

ANNUAL REPORT 2024

*Your Research Partner in the Fight
Against Cancer*



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MESSAGE FROM THE PRESIDENT

This year marked my 10th year as CEO of Cancer Research And Biostatistics (CRAB). As in previous years, 2024 brought new challenges and exciting opportunities that advanced our mission to conquer cancer and improve patient outcomes through innovative clinical trials and data science.

We were honored to support an early cancer detection study through the Cancer Screening Research Network (CSRN) as part of the Statistics and Data Management Center, in collaboration with our colleagues at Fred Hutch. This partnership reflects our ongoing commitment to advancing research that promotes early detection and timely intervention.



In November, we received the Request for Applications for our NCTN competitive renewal, with a February 2025 submission deadline. Our team, together with our colleagues at Fred Hutch Cancer Center, worked diligently through the latter part of the year to prepare a strong proposal that reflects CRAB's continued value to SWOG and the national clinical trials network.

In 2024, we opened six new SWOG clinical trials, including myeloMATCH, a precision medicine master protocol for patients with acute leukemia or myelodysplastic syndrome. Lung-MAP launched Lung-MAP 3.0, expanding assay options for patient-matching to appropriate sub-studies and increasing accrual, further strengthening its legacy of innovation in biomarker-driven research.

Our global engagement efforts continued through the SWOG Latin America Initiative. Dacia Christin, Rachael Sexton, and Dr. John Crowley organized a clinical trials workshop in Lima, Peru, as part of the ongoing SWOG Latin America Initiative.

Key findings from Module 2 of the ctMoniTR project were presented at the Friends of Cancer Research Annual Meeting in the fall. As the Independent Analysis Center for this initiative, we are proud to help advance ctDNA monitoring in clinical trials as a potential early indicator of long-term efficacy, bringing us closer to real-time, non-invasive tools for tracking treatment effectiveness.

MESSAGE FROM THE PRESIDENT

We also completed the analyses for the 9th Edition TNM staging project for lung cancer, mesothelioma, and thymic carcinoma. These findings, soon to be published in AICC and UICC, will inform global staging standards for years to come, enabling clinicians worldwide to deliver more precise, evidence-based care. Since the early 2000s, CRAB has co-authored more than 60 manuscripts in support of this vital global effort.

Finally, we deepened our collaboration with Dr. Graham Nichol, Director of the University of Washington-Harborview Center for Prehospital Emergency Care, submitting several research proposals and manuscripts aimed at improving outcomes in emergency care settings.

As we look to the year ahead, I am proud of what we have achieved and deeply grateful for our dedicated team and Board of Directors, whose expertise and passion continue to drive meaningful progress. The work we do—designing smarter trials, analyzing complex data, and advancing global health research—ultimately translates into better treatments, earlier diagnoses, and more hopeful outcomes for patients and their families. Thank you to all of our partners for your steadfast support in our mission.

A handwritten signature in blue ink, appearing to read 'Antje Hoering'.

Antje Hoering, PhD
President, Chair &
CEO

NCI PROJECTS

Advancing Early Cancer Detection Through the CSRN Vanguard Study

In 2024, CRAB was honored to receive a grant as part of the Statistics and Data Management Center (SDMC) at Fred Hutch Cancer Center (Fred Hutch) to support a groundbreaking initiative: the Vanguard Study, the first clinical trial of the newly established Cancer Screening Research Network (CSRN). The Vanguard Study aims to evaluate the effectiveness of Multi-Cancer Detection (MCD) assays, an emerging class of tests designed to facilitate earlier cancer detection. These assays identify molecular cancer signatures by detecting specific proteins and circulating tumor DNA (ctDNA) that may signal the presence of cancer in the body—with the goal of detecting cancer well before symptoms appear.

Fred Hutch, based in Seattle, serves as the coordinating and communications center for CSRN. CRAB is collaborating closely with biostatisticians at Fred Hutch to lead the SDMC, bringing together deep expertise in statistical and data management strategies critical to the success of this ambitious project.

