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PSNRESEARCH
Accelerate your clinical success.



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www.PSNResearch.com

**Your unique international Full Service CRO,
expert in Medical Device & IVD clinical developments**

Local Knowledge | International Coverage | Holistic Approach

Your Medical Devices (MD) & In Vitro Diagnostic Medical Devices (IVD) Lifecycle CRO Expert (from strategic consultancy until Reimbursement & Post-market studies)



Why Choose PSNResearch?

- PSNResearch is a unique international mid-size CRO offering a customised Full Service dedicated to Medtechs
- Decades of experience in supporting MD & IVD clinical developments
- Consistent quality systems
- Global Presence. Regional Expertise
- Regular Steering Committee securing higher level of attention
- Over 23 years financial & staff turnover stability
- On-time project delivery in respect of budget
- Open & transparent collaboration

Seeking a Medical Device & IVD experienced Team to support your study,

THINK
PSNResearch
Your dedicated CRO

Recognized experience in MD & IVD Developments:

In the past five years, PSNResearch has completed over 127 studies for Class II and III medical device, IVD & combination products, including more than 38,194 patients and 2,893 sites. Our team gathers 440 clinical & technical experts, strategically located across Europe and North/South America. Our specialists have decades of combined clinical research experience. From simple Proof Of Concept studies to large Pivotal, complex trials across multiple countries, to support FDA & CE mark certification. Our experience integrates a complete suite of Commercialization & Outcomes practices including Health Economics & Outcome Reports (HEOR), Pricing & Market Access, Epidemiology, Non Interventional Studies & Clinical Outcomes Assessments

Large spectrum of therapeutics expertise:



Strategic Full Service CRO solutions to meet your Medtech needs:

- ✓ Strategic Consultancy Services
- ✓ Feasibility
- ✓ Site Selection & Management
- ✓ Regulatory Affairs
- ✓ Study Start Up
- ✓ Project Management
- ✓ Global Clinical Operations & Monitoring
- ✓ Data Management
- ✓ Biostatistics
- ✓ Safety & Materiovigilance Services
- ✓ Medical Affairs
- ✓ Medical Writing
- ✓ Quality & Audits
- ✓ Vendor Management
- ✓ Legal Representation
- ✓ Technology
- ✓ Imaging
- ✓ Flexible Resourcing Solutions

New EMA Requirements

PSNResearch will guide you through key steps to comply with the European Union's Medical Device Regulation of 2017.

EU MDR 2017/745 steps:

- Decide the intended use and classification of the planned medical device
- Establish the necessary processes and resources
- Minimize the risks and fulfil the general safety and performance requirements
- Complete the clinical evaluation investigation
- Compile the technical documentation
- Make arrangements for distribution
- Register the device and the manufacturer
- Complete the conformity assessment
- Complete the final administrative procedures before launch
- Fulfil the ongoing obligations in the post launch phase



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