Trial Accrual
  - Interventional treatment
  - Institutional
  - DOT
  - PI
  - Demographics (e.g. gender, race, ethnicity, age, and health professional shortage area status)
- Study Activation Timelines
  - Overall
  - Sponsor type
  - Disease team
  - Study state changes

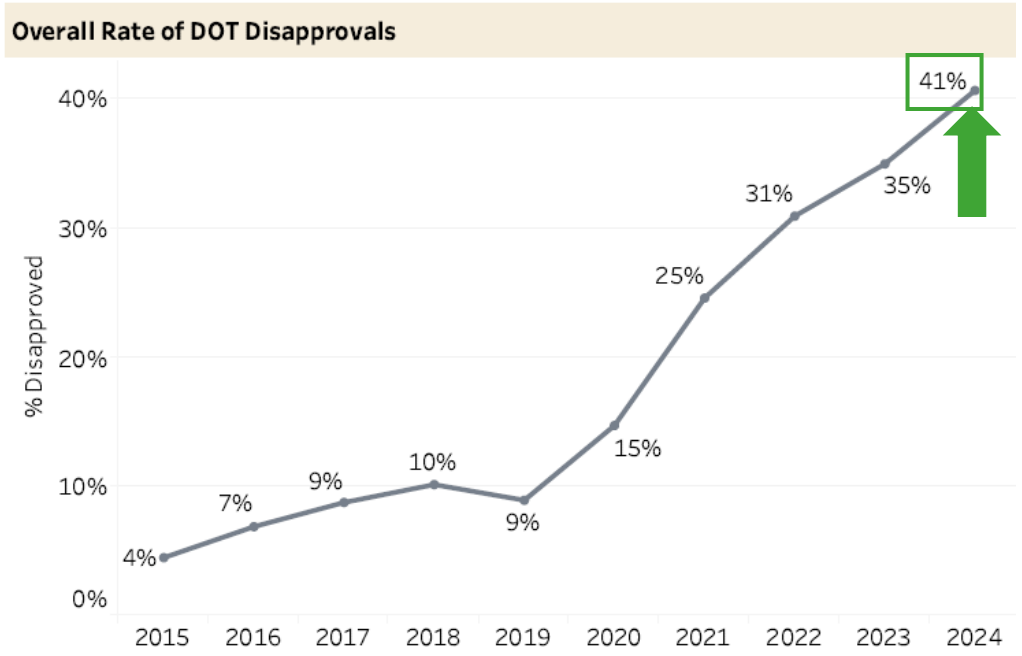
Disease-Oriented Team (DOT) Scorecard

Category	Low (1)	Neutral (3)	High (5)	Raw Score	Weight	Total Score
Catchment Area	Is not a disparity in the catchment area or a top disease site[1]	Either a disparity in the catchment area or a top disease site[1]	Both a disparity in the catchment area and a top disease site[1]		3	0
Competing Studies or In Development	≥ One study	One with suspension or will not overlap[2]	Zero/No Known		2	0

