ThermoFisher SCIENTIFIC

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ClinOpt

Clinical Optimization for Smarter, Low-Deviation Trial Design

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PROJECT OVERVIEW

Problem Statement

90%

of drug candidates fail in clinical trials

→ Nearly half due to protocol design & execution flaws

ClinOpt empowers clinical scientists to design smarter, low-deviation protocols.

Uses **historical trial data** to assess how **design choices** like eligibility or visit schedules **affect deviations**.

By turning intuition into evidence, ClinOpt helps **reduce trial complexity** and improve **execution success**.

Data

1000+ Protocols

- Covers 23+ specialties
- Free-text data format
- Rich data (trial endpoints, patient eligibility criteria…)

1.4M+ Deviations

- Sourced from Thermo Fisher internal deviation logs
- Categorized by types
- Text descriptions and status

PROJECT GOAL

Translate clinical intuition into data-driven protocol design decisions

METHODOLOGY

1. Smart Clustering

Goal: Establish baseline deviation rates

- **Group** trials by features (e.g. therapeutic area)
- **Selection** based on mutual information, χ^2 and clinical relevance.
- Ensures comparisons are made across **meaningful subgroups**

Features	Mutual Information
Sponsor	4.13
Therapeutic Area	**2.32**
Phase	1.31

CLINOPT ENGINE

2. Feature Generation

Goal: Let scientists statistically test design hypothesis

- Users frame protocol-based **questions**
- NLP agent **extract and verify structured binary/categorical information**
- Supports criteria like “Is having a history of strokes an exclusion criteria?”
- Features are meant to **explain deviation count variation** within each subgroup

3. Causal Inference (DML)

Double Machine Learning (DML)
→ A technique that separates prediction from inference
→ Controls confounders to isolate causal effects

Setup

- Grouped trials (e.g. ophthalmology)
- Outcome: deviation count
- Features: initial protocol parameters and user-defined treatments

Adjustments

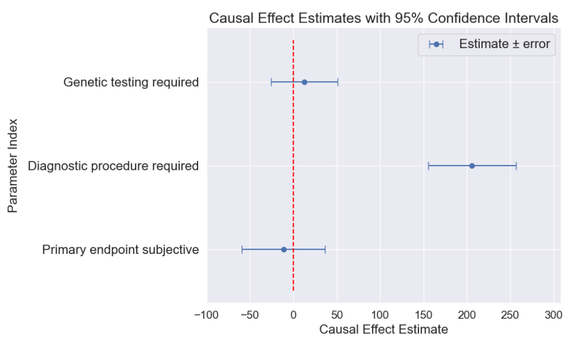
- Confounders: trial phase, sponsor, country…
- Use ML to estimate nuisance
- Balance covariates

Results

- Estimate causal effect size
- Standard Error, Confidence Intervals
- Feature importance ranking

RESULTS

Study Case



- Tested ClinOpt on oncology trials to assess which features drive deviation rates.
- Found that inclusion criteria requiring diagnostic procedures (e.g. MRI, CT…) **significantly** increase deviations.

Business Impact

50+

Potential hours saved per case

↓ 70%

Manual work

$37.5k – $119k

Potential savings per case