SAFETY REPORTING (CTIMPs) FOR UK HEALTH DEPARTMENTS' RESEARCH ETHICS SERVICE (RES)

SSAR = Suspected Serious Adverse Reaction
SUSAR = Suspected Unexpected Serious Adverse Reaction

A *serious adverse reaction* is an untoward and unintended response to an IMP at any dose, that:

(a) results in death;
(b) is life-threatening;
(c) requires hospitalisation or prolongation of existing hospitalisation;
(d) results in persistent or significant disability or incapacity; or
(e) consists of a congenital anomaly or birth defect.

An adverse reaction is *unexpected* if its nature and severity are not consistent with the information about the medicinal product in question set out:

- In the case of a product with marketing authorisation, in the Summary of Product Characteristics for that product
- In the case of any other IMP, in the Investigator's Brochure relating to the trial in question

Reporting date for periodic safety reports:

IMP with a marketing authorisation in any EU member state — The International Birth Date for the product
IMP without a marketing authorisation — The date on which any trial of the IMP being conducted by the sponsor was first authorised by a competent authority in any EU member state

For more detailed guidance, see the European Commission guidance on adverse reaction reporting (ENTR/CT3) available from:
http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm

	Who	When	What	How	To Whom
Reporting of individual SUSARs	Sponsor, sponsor's legal representative or Chief Investigator.	(a) or (b) must be reported within 7 days of the sponsor becoming aware of the event. Any additional information must be reported within 8 days of sending the first report. (c) (d) or (e) must be reported within 15 days of the sponsor becoming aware of the event.	Any SUSAR in the relevant trial in the UK.	RES Safety Report Form (CTIMPs), enclosing: SUSAR report (no form prescribed but should be in the format set out in the current version of *ICH Topic E2B – Clinical Safety Data Management).*	The REC which issued the favourable ethical opinion. REC Manager will acknowledge within 30 days.

	Who	When	What	How	To Whom
Annual safety reporting	Sponsor, sponsor's legal representative or Chief Investigator.	Annually – within 60 days of reporting date.	List all worldwide SSARs in the reporting period, i.e. both expected and unexpected. Summarise any issues affecting safety of participants.	RES Safety Report Form (CTIMPs), All annual safety reports should be in the format for Development Safety Update Reports (DSUR) set out in the ICH E2F guideline (available at http://ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html).	Each REC responsible for a trial of the IMP (use separate covering form for each).
Urgent safety measures	Sponsor, sponsor's legal representative or Chief Investigator. *Or exceptionally by local Principal Investigator (PI).*	(i) Immediately (by telephone) (ii) Within 3 days (in writing).	Reasons for the urgent safety measures and the plan for further action.	(i) By telephone. (ii) Notice in writing.	The REC which issued the favourable ethical opinion.

PROGRESS REPORTING (CTIMPs)

Type	Who	When	How	To Whom
Progress reports	To be submitted by sponsor, sponsor's legal representative or Chief Investigator (CI). Must always be signed by CI.	Annually (starting 12 months after the date of the favourable opinion). *The REC may exceptionally request more frequent reports.*	Annual progress report form (CTIMPs), available from the HRA website.	The REC which issued the favourable ethical opinion.
Declaration of the conclusion or early termination of the research (CTIMPs)	Sponsor, sponsor's legal representative or CI.	Within 90 days (conclusion). Within 15 days (early termination). *The end of the trial should be defined in the protocol.*	Using the form prescribed by the European Commission (Annex 3 to ENTR/CT1), available from EudraCT website.	The REC which issued the favourable ethical opinion.
Summary of final report	Sponsor, sponsor's legal representative or CI.	Within one year of the conclusion of the research.	No standard format. The summary should include information on whether the study achieved its objectives, the main findings and arrangements for publication or dissemination including feedback to participants.	Main REC for the trial. The REC which issued the favourable ethical opinion.

All reports will be acknowledged within 30 days by the REC Manager. If any issues are raised, the REC may write to the Chief Investigator or sponsor for further information or clarification.