MODULE HANDBOOK

INTRODUCTION TO CLINICAL TRIALS

STATISTICS UNDERGRADUATE PROGRAM
DEPARTMENT OF STATISTICS
FACULTY OF SCIENCE AND DATA ANALYTICS
INSTITUT TEKNOLOGI SEPULUH NOPEMBER
SURABAYA

ENDORSEMENT PAGE

	MODULE HANDBOOK **INTRODUCTION TO CLINICAL TRIALS** **STATISTICS UNDERGRADUATE PROGRAM** **DEPARTMENT OF STATISTICS** **INSTITUT TEKNOLOGI SEPULUH NOPEMBER**

Proses *Process*	Penanggung Jawab *Person in Charge*			Tanggal *Date*
	Nama *Name*	Jabatan *Position*	Tanda tangan *Signature*	
Perumus *Preparation*	Jerry Dwi T.P., S.Si, M.Si, Ph.D	Dosen *Lecturer*		
Pemeriksa dan Pengendalian *Review and Control*	Dr. Santi Wulan P, S.Si., M.Si; Jerry Dwi T.P., S.Si, M.Si, Ph.D	Tim kurikulum *Curriculum team*		
Persetujuan *Approval*	Jerry Dwi T.P., S.Si, M.Si, Ph.D	Koordinator RMK *Course Cluster Coordinator*		
Penetapan *Determination*	Dr. Kartika Fithriasari, M.Si	Kepala Departemen *Head of Department*		

MODULE HANDBOOK
INTRODUCTION TO CLINICAL TRIALS

Module name	INTRODUCTION TO CLINICAL TRIALS	
Module level	Undergraduate	
Code	SS234754	
Course (if applicable)	INTRODUCTION TO CLINICAL TRIALS	
Semester	7	
Person responsible for the module	Jerry Dwi T.P., S.Si, M.Si, Ph.D	
Lecturer	Dr. Santi Wulan P, S.Si., M.Si; Jerry Dwi T.P., S.Si, M.Si, Ph.D	
Language	Bahasa Indonesia and English	
Relation to curriculum	Undergradute degree program, elective, 7th semester.	
Type of teaching, contact hours	Case method, Non-SCL, other SCL method	
Workload	1. Lectures [L]: 3 x 50 = 150 minutes per week. 2. Exercises and Assignments [EA]: 3 x 60 = 180 minutes (3 hours) per week. 3. Independent Learning [IL]: 3 x 60 = 180 minutes (3 hours) per week.	
Credit points	3 credit points (SKS) Equivalent to 4.8 ECTS	
Requirements according to the examination regulations	A student must have attended at least 80% of the lectures to sit in the exams.	
Mandatory prerequisites	-	
Learning outcomes and their corresponding PLOs	CLO. 1 Able to explain the concepts of descriptive statistics and inference for clinical trial data CLO. 2 Able to utilize clinical trial data to support work completion CLO.3 Able to formulate problem solutions by analyzing clinical trial data and interpreting them appropriately CLO.4 Able to use the necessary computing techniques and modern computer devices and able to choose appropriate methods for clinical trial data in solving real problems	PLO-5 PLO-7 PLO-9
Content	-	
Assessment and its weight	Task 1 (25%) Mid Exam (25%) Task 2 (25%) Final Exam (25%)	
Media employed	LCD, whiteboard, websites (myITS Classroom), zoom	

Reading list	1. -

	INSTITUT TEKNOLOGI SEPULUH NOPEMBER **FAKULTAS SAINS DAN ANALITIKA DATA** **PROGRAM STUDI SARJANA STATISTIKA** **DEPARTEMEN STATISTIKA**

RENCANA PEMBELAJARAN SEMESTER/
SEMESTER LEARNING PLAN

MATA KULIAH (MK)/ *Course*	**KODE/** *Code*	**Rumpun MK/** *Course Group*	**BOBOT (sks)/** *Weight (credit)*		**SEMESTER/** *Semester*	**Tgl Penyusunan/** *Drafting Date*
PENGANTAR UJI KLINIS/ *INTRODUCTION TO CLINICAL TRIALS*	SS234754	Statistika Lingkungan dan Kesehatan	**T=3**	**P=0**	VII	Januari 2023

