



**MD-CLINICALS**  
FULL-SERVICE MEDICAL DEVICE CRO



**SOLUTION DRIVEN.  
QUALITY ASSURED.**

Medical device clinical investigations without the fuss and worry.

EUROPE • ASIA • SOUTH AMERICA • MIDDLE EAST  
CLINICAL INVESTIGATIONS & EVALUATIONS  
GLOBAL REGULATORY CONSULTANTS  
QUALITY ASSURANCE EXPERTS

NEXT 

[www.md-clinicals.com](http://www.md-clinicals.com)



*With services tailored to your specific needs, we offer flexible solutions that are as unique as your product - to assure you the quickest and most effective path to market.*

We're **passionate** about medical devices.

With over 30 years of experience in managing medical device clinical investigations around the globe, we have what it takes to move your product to market swiftly and cost-effectively, saving you precious time and money in the process.

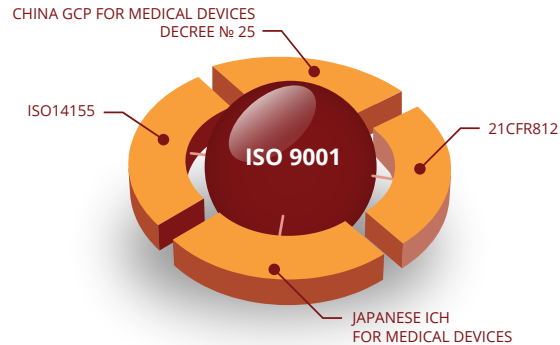
Our unsurpassed clinical and regulatory expertise in medical device market access combined with rigorous anticipatory approach and strong communication means you avoid the unnecessary delays and unexpected problems that affect eight out of ten clinical trials in the world today.

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## Global clinical expertise with local, quality monitoring and project management.



Because medical device clinical investigations are highly specific, our team of experienced, multilingual monitors and project managers are exclusively dedicated to medical devices and work according to our certified ISO 9001 quality system while taking into account cultural nuances to save you critical time and resources for clinical investigation management throughout Asia, Europe, South America and the Middle East.



### Clinical evaluations and investigations from A to Z:

- Global clinical strategy development including reimbursement
- Clinical evaluation report writing
- Protocol design and development
- Investigator brochure writing
- Instructions for use
- Case report form development
- Compliant informed consent
- Site selection
- Investigator meetings
- Clinical trial agreements
- Regulatory and Ethics Committee submissions
- Clinical project management
- Product training
- Site monitoring
- Site management (CRC)
- Medical monitoring – Safety reporting
- Clinical report writing
- Data management and statistics
- Clinical auditing



## Market access expertise

for fast and smooth sailing across five continents.

Our team of regulatory and quality experts adopt the most cost-effective approach in compliance with local regulations to get your medical device registered rapidly and efficiently. We also offer a range of industry-leading services designed to optimize the positioning of your product.

- Regulatory strategy development
- Medical device registration
- Quality management systems
- Local representation

## Regulatory network

Our international regulatory expertise spans the following countries:



- Argentina
- Australia
- Brazil
- Chile
- China
- Europe
- Hong Kong
- India
- Indonesia
- Israel
- Malaysia
- Mexico
- Myanmar
- New Zealand
- Philippines
- Saudi Arabia
- Singapore
- Taiwan
- Thailand
- Vietnam
- USA

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