

Clinical Trials Office Bulletin

December 2010

Welcome to the second edition of the Clinical Trials Office Bulletin. We hope you find this information helpful, which is aimed at raising awareness of relevant Clinical Trial of Investigational Medicinal Product (CTIMP) trial issues. If you have any suggestions for future articles, please email us at r&dtu@addenbrookes.nhs.uk

CLINICAL TRIALS OFFICE (CTO) UPDATE

We are pleased to announce that the CTO has grown since our last Bulletin in September and we welcome 5 new members to the team:

CTU Director

Ian Wilkinson took up the position of Director on 1st November.

Senior Statistician

Simon Bond joined us from the Cambridge Cancer Trials Centre on 13th September.

Quality Assurance Manager

Carolyn Sexton joined us from the Cambridge Cancer Trials Centre on 18th October and her time will be split between the CTO and the Clinical Research Facility.

Clinical Trial Monitor

Sarah Cheung joined from the Joint Clinical Trials Office, Guys & St Thomas's NHS Foundation Trust on 22nd November.

Clinical Trial Coordinator

Carrie Bayliss changed roles and started as a Clinical Trial Coordinator on 1st December.

We are also sad to announce that 2 members of our existing team will be moving on and leaving the Trust.

Helena Heanue-Travers who has been a Clinical Trial Monitor with the Clinical Trials Office since July 2009, will be leaving us at the end of the year to take up a new post in Ireland.

Mina Muthurajah who recently moved into the CTO from R&D has been with the Trust since June 2009 and will be leaving us at the end of January to start further education.

We wish them every success in their new roles.

END OF TRIAL NOTIFICATIONS

End of Trial notifications now only need to be submitted to the MHRA for international trials when the trial has ended globally. In the UK however the MHRA CTU would encourage sponsors to continue to send in a notification to them when the UK aspect of the trial has ended. This can take the form of a letter rather than the Annex 3 form if reported prior to the global end of the trial. Until an end of trial notification is received by the MHRA the annual service fee for the CTA will continue to be charged.

All End of Trial notifications should be copied to the CTO, including covering letters and if included, the Final Study Report at the same time as submission to the REC and/or MHRA.

MHRA INSPECTION UPDATE

The R&D Department and Clinical Trials Office (CTO) would like to thank all trial teams for their hard work and collaboration during the MHRA GCP Inspection that was performed on 9-11th November. The Inspection was performed by two MHRA Inspectors who reviewed Trust systems & processes relating to Clinical Trials involving IMPs (CTIMPs). Six sponsored CTIMPs and two hosted CTIMPs were selected for review.

Inspection preparation activity required trial teams to ensure their Trial Master File documentation was completely inspection-ready and to meet frequently with CTO staff assisting them. During the Inspection there were a large number of information/document requests by the Inspectors – and we appreciate the assistance of trial teams who helped CTO staff process these requests promptly.

During the well attended close-out meeting, the Inspectors provided preliminary findings of the Inspection – in summary there were no critical findings and 2 major findings (Organisation oversight of clinical trials and Pharmacovigilance). There were also 10 other findings relating to: Training, Consent, Protocol Compliance, Medical Oversight, REC Approval, Monitoring, IMP Management, Insurance, Contracts/Agreements and Computerised Systems.

What happens next?

We have now received the GCP Inspection Report and in due course study-specific findings will be distributed to the relevant trial teams, for writing up a Corrective and Preventative Action Plan (CAPA). A formal response to the MHRA will be drafted, in consultation with these trial teams.

More detailed feedback on the Inspection findings applicable to all CTIMPs will be provided to all trial teams in the New Year, once the response to the MHRA has been submitted.

NEW AMENDMENT PROCESS

The new European Commission guidance states that substantial amendments should only be notified to the REC or MHRA if the amendment is both substantial and relates to the application to that body. Copies of substantial amendments should no longer be provided to the other body for information only.

EudraCT Annex 2 is the form for notification of substantial amendments to the ethics committee and/or MHRA for clinical trials of investigational medicinal products. The form is accessible from the Amendment Tab of the REC form and the MHRA Medicines form after submission of the initial application in the IRAS system.

Also under the guidance it is the sponsor's responsibility to determine whether an amendment is substantial and if so who should be notified.

In line with this guidance a new process is being piloted by the CTO and R&D Departments which will require all Sponsored CTIMP amendments to be reviewed by the Clinical Trial Coordinator (CTC) assigned to your trial prior to submission to the REC and/or MHRA. Once the CTC has confirmed that there are no Sponsor Objections the amendment may be submitted to the relevant body.

The CTO will liaise directly with R&D to ensure that all approvals are received and any governance issues addressed within the 35 day REC & MHRA approval timeline. This new process is due to be implemented across all Sponsored CTIMPs at the beginning of February 2011. Further details and guidance will be provided to all the trial teams towards the end of January.

SOP UPDATE

Since our last bulletin in September the following SOP's relevant to Clinical Trials of Investigational Medicinal Products have been implemented:

1. EU Clinical Trial of Investigational medicinal product (CTIMP) archiving: SOP 22 Version 1. This SOP provides clear guidance to study teams on the practicalities and considerations for archiving clinical trial related documentation.
2. Serious Breach of GCP or Protocol: SOP 005 Version 3. This updated version includes a considerable update on the identification, escalation and notification of serious breaches of GCP and/or the study protocol.
3. Delegation of Roles and Responsibilities for Trust sponsored Clinical Trials of Investigational Medicinal Products: SOP 004, Version 3.0. This updated version provides clarification on sponsor delegated duties to the CI/PI
4. Preparing for and facilitating regulatory (MHRA) inspection: SOP 21, Version 1.0. This SOP informs trials teams of inspection process, in addition to providing information about roles and responsibilities of all parties concerned.
5. EU Clinical Trial End of Trial Procedures: SOP 15, Version 1.0. This SOP informs the trials teams of the requirements for timely submission of End of Trial Notifications, and the End of Trial Report and closure of participating sites.

Please ensure that you read the above SOP's in their entirety at the earliest opportunity.

The clinical Trials Office is busy developing a number of tools to provide assistance and to supplement existing SOP'S. We are also in the process of updating the Pharmacovigilance and monitoring SOP to name but a few.

All current SOP's can be located:

http://www.cuh.org.uk/research/researchers/document_library.html

Please note it is each study team member's responsibility to ensure that they read and keep up to date with all clinical trial related SOPs. If you require further clarification on any of the SOP's e-mail or call the Clinical Trials Office we would be happy to help!

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