MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Current

Here you will find, among other things, information and references to current courses of the KKS Magdeburg
well as events and other information on the topic of academic research.

Courses from KKS Magdeburg

The KKS Magdeburg offers the following need-based training courses.

AMG refresher course
MP refresher course
MP supplementary course

More Info here

Current Public Grants (BMBF / DFG)

Public funding opportunities, in particular for clinical studies/clinical trials with drugs or medical devices (Inve

Do you have a project idea?! We will gladly support you with the application together with the Referat für Fo

Please also involve us as early as possible before submitting an initial project outline/idea or an application.
trial with a drug or medical device (IIT) for which the OvGU, Faculty of Medicine, must act as a sponsor by la

Bundesministerium für Bildung und Forschung (BMBF)

Deutsche Forschungsgemeinschaft (DFG)

Events Clinical and Health Services Research

You can also find more events here:

http://www.med.uni-magdeburg.de/Forschung.html

- TMF: Kick-off Meeting der AG Register

Berlin: 08.02.2023 (13:00-16:00 Uhr)

The TMF starts a new working group on registries. The kick-off meeting will take place in Berlin. Among oth
collection of topics and the work plan for the new WG Register.

Registration: https://eveeno.com/244041460

- DGPharMed: Workshop IT-Validierung

Frankfurt: 08.03.2023

DGPharMed is organizing a workshop on IT validation in March that will focus on new guidelines, technolog

- How to qualify infrastructure in a cloud environment (IaaS)?

- What depth of validation is required?

- What do the new guidelines such as GAMP 5 (rev2), Computer System Assurance (FDA), and EMA guide

- What is necessary for a coherent IT study documentation (e.g. eCRF, IRT, ePRO)?

- Identification of common stumbling blocks

- Inspection readiness: documentation with IT reference (e.g. eTMF)?

For more information, see:

https://mcusercontent.com/17a432d677390d03e90f827b0/files/73952f0c-8d81-6dc4-251f-85da7968c286/D

- DVMD: Spring Symposium with focus on "Medical Registers

Munich: 21.03.2023

The spring symposium of the German Association for Documentation and Information Management in Medi
challenges for documentation and information management for medical registries.

Among other things, the conference program will take a closer look at different registers and describe their s
practical relevance, the focus will also be on concrete recommendations for action and different digitization s
presented. Furthermore, the participants will be informed about the implementation of new registers.

The program and more information can be found at:

https://dvmd.de/wp-content/uploads/2023/01/Programm_DVMD-Symposium2023.pdf

https://dvmd.de/events/4-dvmd-fruehjahrssymposium

- EbM Network: EbM Congress "Health and Climate - EbM for the Future".

Potsdam and virtual: 22-24.03.2023

The EbM Congress 2023 will take place under the motto "Health and Climate - EbM for the Future" from 22-
and the early bird rate is valid up to and including January 14, 2023

More information and registration: : https://www.ebm-kongress.de/

- DIA: DIA Europe 2023

Basel: 22.-24.03.2023

The DIA Europe Congress will take place from March 22 to 24 in Basel. This year the following topics will be

• Artificial Intelligence and Data Science

• EU Health Policy and Regulatory Strategy

• Medical Devices and Combination Products

• Professional Development

You can find more information at:

https://www.diaglobal.org/en/flagship/dia-europe-2023/about/conference

- TMF: Registertage - Save the date

Berlin: 08/09.05.2023

The TMF Register Days will take place in Berlin on May 08 and 09, 2023. The congress is thematically aime researchers.

Register researchers to discuss current developments and challenges for medical registers in health service exchange approaches for the further development of the registered landscape.

For more information, please visit:

https://tmf-ev.de/Termine/ctl/Details/Mid/785/ItemID/1706.aspx

http://www.med.uni-magdeburg.de/Forschung.html

- BPI und KKS-Netzwerk: Workshop Investigator Initiated Trials

Berlin: 11.01.2023

Die Unterstützung von akademischen IITs - Investigator Initiated Trials ist mittlerweile im Alltag vieler pharm ein fester Bestandteil geworden. Durch partnerschaftliche Kooperationen zwischen Ärzten und Herstellern k gewonnen werden, die sowohl der Patientenversorgung zugutekommen als auch wichtige Informationen für tauchen immer wieder auf beiden Seiten Fragen zur konkreten Umsetzung auf. Neben den unterschiedliche Kooperationsprojekten ist von besonderem Interesse, wie eine Unterstützung von IITs durch Hersteller unte Vorgaben realisiert werden kann.

