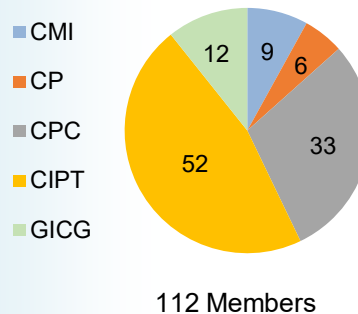# Biostatistics Shared Resource

Aims

- Provide statistical support to study planning, design and data analysis

- Support every type of cancer study, including investigator-initiated trials, population-based intervention studies, observational studies, and basic science experiments

- Support study activities including randomization, trial monitoring, interim analysis, the generation and interpretation of data analysis reports, and publications

- Develop and implement novel statistical methods for cancer research
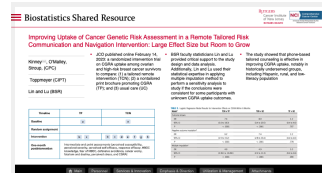
Research Program Support (2018–2022)

Pie chart legend:
- CMI: 9
- CP: 6
- CPC: 33
- CIPT: 52
- GICG: 12

112 Members

Publications

Co-Authored	140
IF >10	13

Peer-Reviewed Grants

All	29
NCI	16

CPC, CIPT

Improving Uptake of Cancer Genetic Risk Assessment in a Remote Tailored Risk Communication and Navigation Intervention: Large Effect Size but Room to Grow

J Clin Oncol, 2023

CPC, CIPT

Association of Body Mass Index, Central Obesity, and Body Composition with Mortality Among Black Breast Cancer Survivors

JAMA Oncol, 2021

CIPT

Phase I Trial of Pembrolizumab Administered Concurrently With Chemoradiotherapy for Locally Advanced Non-Small Cell Lung Cancer

JAMA Oncol, 2020

CIPT

Burkitt lymphoma in the modern era: real-world outcomes and prognostication across 30 US cancer centers

Blood, 2021

CMI, GICG

Autophagy promotes mammalian survival by suppressing oxidative stress & p53

Genes Dev, 2020

Biostatistics Shared Resource

Rutgers
Cancer Institute
of New Jersey
RUTGERS HEALTH

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute
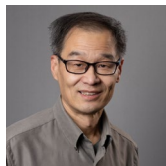
Leading Personnel & Roles

Hao Liu, PhD
Director
Survival analysis, Bayesian trials, Phase I and II trials, Basic and Population Science

Yong Lin, PhD
Faculty Statistician
Survival analysis, Phase I and II trials, Animal Experiments and Population Science

Shou-En Lu, PhD
Faculty Statistician
Mediation and moderation analysis, Basic and Population Science
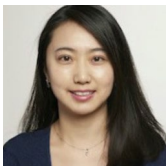

Dirk Moore, PhD
Faculty Statistician
Survival analysis, Phase I and II trials, Basic and Population Science

Pamela Ohman-Strickland, PhD
Faculty Statistician
Cluster RCT, Population Science

Liangyuan Hu, PhD
Faculty Statistician
Causal inference, Bayesian analysis, Population Science

New Faculty

Elizabeth Handorf, PhD (Jul 01, 2023)
New recruit

Staff Statisticians

Shengguo Li, PhD
Staff Statistician

Chunxia Chen, MS
Staff Statistician

Services & Innovation

New

- Novel statistical methods to support cancer research, e.g., early phase clinical trials, causal mediation analysis for cancer prevention and control

- Analysis of large-scale emerging datasets including genomics, metabolomics, proteomics and electronic health records

- Support for the design and analysis of population-based studies and implementation science including cluster randomized trials

- Faculty and staff recruitment plan based on needs assessment survey (see attachments)

Continuing

- Statistical support to research projects, study design, conduct and study monitoring
  - Computation, statistical analyses, data reports/publications

- Development of novel statistical methodology supporting cancer research

- Statistical review of study protocols and grant proposals

- Education and training activities
  - Annual Clinical Trial Design course for the clinical fellows in CINJ fellowship programs (BSR faculty Liu and Moore)
  - K-award support
  - All BSR faculty members are also part of SPH who participate in teaching courses

Biostatistics Shared Resource

RUTGERS
Cancer Institute
of New Jersey
RUTGERS HEALTH

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

Improving Uptake of Cancer Genetic Risk Assessment in a Remote Tailored Risk Communication and Navigation Intervention: Large Effect Size but Room To Grow

