The new Clinical Trial Regulation explained…break-time sessions to ease your transition! - References and information sources, December 2021

1. **Legislation**
   - Regulation 536/2014: https://ec.Europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
   - Commission Delegated Regulation (EU) 2017/1569 specifying principles and guidelines for good manufacturing practices and arrangements for inspections; https://eur-lex.europa.eu/eli/reg_del/2017/1569/oj

2. **EU Guidance**
   - Current and future Commission guidelines: https://ec.europa.eu/health/documents/eudralex/vol-10
   - General Q+A (September 2021, this document is updated from time to time, please reference the most up to date version): https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf
   - Transition: 2018_05_CTFG_Best_Practice_Guide_for_sponsors_of_transition_multinational_clinical_trials.pdf (hma.eu)
   - Transparency: https://www.ema.europa.eu/en/documents/other/appendix-disclosure-rules-functional-specifications-eu-portal-eu-database-be-audited_en.pdf
   - Risk proportionate approaches: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_04_25_risk_proportionate_approaches_in_ct.pdf
   - Reflection paper on risk based quality management in clinical trials: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-risk-based-quality-management-clinical-trials_en.pdf
   - Auxiliary meds: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_06_28_recommendation_on_axmps.pdf
   - Serious breaches: https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-notification-serious-breaches-regulation-eu-no-536/2014-clinical-trial-protocol_en.pdf

3. **Training events**
   - HPRA webinars, November 2021: http://www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/clinical-trial-regulation-(regulation-(eu)-no-536-2014)/
   - Commission training course March 2021: https://ec.europa.eu/health/human-use/events/ev_20210309_en
   - EMA Clinical Trials Information System (CTIS): Virtual information day: https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-virtual-information-day
   - EMA Webinar for small and medium-sized enterprises (SMEs) and academia on the Clinical Trials Regulation and the Clinical Trials Information System (CTIS): https://www.ema.europa.eu/en/events/webinar-small-medium-sized-enterprises-smes-academia-clinical-trials-regulation-clinical-trials

4. **Clinical Trials Information System (CTIS)**
   - EMA Clinical Trials Information System: training and support: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support
   - EMA Training Modules on CTIS: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme
   - Guide to CTIS Training Material Catalogue: https://www.ema.europa.eu/en/documents/other/guide-ctis-training-material-catalogue_en.pdf
   - EMA Clinical Trials Information System (CTIS) highlights: https://www.ema.europa.eu/en/news-events/publications/newsletters#clinical-trials-information-system-(ctis)-highlights-section
   - EMA Clinical Trial Information System (CTIS) – Sponsor Handbook: https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_en.pdf
   - CTIS Structured data form – notifications: https://www.ema.europa.eu/documents/template-form/clinical-trial-information-system-ctis-structured-data-form-notifications_en.xlsx
   - Sponsors Workspace Roles-permission matrix summary: https://www.ema.europa.eu/en/documents/other/sponsor-workspace-summary-role-permissions_en.pdf
   - Summary of roles Management of roles and permissions in the sponsor workspace CTIS Training Programme – Module 7: https://www.ema.europa.eu/en/documents/other/sponsor-workspace-summary-roles_en.pdf
   - FAQs Management of roles and permissions CTIS Training Programme – Module 7: https://www.ema.europa.eu/en/documents/other/faqs-management-roles-permissions-ctis-training-programme-module-07_en.pdf

5. **Department of Health (DoH)**
   - https://www.gov.ie/en/organisation/department-of-health/

6. **National Research Ethics Committee**
   - https://www.nrecoffice.ie/

7. **Others**
   - CTFG: https://www.hma.eu/ctfg.html
   - General information: https://www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/clinical-trial-regulation-(regulation-(eu)-no-536-2014)Fee consultation: https://www.hpra.ie/homepage/medicines/news-events/item?t=/public-consultation-on-proposed-clinical-trial-fees-for-2022&id=842e1026-9782-6eee-9b55-ff00008c97d0
   - EMA Account Management: https://register.ema.europa.eu/identityiq/login.jsf

8. **IMPs**
   - Batch certificate template: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-4/template_imp_batch_certification.docx
   - New Commission guidelines on GMP for IMPs: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/guideline_adopted_1_en_act_part1_v3.pdf