Guide to the DIAMOND ePortfolio
HOW AND WHY TO USE THE PLATFORM
DIAMOND will provide a limited number of clinical research professionals within the CTSA Consortium access to an ePortfolio account on Portfolium. A list of institutions belonging to the CTSA Consortium can be found here: https://ncats.nih.gov/ctsa/about/hubs

Once you created a DIAMOND ePortfolio, follow this guide to get started:

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CREATE A DIAMOND ePORTFOLIO ACCOUNT

There are 2 ways to create an ePortfolio on Portfolium.

1) Fill out the DIAMOND ePortfolio Registration form and receive access to exclusive DIAMOND resources including customized guides and profiles:
   https://is.gd/diamondeportfolio

2) Create a standard user account directly through Portfolium Please note that you will not receive additional DIAMOND resources if you chose to set up your portfolio using a standard user account:
   https://help.portfolium.com/portfolium-com/join-portfolium/create-an-account

SETUP YOUR BASIC PROFILE
   https://help.portfolium.com/portfolium-com/profile/profile-section

Tips for setting up your Profile:

- Upload a photo (headshot)
- Upload a cover “banner” image (you can find one by googling free banner images, or create one)
- Write a tagline e.g., “Clinical research professional dedicated to excellence”
- Add your LinkedIn URL
- Add your Twitter and other social media (as appropriate)
  o TIP: Avoid social media links that are more informal- only post your professional social media”

Additional Profile Features:

- Write an Introduction (a short bio or brief overview of your professional self)
- List any Clubs, Affiliations, Programs, and Professional Memberships
- List Certifications and Licensure
Privacy can be an important issue when you showcase your work openly. Privacy is also personal. You have options for your settings. Some set their privacy to “Only those I’m connected to”. This is optimal for the DIAMOND project where you are encouraged to connect within and outside of your institution to other Clinical Research Professionals.

You can also set your privacy to totally private- e.g., only you can see your eportfolio in Portfolium. Some chose to use that setting when first beginning. When ready for open sharing and connecting, you can then change the setting to “only those I am connected to”. You can ask people to connect to you or you can accept invitations to connect at your discretion. Connections must also have a Portfolium in order to “connect.”

When setting to **private**, only you can access and view your Portfolium, but it will also allow you to provide limited access, e.g., to professors, colleagues, supervisors, or potential employers you provide your private Portfolium URL code to can see your Portfolio.

You can also set privacy for specific work you post- for instance, if you wanted to maintain a reflective journal that was for your eyes only, you can set that project as private when you are posting it to your Portfolium.
Tips for further privacy considerations.

- Only upload a PDF of your work.
- Images can include a creative commons license icon
- Create a cover page for your project to show on the initial icon- you can create that as a single PPT slide and upload it.
- If you upload an image- do you have copyright permission to use it? Is the image professional?
- You can designate a specific project as for your eyes only, even if you are set to fully private or “connections only”.
  - Before you click to share, you will be asked about the privacy setting for this new item. Set to private if it is something for your eyes only – e.g., your personal reflections, diaries, goals, etc.

Note that for each project uploaded there is a Portfolium embedded copyright statement at the bottom of the screen:

© 2008 All content within this project is strictly the property of (Portfolium owner) and is not for public use without permission. [Report Abuse](https://help.portfolium.com/portfolium-com/projects/project-visibility)
GET STARTED USING PORTFOLIUM

The instructions in the User Guide entry below can help you get started in 3 easy steps.

https://help.portfolium.com/portfolium-com/what-is-portfolium/getting-started-in-3-steps

CREATE A NEW PROJECT

https://help.portfolium.com/portfolium-com/projects/adding-a-project-to-your-portfolio

DIAMOND encourages you to upload evidence of your training experience to your portfolio, including training descriptions, certifications, and assessment results. When creating a new entry (aka project) - go to the Portfolio tab and click “add a project.”

