

## Appendix 3

### **Development Safety Update Report Reporting Timeframe Guidance Document**

The following should be used in conjunction with the **Development Safety Update Report working illustration- Appendix 1**

- The Development Safety Update Report (DSUR) is due on the anniversary of the MHRA clinical trial authorisation. This is known as the **Data Lock Point**
- The Research & Innovation (R&I) office will send an email to the Principal Investigator **31 days PRIOR** to the **Data Lock Point**. Attached to this email will be:
  - DSUR Guidelines
  - Template DSUR form

The email will include a date to return the completed DSUR to the R&I OFFICE. This is the **Data Lock Point PLUS 21 days**. Investigators are welcome to submit the DSUR to the R&I office for initial review prior to signing to ensure that they are completing the document to the required standards, providing the specified timeframes are adhered to

- If the completed DSUR is not returned to the R&I office by this stipulated date the Principal Investigator will be emailed to offer a further 7 days for completion. If this extended deadline is not met the **UHL Procedure for non-compliance will be implemented as per SOP S-1016 UHL**
- Once the completed DSUR has been returned to the R&D office, it will be reviewed and signed by the appropriate person/s
- The R&I office will submit the completed, signed and dated DSUR to the appropriate regulatory bodies by the final submission date which is the **Data Lock Point PLUS 60 days**
- The R&I office will send an acknowledgement to the Principal Investigator along with a copy of the signed DSUR. This must be filed in the trial master/site file