Throughout the past year, CRAB staff have been laying the groundwork for this complex, multi-faceted study. In 2024, our teams have focused on specifying technical and operational requirements, designing custom systems and applications, and preparing the study for launch in summer 2025. In parallel, we are developing new databases for collecting data, including use of Participant Reported Outcomes (PROs).



NCI PROJECTS

SWOG Study Activations

In 2024, CRAB's study builders successfully activated six clinical trials: S2303, MYELOMATCH, MM1YA-S01, S2308, S2312, and S1900J. A notable highlight is the MyeloMATCH trial, a precision medicine umbrella trial designed for patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). This groundbreaking initiative marks a significant advancement in SWOG and CRAB's commitment to offering innovative and personalized clinical trial options, reflecting our dedication to improving patient outcomes through cutting-edge research.

NCTN Grant Resubmission

The planned submission of a key research grant from the U.S. National Cancer Institute (NCI) has been delayed by a year. Every six to seven years, Fred Hutch Cancer Center and CRAB apply for renewed funding to continue their vital work with the SWOG Cancer Research Network. These grants, which support groundbreaking cancer research and clinical trials, are awarded through the NCI's National Clinical Trials Network (NCTN) and the Community Oncology Research Program (NCORP). The NCTN grant application is now scheduled for early 2025, with the NCORP application following later that year. While this delay shifts our timeline, it does not disrupt our work.

Participant Recruitment is Key for SWOG Clinical Trials

In 2024, CRAB's Clinical Trial Recruitment and Retention Specialist, Jamie Sundstrom, continued to support SWOG clinical trials by collaborating with the Recruitment and Retention Committee (RRC), Leadership Council on Representation, study teams, site staff, and SWOG Patient Advocates. The primary focus of the RRC is increasing participant accrual and improving representation across the SWOG clinical trial portfolio. The RRC's "TAKE ACTION" symposia continued in 2024, bringing together experts from multiple modalities to educate SWOG membership on strategies to better engage specific patient populations in clinical trials. Additionally, study team presentations were integrated into monthly RRC meetings to allow study investigators to collaboratively address accrual challenges. Collaborations, tailored support, and commitment to improving SWOG practices play an important role in ensuring SWOG's research efforts are accessible and responsive to participant and community needs.

NCI PROJECTS

SWOG Latin America Initiative

In 2024, the five member institutions of the SWOG Latin America Initiative (SLAI) recruited more than 200 patients to publicly-funded cancer trials—more than double the previous record-breaking year. One of the year's highlights was a 3-day clinical trial training conference at the Instituto Nacional de Enfermedades Neoplásicas in Perú, where U.S. and Peruvian investigators provided a well-attended hybrid training for early and mid-career investigators. The SLAI team at CRAB continues to advocate for expanding trials to SWOG sites in Latin America, recognizing that broader participation enhances trial generalizability and advances evidence-based knowledge to improve cancer treatments and the quality of life for patients, their caregivers, and cancer survivors.



SWOG Lung-MAP and Pragmatica Lung Update

2024 saw the implementation of Lung-MAP "3.0", the third transformational change to the Lung-MAP master protocol in order to adapt to the changing clinical landscape. This major revision allows the option to use previously completed genomic testing done outside of the study for sub-study assignment, in addition to the on-study biomarker testing option. CRAB team members in Data Operations and Applications Development were deeply involved in the logistical and technical improvements needed to provide this highly requested option to sites and participants. S2302 Pragmatica-Lung, a streamlined Phase III study following Lung-MAP's positive sub-study S1800A in patients with advanced non-small cell lung cancer previously treated with chemotherapy and immunotherapy, successfully completed accrual in December 2024, enrolling more than 800 participants in less than two years!

NCI PROJECTS

SWOG Group Meetings and Clinical Trials Training

SWOG held hybrid Group Meetings in the Spring and Fall of 2024. The hybrid model provides opportunity for both in-person interaction as well as remote participation at these informative SWOG meetings. CRAB Data Coordinators conducted its annual Clinical Trials Training Course in the spring to 266 registered attendees. In the fall, CRAB staff presented the tenth annual SWOG NCI Community Oncology Research Program (NCORP) Research Base Clinical Trials Workshop to 288 registered attendees. These workshops provide training and information to oncology research professionals and site investigators on a variety of topics related to conducting research in the areas of therapeutic studies, prevention, screening and surveillance, palliative care, symptom management and survivorship and cancer care delivery. These workshops are made possible by generous funding from The Hope Foundation for Cancer Research, a public charity that supports SWOG.