Kinney✉, O'Malley, Stroup, (CPC)

Toppmeyer (CIPT)

Lin and Lu (BSR co-authors)

J Clin Oncol, 2023
Feb 14;JCO2200751

- JCO published online February 14, 2023: a randomized intervention trial on CGRA uptake among ovarian and high-risk breast cancer survivors to compare: (1) a tailored remote intervention (TCN); (2) a nontailored print brochure promoting CGRA (TP); and (3) usual care (UC)

- BSR faculty statisticians Lin and Lu provided critical support to the study design and data analysis. Additionally, Lin and Lu used their statistical expertise in applying multiple imputation method to perform a sensitivity analysis to study if the conclusions were consistent for some participants with unknown CGRA uptake outcomes

- The study showed that phone-based tailored counseling is effective in improving CGRA uptake, notably in historically underserved groups, including Hispanic, rural, and low-literacy populations

Timeline	TP	TCN
Baseline	a	a
Random assignment		
Intervention	b c	b c d e f g h
One-month postintervention	Intermediate end point assessments (perceived susceptibility, perceived severity, perceived self-efficacy, response efficacy, HBOC knowledge, fear of HBOC, defensive avoidance, cancer worry, fatalism and destiny, perceived stress, and CGRA)	

TABLE 3. Logistic Regression Model Results for Intervention Effects on CGRA Within 6 Months

Model[a]	TCN v TP	TCN v UC	TP v UC
Outcome known			
OR	7.4	8.9	1.2
95% CI	(3.0 to 18.3)	(3.4 to 23.5)	(0.4 to 4.0)
P	< .0001	< .0001	.767
Negative outcome imputation[b]			
OR	6.2	7.4	1.2
95% CI	(2.5 to 15.2)	(2.8 to 19.4)	(0.4 to 4.0)
P	< .0001	< .0001	.778
Multiple imputation[c]			
OR	4.9	4.9	1.0
95% CI	(2.351 to 10.281)	(2.2 to 11.3)	(0.4 to 2.6)
P	< .0001	< .0001	.994

Association of Body Mass Index, Central Obesity, and Body Composition with Mortality among Black Breast Cancer Survivors
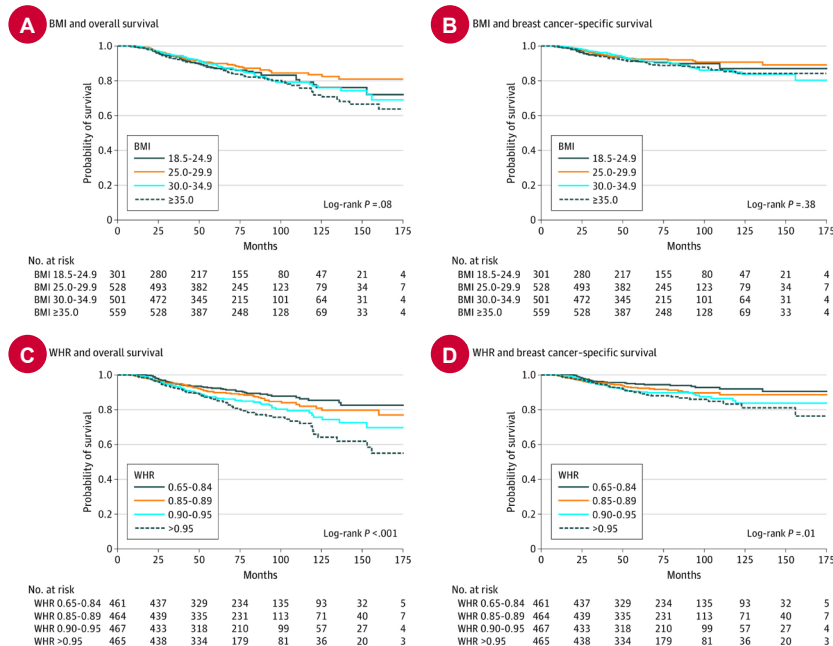
Qin, Zeinomar, Bandera (CPC) ✉
Omene (CIPT)

Lin and Xu (BSR co-authors)

JAMA Oncol, 2021
10.1001/jamaoncol.2021.1499

Kaplan-Meier curves for all-cause and breast cancer-specific survival by Body Mass Index (BMI) and Waist-to-Hip Ratio (WHR)

- BSR statisticians Lin and Xu applied the advanced statistical method of the Fine and Gray subdistribution hazard model for competing risk data to analyze breast cancer-specific mortality

