

Title: Study Progress Reporting	
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Version	Description of update	Date Effective
1.0	Clarification added regarding non-REC study annual progress reporting, footnote added, HRA added to abbreviations list.	05/03/2021

1. Scope

1.1 This Standard Operating Procedure (SOP) applies to all researchers involved in projects that are sponsored or co-sponsored by Bournemouth University (BU). Such studies (where required) will have received favourable ethical opinion from a Research Ethics Committee (REC) and as such are required to prepare and submit an Annual Progress Report (APR). Studies that received Health Research Authority (HRA¹) approval only should send the report to approvals@hra.nhs.uk.

1.2 This SOP applies to all researchers involved in Clinical Trials of Investigational Medicinal Products (CTIMPs), and other interventional studies involving a medicinal product (MP), that are sponsored by BU. These studies will have obtained MHRA Clinical Trials Authorisation, in addition to favourable REC opinion. As such, researchers are required to prepare and submit a Development Safety Update Report (DSUR).

2. Responsibilities

The *Chief Investigator (CI)/Researcher* is responsible for completing and submitting APRs and DSURs, as delegated by the *Sponsor*. They are also responsible for filing all reports in the Trial Master File (TMF).

The *Sponsor, via Research Development & Support (RDS)* is responsible for reviewing all APRs and DSURs prior to submission to the relevant body.

3. Procedure

3.1 APRs should be submitted annually for all research projects that have NHS REC favourable opinion or HRA approval. The first APR must be submitted 12 months after the date of the favourable opinion/approval, within 30 days of the date, whether recruitment has

¹ Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval

started or not. If recruitment has not yet started, then the reason for this should be included in the APR.

3.2 The APR should be completed on the appropriate HRA Annual Progress Report Form. The most recent versions are available on the Health Research Authority (HRA) website – <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/>

3.3 The signed APR should be submitted to the REC that granted the favourable opinion for the non-interventional research project, in hard copy or by email. This can be done by the Sponsor, but APRs must be signed by the CI. For non-REC studies, the report should be sent to approvals@hra.nhs.uk. The APR should then be copied to the Sponsor and the NHS R&D departments that have granted Trust agreement.

3.4 With regard to interventional projects, the CI/Researcher should forward the draft APR to the Sponsor's Clinical Governance Advisor for their review, at least two weeks before the submission date. The Sponsor will then review the draft copy of the APR and will confirm whether it can be submitted, or if there are any required changes and further review.

3.5 All APRs will be acknowledged in writing by the REC/HRA within 30 days of receipt. The REC/HRA will write to the CI requesting further information should they require it, possibly requesting that the CI attend a meeting with the REC to discuss study progress.

3.6 The REC does not need to re-issue their favourable opinion each time they receive a progress report.

3.7 The CI/Researcher must ensure that a copy of the APR, acknowledgement, and any other communication with the REC/HRA, Sponsor or R&D are filed in the TMF.

3.8 If an APR is not received by the REC by the due date, then they will send a reminder. If after this reminder the report is not received after one month, then the REC Manager will consider what should be done (review of a favourable opinion, study termination etc.).

3.9 Following receipt of the first APR, the Chair of the main REC has the discretion to waive the requirement for further reports, on receipt of a written request by the CI. This may be a valid request when the study has completed recruitment or assessments, but has a long period of follow-up with minimal participant involvement.

Preparing and submitting Development Safety Update Reports (DSURs) to the MHRA and NHS REC

3.10 DSURs are required for CTIMPs and other interventional studies involving medicinal products that are also used in a CTIMP, sponsored or co-sponsored by BU.

3.11 DSURs are submitted annually, with the first DSUR due 12 months after the date of the Clinical Trials Authorisation (CTA), and must be submitted within 60 days of the date.

3.12 The MHRA guidance on completing DSURs is available here - <https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#submit-development-safety-update-reports-dsurs>

3.13 In completing the DSUR, the Summary of Product Characteristics (SmPC/SPC) and/or Investigator Brochure (IB) should be reviewed in order to ensure that the safety profile does not need to be updated. The date the SmPC/SPC has been checked or updates made to the IB, should be recorded in the DSUR.

3.14 The CI/Researcher should forward the DSUR to the Sponsor for review, at least 2 weeks prior to the required submission date. The Sponsor will then review the report and will confirm whether it can be submitted, or if there are any required changes and further review.

3.15 The signed DSUR and any associated documents (e.g. the IB), should be submitted to the MHRA via the Common European Submission Portal via <http://cesp.hma.eu/Home>. The CI/Researcher should inform the Sponsor once it has been submitted and confirmation from the portal, filed in the TMF. The MHRA do not always acknowledge DSURs, however the CI should contact RDS via researchgovernance@bournemouth.ac.uk should any issues arise once the MHRA have reviewed the report.

3.16 The CI/Researcher must also ensure that DSURs are submitted to the NHS REC that provided the favourable opinion. The DSUR should be sent alongside a completed CTIMP Safety Report which is available on the HRA website – www.hra.nhs.uk.

3.17 The CI/Researcher must ensure that a copy of the DSUR, acknowledgement and any communication with the MHRA, REC, Sponsor and R&D are filed in the TMF.

3.18 Should there be more than one BU sponsored or co-sponsored trial involving the same MP, the Clinical Governance Advisor will liaise with the CIs involved to ensure that one report is produced for all concerned trials.

3.19 Trials involving combination/multi-drug therapies usually require a single DSUR to be prepared and submitted. Exceptions to this rule shall be discussed with the Clinical Governance Advisor prior to preparing the first DSUR.

4. Abbreviations and definitions

APR	Annual Progress Report
CGA	Clinical Governance Advisor
CI	Chief Investigator
CTIMPs	Clinical Trial of an Investigational Medicinal Product
DSUR	Development Safety Update Report
HRA	Health Research Authority
IB	Investigator Brochure
MHRA	Medicines and Healthcare products Regulatory Agency
MP	Medicinal Product
R&D	Research and Development (NHS Research Governance)
REC	Research Ethics Committee
SmPC/SPC	Summary of Product Characteristics
TMF	Trial Master File

5. Related documentation and references

Common European Submission Portal. (n.d.). CESP. [online] Available at: <http://cesp.hma.eu/Home> [Accessed 9 Jul. 2018]

GOV.UK. (2018). Clinical trials for medicines: manage your authorisation, report safety issues. [online] Available at: <https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#submit-development-safety-update-reports-dsurs> [Accessed 9 Jul. 2018]

Health Research Authority. (2018). Progress reports. [online] Available at: <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/> [Accessed 9 Jul. 2018]