

DOM CRE Manager of Regulatory Relations
Roles and Responsibilities

Regulatory Goal: Improve effort-tracking methods to provide a fuller picture of MOU pricing

1. Management of all Regulatory team members and activities (40%)
 2. Being a resource/primary contact for regulatory in the CRE (15%)
 3. Tracking all regulatory processes (startup, amendments, etc.) and effort (15%)
 4. Leading regulatory portions of required meetings (15%)
 5. Management of regulatory documents, including long-term storage (15%)

1. Management of all Regulatory team members and activities (40%)
 - a. Assign study startup and active study duties to team
 - b. Provide support when necessary
 - c. Meet with team regulatory to address any barriers to success
2. Being a resource/primary contact for regulatory in the CRE (15%)
 - a. Problem solve, provide solutions and guidance on regulatory issues
 - b. Point person for overall regulatory questions/concerns
 - c. Provide assistance/planning when necessary
3. Tracking all regulatory processes (startup, amendments, etc.) and effort (15%)
 - a. Ensure all effort tracking and work completed data is maintained appropriately
 - b. Prepare figures for MOU assessment
 - c. Provide input on areas of concern, including delays, compounding issues, etc.
 - d. Submission of amendment RPLs
4. Leading regulatory portions of required meetings (15%)
 - a. Meet independently with collaborators/CRE leadership when required
 - b. Attend meetings and provide status reports on regulatory activities as required
5. Management of regulatory documents, including long-term storage (15%)
 - a. Oversee storage of regulatory documents both electronically and physically, throughout study
 - b. Maintain documents in long-term storage
 - c. Destroy documents when required