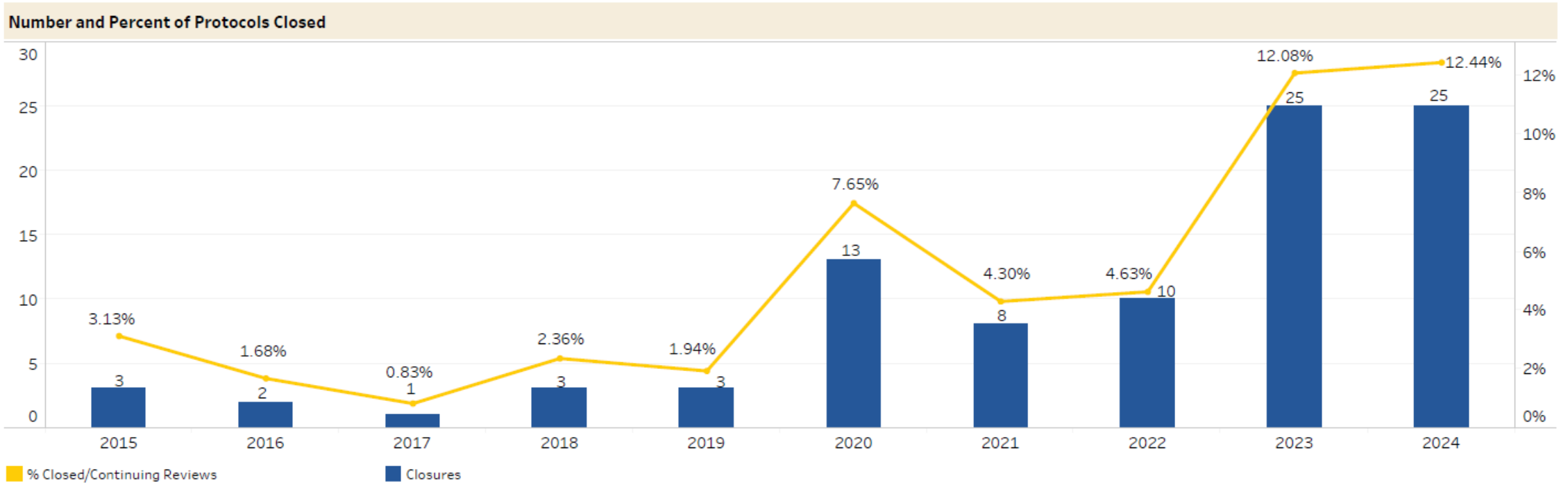
Category	Low (1)	Med-Low (2)	Neutral (3)	Med-High (4)	High (5)	Raw Score	Weight	Total Score
Investigator Input	Industry authored with no investigator input	NCTN or industry authored with investigator input	Investigator authored from another institution	UCI investigator authored and/or UCI held IND or non-UCI authored and originated from UCI science	Investigator authored and originated from UCI basic science		3	0
Scientific Interest[3]	Modification in volume/frequency of established therapy	FDA-approved agent in another indication or IND exempt	Conducted under an IND	Early phase (I or I/II) trial	Early phase trial with novel agent, modality or approach with high impact potential or any potential for practice changing		2	0
Investigator Academic Credit/Involvement	Unknown or no authorship	Only if lead site or high accrual	Authorship regardless of lead site or high accrual or participation on steering committee	Guaranteed but not 1st or senior	1st or senior authorship		2	0
Overall Accrual Target	< 5 patients	< 5 patients but rare	5 to 7 patients	> 7 but ≤ 10 patients	> 10 patients		3	0
Total Weighted Score	**Score =**	0	**Total Possible =**	75	**Percentage =**	0%		

Disease-Oriented Team (DOT) Approvals & Disapprovals





Protocols Closed by the PRMC



Future Plans

AIMS

1 Two-Stage Review

- Ensure judicious review of protocol, matching trials with Catchment Area population
- Decrease the number of low accruing trials in the portfolio

2 Comprehensive Review

- Prioritize trials that match the Catchment Area

3 Ongoing Monitoring

- Close low accruing trials after 12-18 months of no patient enrollment (if not a rare trial)

