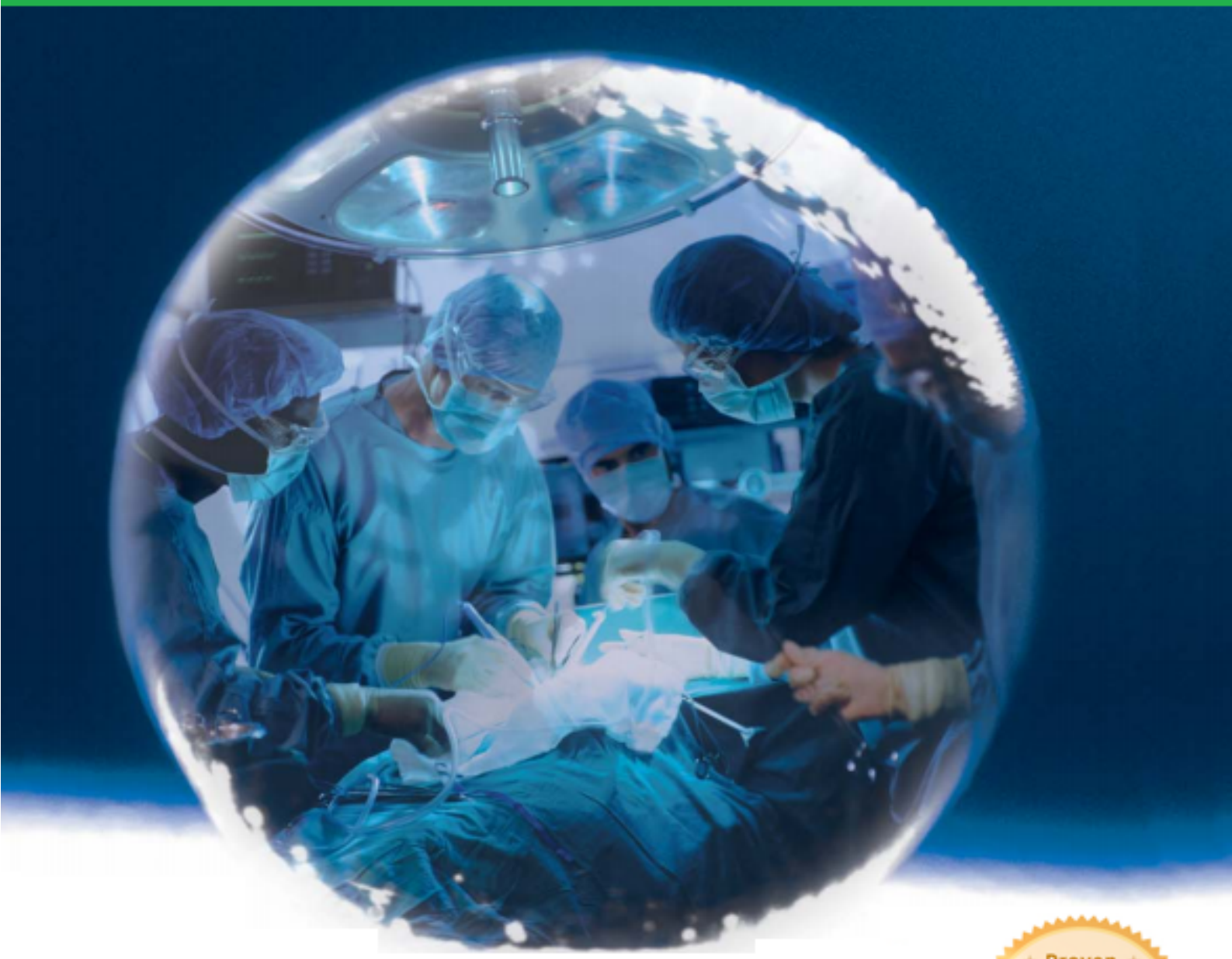
MEDICAL DEVICE CE MARKING
& CLINICAL EVALUATION



Proven Regulatory EXCELLENCE

I 3 CONSULTING

CLINICAL EVALUATION

Recent amendments made to the Medical Device Directive (MDD 93/42/EEC) state that every medical device affixing CE Logo, regardless of its classification, must have a clinical evaluation report in its Technical File / Design Dossier.

The Directive's specific focus on implantable or class III medical devices gives the false impression that clinical investigation does not apply to other Medical devices. This has led to the current situation where clinical trials are rarely done in the pre-market steps of medical devices development.

With the implementation of Directive 2007/47/EC, clinical evaluation has become a central element of regulatory compliance under the Medical Device Directive and Active Implantable Medical Device Directive.

Manufacturers of innovative technologies face the greatest impact, as they must present complete and sufficient clinical evaluation files to ensure timely assessment and favourable review of their products.

