Reviewing a Clinical Study Protocol

You have just been assigned to a new study. How should you prepare and get up to speed? What key information do you need to know about the protocol?

As you start, review these sections and either jot down main points here or flag the section in the protocol for easy future reference. Use the check boxes so you know which areas you have reviewed. Once you have completed this outline of key sections, go back and review the entire protocol from start to finish and add any study specific nuances to the "My Notes" section on the next page.

As a bonus tip, also review the informed consent template for this study so you can learn about the study from the patient's prospective.

- [ ] **Study Rationale/Background:**

- [ ] **Study Population:**

- [ ] **How Many Sites:**

- [ ] **Which Countries and Patients Needed per Site:**

- [ ] **Inclusion Criteria:**

- [ ] **Exclusion Criteria:**

- [ ] **Study Synopsis Review:**

- [ ] **Schedule of Assessments:**

- [ ] **Investigational Product:**

- [ ] **Allowable Medications:**

- [ ] **Prohibited Medications:**

- [ ] **Adverse Events:**

- [ ] **Serious Adverse Events:**

Your project team or Clinical Research Associate will provide study specific training to you so you can ask more questions about the project, overall study status and timelines.

My Notes