



NBME®

IMPROVING HEALTHCARE AROUND
THE WORLD THROUGH ASSESSMENT

NATIONAL BOARD OF MEDICAL EXAMINERS®



CLINICAL
RESEARCH
PROGRAM SM



THE NBME CLINICAL RESEARCH ASSESSMENT PROGRAM: WHY NOW?

The introduction of a Clinical Research Program aligns with the NBME's mission to protect the public by measuring the knowledge of individuals who conduct research that generates valid evidence.

The goal of clinical research is to find better ways to prevent, detect, or treat diseases. Studies are carefully designed to determine the safety and effectiveness of new treatments. The cost of bringing a new product to market is high; an assessment provided by an objective third party, such as NBME, that establishes a baseline of required knowledge and evaluates the competence of the individuals who conduct research may reduce one element of risk in the process.

Healthcare professionals enter the field of clinical research through many routes. Learning via on-the-job training, certificate programs, fellowships, or master's degrees leads to variability in the knowledge and skill levels of study personnel. While sponsors, organizations that provide support for clinical research activities, and sites that conduct research have made significant investments in staff training and education, there is no standardized assessment for clinical research professionals.

“The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions. Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.”

– Declaration of Helsinki

THE CLINICAL RESEARCH PILOT ASSESSMENT

In the first phase of the Clinical Research Program, the NBME has developed the Clinical Research Pilot Assessment to identify strengths as well as gaps in clinical research professionals' knowledge. The Pilot is designed to provide a baseline for a universally recognized, unbiased measure of the competence of clinical research professionals to perform safe, effective research.

Based upon sound principles of measurement with oversight from nationally recognized experts, the Clinical Research Pilot Assessment is designed to measure foundational mastery of clinical research knowledge. The assessment consists of 150 multiple-choice questions covering these important domains:

- Ethics
- Regulations and Guidance
- Study Design and Statistics
- Study Conduct
- Safety
- Data Management

There are two examinations within the Clinical Research Pilot Assessment, differentiated by the responsibilities and knowledge covered within each.

The first examination in the Clinical Research Pilot Assessment is for individuals responsible for:

- Overseeing the progress and conduct of a trial at a site or sites;
- Ensuring site feasibility and qualifications of site personnel;
- Providing regulatory oversight;
- Ensuring protocol compliance;

- Ensuring that adverse events are collected and reported appropriately;
- Ensuring that data are collected and recorded correctly;
- Managing the control of investigational products.

These responsibilities are usually associated with clinical research associates (sponsor-designated study monitors), clinical research coordinators, or clinical research managers.

The second examination is for individuals responsible for:

- Performing study-related procedures and/or making study-related decisions as a sub-investigator or a novice principal investigator;
- Ensuring the ethical conduct of the research as the principal investigator in a non-interventional study;
- Overseeing a clinical research study as a novice principal investigator by protecting human subjects' rights, safety and welfare, and complying with the protocol by adhering to institutional state and federal regulations;
- Providing medical oversight in a study as a newly designated medical monitor.

These responsibilities are usually associated with fellows participating in clinical research or novice clinical research investigators.

WHO CAN TAKE THIS ASSESSMENT?

Ideal candidates are clinical research associates, clinical research coordinators, and fellows, although any individual engaged in clinical research may participate.

BENEFITS OF PARTICIPATING IN THE PILOT

As the nationally recognized leader in providing unbiased, reliable, and valid examinations for the health professions, the NBME is uniquely positioned to provide a high-quality assessment using rigorous methods in collaboration with nationally recognized subject matter experts in the field of clinical research.

For individuals, the examination will be beneficial for professional development, standardized demonstration of knowledge, and potential career mobility. For organizations, institutions, and agencies, the examination will provide information on the relative strengths and weaknesses of a group of examinees in relation to the content domains.

The goal of the Clinical Research Program is to provide the following benefits to a spectrum of organizations within the clinical research field:

- Establishment of a baseline of required knowledge;
- Standardized documentation of core competencies and skills;
- Identification of competency gaps;
- Enhancement of training, education, and remediation; and
- Enhancement of professional development, recognition, and career mobility.

ABOUT THE CLINICAL RESEARCH PILOT ASSESSMENT

Candidates are currently being invited to participate in the Pilot Assessment, which will be held in October 2015 at locations in the United States. All pilot examinees will complete the assessment without charge and receive performance feedback on their strengths and weaknesses in the major content domains of the assessment.

After completing the Clinical Research Pilot Assessment, examinees will be asked to fill out a short survey to provide feedback to NBME about the content and difficulty level of the assessment. Organizations will receive aggregate data results for the major content domains of the assessment, which may be useful in planning future training for their examinees.

Applications for the Clinical Research Pilot Assessment are being accepted now. For more information, contact CRP@nbme.org.



NBME: IMPROVING HEALTHCARE AROUND THE WORLD THROUGH ASSESSMENT

The NBME is an independent, not-for-profit organization that provides valid and reliable examinations for the health professions. Protection of the health of the public through state-of-the-art assessment of health professionals is our mission, along with a major commitment to research and development in evaluation and measurement. We provide a variety of assessment services globally to the health professions.

Our organization was founded in 1915 in response to the need for a voluntary, nationwide examination that medical licensing authorities could accept as the standard by which to judge candidates for medical licensure. Since that time, the NBME has continued, without interruption, to provide high-quality examinations for this purpose, and has become a model and a resource of international stature in testing methodologies and evaluation in medicine.

NEED MORE INFORMATION?

To learn more about the CRP Assessment Pilot Program or future project development, contact CRP@nbme.org.



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