Clinical Evaluation Report

Clinical Evaluation & Clinical Investigation of Medical Devices

Reports and Services as per MEDDEV 2.7.1 Rev 4:2016

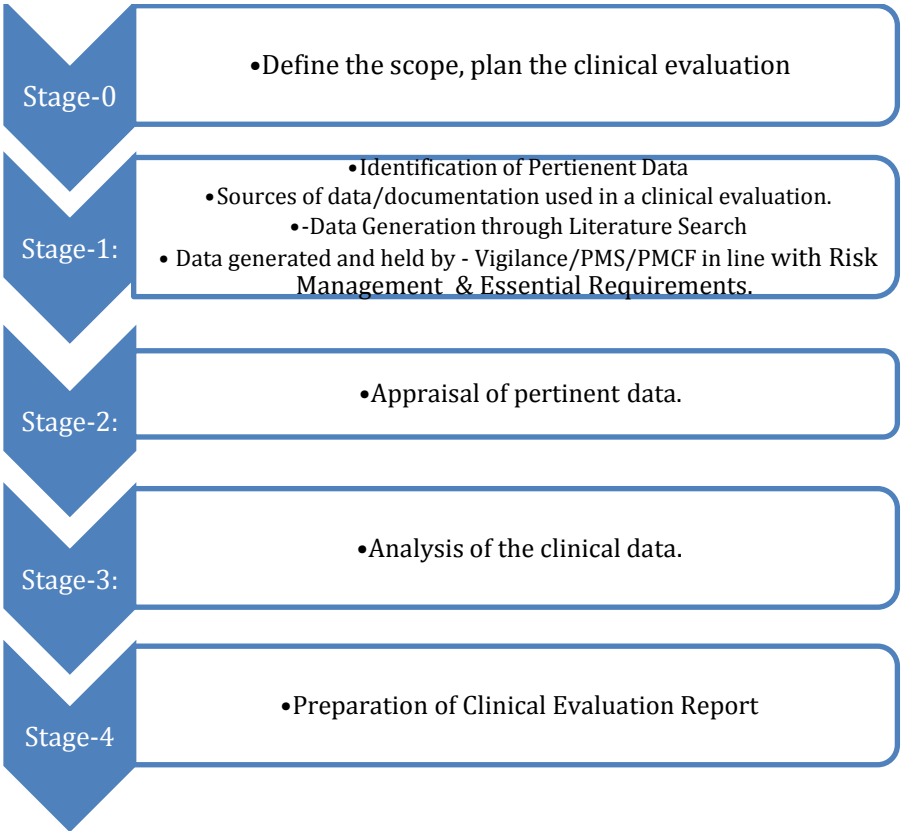
Medzus consultancy of Clinical Evaluation & Clinical investigation in medical device helps manufacturer to maintain & supporting regulatory records to obtain high ethics value to the products.

Medzus follows various harmonised standards and delivers quality services through our highly competent technical expertise. Medzus adheres to widely accepted writing practices and follows GCP while preparing clinical evaluation report according to MEDDEV requirements.

Activity and Services we offer through Medzus Consulting:

- Guidance on **MDR 2017/745 requirement**
- MEDDEV Vigilance; **system setup and control**
- Clinical Evaluation/Clinical Investigation; **Documentation, Development of protocol/procedure**
- Record and maintain; **clinical data/AE/Clinical evaluation/Clinical performance and safety**
- Residual Risk as per ISO 14971; **GAP Analysis and Risk Management**
- IFU **warnings and Contraindications**
- Post Market Surveillance (PMS) & Post Market Clinical Follow Up (PMCF); **Process and Plans**
- Clinical Trials **if required**
- Data from predicate / equivalent device; **Demonstration**

Stages of Clinical Evaluation:



For Complete quote or detailed proposal.
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