- The first file you link will be like a “cover page” for your project. Consider using an image to provide great visual impact.
- Then upload your project file. For your added protection, please consider saving your file as a PDF.
- Link your skills by selecting ALL Core Competency SKILLS that apply. This will populate your skills counts on the Left Horizontal Banner. So that your skills can be quantified by Competency Domain, be sure to use the following Domain Titles to link your skills:
  - Scientific Concepts & Research Design
  - Ethical & Participant Safety Considerations
  - Investigational Products Development & Regulation
  - Clinical Study Operations (GCPs)
  - Study & Site Management
  - Data Management & Informatics
  - Leadership & Professionalism
  - Communication & Teamwork
- Start off by uploading materials that you have set aside in files – for instance, CITI Training Certificates (HSP, GCP, RCR). This will help you get a handle on the process.
- You can edit a project that you have uploaded.
- Be aware of what you are allowed to or not allowed to upload. For instance, some journals have copyright restrictions that may prohibit uploading a PDF of a published article unless an embargo period has lapsed. Instead, place a header page that has the Citation and the Abstract with your contact information for reprints.
SKILLS: CORE COMPETENCIES FOR CLINICAL RESEARCH PROFESSIONALS.

- As described above, you should tag trainings, certifications, assessment results, or any other artifact you upload as a project with relevant competences and other skills.
- For the DIAMOND ePortfolio, you should include work, professional and training examples for each of the Core Competency Domains. This may also include training experiences through the DIAMOND Portal (http://diamondportal.org)
- Some uploads are associated with more than one skill - that’s OK!
- As you tag your projects to those Core Competencies, your skills “counter” will indicate how many items you have uploaded per skill.

(http://www.clinicaltrialcompetency.org/framework-domains-1/)

<table>
<thead>
<tr>
<th>COMPETENCY DOMAIN</th>
<th>TOPICS</th>
<th>ePORTFOLIO PROJECT EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Concepts &amp; Research Design</td>
<td>Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials</td>
<td>- Literature Search&lt;br&gt;- Analysis plan</td>
</tr>
<tr>
<td>Ethical &amp; Participant Safety Considerations</td>
<td>Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial</td>
<td>- CITI Human Subject Protection Certificate&lt;br&gt;- Informed consent checklist</td>
</tr>
<tr>
<td>Investigational Products Development &amp; Regulation</td>
<td>Encompasses knowledge of how investigational products are developed and regulated</td>
<td>- PowerPoint on background for a new study</td>
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</tbody>
</table>
| Clinical Study Operations (GCPs) | Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product | - CITI GCP Training  
- Staff in-service for a new study |
|----------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Study & Site Management | Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs) | - SOP you have developed  
- Study tools |
| Data Management & Informatics | Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database | - CRF designs  
- Data management training certificates |
| Leadership & Professionalism | Encompasses the principles and practice of leadership and professionalism in clinical research | - Membership to professional associations  
- SoCRA Certification |
| Communication & Teamwork | Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial | - Recorded Presentation  
- Publication  
- Abstract Submission  
- Posters |

If you are new to Portfolium and registered for your portfolio through DIAMOND, you will find information about the competencies listed above in two places in your portfolio: (1) the Skills section in your profile and (2) the Assignments section in your portfolio.
WHAT KINDS OF PROJECTS SHOULD I UPLOAD TO MY ePORTFOLIO?

