



**Novella**  
CLINICAL

## Moving Potential. Forward.

You see beyond the clinical trial.  
Your ultimate goal is to give people  
a better quality of life and  
more opportunities to enjoy those  
special moments.

Novella Clinical is proud to be  
a part of your mission.

Our promise is to give your clinical program the individual attention it deserves.



### Biopharma Development

With therapeutic and in-country expertise, we bring your clinical program global presence with local service.

### Medical Device Development

We fully understand the special nuances and unique environment that your device programs require, ensuring their overriding success.

### Clinical Resourcing

Our unrivaled ability to strategically resource quality people to the right clinical trial gets you to market quicker while safeguarding your budget.

Formerly known as PharmaLinkFHI, Novella Clinical is created from the combined strengths of PharmaLinkFHI, Matrix Clinical and eReady Monitors.

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## You're Not a Pharmaceutical Company. Don't Be Treated Like One.

As a development company maneuvering your medical device through today's regulatory environment, you may have found that your outsourcing providers don't recognize the difference between a PMA and an NDA. We do. We understand that simply taking a drug development mentality and applying it to a device program is unfortunately too often the case. Now, more than ever, choosing the right outsourcing partner to help guide and support you is critical.

### Device Expertise.

Novella Clinical has complete knowledge of your specific device requirements and challenges, such as study design, regulatory planning and CMS reimbursement, language nuances and the specific staffing expertise needed. In fact, with access to more than 500 device-expert professionals, we staff our programs with teams who know the device market and bring value to your program. And, because we are ISO 9001-2008 certified, we share the same quality systems and quality rigor that you do.

To date, we have worked with four of the five leading device companies and assisted numerous others in running 510(k), PMA and post-marketing programs – everything from 10 to 7,000 patients, from 2 to 150+ investigational sites.

Our device experience includes, but is not limited to:



- Cardiovascular
  - Cardiovascular stents
  - Peripheral stents
  - ICDs
  - LVADs
  - Leads
  - Pacemakers
- Metabolic
- Neurology
- Oncology
- Orthopedic
- Renal
- Women's Health
- Wound Healing

### The eClinical Advantage.

Novella Clinical provides a unique approach for sponsors in the medical device arena. Known as the eClinical experts, we combine therapeutic and operational insight with eClinical processes and advanced technologies. Unlike most CROs that utilize technology, but implement programs using outdated paper processes, Novella Clinical was built from the ground up on a technology platform using eClinical processes. Over the past decade we have refined those processes to deliver a unique clinical trial that brings our sponsor's full transparency, smarter trial management and greater efficiencies including faster database locks – which means getting your new or refined device to the people who need them, faster.