

## CLINICAL RESEARCH ASSOCIATE STARTER KIT

*As a CRA, this is what your first 3 months will look like, if you are hired into the CRA I position or higher.*

*If you are hired into an entry-level role, which means the organization intends to train you, your schedule may look slightly different. Simply add 30 days after “week 1” for your CRA training.*

### **CRA's hired into CRA 1 or higher**

<b>Timeline</b>	<b>Task</b>	<b>Expectations/ Resources/Systems</b>
1 <sup>st</sup> week	Company Introduction and orientation	
2 <sup>nd</sup> and 3 <sup>rd</sup> week	Training on Company SOPs, systems, and policies.	<ul style="list-style-type: none"> <li>• Time management systems (SAP),</li> <li>• Travel scheduling and expense systems (concur)</li> <li>• IT systems (trouble shooting and systems access)</li> <li>• HR systems (PTO request, Pay, and Tax documents)</li> <li>• LMS-learning management system (SOPs, Work Instructions, and Process documents.)</li> <li>• Intranet/SharePoint</li> <li>• Use of VPN and Authenticator apps</li> <li>• GCP training – ACRP, Brookwood, etc.</li> </ul>
4 <sup>th</sup> and 5 <sup>th</sup> week	Study-specific training	<ul style="list-style-type: none"> <li>• Protocol training (electronic documents delivered to your email, LMS, or CTMS) depending on what the company uses.</li> <li>• Pharmacy manual</li> <li>• Investigator Brochure or instructions for use</li> <li>• Lab Manual</li> <li>• eTMF plan</li> <li>• PSV slides</li> <li>• SIV slides</li> <li>• Monitoring Plan</li> <li>• Study Intranet/SharePoint</li> <li>• Internal Server</li> <li>• Standard Operational Manual</li> <li>• Vendor training materials (EDC, IWRS, ePRO, etc.)</li> </ul>
6 <sup>th</sup> week to 8 <sup>th</sup> week	Site assignment and Transition	<ul style="list-style-type: none"> <li>• If you are on an <b>ongoing study</b>, you may inherit some sites. This means someone will hand-off some sites to you.</li> </ul>

		<ul style="list-style-type: none"> <li>○ If this is the case, the <b>outgoing CRA</b> will schedule a call/meeting with you, as the <b>incoming CRA</b> to discuss the overall site status with you.</li> <li>○ The call is followed by signing of the transition form.</li> <li>○ After the form is signed by <b>incoming CRA, outgoing CRA</b>, and sometimes <b>lead and project manager</b>, the outgoing CRA will notify the site. Only after the site is notified will you be able to reach out to the site and resume your role as the site's monitor.</li> <li>● If you are on a brand-new study, then you may be required to perform site selection visits and site initiation visits. <ul style="list-style-type: none"> <li>○ <b>Sites are not permanently assigned to CRAs only until after the SIV.</b> This means CRAs can be called to cover selection and initiation visits, without being the permanent CRAs for those sites.</li> <li>○ Most leads wait until 75% of Sites have been SIV'd before they assign permanent CRAs. The permanent assignments are usually determined by geographical regions and site experience.</li> </ul> </li> </ul>
9 <sup>th</sup> week	Permanent assignment	<ul style="list-style-type: none"> <li>● By week 9, you've probably completed all your onboarding tasks and now required to go on site.</li> <li>● Purchase "<b>The Clinical Monitor's Planner</b>" to determine how to prepare and what to do during your visit. <a href="#">The Clinical Monitor's Planner/</a></li> </ul>

*The timeline are fair estimates of how most organizations operate. These timelines may be expedited based on the needs of the organization; however, the Tasks, Expectations, Resources, and Systems ALWAYS FOLLOW this order.*