- The study showed that obesity and adiposity were associated with all-cause and breast cancer-specific mortality among Black breast cancer survivors, which can be useful tools for identifying high risk patients among Black women with breast cancer

Biostatistics Shared Resource

Phase 1 Trial of Pembrolizumab Administered Concurrently with Chemoradiotherapy for Locally Advanced Non-Small Cell Lung Cancer
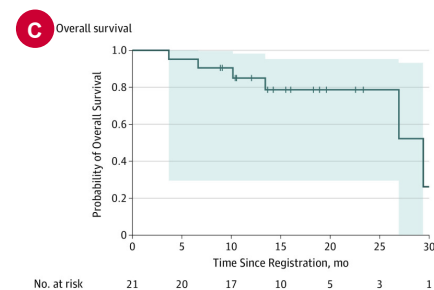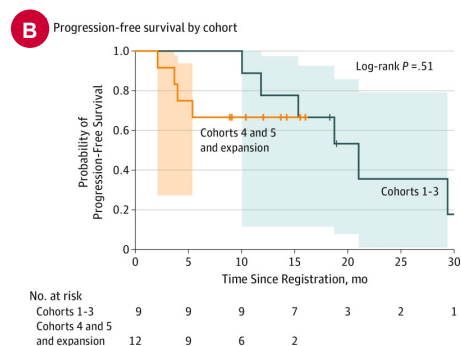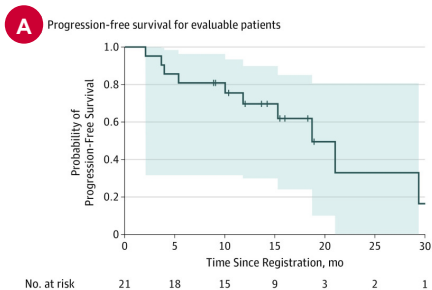
Jabbour (CIPT) ✉

Aisner, Malhotra (CIPT)

Lin (BSR co-author)

JAMA Oncol, 2020
6(6):848-855

- In a collaboration with CIPT members Jabbour, Aisner and Malhotra, BSR faculty biostatistician Lin provided statistical design and analysis of a phase I trial of pembrolizumab administered concurrently with chemoradiotherapy for locally advanced non–small cell lung cancer

- Lin carefully estimated the probability of dose-toxicity response curves in the sample size justification of the phase I trial and provided statistical support to the data analysis for this trial

- The study demonstrated that combined treatment with PD-1 inhibitors and chemoradiotherapy for stage III NSCLC is tolerable, with promising 12 month of PFS of 69.7%

A Progression-free survival for evaluable patients

B Progression-free survival by cohort

C Overall survival

## Burkitt Lymphoma in the Modern Era: Real-world Outcomes and Prognostication Across 30 US Cancer Centers

Evens (CIPT) ✉

Lin (BSR co-author)

Blood, 2021
137(3): 374–386

- BSR faculty statistician Lin applied the advanced statistical techniques of Harrell's C concordance coefficients and nonparametric bootstrap for variable selection and assessment of model fit that are critical for the scientific result

