10. Dezember 2021 – 07. Januar 2022

MEGRA NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Procedural timetables (updated)
- Timetable: Type II variation and worksharing application weekly assessment
- Timetable: Type II variation and worksharing application monthly assessment
- Timetable: Type II variation and worksharing application assessment – ATMP
- Timetable: Post-authorisation measure (PAM) assessed by PRAC
- Timetable: Post-authorisation measures (PAMs) assessed by PRAC – ATMP
- Timetable: Initial (Full) Marketing Authorisation application accelerated assessment timetables
Published on: *13 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/submission-dates/procedural-timetables

International regulators' reflections on remote approaches to GCP and GMP regulatory oversight during COVID-19 pandemic
Published on: *13 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/news/international-regulators-reflections-remote-approaches-gcp-gmp-regulatory-oversight-during-covid-19

Newsletter: News bulletin for small and medium-sized enterprises - Issue 54
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/newsletter/news-bulletin-small-medium-sized-enterprises-issue-54_en.pdf

EMA framework of interaction with healthcare professionals: 10 years of implementation
Published on: *15 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/ema-framework-interaction-healthcare-professionals-10-years-implementation_en.pdf

EMA launches the Regulatory Science Research Needs initiative
Published on: *15 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/news/ema-launches-regulatory-science-research-needs-initiative

Note on European Medicines Agency's involvement in HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment
Published on: *21 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/note-european-medicines-agencys-involvement-horizon-hlth-2022-tool-11-02-new-methods-effective-use/synthetic-data-regulatory-decision-making/health-technology-assessment_en.pdf

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Report - European Medicines Agency-Nuclear Medicines Europe meeting
Published on: *21 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/report/report-european-medicines-agency-nuclear-medicines-europe-meeting_en.pdf

Eligible healthcare professionals' organisations (updated)
Published on: *04 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/partners-networks/healthcare-professionals/eligible-healthcare-professionals-organisations

COVID-19: latest updates
Published on: *05 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-latest-updates

Member states contact points for translations review (updated)
Published on: *06 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/member-states-contact-points-translations-review_en.pdf

Contact details of national competent authorities for requests of translation exemptions falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages (updated)
Published on: *06 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/contact-details-national-competent-authorities-requests-translation-exemptions-falling-under-art-633/83/ec-cases-shortages_en.pdf

Meeting summary - Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations (24 Nov 2021)
Published on: *06 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/report/meeting-summary-annual-patients-consumers-working-party-pcwp-healthcare-professionals-working-party_en.pdf

Pharmakovigilanz – PRAC

Highlights - 16th industry stakeholder platform - operation of European Union (EU) pharmacovigilance (updated)
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/minutes/highlights-16th-industry-stakeholder-platform-operation-european-union-eu-pharmacovigilance_en.pdf

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PRAC: Agendas, minutes and highlights (updated)
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/prac/prac-agendas-minutes-highlights

List of medicinal products under additional monitoring (updated)
Published on: *15 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/additional-monitoring/list-medicinal-products-under-additional-monitoring_en-0.pdf

List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)
Published on: *22 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/list-european-union-reference-dates-frequency-submission-periodic-safety-update-reports-psurs_en.xls

Extended EudraVigilance medicinal product dictionary (XEVMPD) e-learning
Presentations available:
- Session 1.0 – Introduction
- Session 1.2 – Registration with EudraVigilance
- Session 2.4 - Operation types, data quality and data ownership
- Session 3: Database Architecture
Published on: *04 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training#xevmpd-e-learning-presentations-section

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training: frequently asked questions (updated)
Published on: *04 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-frequently-asked-questions_en.pdf

PRAC recommendations on safety signals (updated)
Published on: *06 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/signal-management/prac-recommendations-safety-signals#prac-recommendations-on-safety-signals-section

List of signals discussed at PRAC since September 2012
Published on: *06 - January - 2022*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/list-signals-discussed-prac-september-2012_en.xlsx

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Zulassung – Regulatory Affairs

IRIS guide to registration (updated)
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration_en.pdf

Checklist for the submission of Type IA and Type IB (without linguistic review) product information annexes and Annex A (if applicable) - human (updated)
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/template-form/checklist-submission-type-ia-type-ib-without-linguistic-review-product-information-annexes-annex-if_en.pdf

Register of deadlines to put a medicinal product on the market In accordance with Article 33 of the Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (updated)
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/register-deadlines-put-medicinal-product-market-accordance-article-33-regulation-ec-no-1901/2006-european-parliament-council-12-december-2006_en.pdf

