



OrphaCare is a subsidiary of AOP Health that specializes in medical devices and patient support solutions for treating rare and complex diseases.

To enhance our team we are looking for a:

Manager, ClinOps (OrphaCare)

59425 Unna | Full-time employee | Start: as of now |



We are looking for a Manager, ClinOps at OrphaCare to drive the successful planning, execution, and oversight of clinical investigations for innovative Class III medical devices. In this role, you will act as the operational lead across all clinical trial activities—from study start-up to close-out—ensuring high-quality, compliant, and timely delivery in line with regulatory requirements and company standards. You will work cross-functionally and with external partners to translate clinical strategy into operational excellence.

What Your Day To Day Will Look Like

- Lead end-to-end operational planning, execution, and oversight of clinical investigations
- Translate clinical investigation plans into detailed operational strategies, timelines, and deliverables
- Manage study start-up, site selection, feasibility, and activation activities
- Oversee site management, study logistics, and documentation (including eTMF readiness)
- Act as primary operational contact for investigative sites and ensure effective communication and training
- Ensure studies are conducted in accordance with ISO 14155, EU MDR, ICH-GCP, and internal SOPs
- Drive vendor and CRO selection, contracting, onboarding, and performance management
- Monitor vendor deliverables, KPIs, budgets, and timelines in collaboration with internal stakeholders
- Coordinate cross-functional teams (e.g., Clinical, RA, QA, Data, Statistics, Safety, R&D)
- Ensure inspection readiness and support audits and regulatory inspections
- Identify and escalate risks related to quality, timelines, or compliance
- Maintain study trackers, documentation, and operational reporting

Your Qualifications And Experience

- Minimum 5 years of experience in clinical operations or clinical project management

- Proven experience in managing clinical studies, including vendor oversight and cross-functional coordination
- Strong experience in medical device clinical investigations (Class III/high-risk devices preferred)
- Solid knowledge of ISO 14155, EU MDR 2017/745, and ICH-GCP/GxP standards
- Experience with CRO/vendor management and inspection readiness
- Bachelor's or Master's degree in Life Sciences, Biomedical Engineering, Medicine, or a related field
- Fluency in English (written and spoken); additional languages are an advantage
- Strong organizational skills, attention to detail, and ability to manage complex projects
- Excellent communication skills and ability to work effectively in a matrix environment
- Willingness to travel at least 1 week a month to our Vienna office

Our offer

- Join a high-performing team within an open, collaborative corporate culture that encourages initiative and the contribution of new ideas.
- Benefit from a structured onboarding process and ongoing training opportunities to support your professional development.
- Enjoy a bonus scheme and comprehensive benefits
- Access continuous personal and professional development opportunities within an international environment.

If you would like to work as a team player in an international environment and can identify with our values "Agile, Ambitious, Aligned, Accountable and Appreciative", then: Take this CHANCE and

Main Benefits



Bonus



Homeoffice



Employee mobile phone



Flexible working hours



Laptop



Initial and continuing education



Employee events

Your Contact



Kenny Trappi

Talent Acquisition Manager

Further information on our website:

aop-health.com