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Reg Auth'y	Title/Topic	Link	Issue date	Effective Date
HRA	Complex Innovative Trials: calls for new guideline adoption to get medicines to patients faster	https://www.hra.nhs.uk/about-us/news-updates/complex-innovative-trials-authors-call-new-guideline-adoption-get-medicines-patients-faster/ and https://www.hra.nhs.uk/about-us/news-updates/complex-innovative-trials-rethinking-clinical-trials-blog-hra-engagement-manager-will-navaiee/ and https://www.nature.com/articles/s41416-019-0653-9	06-Jan-20	
HRA	HRA and REC email addresses have changed	https://www.hra.nhs.uk/about-us/news-updates/our-email-addresses-are-changing/ and https://www.hra.nhs.uk/about-us/contact-us/updated-rec-email-addresses/	4 Feb 20	
HRA	Research in a public health emergency (expedited REC procedures)	https://www.hra.nhs.uk/about-us/news-updates/research-public-health-emergency/	10 Feb 20	
HRA	Artificial Intelligence in Healthcare – HRA Blog	https://www.hra.nhs.uk/about-us/news-updates/ai-healthcare-blog-dr-vicky-chico/	29-Jan-20	
HRA	Updated model Clinical Trial Agreements	https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mCTA-CROmCTA	March 20	
HRA	Amendment submission tool	https://www.hra.nhs.uk/about-us/news-updates/new-online-submission-amendments-and-amendments-tool-launches-2-june/	2 June 20	
HRA	New public involvement service for COVID-19 studies	https://www.hra.nhs.uk/about-us/news-updates/new-public-involvement-service-covid-19-studies	28 May 20	
HRA	The rise of Complex Innovative Design (CID) trials during the COVID-19 pandemic	https://www.hra.nhs.uk/about-us/news-updates/rise-complex-innovative-design-cid-trials-during-covid-19-pandemic-blog-hra-engagement-manager-will-navaie/	20 May 20	

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HRA	New podcast series looking at innovative trail design launches	https://www.hra.nhs.uk/about-us/news-updates/new-podcast-series-looking-innovative-trail-design-launches/	30 Jul 20	
HRA	Pharmacy Assurance accepting non-oncology study types from the autumn	https://www.hra.nhs.uk/about-us/news-updates/pharmacy-assurance-accepting-new-study-types/	30 Jul 20	
MHRA	Brexit: The Transition Period	https://www.gov.uk/transition		
MHRA	MHRA/HRA Combined Ways of Working (cWOW)	https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/	27-Nov-19	
MHRA	MHRA Blogs on GCP	https://mhrainspectorate.blog.gov.uk/category/good-clinical-practice/	Ongoing	
MHRA	MHRA Blogs on medicines regulatory environment	https://medregs.blog.gov.uk/	Ongoing	
MHRA	Updated Guidance: Notify MHRA about a clinical investigation for a medical device	https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device	24 Jan 20	
MHRA	Managing clinical trials during Coronavirus (COVID-19)	https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19	24 Mar 20 22 Apr 20	
MHRA	Guidance: Approval of GxP documents when working from home during the coronavirus (COVID-19) outbreak	https://www.gov.uk/guidance/approval-of-gxp-documents-when-working-from-home-during-the-coronavirus-covid-19-outbreak?utm_source=e8808181-9625-4a7b-8f51-fb267725f4cf&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate	9 Apr 20	

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MHRA	Regulatory flexibility during Covid-19	https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19	19 May 20	
MHRA	Annual review of GCP Referrals 2019	https://www.gov.uk/government/statistics/annual-review-of-good-clinical-practice-referrals?utm_source=f9fb248c-4ed8-4c14-b483-0c42c3287b38&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate	29-May-20	
MHRA	GCP Inspection metrics 2017-18	https://www.gov.uk/government/publications/good-clinical-practice-inspection-metrics-2007-to-present?utm_source=24b5d9f3-cd23-46cf-a6bc-0bc928687686&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate	4-May-20	
MHRA	How healthcare providers can prepare for 1 January 2021	https://www.gov.uk/guidance/how-healthcare-providers-can-prepare-for-brexit	4 Aug 20	
NIHR	Changes to NIHR costing methodology from 2020/21	http://www.rdforum.nhs.uk/content/2019/10/29/changes-to-nihr-costing-methodology-from-2020-21/	29-Oct-19	01-Apr-20
NIHR	Framework for restart for studies paused due to COVID-19	https://www.nihr.ac.uk/news/supporting-the-restart-of-paused-nihr-research-activities/24890	21 May 20	
ABPI	New Publication: Working with patients and patient organisations	https://www.abpi.org.uk/publications/working-with-patients-and-patient-organisations-a-summary/	4 May 20	
UK R&D Forum	Excess Treatment Cost Payment Changes	http://www.rdforum.nhs.uk/content/2020/06/25/excess-treatment-cost-payment-changes-an-update-from-nhs-england-and-nhs-improvement-and-the-department-of-health-and-social-care/	25 Jun 20	

