



Medicines & Healthcare products
Regulatory Agency



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Sent by Special Delivery and by email to:

14 March 2016

INFRINGEMENT NOTICE
Served pursuant to regulation 48 of the
Medicines for Human Use (Clinical Trials) Regulations 2004

Dear Dr Connell

Skin derived fibroblasts for the treatment of refractory achilles tendonitis. Published in the Journal of Bone and Joint Surgery (J. Bone Joint Surg Am, 2012;94:193-200).

The Secretary of State for Health is serving this Infringement Notice on Dr David Connell under regulation 48 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) (the Regulations).

A triggered inspection conducted on 20 September 2012, as a result of the Serious Breaches Notification from the Royal National Orthopaedic Hospital (RNOH), revealed the following breaches of the Regulations:

1. The trial was started without first being authorised by the Licensing Authority (Regulation 12(1)).
2. The trial was started without first having obtained a favourable opinion from an appropriate ethics committee (Regulation 12(1)).
3. Investigational medicinal products were supplied to subjects under the auspices of the trial without a clinical trial authorisation in place (Regulation 13(1)).

4. The trial was not being conducted in accordance with the conditions and principles of good clinical practice (Regulation 28(1)). The principles breached were:
 - The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society, Schedule 1, part 2 (1) of the Regulation. In particular as this trial was an Advanced Therapy Investigational Medicinal Product trial there is a requirement for long term follow up of patients in the trial, which was not undertaken.
 - Source data was not retained therefore it is not possible to verify that the data had been reported accurately. Schedule 1, part 2 (9).
5. The essential documents relating to the clinical trial which enable both the conduct of the clinical trial and the quality of the data produced to be evaluated were not retained (Regulation 31A).

You are required to put in place preventative measures to ensure that these breaches do not recur, and that any future clinical trial activity in the UK in which you participate is conducted in a manner fully compliant with the Regulations.

You are also required to provide to the MHRA any data and documents relating to the trial; this is to enable us to confirm that we have correctly identified and contacted all patients.

In particular, you must implement effective mechanisms:

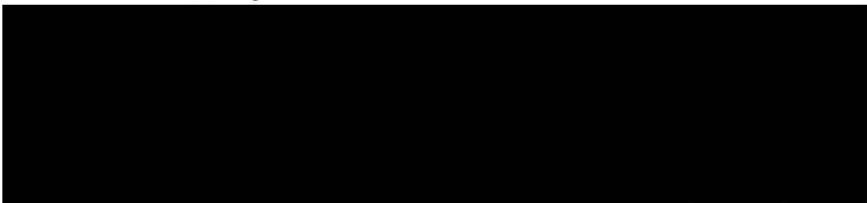
- To check that both a regulatory authorisation and a favourable ethical opinion are in place prior to commencement of any future trial conducted by yourself in accordance with Regulation 12.
- To ensure that investigational medicinal products are supplied to a subject in relation to a clinical trial in accordance with Regulation 13.
- To ensure all trial data is retained in accordance with Regulation 31A
- To ensure the principles of GCP are complied with, in particular Schedule 1, part 2

You are reminded that each of the breaches identified in this Notice constitutes a criminal offence punishable by a fine or up to 2 years imprisonment (see regulations 49 and 52).

We look forward to hearing from you within 21 days of the date of this letter to confirm that these measures will be implemented for any future clinical trials in the UK. If you fail to confirm this within 21 days further action against you, including criminal prosecution will be considered.

You should also note that this Notice, plus any responses, will also be provided to the European Medicines Agency (EMA) and the HRA and may be published on the MHRA website

Yours sincerely



Bernadette Sinclair-Jenkins

A person authorised to sign on behalf of The Secretary of State for Health

Email: IAGSecretariat@mhra.gsi.gov.uk