

| DEPARTMENT OF STATISTICS | | | | <i>Certificate courses (PG students)</i> | | | | |
|--------------------------|--------------------|-------------|--------------------------------|--|---------------------|-----|-----|-------|
| Sem | Course Type | Course Code | Course Title | Credits | Total Contact Hours | CIA | Ext | Total |
| | Certificate Course | | Statistics for Clinical Trials | 2 | 30 | 50 | 50 | 100 |

| Nature of Course | | | |
|---------------------|---|--|---------------------------|
| Knowledge and skill | ✓ | | Employability oriented |
| Skill oriented | ✓ | | Entrepreneurship oriented |

| Unit | Description | Hours |
|------|--|-------|
| 1 | Introduction to clinical trials : the need and ethics of clinical trials, bias and random error in clinical studies, conduct of clinical trials, overview of Phase I-IV trials, multi-center trials. | 6 |
| 2 | Data management : data definitions, case report forms, database design, data collection systems for good clinical practice | 6 |
| 3 | Design of clinical trials : parallel vs. cross-over designs, cross-sectional vs. longitudinal designs, review of factorial designs, objectives and endpoints of clinical trials, design of Phase I trials, design of single-stage and multi-stage Phase II trials, design and monitoring of Phase III trials with sequential stopping, design of bioequivalence trials | 6 |
| 4 | Reporting and analysis : analysis of categorical outcomes from Phase I - III trials, analysis of survival data from clinical trials. Surrogate endpoints : selection and design of trials with surrogate endpoints, analysis of surrogate endpoint data. | 6 |
| 5 | Meta-analysis of clinical trials | 6 |

References:

1. S. Piantadosi (1997). Clinical Trials : A Methodologic Perspective. Wiley and Sons.
2. C. Jennison and B. W. Turnbull (1999). Group Sequential Methods with Applications to Clinical Trials, CRC Press.
3. L. M. Friedman, C. Furburg, D. L. Demets (1998). Fundamentals of Clinical Trials, Springer Verlag.
4. J. L. Fleiss (1989). The Design and Analysis of Clinical Experiments. Wiley and Sons.
5. E. Marubeni and M. G. Valsecchi (1994). Analyzing Survival Data from Clinical Trials and Observational Studies, Wiley and Sons.