

Protocol Synopsis Template

Date YYYY/MM/DD

Title and name of Principal Investigator

Name of Institution

Address

Telephone

Email

Study Title

Study design (a one-sentence summary)

Study centre(s) and number of subjects planned (The address where the study will be conducted, number of patients planned and if applicable distribution of patients per site)

Study period (month & year) Estimated Start date (first patient enrolled)

Estimated End date (last patient completed follow up)

First data available for presentation

Study objectives

Study population (Short description of target population and indication studied, including relevant criteria for exclusion/inclusion)

Investigational product/comparator (State the devices / products that will be investigated / used and for comparative studies also the comparator/s)

Outcome variables

Materials and method

Statistical methods (Describe where relevant the statistical methods to be used, the populations to be analysed (e.g. determination of sample size, intention to treat, per-protocol), and any interim analyses)

Publications & Presentations (Describe your plans with regard to publications or public presentations i.e. what journals or conferences/meetings)

Total study cost (Provide an estimate for the total study cost divided on main activities)

Requested support (Describe extent of requested support – financial or other support e.g. products)

Details of products requested

Product / Ref.No / Quantity

Product / Ref.No / Quantity

Product / Ref.No / Quantity

Product / Ref.No / Quantity

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Product / Ref.No / Quantity

Product / Ref.No / Quantity

Products will be distributed to the below contact person and address

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