You should post evidence of your clinical research professional role that can take the form of:

- CV/Resume
- References
- Job Description
- Education
- Academic Transcripts
- Work Products
- Certificates
- Certifications
- Abstracts
- Publications
- White Papers
- Posters
- Presentations
- Awards
- Continuing Education
- Post Degree Coursework
- Reflective Journaling (Private)
- Goals (Private)
- Performance Evaluations (Private)

BEST PRACTICES WHEN SELECTING PROJECTS TO UPLOAD

1. **Identify your strengths in your knowledge, skills and abilities.**
   Reflect on your past experience and work to identify on your current knowledge, skills and abilities. This is an ongoing process, so be prepared to revisit, and revaluate your conclusions on a regular basis while maintaining your ePortfolio. There is no single right way to reflect to identify on your current knowledge, skills and abilities. Consider utilizing the following options if they are right for your needs:

   - Complete the Clinical Research Professional Core Competencies Self-Assessment provided in this guide.
   - Review the training and assessment opportunities found on the DIAMOND portal by the relevant competency domains.
   - Talk to your colleagues about their skills in order to get a better sense of your own; these conversations can take place through the DIAMOND ePortfolio platform.
   - Review the profiles of colleagues you perceive as being less, equally and more skilled then yourself.
   - Consult relevant position descriptions and promotion policies provided by your employer.
   - Consult professional development resources provided by professional associations serving clinical research professionals.
2. **Gather your evidence/documentation.**
Make a plan for populating your ePortfolio by systematically collecting any items that might be relevant in folders on your personal computer. As you get your ePortfolio underway, create a folder entitled “add to my ePortfolio” and then file it elsewhere after uploading. Selectively choose the best items to show skills you want to highlight. Paper forms/certificates can be scanned as a PDF.

Reflect and identify from the relevant information and documentation you have gathered for your ePortfolio which items will support your clinical research professional core competency attainment.

As you look at each item it may be helpful to ask yourself these three questions:
• “Does this item have a positive impact?”
• “What does this item show about my skills/competencies in clinical research?”
• “What does this item show that I have learned?”

3. **Put your best foot forward.**
Choose portfolio items that make you look good. Review each item that you are considering. Ensure it is:
• free of errors and formatted appropriately
• reliable, authentic and current
• permitted (i.e. only share documents that are free from revealing confidential information from present and past employment, research sponsors, or volunteer organizations you have worked for).
NEW USER FAQs

- There are additional instruction guides found within Portfolium.
  - To access those, hover/click on your profile picture (located in the top right corner).
  - Select “user guide” from the vertical menu that pops up.
  - Click on “portfolium.com” user guide. This will open up a searchable user guide.
  - Search and find!

- Additional help is found in the bottom right corner icon where you can contact LIVE HELP at Portfolium who are known to be highly responsive and helpful.

- Click here to access a webinar recording for new users to find out about further DIAMOND ePortfolio resources.

CAN I SEE AN EXAMPLE PORTFOLIUM?
An exemplar for Portfolium can be found at:

- https://portfolium.com/JessicaSaunder2

This clinical research professional and Portfolium user generously agreed to allow their profile to be publicly accessible. Note the number of skills she provided evidence of. Some of this individual’s work examples come from her clinical research coursework.

CONNECT WITH THE DIAMOND TEAM AND PARTICIPANTS ON PORTFOLIUM!
Feel free to connect with the following DIAMOND Team Members or participants:

- Carolynn Thomas Jones Portfolium: https://portfolium.com/jones5342
WHY SHOULD I HAVE A CAREER DEVELOPMENT ePORTFOLIO IN CLINICAL RESEARCH?

Listed below are some key reasons why you should consider having a career development ePortfolio. Click here to access a video summarizing these reasons.

1. **Demonstrates professional growth as documentation and application of knowledge and skills.**
   - 93% of employers say demonstrated skills are more important than a degree. ¹
   - ePortfolios can be used as a tool in the employment process. ²

2. **Presents evidence of acquired domain-based clinical research competencies that are durable:**
   - Applied clinical research and other active learning skills
   - Goal setting (both education and career)
   - Independent learning/autonomy
   - Collaborative learning
   - Education and Training Evidence
   - Self-assessment, self-evaluation and self-regulating skills
   - Digital literacy skills
   - Work readiness
   - Lifelong learning
   - Self-management
   - Self-awareness