SWOG Centralized Monitoring 2024

All SWOG studies with a registrational intent require central monitoring. In 2024, CRAB's central monitoring team concluded reviews for SWOG study S1806, a Phase III trial of concurrent chemoradiotherapy with or without Atezolizumab in bladder cancer, and S1914, a Phase III trial of Atezolizumab with radiation versus radiation only in NSCLC. A new study, S1800E, a Phase II/III Study of Docetaxel and Ramucirumab with or without Cemiplimab, is pending activation for monitoring.

NCI PROJECTS

Advancing Precision Medicine Through MATCH Trials

SWOG and CRAB continue to play a critical role in advancing precision medicine and umbrella trials through their involvement in three innovative MATCH trials: ComboMATCH, iMATCH, and myeloMATCH.

CRAB is contributing to the further development of the myeloMATCH program and is responsible for the design and build of the data collection systems to the recently activated myeloMATCH platform trial. myeloMATCH focuses on identifying and testing targeted therapies based on genetic alterations found in the cancer cells of individuals with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS)—two historically challenging diseases with limited progress in treatment over recent decades.

To support the myeloMATCH trials, CRAB is also enhancing its Specimen Tracking System (SpecTrack). The National Cancer Institute (NCI) selected SpecTrack to replace their previous tracking tool, recognizing its cutting-edge capabilities to support these complex studies.



Impactful SWOG Trials

We continue to participate in SWOG myeloma and breast cancer trials that change practice after publication. SWOG S1007 and S8814 were used to guide patient treatment with chemotherapy and endocrine therapy with early stage HR+, HER2- breast cancer and the results have been incorporated into EXACT Sciences decision algorithm for optimal treatment.

Additionally, we showed in S1007 that Black participants have 37% worse outcomes than White participants, while Asian participants had 36% better outcomes than white participants. There was some attenuation when other factors were included, but the overall findings remain largely unchanged. We continue to search for explanations for these findings.

GENERATING BUZZ

nCoup

SWOG continues its collaboration with nCoup, an organization that provides advanced technology solutions, to automate data transferred from Electronic Health Record to the Electronic Data Capture systems used in clinical research. Presently, ten SWOG trials employ this innovative technology, with additional trials under consideration. CRAB works closely with nCoup to implement their technology into Medidata Rave. Early results demonstrate promising outcomes, with participating sites expressing appreciation for the time savings and improvements in data quality. We anticipate publishing a peer-reviewed article January 2025 to share further insights into the observed enhancements in time efficiency and data integrity.

Society for Clinical Trials (SCT)

Chris Cook, CRAB's Chief Technology Officer, presented at the 2024 Society for Clinical Trials conference in Boston, Massachusetts. This conference convenes members of the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups, clinical research entities, and other sectors. His presentation, "Expanding the Use of Artificial Intelligence (AI) While Protecting Data Privacy in Clinical Trials," highlighted CRAB's efforts to integrate AI into its processes, enhancing efficiency while maintaining strict data privacy standards.

ASH Clinical Training Institute

For the eighth consecutive year, CRAB Chief Executive Officer Antje Hoering was invited to serve on the faculty for the American Society of Hematology's (ASH) Clinical Research Training Institute. The training is a year-long education and mentoring program for fellows and junior faculty specializing in hematology. As a member of the ASH faculty, Antje mentors young oncologists and physician scientists, providing individualized education and mentoring on clinical research methods, research collaborations, statistical analysis, and career advancement.

