



UPSTATE CAROLINA

Connector

November 2021

Issue Highlights

- Newly Activated Studies
- The Cancer Letter
- CCDR Accruals
- Diving into Disparities
- QA with Kelsey



NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health

Happy Thanksgiving!



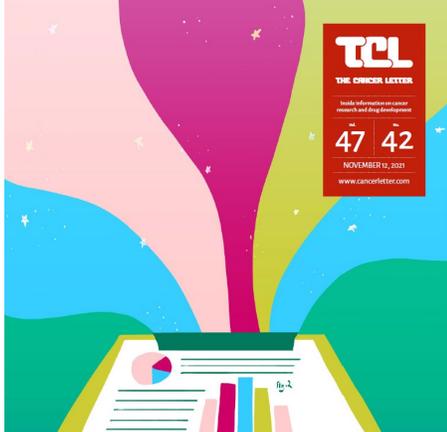
Newly Activated Studies

These studies have recently activated. More information can be found on [CTSU](#).



- NRG-HN009: Randomized Phase II/III Trial of Radiation with High-Dose Cisplatin (100 mg/m²) Every Three Weeks Versus Radiation with Low-Dose Weekly Cisplatin (40 mg/m²) for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)
- EAQ202: Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials
- NRG-GU010: Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification And Intensification Clinical Trial Evaluation (GUIDANCE)

The Cancer Letter



PROJECT EQUITY: FDA CONSIDERS OPTIONS TO INCREASE DIVERSE ENROLLMENT IN CLINICAL TRIALS

The agency is in the process of crafting a guidance that would define what constitutes a "health disparity" and how FDA would interpret "adequate representation" of ethnic and racial minorities in clinical trials, sources said.

→ PAGE 4

FDA & NCI: IT'S TIME TO FIX DISTORTED ACCESS TO CLINICAL TRIALS AND NOVEL THERAPIES

APRA-H, THE KEY ELEMENT OF BIDEN CANCER AGENDA, FACES UNCERTAIN FUTURE.

→ PAGE 22

WALTER LAWRENCE, CANCER SURGEON AND CIVIL RIGHTS HERO, DIES AT 74

APPROVAL OF AN IMMUNOTHERAPY FOR ADVANCED BLCA INDICATION GIVES US NEW REASONING FOR FINDING EARLY STAGE DISEASE

→ PAGE 33



CARYN LERMAN'S AACI PRESIDENTIAL INITIATIVE: CLOSE THE DIVERSITY GAP IN THE CANCER CENTERS' WORKFORCE

The Association of American Cancer Institutes is designing two programs to address systemic underrepresentation of racial and ethnic minority physicians and scientists in leadership positions in oncology.

→ PAGE 4

SHARPESS: IT'S TIME TO CONFRONT THE CURRENT REALITY OF CANCER AND UNRAVEL IT

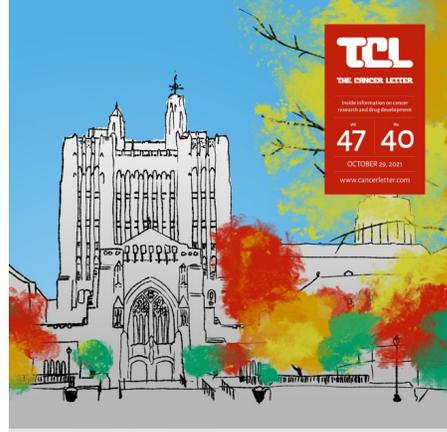
DEBUTARY ELISHA ESTEV, LEUKEMIA EXPERT, STATISTICIAN, GENTLE SOUL AND FRIEND

→ PAGE 33

EDWIN: EDWINO CEJAN, CREATOR OF THE 'TRIPLE UP' AND THE WILCOX-CEJAN TEST, DIES AT 92

TRIALS' REGULATIONS NO LONGER EXPERIMENTAL—PROSTATE CANCER PATIENTS SHOULD HAVE ACCESS TO PROTON THERAPY

→ PAGE 44



ERIC WINER TALKS ABOUT HIS VISION FOR YALE CANCER CENTER—AND HIS RETURN TO NEW HAVEN

Eric P. Winer will begin his job as director of Yale Cancer Center and physician-in-chief of Smilow Cancer Hospital at Yale on Feb. 1, but he has started his "listening tour" early.

