Medicines & Healthcare products
Regulatory Agency

Quarterly Summary Reports – guidance and template for manufacturers / sponsors

August 2024

Quarterly Summary Reports

As per the conditions of MHRA approval for a clinical investigation, in addition to the reporting of individual serious adverse events as detailed above, please provide quarterly summary reports providing an update on the latest overall safety profile for the investigation. This reporting template is for devices only and should also be used for device related reporting on any combined studies.

Detail on any Investigational Medicinal Product IMP under investigation should not be included.

When providing these summaries please use the following template:

	UK only	Global
Date of first implant / treatment		
Total number of enrolled participants from the start of the study		
Total number of participants implanted/treated		
Total number of devices used		
Total new enrolments this quarter		
Total number of SAEs to date		
Number of new SAEs this quarter		
Total device deficiencies to date		
Number of new device deficiencies this quarter		

Serious adverse events

Event Type (Preferred Term) – e.g.	Number of events/patients affected e.g.	Percentage of patients affected	Number of patients affected	Percentage of patients affected	Number of patients affected	Percentage of patients affected	Expected % rate of SAE (based upon extensive literature review)	Literature References
	Current reporting quarter		Previous reporting quarter		Total study period			
Blood loss anaemia	3/2	%		%		%		
Febrile neutropenia	4/4	%		%		%		

Acute coronary syndrome	6/4	%		%		%		

Device deficiencies

DD term – e.g.	Current report: Number of Events – e.g.	Current report: Number (N) of Participants Affected – e.g.	Current report: % of Participants Affected (N/ patients treated) in current report – e.g.	Previous report: % of Participants Affected (N/ patients treated) in previous report – e.g.
Device malfunction	1	1	%	%

Please confirm the rationale for the order/grouping of different event types and device deficiencies. For example, for event types this may be grouping by System Organ Class.

Please highlight rows where the percentage of affected patients has increased compared to the previous quarter.

Please provide the narratives of i) patient deaths ii) USADEs and iii) DDs with SADE potential which have occurred within the last quarter within this investigation. This should include date of treatment, date of event, and any prior SAEs.

For patient deaths, the cause of death where known and whether considered related to the procedure and/or to the device in the assessment of the investigator and the sponsor should be confirmed as clearly as possible. The total mortality and mortality rate within the investigation should also be confirmed.

Overall summary of the report

In this section, please include a summary analysis of the serious events and device deficiencies together with the manufacturer's conclusions

Notes

1. Appropriate diligent unbiased consideration is needed when undertaking a review of any applicable available comparable evidence such as with published literature. Efforts should be made to drive an unbiased discussion

that should account and reflect available evidence irrespective of favourable or unfavourable outcomes and that where possible rationale / explanation is provided on any key divergent differences in results between the current study and other published data.

2. When providing the tables/report, please ensure it contains detailed information on SAEs for the **entire** duration of the investigation, not just those which have occurred during this quarter.

3. The first quarterly report should be submitted as soon as possible after the end of the first quarter after the first patient has been treated. Quarterly reports should contain data from ALL study sites (UK, EU, WW)

4. Where possible, please present data indicating how many / what percentage are device / procedure related.

5. Please use standard MedDRA terms.

6. An up-to-date copy of the SAE spreadsheet should be provided with the quarterly report.

7. Please submit your report via the MORE portal, quoting your MHRA reference number e.g. **CI/2023/XXXX**

8. See how to register for the MORE portal. Guidance on how to submit reports via MORE can be found here.

9. For all queries, please contact info@mhra.gov.uk

Revision History

This version	Date published	Changes
V 1.0	July 2024	n/a
V 1.1	August 2024	• Removed distinction between annual reports and quarterly reports. • Removed requirement for annual reports for Q4 • Removed requirement for cc'ing reports to an MHRA email when reporting via MORE • Fixed formatting errors