Clinical Trials Project Management Series 2:
Templates, Tools, and References Companion Guide

- **CWRU Weatherhead Executive Education, Project Leadership Certificate Program**
- **FDA Guidance Document Search:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents
    - Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND
    - Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring
        - A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers
- **HHS/NIH Resources**
    - **Health and Human Services (HHS) Clinical Research Study Investigator's Toolbox**
        - Data and Safety Monitoring Board: guidelines, templates, and checklists
        - Manual of Procedures (MOP, aka Manual of Operations): outline and guidelines for both single-site and multi-site studies.
        - Data Management Tips
        - Regulatory document templates: investigational product accountability, delegation of authority log, adverse event reporting, and more.
    - **National Institute of Dental and Craniofacial Research Clinical Researcher Toolkit, Planning & Start-up**
        - Templates: Clinical Data Management Plan, Manual of Operations, Monitoring plan, Quality Management, Safety Monitoring
- **Coverage Analysis**
    - CITI program module (if available through your institution)
    - Medicate Coverage, Clinical Trials: Final National Coverage Decision
- **Risk Assessment**
    - Transcelerate Risk Based Monitoring Initiative: Risk Assessment and Categorization Tool RACT Template and example
- **Corrective and Preventative Action Plans**
    - 5 Whys Root Cause Analysis Template
    - SoCRA Article, Resolving and Preventing Repetitive Problems in Clinical Trials: a case study to further explore the processes of Root Cause Analysis and Corrective and Preventative Action Plans.
- **Monitoring and Auditing**
    - USC School of Pharmacy, Department of Regulatory and Quality Sciences
        - Course Catalog, USC Regulatory Science/SC CTSI
            - Monitoring of a Clinical Trial Site course: includes templates for monitoring plan, risk-based monitoring plan development guidelines, SOP templates and checklists
            - Auditing of a Clinical Research Site course: includes templates for audit plans and reports, SOPs and checklists