

# Regulatory, Clinical, and Lab Support for **Neurovascular Intervention Devices**



Neurovascular intervention is a fast-moving field where device design and clinical practice both advance quickly. RQM+ supports manufacturers of flow diverters, stents, coils, liquid embolics, and thrombectomy systems across regulatory, clinical, laboratory, and reimbursement work. Our specialists work as one on the same program from the start, with trial design that accounts for how quickly standard of care can change.

## Services at a glance

### Regulatory & Quality

Regulatory strategy for neurovascular devices across the full sub-category range, from embolic coils to thrombectomy systems



### Lab & Material Science

Validated analytical chemistry across catheter polymer extractables and leachables (E&L), hydrophilic coating characterization, nitinol surface analysis, and liquid-embolic chemistry



### Clinical Trials

Trial design that anticipates changes in standard of care over the course of a study, a known risk factor for neurovascular trials



### Reimbursement

Reimbursement strategy support as novel device categories establish new coverage pathways



## Service details



### Regulatory & Quality

RQM+ develops regulatory strategy for neurovascular devices across the full sub-category range, from embolic coils to next generation thrombectomy systems. Submissions are built for both U.S. and EU pathways.



### Clinical Trials

Neurovascular trial design anticipates changes in standard of care over the life of a study, which is a known risk factor in this field. Endpoints and comparators are planned to stay valid as thrombectomy and flow-diversion practice advances.



### Lab & Material Science

Jordi Labs, an in-house, FDA-recognized laboratory, runs validated analytical chemistry across catheter polymer extractables and leachables (E&L), hydrophilic coating characterization, nitinol surface analysis, and liquid-embolic chemistry. Lumo™, our neural-network response-factor prediction platform, flags biocompatibility and E&L risks early.



### Reimbursement

Reimbursement strategy support helps novel device categories, such as next-generation thrombectomy systems, establish new coverage pathways. Health-economics planning is matched to where the category is heading.

### The MedTech CRO

Former FDA and notified body experts on staff

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1,300+ regulatory, testing, and clinical development programs delivered

...

1,000+ MedTech clients

Liquid-embolic and polymer chemistry capability is validated across the full range of neurovascular device sub-types.

### Want to learn more about RQM+ support for neurovascular intervention devices?

Our team can walk you through regulatory, clinical, laboratory, and reimbursement support for your program.

Connect with our team

Let's make your MedTech program happen.

**RQM+**  
Evolving MedTech

RQM+ is The MedTech CRO, accelerating innovation to patient impact. Our tailored solutions deliver regulatory and quality expertise, FDA-recognized laboratory services, clinical trials, and reimbursement strategies across device types and therapeutic areas to bring life-changing technologies to patients — faster, safer, better.

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