The clinical operations services provided by ECRIN staff for academics and SMEs are <u>ISO 9001:2015 certified</u>. At the heart of our clinical operations service offer is our expertise and overarching support that we can provide to sponsors and investigators from their first contact through to the close out of their clinical study. The image below outlines the different ways in which ECRIN can support you.



- · Outline roles and responsibilities
- Available funding sources
- Eligibility for funding and ECRIN support
- Regulatory inquiries



- Trial design and methodology
- Regulatory, ethical, and insurance requirements
- · Funding application support
- Task distribution for multinational study management & selection of qualified CTUs
- Cost evaluation
- · Protocol peer review
- Strategies for site selection and patient recruitment



- · Study management and coordination
- · Regulatory and ethical submission
- Monitoring
- Vigilance
- Data management
- Statistical analysis



RISK ASSESSMENT

Assessment of feasibility, resources, and strategies for mitigation



EXPERTISE & OVERARCHING SUPPORT

Support to sponsor and PI throughout the maturation and execution of their ideas