



ROCKET: Radiation Oncology Committee to Advance Knowledge and Education through Clinical Trials

Program Objective: To efficiently develop and conduct early phase clinical trials in the Medical College of Wisconsin (MCW) department of Radiation Oncology to support the Cancer Center mission for advancing cancer care.

Background: Institutional early phase clinical trials are the foundation for national and international multisite trials that change and advance the standards of care and provide pilot data to support National Institutes of Health (NIH) grants. Unlike pharmaceutical funding for drug development, radiation therapy device manufacturers have little to no financial incentives to sponsor early phase radiation therapy trials. The MCW department of Radiation Oncology is internationally known for innovations in radiation therapy delivery, however early phase clinical trial development is constrained by limited funding sources. The ROCKET program was developed to fund MCW investigator initiated clinical trials (IITs) focused on radiation therapy.

Mission: Efficiently develop and support impactful early phase clinical trials that provide pilot data for extramural funding, develop therapies for National Cancer Institute's (NCI) National Clinical Trials Network (NCTN) or other multisite trials. Collaborate with multidisciplinary clinical teams and basic scientists to integrate translational research and meaningful secondary and exploratory endpoints. Provide mentorship for early career investigators from early concept development to trial completion.

Leadership Team (Appendix A): The team is led by a clinical director and two co-directors who report to the department Chairman. The committee members are from each area critical for protocol development and meeting program objectives and include Medical Physics, Translational and Basic Science, Education, and Biostatistics

Program Manager: This full-time position is integral to the success of the program. Key functions include facilitation of study development to activation, organizing meetings, assisting with writing and budgets in close collaboration with the MCW Cancer Center Clinical Trials Office (CCCTO). After trial activation the manager monitors trial performance. For trials activated at the Clement J. Zablocki Veterans Affairs Medical Center (ZVAMC), the manager serves as the liaison between the MCW CCCTO and the ZVAMC Clinical Trials Office.

Protocol Development Workflow (Appendix B): Clinical trial proposals are presented at a monthly department research meeting where feedback is provided to improve strategies and strengthen trial design. After initial approval, proposals are given support to complete the study concept including biostatistics and assistance creating a multidisciplinary study team with inclusion of basic science and medical physics endpoints. Once the concept is fully approved by the ROCKET program, the full protocol is written with the assistance of the program manager and the clinical medical writer in the Cancer Center. The full protocol follows the Cancer Center rigorous review process prior to IRB submission, approval, and activation. The leadership team also assists in identifying additional funding sources to supplement ROCKET funding. ROCKET supports the CCCTO cost and additional funds are required to support non-clinical endpoints included in the trial.

Approval Criteria: Innovation, science, multidisciplinary collaboration, future directions, and feasibility.



Mentorship: The ROCKET structure for protocol development provides mentorship as needed and on trial-by-trial basis. First time principal investigators are given 2 days of protected time from clinical duties for writing the study. A resident is assigned to each developing study to learn the process of clinical trial development, activation, and conduct.

Program Highlights (Appendix C):

