Guidelines for using the Group Specific Appendix

V3.0 Model

- Logos for the Trial, Lead and Collaborating Group should be inserted at the top of the first page.
- Where square brackets exist [ ], trial specific information should be added.

- Disclaimer

  The GSA may be adapted and used according to the needs of the trial and the requirements of the country. An agreement must be made between the Lead Group and the Collaborating Group regarding the purpose of this document:

  - an appendix to the Main protocol (submitted for appropriate approvals)
  - an appendix to the Contract (usually referred to as the Intergroup Agreement)
  - as an operational guide only

- Ensure the Version number and date for the GSA Model Template remains in situ and add a version/date for the specific GSA (i.e. there will be 2 sets of version numbers and dates)
- Remove the revision history box from your individual GSA before finalizing (this is for the model template only)

- The 'style' used is 'formal'.
- The index will need to be updated following acceptance of your final version
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Sections 1 through to 15 can be amended as applicable, the model is for guidance as to what may be included in the GSA, it is not an exhaustive list and some sections may not be applicable (depending on nature of trial, countries where the GSA is being used or its purpose).

Section 5 is written for the use of paper CRFs (this section will require amending if eCRFs

are being used).

Section 6 will need to be adapted as necessary depending upon whether:

1. Lead Group are completing regulatory requirements for ALL countries **or** whether each country are required to carry out onward regulatory reporting according to national requirements.

Section 7 will need to be adapted depending on the level of monitoring documented in the Risk Assessment and/or Monitoring Plan

Section 11 will need amending depending on whether the trial is an academic or pharmaceutical sponsored trial and which countries it is being carried out in. The text in this section includes standard phrases which may be deleted or used as applicable.

Section 14 can be removed if there is no financial support available for the trial.

Section 15 can be removed if the authorship has been addressed in another document (e.g. Intergroup Agreement)