Learnings initiative webinar for optimal use of big data for regulatory purpose
Presentations available
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/events/learnings-initiative-webinar-optimal-use-big-data-regulatory-purpose

Report - EU Big Data Stakeholder Forum 2021
Published on: *20 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/report/report-eu-big-data-stakeholder-forum-2021_en.pdf

Guideline on the acceptability of names for human medicinal products processed through the centralised procedure (updated)
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure

Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg) - Rev. 6
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/scientific-guideline/guideline-core-smpc-human-normal-immunoglobulin-intravenous-administration-ivig-rev-6_en.pdf

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European Medicines Regulatory Network Data Standardisation Strategy
Published on: *17 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/european-medicines-regulatory-network-data-standardisation-strategy_en.pdf
https://www.ema.europa.eu/en/about-us/how-we-work/big-data (overview)

CHMP: Agendas, minutes and highlights (updated)
Published on: *20 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/chmp/chmp-agendas-minutes-highlights#minutes-section

Procedural guidance for variant strain(s) update to vaccines intended for protection against Human coronavirus
Published on: *21 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-guidance-variant-strains-update-vaccines-intended-protection-against-human-coronavirus_en.pdf

Pre-authorisation guidance (updated)
"European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure" available
Published on: *22 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pre-authorisation-guidance

European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure (updated)
Published on: *22 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure_en-0.pdf (clean)
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure-document_en.pdf (tracked changes)

European Medicines Agency post-authorisation procedural advice for users of the centralised procedure (updated)
Published on: *22 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure_en.pdf (clean)
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure-document_en.pdf (tracked changes)

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Orphan Drugs und neuartige Therapierichtungen (ATMP)

Translations required with the submission of an application for orphan medicinal product designation (updated)
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/template-form/translations-required-submission-application-orphan-medicinal-product-designation_en.pdf

Template - Translations required with the submission of an application for transfer of orphan medicinal product designation (updated)
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/template-form/template-translations-required-submission-application-transfer-orphan-medicinal-product-designation_en.pdf

Advanced therapy classification (updated)
Published on: *20 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification

COMP: Agendas, minutes and meeting reports (updated)
New minutes and meeting reports available
Published on: *21 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/comp/comp-agendas-minutes-meeting-reports#minutes-section

Qualität – Quality

Overview of comments received on 'Draft ICH guideline M7 on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk - Addendum - Step 2b' (updated)
Published on: *15 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/comments/overview-comments-received-draft-ich-guideline-m7-assessment-control-dna-reactive-mutagenic_en.pdf

Draft International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline Q9 (R1) on quality risk management - Step 2b
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/scientific-guideline/draft-international-conference-harmonisation-technical-requirements-registration-pharmaceuticals_en-1.pdf

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Nitrosamine Implementation Oversight Group (NIOG) - second meeting with pharmaceutical industry
"Agenda, highlights, and presentations available"
Published on: *17 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/events/nitrosamine-implementation-oversight-group-niog-second-meeting-pharmaceutical-industry

(Prä-) Klinische Forschung – Research and Development

Quick guide: User access management - CTIS Training Programme - Module 03
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/quick-guide-user-access-management-ctis-training-programme-module-03_en.pdf

Getting started with CTIS: Sponsor quick guide
Published on: *13 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/getting-started-ctis-sponsor-quick-guide_en.pdf

Quick guide: How to use the Organisation Management Service (OMS) - CTIS Training Programme - Module 03
Published on: *13 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/quick-guide-how-use-organisation-management-service-oms-ctis-training-programme-module-03_en.pdf

Quick guide: Introduction to CTIS for public users - CTIS Training Programme - Module 22
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/quick-guide-introduction-ctis-public-users-ctis-training-programme-module-22_en.pdf

FAQs: Introduction to CTIS for public users - CTIS Training Programme - Module 22
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/faqs-introduction-ctis-public-users-ctis-training-programme-module-22_en.pdf

Step-by-step guide : Create, submit and withdraw a clinical trial application and nonsubstantial modifications - CTIS Training Programme - Module 10
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/step-step-guide-create-submit-withdraw-clinical-trial-application-nonsubstantial-modifications-ctis_en.pdf

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Step-by-step guide : Union Controls in CTIS - CTIS Training Programme - Module 21
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/step-step-guide-union-controls-ctis-ctis-training-programme-module-21_en.pdf

FAQs : Union Controls in CTIS - CTIS Training Programme - Module 21
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/faqs-union-controls-ctis-ctis-training-programme-module-21_en.pdf