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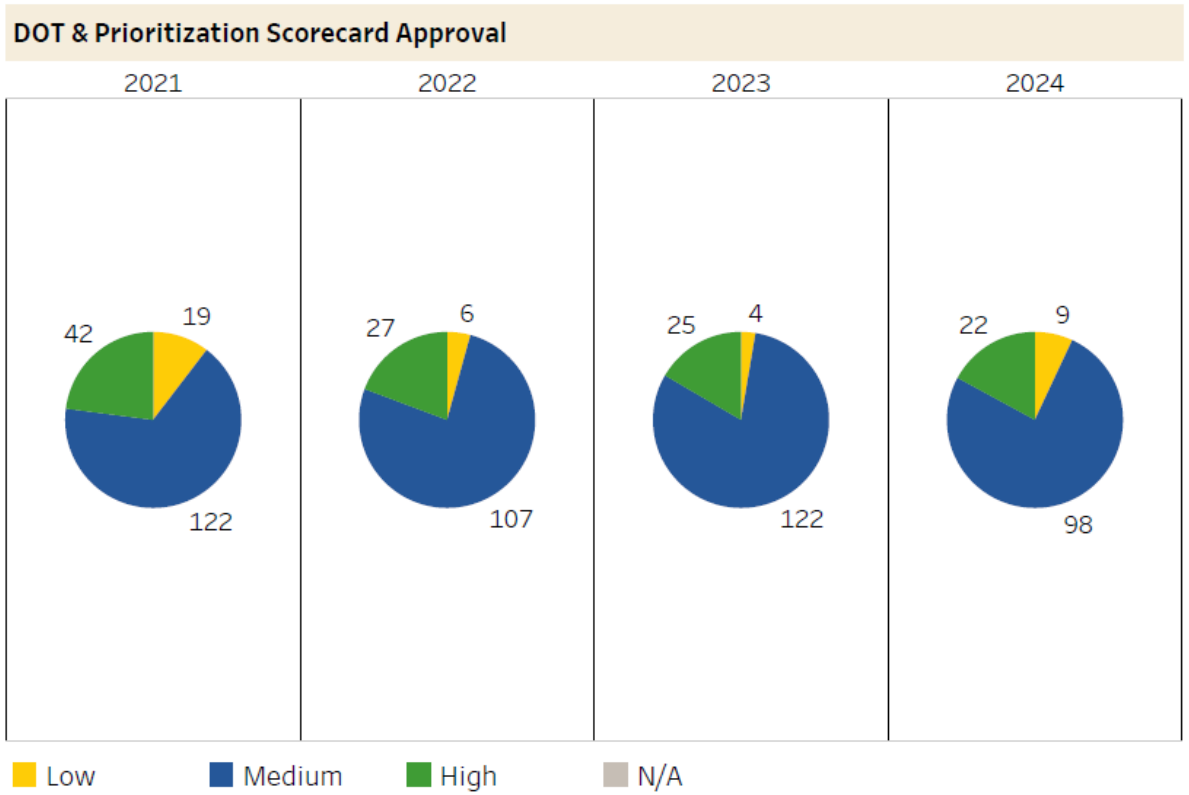
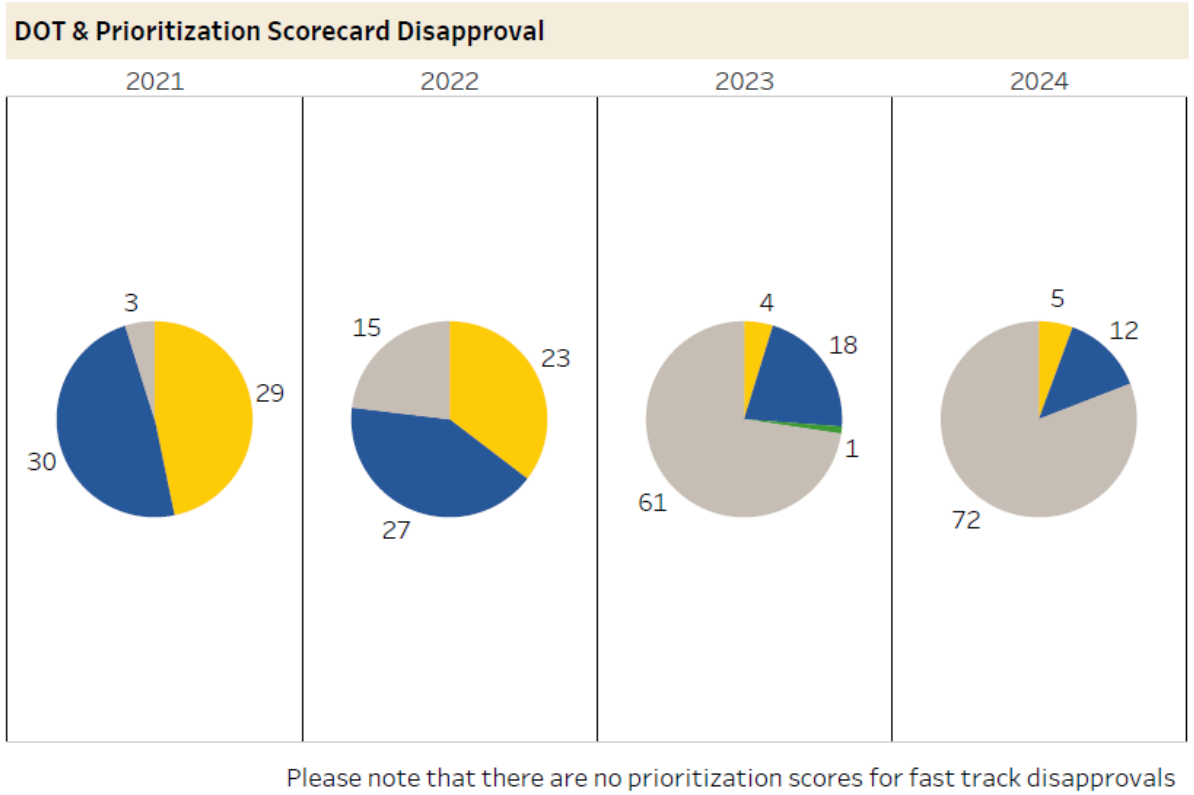
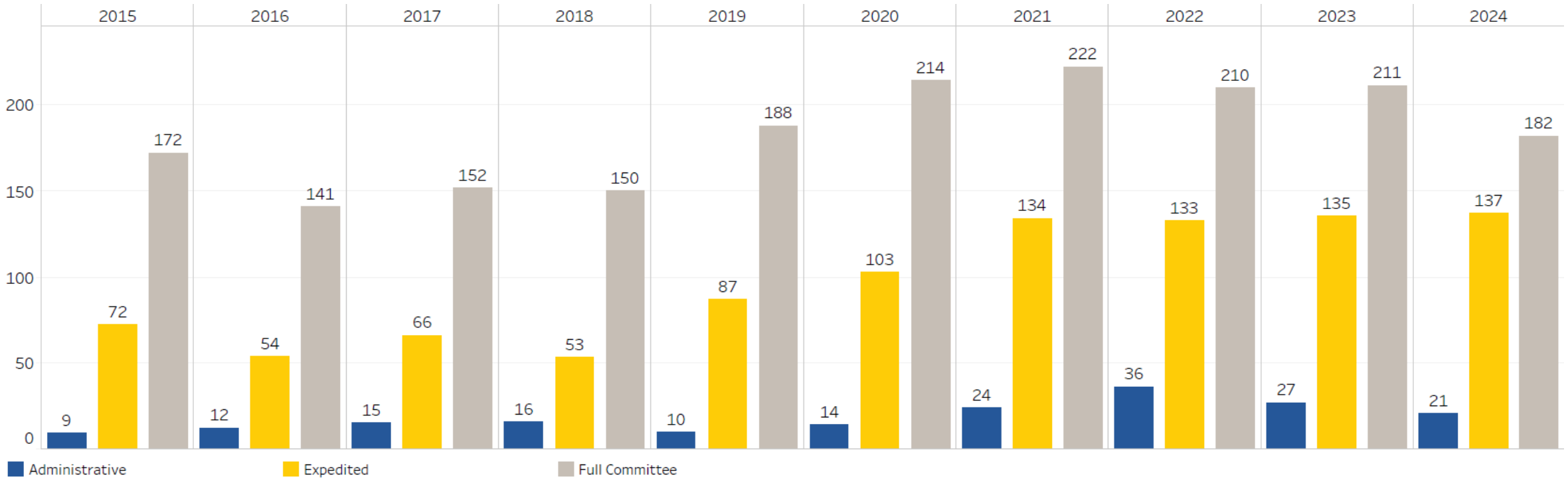
Questions?

