Reduction in turnaround time by 20%-25% for CER creation of legacy products/ class I devices/ newly classified medical devices

Successfully delivered more than 55+ CERs for Cardiovascular specialty

Mature processes ensure active post market oversight with high quality reports through:

- 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
- MAUDE data analysis
- State of the Art (SOTA)
- Risk-benefit assessment
- Re-assessment of claims

Team Size	Model	Performance	Business Impact	Risk Classes
25	Outcome based	Standardization across 35 manufacturing sites + CER updates as per MDR compliance	Submissions initiated to Notified Body	Class II and Class III

Reference mockup image