Data and Safety Monitoring Board (DSMB)

OPEN Report

Date of report: 20XX

How to use this template report

Instructions to researchers are in purple italics – instructions should be deleted once that section has been completed. Where sample wording is given, it is highlighted in green italics.

> *This report template is designed to be used by the trial statistician and research team for preparing a summary of trial progress and conduct for the DSMB. All data in the open report should be presented in an aggregated manner (i.e. not by treatment group). The report should be reviewed by the DSMB members in conjunction with the principal investigator, co-investigators, the trial statistician and research staff as part of an OPEN MEETING.*
>
> *A separate report should be prepared for review by the DSMB at CLOSED MEETINGS, which are attended only by the DSMB members and the statisician who produced the report. This report will contain the same data as the open report, but will will be presented by treatment arm (which may or may not be masked). Closed reports should be stored confidentially.*

Name of trial	XXX
Meeting date	XX XX 20XX

Data and Safety Monitoring Board Report produced by:

XXX
Murdoch Childrens Research Institute
Royal Children's Hospital
Melbourne

This report is based on data up to and including the first <XXX> participants.

Trial Summary

This trial is XXX (*insert design summary*)
***Example text**: "a multicentre, randomised, masked, controlled trial with a parallel group design of XX versus XX.*

The planned number of participants is XXX (XXX per group).

Up to the enrollment of the XXth participant (XX XX 20XX), the trial has actively randomised at the following centres:

- XX
- XX

With parental consent, eligible infants are XXX (*describe reatment assignment)*.
***Example text**: "randomly allocated using a web-based randomisation server, with stratification by XX, to receive XX or XX."*

The primary aim of the study is XXX.

Secondary aims of the study are:

1) XX
2) XX

The current report includes the first XX participants recruited and their follow-up data collected up to and including the XX of XX 20XX, to allow for full data entry, data cleaning, data analysis, and report writing. The XX participant was randomised on the XX of XX 20XX.

Protocol amendments

Version XXX, XX XX 20XX is the most recent version of the protocol. The previous versions of the protocol were amended in regards to:

- XX
- XX

1. Recruitment

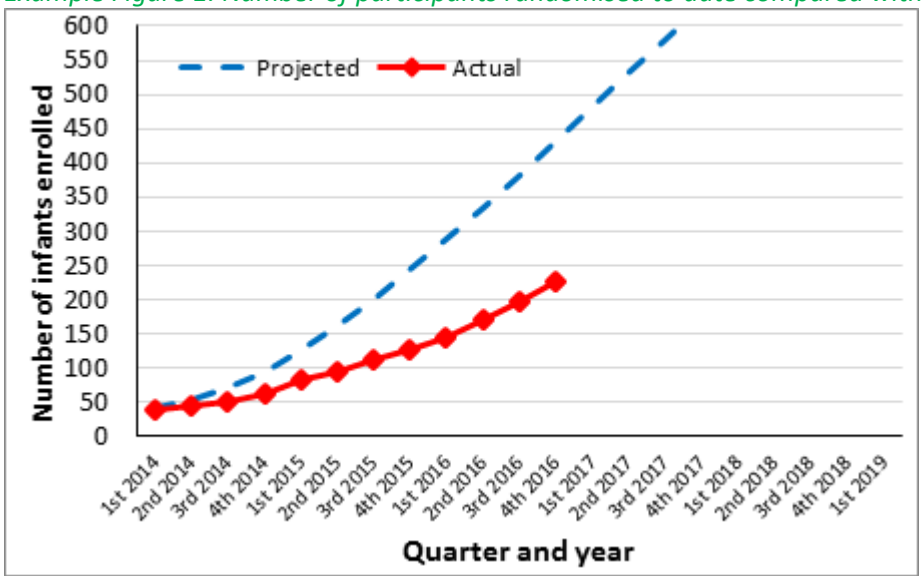
Figure 1 shows the accrual of the first XXX participants into the study up to the XX of XX XXX, and Table 1 shows a breakdown of these participants by randomisation stratum. Randomisation of participants into the treatment arms was stratified by XXX and XXX .

Since the beginning of the study, there have been issues related to the randomisation procedure for XX participants. Details are listed below.