OTORISASI/ *AUTHORIZATION*	**Pengembang RPS/** *RPS Developer*	**Koordinator RMK/** *Course Group Coordinator*	**Ketua PRODI/** *Head of Department*
	Dr. Santi Wulan P, S.Si., M.Si; Jerry Dwi T.P., S.Si, M.Si, Ph.D	Jerry Dwi T.P., S.Si, M.Si, Ph.D	Dr. Kartika Fithriasari, M.Si

Capaian Pembelajaran (CP)/ *Learning Achievement*	**CPL-PRODI yang dibebankan pada MK/** *PLO*	
	CPL-5	Mampu menerapkan teori statistika pada metode statistika
	CPL-7	Mampu menggunakan perangkat komputasi modern untuk menyelesaikan permasalahan statistik
	CPL-9	Mampu menerapkan metode statistika dengan tepat serta mengevaluasinya untuk menganalisis permasalahan teoritis dan riil
	PLO-5	*Able to apply statistical theory to statistical methods*
	PLO-7	*Able to use modern computing devices to solve statistical problems*
	PLO-9	*Able to apply statistical methods correctly and evaluate them to analyze theoretical and real problems*

<table>
<tr><td></td><td>Capaian Pembelajaran Mata Kuliah (CPMK)/
CLO</td></tr>
<tr><td></td><td>CPMK. 1 Mampu menjelaskan konsep statistika deskriptif dan inferensia untuk data uji klinis
CPMK. 2 Mampu memanfaatkan data uji klinis untuk mendukung penyelesaian pekerjaan
CPMK. 3 Mampu memformulasikan penyelesaian masalah dengan menganalisis data uji klinis serta menginterpretasikan dengan tepat
CPMK. 4 Mampu menggunakan teknik komputasi dan perangkat komputer modern yang diperlukan serta mampu memilih metode yang sesuai bagi data uji klinis dalam menyelesaikan masalah riil

CLO. 1 Able to explain the concepts of descriptive statistics and inference for clinical trial data
CLO. 2 Able to utilize clinical trial data to support work completion
CLO.3 Able to formulate problem solutions by analyzing clinical trial data and interpreting them appropriately
CLO.4 Able to use the necessary computing techniques and modern computer devices and able to choose appropriate methods for clinical trial data in solving real problems</td></tr>
<tr><td></td><td>Matrik CPL – CPMK
PLO-CLO Matrix
<table>
<tr><td></td><td>CPL-5</td><td>CPL-7</td><td>CPL-9</td></tr>
<tr><td>CPMK-1</td><td>✓</td><td></td><td>✓</td></tr>
<tr><td>CPMK-2</td><td>✓</td><td></td><td>✓</td></tr>
<tr><td>CPMK-3</td><td></td><td>✓</td><td>✓</td></tr>
<tr><td>CPMK-4</td><td></td><td>✓</td><td>✓</td></tr>
</table></td></tr>
<tr><td>Deskripsi Singkat MK/
Course Description</td><td>-</td></tr>
<tr><td>Bahan Kajian: Materi Pembelajaran/
Course Material</td><td>Teori Statistika
Statistical Theory</td></tr>
<tr><td>Pustaka/
References</td><td>Utama/Primary:
1. -
Pendukung/Secondary:
1. -</td></tr>
</table>

Dosen Pengampu/ ***Lecturers***	Dr. Santi Wulan P, S.Si., M.Si; Jerry Dwi T.P., S.Si, M.Si, Ph.D
Matakuliah syarat/ ***Pre-requisite Course***	-

Mg Ke- ***Week***	**Kemampuan akhir tiap tahapan belajar (Sub-CPMK)** ***Final capability for each learning step***	**Penilaian** ***Evaluation***		**Bantuk Pembelajaran, Metode Pembelajaran, Penugasan Mahasiswa,** **[Estimasi Waktu]** ***Learning Format Learning Methods Assignment for Student*** **[Estimated Time]**		**Materi Pembelajaran** **[Pustaka]** ***Learning Material [References]***	**Bobot Penilaian (%)** ***Evaluation Weight (%)***
		Indikator ***Indicator***	**Kriteria & Bentuk** ***Criteria and Format***	**Luring** ***Offline***	**Daring** ***Online***		
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**(8)**
1	Pengenalan Uji Klinis *Introduction to Clinical Trials*						
2	What's the Question? *What's the Question?*						