- The study called attention to the critical prognostic factors that drive outcomes across the full continuum of adult patients with Burkitt lymphoma (BL) in the United States
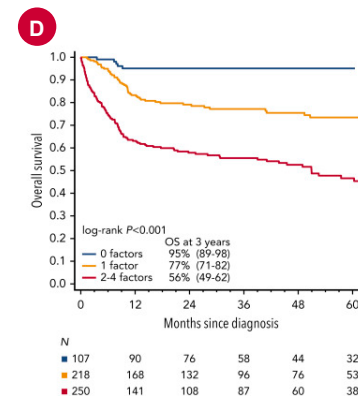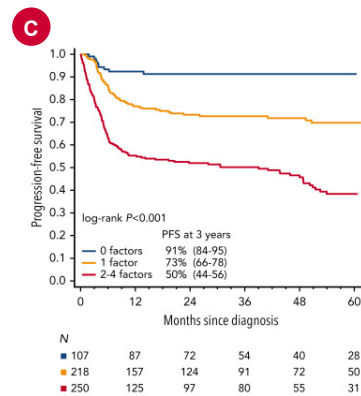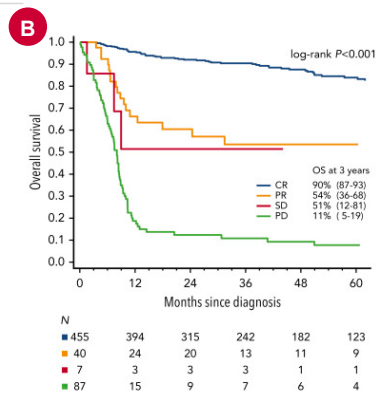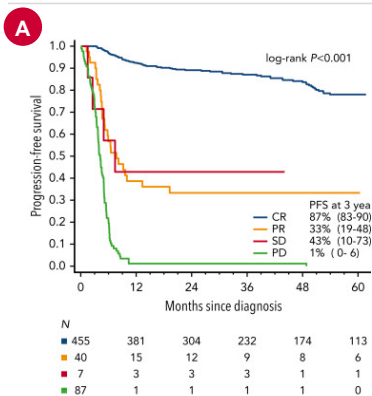
Autophagy Promotes Mammalian Survival by Suppressing Oxidative Stress and p53
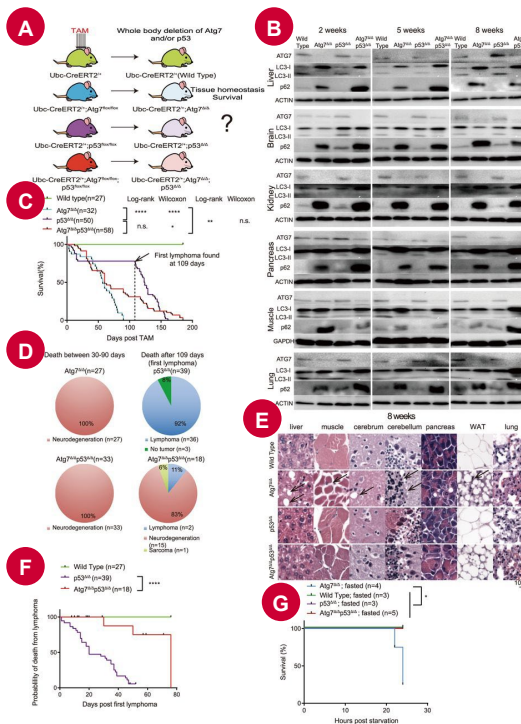
White (CMI) ✉

Hu (GICG)

Moore (BSR co-author)

Genes Dev, 2020
34(9-10):688-700

BSR statistician Moore applied the Log-rank and Gehan-Breslow-Wilcoxon tests to analyze survival data for the animal experiments

The study showed that the tissue-specific roles for autophagy and functional dependencies on the p53 and NRF2 stress response mechanisms

- Atg7Δ/Δ, p53Δ/Δ mice have extended life span, delayed tissue damage and neurodegeneration compared with Atg7Δ/Δ mice

- (A) Experimental design for generation of shown murine strains

- (B) Western blot for ATG7, p62, and LC3 at the indicated times of the indicated tissues and murine strains

- (C) Kaplan-Meier survival curve of murine strains. Dotted line indicates 109 d, when the first lymphoma was identified in p53Δ/Δ mice. (n.s,) Not significant; (*) P < 0.05; (**) P < 0.01; (****) P < 0.0001 (log-rank test and Gehan-Breslow-Wilcoxon test as indicated).Data are presented as mean ± SD. n = 6. *P < 0.001; **P < 0.0001, mixed model analysis with Bonferroni's adjusted P values

- (D) Percentage distribution for the cause of death of murine strains

- (E) Representative Histology of shown tissues of various murine strains

- (F) Kaplan-Meier survival curve of murine strains that died after 109d. Black dots on the survival curve indicate the censoring times that mice died of no tumor development. (****) P < 0.0001 (log-rank test).(G) Kaplan-Meier survival curve of murine strains during starvation at 10 d after TAM. (*) P < 0.05 (log-rank test)

Biostatistics Shared Resource

Rutgers
Cancer Institute
of New Jersey
RUTGERS HEALTH

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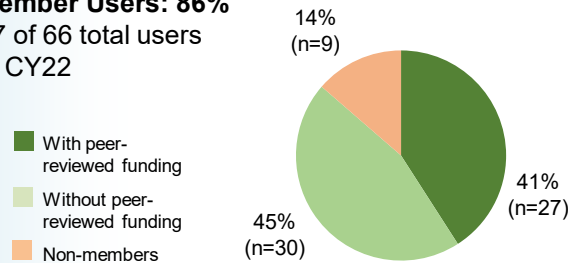National Cancer Institute

