A guide to designing a Case Report Form

The purpose of this template is to assist investigators and study personnel in designing a comprehensive Case Report Form. It is important to note that:

- *A well designed case report form is essential for capturing data specified within the protocol as relating to defined endpoints*
- *Data which is not specified within the protocol as required should not be captured*
- *Time spent on creating a comprehensive case report form will avoid problems during the study conduct and reduce the risk of data being missed*

*The following is a tool to facilitate the development of a case report form. It is by no means a definitive layout for a case report form but more to provide guidance to the kind of things expected. Not all of these sections will be relevant for every case report form and the exact content of your case report form will depend on the specific study research design. An * indicates sections that should appear in all case report forms.*

General comment

- ✓ *Make sure to include page numbering in the form of "X of Y" (1 of 10, 2 of 10 etc.) in the footer of the document – as shown in this document*
- ✓ *Italic content is for reference only and must be deleted from the final case report form*
- ✓ *The template can be customised to suit the individual study design. Sections can be added or deleted as required provided they are not marked as mandatory (*)*
- ✓ *The template can be used in either paper or electronic format*

The following should be included in every case report form:
Front page
Case report form completion instructions
Demographics (protocol specific)
Informed consent process
Inclusion and Exclusion criteria
Eligibility sign off
Investigational medicinal product
Trial related assessments
Study completion
Adverse events page
Concomitant medication form
Principal Investigator sign off

The template includes a number of optional forms e.g. biochemistry results, other study specific forms can be adapted for individual study requirements.

Text in red and italics indicates are for trial specifics and should be changed to normal black text before printing