**European Medical Writers Association (EMWA)**

**Resources for Medical Writers**

<https://www.emwa.org/resources/resources-for-medical-writers/>

| Agency | Topic | Date | Website links |
| --- | --- | --- | --- |
| **EMA** | Statistics | 30 July 2020 | <https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-sensitivity-analysis-clinical-trials-guideline-statistical-principles_en.pdf> |
| **ICH** | Statistics | 4 December 2019 | <https://www.ich.org/news/ich-e9r1-addendum-reaches-step-4-ich-process> |
| **EMA** | Lay Summary | 26 January 2017 | <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf> |
| **EMA** | PV | 02 March 2020 | <https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vii-periodic-safety-update-report-explanatory_en.pdf> |
| **EMA** | PV | 7 November 2018 | [https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidelines-good-pharmacovigilance-practices-gvp-introductory-cover-note-last-updated-chapter-piv\_en.pdf](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidelines-good-pharmacovigilance-practices-gvp-introductory-cover-note-last-updated-chapter-piv_en.pdf%20) |
| **ICH** | Clinical trials | May 2019; 30 September 2019 | <https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E8/E8-R1EWG_Step2_DraftGuideline_2019_0508.pdf> |
| **FDA** | GCP | Draft version endorsed 8 May 2019.  Public consultation open until 30 September 2019 | <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e8r1-general-considerations-clinical-studies> |
| **EMA** | Bioanalytical method validation | Public consultation open until: 01 September 2019 | [https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-guideline-m10-bioanalytical-method-validation-step-2b\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-guideline-m10-bioanalytical-method-validation-step-2b_en.pdf%20) |
| **EMA** | Paediatrics | 17 October 2018 | [http://esubmission.ema.europa.eu/paediatric\_submissions/Guidance%20on%20paediatric%20submissions.pdf](http://esubmission.ema.europa.eu/paediatric_submissions/Guidance%20on%20paediatric%20submissions.pdf%20) |
| EMA | Paediatrics | 04 October 2018 | <https://www.ema.europa.eu/en/human-regulatory/research-development/paediatric-medicines/paediatric-investigation-plans/paediatric-investigation-plans-templates-forms-submission-dates> |
| **FDA** | Paediatrics | April 2018 | <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM530012.pdf> |
| **FDA** | Paediatric | 22 January 2019 | [https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM629683.pdf](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM629683.pdf%20) |
| **FDA** | GCP | 28 February 2018 | <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM464506.pdf> |
| **EMA** | GCP | 3 February 2016 | <https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-clinical-practice-e6r2-4-step-2b_en.pdf> |
| **FDA** | GCP | Draft version endorsed 8 May 2019.  Public consultation open until 30 September 2019 | <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e8r1-general-considerations-clinical-studies> |
| **ICH** | Biopharma | 4 December 2019 | <https://www.ich.org/news/ich-m9-and-qas-reach-step-4-ich-process> |
| **ICH** |  | June 2018 | <http://www.ich.org/ichnews/newsroom/read/article/ich-q3dr1-revision-reaches-step-2b-of-the-ich-process-copy-1.html> |
| **EMA** | Medical devices | Q&A released: 22 October 2019  Medical devices:  26 May 2020  In vitro devices:  26 May 2022 | <https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-implementation-medical-devices-vitro-diagnostic-medical-devices-regulations-eu/745-eu-2017/746_en.pdf> |
| **FDA** | NDAs/INDs | 22 October 2019 | <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identification-manufacturing-establishments-applications-submitted-cber-and-cder-questions-and> |
| **FDA** | NDAs/INDs | 29 October 2019 | <https://www.fda.gov/media/132079/download> |
| **FDA** | NDAs/INDs | May 2019 | <https://www.fda.gov/media/124848/download> |
| **FDA** | NDAs/INDs | February 2019 | <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM631943.pdf> |
| **FDA** | NDAs/INDs | February 2019 | <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM631941.pdf> |
| **FDA** | NDAs/INDs | 3 January 2018 | <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM591134.pdf> |
| **Health Canada** | CTD | September 2019 | <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/activities/announcements/notice-mandatory-use-electronic-common-technical-document-ectd-format.html> |
| **EMA** | Medical devices | 27 February 2019 | <https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-implementation-medical-devices-vitro-diagnostic-medical-devices-regulations-eu/745-eu-2017/746_en.pdf> |
| **EMA** |  | 31 January 2019 | <https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-quality-non-clinical-clinical-requirements-investigational-advanced-therapy_en.pdf> |
| **EMA** | Risk Management | Start of public consultation 01 Feb 2018 – End of consultation 30 Apr 2018 | <http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500242959.pdf> |
| **EMA** | RMP | 31 October 2018 (published on EMA website 30 November 2018) | <https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidance-format-risk-management-plan-rmp-eu-integrated-format-rev-201_en.pdf> |
| **FDA** | Protocol | April 2018 | <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM498793.pdf> |
| **FDA** | PK/PD | 4 Sep 2018 | <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM531207.pdf> |