→ PAGE 5

DANNY WELSER: mRNA VACCINES MAY BECOME A VIABLE TREATMENT FOR CANCER BECAUSE OF COVID-19 PANDEMIC

BILL BIDEN'S VISIT TO HOLLINGS BRINGS BARBARES TO MANAHOA AND MISSED DURING THE PANDEMIC

→ PAGE 26

IN THE ENDWIVES: NED SHARPESS TO DELIVER PAUL CALABRESE MEMORIAL LECTURE, NOV. 2

TRIALS' REGULATIONS REMOVING BARRIERS TO CANCER CARE IN UNDERSERVED COMMUNITIES

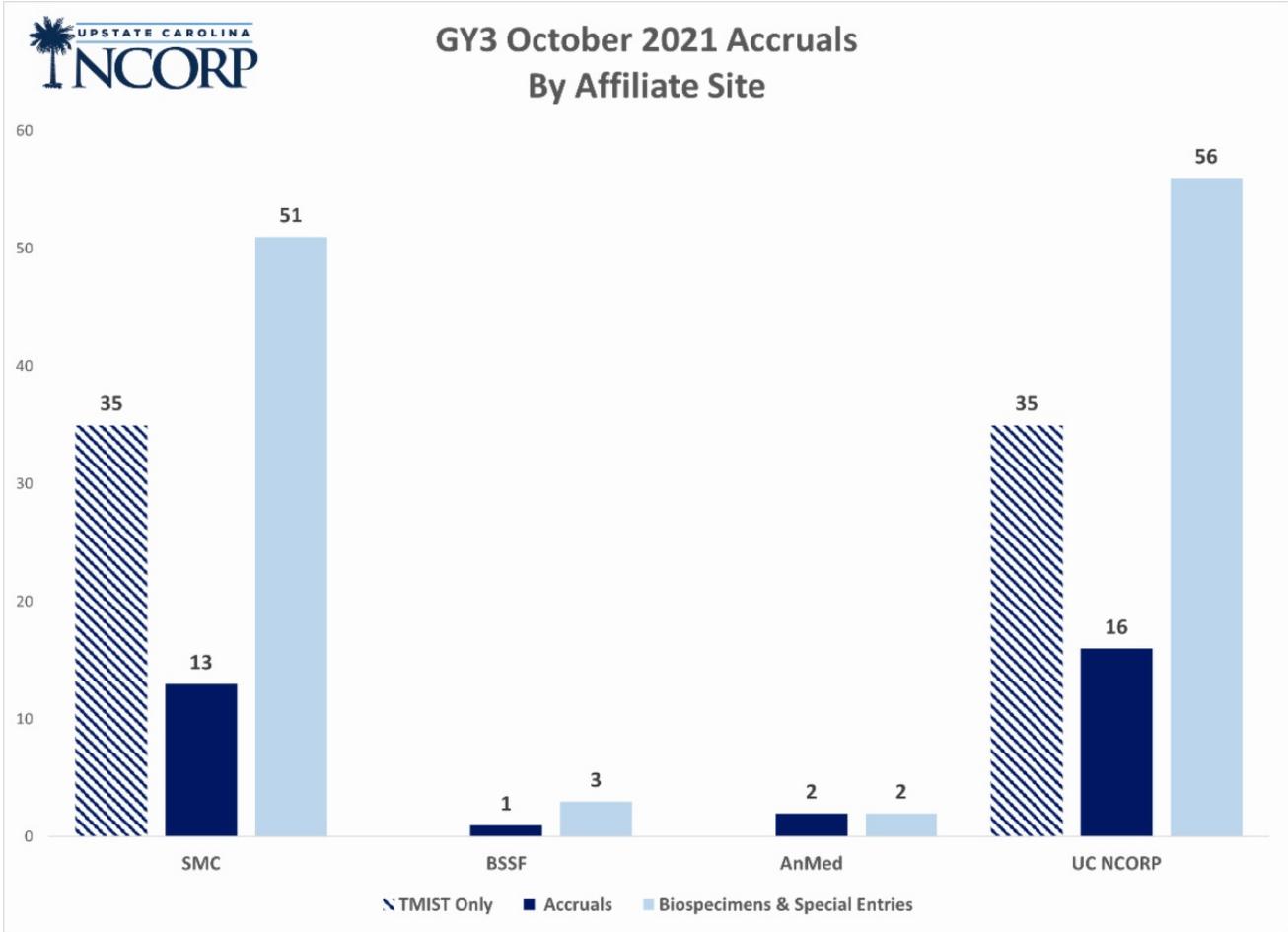
→ PAGE 25

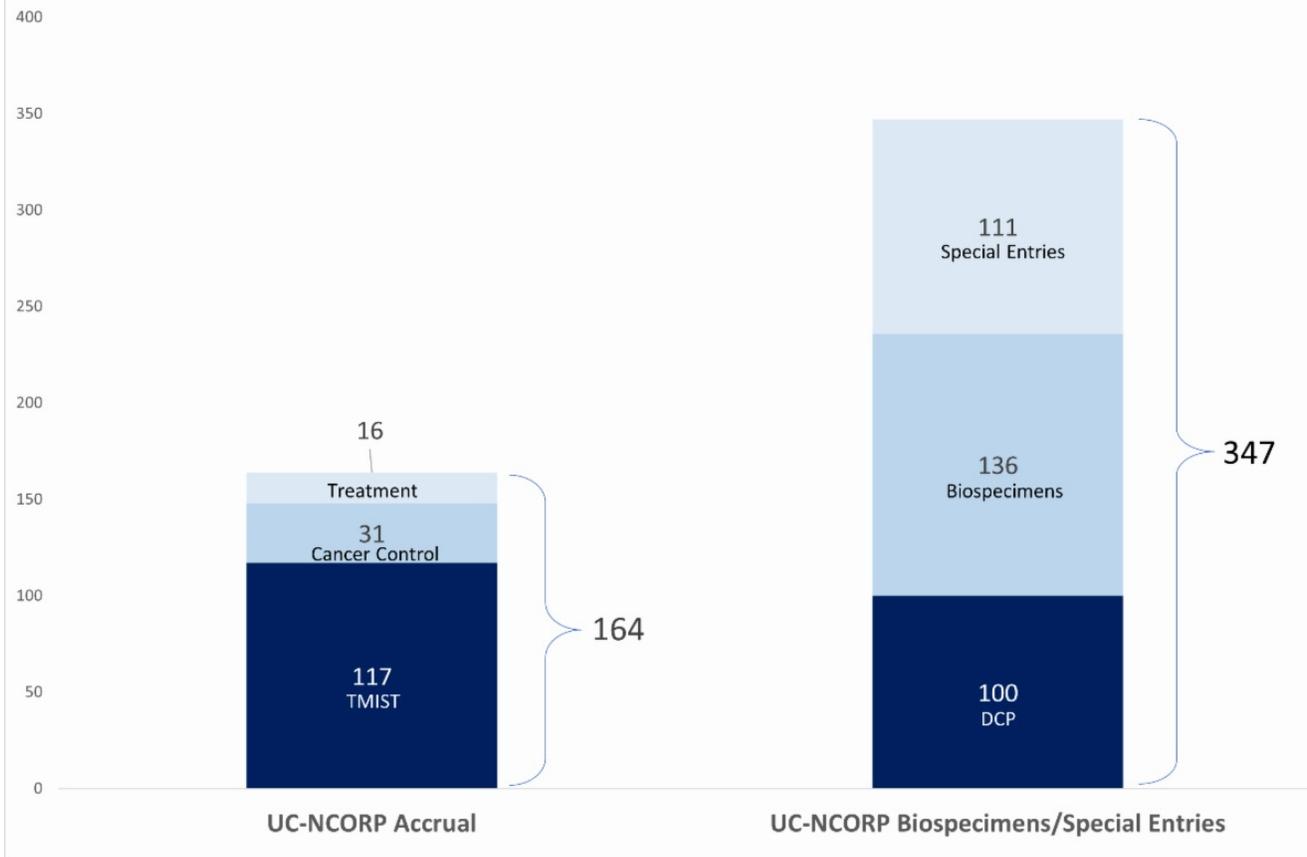
November 12, 2021

November 5, 2021

October 29, 2021

Accruals & Biospecimens—Special Entries



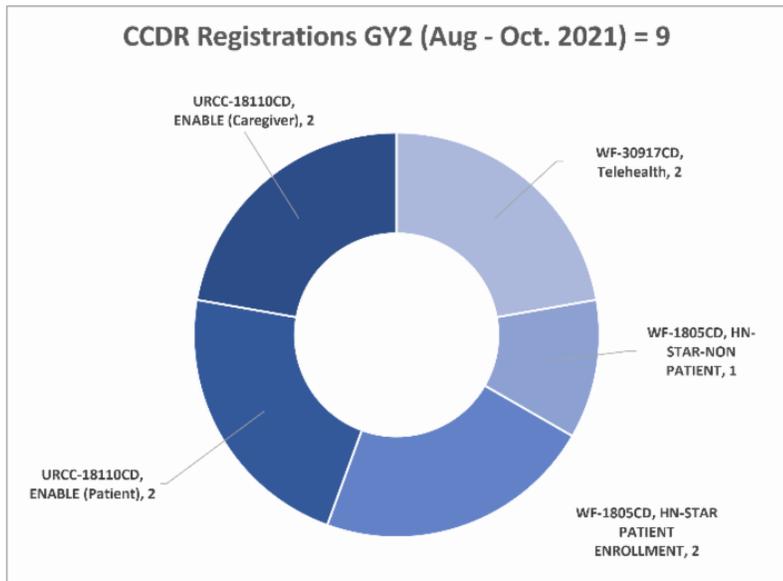


Under-Represented Populations

Underrepresented Populations

| All Accruals | Aug 2021 | Sept 2021 | Oct 2021 | Goal GY3 | Status GY3 |
