STANDARD OPERATING PROCEDURE FOR CREATING REPORTS FOR THE INDEPENDENT DATA MONITORING COMMITTEE

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1. PURPOSE

This document describes the procedure to create reports requested by an Independent Data Monitoring Committee (IDMC) in compliance with the principals of Good Clinical Practice.

2. SCOPE

This Standard Operating Procedure (SOP) applies to Clinical Trials of Investigational Medicinal Products (CTIMPs) and clinical research sponsored or co-sponsored by the University of Dundee or NHS Tayside.

This SOP applies to all members of staff involved in the preparation of a report for an IDMC. It is not applicable to studies without an IDMC but can be used as guidance for the preparation of reports requested by other trial management oversight groups or committees.

3. RESPONSIBILITIES

The Guideline on Data Monitoring Committees provided by the European Medicine Agency (EMA) and ICH Guideline E6 Guideline for Good Clinical Practice is the basis of this SOP.

An IDMC is a group of independent experts external to a study assessing the progress, safety data and if needed, critical efficacy endpoints of a clinical study. In order to do so an IDMC may review unblinded study information (on a participant level or treatment group level) during the conduct of the study. Based on its review, the IDMC provides the sponsor and/ or the Chief Investigator (CI) with recommendations regarding study modification, continuation, or termination. IDMCs are also known by different names like Data Monitoring Board or Data Safety Monitoring Committee (Board).

The content of the IDMC report must be sufficient to enable the IDMC to assess the progress of a clinical study, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the CI and sponsor whether to continue, modify, or stop a study.
It should be noted that an IDMC is not needed for all clinical trials and the management and oversight of the trial must be detailed in the protocol.

4. PROCEDURE

Key Points

- The format and content of the IDMC report is directed by the Chair of the IDMC.
- The template report should be created using dummy data sets *i.e.,* not real data.
- The study statistician may prepare unblinded IDMC reports for **unblinded** trials.
- The study statistician must not prepare unblinded IDMC reports for **blinded** trials. In this situation, an alternative statistician must create the unblinded IDMC reports.
- The study statistician should not receive any unblinded data, only the IDMC and alternative statistician creating the IDMC reports, should see unblinded data.

4.1 Creating the initial IDMC Report

Unblinded and Blinded Studies

4.1.1 The CI must ensure an IDMC charter is in place and all members of the IDMC agree to the terms and conditions of the charter. The signed charter must be stored in the Trial Master File (TMF) and Sponsor File.

Unblinded Studies

4.1.2 At the start of the study, the CI must identify the statistician responsible for the creation of the template report for the IDMC ("Responsible Statistician"). This should be recorded in the TMF and the Chair of the IDMC informed.

4.1.3 The Responsible Statistician may be the study statistician or an alternative statistician.

4.1.4 The CI and Chair of the IDMC should provide the Responsible Statistician with the signed IDMC charter and the names and email addresses of the IDMC members.

4.1.5 The Responsible Statistician should make the Chair of the IDMC aware of the format and content of the report. The Responsible Statistician must create a separate electronic folder for each IDMC report that is created, to ensure that all data and programs used at the time are saved for review.

4.1.6 The initial IDMC report should then be created by the Responsible Statistician on a dummy randomisation and provided to the Chair of the IDMC for review. Any changes identified in the review should be incorporated into the report until the report is deemed final.

4.1.7 The Responsible Statistician should add the correct group assignment to the report and provide the report to the IDMC or the individual responsible for organising the IDMC, at least 7 days prior to the IDMC meeting, or as agreed with the Chair of the IDMC.

Blinded Studies

4.1.8 If the study is blinded, the study statistician can only prepare template IDMC reports (using dummy data), and the programs used to generate the data for the IDMC

report. The report containing unblinded data should be created by an alternative statistician ("Alternative Statistician").

4.1.9 Blinded studies will have the study statistician as the Responsible Statistician, responsible for producing the report template, AND an Alternative Statistician, responsible for generating the unblinded report OR just an Alternative Statistician to produce the template and the unblinded reports.

