



D Y PATIL
DEEMED TO BE
UNIVERSITY
— SCHOOL OF —
MEDICINE
NAVI MUMBAI

Clinical Research Unit (CRU)

The Clinical Research Unit (CRU) of the School of Medicine is located in the Department of Pharmacology on the 5th floor, D Y Patil University School of Medicine building.

The CRU provides a location and skilled staff for investigators conducting inpatient and outpatient clinical and translational research at the D Y Patil Deemed to be University, Navi Mumbai.

The CRU services include clinical research facilities (supporting both outpatient and inpatient studies) and research support services.

The CRU functions as a Site Management Organization (SMO) that provides clinical trial related services to a contract research organization (CRO), a pharmaceutical company, a biotechnology company, a medical device company or investigators at D Y Patil University.

Roles and responsibilities of SMO:

1. Contract with CRO's and sponsors
2. Submission for Independent Ethics Committee (IEC) approval
3. Patient Counselling
4. Patient Recruitment
5. Patient Follow-up
6. Informed consent administration
7. Site feasibility and site selection activities
8. Site initiation and trial close-out operations
9. Trial-related documents archival and maintenance
10. Reporting serious adverse events to the Sponsor or CRO and the IRB/IEC
11. Ensuring protocol compliance
12. Advising & alerting investigators of potential protocol violations
13. Advising & alerting investigators of potential ICH-GCP violations