3	Study Population and Basic Study Design *Study Population and Basic Study Design*						
4	Metode-metode Randomisasi *Randomization Methods*						
5	Permasalahan Ukuran Sample *Sample Size Issues*						
6	Pemantauan Data, Fungsi Komite Pemantau dan Metode Statistik *Data Monitoring, Monitoring Committee Function and Statistical Methods*						
7	Penilaian Kualitas Hidup *Quality of Life Assessment*						
8	**ETS/*Midterm***						
9	Bridging Studies and Multi-Regional Clinical Trials *Bridging Studies and Multi-Regional Clinical Trials*						
10	Survival Analysis *Survival Analysis*						
11	Analisis Meta *Meta Analysis*						
12	Permasalahan dalam Analisis Uji Klinis Acak *Issues in Analysis of Randomized Clinical Trials*						
13	Biomarkers *Biomarkers*						

14	Patient/Trial Closeout and Reporting of Clinical Trials *Patient/Trial Closeout and Reporting of Clinical Trials*						
15	Protokol dan Prosedur Manual *Protocols and Manual of Procedures*						
16	**Evaluasi Akhir Semester / Ujian Akhir Semester/*Final Exam***						

	RENCANA ASESMEN & EVALUASI *Assessment and Evaluation Plan* Program Studi Sarjana Statistika / *Statistics Undergraduate Program* **PENGANTAR UJI KLINIS** / *INTRODUCTION TO CLINICAL TRIALS*	**RA&E** SLK-54

Kode MK: SS234754 *Course Code:* *SS234754*	**Bobot sks (T/P):** 3 *CREDITS : 3*	**Rumpun MK:** Statistika Lingkungan dan Kesehatan *Course cluster:* *Environment and Health Statistics*	Smt: VII *Semester VII*
OTORISASI *AUTHORIZATION*	**Penyusun** *Author* Dr. Santi Wulan P, S.Si., M.Si; Jerry Dwi T.P., S.Si, M.Si, Ph.D	**Koordinator RMK** *Coordinator of course cluster* Jerry Dwi T.P., S.Si, M.Si, Ph.D	**Kaprodi** *Head of Department* Dr. Kartika F, M.Si.

Mg ke (1)	Sub CP-MK (2)		Bentuk Asesmen (Penilaian) / Evaluation Type (3)	Bobot / Scoring (%) (4)
	No	Kemampuan akhir / Final Capability		
1		Pengenalan Uji Klinis *Introduction to Clinical Trials*		
2		What's the Question? *What's the Question?*		
3		Study Population and Basic Study Design *Study Population and Basic Study Design*		
4		Metode-metode Randomisasi *Randomization Methods*		
5		Permasalahan Ukuran Sample *Sample Size Issues*		
6		Pemantauan Data, Fungsi Komite Pemantau dan Metode Statistik *Data Monitoring, Monitoring Committee Function and Statistical Methods*		
7		Penilaian Kualitas Hidup *Quality of Life Assessment*		
8		Evaluasi Tengah Semester *Mid Semester Evaluation*		
9		Bridging Studies and Multi-Regional Clinical Trials *Bridging Studies and Multi-Regional Clinical Trials*		

10		Survival Analysis *Survival Analysis*		
11		Analisis Meta *Meta Analysis*		
12		Permasalahan dalam Analisis Uji Klinis Acak *Issues in Analysis of Randomized Clinical Trials*		
13		Biomarkers *Biomarkers*		
14		Patient/Trial Closeout and Reporting of Clinical Trials *Patient/Trial Closeout and Reporting of Clinical Trials*		
15		Protokol dan Prosedur Manual *Protocols and Manual of Procedures*		
16		Evaluasi Akhir *Final Evaluation*		
Total Bobot Penilaian				**100%**