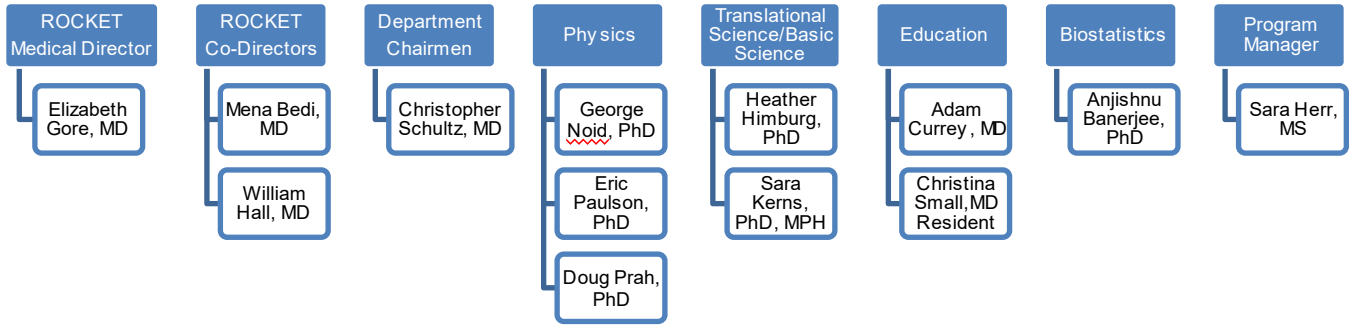
- ROCKET program commenced in September 2020.
- The first trial was activated in August 2021.
- Four clinical trials have gone through the entire ROCKET trial development process and are accruing patients.
- Four additional trials are approved by ROCKET and are in various stages of development.
- Five trials active prior to ROCKET are supported by ROCKET allowing for completion.
- Two trials have been opened at the ZVAMC creating a seamless regulatory pathway for collaboration between the ZVAMC and MCW IITs and are giving Veterans access to innovative trials.
- Trial supported represents multiple disease sites including Head and Neck, Central Nervous System, Esophagus, Pancreas, Rectal, Lung, Genitourinary and Gynecologic malignancies.
- Innovations being studied include MR treatment delivery, low dose rate radiation, image fusion/planning, radioprotectants, hypo-fractionated radiation, and radiation for potentiation of immunotherapy.

Resources and Allocation: The first 5 years of the program (2020-2025) are supported by the Dean's Fund. These funds are used for salary support for the ROCKET program manager and biostatistics, and to cover incurred CCCTO cost to run the studies. The MCW CCCTO total cost for each clinical trial from activation to completion ranges from \$55,000 to \$250,000. The cost depends on the number of patients and complexity of the trial. Other funding sources used for translational endpoints include Cancer Center Pilot Grants, MCW New Faculty Pilot Grant, NIH funding, and private donors.



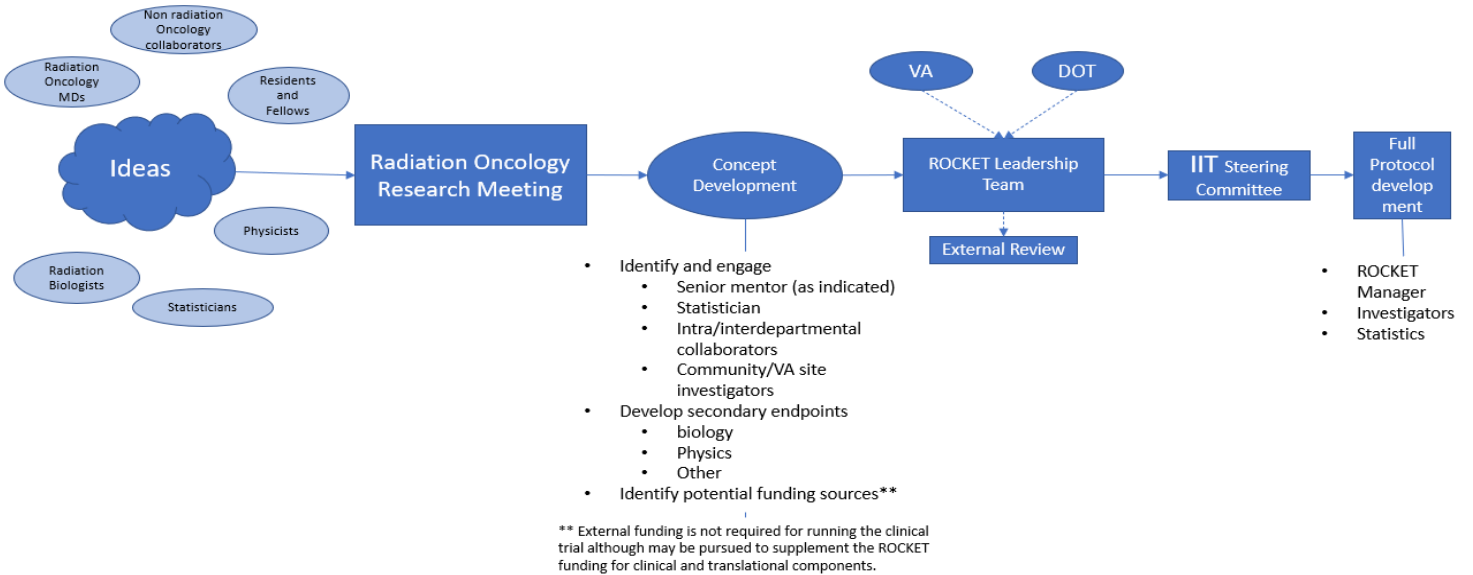
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Appendix A ROCKET Program Organizational Structure