Disease-Oriented Team (DOT) Reviews & Disapprovals

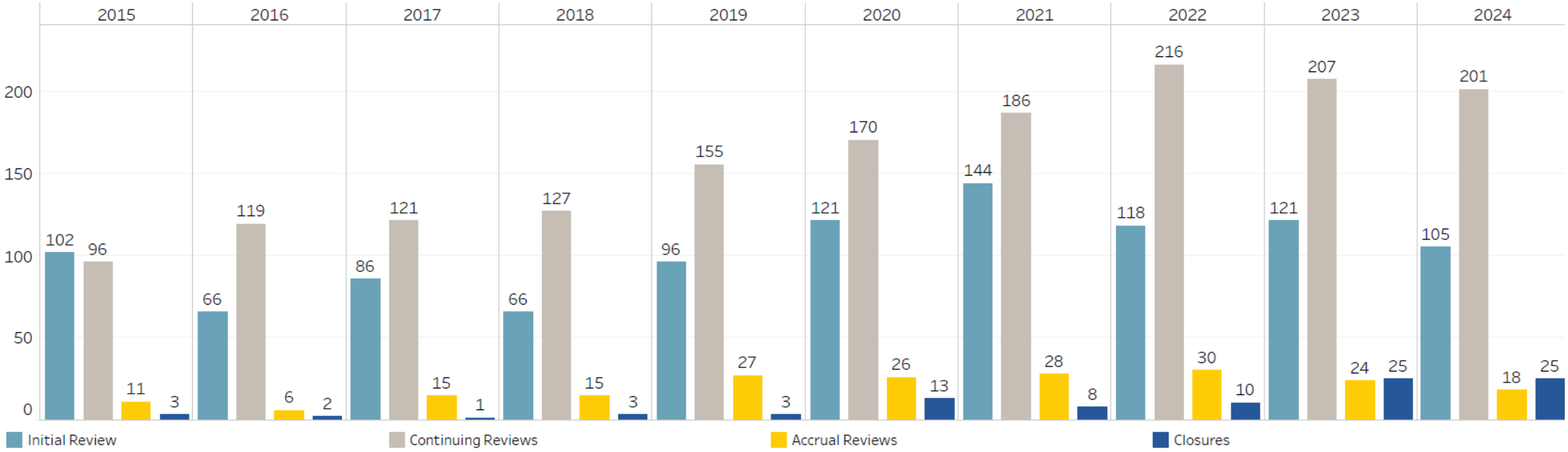




Type of Reviews by the PRMC



Protocols Reviewed by the PRMC



Top Catchment Area Disease Sites: Data Table 3 and 4 Comparison