



Medical Device & Diagnostics Fact Sheet



Device Trial Experience

- Feasibility/Proof of Concept
- Pivotal
- Post Market Support/Registry
- 510(k)
- Class II/III IDE
- Combination Products
- Biologics
- Diagnostics

Contact Us

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Locations

Durham, North Carolina (HQ)
Wilmington, North Carolina
Boulder, Colorado
Columbus, Ohio
Stevenage, UK

Company

Novella Clinical is a full service clinical research organization (CRO) supporting the medical device industry through pilot, pivotal and post approval studies. From initial regulatory assessments to post approval/market studies, Novella Clinical provides the experience and insight to bring your device to market on time and on budget. In fact, Novella has earned preferred vendor status with two of the top five medical device companies.

Novella's MD&D management team has over 25 years medical device clinical research experience and is dedicated to true Sponsor/CRO collaboration and proactive trial management. As a result, Novella has developed structured relationship management systems leading to intellectually engaged project teams and highly satisfied clients. Novella's transparent, collaborative and proactive approach allows our clients to move devices and diagnostic tools to market faster.

Core Services

- Program Management
- eCRF Design & Programming
- EDC Application Hosting (Oracle's InForm™)
- Study Start-Up & Investigator Recruitment
- eClinical Investigator & Staff Training
- Clinical Monitoring
- Data Management
- Biostatistics
- Medical Writing
- Medical Monitoring
- Pharmacovigilance and Product Safety

Consulting Services

Novella integrates deep clinical expertise with industry leading technologies and a proven approach to support, streamline and expertly resource the entire product development process.

- Regulatory Assessments (U.S. and Europe)
- Class II 510(k) Meeting Request and Submission Dossiers
- Pre-IDE Meeting Participation
- Report of Prior Investigations
- Protocol Development
- Class III PMA Support (Medical/Clinical)
- Clinical Development Support
- IDE Regulatory Support and Submissions
- Reimbursement Strategies
- Clinical Development Cost Analysis
- Post-Market Support
- Agency Audit Support and Warning Letter Resolution
- Device Specific SOP Development
- Health Economic Licensing and Analysis
- Safety Reporting
- FDA BIMO Field Inspection Preparation
- Device Classification/Predicate Device Searches
- Import/Export Requirements and Management
- Creation of Technical Design Files



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Technology Experience

Novella was built on a technology platform using eClinical processes and remains a market leader in technology utilization:

- Merge's Veracity™
- Oracle's InForm™ v5.0 (host)
- Medidata's Rave® Aspire to Win Partner
- Oracle Argus Safety (host)
- JReview®
- InfoLink 2 CTMS

Quality

In 2004 the company achieved ISO 9001:2000 certification, a global standard for quality management. We were recertified in 2008. Additionally:

- ISO 9001: 2008 Certified
- Registered by Underwriters Laboratory
- FDA BIMO (no observations or recommendations) and MHRA inspections (classified as a low risk CRO)

Therapeutic Area	Device
Orthopedic/Spine	Spinal fixation, orthopedic hip, rotator cuff device, neurostimulation device
Cardio/Vascular	Pacemakers, internal cardiac defibrillators (ICD), cardiac lead replacements, resynchronization therapy, cardiac ablation catheters, vascular stent grafts, ventricular assist devices, endovascular devices, carotid stents, bare metal stents (BMS), drug eluting stents (DES), stem cells, AAA stents, ablation device, combination products, bypass grafts
General Surgery	Drug delivery systems, general surgery devices, transvaginal tape
Wound Healing	Extra cellular scaffolds, combination product growth factor, electrical stimulation
Nephrology	Renal assist device, stent grafts
Oncology	Cryoablation focal probes (tumor type: prostate)
Infection	Diagnostic single assay panels
Urology	Neuromodulation device
Endocrinology	Diagnostic glucometers, insulin pump