TATA ELXSI

CLINICAL EVALUATION REPORT CONSULTING & WRITING SERVICES

Assess | Analyze | Execute

Trending

Medical device companies are required to make significant organization-wide changes to comply with the new European Union Medical Device Regulations (EU MDR) and to market their devices in the region.

As per article 61 of the EU MDR, companies are required to re-look at their clinical and performance evaluation reports (CERs/ PERs), and present convincing interpretations to justify clinical safety and performance of the device.

Moreover, 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.

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 the companies

- CER creation for newly classified and up-classified devices
- Clinical data availability & readiness
- Rigorous interpretation from high volume data
- Standardizing Post-Market Clinical Follow-up (PMCF) & Periodic Safety Update Report (PSUR) formats
- Clinical testing requirement for products earlier exempted
- Keeping track of annual safety updates and maintaining dynamic data records
- Benefit risk analysis of alternate therapies
- Establishing state of the art (SOTA) with an extensive amount of supporting clinical data and applicable standards

Benefits sought by the companies

- 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
- Faster turnaround time to update CERs

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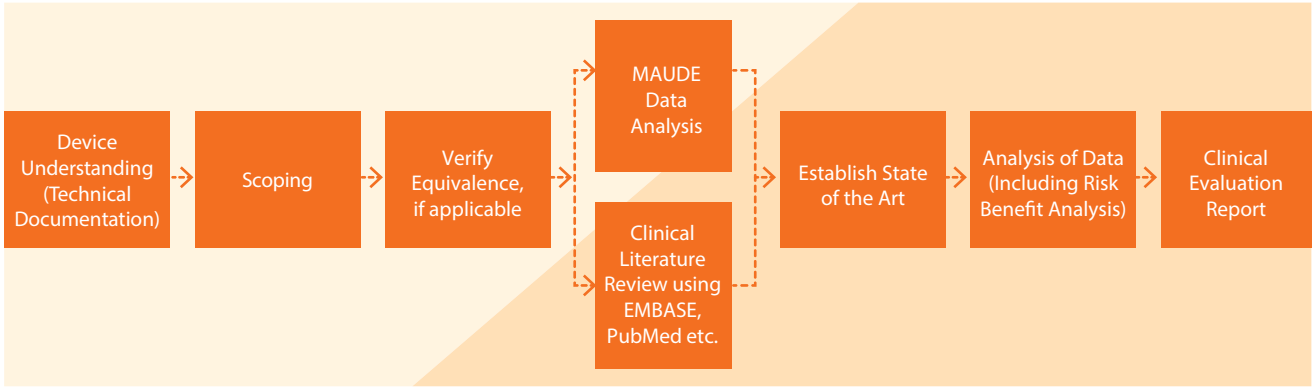
Tata Elxsi's Service Framework Components

- Standard SoP & customizable templates
- Cross-functional domain expertise
- Access to literature databases
- Established QMS procedures
- Secure data management infrastructure
- Proprietary assessment methodology for CER/ PER sufficiency



CER Creation/ Update- Process Workflow

Service offerings

- Gap analysis w.r.t MDR and MEDDEV 2.7/1 Rev 4
- Preparation of clinical evaluation plan | PMCF plan & report | Literature review plan, strategy & report
- Creation/ update of Clinical Evaluation Report (CER)
- Data gathering, analysis & interpretation: Literature search & appraisal | Sales & complaints data | Risk analysis | Clinical investigation | Post-market surveillance | CAPA
- MAUDE data analysis
- Establishing 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) with extensive industry experience
- MEDDEV 2.7/1 Rev 3 and MEDDEV 2.7/1 Rev 4 experience
- Data security in compliance with ISO 27001:2013
- Comprehensive in-house training modules for quick team ramp up
- CER creation/ update expertise across various specialties, such as cardiovascular, urology, general surgery, respiratory, neurology, etc.

Cases

Reduction in turnaround time by 20 – 25% for CER creation

Successfully delivered 105+ CERs for legacy products/class I, II and III devices, and initiated submissions to notified body

Developed high quality CERs in crunched timeline

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

Risk benefit profiling in response to notified body intervention

Risk benefit assessment and report creation for endoscopic instruments in response to high number of complaints and notified body intervention

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