Performance schedule for the course Methodology of clinical research as a part of the Postgraduate Study "Medicine based on evidence"

16.09.2017.

Lectures

Prof. Eduard Vrdoljak, MD, PhD

P1 (09 00 - 09 45) – Drug development

P2 (09 50 - 10 35) – Planning of clinical trials

Ass.prof. Tihana Boraska Jelavic, MD, PhD

P3 (10 40 - 11 25) – The recruitment process and enrolment of subjects into clinical trials

Pause (11 25 - 11 55)

Seminars

Ass.prof. Marijo Boban, MD, PhD

S1 (11 55 - 12 40) – Safety procedures during clinical trials

S2 (12 45 – 13 30) – Safety basics during clinical trials

Recommended literature:

1. Bellary S, Krishnankutty B, Latha MS. Basics of case report form designing in clinical research. Perspect Clin Res. 2014;5(4):159-66.
2. Russell JS, Colevas AD. Adverse event monitoring in oncology clinical trials. Clin. Invest. 2013;3(12):1157–65.
3. DeMets DL, Ellenberg SS. Data Monitoring Committees —Expect the Unexpected. N Engl J Med. 2016;375:1365-71.

List of participants responsible for preparing the seminar:

ADAMOVIĆ IVAN

BLOSS HEINZ-GEORG

17.09.2017.

Ass.prof. Tomislav Omrcen, MD, PhD

S3 (09 00 - 09 45) – Monitoring in clinical trials

S4 (09 50 - 10 35) – Audit in clinical trials

S5 (10 40 - 11 25) – Inspection in clinical trials

Recommended literature:

1. Morgan-Linnell SK, Stewart DJ, Kurzrock R. U.S. Food and Drug Administration Inspections of Clinical Investigators: Overview of Results from 1977 to 2009. Clin Cancer Res 2014;20(13). DOI: 10.1158/1078-0432.CCR-13-3206
2. Gobel C, Baier D, Rufhus B, Hundt F. GCP inspections in Germany and Europe following the implementation of the Directive 2001/20/EC. GMS German Medical Science 2009;7, ISSN 1612-3174
3. Morrison BW, Cochran CJ, White JG, et al. Monitoring the quality of conduct of clinical trials:a survey of current practices. Clinical Trials 2011; 8: 342–9.
4. Olsen R, Bihlet AR, Kalakou F, Andersen JR. The impact of clinical trial monitoring approaches on data integrity and cost—a review of current literature. Eur J Clin Pharmacol 2016;72:399–412
5. Bhatt A. Quality of clinical trial: A moving target. Perspectives in Clinical Research 2011; Vol 2 , Issue 4. DOI: 10.4103/2229-3485.86880.
6. Powell-Smith A and Goldacre B. The TrialsTracker: Automated ongoing monitoring of failure to share clinical trial results by all major companies and research institutions [version 1; referees: 2 approved] *F1000Research* 2016, 5:2629 (doi:10.12688/f1000research.10010.1)

List of participants responsible for preparing the seminar:

GOEBEL HOLGER

MAYER DIRK

POHLIG CHRISTIAN

Pause (11 25 - 11 55)

Ass.prof. Branka Petric Mise, MD, PhD

S6 (11 55 - 12 40) – Clinical trial results

S7 (12 45 – 13 30) – Legal aspects of clinical trials

Recommended literature:

1. Drazen JM, Harrington DP, McMurray J, Were JH, Woodcock J: The porimary outcome is positive - Is that good enough?. NEJM 2016; 375:971-9. doi:10.1056/NEMJra1601511.

List of participants responsible for preparing the seminar:

FRANKE CHRISTIAN

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