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ICH	ICH E9R1: Addendum on Estimands and Sensitivity Analysis on Clinical Trials to the Guideline on Statistical Principles for Clinical Trials	https://database.ich.org/sites/default/files/E9-R1_Step4_Guideline_2019_1203.pdf	20-Nov-19	20-May-20
ICH	ICH M1: ICH M1 Points to Consider Working Group and MedDRA MSSO - Communication on Coronavirus	https://admin.ich.org/sites/default/files/inline-files/ich_m1_ptc_wg-msso_communication_on_coronavirus-1_april_2020.pdf		01 Apr 20
ICH	ICH E6R3 Summary: Summary of the E6(3) Stakeholder Engagement Approach available now on the ICH website.	https://admin.ich.org/sites/default/files/2020-05/E6-R3_PublicEngagemenSummary_2020_0421.pdf		21 Apr 20
ICH	The E2B(R3) User Guide v1.1 is available for download in the Implementation Package version 1.08 on the ESTRI webpage.	https://www.ich.org/page/e2br3-individual-case-safety-report-icsr-specification-and-related-files	10 Aug 20	
EMA	Brexit-related guidance for companies	https://www.ema.europa.eu/en/about-us/brexit-uk-withdrawal-eu/brexit-related-guidance-companies		
EMA	Guideline on clinical investigation of medicinal products for the treatment of gout	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-investigation-medicinal-products-treatment-gout-first-version_en.pdf	14-Nov-19	01-Jun-20
EMA	Mandatory use of international standard for the reporting of side effects to improve safety of medicines	https://www.ema.europa.eu/en/news/mandatory-use-international-standard-reporting-side-effects-improve-safety-medicines and the new guide: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-union-individual-case-safety-report-icsr-implementation-guide_en.pdf	15-Jan-20	30 June 2022
EMA	Position Statement on UK withdrawal from the EU on 31 January 2020	https://www.ema.europa.eu/en/news/uk-withdrawal-eu-31-january-2020	31-Jan-20	

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EMA	Guidance on the management of clinical trials during COVID-19 pandemic	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf	28 Apr 20	
EMA	Application of the Medical Devices Regulation delayed by one year (to 26 May 2021).	https://ec.europa.eu/commission/presscorner/detail/en/ip_20_718	23 Apr 20	
EMA	EMA/CHMP/SAWP/120610/2020: Qualification opinion of clinically interpretable treatment effect measures based on recurrent event endpoints that allow for efficient statistical analyses	https://www.ema.europa.eu/en/documents/other/qualification-opinion-clinically-interpretable-treatment-effect-measures-based-recurrent-event_en.pdf		14-Apr-20
EMA	EMA/INS/GCP/467532/2019: Notice to sponsors on validation and qualification of computerised systems used in clinical trials	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/notice-sponsors-validation-qualification-computerised-systems-used-clinical-trials_en.pdf		07-Apr-20
EMA	Update to EMA guidance in forms of questions and answers (Q&As) on good clinical practice (GCP) – Q & A 8 & 9 updated	https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/qa-good-clinical-practice-gcp#gcp-matters-section	Apr 20	
EMA	EMA/158330/2020 Rev. 1: Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials	https://www.ema.europa.eu/en/documents/scientific-guideline/points-consider-implications-coronavirus-disease-covid-19-methodological-aspects-ongoing-clinical_en-0.pdf	26 Jun 20	
FDA	Draft guidance on Research Participant confidentiality	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	Nov-19	
FDA	Final Guidance on Adaptive Clinical Trial Designs	https://www.fda.gov/media/78495/download	20-Dec-19	
FDA	Draft guidance on demonstrating substantial evidence of drug effectiveness	https://www.fda.gov/media/133660/download	20-Dec-19	
FDA	New policy on emergency unblinding	https://www.niaid.nih.gov/sites/default/files/POL-A15-OPC-00600-DAIDS-Emergency-Unblinding-Policy-Final.pdf	20-Dec-19	

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FDA	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	27 Mar 20	
FDA	Draft Guidance: Contact Dermatitis from Topical Drug Products for Cutaneous Application: Human Safety Assessment	https://www.fda.gov/media/135888/download	March 2020	
FDA	COVID-19: Developing Drugs and Biological Products for Treatment or Prevention	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention		11-May-20
FDA	COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-public-health-emergency-general-considerations-pre-ind-meeting-requests-covid-19-related		11-May-20
FDA	Development of Anti-Infective Drug Products for the Pediatric Population	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-anti-infective-drug-products-pediatric-population	June 2020	
FDA	Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry	https://www.fda.gov/media/139145/download		16 Jun 20
FDA	Patient-Focused Drug Development: Collecting Comprehensive and Representative Input	https://www.fda.gov/media/139088/download		16 Jun 20
FDA	Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment	https://www.fda.gov/media/79516/download		23 Jun 20
FDA	Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment	https://www.fda.gov/media/75149/download		23 Jun 20

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FDA	Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-patients-hiv-hepatitis-b-virus-or-hepatitis-c-virus		July 20
FDA	Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-patients-organ-dysfunction-or-prior-or-concurrent		July 20
FDA	Cancer Clinical Trial Eligibility Criteria: Brain Metastases	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-brain-metastases		July 20
FDA	Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-minimum-age-considerations-inclusion-pediatric-patients		July 20
NMPA (China)	China Drug Law reforms	http://english.nmpa.gov.cn/ and https://www.bloomberg.com/news/articles/2019-03-23/china-pledges-stronger-reform-on-approving-monitoring-new-drugs		01-Dec-19