GENERATING BUZZ

CRAB CEO on ASA Board

2024 was the first year that Antje served on the American Statistical Association (ASA) board of governors as the publications' representative. The ASA is a professional organization dedicated to promoting the practice and advancement of statistics. Currently, the field is experiencing swift transformations and challenges, particularly in the context of Artificial Intelligence, affecting peer-review processes and publications. Antje has enjoyed serving in this role.



ctMoniTR Module 2 Analyses Presented in DC

On November 12th in Washington DC, the results from the ctMoniTR project were presented at the Friends of Cancer Research Annual Meeting entitled "A Common Strategy for Using ctDNA as an Intermediate Endpoint in Prospectively Designed Trials." The meeting included several panel discussions and presentations with experts from the FDA, academia, patient advocacy groups, and representatives from the pharmaceutical, sequencing, and diagnostic industries. As the Independent Analysis Center for the ctMoniTR project, CRAB's work was showcased, with evidence supporting a strong association between ctDNA levels and Overall Survival among advanced NSCLC receiving Anti-PD(L)1 immunotherapy or chemotherapy.

GENERATING BUZZ

IASLC SPFC Meeting in Denver

CRAB statisticians virtually attended the International Association for the Study of Lung Cancer (IASLC) 9th Edition Staging and Prognostic Factors committee meeting. The new TNM Staging criteria for Lung Cancer, Mesothelioma, and Thymic Carcinomas were presented and learnings from the 9th Edition project were discussed. CRAB's contributions to the project were acknowledged, with over 300,000 patients analyzed and 62 papers published since CRAB began working with IASLC in the early 2000's.



INTERNATIONAL
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FOR THE STUDY
OF LUNG CANCER

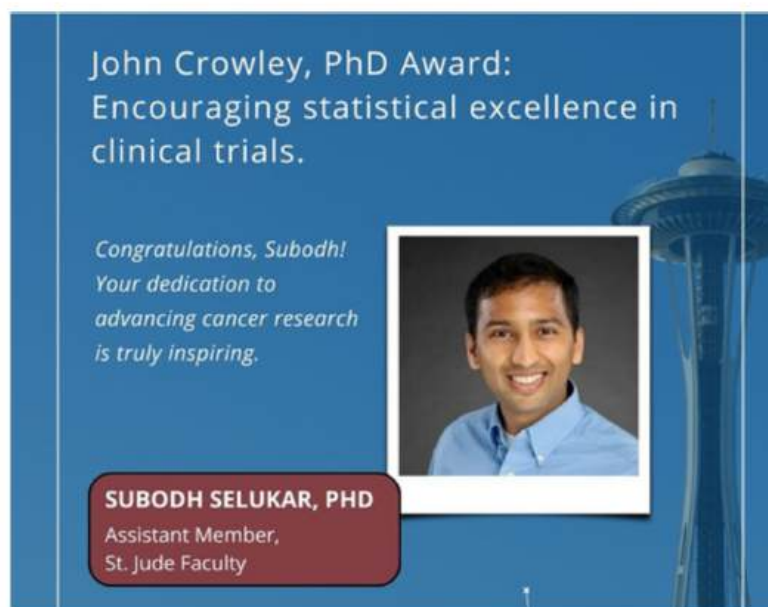
Cancer Research And Biostatistics (CRAB)

Since 2000, CRAB has conducted statistical analyses in the IASLC staging researches.

Analysis by CRAB (as of August 2024)

	First Project (7th)	Second Project (8th)	Third Project (9th)	TOTAL
Lung Cancer	100,869 cases 12 papers	94,708 cases 15 papers	124,581 cases 11 papers	320,158 cases 38 cases
Thymus		10,808 cases 5 papers	11,347 cases 6 papers	22,155 cases 11 pages
Mesothelioma	3,101 cases 3 papers	3,519 cases 4 papers	3,598 cases 6 papers	10,218 cases 13 papers
TOTAL	103,970 cases 15 papers	109,035 cases 24 papers	139,526 cases 23 papers	352,531 cases 62 paper

GENERATING BUZZ



John Crowley Award

The recipient of the 2024 John Crowley Award was Dr. Subodh Selukar of St. Jude Children's Research Hospital. This honor is for early to mid-career scientists to boost their careers by developing collaborations with the SWOG Statistics and Data Management Center colleagues.

Dr. Selukar, a 2021 graduate of the University of Washington Department of Biostatistics, visited CRAB and the Fred Hutch September 30 - October 4, and delivered a lecture in the Crowley Conference Room at CRAB entitled "Toward cure models for clinical trials: applications to small-sample oncology trials with rare events." He also took advantage of his time in Seattle to further ongoing collaborations with Dr. Megan Othus of SWOG.

