

Note-To-File

A note to file should:

- Be generated on a case-by-case basis
- Be signed and dated by the individual who is writing it
- Be legible if handwritten
- Explain clearly and *specifically* the reason for the error/omission/discrepancy or process/policy it aims to address
- Should include any corrective action or follow-up when applicable
- Be filed in the Trial Master File to which it applies

Note To File:

Study Short Title: GC-SHealD (Glucocorticoids and Skin Healing in Diabetes)

Study Full Title: A double-blind, randomized, placebo-controlled phase II pilot trial investigating efficacy, safety and feasibility of 11 β -hydroxysteroid dehydrogenase type 1 inhibition by AZD4017 to improve skin function and wound healing in patients with type 2 diabetes

Approved Protocol: 2.0 24/10/2018

Sponsor Name: University of Leeds

Sponsor Number: ED17/93260

EudraCT Number: 2017-001351-31

ISRCTN: 74621291

From: Ana Tiganescu (GC-SHealD Scientific Lead)

To: GC-SHealD Trial Master File

Re: Incorrect CRF and database field titles

Date: 29th October 2020

This is to clarify that due to an administrative error uncovered after the database was finalized and locked, the unit provided in the field title in the CRF and the TestResultsPostTrial tab of the database for 1) 24 hour 11 β -HSD1 activity radioimmunoassay (% conversion per hour) and 2) 24 hour 11 β -HSD1 activity ELISA (% conversion per hour) does not match the recorded data. Both these fields actually contain data for activity over 24 hours (i.e. the activity data was not divided by 24 to give activity per hour as stated in the Protocol 2.0). There is no approved standardization for this outcome measure and both unit formats are reported in the literature.

As the original paper on which this outcome measure was based states activity over 24 hours (i.e. consistent with the CRF data), the report headings will be corrected to 1) 11 β -HSD1 activity radioimmunoassay (% conversion per 24 hours) and 2) 11 β -HSD1 activity radioimmunoassay (% conversion per 24 hours). However, the database has now been locked to further amendment. Therefore we have decided to leave the units in the field titles of the CRF and database unchanged.

The trial statistician and Sponsor are in agreement that, as all activity data was collated by one operator who handled the affected data consistently, this is an appropriate course of action. As this error was discovered after completion of data reporting to EudraCT, affected EudraCT data field titles will also be corrected and a copy of this file note explaining the change will be appended.

Signature:

A handwritten signature in black ink, appearing to be 'R. Smith', followed by a horizontal line.

9th Nov 2020