|-------------------------|----------|-----------|----------|----------|------------|
| AYA (15-39 yrs.) | 2 | 1 | 2 | 4% | 10% |
| Older Adults (>65 yrs.) | 24 | 16 | 13 | 55% | 33% |
| African American | 12 | 15 | 12 | 17.6% | 24% |
| Other Minorities | 1 | 2 | 0 | 0.4% | 1.8% |
| Hispanic | 1 | 1 | 0 | 1% | 1.2% |
| Rural | 23 | 26 | 19 | 35% | 42% |

CCDR Registrations GY2 (Aug - Oct. 2021) = 9



| Protocol | SMC | BSSF | AnMed |
|---------------------------------|----------|----------|----------|
| NRG-CC007CD | 0 | 0 | 0 |
| WF-30917CD | 2 | N/A | N/A |
| WF-1805CD | 1 | 1 | 0 |
| WF-1805CD (NON-PATIENT) | 0 | 0 | 1 |
| URCC-18004CD (Sites registered) | 0 | 0 | N/A |
| URCC-18110CD (NON-PATIENT) | 0 | N/A | N/A |
| URCC-18110CD (PATIENT) | 2 | N/A | N/A |
| URCC-18110CD (CAREGIVER) | 2 | N/A | N/A |
| Site Total | 7 | 1 | 1 |
| UC-NCORP Total | 9 | | |



Collaborating to Develop New Practice Randomization Trials for NCORP Cancer Care Delivery Research (CCDR)

The National Cancer Institute (NCI) Division of Cancer Control and Population Sciences (DCCPS) will host a series of webinars to increase familiarity with purpose of and key methodological considerations in cluster

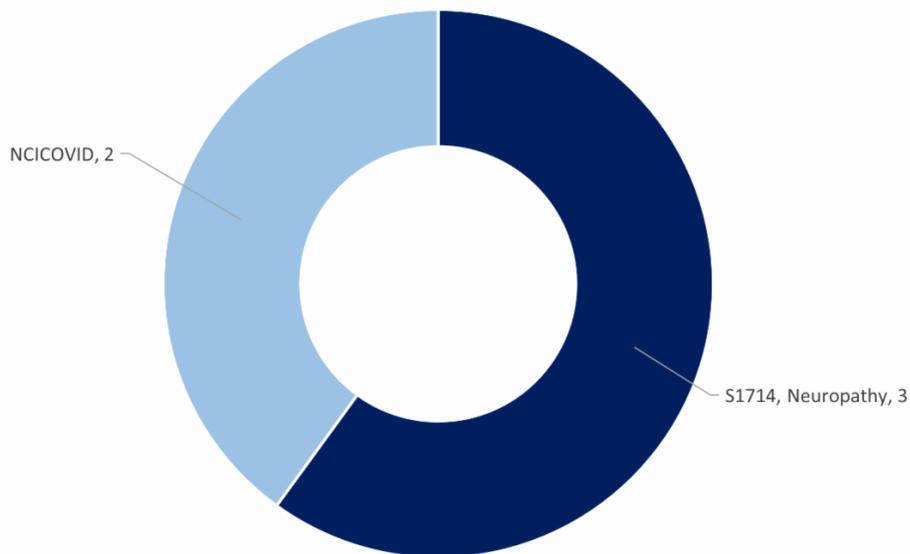
randomized trials, share experiences about conducting cluster randomized trials in NCORP CCDR (10 protocols to date), and discuss strategies for the design and conduct of future cluster randomized trials that balance scientific rigor and feasibility.

