



# MEDIZINISCHE FAKULTÄT UNIVERSITÄTSKLINIKUM 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 as 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 (Investigator Initiated Trials)

Do you have a project idea?! We will gladly support you with the application together with the [Referat für Forschung](#)

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

**[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 other things, the 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, technology

- 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/DGPharMed\\_IT\\_Validation\\_Workshop\\_08.03.2023.pdf](https://mcusercontent.com/17a432d677390d03e90f827b0/files/73952f0c-8d81-6dc4-251f-85da7968c286/DGPharMed_IT_Validation_Workshop_08.03.2023.pdf)

## **- 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 Medicine (DVMD) will focus on the 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 practical relevance, the focus will also be on concrete recommendations for action and different digitization approaches 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/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 22.03.2023 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 aimed at 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 pharmazeutischer Unternehmen ein fester Bestandteil geworden. Durch partnerschaftliche Kooperationen zwischen Ärzten und Herstellern können gewonnen werden, die sowohl der Patientenversorgung zugutekommen als auch wichtige Informationen für die Forschung tauchen immer wieder auf beiden Seiten Fragen zur konkreten Umsetzung auf. Neben den unterschiedlichen Kooperationsprojekten ist von besonderem Interesse, wie eine Unterstützung von IITs durch Hersteller unter realistischen Vorgaben realisiert werden kann.

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

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#### **- 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

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

**- BMG: Amendment of the Special Fee Schedule**

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

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

[https://www.dfg.de/foerderung/info\\_wissenschaft/2023/info\\_wissenschaft\\_23\\_01/index.html](https://www.dfg.de/foerderung/info_wissenschaft/2023/info_wissenschaft_23_01/index.html)

Regulation (EU) 536/2014 introduced a new definition for non-interventional studies, which was also incorporated into the German Medicines Act. The introduction of a new definition of non-interventional studies is the reason for the revision of the joint recommendations of the BfArM and the PEI on post-authorization safety studies (PASS). The recommendations jointly issued by BfArM and PEI on post-authorization safety studies (PASS) dated December 15, 2019, will be repealed and replaced by the "Joint Recommendations of the Federal Institute for Drugs and Medical Devices and the European Medicines Agency on Post-Authorization Safety Studies Pursuant to Section 67(6) of the German Medicines Act and 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](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 the BfArM. Information on the application for a decision on the obligation to obtain approval is compiled on the BfArM website.

<https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/Klinische-Pruefungen-und-Leistungsstudien/Antrag-auf-Entscheidung-zur-Pflicht-zur-Zulassung-von-Medizinprodukten>

### **- 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 of the joint consulting concept in order to demonstrate the potential added value of the joint consulting concept in order to establish a best-practice model. The focus of the scientific consultations in phase 2 of the SNSA pilot project is on clinical trials.

<https://www.pei.de/DE/newsroom/hp-meldungen/2022/221123-snsa-pilotphase-2-startet-ab-2023.html?nn=1>

### **- AKEK: Handout on certificates and webinars**

The Working Group of Medical Ethics Committees has published a handout on certificates and webinars. The handout contains information on the requirements for continuing education courses for investigators and members of an investigative team, as well as on the requirements for continuing education courses for examiners and members of an examination team/group. The handout is available in German and English.

[https://www.akek.de/wp-content/uploads/2022-11-04\\_Handreichung-zu-Zertifikaten-Webinare.pdf](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 are available on the AKEK website.

[https://www.akek.de/wp-content/uploads/2022-12-09\\_FAQ\\_final.pdf](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 version)**

New sample texts on patient consent (patient, proband) for applications according to CTR and applications according to AMG are available on the AKEK website 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 AKEK veröffentlicht.

<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 into several 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 implemented at all MII centers. Beginning January 2, 2023, and ending February 28, 2023, the module's enhanced specification, Version 2.0, is being implemented.

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

## **- EMA: Recommendation paper on decentralised elements in clinical trials**

On December 13, the Recommendation Paper on decentralized elements in clinical trials was published by the EMA. It covers the areas of clinical trial oversight, patient consent, supply and administration of investigational medicines, study-specific procedures (e.g. 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](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 (CTX research).**

Under the lead topic "How is the EU regulation on clinical trials of medicinal products evaluated one year after its implementation?" the first experiences in the Bundesgesundheitsblatt are reported.

<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 (DiGA) and digital care applications (DiPA). These criteria will form the basis for new certificates with which manufacturers of health and care apps can prove compliance with the requirements of the European General Data Protection Regulation and the extended requirements of the German Digital Health Act (DiGgG).

[https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/Datenschutzkriterien/\\_artikel.html](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 at academic organizations.

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

Potential candidates can contact their national competent authority or the EMA ( ) to express their interest in participating in the pilot project. Further information is available on the EMA website.

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

## - **EMA: CTIS**

As of January 31, 2023, all initial applications for clinical trials in the European Union (EU) must be submitted through the Clinical Trials Information System (CTIS).

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

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

The ICH Guideline E19 (selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials) has been adopted by the CHMP. 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-data-collection\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-e19-selective-approach-safety-data-collection_en.pdf)

## - **ICH Q9 Quality risk management (R1) published**

In our news of December 14, 2020, we had reported on the announcement by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) regarding the final version of the Quality Risk 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 [Intranet](#) zur . Additional documents/templates are available from us upon request.

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Anfahrt und Lageplan

KKS-Nutzungsordnung\_ZMF ☐

KKS Beratungsanfrage ☐

Hinweisblatt Studienplanung ☐

Kurzleitfaden Eine Studie-Ein Votum ☐

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Bundesministerium für Gesundheit

European Medicines Agency **EMA**

Registrierung **DRKS**

Ethikkommission **AKEK**

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