3. **Leverages career opportunities and growth** providing more visibility to current and potential employers who are: (a) searching for people with your knowledge, abilities and skills (b) evaluating your performance for a raise or promotion.
   - Work samples are the best indicator of authentic on-the-job performance and competency attainment. ³
   - Potential employers recall on your abilities via an ePortfolio (80%) compared to a paper CV/Resume (30%). ¹
   - Having an ePortfolio puts you out there!
     - 56% of all hiring managers are more impressed by a candidate’s personal website than any other personal branding tool—however, only 7% of job seekers actually have a personal website. ⁴
80% of job openings are never advertised; the average number of people who apply for any given job is 118; and only 20% of applicants ever get an interview.  

4. **The process of building and maintaining an ePortfolio** solidifies and strengthens your experience, what you have learned and gained over time, through your reflection of your various clinical research experiences.

5. **Technology today** provide easy solutions to ePortfolio development that are not confusing or cumbersome and are in keeping with evolving trends in workforce development.
CLINICAL RESEARCH PROFESSIONAL CORE COMPETENCIES SELF-ASSESSMENT

**DOMAIN 1: Scientific Concepts and Research Design:** *Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.*

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<tbody>
<tr>
<td><strong>Apply scientific principles when implementing a clinical or behavioral study.</strong></td>
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<td><strong>Implement data collection.</strong></td>
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<td><strong>Identify the research hypothesis in a study protocol.</strong></td>
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<td><strong>Identify primary &amp; secondary endpoints for use in data analysis.</strong></td>
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<td><strong>Review a clinical study protocol to ensure all elements are included.</strong></td>
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<td><strong>Compare &amp; assess the quality of results to study reports/publications.</strong></td>
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**DOMAIN 2: Ethical and Participant Safety Considerations:** *Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial*

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<tr>
<td><strong>Demonstrate the importance of clinical trial activities per protocol.</strong></td>
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<td><strong>Explain clinical equipoise &amp; therapeutic misconception, on patient understanding.</strong></td>
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<tr>
<td><strong>Consistently apply knowledge of clinical equipoise and therapeutic misconception.</strong></td>
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<tr>
<td><strong>Recognize, interpret, &amp; seek assistance to address participant concerns of therapeutic misconception or clinical equipoise.</strong></td>
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<tr>
<td><strong>Critically appraise and implement the principles of human subject protection and privacy.</strong></td>
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<td><strong>Communicate potential risks/hazards, &amp; benefits with terminology understandable to potential study participants in informed consent.</strong></td>
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<tr>
<td><strong>Apply knowledge of key regulations/guidelines with safety information in drafting informed consent.</strong></td>
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<tr>
<td><strong>Apply safeguards with research participants.</strong></td>
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<tr>
<td><strong>Anticipate situations when research participants may be considered vulnerable.</strong></td>
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<tr>
<td><strong>Compare/contrast ethical principles guiding clinical research across different global regions (e.g., ICH guidelines vs. FDA regulations, other country regulations).</strong></td>
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</table>
Examine conducting clinical trials in low and middle-income countries & differentiate the potential types of exploitation and benefits that populations in these countries may face in the conduct of a global clinical trial.

Articulate the necessity for a homogeneous patient population and consistency in protocol recruitment

Describe implications of deviations from inclusion/exclusion criteria on data quality and study validity & results generalizability.

Develop study materials to ensure application of inclusion/exclusion criteria.

Determine eligibility of study participants for complex studies (e.g., biomedical or interventional).

**DOMAIN 3: Investigational Products Development and Regulation:** *Encompasses knowledge of how investigational products are developed and regulated*

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Demonstrate an understanding of current events that inform guidelines & regulatory processes with FDA regulations/guidelines and those on a global scale.

List specific roles and responsibilities for each of the institutions participating in the investigational products development process (investigators, sponsors, CROs and regulatory bodies).