Date:
ID(s):
Problem:
Resolution:

Summaries of baseline and outcome data is presented for all of the XXX participants who have been randomised and have data available.

*Example Figure 1: Number of participants randomised to date compared with projected recruitment**



** Recruitment was originally estimated to take XXX years.*

Table 1: Recruitment by randomisation stratum

	Total
Number of Participants Randomised	**XXX**
Number of Participants Randomised by XX	
XX	XX
XX	XX
Number of Participants Randomised by XX	
XX	XX
XX	XX

Currently XX (XX%) participants have been evaluated for the primary outcome (table 2).

Table 2: Participant disposition

	Total N=XXX
Baseline Data Available	XX (XX%)
Primary Outcome Data Available	XX (XX%)
Secondary Outcome 1 Data Available	XX (XX%)
Secondary Outcome 2 Data Available	XX (XX%)
Excluded from the study[(1)]	XX (XX%)
Withdrawn from the study[(2)]	XX (XX%)

[(1)] *reasons*

[(2)] *reasons.*

2. Participant Characteristics

Table 3 shows the baseline characteristics of the XXX participants recruited to date.

Table 3: Baseline characteristics

	Total N=xxx
Number of participants with baseline data available [(1)] **XXX**	**xxx**
XXX	
XXX	

SD = Standard Deviation

[(1)]*Percentages in the tables are of those with data available*

3. Primary and secondary Outcomes (if applicable)

Table 4 shows a summary of the primary outcome data.

Table 4: Primary outcome data

	Total N=xxx
Primary outcome data available [(1)]	**xxx**
xxx	**xxx**
(missing)	(X*)

[(1)]*Percentages are of those with data available*

Table 5 shows a summary of the secondary outcomes of interest for the DSMB meeting .

Table 5: Secondary outcomes data

		Total N=xxx
Secondary outcomes data available [(1)]		xxx
Outcome 1		xx (xx%)
	(missing)	(X*)
Outcome 2		xx (xx%)
	(missing)	(X*)

[(1)] Percentages are of those with data available

4. Safety

4.1 Adverse events

Table 6 shows a summary of all of the adverse events (AEs) that have occurred up to the XX of XX 20XX.

Table 6: Adverse Events

		Total N (%*)
Number of Participants Randomised		XX
Participants who had at least one AE**		XX (XX%)
Number of AEs:		XX
Number of AEs by	XX	XX
category:	XX	XX
	XX	XX

** Percentage of participants with data available*

***AE=Adverse event*

4.2 Serious adverse events

Up to the XX of XX 20XX, XX serious adverse event (SAE) occurred in XX participants. These are summarised in table 7 below.

Details of the unexpected SAE are reported in the Appendix for examination by the DSMB.

Table 7: Serious Adverse Events

	Total N=xxx
Participants who experienced Serious Adverse Events	XX (XX %)
Total number of SAEs	XX
Unexpected death(1)	XX (XX %)
Life-threatening deterioration(1)	XX (XX %)
Medical occurrence that will prolong hospitalization(1)	XX (XX %)
Medical occurrence that could have become serious if untreated(1)	XX (XX %)
Relationship of the SAE to the infants enrolment in the OPTIMIST-A trial (1)**:**	
Unrelated	XX (XX %)
Possibly related	XX (XX %)

(1) Percentages are calculated on the total number of SAE

4.3 Suspected Unexpected Serious Adverse Reaction (SUSAR)

Up to the XX of XX 20XX, XX Suspected Unexpected Serious Adverse Reactions (SUSAR) occurred in XX participants. These are summarised in table 8 below.

Details of these SUSARs are reported in the Appendix for examination by the DSMB.

Table 8: Suspected Unexpected Serious Adverse Reactions

	Total N=xxx
Participants who experienced a SUSAR	XX (XX %)
Total number of SUSARs	XX
<insert one line summary>	XX (XX %)
<insert one line summary>	XX (XX %)
<insert one line summary>	XX (XX %)
<insert one line summary>	XX (XX %)

(1) Percentages are calculated on the total number of SUSARs

4.3 Significant Safety Issues (SSI)

A Significant Safety Issue (SSI) is defined as "A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial." (NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods EH59, November 2016).