Guide to CTIS training material catalogue (updated)
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/guide-ctis-training-material-catalogue_en.pdf

Step-by-step guide: How to respond to requests for information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/step-step-guide-how-respond-requests-information-received-during-evaluation-clinical-trial_en.pdf

Reference materials for clinical trial sponsors (new or updated)
- Getting started with CTIS: Sponsor quick guid
-Clinical Trial Information System (CTIS) structured data form - Initial application, additional Member State Concerned, substantial modification, non-substantial
- Clinical Trial Information System (CTIS) structured data form - Multi trial substantial modification
- Clinical Trial Information System (CTIS) structured data form - Notifications
- Clinical Trial Information System (CTIS) structured data form - Request for information (RFI)
- Clinical Trial Information System (CTIS) structured data form - Annual Safety Report (ASR)
- Clinical Trial Information System (CTIS) list values
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support#reference-materials-for-clinical-trial-sponsors-section

Newsletter: Clinical Trials Information System (CTIS) highlights - December 2021
Published on: *13 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/newsletter/clinical-trials-information-system-ctis-highlights-december-2021_en.pdf

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Instructor's guide: How to respond to Requests for Information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11 (updated)
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/instructors-guide-how-respond-requests-information-received-during-evaluation-clinical-trial_en.pdf

FAQs: How to respond to Requests for Information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11 (updated)
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/faqs-how-respond-requests-information-received-during-evaluation-clinical-trial-application-ctis_en.pdf

Instructor's guide: How to manage a CT - CTIS Training Programme - Module 05 (updated)
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/instructors-guide-how-manage-ct-ctis-training-programme-module-05_en.pdf

FAQs: How to manage a CT - CTIS Training Programme - Module 05 (updated)
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/faqs-how-manage-ct-ctis-training-programme-module-05_en.pdf

Step-by-step guide: How to manage a CT - CTIS Training Programme - Module 05
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/step-step-guide-how-manage-ct-ctis-training-programme-module-05_en.pdf

Quick guide: How to manage a CT - CTIS Training Programme - Module 05
Published on: *16 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/quick-guide-how-manage-ct-ctis-training-programme-module-05_en.pdf

Instructor's guide: How to create, submit and withdraw a Clinical Trial Application - CTIS Training Programme - Module 10 (updated)
Published on: *17 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/instructors-guide-how-create-submit-withdraw-clinical-trial-application-ctis-training-programme_en.pdf

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Checklist of required fields per application type - CTIS Training Programme - Module 10 (updated)
Published on: *17 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/checklist-required-fields-application-type-ctis-training-programme-module-10_en.pdf

FAQs: How to create, submit and withdraw a Clinical Trial Application - CTIS Training Programme - Module 10 (updated)
Published on: *17 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/other/faqs-how-create-submit-withdraw-clinical-trial-application-ctis-training-programme-module-10_en.pdf

Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol
Published on: *17 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/scientific-guideline/guideline-notification-serious-breaches-regulation-eu-no-536/2014-clinical-trial-protocol_en.pdf

Appendix III b – Information to be submitted with a notification of a serious breach - Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol
Published on: *17 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/documents/template-form/appendix-iii-b-information-be-submitted-notification-serious-breach-guideline-notification-serious/2014-clinical-trial-protocol_en.docx

PRIME: priority medicines (updated)
"New: Draft guidance on generating robust quality data for PRIME products is available for public consultation:
- Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications
Other new documents:
- Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 13-16 December 2021 (new)
- List of products granted eligibility to PRIME (updated)"
Published on: *21 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines

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Kinderarzneimittel – Paediatrics

PDCO: Agendas, minutes and meeting reports (updated)
New agenda and meeting report available
Published on: *15 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/committees/pdco/pdco-agendas-minutes-meeting-reports#meeting-reports-section

Enpr-EMA newsletter 2021
Published on: *20 - December - 2021*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/newsletter/enpr-ema-newsletter-2021_en.pdf

Pflanzliche Arzneimittel – Herbal medicines

No news published

European Commission

Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
Published on: *16 - December - 2021*
For more information, please refer to:
https://eur-lex.europa.eu/eli/reg_impl/2021/2226/oj

EU-UK relations: Commission delivers on promise to ensure continued supply of medicines to Northern Ireland, as well as Cyprus, Ireland and Malta
Published on: *17 - December - 2021*
For more information, please refer to:
https://ec.europa.eu/commission/presscorner/detail/en/ip_21_6911

