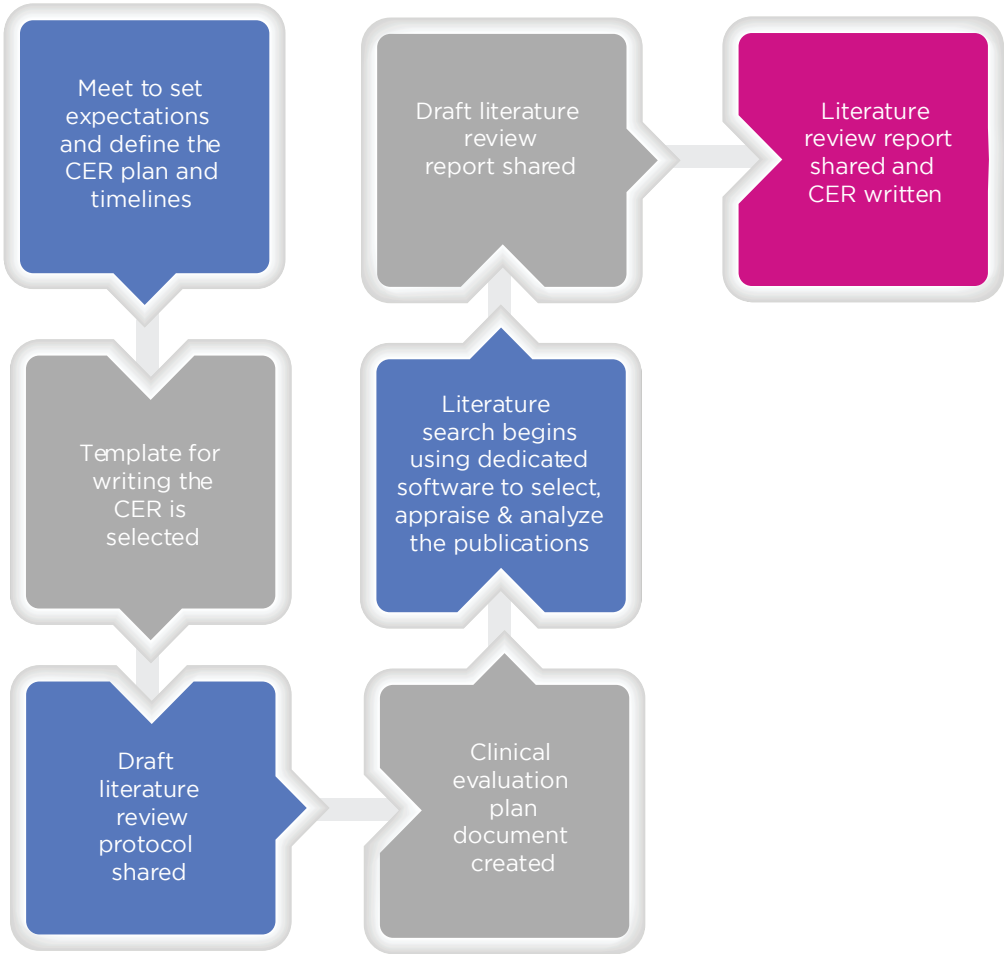
YOUR PARTNER IN THE CLINICAL EVALUATION PROCESS

Ensuring compliance with the Medial Device Regulation (MDR) in the changing medical device environment means having a complete and current clinical evaluation report (CER). BBA's team of regulatory, clinical affairs, physicians are skilled at writing quality clinical evaluation reports that are consistent with regulatory expectations. A team comprised of the Senior Medical Director, Medical Writer and Clinical Director at BBA are here to help write CER's.

COMMONLY A CER INCLUDES

- Technical device description and intended application
- Intended therapeutic or diagnostic claims
- Patient Populated Treated
- Clinical evaluation and data types
- Summary and appraisal of clinical and other data
- Description of analyses used to assess product literature and other data sources
- Conclusions about safety and performance
- Recommendations on changes tolabeling and risk management files
- Post market surveillance plans for subsequent CERs

APPROACH TO WRITING CER'S



With BBA writing the CER for your medical device the result will be a well written, scientifically valid, regulatory compliant, high-quality document that can also be added to the technical file.

CONNECT WITH BBA AT: info@bbacro.com or follow us on Linkedin or Twitter today.