4.1.10 At the start of a blinded study, the CI must identify the Alternative Statistician. This should be recorded in the TMF and the Chair of the IDMC informed. The Alternative Statistician is usually a non-voting member of the IDMC.

4.1.11 The CI should provide the Responsible Statistician and/or the Alternative Statistician with the signed IDMC charter and the names and email addresses of the IDMC members.

4.1.12 The Responsible Statistician and/or Alternative Statistician should discuss the format and content of the report with the Chair of the IDMC. The Responsible Statistician and/or Alternative Statistician must create a separate electronic folder for each IDMC report that is created, to ensure that all data and programs used at the time are saved for review. The Alternative Statistician should create an electronic folder for each IDMC report in an area that is not accessible to the trial team as per their local SOPs. Data and programs should be stored there until the study is completed.

4.1.13 The initial IDMC report should then be created by the Responsible Statistician and/or Alternative Statistician on a dummy randomisation and provided to the Chair of the IDMC for review. Any changes identified in the review should be incorporated into the report until the report is deemed final.

4.1.14 If the Responsible Statistician has produced the template report on behalf of the Alternative Statistician, they should provide the programs and data necessary for the creation of the IDMC report to the Alternative Statistician.

4.1.15 The Responsible Statistician, or individual responsible for organising the IDMC if there is no Responsible Statistician, should contact the person responsible for holding the blinding and, using local procedures, approve the release of the unblinded allocation data to the Alternative Statistician.

4.1.16 The Alternative Statistician should add the unblinded group assignment to the programs and create an unblinded IDMC report. This report should be provided to the IDMC, or the individual responsible for organising the IDMC, no less than 7 days prior to the meeting or as agreed with the Chair of the IDMC.

4.2 Creating the follow-up IDMC Report

4.2.1 After the first IDMC meeting, the CI should provide the letter of recommendation from the IDMC on the report to the trial statistician.

4.2.2 Each new IDMC report (unblinded report or template) should be created in a separate electronic folder to allow audit of all IDMC reports after the study closes.

4.2.3 Any changes or additional tables requested by the IDMC should be incorporated into the next version of the IDMC report or template by the Responsible Statistician.

4.2.4 The process of finalising follow up IDMC reports for unblinded and blinded should be performed as indicated in section 4.1.

4.3 Archiving the IDMC Report after the study

4.3.1 All electronic and paper documentation created in association with the preparation of the IDMC reports is part of the TMF and should be archived with the TMF. The Responsible Statistician and/or the Alternative Statistician must provide all paper and electronic data, programs, and listings to the study team to be archived.

4.3.2 Both the unblinded and blinded versions of the IDMC reports should be archived with the study documentation.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
EMA	European Medicine Agency
IDMC	Independent Data Monitoring Committee
ICH	International Council for Harmonisation
SOP	Standard Operating Procedure
TMF	Trial Master File

6. ASSOCIATED DOCUMENTS & REFERENCES

ICH Topic E6, Guideline for Good Clinical Practice (CPMP/ICH/135/95) July 2002, European Medicines Agency.

Guideline on Data Monitoring Committees (EMEA/CHMP/EWP/5872/03 C) January 2006, European Medicines Agency.

Guidelines for Standard Operating Procedures for Good Statistical Practice in Clinical Research, Statisticians in the Pharmaceutical Industry, June 2000.

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
3	Tracy Petrie (Quality Assurance Support Officer)	18/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
4	Petra Rauchhaus (Clinical Trials Statistician)	25/06/2021	Scheduled review. Minor changes to section 3 to state that IDMC provides the sponsor and/ or the Chief Investigator (CI) with recommendations but only recommends to sponsor whether to continue, modify, or stop a study.

5	Petra Rauchhaus (Clinical Trials Statistician)	26/06/2023	Scheduled review no updates required.

8. APPROVALS

Approved by:	**Date:**
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	23 June 2023