

PH.D. PRE-COURSE WORK EXAMINATION SYLLABUS

Paper II: Recent Advances in Clinical Research

Sr. No.	Topic	Details	Hours
1	Adaptive Clinical Trial Designs	<ul style="list-style-type: none"> - Bayesian adaptive designs - Sample size and Power estimation methods, sampling and recruitment - Designing Seamless randomized blinded Phase II/III trials - Platform trials and master protocols - Designing questionnaires, interviews and online surveys 	3
2	Real-World Evidence in Clinical Research	<ul style="list-style-type: none"> - Big data analytics in healthcare - Pragmatic clinical trials - Use of electronic health records in clinical research and Data Management - Regulatory perspectives on real-world evidence 	3
3	Patient-Centered Outcomes Research	<ul style="list-style-type: none"> - Patient-reported outcome measures (PROMs) - Patient preference studies - Stakeholder engagement in clinical research - Health-related quality of life assessment - Writing a project proposal for obtaining funds 	3
4	Precision Medicine and Biomarkers	<ul style="list-style-type: none"> - Pharmacogenomics in clinical trials - Liquid biopsy and circulating tumor DNA - Imaging biomarkers in drug development - Companion diagnostics-Designing Case Control Studies 	3
5	Digital Health Technologies in Clinical Trials	<ul style="list-style-type: none"> - Wearable devices and sensors - Mobile health applications - Remote patient monitoring - Virtual and decentralized clinical trials - Role of Artificial Intelligence in Health Research 	3
6	Advanced Statistical Methods	<ul style="list-style-type: none"> - Causal inference methods - Machine learning in clinical data analysis - Propensity score methods - Network meta-analysis 	3
7	Ethical Considerations in Modern Clinical Research	<ul style="list-style-type: none"> - Informed consent in the digital age - Data privacy and security in multicenter clinical trials 	3

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		<ul style="list-style-type: none"> - Ethical issues in clinical trials and gene therapy trials - Global health equity in clinical research 	
8	Innovative Clinical Trial Operations	<ul style="list-style-type: none"> - Risk-based monitoring strategies - eConsent and ePRO implementation -Blockchain in clinical trial data management - Artificial intelligence in site selection and recruitment 	3
9	Regulatory Science Advancements	<ul style="list-style-type: none"> - Accelerated approval pathways - Global regulatory harmonization efforts - Adaptive licensing and rolling reviews - Post-marketing surveillance strategies 	3
10	Translational Research Methods	<ul style="list-style-type: none"> - 'Omics' technologies in clinical research - In silico trials and predictive modeling - Organoids and 3D cell culture models - Microbiome research in clinical trials 	3
11	Health Economics and Outcomes Research	<ul style="list-style-type: none"> - Cost-effectiveness analysis in clinical trials - Value-based healthcare assessments - Payer perspectives in trial design - Comparative effectiveness research methods 	3
12	Emerging Therapeutic Modalities	<ul style="list-style-type: none"> - Gene therapy and gene editing trials - CAR-T cell therapy studies - RNA therapeutics clinical development - Psychedelic medicine trials 	3

Total Hours: 36