Questions and Answers on Commission Proposal to ensure continued supply of medicines to Northern Ireland, as well as Cyprus, Ireland and Malta
Published on: *17 - December - 2021*
For more information, please refer to:
https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_6912

Member State Data on cross-border healthcare – Year 2020
Published on: *17 - December - 2021*
For more information, please refer to:
https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2020_msdata_en.pdf

Annual report from EMA to the Commission on the application of the Regulation on medicines for children
Published on: *20 - December - 2021*
For more information, please refer to:
https://ec.europa.eu/health/sites/default/files/files/paediatrics/2020_annual_report.pdf

Presentations - Meeting of the Subgroup on Cancer (16 December 2021)
Published on: *21 - December - 2021*
For more information, please refer to:
https://ec.europa.eu/health/non_communicable_diseases/events/ev_20211216_en

EDQM

New-format order confirmation for reference standards and publications
Published on: *10 - December - 2021*
For more information, please refer to:
https://www.edqm.eu/en/news/new-format-order-confirmation-reference-standards-and-publications

European Pharmacopoeia Supplement 10.8 now available
Published on: *15 - December - 2021*
For more information, please refer to:
https://www.edqm.eu/en/news/european-pharmacopoeia-supplement-108-now-available

BSP study outcomes published in Pharmeuropa Bio & Scientific Notes
Published on: *21 - December - 2021*
For more information, please refer to:
https://www.edqm.eu/en/news/bsp-study-outcomes-published-pharmeuropa-bio-scientific-notes

All you ever wanted to know about Ph. Eur. procedure 4 but never dared to ask!
Published on: *23 - December - 2021*
For more information, please refer to:
https://www.edqm.eu/en/news/all-you-ever-wanted-know-about-ph-eur-procedure-4-never-dared-ask

Pharmeuropa 34.1 just released
"All new European Pharmacopoeia (Ph. Eur.) texts and texts that have undergone technical revisions are published in Pharmeuropa for public consultation. The deadline for comments on Pharmeuropa 34.1 is 31 March 2022."
Published on: *05 - January - 2022*
For more information, please refer to:
https://www.edqm.eu/en/news/pharmeuropa-341-just-released

"CEP of the future": project update
Published on: *06 - January - 2022*
For more information, please refer to:
https://www.edqm.eu/en/news/cep-future-project-update

Medizinprodukte

Medical devices (updated)

"A draft procedural guidance document is available on the consultation procedure whereby notified bodies seek a scientific opinion from EMA, together with a question-and-answer (Q&A) document on practical arrangements. […] To submit comments on the draft guidance, email a completed commenting form linked in the guidance document to companiondiagnostics.consultation@ema.europa.eu by 20 February 2022."

New documents available:

- *Questions & answers-practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies*
- *Guidance on the procedural aspects for the consultation to the European Medicines Agency by a notified body on companion diagnostics*
- *Application form for consultation by a notified body on a companion diagnostic*
- *Consultation on companion diagnostic - Assessment report template*

Published on: *20 - December - 2021*

For more information, please refer to:

https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices

Progressive roll-out of the In Vitro Diagnostic Medical Devices Regulation

Published on: *20 - December - 2021*

For more information, please refer to:

https://ec.europa.eu/commission/presscorner/detail/en/ip_21_6965

CMDh

CMDh Agenda 14-16 December
Published on: *13 - December - 2021*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Agendas/2021_12_CMDh_Agenda.pdf

National recommendations for requests to act as RMS
Published on: *14 - December - 2021*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/DCP/CMDh_020_2009_Rev31_12_2021_Decentralised_Procedure_-_Requests_to_act_as_RMS.pdf

CMDh Minutes 9-11 November
Published on: *20 - December - 2021*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2021_11_CMDh_Minutes.pdf

Report from the CMDh meeting held on 14-16 December 2021
Published on: *22 - December - 2021*
For more information, please refer to:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/CMDh_pressreleases/2021/12_2021_CMDh_press_release.pdf

Humanarzneimittel - Deutschland

Datenübermittlung nach § 52b Absatz 3f AMG
„Punktuelle Aktualisierung der Liste der Fertigarzneimittel mit einer Verpflichtung zur regelmäßigen Datenübermittlung nach § 52b Absatz 3f AMG, welche im Anhang der Liste ersichtlich ist“
Veröffentlicht am: *14 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Datenuebermittlung-52b-3f-AMG/_artikel.html

Aktuell laufende und bestätigte Arzneimittel-Härtefallprogramme
„Die Liste der bestätigten Arzneimittel-Härtefallprogramme wurde aktualisiert.“
Veröffentlicht am: *17 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Klinische-Pruefung/Compassionate-Use/compUse-tabelle.html

