

JOB TASK ANALYSIS OVERVIEW

The aim of the Society of Clinical Research Associates (SOCRA) Certified Clinical Research Professional (CCRP) certification examination is to evaluate if eligible candidates have the requisite knowledge and skills to perform the job tasks that are critical for successful practice as a clinical research professional. To ensure that the SOCRA CCRP certification stays relevant and current, every five to seven years SOCRA conducts a Job Task Analysis (JTA) with current CCRPs to review and validate the job requirements for safe practice as a certified clinical research professional. The JTA was facilitated by a psychometrician with expertise in statistics specific to certification, licensure, and educational measurement, as well as certification program and examination development.

In 2024, SOCRA conducted the most recent JTA for the SOCRA Certified Clinical Research Professional program to identify the duties and tasks performed by clinical research professionals, and to update the Exam Outline which serves as the blueprint for the SOCRA CCRP examination. The first phase of this JTA involved a panel of clinical research subject matter experts (SME) meeting to review and update the purpose, job role, target audience, eligibility criteria, and requirements for certification as a CCRP. The SME panel then reviewed and updated the job tasks performed by clinical research professionals developed in **2017 and** grouped them into three phases of research (Research Study Start-Up, Research Study Maintenance, and Research Study Closure) considered to be primary job duties for CCRPs. The updated tasks and phases were assembled into an updated CCRP Certification Exam Content Outline that would be further reviewed and validated during the next phase of the JTA. The SME panel that performed this first phase of the JTA was composed of nine (9) clinical research professionals from the United States, Canada, and the United Kingdom, serving as a representative sample of the total CCRP population.

During the second phase of the JTA, the 18 job tasks defined by the SME panel in phase 1 were assembled into an online survey and distributed to clinical research professionals who practice throughout the world. The survey asked respondents to rate the importance of each task on a five point scale ranging from "1. Not Important at all" to "5. Extremely Important" as it relates to successful job performance as a clinical research professional. Participants were also asked to rank the order of importance of each task, and estimate the frequency with which they perform each of the job tasks. The survey was sent to more than 50,000 clinical research professionals, with a total of 1,188 providing job task data and another 607 providing only demographic questions. While the response rate was low, the 1,188 useable responses provided more than enough statistical power for all analyses.

The final phase of the JTA involved another meeting with the original SME panel to review the results of the validation survey to establish a test blueprint for the CCRP certification examination. The psychometrician presented results from the validation survey and lead a discussion with the SME panel to determine the final weights of each task in the CCRP Exam Content Outline. Demographic data from the group of respondents to the 2024 JTA validation survey was largely similar to the demographic data from respondents to the 2017 JTA validation survey, with the panel deciding that the sample was representative of the population of clinical research



professionals. The panel then reviewed seven write-in responses to a question asking, "Are there any tasks or activities performed by clinical research professionals that were not listed and that you feel are important to successful practice as a clinical research professional," ultimately deciding that the responses were either not relevant for candidates newer to the profession, out of scope for clinical research professionals, or already covered in the CCRP Exam Content Outline.

The validation survey data confirmed the tasks defined by the SME panel to be important to the role of the clinical research professional, with the mean rating of all 18 tasks being considered "Important" or more, and 14 out of 18 tasks having a mean rating considered to be "Very Important" or more. This supported the inclusion of all 18 tasks in the final CCRP Certification Exam Content Outline.

The panel then reviewed the importance ratings of the job tasks, as well as the importance and percentage of time ratings of the three research phases to establish the final Exam Outline (a.k.a., test blueprint) for the CCRP certification examination. This data was utilized to establish the percentage "weight" and associated job tasks assigned to each research phase, resulting in the final Exam Outline for the CCRP Certification Exam shown below:

1. Research Study Start-Up (40%)
 - a. Coordinate the development of initial research study protocol
 - b. Create or obtain research study documents (e.g., informed consent, essential documents, case report forms, or financial disclosure statements)
 - c. Obtain research study approval from necessary stakeholders (i.e., IRB, research study sponsor, and relevant regulatory authorities)
 - d. Obtain research study product, related materials, equipment, tools and aids
 - e. Select research study sites
 - f. Train research study staff members
 - g. Evaluate research study's compliance with relevant local, state and provincial laws
2. Research Study Implementation (50%)
 - a. Execute the research study in accordance with the protocol
 - b. Assure regulatory compliance
 - c. Manage research study product
 - d. Identify, document & report research study anomalies
 - e. Manage subjects
 - f. Manage research study data and documentation
 - g. Communicate with research study stakeholders
 - h. Perform / participate (in) a research study audit
3. Research Study Closure (10%)
 - a. Perform/participate (in) a research study closeout visit
 - b. Develop & submit research study closure reports
 - c. Archive/retrieve research study records



A detailed CCRP Exam Outline is available on the SOCRA website (<https://www.socra.org/assets/Certification/2501.1-Major-Content-Outline-241007.pdf>) to help candidates prepare for the CCRP Certification Exam. This Exam Outline presents the job tasks in which clinical research professionals must demonstrate competence to earn the CCRP. The job tasks are grouped under the research phase in which they are performed. The three research phases are presented as “Major Content Areas.” Each task has a list of topic areas and knowledge statements that further define the knowledge and skill required to competently perform the job task. Candidates preparing to sit for the CCRP certification examination can benefit from becoming familiar with this Exam Outline, as all exam questions are based on it. It is the position of SOCRA and the CCRP Certification Committee that the recommendations outlined in the CCRP Exam Outline are not exhaustive of the qualifications of **clinical research** professional but represent the minimum level of proficiency and knowledge required for safe practice as a CCRP.

