PGDBD-Elective course IV

IT 607 Personalized medicine and clinical trials

Genomics and personalized medicine. ENCODE project and mapping of the functional genome. Next generation sequencing and multi-gene approaches. Pharmacogenetics and pharmacogenomics.
Epigenetics. Diabetes and DNA methylation. Proteomics and metabolomics.
Integrative medicine. Nutrition and exercise.
Placebo effect. Psychological factors and neurobiology.
Personalized medicines for cancer. Oncogenes and molecular abnormalities. Tumor subtypes and personalized diagnostics. MicroRNA. Overview of Liquid biopsy and Immunotherapy.
Personalized medicine approaches for other diseases such as Type II diabetes, Rheumatoid Arthritis, Multiple sclerosis, cardiovascular disease and AIDS.

Biomarkers for personalized medicine. Druggable genome. Genome-wide association studies (GWAS). International HapMap project. Clinical biomarker discovery and somatic mutations. Moral and ethical issues.

Clinical trial fundamentals. Phase I, Phase II, Phase III and Phase IV trials.

Ethical considerations in clinical trial. Safety, Privacy and confidentiality.
Trial with extensive data collection. Superiority vs non-inferiority trials. Intervention.

Response variables. Biomarkers and surrogate response.
Considerations for study population in clinical trials. Pharmacogenetics and generalizations. Recruitment.
Trial design. Randomized control traits. Concurrent studies. Historical data and limitations. Cross-over design. Withdrawal studies. Factorial design. Hybrid designs.
Randomization process. Simple, blocked, stratified and adaptive randomization procedures.
Blinding. Single, double and triple blind trials.
Sample sizes and baseline assessments. Reporting harm. Health related quality of life (HRQL) measures. Methodological and design issues.
Multi center trials. Large, simple trials.
Regulatory issues. Pretrial requirements. Interventions. Post trial requirements. Comparative overview of pretrial, during trial and post trial regulatory requirements in Indian, USA and Canada.

Practicals:

1. Case studies on clinical data analysis, specially on large cohorts.

Additional requirements for Project work:

This will depend on individual labs. Large scale bid data bases project will be implemented using compute intensive tasks such as traditional and deep machine learning, high throughput docking, MD simulations of large libraries and long time scales, genomic data analysis protocols and other related works based in student/guide synergies.