Bulletin zur Arzneimittelsicherheit Ausgabe 4 - Dezember 2021
Veröffentlicht am: *17 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Publikationen/Bulletin/Ausgaben/2021/4-2021.pdf?__blob=publicationFile

Verkehrsfähige Arzneimittel im Zuständigkeitsbereich des BfArM
Veröffentlicht am: *21 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/AM_statistik/statistik-verkf-am-zustBfArM.html

Stellungnahme zur Einstufung von selenhaltigen Produkten (Nr. 02/2021)
Veröffentlicht am: *22 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/abgrenzung/Expertenkommission/stellungnahmen/2021-02.pdf?__blob=publicationFile

Workflow und Fristen für Änderungen
Veröffentlicht am: *22 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Packungsgroessen/antragsformular-workflow/packungsgroessen-workflow-aenderungen-messzahlen.pdf?__blob=publicationFile

Arzneimittelklassifikation: BfArM veröffentlicht amtliche Fassung der ATC-Klassifikation mit definierten Tagesdosen
Veröffentlicht am: *23 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.dimdi.de/dynamic/de/das-dimdi/aktuelles/meldung/amtliche-atc-klassifikation-mit-ddd-fuer-2022-veroeffentlicht/
https://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/2021/pm13-2021.html?nn=470400

Humanarzneimittel - Deutschland

Referenzdatenbank für Fertigarzneimittel gemäß § 31b SGB V
„Die Daten werden im ersten Quartal 2022 erstmalig zur Verfügung gestellt und dann 14-tägig zum 1. und 15. eines jeden Monats aktualisiert.“
Veröffentlicht am: *23 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Arzneibuch/Arzneibuchkommissionen/_artikel.html

Ergebnisprotokoll der 2. Sitzung der Expertengruppe Off-Label am 08. November 2021
Veröffentlicht am: *03 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppen-Off-Label/Protokolle/20211108_Sitzung_2.html?nn=596098

Maßnahmen des BfArM im Bereich Lieferengpässe
Aktuell in den Rubriken "Maßnahmen des BfArM auf Basis des § 4 Abs. 1 MedBVSV"; "Maßnahmen des BfArM auf Basis des § 4 Abs. 5 MedBVSV" und "Maßnahmen des BfArM auf Basis der §§ 10 Absatz 1a und 11 Absatz 1c AMG"
Veröffentlicht am: *03 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html

Mitglieder der Expertengruppen (aktualisiert)
Veröffentlicht am: *03 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Expertengruppen-Off-Label/Mitglieder-Liste.html?nn=986770

Ergebnisprotokoll der 36. Sitzung der Task Force zur Sicherstellung der medikamentösen Versorgung in der Intensivmedizin - Telekonferenz vom 30.11.2021
Veröffentlicht am: *03 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Jour-Fixe/protokolle/ICU_Taskforce_Protokoll_36.html

Stellungnahmen der Internationalen Koalition der Arzneimittelbehörden (ICMRA) unter Beteiligung des Paul-Ehrlich-Instituts
Veröffentlicht am: *03 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/positionen/icmra/position-icmra-stellungnahmen.html;jsessionid=CDB776FFA7A229080BD017CCD2E0D470.intranet222?nn=170928

Statistik "Besondere Therapierichtungen und Traditionelle Arzneimittel"
Veröffentlicht am: *04 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Statistiken/AM_statistik/Besondere_Therapierichtungen_statistik/statistik-bescheidzahlen.html

Humanarzneimittel - Deutschland

Ergebnisprotokoll der 46. (konstituierende) Sitzung der Kommission für Arzneimittel für Kinder und Jugendliche (KAKJ) vom 09.09.2020
Veröffentlicht am: *04 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Zulassung/Arzneimittel-fuer-Kinder/KAKJ_Kommission-fuer-Arzneimittel-fuer-Kinder-und-Jugendliche/Protokolle/protokoll_46.html

Sicherheit, Immunogenität und Austauschbarkeit von Biosimilars
Veröffentlicht am: *05 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.pei.de/DE/newsroom/hp-meldungen/2022/220105-biosimilars-sicherheit-monoklonale-antikoerper-im-fokus.html;jsessionid=3275156126DE0B7D63C8DD63AA4C6A2B.intranet221?nn=170852

