TATA ELXSI

CLINICAL EVALUATION REPORT CONSULTING & WRITING SERVICES

Assess | Analyze | Execute

Trending

Medical Device OEMs are required to make significant organization-wide changes to comply with the new European Union Medical Device Regulations and to market their devices in the region.

Also, the need to have increased transparency and documentation is adding to the administrative burden. This may have significant business implications in the form of loss of revenue and increased time to market.

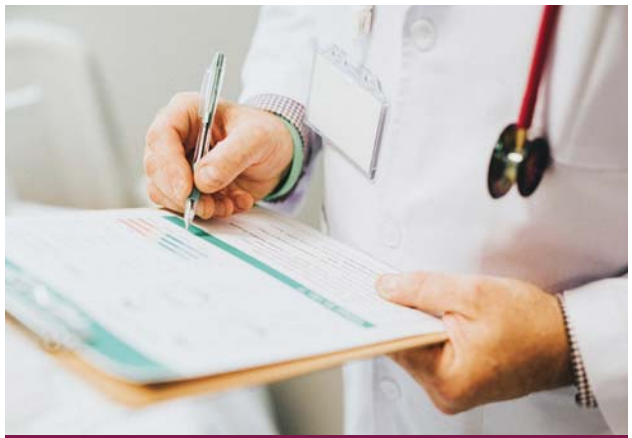
Amongst the various changes, are the new requirements for gathering clinical evidence and presenting Clinical Evaluation Report (CER). Due to the stringent requirements, OEMs are required to improve their post-market oversight, re-look at their clinical and performance evaluation reports, and present convincing interpretations to justify clinical safety and performance of the device.

MDR Impact over CER

- Rigorous post-market oversight
- More rigorous clinical evidence for class III and implantable devices
- Systematic clinical evaluation for class IIa and IIb devices
- Re-classification of devices

Challenges for OEMs

- CER creation for newly classified and up-classified devices
- Clinical data availability & readiness
- Rigorous interpretation from high volume data
- Standardizing PMS and PMCF formats
- Clinical testing requirement for products earlier exempted
- Annual safety updates
- Benefit-risk analysis of alternative therapies
- State Of The Art (SOTA) - Extensive Vs. Brief



Benefits Sought by the OEMs

- Active post-market oversight to help improve on existing features, make devices more robust and enhance consumer trust in the brand
- High-quality CERs to build a good reputation for notified body approvals and prevent episodes of rejection and subsequent product discontinuation chances
- Thorough, objective and reproducible search strategy to get the most from literature searches in the scoping stage

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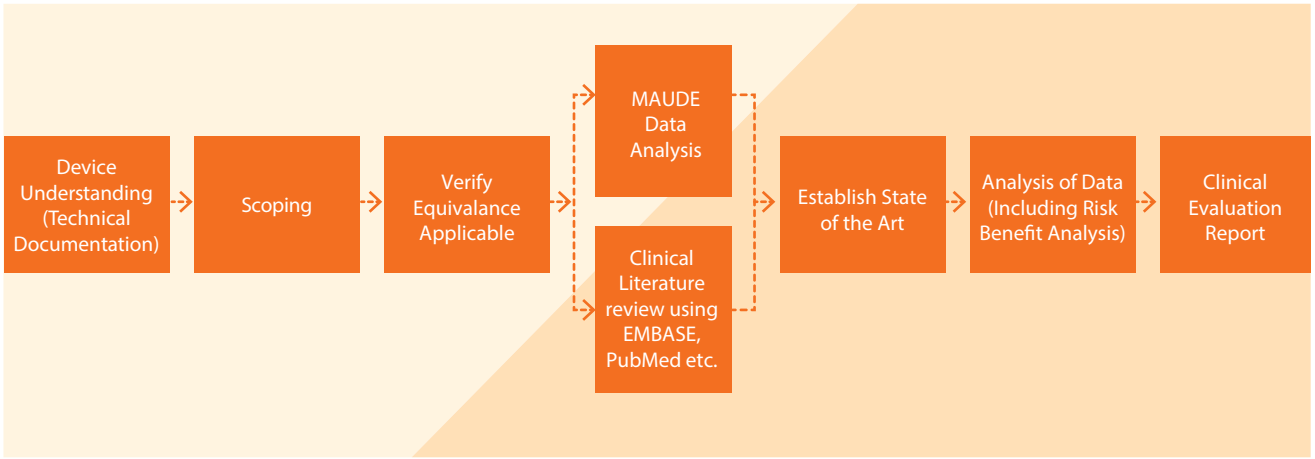
Tata Elxsi CER creation/ update- Process workflow



Service offerings

- Gap analysis w.r.t MDR and MEDDEV 2.7.1/Rev 4
- Prepare clinical evaluation plan | PMCF plan & report | Literature review plan, strategy & report
- Clinical Evaluation Report (CER) creation/ update
- Data gathering, analysis & interpretation: Literature search & appraisal | Sales & complaints data | Risk analysis | Clinical investigation | Post-market surveillance | CAPA
- MAUDE data analysis
- State of the Art (SOTA)
- Risk-benefit assessment
- Re-assessment of claims

Differentiators

- Diverse team of medical writers, clinical data evaluators, system engineers and physicians/ surgeons (MD)
- MEDDEV 2.7.1/Rev 3 and MEDDEV 2.7.1/Rev 4 experience
- Regulatory as a Service (RaaS) engagement model to accommodate the customer's changing needs
- Data Security in compliance with ISO 27001:2013
- Comprehensive in-house Training modules
- CER creation/update expertise across cardiovascular, urology, general surgery, respiratory and neurology specialties

Cases

Developed high-quality CERs in a crunched timeline

CER creation for general surgery legacy product in a span of 10 days to prevent discontinuation from the market

Creation of CERs, SOPs, and Templates

Reviewed and updated existing CERs, SOPs and templates in line with MEDDEV 2.7.1/Rev 4 guidelines and EU MDR requirements for compliance

High number of complaints and Notified Body intervention

Creation of Risk-Benefit Assessment and report for endoscopic instruments in response to a high number of complaints and notified body intervention

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