Programm: https://www.kks-netzwerk.de/veranstaltungen/gemeinsameveranstaltungen/

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More information and registration: : https://www.ebm-kongress.de/

- TMF/GBN: 11. National Biobank Symposium - Call for Papers

Berlin: 25.-26.05.2023 in Berlin

Researchers from all disciplines, biobank operators and industry are cordially invited to actively participate on the following topics:

1. Future Directions of Biobanking

2. Requirements and technologies

3. IT

4. international biobanking

5. ethics, data protection, regulations

6. shortage of skilled workers, global supply chains, energy crisis (cost structures)

7. scientific benefits of biobanking, scientific results & success stories

Deadline: 22.01.2023

https://www.tmf-ev.de/News/articleType/ArticleView/articleId/4891.aspx

Other information

- BMG: Amendment of the Special Fee Schedule

The BMG's Special Fee Schedule was adjusted in January 2023. The fee framework for the evaluation of "T
536/2014 is now also specified here (Annex Section 5). The amount of the fees is specified as 500 to 5700

https://www.gesetze-im-internet.de/bmgbgebv/index.html#BJNR439100021BJNE000702116

- Federal funding approved for gene and cell therapy center

At the end of 2022, the Budget Committee of the German Parliament decided that four million euros would b
the establishment of a center for gene and cell therapy in Berlin. In the medium term, more than 40 million e
used for planning in the coming years - for example, for an architectural tender, workshops, and the develop

For more information, see the news section of the Ärzteblatt:

https://www.aerzteblatt.de/nachrichten/138772/Bundesmittel-fuer-Gen-und-Zelltherapiezentrum-bewilligt

- DFG: DFG: Publication of final reports

In order to broaden the scientific information base and contribute to the necessary cultural change in scienti
more accessible. In the future, grant recipients will be asked to make a part of the final report intended for pu
will be supported by corresponding templates that specify a structuring into a part intended for publication a
reports provide the DFG with the link to the location in the selected repository, the reports will be searchable

https://www.dfg.de/foerderung/info_wissenschaft/2023/info_wissenschaft_23_01/index.html

- BfArM/PEI: Joint recommendations on the notification of observational studies and non-interventio

Regulation (EU) 536/2014 introduced a new definition for non-interventional studies, which was also incorpo
of non-interventional studies is the reason for the revision of the joint recommendations of the BfArM and th
studies (PASS). The recommendations jointly issued by BfArM and PEI on post-authorization safety studies
2019, will be repealed and replaced by the "Joint Recommendations of the Federal Institute for Drugs and M
Notification of Post-Authorization Safety Studies Pursuant to Section 67(6) of the German Medicines Act an
Pursuant to Section 63f of the German Medicines Act" dated December 15, 2022.

https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Nichtinterventionelle-Studien/_artikel.html

- BfArM: Application for a decision on the obligation to approve a clinical trial of a medical device

If the regulatory classification of a planned clinical trial or performance study cannot be clarified, the parties
clinical trial/performance study may submit an application for a decision on the requirement for approval to t
MPDG. Information on the application for a decision on the obligation to obtain approval is compiled on the

https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/Klinische-Pruefungen-und-Leistungsstudien/Antrag-au

- PEI: Pilotphase 2 des Simultaneous National Advice (SNSA) startet ab 2023

The aim of the pilot project is to make drug developers increasingly aware of the benefits of the SNSA - part
academia and industry - and to demonstrate the potential added value of the joint consulting concept in orde
best-practice model. The focus of the scientific consultations in phase 2 of the SNSA pilot project is on clinic

https://www.pei.de/DE/newsroom/hp-meldungen/2022/221123-snsa-pilotphase-2-startet-ab-2023.html?nn=

- AKEK: Handout on certificates and webinars

The Working Group of Medical Ethics Committees has published a handout on certificates and webinars. Th
training certificates for continuing education courses for investigators and members of an investigative team
events or eLearning.

https://www.akek.de/wp-content/uploads/2022-11-04_Handreichung-zu-Zertifikaten-Webinare.pdf

In addition, FAQs on curricular training courses for examiners and members of an examination team/group

https://www.akek.de/wp-content/uploads/2022-12-09_FAQ_final.pdf

- AKEK: New sample texts patients/test persons in clinical studies according to CTR and AMG (old v

New sample texts on patient consent (patient, proband) for applications according to CTR and applications
and published on the website.