Humanarzneimittel - Österreich

PSUR-outcome: Bimatoprost
Mustertext veröffentlicht
Veröffentlicht am: *21 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/211221_Mustertext_Bimatoprost.pdf (Mustertext)
https://ec.europa.eu/health/documents/community-register/html/ho27620.htm (EC link)

PSUR-outcome: Dexmedetomidin
Mustertext veröffentlicht
Veröffentlicht am: *21 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/211221_Mustertext_Dexmedetomidin.pdf (Mustertext)
https://ec.europa.eu/health/documents/community-register/html/ho27005.htm (EC link)

PSUR-outcome: Metamizol
Mustertext veröffentlicht
Veröffentlicht am: *03 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/07_Unternehmen/PV-Mustertexte/220103_Mustertext_Metamizol.pdf (Mustertext)
https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_document-psusa?sort=field_ema_computed_date_field&order=desc (EMA link)

Handbuch zur Befuellung des Suchtmittelnachweisungsformulars 2021 (L_I120) (neu)
Veröffentlicht am: *30 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/I/L_I120_Handbuch_zur_Befuellung_des_Suchtmittelnachweisungsformulars.pdf (Handbuch)
https://www.basg.gv.at/fuer-unternehmen/arzneimittel-informationen/suchtmittel/formulare-stammdaten#c18118 (Überblick)

Formular: Suchtmittel Nachweis 2021 (F_I20) (neu)
Veröffentlicht am: *30 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/I/F_I20_Suchtmittel_Nachweis_2021.xlsm

Suchtmittel Stammdaten_30122021 (neu)
Veröffentlicht am: *30 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/I/Suchtmittel_Stammdaten_30122021.xlsx

Humanarzneimittel - Österreich

COVID-19 Kurzmeldungen
Veröffentlicht am: *16 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/marktbeobachtung/amtliche-nachrichten/detail/covid-19-1

Aktuelle Statistiken
Veröffentlicht am: *07 - Januar - 2022*
Weitere Informationen finden Sie unter:
http://www.bfarm.de/DE/Aktuelles/Statistiken/_node.html;jsessionid=664CAB9AF42789DE7F027B18FD4641A6.internet561

Humanarzneimittel - Schweiz

Praxisauslegung – Anforderungen der Medizinprodukteverordnung für Importeure im Falle von Kombinationsprodukten
Veröffentlicht am: *10 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/praxisauslegung-anforderungen-mepv-importeure-kombinationsprodukte.html

ICH und IPRP Meetings – Swissmedic hat erneut den stellvertretenden Vorsitz der ICH-Generalversammlung inne
Veröffentlicht am: *17 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/ich-iprp-meetings-swissmedic-erneut-stellvertretenden-vorsitz.html

Klinische Versuche mit Arzneimitteln
„Papierlose Einreichung ab dem 01. Januar 2022 […] Bitte beachten Sie ferner, dass die elektronische Einreichung der Gesuchsunterlagen per Filetransfer-Service nur noch bis 31.12.2021 möglich sein wird. Ab dem 01.01.2022 ist die elektronische Einreichung von Gesuchsunterlagen nur noch per CD/DVD möglich“
Veröffentlicht am: *20 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/clinical-trials/klinische-versuche-mit-arzneimitteln.html

FAQ - Meldungen von Medizinprodukten
„Im neuen Merkblatt finden Sie Antworten zu häufig gestellten Fragen rund um die Meldungen von Medizinprodukten.“
Veröffentlicht am: *21 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/marktzugang/meldung-medizinprodukten.html

Meldung Mandat als Schweizer Bevollmächtigter (CH-REP) – Neues Formular
Veröffentlicht am: *23 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/uebersicht-medizinprodukte/formular-mandat-chrep.html

FSN-Vorgaben zur Publikation
„Sicherheitsanweisungen im Feld (Field Safety Notice, FSN), die Produkte auf dem Schweizer Markt betreffen, werden auf der Swissmedic Internetseite publiziert, in der Form und mit den Inhalten wie sie vom Hersteller zur Verfügung gestellt wurden.“
Veröffentlicht am: *27 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/vorkommnisse---fsca-melden--materiovigilance-/hersteller---inverkehrbringer.html

Humanarzneimittel - Schweiz

Stand Zulassungen zur Bekämpfung von Covid-19
Veröffentlicht am: *27 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/stand-zl-bekaempfung-covid-19.html

Aktualisierung des Merkblattes zu den Pflichten der Wirtschaftsakteure
„Medizinprodukte – Swissmedic hat die Information zu den Angaben des Schweizer Bevollmächtigten und des Importeurs auf dem Produkt und dessen beiliegenden Dokumenten aktualisiert (Kapitel 6).“
Veröffentlicht am: *30 - Dezember - 2021*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/uebersicht-medizinprodukte/aktualisierung-mb-pflichten-wirtschaftsakteure.html

