Learning Modules available in CLASS

An Overview of NRG
Target Audience: All NRG members
The history and formation of NRG, its organizational structure, key leadership, and legacy groups. The learning objectives of this module include the following:

- NRG's place in national cancer research and the NCTN
- How NRG Oncology was formed
- The organizational structure of NRG
- How NRG is funded
- The day-to-day work being done by NRG staff and its membership

The Role of the Patient Advocate
Target Audience: Patient Advocates, Investigators, Clinical Research Staff
The historical role of advocates, focusing on research advocacy and the role of Patient Advocates within NRG. The learning objectives of this module will help:

- Define the role of a Patient Advocate
- Outline the competencies you will earn throughout your training
- Understand the contributions of Patient Advocates within NRG

The NRG Patient Advocate Committee
Target Audience: NRG Patient Advocates
The background on the NRG PAC, the committee's history, leadership, roles, expectations, and competencies. The learning objectives of this module are:

- Understanding the structure of the PAC within NRG's organization
- Knowing fellow members and their contributions
- Checklist for new PAC members
- Learning about the PAC Charter
- Expectations, activities, and competencies

Assigned Committee Activity
Target Audience: NRG Patient Advocates, NRG Committee Leaders
The role of Patient Advocates on assigned committees, participating in meetings, and expectations at semiannual meetings. This course covers:

- The process of being assigned to a committee
- The role of the Patient Advocate Liaison within an assigned committee
- Expectations of Patient Advocates and committee leaders
- The logistics of committee meetings

The Lifecycle of a Clinical Trial at NRG Oncology – Part 1 of 2
Target Audience: NRG Patient Advocates
This module is geared toward educating patient advocates about the clinical trial process from

conception of a research idea, concept reviews, all the way to protocol activation. Upon completion, the participants will:

- Learn the definition of a clinical trial and the phases of trials within a cooperative group setting.
- Understand NRG's role in clinical trial development
- Recognize the stages and requirements of patient advocate engagement from concept to activation

The Lifecycle of a Clinical Trial at NRG Oncology – Part 2 of 2
Target Audience: NRG Patient Advocates
This module is geared toward educating patient advocates about the clinical trial timeline from the point of activation, maintaining a trial, and the process of closing a trial. Upon completion, participants will:

- Learn about the study activation process for NRG Oncology, and for participating sites.
- Better understand how NRG manages ongoing trials.
- Recognize what happens when an NRG study has been completed.
- Understand the value of patient advocate feedback even after the trial has ended.

Patient Reported Outcomes (PROs)
Target Audience: NRG New Investigators, CRAs
This course provides NRG members an overview of the data collection and submission processes for Patient Reported Outcomes (PROs), Quality of Life (QOL), and Neurocognitive Function (NCF). Upon completion, you will:

- Understand the significance of PROs, QOL and NCF within NRG research.
- Understand the requirements for PRO and NCF data collection and the importance of timely data collection.
- Become familiar with NRG electronic data collection systems like Medidata ePRO and VisionTree.
- Know the lifecycle of data collection requirements from study activation to final closure.
- Know the resources to utilize for questions or assistance.

Study Design: An Introduction to Study Design
Target Audience: NRG New Investigators
This course introduces study designs for phases 1, 2, and 3 clinical trials at NRG Oncology. Upon completion, you will:

- Know the considerations and safety assessments of phase 1 clinical trials.
- Understand and identify standard trial design methods.
- Understand phase 2 and phase 3 trials design and considerations.
- Know the role that Patient Reported Outcomes (PROs) play in cancer trials.

Study Design: Specialized Study Design
Target Audience: NRG New Investigators
This course discusses Cluster Randomized Trials, Prevention Trials, and Adaptive/Non-Adaptive Trials. Upon completion, you will:

- Understand when to use Cluster Randomized trials, their issues, extensions, and distribution.
- Know the purpose of prevention trials and observational studies, and their design challenges.
- Understand the principles of adaptive design trials, their advantages and limitations.

NRG Adverse Event Reporting
Target Audience: Protocol Support Committee
This course introduces the guidelines and expectations for timely routine and expedited adverse event reporting. Upon completion, you will:

- Understand what AE reporting guidelines and when to use them.
- Be familiar with Rave-CTEP integration.
- Understand the purpose and requirements of expedited reporting.

NRG Quality Assurance Audits
Target Audience: Protocol Support Committee
This course outlines how NRG's audits ensure the integrity and accuracy of clinical trial data, compliance regulations, and patient safety. Upon completion, you will:

- Understand the purpose of audits and their timelines.
- Understand the regulatory components of audits.
- Be familiar with deficiency examples.

NRG RECIST: Response Evaluation Criteria in Solid Tumors
Target Audience: Protocol Support Committee
This course will introduce you to the basic methodology of RECIST and other response criteria with practical applications. Upon completion, you will:

- Gain knowledge of response criteria for solid tumors.
- Understand the types of imaging modalities.
- Distinguish between complete response, partial response, stables disease and progressive disease.
- Understand the documentation of baseline disease burden and response assessment.

NRG Pathology & Biospecimen Collection
Target Audience: Protocol Support Committee
This course will discuss the basics of pathology and translational research specimen requirements and submissions. Upon completion, you will:

- Know the rules and parameters of biospecimen collection.
- Understand the process of tissue and blood collection, tubes, and labels.
- Understand how to populate forms and documents.

NRG RT Credentialing
Target Audience: Protocol Support Committee
This course will provide guidelines and expectations for RT Credentialing for NRG Oncology trials. Upon completion, you will:

- Know the purpose of Case Review and its services.

- Understand the data management process and the TRIAD application.
- Be familiar with how protocols affect credentialing and compliance.

Adverse Event Reporting
Target Audience: NRG New Investigators, CRAs
This course introduces the guidelines and expectations for timely routine and expedited adverse event reporting. Upon completion, you will:

- Learn about routine AE reporting and expedited AE reporting requirements for NRG trials.
- Be familiar with Rave-CTEP integration

Quality Assurance Audits
Target Audience: NRG New Investigators, CRAs
This course outlines how NRG's audits ensure the integrity and accuracy of clinical trial data, compliance regulations, and patient safety. Upon completion, you will:

- Be familiar with NCI guidelines for auditing clinical trials for the NCTN program
- Understand components of an audit at your site
- Identify best practices for corrective and preventive action plans