

- Location: Lausanne (Epalinges, Biopôle), Switzerland
- Full-time position (100%)
- Travel 50%-70% (Switzerland, Europe)

About Volumina Medical

Volumina Medical is a Swiss medtech company developing innovative implantable, resorbable medical devices in the fields of dermatology, aesthetic medicine, and plastic & reconstructive surgery. We work with leading clinicians to generate high-quality clinical evidence and to translate it into safe and meaningful patient outcomes.

The opportunity

We are seeking a motivated and experienced Clinical Research Associate (CRA) to support our clinical programs across Switzerland and Europe. In this role, you will be the sponsor-side interface with investigational sites, ensuring that clinical investigations are conducted in compliance with the clinical protocol, applicable regulations, and Good Clinical Practice (GCP) standards (including ISO 14155 for medical devices). You will partner closely with Clinical, Regulatory Affairs, Quality, and external investigators/CROs to deliver audit-ready documentation and reliable, high-integrity clinical data.

Key responsibilities

1) Study start-up & site activation

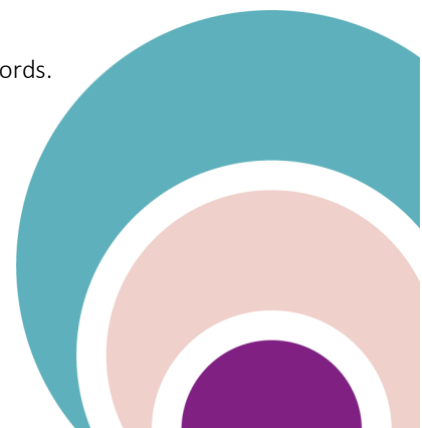
- Act as a primary point of contact for assigned investigational sites; build trusted partnerships with Principal Investigators and site teams.
- Support feasibility, site identification/selection, and activation, including collection/review of essential documents.
- Coordinate and/or support ethics and regulatory submissions (as delegated) and ensure approvals are in place prior to site initiation.
- Deliver and document site training (protocol, eCRF/EDC, safety reporting, device accountability) and contribute to investigator meetings.

2) Monitoring, oversight & issue management

- Conduct site qualification, initiation, monitoring (on-site/remote), and close-out visits in line with the Monitoring Plan and risk-based monitoring approach.
- Verify participant protection (informed consent), protocol compliance, and accurate documentation at the site level.
- Perform source data verification and data review to ensure accuracy, completeness, and consistency; manage queries, deviations, and corrective actions in collaboration with the study team and sites.
- Collect and process study-related information (including adverse events, device deficiencies, and complaints) in alignment with the Quality Management System and applicable vigilance processes.
- Support sponsor oversight of CRO/site activities as applicable (e.g., QC review of monitoring reports, visit frequency, metrics tracking).

3) Documentation, TMF/eTMF & inspection readiness

- Ensure timely and high-quality documentation of all monitoring activities (trip reports, follow-up letters, issue logs) and maintain traceable communication records.
- Contribute to the health of the Trial Master File (TMF/eTMF), ensuring audit/inspection readiness throughout the study lifecycle.
- Support preparation for audits/inspections (site and sponsor), including readiness checks and follow-up on findings.



4) Clinical evidence generation & reporting support

- Support drafting/review of key clinical documents (protocols, Investigator's Brochure, eCRF/CRF, monitoring plans, and related study materials).
- Contribute to data review, analysis summaries, and inputs to clinical study reports and other evidence packages as needed.
- Perform targeted literature reviews to support clinical strategy, safety/performance claims, and clinical evaluation activities.

Experience, qualifications & skills

- Bachelor's degree (or higher) in Life Sciences, Nursing, Biomedical Engineering, or related field.
- 3–5+ years of experience as CRA/Monitor, ideally in medical devices and/or dermatology/aesthetics clinical investigations.
- Demonstrated experience in early-phase and/or pivotal clinical trials (site management, SDV/data review, deviations, close-out).
- Working knowledge of ISO 14155, ICH-GCP principles, and applicable regulatory/ethics requirements for device clinical investigations.
- Hands-on experience with eTMF/eTMF workflows, EDC systems, query management, and inspection-ready documentation practices.
- Excellent organization, communication, and problem-solving skills; ability to work autonomously in a fast-paced, startup environment.
- High integrity, attention to detail, and a strong commitment to participant safety and data quality.
- Fluent English is required; French is strongly preferred; German is a plus.
- Willingness to travel extensively (approx. 50–70%) across Switzerland and Europe.
- Right to work in Switzerland (Swiss or EU/EFTA citizenship, or valid Swiss permit).

Nice-to-have

- Experience with dermal fillers, soft tissue regeneration, or aesthetic implants clinical studies.
- Familiarity with 3D photography systems used for standardized outcome assessment.
- Experience with decentralized/remote monitoring tools and site engagement strategies.

What we offer

- Impactful work on innovative, first-in-class clinical programs in soft tissue regeneration.
- A dynamic and stimulating environment on a leading life-science campus (Biopôle) with multidisciplinary collaboration.
- Competitive compensation package aligned with experience and responsibilities.
- A culture anchored in scientific integrity, patient safety, and operational excellence, with meaningful opportunities for growth.

Volumina Medical is committed to building an inclusive workplace where different ideas, backgrounds, and perspectives are valued. We recruit based on skills and potential, and we encourage applications from all qualified candidates.

How to apply

Please email your CV, work certificates and references, and a short motivation letter to:

- gilles.bioley@volumina-medical.ch
- amelie.beduer@volumina-medical.ch

Subject line: "CRA – Clinical Research Associate". Please include your earliest possible start date.

