

## Medical Devices

Successful product development paths are often guided by thoughtful regulatory, economic and development strategies, as well as meticulous detail to clinical trial execution. From the first stages of getting your device classified by regulatory authorities through market surveillance on your approved product, our team of experienced professionals can help you mitigate risk by navigating regional or global regulations that apply to your device.

### MEDICAL DEVICE DEVELOPMENT

A wide range of clinical investigations with medical devices including:

In Vitro Diagnostic MD

Implantable MD

Borderline Cases

### SERVICES INCLUDE:

Project Management  
Medical Writing  
Regulatory  
Devicevigilance  
Data Management & Statistics

### Medical Device Experience

- Laser systems for glaucoma
- Minimally invasive glaucoma shunts (MIGS)
- Influenza vaccine/device combination
- Advanced macular degeneration monitoring device
- Diabetic retinopathy AI software
- Reagents for ex-vivo T-cell depletion for GVHD
- Drug coated balloon PTA catheter for treatment of dysfunctional native and synthetic AV fistulae
- VytronUS ablation system for treatment of symptomatic drug-refractory paroxysmal atrial fibrillation
- Remedē® system in patients with central sleep apnea
- Tempered infusions for induction and maintenance of normothermia in refractory febrile patients
- Catheter ablation vs. standard treatment for left ventricular dysfunction and atrial fibrillation