Emphasis

- Biostatistics collaborations lead to external grants, including K awards and funded IITs

- BSR has a wide spectrum of statistical expertise for cancer research including Bayesian designs for phase I/II trials, cluster randomized trials, causal inference

- BSR faculty biostatisticians are also faculty of Rutgers School of Public Health, providing opportunities for statistical methodology development, training and education
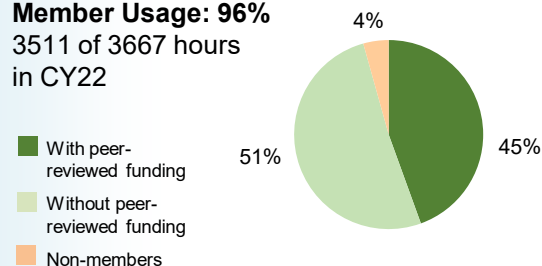
Future Directions

- Expand our expertise in several areas of critical needs for cancer research including:

  - statistical designs for phase I/II clinical trials

  - novel designs for population science and implementation science, data science, and

  - machine learning

- Actively recruit an additional 3 FTE faculty statisticians based on the strategic plan and needs-assessment approved by the CINJ Director

Biostatistics Shared Resource
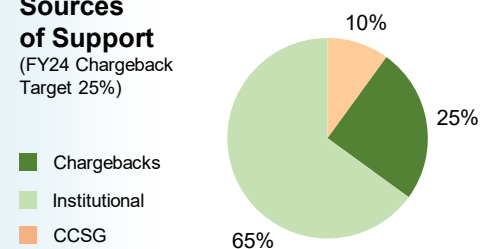
Utilization & Management

Member Users: 86%
57 of 66 total users in CY22

- With peer-reviewed funding
- Without peer-reviewed funding
- Non-members

14% (n=9)
41% (n=27)
45% (n=30)

Member Usage: 96%
3511 of 3667 hours in CY22

- With peer-reviewed funding
- Without peer-reviewed funding
- Non-members

4%
45%
51%

Sources of Support
(FY24 Chargeback Target 25%)

- Chargebacks
- Institutional
- CCSG

10%
25%
65%

FY24 Chargeback Target: 25%

Satisfaction Survey for CY22 services

79%

- Satisfied (11)
- Dissatisfied (2)
- Neutral (1)
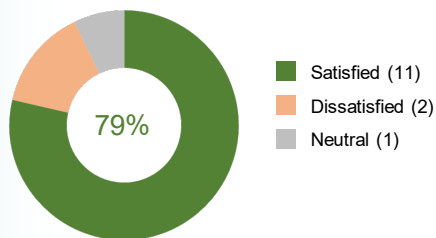
Participated: 14 of 57 members (25%)

Organization & Governance

BSR
6.3 FTE

→

SRACs
- Advisory Committee meets annually
- Discusses operational and scientific progress
- SRM supports organization

→

SRM
- SR Faculty Directors report to the AD of SR
- SRM tracks and supports SRAC recommendations, productivity, service development, outreach

→

CINJ Director
- RLC
- Finance & Admin
- EAB

Biostatistics Shared Resource
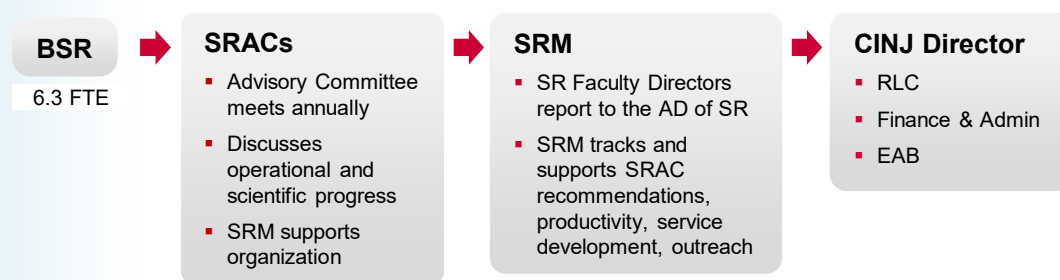
Supporting Information

Program Support

- Publications
- Grants
- 5 Year User List
- Needs Assessment

Advisory Committee

- FY23 Presentation
- Action Items
- Notes

Quality Satisfaction

- Annual Survey Action Items

SR Usage

- CY22 Usage

Submitted Information

- Research Strategy
- Aims
- SRM Research Strategy