Happy Birthday Swissmedic
Veröffentlicht am: *01 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/happy-birthday-swissmedic.html

Anpassung der Wegleitung Befristete Zulassung Humanarzneimittel HMV4
Veröffentlicht am: *01 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpassung-wl-befristete-zulassung-ham.html

Anpassung der Wegleitung Projekt Orbis HMV4
„Praxisänderung Projekt Orbis: Versand von Swissmedic Information Requests neu ausschliesslich an Gesuchstellerin in der Schweiz“
Veröffentlicht am: *01 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpssung-wl-projekt-orbis.html

Nachtrag 10.6 der Europäischen Pharmakopöe in Kraft
„Seit 1. Januar 2022 ist der Nachtrag 10.6 zur Europäischen Pharmakopöe in Kraft.“
Veröffentlicht am: *01 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/legal/pharmacopoea/wichtige-informationen/nachtrag_10_6_europaeischen_pharmakopoee.html

Meldung von Verdacht auf illegalen Arzneimittelhandel
„Das Formular zur Einreichung einer Meldung steht neu nur noch online zur Verfügung“
Veröffentlicht am: *03 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/meldung_verdacht_illegalen_arzneimittelhandel.html

Humanarzneimittel - Schweiz

Neue Liste der publizierten (Direct) Healthcare Professional Communications (DHPC/HPC)
Veröffentlicht am: *05 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/health-professional-communication--hpc-.html

Swissmedic Journal Dezember 2021
Veröffentlicht am: *06 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/dam/swissmedic/de/dokumente/stab/journal/swissmedic_journal122021.pdf.download.pdf/Swissmedic%20Journal%2012-2021.pdf

Aktualisierte Vorgabedokumente
„-MU100_00_001d_PU Information zu unzulässigen Produkten wie Tees oder Kapseln mit Senna (1.01.2022)
-MU600_00_006d_MB Beschaffung von Medizinprodukten in Gesundheitseinrichtungen (07.01.2022)
-MU600_00_016d_MB Pflichten Wirtschaftsakteure CH (30.12.2021)
-I-503.RL.02-A01d COVID-19 Inspektionssetup Checkliste (05.01.2022)
-I-SMI.TI.18e Legal requirements and mandatory due diligence by Swiss firms wishing to engage in foreign trade with medicinal products from Switzerland (04.01.2022)
-MU104_20_001d_MB Meldepflicht Verdacht auf illegalen Arzneimittelhandel (01.01.2022)
-ZL000_00_048d_WL_Wegleitung Projekt Orbis HMV4 (01.01.2022)
-ZL109_00_001d_WL Wegleitung Befristete Zulassung Humanarzneimittel HMV4 (01.01.2022)“
Veröffentlicht am: *07 - Januar - 2022*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents.html

Fragen an das Netzwerk

Falls Sie eine Frage haben, die Sie gerne in unserem Netzwerk diskutieren würden, senden Sie uns einfach eine E-Mail an info-as@megra.org zur anonymen Publikation im nächsten Newsletter.*

*Bei der Beantwortung der Fragen handelt es sich um eine Zusammenfassung von persönlichen Meinungen und Erfahrungswerten der MEGRA Mitglieder mit keinem Anspruch auf Rechtssicherheit. Wir empfehlen zur Absicherung die Konsultation entsprechender zugrunde liegender Regularien.

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

Keine Veranstaltungen veröffentlicht

Österreich

AGES Online-Kurs R for Data Science - Basiskurs
Ort: *Online via Zoom*
Termin:
26. bis 27. - Januar - 2022
06. bis 07. - April - 2022
Weitere Informationen finden Sie unter:
https://www.ages.at/service/ages-akademie/basg-veranstaltungen-neu/details/kalender/detail/event/ages-online-kurs-r-for-data-science-basiskurs-1/ und
https://www.ages.at/service/ages-akademie/basg-veranstaltungen-neu/details/kalender/detail/event/ages-online-course-r-for-data-science-basic/

BASG-Gespräch: IT-Neuigkeiten für den regulatorischen Bereich
Ort: *Wien oder online*
Termin: *06 - April - 2022 von 13:00 - 17:00 Uhr*
Weitere Informationen finden Sie unter:
https://www.ages.at/service/ages-akademie/basg-veranstaltungen-neu/details/kalender/detail/event/basg-gespraech-it-neuigkeiten-fuer-den-regulatorischen-bereich-1/

