

## Planning & Execution

**Evaluation and planning of clinical development projects**

**Project team:**  
- Qualifications  
- Training  
**For the assigned project and functions**

**Regulatory and IEC submissions**

**Coordination of:**  
- Project team including vendors  
- Pertinent clinical operations  
**To ensure project objectives are met timely and on budget**

## Quality & Risk Control

**Adherence to:**  
- ICH GCP  
- Scientific & regulatory requirements  
- Clinical study protocol  
- Relevant SOPs for clinical operations

**Trial Master File (TMF):**  
- Handling  
- Review

**Audit:**  
- Responses  
- Appropriate resolutions

**Surveillance of monitoring and overall clinical trial performance to safeguard:**  
- Subject safety  
- Data quality and integrity