**Mock Document #5: Clinical Operations Manual (COM) / Site Management Guide**

**Title:** *Clinical Operations Manual – Study HF-203 (Dapagliflozin in HFrEF)*  
**Version:** 1.2  
**Prepared by:** Clinical Trial Management Team  
**Date:** [Fictional] January 2024  
**Audience:** Clinical Site Staff, CRAs, Trial Managers

**1. Study Overview**

This manual provides detailed operational guidance for executing Study HF-203, including visit schedules, drug handling, safety reporting, and withdrawal management. It supplements the full protocol and is required reading for all site investigators and monitors.

**2. Participant Enrollment and Screening**

* **Informed Consent:** Must be obtained before any protocol-related procedure
* **Eligibility Review:** Investigator must complete checklist based on CSP-defined inclusion/exclusion
* **Randomization:** Per IWRS after eligibility confirmed
* **Screen Failure Documentation:** Reason must be recorded in the EDC system

**3. Study Drug Handling**

* **Accountability Logs:** Required for all IP shipments and returns
* **Storage Conditions:** 15–30°C, away from direct sunlight; controlled access
* **Blinding:** Product and placebo identical in packaging and labeling
* **Return & Destruction:** Unused product returned to sponsor or destroyed per SOP

**4. Adverse Event Monitoring**

* **Assessment Frequency:** At every visit and during unscheduled contacts
* **Documentation:** AE/SAE entries must be made in EDC within 24 hours
* **Causality Assessment:** Performed by PI
* **Reporting Hierarchy:** Site → CRA → Sponsor Pharmacovigilance → Regulatory

**5. Withdrawal and Discontinuation**

* **Voluntary Withdrawal:** Participant can exit at any time, reason to be recorded
* **Investigator-Initiated:** Due to AE, protocol non-compliance, or safety concerns
* **EOS Visit Completion:** Encourage final assessments per CSP
* **Discontinuation of Study Drug Only:** Follow Section 7.2 of CSP (e.g., QTcF >500 ms, eGFR <15)

**6. Visit Management and Source Documentation**

* **Visit Windows:** ±2 days acceptable unless otherwise noted
* **Remote Monitoring:** Permitted under COVID-19 contingency if IRB approved
* **CRF Completion:** Within 3 days of visit
* **Source Data Verification (SDV):** 100% SDV required for primary endpoint visits

**7. Site Responsibilities**

* Maintain delegation logs
* Complete site initiation training
* Store signed ICFs and study records for ≥15 years
* Comply with GCP and local regulatory authority requirements

**Supports CSP Prompts Like:**

* #HC\_AI\_Withdrawal\_And\_Discontinuation#
* #HC\_AI\_AE\_Monitoring#
* #HC\_AI\_Study\_Drug\_Accountability#
* #HC\_AI\_Treatment\_Assignment#