- **Realities of Practice Randomized Trials in NCORP CCDR**
 - December 7, 2021 | 4:00 – 5:30 p.m.
- **Making the Numbers Work: Design Considerations in NCORP CCDR Trials**
 - January 26, 2022 | 4:00 – 5:30 p.m.

Registration

All About AYA

AYA Accrual GY3 Aug - Oct 2021 - 5



AYA Accruals August 2021-October 2021

Diving into Disparities

Pancreatic Cancer Awareness Month

November is Pancreatic Cancer Awareness Month. This annual initiative empowers, educates, and inspires communities impacted by pancreatic cancer to raise awareness and support research. Cancer of the pancreas remains one of the deadliest cancer types (Ilic & Ilic, 2016), representing 3% of all new cancer cases in the U.S., with no early detection strategy (Siegel et al., 2016 SEER Cancer Statistic Review). Epidemiological studies indicate that diabetes mellitus is a significant risk factor for pancreatic cancer (Pizzato, Turati, Rosato, & Vecchia, 2019). However, the complex and multidirectional association between the two needs further research. Additionally, health disparities in the treatment of pancreatic cancer exist across many groups, including race and ethnicity, socioeconomic status (SES), and insurance status (Noel & Fiscella, 2019). Evidence suggests that African Americans, and Hispanics, tend to present at diagnosis with later-stage disease, have lower surgical resection rates, and experience higher morbidity and mortality rates than Caucasian Americans. Considering structural barriers to pancreatic cancer treatment and no current screening recommendations, identifying risk factors to pancreatic cancer is essential for primary prevention and future cancer control strategies.

In order to contribute to the development of an early detection strategy for pancreatic cancer that will hopefully lead to improved management and survival outcomes, Gibbs Cancer Center and Research Institute is participating in “A Prospective Study to Establish a New Onset of Hyperglycemia and Diabetes Cohort (NOD)” protocol. This observational cohort study seeks to assemble a cohort of participants, age 50–85, with new-onset diabetes and to create a large biobank of blood samples and data to measure the incidence of pancreatic ductal adenocarcinoma (PDAC) with high blood sugar. This collaboration shows the importance of oncologists, non-oncologists, clinicians, researchers, community health workers, and other healthcare providers joining the pancreatic cancer campaign’s call-to-action to educate the world and advocate for research that will provide an early detection strategy to save lives.



Documentation Reminders

- If a patient withdraws, need to be specific on what they withdrew from
 - All further data abstraction or procedures, treatment only, procedures only, etc.
- If specimens cannot be obtained, need to document specifics as to why
 - Could not collect after 2 attempts, patient refused, inadvertently missed, etc.
- All contact attempts should be documented
 - Phone calls, mail, MyChart, email, etc.
- All visits should have documentation from Coordinators
- Source being completed must be attributable and contemporaneous
 - Initialed and dated
 - Electronic signatures in EPIC (Audit trail has name and date completed)



Do you have any staff you would like highlighted in The Connector?
Please submit it by the 15th of the month to Alaina: akennedy@srhs.com



Connect with us on
LinkedIn!
[@UpstateCarolinaNCORP](https://www.linkedin.com/company/upstatecarolinacorp)

[Click here to visit our website](#)

Administrator
Kamara Mertz-Rivera, MA, CCRP
Email: UpstateNCORP@srhs.com
Phone: 864-560-6104

Quality Assurance
Kelsey Bridges, MSHS, ACRP-CP
Email: UpstateNCORPQA@srhs.com
Phone: 864-560-1961

Regulatory
Laura Bailey, BS, CCRP
Email: UpstateNCORPRegulatory@srhs.com
Phone: 864-560-6954

CCDR Coordinator
Melyssa Foust, MSN, RN, OCN
Email: UpstateNCORPCCDR@srhs.com
Phone: 864-560-1035

Finance
Alex Akkary, MBA
Email: UpstateNCORPFinance@srhs.com
Phone: 864-560-6967

AYA Coordinator
Heather Schwartz, MPH, HTL
Email: heather_schwartz@bshsi.org

