GÖTEBORGS UNIVERSITET

INSTITUTIONEN FÖR MEDICIN

MKB800 Metodik inom klinisk läkemedelsprövning och biostatistik, 7,5 högskolepoäng

Methodology in clinical drug development and biostatistics, 7.5 credits

Avancerad nivå / Second Cycle

Litteraturlista för MKB800, gällande från och med vårterminen 2024

Litteraturlistan är fastställd av Institutionen för medicin 2024-02-13 att gälla från och med 2024-02-13.

Se bilaga.

Litteraturlista / Literature list MKB800

Metodik inom klinisk läkemedelsprövning och biostatistik, 7,5 hp

Methodology in clinical drug development and biostatistics, 7.5 credits

BÖCKER / BOOKS

Pocock, Stuart J. **Clinical trials : a practical approach**, Chichester: Wiley, 1983

Björk Jonas, **Praktisk statistik för medicin och hälsa**: Liber

LÄNKAR / LINKS

- WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

World Medical Association, https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

ICH RIKTLINJER / ICH GUIDANCES

- ICH Topic E8: General Considerations for Clinical Trials

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ich-guideline-e8-r1-general-considerations-clinical-studies_en.pdf

- ICH Topic E4: Dose-Response Information to Support Drug Registration

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-4-dose-response-information-support-drug-registration-step-5_en.pdf

- ICH Topic E6: Guideline for Good Clinical Practice

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice-e6r2-step-5_en.pdf

- ICH topic E10: Choice of Control Group and Related Issues in Clinical Trials

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-10-choice-control-group-clinical-trials-step-5_en.pdf

- ICH topic E9: Statistical Principles for Clinical Trials

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-9-statistical-principles-clinical-trials-step-5_en.pdf

Addendum:

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-and-sensitivity-analysis-clinical-trials-guideline-statistical-principles-clinical-trials-step-5_en.pdf

- ICH Topic E3: Structure and Content och Clinical Study Reports

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-3-structure-and-content-clinical-study-reports-step-5_en.pdf

LÄKEMEDELSVERKET, SVERIGE / MEDICAL PRODUCTS AGENCY (MPA), SWEDEN

- Vägledning (version 2) till Läkemedelsverkets föreskrifter (LVFS 2011:19) om kliniska läkemedelsprövningar på människor

https://www.lakemedelsverket.se/sv/lagar-och-regler/foreskrifter/2011-19

EUROPEISKA UNIONEN / EUROPEAN UNION

- REGULATION No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC.

https://health.ec.europa.eu/medicinal-products/clinical-trials_en#guidelines-on-the-conduct-of-clinical-trials

- 2011/C 172/01: Communication from the Commission — Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (‘CT-3’)

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:172:0001:0013:EN:PDF

- CPMP/EWP/908/99: POINTS TO CONSIDER ON MULTIPLICITY ISSUES IN CLINICAL TRIALS

https://www.ema.europa.eu/en/documents/scientific-guideline/points-consider-multiplicity-issues-clinical-trials_en.pdf

- EMA/CPMP/EWP/1776/99 Rev. 1: Guideline on Missing Data in Confirmatory Clinical Trials EMA, European Medicines Agency,

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-missing-data-confirmatory-clinical-trials_en.pdf

- CPMP/EWP/482/99: POINTS TO CONSIDER ON SWITCHING BETWEEN SUPERIORITY AND NON-INFERIORITY, EMA, European Medicines Agency,

https://www.ema.europa.eu/en/documents/scientific-guideline/points-consider-switching-between-superiority-and-non-inferiority_en.pdf

CONSORT 2010 Checklist, Explanations and Elaboration document, The CONSORT Group, 2010 CONSORT hemsida. Click CONSORT 2010 -> CONSORT Checklist for study report checklist with explanations. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

BMJ, 2010, Artikel med checklista, förklaringar och bakgrund (open access)

ARTIKLAR / ARTICLES

Mitra et. al. "Local Change in Urinary Bladder Contractility Following CNS Dopamine Denervation in the 6-OHDA Rat Model of Parkinson's Disease.", J Parkinsons Dis. 2015;5(2):301-11. doi: 10.3233/JPD-140509.

Reference material concerning ANOVA. HyperStat Online Statistics Textbook

LÄNK

Donders et. al., " Review: A gentle introduction to imputation of missing values", Journal of Clinical Epidemiology 59 (2006) 1087e1091

LÄNK

Översikt över litteraturlistor/motsvarande

Finns det en orättvis könsfördelning när det gäller författare i bibliografin? Könsfördelningen har utvärderats och verkar vara ojämnt fördelad mot manliga författare. Det finns dock inga alternativa böcker.

Review of literature lists/equivalent

Is there an unfair gender distribution regarding authors in the bibliography? The gender distribution has been evaluated and seems to be unequally distributed towards male authors. However, there are no alternative books.