UNIVERSIDADE ESTADUAL DE MARINGÁ
PRÓ-REITORIA DE ENSINO

PROGRAMA DE DISCIPLINA

Curso:	Programa de Pós-Graduação em Bioestatística
Modalidade:	Mestrado e Doutorado
Departamento:	PBE
Centro:	De Ciências Exatas

COMPONENTE CURRICULAR

Nome: ***Introduction to Clinical Trials***			Código: **DES4081**
Carga Horária: **30 horas**	Crédito(s): **2**	**OPTATIVA**	Ano Letivo: **2026**

1. EMENTA

This course covers the main modern clinical trial designs, pilot/feasibility, dose-escalation, proof-of-concept/dose-ranging, basket/umbrella/platform, group-sequential/adaptive, and pragmatic trials, combining theory with hands-on R programming practice.

2. OBJETIVOS

Enable students to understand the rational and statistical principles of the main clinical trial designs and to implement and evaluate them in R.

3. CONTEÚDO PROGRAMÁTICO

1. Introduction, Pilot and Feasibility trials
2. Dose-Escalation trials
3. Proof-of-Concept and Dose-Ranging trials
4. Basket, Umbrella and Platform trials
5. Group-Sequential and Adaptive trials
6. Pragmatic trials
7. Application in an R Coding Project

4. METODOLOGIA

Classes take place in a computer lab, combining short theoretical lectures with guided practical exercises in R, culminating in a final coding project.

5. AVALIAÇÃO

Assessment is based on a applied R coding projects. The projects will evaluate students' ability to translate clinical trial methodology into correct, well-documented, and interpretable R code, as well as their ability to summarize and interpret the simulation results.

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6. REFERÊNCIAS

6.1- Básicas (Disponibilizadas na Biblioteca ou aquisições recomendadas)

PIANTADOSI, S; MEINERT, CL, Editors. *Principles and practice of clinical trials.* Springer Nature; 2022 Jul 19.

DAIMON, T; HIRAKAWA, A; MATSUI, S. *Dose-finding designs for early-phase cancer clinical trials: A brief guidebook to theory and practice*. Springer; 2019 May 21.

WASSMER, G; BRANNATH, W. *Group sequential and confirmatory adaptive designs in clinical trials.* Cham: Springer International Publishing; 2016 Jul 4.

*Disciplina aprovada em reunião do Conselho Acadêmico do PBE, em reunião realizada no dia 14/07/2026, conforme Ata nº 103.