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Reg Auth'y	Title/Topic	Link	Issue date	Effective Date
Legislation	Medicines and Medical Devices Act 2021	https://www.legislation.gov.uk/ukpga/2021/3/enacted	11 Feb 21	
HRA	COVID-19 Study Planning	https://www.hra.nhs.uk/about-us/news-updates/are-you-planning-research-study-looking-covid-19/	1 Sep 20	
HRA	Changes to ARSAC research application process	https://www.hra.nhs.uk/about-us/news-updates/changes-arsac-research-application-process	3 Sep 20	
HRA	Complex innovative design trials -Podcasts	https://www.hra.nhs.uk/about-us/news-updates/podcast-series-on-complex-innovative-design-trials/	2 Sep 20	
HRA	Removal of commercial Organisation Information Document	https://www.hra.nhs.uk/about-us/news-updates/removal-commercial-organisation-information-document/	5 Nov 20	
HRA	Making changes to a research study to manage the impact of COVID-19	https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/	25 Nov 20	
HRA	Guidance for health and social care researchers at the end of the Transition Period	https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/guidance-health-and-social-care-researchers-end-transition-period/	5 Jan 21	
HRA	Fast Track Ethics Review Pilot	https://www.hra.nhs.uk/about-us/news-updates/fast-track-ethics-review-pilot-opens-january/	3 Dec 20	1 Jan 21
HRA	Technical Assurances update: MPE/CRE review procedure and generic risk statement	https://www.hra.nhs.uk/about-us/news-updates/technical-assurances-update-mpecre-review-procedure-and-generic-risk-statement/	3 Dec 20	
HRA	HRA London office address changed on 1 Jan 2021	https://www.hra.nhs.uk/about-us/news-updates/our-london-office-address-changing/		1 Jan 21
HRA	HRA amendment tool on IRAS updated	https://www.hra.nhs.uk/about-us/news-updates/weve-updated-our-amendment-tool-on-iras	3 Dec 20	

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HRA	New weekly podcast series looks at innovation in trial design and study delivery during the COVID pandemic	https://www.hra.nhs.uk/about-us/news-updates/new-podcast-series-looks-innovation-trial-design-and-study-delivery-during-covid-pandemic/	28 Jan 21	
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	How healthcare providers can prepare for 1 January 2021	https://www.gov.uk/guidance/how-healthcare-providers-can-prepare-for-brexit	4 Aug 20	
MHRA	Clinical Trial Registrations post Brexit	https://www.gov.uk/government/collections/mhra-post-transition-period-information	4 Sep 20	
MHRA	Guidance on substantial amendments to a clinical trial from 1 January 2021	https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial-from-1-january-2021--2	31 Dec 20	
MHRA	List of approved countries for authorised human medicines from 1 January 2021	https://www.gov.uk/government/publications/list-of-approved-countries-for-authorised-human-medicines-from-1-january-2021--2	31 Dec 20	
MHRA	Procedures for UK Paediatric Investigation Plan (PIPs) from 1 January 2021	https://www.gov.uk/guidance/procedures-for-uk-paediatric-investigation-plan-pips-from-1-january-2021	31 Dec 20	
MHRA	Guidance on qualified person responsible for pharmacovigilance (QPPV) including pharmacovigilance system master files (PSMF) from 1 January 2021	https://www.gov.uk/guidance/guidance-on-qualified-person-responsible-for-pharmacovigilance-qppv-including-pharmacovigilance-system-master-files-psmf-from-1-january-2021	04-Sep-20	
MHRA	Guidance for industry on MHRA's expectations for return to UK on-site inspections	https://www.gov.uk/guidance/guidance-for-industry-on-mhras-expectations-for-return-to-uk-on-site-inspections	11-Aug-20	

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MHRA	Update to covering letter and fee requirements for CTAs	https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk	16-Oct-20	
MHRA	CESP no longer available for UK studies from 1 Jan 2021	https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021	01-Sep-20	
MHRA	MHRA contact information updated for CTA enquiries	https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#clinicaltrialapplication	16-Oct-20	
MHRA	Procedures for UK PIPs from 1 January 2021	https://www.gov.uk/guidance/procedures-for-uk-paediatric-investigation-plan-pips-from-1-january-2021	27-Oct-20	
MHRA	Making payments to MHRA	https://www.gov.uk/guidance/make-a-payment-to-mhra	29-Oct-20	
MHRA	Clinical trials applications for Coronavirus (COVID-19) (Update)	https://www.gov.uk/guidance/clinical-trials-applications-for-coronavirus-covid-19	09-Nov-20	
MHRA	Guidance on minimising disruptions to the conduct and integrity of clinical trials of medicines during COVID-19 (updated)	https://www.gov.uk/guidance/guidance-on-minimising-disruptions-to-the-conduct-and-integrity-of-clinical-trials-of-medicines-during-covid-19#history	13-Nov-20	
MHRA	On-site access to Electronic Health Records by Sponsor representatives in clinical trials.	https://www.gov.uk/guidance/on-site-access-to-electronic-health-records-by-sponsor-representatives-in-clinical-trials	26-Nov-20	
MHRA	COVID-19 treatments: making a proposal for clinical trials (updated guidance)	https://www.gov.uk/government/publications/covid-19-treatments-making-a-proposal-for-clinical-trials	16-Dec-20	
MHRA	Guidance on submitting clinical trial safety reports from 1 January 2021	https://www.gov.uk/guidance/guidance-on-submitting-clinical-trial-safety-reports-from-1-january-2021 and https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021	18-Dec-20	