Up to the XX of XX 20XX, XX SSIs occurred.

Details of these SSIs are reported in the Appendix for examination by the DSMB.

Table 9: Significant Safety Issues

	Total N=xxx
Total number of SSIs	XX
<insert one line summary>	XX
<insert one line summary>	XX
<insert one line summary>	XX
<insert one line summary>	XX

4.4 Ugent Safety Measure (USM)

An Ugent Safety Measure (USM) is defined as "A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety." (NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods [EH59], November 2016)

Up to the XX of XX 20XX, XX USMs occurred.

Details of these USMs are reported in the Appendix for examination by the DSMB.

Table 10: Ugent Safety Measures

	Total N=xxx
Total number of USMs	XX
<insert short summary>	XX
<insert short summary>	XX
<insert short summary>	XX
<insert short summary>	XX

5. Protocol deviations including Serious Breaches

5.1 Serious Breaches

A Serious Breach is defined as:"A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree: a) The safety or rights of a trial participant, or b) The reliability and robustness of the data generated in the clinical trial. Note: this guidance's definition of serious breach differs from the definition in the Australian Code for the Responsible Conduct of Research and is about deviations from the requirements of Good Clinical Practice or the clinical trials protocol." (NHMRC Guidance: Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods [EH59A], 2018).

Up to the XX of XX 20XX, XX Serious Breaches occurred.

Details of these Serious Breaches are reported in the Appendix for examination by the DSMB.

Table 11: Serious Breaches

	Total N=xxx
Total number of USMs	XX
<insert short summary>	XX
<insert short summary>	XX
<insert short summary>	XX
<insert short summary>	XX

5.2 Protocol Deviations including deviations requiring exclusion from the per-protocol analysis

The following table shows a summary of those protocol deviations requiring exclusion from the per-protocol analysis.

Table 10: Protocol deviations requiring exclusion from the per-protocol analysis

	Total n(%*)
Number of participants with protocol deviations <u>requiring exclusion from the per-protocol analysis</u>	XX (XX %)
- PPA exclusion due to <*insert category*>	XX
- PPA exclusion due to <*insert category*>	XX
- PPA exclusion due to <*insert category*>	XX

** Percentage of participants with data available*

6. Appendices

Appendix 1: Details of SAEs

HREC Reference #	xxx
Name of trial	
Principal Investigator	
Date that SAE occurred :	
Date Investigator became aware of SAE :	
Participant ID :	
Internal or External (see above definition):	
Event description and management :	
Event outcome (synopsis):	
Expectedness of the SAE (PI Opinion):	☐ Expected ☐ Unexpected
Relationship to the study drug	☐ Unrelated ☐ Possibly related ☐ Probably Related ☐ Definitely Related

Appendix 2: Details of SUSARs

HREC Reference #	xxx
Name of trial	
Principal Investigator	
Date that SUSAR occurred :	
Date Investigator became aware of SUSAR:	
Participant ID :	
Internal or External (see above definition):	
Event description and management :	
Event outcome (synopsis):	
Name of study drug suspected	
Relationship to the study drug	☐ Possibly related ☐ Probably Related ☐ Definitely Related

Appendix 3: Details of SSIs

HREC Reference #	xxx
Name of trial	
Principal Investigator	
Date of SSI :	
Date Investigator became aware of SAE :	
Participant ID (where relevant):	
Internal or External (see above definition):	
Event description and management :	
Event outcome (synopsis):	

Appendix 4: Details of USMs

HREC Reference #	xxx
Name of trial	
Principal Investigator	
Date of USM :	
Participant ID :	
Internal or External (see above definition):	
Event description and management :	
Event outcome (synopsis):	
Relationship to the study drug	☐ Unrelated ☐ Possibly related ☐ Probably Related ☐ Definitely Related

Appendix 4: Details of Serious Breaches

HREC Reference #	xxx
Name of trial	
Principal Investigator	
Date of Serious Breach :	
Date Investigator became aware of SAE :	
Participant ID (where relevant):	
Internal or External (see above definition):	
Serious Breach description and management :	
Serious Breach outcome (synopsis):	