In addition, a handout for the ethics committees was published, which deals with the procedure for research
according to the CTR.

https://www.akek.de/arzneimittelgesetz-amg/

- AKEK: Checklist of documents to be submitted for PMCF studies

Eine Checkliste der einzureichenden Unterlagen bei PMCF-Studien wurde ebenfalls auf der Website des AK

https://www.akek.de/medizinproduktegesetz-mpg/

- MII: Announcement for commenting on the core data record module medication from 02.01.2023 on

For the common, cross-institutional use of data, a core data set is defined within the MII, which is subdivided MII sites.

The Medication module contains data elements for documenting medication prescriptions and administration modules of the MII's core data set. In early 2020, the Medication module was reconciled in version 1.0 and h centers. Beginning January 2, 2023, and ending February 28, 2023, the module's enhanced specification, V

https://www.medizininformatik-initiative.de/de/ankuendigung-zur-kommentierung-des-kerndatensatzmoduls-

- EMA: Recommendation paper on decentralised elements in clinical trials

On December 13, the Recommendation Paper on decentralized elements in clinical trials was published by oversight, patient consent, supply and administration of investigational medicines, study-specific procedures source data), and monitoring.

In addition, an overview of national regulations for specific DCT elements is included in the appendix.

https://health.ec.europa.eu/system/files/2022-12/mp_decentralised-elements_clinical-trials_rec_en.pdf

- Bundesgesundheitsblatt: First experiences with the implementation of EU Regulation 536/2014 (CT research.

Under the lead topic "How is the EU regulation on clinical trials of medicinal products evaluated one year aft experiences in the Bundesgesundheitsblatt

https://rdcu.be/c1L5q

- **BfArM: Data protection criteria for digital health apps and digital care apps**

The BfArM has published new test criteria for data protection requirements for digital health applications (Di
these criteria will form the basis for new certificates with which manufacturers of health and care apps can p
cover both the requirements of the European General Data Protection Regulation and the extended require

https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/Datenschutzkriterien/_artikel.html

- **EMA: Pilot project to support academic developers of ATMPs.**

In a new pilot project, the EMA would like to support the development of ATMPs. The pilot project is aimed s
organizations.

The EMA will provide enhanced regulatory support for up to five selected ATMPs developed exclusively by a

Potential candidates can contact their national competent authority or the EMA ( ) to express their interest in
information.

https://www.ema.europa.eu/en/news/ema-pilot-offers-enhanced-support-academic-non-profit-developers-ac

- EMA: CTIS

As of January 31, 2023, all initial applications for clinical trials in the European Union (EU) must be submitte

https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-informati

- **ICH: Guideline on the selective use of safety data collection in certain clinical trials**

Die ICH Guideline E19 (selective approach to safety data collection in specific late-stage pre-approval or po
through the CHMP accepted. As of March 16, 2023, this guideline will be in effect.

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-e19-selective-approach-safety-c

- ICH Q9 Quality risk management (R1) published

IIn our news of December 14, 2020, we had reported on the announcement by the International Council for
Management Guidelines. The final version has now been published.

https://www.ich.org/page/quality-guidelines

KKS documents for study planning in study centers.

We will gladly provide you with forms and SOPs in the Intranetzur .
Additional documents/templates are available from us upon request.

Kontakt & Anschrift
Dr. rer. nat. Antje Wiede
Leiterin des KKS

Tel.: 0391/67-21 838
Fax: 0391/67-15 898
kks@med.ovgu.de

Otto-von-Guericke-Universität
Medizinische Fakultät,
KKS Magdeburg
Leipziger Str. 44
39120 Magdeburg
Haus 1, Ebene 4, rechts

Anfahrt und Lageplan

KKS-Nutzungsordnung_ZMF

KKS Beratungsanfrage

Hinweisblatt Studienplanung

Kurzleitfaden Eine Studie-Ein Votum

Schulungsangebote intern NEU

Regularien

Links
KKS-Netzwerk
BfArM
BfS
Paul-Ehrlich-Institut **PEI**
Bundesministerium für Gesundheit
European Medicines Agency **EMA**
Registrierung **DRKS**
Ethikkommission **AKEK**
ICH