



קורס מספר: 283.4658

שנת הלימודים: תשפ"ד

סמסטר ב

### סילבוס קורס מתוקשב:

יסודות ויישומים של ניסויים קליניים Fundamentals, and applications of clinical trials

**מרצה:** פרופ' סטיבן לוין

**דרישות קדם:** אין

**קהל יעד:** קורס בחירה כללי לכל התוכניות וההתמחויות.

**מטרות הקורס:** הקורס הנוכחי יכיר את הסטודנטים עם (1) השיקולים הבסיסיים מאחורי תכנון ניסויים קליניים, (2) אתגרים של תוקף בניסויים קליניים, ו-(3) דוגמאות לניסויים קליניים במסגרות רפואיות. עד סוף הקורס, הסטודנטים (1) יכירו את הרקע לניסויים קליניים, (2) יהיו מסוגלים להעריך את התכנון והיישום של ניסוי קליני באופן ביקורתי, (3) יבינו את האתגרים לתוקף של הניסויים הקליניים, (4) יתמצאו ביישומים של ניסויים קליניים במספר תחומים.

**מבנה הקורס:**

**מתודולוגיה:** הרצאות, סרטונים, מקרה בוחן, הערכות עצמיות

נוכחות חובה ב 80% מהמפגשים.

**הערכת הקורס:**

100% חיבור

החיבור יהיה לבחירה של 1 מתוך 3 האפשרויות הבאות: (1) סקירת ספרות של נושא/ים ספציפיים בתכנון ניסוי קליני עבור הפרעה ספציפית. (2) סקירת ספרות לגבי הבט של מחקר ניסוי קליני. (3) הניתוח הסטטיסטי של נתוני [clinicaltrials.gov](https://clinicaltrials.gov).

ציון עובר: 60



## תוכן הקורס:

### Fundamentals

Clinical trials: history and background, ethics, registration, conduct, and data sharing

Hypothesis testing

Basic study design

Outcome definition

Study population selection (exclusion and inclusion), safety, under-representation, and generalization: vulnerable populations and minority groups.

### Challenges to validity

Adherence (non-adherence) and dropout

Placebo, placebo study designs, placebo response, and nocebo.

Adverse events: Monitoring and outcomes - harm

### Applications

<https://clinicaltrials.gov/>

COVID-19 (SARS-CoV-2)

Alzheimer's Disease and related dementias

Summary

### יסודות

1. ניסויים קליניים: היסטוריה ורקע, אתיקה,

רישום, ביצוע ושיתוף נתונים

2. בדיקת השערות

3. תכנון מחקר בסיסי

4. הגדרת תוצאה

5. בחירת האוכלוסייה (הוצאה והכללה), בטיחות,

תת-ייצוג והכללה: אוכלוסיות פגיעות וקבוצות

מיעוט.

### תוקף

6. דבקות (אי דבקות) ונשירה

7. פלצבו, מבני מחקרי פלצבו, תגובת פלצבו

ונוצבו.

8. תופעות לוואי: ניטור והשלכות

### יישומים

9. [/https://clinicaltrials.gov/](https://clinicaltrials.gov/)

10. COVID-19 (SARS-CoV-2)

11. מחלת אלצהיימר ודמנציות קשורות

סיכום.

Subject to changes. נתון לשינויים.



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4. Meinert CL, Piantadosi S. Principles and Practice of Clinical Trials. Cham: Springer International Publishing : Imprint: Springer; 2020.
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### Adherence (non-adherence) and dropout

#### Adherence

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## Dropout



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### **Placebo, placebo study designs, placebo response, nocebo**

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## Eligibility creeps, and the professional client.

### Eligibility creep

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### Professional client

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## Schizophrenia

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## Alzheimer's Disease and related dementias

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אם יש לך לקות למידה או מוגבלות/בעיה רפואית שעשויה להשפיע על לימודיך, ושבגינה את/ה זקוק/ה להתאמות  
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לאבחון והתאמות בגין לקות למידה ו/או הפרעת קשב יש לפנות ליה"ל:

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אם יש ברשותך מכתב התאמות מהאוניברסיטה ואת/ה זקוק/ה להנגשה בקורס אנא פנה/י אליי בשעות הקבלה או  
במייל בסמוך לתחילת הקורס.

If you have a disability that may affect your studies and for which you may require accommodations, please contact the Accessibility and Learning Disabilities Department at the Dean of Students office

e-mail: [LDA@univ.haifa.ac.il](mailto:LDA@univ.haifa.ac.il) Phone number: 04-98249265

Students that receive accommodation letters, and need academic adjustments, please meet with me to discuss the provisions of those accommodations as early in the semester as possible.