R für Data Science – Fortgeschritten
Ort: *Wien*
Termin: *05. bis 06. - Oktober – 2022*
Weitere Informationen finden Sie unter:
https://www.ages.at/service/ages-akademie/basg-veranstaltungen-neu/details/kalender/detail/event/r-fuer-data-science-fortgeschritten/

AGES Online-Course R for Data Science - Advanced
Ort: *Online via Zoom*
Termin: *09. bis 10. - November - 2022*
Weitere Informationen finden Sie unter:
https://www.ages.at/service/ages-akademie/basg-veranstaltungen-neu/details/kalender/detail/event/ages-online-course-r-for-data-science-advanced-2/

Schweiz

Keine Veranstaltungen veröffentlicht

Veranstaltungen / Events – Behörden und andere Veranstalter

Europa

Regulatory science research needs launch event
Where: *Online*
Date: *18 - January - 2022, 10:00 - 12:00 (CET)*
For more information, please refer to:
https://www.ema.europa.eu/en/events/regulatory-science-research-needs-launch-event

Introducing DADI: webinar on the digital application dataset integration (DADI) network project to replace electronic application forms
Where: *Online meeting*
Date: *18 - January - 2022, 10:30 - 12:00 CET*
For more information, please refer to:
https://www.ema.europa.eu/en/events/introducing-dadi-webinar-digital-application-dataset-integration-dadi-network-project-replace

CTIS sponsor user training programme - six separate courses
Where: *Online*
Dates:
24 - 27 January 2022, 14:00 - 18:30 (CET)
15 - 18 February 2022, 09:00 - 13:30 (CET)
01 - 04 March 2022, 09:00 - 13:30 (CET)
05 - 08 April 2022, 14:00 - 18:30 (CEST)
10 - 13 May 2022, 09:00 - 13:30 (CEST)
20 - 23 June 2022, 14:00 - 18:30 (CEST)
For more information, please refer to:
https://www.ema.europa.eu/en/events/ctis-sponsor-user-training-programme

Digital application dataset integration (DADI) webinar - common factors in the Fast Healthcare Interoperability Resources (FHIR) data standard for Article 57(2) and electronic application forms (eAF)
Where: *Online meeting*
Date: *25 - January - 2022, 10:30 - 12:00 CET*
For more information, please refer to:
https://www.ema.europa.eu/en/events/digital-application-dataset-integration-dadi-webinar-common-factors-fast-healthcare-interoperability

Veranstaltungen / Events – Behörden und andere Veranstalter

Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: Hands-on training course on using the EudraVigilance system
Where: *Online meeting*
Date:

07 to 11 - February - 2022
14 to 18 - March - 2022
04 to 08 - April - 2022
18 to 20 - May - 2022
13 to 17 - June - 2022
04 to 08 - July - 2022

For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance/eudravigilance-training-support

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - February 2022
Where: *Virtual event*
Date: *14 to 16 - February - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-february-2022

Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - February 2022
Where: *Virtual event*
Date: *17 - February - 2022, 13:30 – 18:15 CET*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-clinical-trial-sponsors

16th industry stakeholder platform - operation of European Union (EU) pharmacovigilance
Where: *Online meeting*
Date: *17 - February - 2022, 09:00 - 13:15 CET*
For more information, please refer to:
https://www.ema.europa.eu/en/events/16th-industry-stakeholder-platform-operation-european-union-eu-pharmacovigilance

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - May 2022
Where: *Virtual event*
Date: *02 to 04 - May - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-may-2022

Veranstaltungen / Events – Behörden und andere Veranstalter

Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - May 2022
Where: *Virtual event*
Date: *05 - May - 2022, 09:00 - 13:15 CET*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-clinical-trial-sponsors-0

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - June 2022
Where: *Virtual event*
Date: *27 to 29 - June - 2022*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-june-2022

Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - June 2022
Where: *Virtual event*
Date: *30 - June - 2022, 13:30 - 18:15 CET*
For more information, please refer to:
https://www.ema.europa.eu/en/events/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training-course-clinical-trial-sponsors-1

SAVE THE DATE! Conference celebrating the publication of the 11th Edition of the European Pharmacopoeia
Where: *Online meeting*
Date: *19 to 21 - September - 2022, 09:00 - 13:15 CET*
For more information, please refer to:
https://www.edqm.eu/en/news/save-date-conference-celebrating-publication-11th-edition-european-pharmacopoeia-19-21