New Edition of Statistics in Clinical Oncology

CRAB Co-founder John Crowley and CRAB CEO Antje Hoering were invited by publishers Taylor and Francis to serve as editors for the fourth edition of their book, "Handbook of Statistics in Oncology." Drs. Crowley and Hoering invited Dr. Megan Othus from the Fred Hutchinson Cancer Center to their editorial team, enriching their collective expertise. This upcoming edition aims to capture the latest advancements in the field, made possible through the valuable contributions of many esteemed colleagues. The editors' goal is to ensure that the resource remains a comprehensive and up-to-date treatise for statistics in oncology clinical trials. Final chapter edits were submitted to the publisher at the end of this year.

COLLABORATIONS

Pioneering the First CTP Study

In 2025, the SWOG Clinical Trial Partnerships (CTP) program plans to reach a significant milestone with the completion of its first CTP trial EDC build for a leukemia study. As the operational framework for SWOG's collaborations with industry partners on drug pipeline development and complex, multi-arm platform trials, CTP represents a new frontier in clinical research and is solely supported by our industry partners.

CRAB's Applications Development team has played a critical role in building and deploying the trial data infrastructure for this initial trial, including the use of CRAB Nebula, CRAB's proprietary electronic data capture (EDC) platform. Integrating CRAB's research services and applications with SWOG's established systems and processes—traditionally centered around Medidata Rave—was a complex but rewarding endeavor. This effort has not only advanced the capabilities of Nebula, but also helped refine workflows and methodologies for future SWOG trials.

The leukemia trial is slated to activate in late spring 2025, paving the way for a pipeline of upcoming CTP studies, including two others slated for 2025.

COLLABORATIONS

Data Monitoring Committee

CRAB remains committed to providing essential services that uphold the integrity and efficiency of clinical trials. One such service, acting as an independent analysis center as Data Monitoring Committee (DMC), is crucial for monitoring the safety and efficacy of clinical trials. We are currently engaged with a client on a randomized Phase 3 trial in lung cancer, where CRAB's responsibilities encompass a comprehensive range of activities. This includes overseeing the DMC charter; developing programming for tables, listings, and figures; data analysis; report generation for DMC review; and facilitating effective and efficient meetings. In addition to these technical tasks, operational support is delivered through a dedicated project manager. This role is pivotal in organizing DMC meetings, documenting, and finalizing minutes and serving as a liaison among CRAB's statistical team, the DMC and the study sponsor.

Friends of Cancer Research

CRAB has served at the Independent Analysis Center for the Friends of Cancer Research "ctDNA for Monitoring Treatment Response" (ctMoniTR) project since 2019. In 2024, CRAB statisticians completed analyses investigating ctDNA as a biomarker for tumor response among advanced NSCLC patients treated with Targeted Kinase Inhibitors (TKI), Anti-PD-(L)1 immunotherapies, and chemotherapies. These results have been presented as posters at the ASCO and SITC conferences and are being prepared for publication. Planning is underway for analyses among other solid tumors (prostate, breast, melanoma, colorectal, cervical cancers).