Recognize the scope of responsibilities of monitoring organizations like Research Pharmacy, Data Safety Monitoring Boards.

Interpret and execute the concepts, major elements, and objectives of investigational products development life cycle management process for medical products.

Describe and apply federal (US, EMA, or other) regulatory laws & guidance during the performance of complex clinical research operations.

Interpret the requirements of ICH GCP, the approved study protocol and sponsor study related SOPs.

Execute the development or editing of study related SOPs, reports, and / or submission for the relevant regulatory approval of the study.

Participate in implementation of Phase 1-3 clinical trials.

Differentiate between the purposes of the IND, NDA, BLA & each phase of clinical development and the research questions answered at each phase.

Assess occurrence & coordinate with PI on classification of adverse events during a clinical trial.

Complete & submit adverse event reports, according to appropriate requirements & timeline.
Compare regional regulations and how their differences could impact the conduct of trials or the review of medical product approvals.

**DOMAIN 4: Clinical Study Operations (Good Clinical Practice):** Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product.

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<tr>
<td>Review &amp; comment on trial protocols to ensure the links between the objective of developing a new intervention and the related trial goal and design is accurate.</td>
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<tr>
<td>Provide input/share ideas, proactively/reactively, on trial design.</td>
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<td>Describe how GCP principles are incorporated into clinical research.</td>
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<tr>
<td>Describe roles and responsibilities of IRB and sponsors as set forth in federal regulations and GCPs.</td>
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<tr>
<td>Performs role in accordance with GCP guidelines.</td>
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<tr>
<td>Participate in the implementation of a clinical research protocol &amp; assure that, with minimal supervision, the ICH Good Clinical Practice Guidelines are being followed during the conduct of research procedures and data collection</td>
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<tr>
<td>Assist in the identification of country-specific regulations that apply during a clinical study.</td>
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<tr>
<td>Apply current processes/procedures for global regulatory agency application requirements clinical studies.</td>
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<tr>
<td>Articulate the specific procedures &amp; elements for control, storage &amp; dispensing of investigational product.</td>
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<tr>
<td>Determine deviations in the process of handling study medication and report/solve the issue.</td>
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<tr>
<td>Differentiate the reporting timelines and requirements for an SAE and SUSAR across various international guidelines (e.g., FDA, EMA, ICH, etc.)</td>
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<tr>
<td>Execute the reporting of an SAE to the appropriate entity based on their respective role.</td>
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<tr>
<td>Apply appropriate protection and privacy safeguards when conducting clinical studies.</td>
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<tr>
<td>Report situations when human research subjects may require protection &amp; privacy.</td>
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<tr>
<td>Recognize existing global regulations &amp; local rules differ among countries in protecting human research subjects &amp; their privacy.</td>
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<tr>
<td>Employ and implement the clinical monitoring plan to complete monitoring tasks/activities.</td>
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<tr>
<td>Address complex monitoring issues with minimal supervision or guidance.</td>
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</table>
Provide guidance to others to resolve simple & moderately complex monitoring issues.

Distinguish between scope of audits conducted by sponsors, IRB and regulatory authority.

Identify research components inspected during a clinical study audit.

Distinguish between routing and for-cause audits and inspections.

Execute safety reporting within required timelines through appropriate channels.

Classify safety issues and report them to regulatory authorities and IRBs.

Implement international guidelines and requirements across relevant agencies (e.g., FDA, EMA, ICH, etc.).

Relate safety issues according to monitoring and pharmacovigilance plans.

**DOMAIN 5: Study and Site Management:** Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)

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</table>

Provide input and guidance in the study selection process, including the ability to assess financial and logistical feasibility of conducting a study at the research site.

Assist in organizing and conducting pre-site visits.

Assist in estimating budgets for a potential study.

Critique and recommend changes to proposed financial budgets, timelines, and amount/type of personnel necessary to conduct a clinical study.

Monitor the progress of a clinical study towards milestones and identify trends or risks during study execution. Implements mitigation plans.

