**IIS Final Report Recommended Format**

The purpose of this document is to assist investigators in writing a final clinical study report. The Final Report is intended to provide Stryker Neurovascular with a comprehensive summary of the study conduct with pertinent analyses and statistical tables or figures, and study conclusions. Depending on the type of study, not all sections will apply.

1. **TITLE PAGE**
* Sponsor Name and Address
* Principal Investigator(s) Name
* Statistician(s) Name
* Imaging Core Laboratory
* Clinical Protocol Number and Approval Date(s)
* Clinical Trial Registry Number
* Date of Report
* Author(s) of Report
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2. **EXECUTIVE SUMMARY OR SYNOPSIS**
* Study type
* Date of first and last patient enrolled
* Evaluations performed
* Primary endpoint result
* Secondary endpoint result
* Adverse event summary
1. **LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS**
2. **ETHICS**
* EC or IRB Approval
* Ethical conduct
* Informed Consent
	+ When and how obtained
1. **INVESTIGATORS AND SITES**
* List with affiliations
1. **STUDY OBJECTIVES**
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* Study design
* Subject population
* Inclusion/Exclusion criteria
* Treatments administered
* Method of randomization
* Blinding
* Duration of treatment
* Adverse Event reporting
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* Sample size determination
* Monitoring plan
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2. **PROTOCOL DEVIATIONS**
3. **DATA ANALYSIS**
* Demographics and other baseline characteristics
* Treatment Compliance
* Results in table format
	+ Statistical tests performed
	+ Handling of missing data
	+ Subgroup analyses
1. **SAFETY EVALUATION**
* Adverse Events
* Serious Adverse Events with relationship to procedure and device
* Deaths
* Unanticipated Adverse Events
1. **DISCUSSION AND OVERALL CONCLUSIONS**
2. **REFERENCES**
3. **APPENDICES**
4. **PUBLICATION PLAN**