Renewal of License to act as Contract Research Organization, Clinical Trial Site, BA/BE Studies Center & Bioanalytical Lab.

**Performance of function as prescribed in the Bio-Study Rules 2017 by the Applicant**

- Creation of application on Form-III of the Bio-Study Rules, 2017 for Licensing of CRO, Clinical Trial Site, BA/BE Studies Center or Bio Analytical Lab
- Submission of Application Dossier as per checklist
- Rectification of Shortcomings

**Actions to be taken by DRAP**

- Receipt of application Dossier
- Preliminary Evaluation by Desk Officer (Within 30 working days)
- Complete

  **Placement before Clinical Study Committee (CSC)**
  - Due to absence of basic requirements. Not Recommended
  - Constitution of inspection panel by CSC or by Chairman CSC.

  **Inspection report placed before Clinical Study Committee (Evaluation of report within 10 working days)**
  - Not Recommended on the basis of panel report
  - Issuance of Rejection letter
  - Rejection letter

  **Observations/Deficiencies**
  - Issuance of Renewed License on positive inspection report, to act as BA/BE Studies Center on Form-IV and/or License to act as CRO, Clinical Trial Site or Bio-Analytical Laboratory on Form-V of the Bio-Study Rules, 2017 issued to the applicant. (valid for 3 years) (Within 15 working days after finalization of CSC meeting minutes & approval)

**Application can submit appeal against decision of CSC to the Authority within 30 days of receipt of decision**

**Recommended**

**Deferred on the basis of shortcomings**