# [Study Name] REPORT for Data and Safety Monitoring Committee (DSMC) Meeting #X – Date

1. **Recruitment:**

Short paragraph to clarify recruitment, e.g. Randomisation within X days of screening. Short definition of Completed (reached primary endpoint, completed X number of assessments)

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| **Site** | **Commenced Recruitment** | **Total number randomised** | **Total number completed** | **Randomisations /mth** |
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| **Total** |  |  |  |  |

1. **Per protocol completions**

Completion is recorded if the participant reached:

* Condition 1
* Condition 2
* Condition 3

Site by site numbers of completion, and reasons are reported in the table below.

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| **Site** | **Condition 1** | **Condition 2** | **Condition 3** | **Total** |
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| **Total** |  |  |  |  |

1. **Serious Adverse Events:**

Attached:

Serious adverse event summary report

Excel file of all Serious Adverse Events to date.

1. **Monitoring:**

Summary of monitoring activities and major findings.

1. **Protocol violations (PVs):**

Short description of PVs presented in table form.

1. **Other data issues:**Short description of any other items for discussion
2. **Other documents needed for this report:**
3. Template 44 SAE Summary Sheet
4. Template 45 Protocol Violation Log