

# WORK INSTRUCTION

## SAE & SUSAR HANDLING PROCEDURE W41

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Author & Position:	Anoushka Teplelow, Assistant R&D Manager
Date:	29/01/15
Signature:	
Approver & Position:	Chris Gardner, R&D Directorate Manager
Date:	29/1/15
Signature:	

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### DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless;

- A study specific SOP exists
- A departmental SOP dictates a different working practice

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**VERSION HISTORY LOG**

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

<b>VERSION</b>	<b>Reviewer</b>	<b>Date Implemented</b>	<b>Details of significant changes</b>
V1.0		19 August 2011	
V2.0	Alison Kerridge. R&D Coordinator & Joanne Lowe, QA Coordinator	30 January 2015	Updated flowcharts to reflect current procedures.

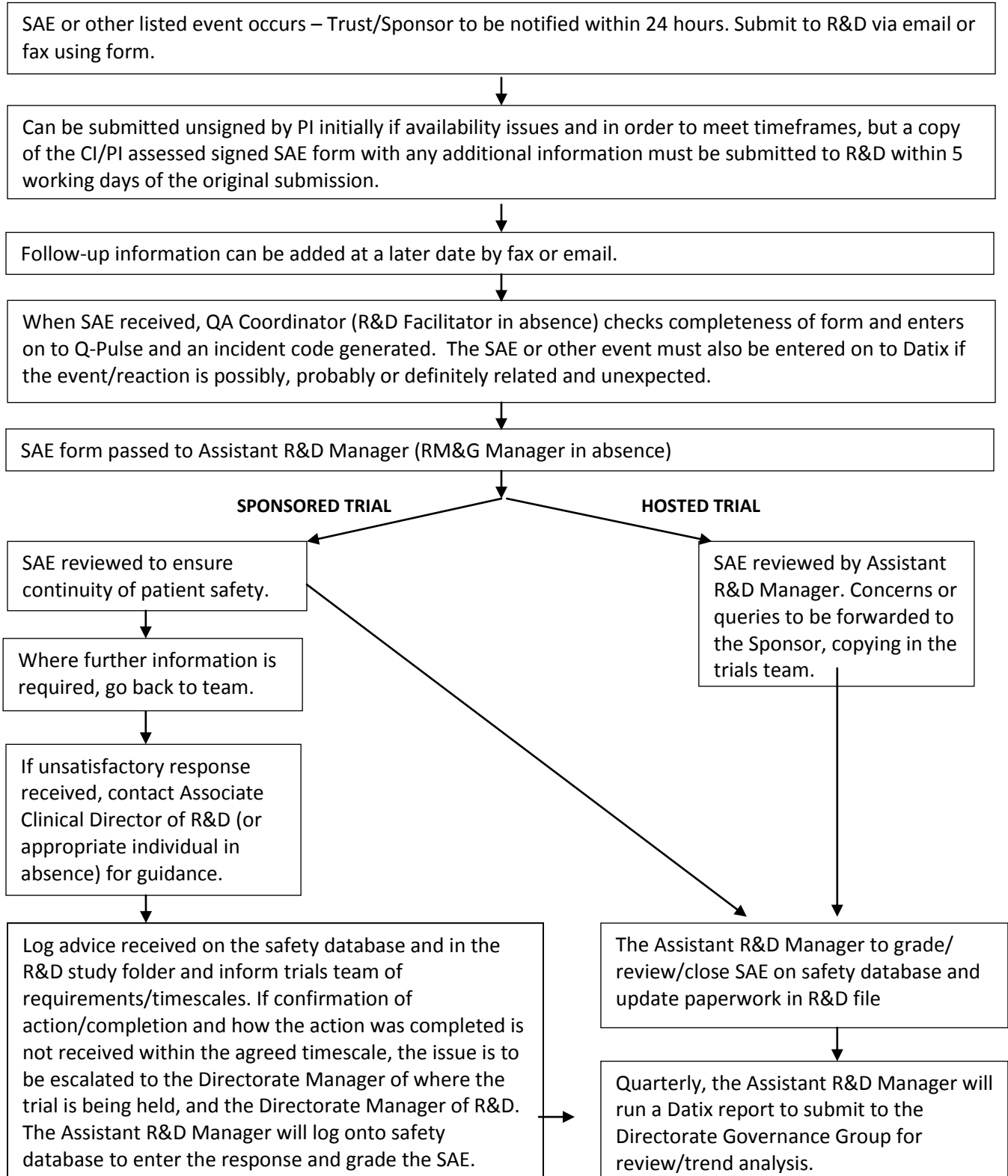
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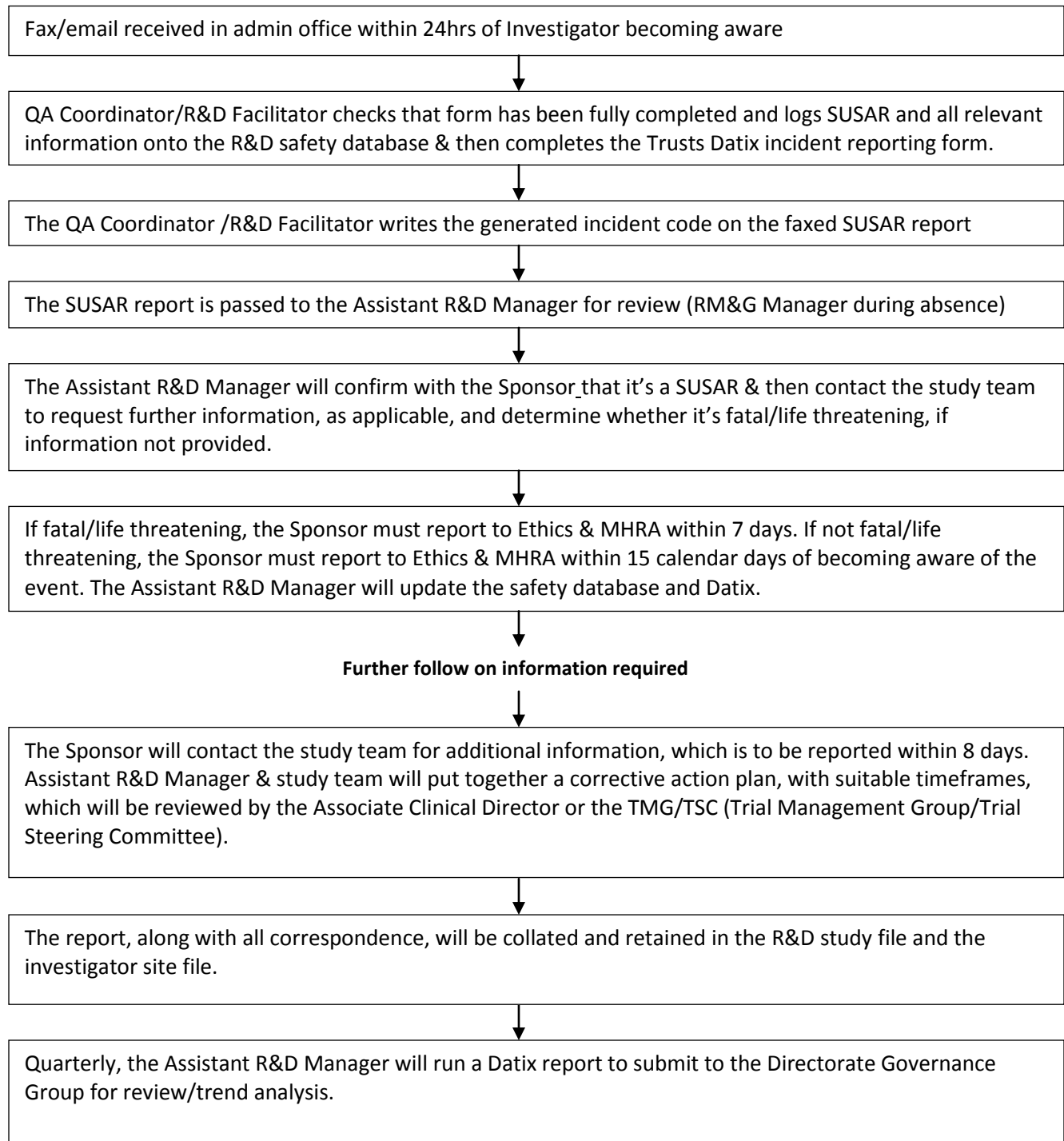
**Procedures**

**1. SAEs reporting to R&D for RD&E Sponsored & Hosted Studies**

For the safety reporting of **AEs/ARs/SARs** and **hosted SUSARs** (as dictated by the protocol), please also follow this detailed flowchart:



## 2. SUSARs reporting to R&D for RD&E Sponsored Studies



**3. Related Documents**

[SOP22](#) Pharmacovigilance  
SOP41 Safety Notifications