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MHRA	Guidance on Project Orbis (Multinational Oncology programme)	https://www.gov.uk/guidance/guidance-on-project-orbis	10 Dec 20	
MHRA	Registration of clinical trials for IMPs and publication of summary results	https://tinyurl.com/yyfkuv3x	31 Dec 20	
MHRA	New MHRA Blog on Reference Safety Information (RSI) for Clinical Trials- Part III.	https://mhrainspectorate.blog.gov.uk/2021/02/05/reference-safety-information-rsi-for-clinical-trials-part-iii/	5 Feb 21	
MHRA	Innovative Licensing and Access Pathway (ILAP)	https://www.gov.uk/government/news/the-mhra-innovative-licensing-and-access-pathway-is-open-for-business?utm_source=71573a1a-d6e8-4752-b1b7-f545eb09e157&utm_medium=email&utm_campaign=govuk-notifications&utm_content=daily	1 Jan 21	
MHRA	GCP Inspection Metrics April 2018 to March 2019	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/961531/GCP_INSPECTIONS_METRICS_2018-2019_final_12-02-21.pdf	12 Feb 21	
MHRA	Managing clinical trials during Coronavirus (COVID-19) – Vaccine Deployment Assessment	https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19	17 Feb 21	
NIHR	COVID-19 - Black and Asian patients	https://www.nihr.ac.uk/news/black-and-asian-patients-have-increased-risk-of-severe-covid-19-at-different-stages-of-the-disease/25850	09-Oct-20	
NIHR	CRN Portfolio Application System (PAF) to be discontinued.	https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm	28-Oct-20	
NIHR	New: National Patient Recruitment Centres	https://www.nihr.ac.uk/news/nihr-launches-new-national-patient-recruitment-centres-for-late-phase-commercial-clinical-research/26154	12-Nov-20	
NIHR	Online tool identifies COVID-19 patients at highest risk of deterioration	https://www.nihr.ac.uk/news/online-tool-identifies-covid-19-patients-at-highest-risk-of-deterioration/26543	19 Jan 21	

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ABPI	Ending the transition period with new border arrangements	https://www.abpi.org.uk/medicine-discovery/uk-and-eu-future-relationship/ending-the-transition-period-with-new-border-arrangements/	1 Jan 21	
UK R&D Forum	Non-Covid trial restart - contracts	http://www.rdforum.nhs.uk/content/2020/09/30/statement-on-commercial-and-non-commercial-site-agreement-contract-variation-at-restart	30 Sep 20	
UK R&D Forum	Upcoming changes to the method of calculating recruitment to time and target for open studies and sites	https://rdforum.nhs.uk/news/entry/7706/	26 Jan 2021	
UK R&D Forum	Data Transfers within EU (EEA)	https://rdforum.nhs.uk/news/entry/7578/	25 Jan 21	
UK R&D Forum	CCG ETC Payments for Devolved Administration-led Studies	https://rdforum.nhs.uk/news/entry/10193/	29 Feb 21	
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	2020EMA/CHMP/QWP/292439/2017: Reflection paper on the pharmaceutical development of medicines for use in the older population.	https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-pharmaceutical-development-medicines-use-older-population-first-version_en.pdf	15 Oct 20	1 May 21
EMA	EMA/CHMP/470185/2020: Questions and answers on Data Monitoring Committees issues	https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-data-monitoring-committees-issues_en.pdf	17 Sep 20	
EMA	EC issues draft decision on flow of personal data to the UK	https://tinyurl.com/yaclun6e, https://tinyurl.com/10dnekqz	19 Feb 21	

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FDA	Limited Population Pathway for Antibacterial and Antifungal Drugs Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/limited-population-pathway-antibacterial-and-antifungal-drugs-guidance-industry		Aug 2020
FDA	Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment	https://www.fda.gov/media/142143/download		14-Sep-20
FDA	Enhancing the Diversity of Clinical Trial Populations - Final Guidance	https://www.fda.gov/media/127712/download		09-Nov-20
FDA	Qualification Process for Drug Development Tools	https://www.fda.gov/media/133511/download		01-Nov-20
FDA	Best Practices in Developing Proprietary Names for Human Prescription Drug Products; Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry		01-Dec-20
FDA	COVID-19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV-2 Infectivity	https://www.fda.gov/media/145128/download		Jan 2021
FDA	Dry Eye: Developing Drugs for Treatment Guidance for Industry (draft guidance)	https://www.fda.gov/media/144594/download	17 Dec 20	