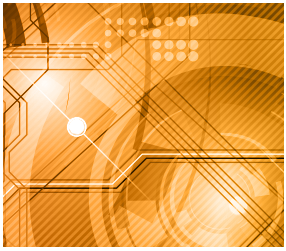
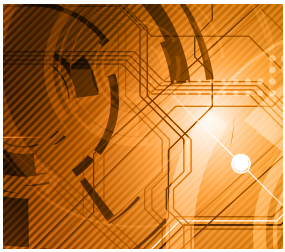
MD-CLINICALS
MEDICAL DEVICE CLINICAL RESEARCH

Your partner for global medical device clinical investigations and market access


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




· MD- CLINICALS SA · Rue des Jordils 40 · 1025 St-Sulpice · Switzerland · Telephone: +41 21 349 96 36 · **www.md-clinicals.com**

We're passionate about medical devices
Absolutely, positively.

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.

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.

- 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
- Data Protection (GDPR) compliance services
- Legal representative

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.

Contact us today for a free consultation at +41 21 349 96 36 or by email: info@md-clinicals.com

Clinical investigations worldwide
including China and South East Asia.

Our specialized local teams truly know the *ins and outs* of conducting clinical investigations throughout South East Asia and China. Our experts in Beijing ensure a successful access to the Chinese market by:

- Determining data required for China market access – type of clinical investigation, how many patients and which investigators
- Site selection especially primary investigator are highly important in China – our local team has access to many Key Opinion Leaders willing to participate in your study
- Legal representative during clinical investigations
- Efficient set-up and management of your clinical investigation
- Auditing of clinical investigations especially to prepare for NMPA site inspections
- Easy, usable data bases – multilingual where required
- Biostatistics services that understand China requirements
- Full service for market access

We ensure compliance to ISO 14155:2020 so you can use data for registration in other territories. We can help you optimize the many opportunities of conducting clinical investigations in Asia.

Regulatory affairs
we help you optimize your resources with sound strategies.

Choosing the right regulatory approach or troubleshooting an existing strategy is something we take very seriously. It is essential to develop a strategy that not only integrates with your business objectives but eliminates as much uncertainty as possible. Through our extensive network of regulators and notified bodies around the globe, we strive to achieve predictability for our clients.

Medical writing
clinical evidence for market access.

Our highly experienced medical writing team specializes in effectively compiling data sets for clinical evidence in support of device approval, market introduction and post-market follow-up.

- Clinical evaluation plan
- Clinical evaluation report
- Post-market surveillance report
- Post-market clinical follow-up report
- Publications

For more information, visit:

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