

 GIG CYMRU NHS WALES	Bwrdd Iechyd Prifysgol Hywel Dda University Health Board	Research & Development Department	
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12.9.2022

EudraCT number: 2011-004245-41

Sponsor's ref: HD/12/031

Full title: Safety, Tolerability and Effectiveness of Glucophage® SR in patients with type – 2 Diabetes and Chronic Kidney Disease (eGFR 30 to 45mL/minute/1.73m²).

Date of early termination of trial: 24/06/2014

Details:

Recruitment rate in the first six months was significantly lower than anticipated. Proposed amendments to the protocol aimed at improving recruitment were not acceptable to Merck Serono and they have exercised their right to terminate support for the trial, withdrawing the supplies of placebo. The Sponsor has no option but to terminate the trial.

Since one patient alone has been recruited it will not be possible evaluate any data collected for overall risk benefit assessment of the investigational medicinal product in any meaningful way.

Yours sincerely



R&D Manager
Hywel Dda University Health Board

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Swyddfeydd Corfforaethol, Adeilad Ystwyth, Hafan Derwen, Parc Dewi Sant, Heol Ffynnon Job, Caerfyrddin, Sir Gaerfyrddin, SA31 3BB	Corporate Offices, Ystwyth Building, Hafan Derwen, St Davids Park, Job's Well Road, Carmarthen, Carmarthenshire, SA31 3BB <i>Bwrdd Iechyd Prifysgol Hywel Dda yw enw gweithredol Bwrdd Iechyd Lleol Hywel Dda Hywel Dda University Health Board is the operational name of Hywel Dda Local Health Board Mae Bwrdd Iechyd Prifysgol Hywel Dda yn amgylchedd di-fwg Hywel Dda University Health Board operates a smoke free environment</i>	Cadeirydd / Chair Maria Battle Prif Weithredwr/Chief Executive Mr Steve Moore	