Development Safety Update Reports

**Reminder will be set on ReDA, in the Governance tab  Project Email Alerts.**

**These should be set up on Reda at time of Final Governance meeting by the allocated JRMO monitor.**
**See Table 1 for details regarding the required actions when a reminder is received, and the escalation process.**

Development Safety Update Report

1st Reminder  to be set one month before the MHRA approval anniversary

Send email to: CI, GCP Monitor, Research Safety inbox, Trial Coordinator (use study generic email account).

Email SUBJECT: **XXX Development Safety Update Report 1st Reminder**

**\*\*\*Automated Reminder\*\*\***

Dear Dr XXX,

**RE: XXX , IRAS Number: 0000**

You are approaching the end of your DSUR reporting period. In one month the reporting period will end and you will have 60 calendar days to submit your DSUR to the MHRA.
For info, the DSUR should cover a one year period, with the last day being the date of the anniversary of your MHRA approval (Grounds of Acceptance letter DDMMMYYYY).

You can find the current template on our website, under SOP 19 <http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-19/>

The DSUR must be submitted via the current MHRA submission portal (<https://mhrabpm.appiancloud.com/suite/sites/MHRA_Submissions>)

No action is required at this time; however, you may wish to start preparing the data for your report. Please ensure a draft report is sent to research.governance@qmul.ac.uk for Sponsor review at least 2 weeks prior to submission.

**Reminder 1 – End of reporting period approaching**

Reminder 2 – Reporting period ends today

Reminder 3 – 14 days left to submit DSUR

Reminder 4 – DSUR is due to arrive at MHRA today

\*\*\*\*\* Please note that the MHRA and regulators use late reports to select studies for inspection as an indicator of failure to comply with GCP. Failure to submit regulatory reports in a timely manner may trigger the sponsor to audit the study and will result in the GCP team escalating to the appropriate CAG lead/institute director and the sponsor representative. Breaches in GCP may result in studies being suspended or withdrawal of sponsorship \*\*\*\*\*

2nd Reminder  to be set on the MHRA approval anniversary

Send email to: CI, GCP Monitor, Research Safety inbox, Trial Coordinator (use study generic email account).

Email SUBJECT: **XXX Development Safety Update Report 2nd Reminder**

**\*\*\*Automated Reminder\*\*\***

Dear Dr XXX,

**RE: XXX , IRAS Number: 0000 ,**

Today is the end of your DSUR reporting period. You now have 60 calendar days to submit your DSUR to the MHRA.
For info, the DSUR should cover a one year period, with the last day being the date of the anniversary of your MHRA approval - today (DDMMMYYYY).

You can find the current template on our website, under SOP 19 <http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-19/>

The DSUR must be submitted via the current MHRA submission portal (<https://mhrabpm.appiancloud.com/suite/sites/MHRA_Submissions>)

Please ensure a draft report is sent to research.governance@qmul.ac.uk for Sponsor review 2 weeks prior to submission.

Reminder 1 – End of reporting period approaching

**Reminder 2 – Reporting period ends today**

Reminder 3 – 14 days left to submit DSUR

Reminder 4 – DSUR is due to arrive at MHRA today

\*\*\*\*\* Please note that the MHRA and regulators use late reports to select studies for inspection as an indicator of failure to comply with GCP. Failure to submit regulatory reports in a timely manner may trigger the sponsor to audit the study and will result in the GCP team escalating to the appropriate CAG lead/institute director and the sponsor representative. Breaches in GCP may result in studies being suspended or withdrawal of sponsorship \*\*\*\*\*

3rd Reminder  to be set 45 days after the MHRA approval anniversary

Send email to: CI, GCP Manager, GCP Monitor, Research Safety inbox and Trial Coordinator (use study generic email account).

Email SUBJECT: **XXX Development Safety Update Report 3rd Reminder**

**\*\*\*Automated Reminder\*\*\***

Dear Dr XXX,

**RE: XXX , IRAS Number: 0000 ,**

Your DSUR is due to be received by the MHRA within 14 days. If you haven’t already done so, please ensure a draft report is sent to research.governance@qmul.ac.uk for Sponsor review.
For info, the DSUR should cover a one year period, with the last day being the date of the anniversary of your MHRA approval (Grounds of Acceptance letter DDMMMYYYY).

You can find the current template on our website, under SOP 19 <http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-19/>

The DSUR must be submitted via the current MHRA submission portal (<https://mhrabpm.appiancloud.com/suite/sites/MHRA_Submissions>)

You will continue to receive reminders until the JRMO receive your final signed report, along with acknowledgment of successful submission from MHRA.

Reminder 1 – End of reporting period approaching

Reminder 2 – Reporting period ends today

**Reminder 3 – 14 days left to submit DSUR**

Reminder 4 – DSUR is due to arrive at MHRA today

\*\*\*\*\* Please note that the MHRA and regulators use late reports to select studies for inspection as an indicator of failure to comply with GCP. Failure to submit regulatory reports in a timely manner may trigger the sponsor to audit the study and will result in the GCP team escalating to the appropriate CAG lead/institute director and the sponsor representative. Breaches in GCP may result in studies being suspended or withdrawal of sponsorship \*\*\*\*\*

4th Reminder  to be set 8 weeks after the MHRA approval anniversary

Send email to: CI, GCP Manager, GCP Monitor, Research Safety inbox and Trial Coordinator (use study generic email account).

Email SUBJECT: **XXX Development Safety Update Report 4th Reminder**

**\*\*\*Automated Reminder\*\*\***

Dear Dr XXX,

**RE: XXX , IRAS Number: 0000**

Your DSUR is due to be received by the MHRA **TODAY**.

If you have already submitted your DSUR then you may still need to send your final signed DSUR to the JRMO, along with acknowledgment of successful submission from MHRA.

If you have not submitted your DSUR you must contact the JRMO on research.governance@qmul.ac.uk to discuss the reason for the delay.

You can find the current template on our website, under SOP 19 <http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-19/>

The DSUR must be submitted via the current MHRA submission portal (<https://mhrabpm.appiancloud.com/suite/sites/MHRA_Submissions>)

Reminder 1 – End of reporting period approaching

Reminder 2 – Reporting period ends today

Reminder 3 – 14 days left to submit DSUR

**Reminder 4 – DSUR is due to arrive at MHRA today**

\*\*\*\*\* Please note that the MHRA and regulators use late reports to select studies for inspection as an indicator of failure to comply with GCP. Failure to submit regulatory reports in a timely manner may trigger the sponsor to audit the study and will result in the GCP team escalating to the appropriate CAG lead/institute director and the sponsor representative. Breaches in GCP may result in studies being suspended or withdrawal of sponsorship \*\*\*\*\*

Table 1: Actions and escalation process relating to each reminder

|  |  |  |
| --- | --- | --- |
|  | **GCP Monitor** (covered by Research Safety in Monitors absence) | **GCP Manager** |
|  |  |  |
| **DSUR 1**Due -90 Days | For info only, no action required. |  |
| **DSUR 2**Due -60 Days | Communicate directly with study team informing end of reporting period. |  |
| **DSUR 3**Due -14 Days | Email to study team (cc GCP Manager) to query lateness of report. | For info. |
| **DSUR 4**Due -00 Days | Formally escalate to Senior GCP manager. | Contact study team and inform Research Governance Operations Manager. |
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