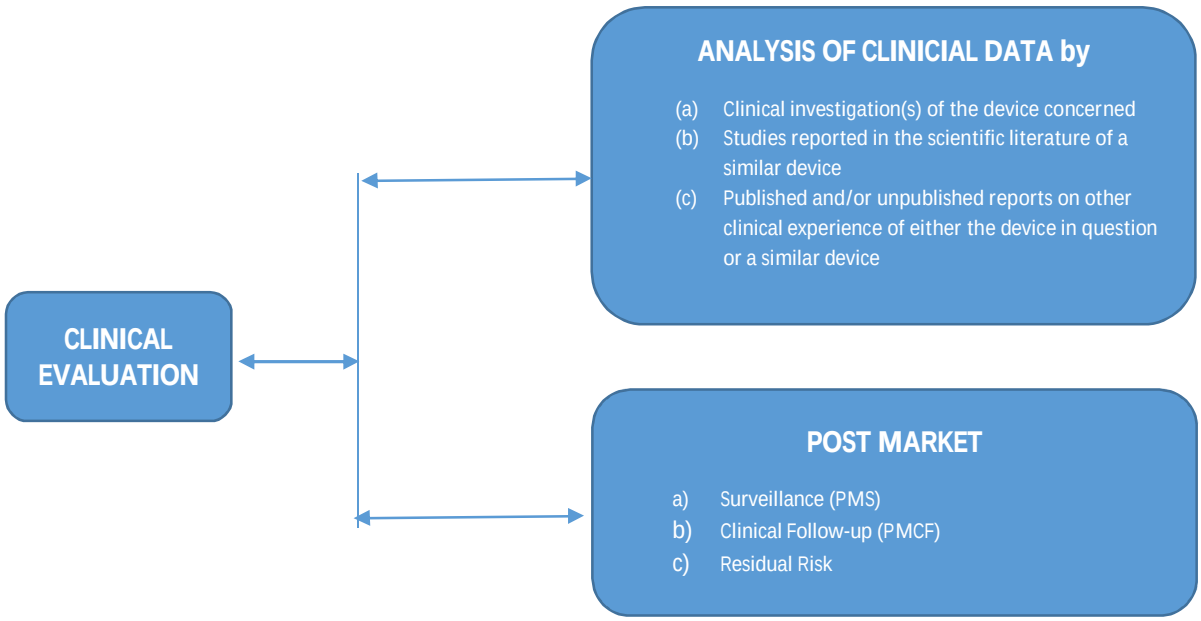
BENEFITS OF CONDUCTING CLINICAL EVALUATION

Regulatory conformance: Conforming to the regulatory framework is necessary and should be done in order to get Notified Body approval for Technical file followed by CE Certification. Choosing to perform a clinical investigation is the best answer to conform to the new requirements of the Medical Device Directive MDD 93/42/EEC.

Early detection and resolution of safety issues: Over 25% of safety alerts are due to manufacturing defects. This high proportion demonstrates the importance of an early detection of potential safety issues. Early assessment gives the manufacturer time to take corrective action and to provide potential damages to the company's reputation.

Manufacturer Image: An early clinical investigation most often results in a positive image and greater usage of the product throughout the healthcare system. A well-designed clinical investigation based on a robust methodology gives a chance to publish a scientific article in a peer-reviewed journal.

HOW TO FOLLOW STANDARD REQUIRMENT



METHODOLOGY WHEN PERFORMING A CLINICAL EVALUATION

The most important part lies in the methodology used. Any evaluation must be conducted following a strict adherence to regulatory requirements is the success of the clinical study. A proper methodology saves lot of time and success.

APPOINT I 3 CONSULTING FOR BETTER NAVIGATION AND RESULTS

Working early with I 3 Consulting for smooth and error free submission to Notified Bodies. Our project manager's work with clients to ensure clinical evaluation was adequate and in line with intended use, labelling, equivalent devices and in conformance with MEDDev Guidelines.

KNOW OUR FEES

Complete our Quote Request Form for a detailed proposal. For more urgent requests, feel free to use our Website Skype link or direct dialling numbers to USA & India.

Activity	Class of Medical Device				
	1	1s/m	11a	11b	111
Guidance on MDD Requirements	$ 50	$ 100	$ 150	$ 200	$ 250
Development of Protocol / Procedure	$ 50	$ 50	$ 50	$ 50	$ 50
Clinical Evaluation & Documentation	$ 300	$ 400	$ 500	$ 600	$ 700
Post Market Surveillance Procedure & Plan	$ 100	$ 150	$ 200	$ 250	$ 300
Post Market clinical follow-up Procedure & Plan	$ 100	$ 150	$ 200	$ 250	$ 300
GAP Analysis of Risk Management File	$ 100	$ 150	$ 200	$ 250	$ 300
Vigilance Control & Related Forms	$ 100	$ 100	$ 100	$ 100	$ 100

Taxes Extra

GET A CUSTOMIZED PROPOSAL

Complete our Quote Request Form for a detailed proposal. For more urgent requests, feel free to use our Website Skype link or direct dialling numbers to USA & India.

CONTACT INFORMATION

INDIA

S8, J J PARK 02, 4 CROSS, BHAVANI NAGAR,
CHRIST SCHOOL ROAD, S.G PALYA,
BANGALORE – 560029
FAX + 91 804 160 8963

TURKEY

ANADOLU BULVARI GIMAT SITESI 3. BLOCK NO: 29
P06105 MUCUNKOY, ANKARA, TURKEY
FAX + 90 312 397 0058

USA

2871 COASTAL DRIVE, AURORA
ILLINOIS – 60503
FAX + 1 815 986 2632

mail to us