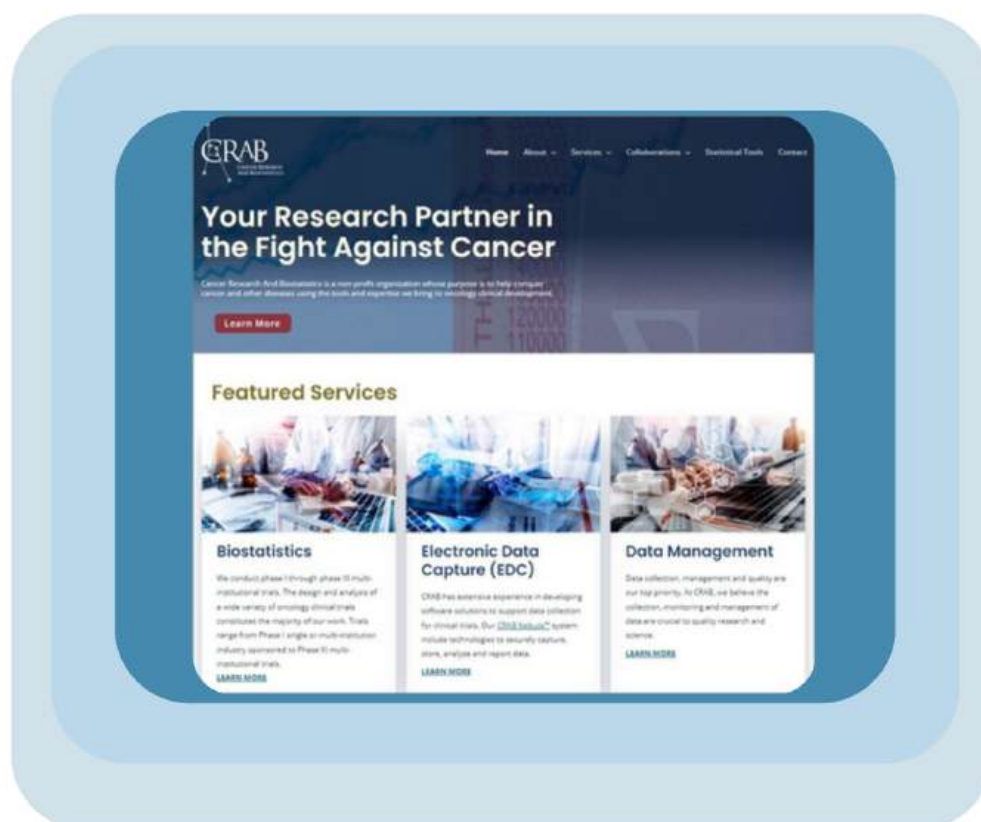
University of Washington Emergency Medicine

Dr. Graham Nichol, Director of the University of Washington-Harborview Center for Prehospital Emergency Care, has partnered with CRAB on research to improve the outcomes of patients with life-threatening cardiac events. Together with Drs. Antje Hoering and Emily Goren, our collaboration has already published two works on cardiac arrest in the journal *Resuscitation*. Additional work on rurality and area deprivation and outcomes after out-of-hospital cardiac arrest were submitted for publication. Together, University of Washington and CRAB submitted a grant with academic collaborators. We also worked on proposals to evaluate advancements in cardiac emergency care with multiple industry partners.

COLLABORATIONS

IASLC Publications

CRAB statisticians contributed to several publications for the IASLC's 9th Edition TNM Staging Classifications for Lung Cancer, Mesothelioma, and Thymic Malignancies. This included the four primary publications for Lung Cancer, defining the T (Tumor), N (Nodal), and M (Metastases) categories along with the TNM Stage Groupings (Katie Nishimura, Adam Rosenthal), and the N/M categories for Thymic Carcinomas and Thymomas (Emily Goren). Ancillary publications on more specialized topics were also published, including an analysis of Spread Through Air Spaces (STAS), a new pathological descriptor used in Lung Cancer (Megan Eisele), the validation of the 9th Edition staging criteria among Neuroendocrine Carcinomas, a histological subtype in lung cancer (Adam Rosenthal). With evidence provided by CRAB, the IASLC's 9th Edition staging criteria recommendations were approved by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) and will be adopted worldwide in 2025. These data-driven revisions enhance staging precision, help support individualized treatment planning and reinforce the essential role of statistics in evidence-based cancer care.



