

Audit Summary Report

Printed on: 21 July 2017

Details	
Number IQA-43	Title Sponsored Trial Publication Process
Status Closed	Audit Type Internal Audit
Lead Auditor Cowie, Richard	

Dates		
Scheduled Start Date 30/06/2017	Scheduled End Date 30/06/2017	Scheduled Duration 0 Day/s
Actual Start Date 26/06/2017	Actual End Date 07/07/2017	Actual Duration 0 Day/s
Closed By Cowie, Richard	Closed Date 17/07/2017	

Findings
<p>Overview</p> <p>To ensure transparency, avoid selective publication and ensure results are available to the public it is mandatory for sponsors to register clinical trials before recruitment of the first participant and to post clinical trial results within one year of completion on a publically accessible database. In the University of Aberdeen/NHS Grampian registration of clinical trials and uploading of results is delegated to the CI by means of the letter of access to EudraCT; which enables data entry to the system. There is no requirement to upload results to clinicaltrial.gov as this is a US website under FDA rules.</p> <p>In May 2017 the University of Aberdeen received an unsolicited 'rapid external audit' from TranspariMED (a Bristol based initiative advocating for more transparency in medical research) regarding preregistration and the publication of results on publically accessible databases. TranspariMED suggested that the University of Aberdeen was not performing some trials in compliance with guidelines and provided a list of those it considered non-compliant. Of the 23 studies highlighted by TranspariMED six were not sponsored by the University of Aberdeen.</p> <p>After an initial check by the Research Governance Manager an appropriate response was provided to TranspariMED by the University of Aberdeen and articles were subsequently published in the Glasgow Herald and Aberdeen Evening Express newspapers.</p> <p>In the response to TranspariMED the University of Aberdeen pledged to conduct an audit of clinical trials</p>

sponsored by them. This audit was conducted by the NHS Grampian/University of Aberdeen Quality Assurance Manager in July 2017. Subsequent periodic audits shall be conducted to identify any further opportunities for improvement.

The audit scope covered registration on the publically available European Medicines Agency (EudraCT) register, clinicaltrials.gov, PubMed.gov and ISRCTN, and the publication of results on one of these registries or signposted from them. The audit included CTIMPs registered since 2004 where the sponsor was University of Aberdeen and/or NHS Grampian.

Each CTIMP identified was checked to see that it was registered correctly on EudraCT. All were registered and a protocol was available, although DAMSEL1 could not be located using the EudraCT number recorded by the sponsor (2012-001185-15). This was subsequently checked with the CI and is the correct reference number supplied by EudraCT on 29-2-12.

TWICS and PRE-EMPT are all still ongoing and the CIs shall be reminded to upload results to EudraCT and publish the results on a publically available database within one year of completion of the studies. DAMSEL2 and BICS have not started at the time of the audit.

The following CTIMPs are finished and published but have not yet posted results on EudraCT:

CF

Published in The Journal of Cystic Fibrosis June 2015 (Vol 14, Supplement 1, Page S93). The CI to provide a link to the publication on EudraCT.

Angina*

A paper has been accepted for publication but has not yet been published. Letter issued to CI authorising him to upload results to EudraCT. CI to update the status and provide a link to the publication when available.

Heart Failure (CHF)

Clinical trial transferred to University of East Anglia. Sponsor status to be updated on EudraCT and results uploaded when available.

DAMSEL1

Published in Journal of Pineal Research May 2014 (Vol 56, Issue, Pages 427-438). CI to upload results to EudraCT.

SUSPEND

Published May 2014 (BioMed Central). CTU to upload results to EudraCT and provide link to publication.

NIAMI*

CTU have attempted to upload results to EudraCT. Status to be updated and link to publication provided when available.

CLASP*

Published in Journal of the American College of Cardiology January 2014 (Vol 63, Issue 3, pages 233-239). CTU to upload results to EudraCT, update status and provide link to publication.

KANNECT*

CI died during study. Published in The British Journal of Psychiatry June 2017 (21D(6) 422-428). TM to upload results to EudraCT, update status and provide link to publication.

HFpEF*

No publication received. Letter issued to CI requesting EudraCT be updated and a link provided to publication.

T-Cell*

PhD project with no publication. CTU to update status on EudraCT.

OMEGA3*

Published in Atherosclerosis (Vol 221, Issue 2, April 2012, Pages 514-520). CTU to upload results to EudraCT and provide link to publication.

ACL

Abstract published on PubMed June 2010. Results to be uploaded to EudraCT and link provided to publication.

L-Arginine in PAD*

Published in the Journal of Vascular Surgery May 2015 (Vol 6, Issue 5, Pages 1292-1298). CI has left UoA, status to be updated in EudraCT.

PAD

Did not recruit and the status, to be updated on EudraCT.

CLASS*

Published on PubMed April 2015. Results to be uploaded to EudraCT, status to be updated and link to be provided to publication.

In each of those marked * the CI has left the employment of University of Aberdeen.

The sponsorship of Heart Failure (CHF) was transferred to the University of East Anglia after the departure of the CI to that institution.

University of Aberdeen already ensures that publication and dissemination of results is covered in GCP training provided to researchers and that they are made aware of their responsibilities. The Research Governance Manager conducts weekly checks on clinicaltrials.gov to review any problem records identified.

During the audit issues were identified locating some publications on-line due to differing titles for the same trial used in different documents.

As a result of the TranspariMED audit several opportunities for improvement have been identified including a requirement that all trial protocols, which are risk assessed for sponsorship by University of Aberdeen and/or NHS Grampian, shall be required to include a statement confirming the sponsor commitment to register trials before first recruitment and report results within one year of completion. Also close-out monitoring visits conducted on sponsored studies shall include a check that entries onto appropriate registries are complete and up to date.

Number Of Non-Conformances	0
Number Of Outstanding Non-Conformances	0
Number Of Observations	1

Number	Details	Type	Status
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1	DAMSEL1 could not be located in the EudraCT register using the number recorded in sponsor documentation (2012-001185-15). This was subsequently checked with the CI and is the correct number issued by EudraCT on 29-2-12.	Observation	na
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Accepted By	Accepted On

Auditor	
Auditor Name	Note
Cowie, Richard	