

DOC	JD-HMT-A01
TYPE	Internship position description
TRACK	Healthcare & MedTech
LEVEL	Student / early career

Clinical Research Intern, Clinical Operations & Site Coordination

Study documentation, site coordination, enrollment and visit tracking, and trial master file organization for device and IVD studies

KEY TO TERMS USED

PROTOCOL	The document defining how a study runs: who qualifies, what is measured, in what order.
ICF	Informed consent form. What a participant reads and signs before taking part.
TMF	Trial master file. The complete, audit-ready record of how a study was conducted.
CRF	Case report form. The structured form used to record each participant's data.
SITE	A hospital or clinic where participants are enrolled and study visits take place.
DEVIATION	Anything that happened differently from the protocol, recorded rather than hidden.

INTENDED ROLE

Clinical studies are won or lost on paperwork discipline: the right document version at the right site, every visit logged, every deviation written down while it is still fresh. This role sits inside that machinery. You will help prepare and organize study documentation, track site activity, and keep the record complete and audit-ready. The emphasis is on accuracy, traceability, and professional judgment about what to escalate, not on arriving with trial experience already in hand.

PRINCIPAL DUTIES

- Support preparation and version control of study documents such as protocols, informed consent forms, case report forms, and site instructions.
- Help organize and maintain trial master file and site file structures so that every document stays current and traceable.
- Track enrollment, visit schedules, and outstanding site actions, and flag anything slipping against the study timeline.
- Prepare meeting agendas, minutes, and follow-up action logs for internal study calls and site check-ins.
- Summarize protocol requirements and study procedures into short reference materials for internal use.
- Research publicly available guidance on good clinical practice and study conduct, and summarize what applies to a given study design.
- Use approved AI tools to draft, summarize, and reformat documents, then verify every requirement and reference against the source document.

EXAMPLE ASSIGNMENTS

Assignments depend on active studies, authorized data access, and the internship timeline. Examples may include:

- A site readiness and document checklist package for an upcoming device or IVD performance study
- An enrollment and visit tracking workbook with a weekly status summary for the study team
- A reorganized trial master file index with a gap list of missing or outdated documents

YOUR FIRST TWO WEEKS

- Read one study protocol end to end and write a one-page plain-language summary of it.
- Learn the file structure and naming rules, then file a backlog of documents correctly.
- Shadow two internal study calls and produce the minutes and action log for both.
- Build the first version of the enrollment tracker and reconcile it against the site's own count.

ABOUT HOPKINS MEDTECH

Hopkins MedTech Group LLC is a U.S. company working in medical technology and in vitro diagnostics. Its work covers clinical performance studies, protocol development and site coordination, data review and quality assurance, and regulatory support for United States and European pathways. The group is also exploring AI and digital health through an early-stage research initiative in facial and skin analysis.

REQUIRED QUALIFICATIONS

- Currently pursuing, or recently completed, a degree in a life science, public health, nursing, biomedical engineering, or a related field, or able to show equivalent project work.
- Strong written English and the ability to write short, precise, unambiguous instructions and summaries.
- Exceptional attention to detail, and comfort with version control, naming conventions, and repetitive checking work.
- Comfortable with spreadsheets and document tools for tracking, formatting, and structured record keeping.
- Discretion with confidential and patient-related information, and the judgment to ask first whenever a rule is unclear.
- No prior clinical trial, CRO, or professional internship experience is required.

PREFERRED QUALIFICATIONS

Not screening criteria. Coursework, labs, personal projects, and self-study all count as evidence.

- Coursework or lab exposure to research methods, biostatistics, human subjects research, or regulatory science
- Familiarity with the vocabulary of clinical studies, such as protocol, informed consent, deviation, and monitoring visit
- Any experience coordinating a project with multiple parties, deadlines, and documents that must stay in sync

WHAT YOU WILL GAIN

- See how a medical device or IVD study actually runs, from document preparation to site coordination and close-out.
- Learn why traceability and documentation discipline decide whether a study survives an audit.
- Practice the coordination skills that clinical research associate and study coordinator roles screen for.
- Leave with concrete examples of study documentation work you can describe in detail in an interview.

DATA HANDLING, PRIVACY, AND RESPONSIBLE AI

Interns work only with data and documents they have been explicitly authorized to access. Patient-identifiable information, study data, client-confidential files, and proprietary materials must never be uploaded to public or unapproved AI services, shared outside the project team, or stored on personal accounts or devices. AI tools may be used only

DELIVERABLES

- An organized study document set with a version log and gap list
- A tracking workbook plus a recurring status summary the team can keep using
- A short written handover describing what you built, how it works, and what remains open

SUPERVISION AND EVALUATION

Interns report to a named project lead, meet on a set weekly cadence, and receive written feedback on each deliverable. Work is evaluated on accuracy and traceability of sources, documentation quality, responsiveness to feedback, judgment about what to escalate, and disciplined use of approved AI tools. We expect steady learning and iteration rather than polished perfection on the first day.

WHAT WE DO NOT EXPECT

- Prior internship experience, or a name-brand employer on your CV.
- Knowing the regulations, tools, or vocabulary before you start; the terms box above is where most people begin.
- Certainty. Saying what the evidence does not support is treated as a strength, not a gap.

APPLICATION AND SELECTION

An application is a CV plus a short note naming the track you want and one project from this document you would like to work on, and why. First-round interviews are with the project lead who would supervise the work, not with a screening panel.

where the project lead has approved them for that task, and all AI-assisted work must be independently verified before it enters any deliverable. The intern and the project lead remain accountable for the final result.

Hopkins MedTech Group LLC provides equal internship and employment opportunities without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, veteran status, or any other legally protected characteristic. Internships are educational in nature; interns do not provide medical advice, make regulatory determinations, or represent the company to any health authority, client, or study site. The AI and digital health initiative described here is early-stage research, not a cleared, approved, or clinically validated product. Assignments, data access, duration, and supervision are confirmed in the final project description.