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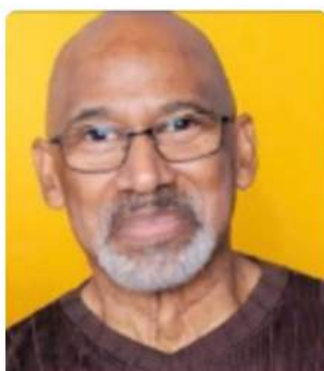


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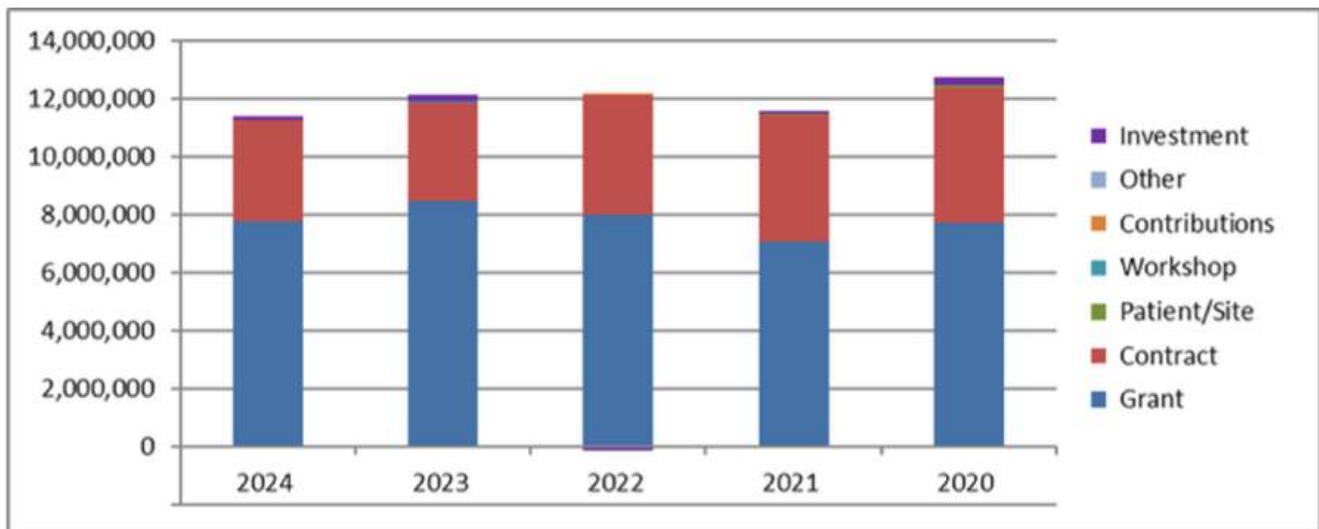
FRIENDS & SUPPORTERS

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AUDIT & FINANCIAL SUMMARY

2024 revenue decreased 6% compared to the prior year. The decrease in revenue was due to reduced SWOG grant funding. Revenue from all SWOG sources was 8% less than the previous year reaching \$9,823,086 in 2024. As in prior years, the NCI's NCTN sustained SWOG, and thus most of CRAB's federal funding in 2024, and was augmented by SWOG CTP projects funded by pharma collaborators. A new NIH funded project - CSRN - contributed an additional \$591,570 in federal and grant revenue. Clinical and Statistical Research Program contract revenue continues to diversify revenues. Unrealized investment income in our reserves and interest on our cash investments were positive in 2024.



Support and Revenue					
	2024	2023	2022	2021	2020
Grant	7,778,126	8,468,545	7,987,013	7,080,797	7,739,288
Contract	3,476,889	3,400,028	4,157,141	4,353,449	4,655,815
Patient/Site	0		0	63,890	61,893
Workshop	14,942	28,018	12,735	0	0
Contributions	8,304	4,309	9,647	13,039	9,592
Other	0		0	101	12,832
Investment	138,806	224,087	(173,406)	84,733	256,965
	\$11,417,066	\$12,124,987	\$11,993,130	\$11,596,009	\$12,736,385
Operating Expenses					
	2024	2023	2022	2021	2020
Research	8,018,128	8,774,912	8,482,772	8,072,898	8,378,183
Workshops	14,796	26,797	12,063	3,308	832
Administration	3,711,103	3,726,140	3,628,826	3,711,171	2,902,275
	\$11,744,026	\$12,527,849	\$12,123,661	\$11,787,377	\$11,281,290

CANCER RESEARCH AND BIOSTATISTICS

OUR MISSION

IS TO HELP CONQUER CANCER AND OTHER
DISEASES USING THE TOOLS AND EXPERTISE WE
BRING TO CLINICAL TRIALS

CLINICAL TRIAL DESIGN
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