Appendix B

ROCKET Program Investigator Initiated Trial Workflow





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Appendix C ROCKET Program Trials

ROCKET TRIALS	DISEASE SITE	PRINCIPAL INVESTIGATOR	ACCRUAL TARGET	TOTAL ACCRUAL
Optimizing Neurocognition with Whole Brain Radiation Therapy (WBRT) using Upfront Pulsed Reduced Dose-Rate (PRDR) Technique (ONCO-RT) - A Phase II Trial of Upfront Pulsed Reduced Dose Rate Whole Brain Radiation Therapy for Brain Metastases	Brain Metastases	Lindsay Puckett, MD	53	13
A Phase I Study of Hypo-fractionated Adjuvant Radiotherapy for Resected Head and Neck Cancers (HART-HN)	Post Op Head and Neck Cancer	Mus Awan, MD	18	11
High Dose Re-Irradiation Utilizing Advanced Deformable Image Registration (DIR) and Individualized Organ at Risk (OAR) Dose Calculations with Organ Specific Toxicity Analysis (Re-DIRICT)	Re-Irradiation, all sites	Elizabeth Gore, MD	90	5
Evaluating Pre-Treatment Vestibular Physical Therapy Rehab for Patients with Vestibular Schwannomas (PREHAB-VS)	Acoustic Schwannoma	Michael Straza, MD, PhD	36	SRC approved
ROCKET SUPPORTED TRIAL				
A Randomized, Phase II Clinical Trial of Stereotactic Body Radiation Therapy or Conventionally Fractionated Concurrent Chemotherapy and Radiation Therapy Preoperatively for Resectable or Borderline Resectable, or Locally Advanced Type A Pancreatic Adenocarcinoma (SOFT-PRE-OP)	Pancreatic Cancer	William Hall, MD	102	70
ROCKET LEGACY TRIALS				
MR Guided Phase II Radiotherapy Dose Escalation in Unresectable Non-Metastatic Pancreatic Cancer (RT-PANCREAS)	Pancreatic Cancer	Beth Erickson, MD	23	23
Study Evaluating Hypo-fractionated Pre-Operative Radiation Therapy for Soft Tissue Sarcomas of the Extremity and Chest-Wall (HYPOFRACTIONATED)	Sarcoma	Manpreet Bedi, MD	35	35
A Phase II Study of MRI-Based Pre-Operative Accelerated Partial Breast Irradiation (PREOP-APBI)	Breast	Adam Currey, MD	40	35
Solid Tumor Imaging MR-Linac (MRL STIM)	MRI	William Hall, MD	295	154
ROCKET TRIALS IN DEVELOPMENT				
Esophagus trial	Esophagus	Lindsay Puckett, MD	TBD	NA
Utilizing Radiation Prior to TKI to Delay Progression for Driver-mutated Non-small Cell Lung Cancer	Lung	Jonathan Thompson, MD	TBD	NA
Phase I Trial of Lisinopril for Radioprotection for Pelvic Malignancies	Bladder Toxicity	Sarah Kerns, PhD, William Hall, MD	TBD	NA
Prostate SBRT for recurrence after EBRT	Prostate Cancer	John Longo, MD, Evan Liang, MD	TBD	NA

Data effective: 7/31/2023