

Regulatory Documents

The various regulatory documents which needs to be submitted to the Regulatory Authorities for product approval are given below:

- Investigational New Drug (IND)
- Clinical Study Protocol
- Informed Consent Forms
- Case Report Forms
- Clinical Study Reports (CSRs)
- Investigator's brochure (IB)
- Safety Narratives

Preferred Style Guide Regulatory Writing

Janet Gough



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