Identify and understand the importance of the quality management plan (QMP) and teach others about the overall scope of the QMP.

Implement risk mitigation steps as defined in the plan and develop a strategy to educate others on its content and application.

Interpret subject recruitment and retention tracking data to determine if changes are needed.

Develop basic methods for capturing and reporting on recruitment and retention.

Apply local and international regulatory requirements to the use of different recruitment tools.
Organize and appropriately process contracts, materials transfer agreements, budgets, indemnification agreements, confidentiality agreements and conflict of interest reporting.

Develop and/or follow SOPs that mitigate legal risks in conducting clinical trials.

Understand and articulate applicable regulations and accurately follow established processes in place to ensure compliance.

Describe the various team roles (Sponsor, PI) and their responsibilities in the compliant conduct of clinical research.

Describe the impact of compliance on the safe and ethical conduct of clinical research studies.

**DOMAIN 6: Data Management and Informatics:** *Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database*

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<tbody>
<tr>
<td>Perform randomization activities to ensure accurate designation of new study participants.</td>
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<td>Describe the statistical requirements to answer the study question (hypothesis) in a study protocol.</td>
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<tr>
<td>Apply all aspects of the clinical data management plan (CDMP) to an active clinical study with regards to the flow of data from the site to the clinical database as well as the flow of data from other sources, for example laboratory electronic uploads, EMR transfers, etc.</td>
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<tr>
<td>Manage queries and recommend whether the flow and quality of the clinical data meets the standards set in the CDMP.</td>
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<tr>
<td>Implement industry, federal and GCP accepted standards and best practices for data management.</td>
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<tr>
<td>Perform data management activities across clinical studies from creation of protocol specific source documents, collection and entry of data and performing quality audits.</td>
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<tr>
<td>Independently ensure compliance with data quality related SOP.</td>
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<tr>
<td>Provide input and share ideas, pro- and reactively, related to data quality and the related processes.</td>
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**DOMAIN 7: Leadership and Professionalism:** *Encompasses the principles and practice of leadership and professionalism in clinical research*

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<tr>
<th>Rating Scale</th>
<th>0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength</th>
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<tbody>
<tr>
<td>Assist in study management using effective communication methods and documentation.</td>
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Train and mentor Fundamental Level staff.

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<tr>
<th>Demonstrate effective time management and organizational skill when managing multiple research related projects.</th>
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<tr>
<td>Recognize, implement, and manage the procedures in a clinical research study to minimize the risks of ethical/professional conflicts.</td>
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<tr>
<td>Implement risk management strategies within role responsibilities.</td>
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<tr>
<td>Apply professional/ethical regulations and international guidelines in each facet of clinical research.</td>
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<tr>
<td>Demonstrate through actions &amp; documentation of tasks during the conduct of clinical research an understanding of how procedures/processes assure professional/ethical conduct.</td>
</tr>
<tr>
<td>Apply regional/country and cultural considerations during study design and conduct.</td>
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<tr>
<td>Incorporate the regulatory requirements during the implementation of multi-country trials.</td>
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**DOMAIN 8: Communications and Teamwork:** *Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial.*

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| Apply professional communication practices written & verbal interactions with other parties to maintain legal/productive relationships during the research study. |
| Describe methods of a published study and basis for the conclusions made from the results obtained. |
| Search literature using key terms to find articles on specific subjects. |
| Explain the difference between a primary source and a secondary source in professional literature. |
| Identify & facilitate the activities essential to ensuring effective team operations during a clinical study. |
| Demonstrate an understanding of the cross-functional team in a communication plan. |
References


4. Smith J. Why every job seeker should have a personal website, and what it should include. Forbes.2013. https://www.forbes.com/sites/jacquelynsmith/2013/04/26/why-every-job-seeker-should-have-a-personal-website-and-what-it-should-include/#f97407f119e1
