Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Dr J.Kerrane
Over Wyre Medical Centre
Wilkinson Way
Preesall
Poulton-Le-Fylde
Lancashire
FY6 0FA

MHRA

151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

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Sent by Special Delivery

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

GCP non-compliances in relation to recruitment of ineligible patients into clinical trials during the period January 2007 to July 2015

EudraCT Number	CTA Reference
[redacted]	

The Secretary of State for Health is serving this Infringement Notice on Dr Jerome Kerrane (GMC Number 4326120) under regulation 48 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) (the Regulations).

A triggered inspection conducted on 07-09 March 2016, and a follow-up inspection conducted 01-02 August 2016, as a result of a Serious Breach Notification, revealed the following breaches of the Regulations:

1. Dr Kerrane enrolled patients into studies for which they were ineligible, based on past medical history or issues associated with contra-indicated concomitant medication in breach of the protocols relating to the trials listed in the table below (Regulation 29 (a))

Protocol Number	Eudract Number	Number of Patients Randomised	Number of Eligible Patients	Number of Ineligible Patients
[redacted]		8	6	2
		6	4	2
		5	3	2
		11	8	3
		6	4	2
		11	9	2
		12	9	3

2. Dr Kerrane amended patient's medical records with false information (i.e. asserting that medication had been provided which would make the patient eligible for the study when that was not the case) which could not be supported via Practice records, statements from Practice staff or acceptable prescribing and dispensing procedures within the Practice in breach of conditions and principles of good clinical practice (Regulation 28 (1)).

3. Dr Kerrane provided written assurance to the Sponsor in response to queries raised during monitoring of the trial that patients had been given medication by Practice nurses when this could not be supported via Practice records, statements from Practice staff or acceptable prescribing and dispensing procedures within the Practice in breach of the conditions and principles of good clinical practice (Regulation 28 (1)).

The Secretary of State's grounds for considering that regulation 29 has been contravened are based on the identification of 16 out of 78 patients (20.5%), recruited into trials where Dr Kerrane was the Principal Investigator, who were incorrectly enrolled into a clinical trial for which they were not eligible (see table above). These patients were ineligible for trial participation due to past medical history or due to issues associated with concomitant medication such as taking prohibited medication or not having previously taken required medication. The ineligibility of these patients was confirmed by the MHRA GCP Inspectors, a representative from NHS England North and a representative from the Sponsor.

The Secretary of State considers that Dr Kerrane has also contravened regulation 28(1) of the Regulations which prohibits any person from conducting a clinical trial otherwise than in accordance with the conditions and principles of good clinical practice. The conditions and principles of good clinical practice are set out in Schedule 1 to the Regulations. The recruitment of ineligible patients into the clinical trials referred to above meant that the following conditions and principles were not complied with:

- At Part 2, paragraph 1, that the rights, safety and well-being of the trial subjects shall prevail over the interests of science and society
- At Part 2, paragraph 8, that the investigator and sponsor shall consider all relevant guidance with respect for commencing and conducting a clinical trial
- At Part 2, paragraph 9, that all clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while confidentiality of records of the trial subjects remains protected

- At Part 2, paragraph 11, that the medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist

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

In particular, you must implement effective mechanisms:

- To determine and fully document the patient's eligibility for entry into a clinical trial based on their full past medical history, screening results and in compliance with the inclusion and exclusion criteria defined within the clinical trial protocol.

- To ensure the principles of GCP are complied with, in particular Schedule 1, part 2.

You are also required to take responsibility for the accuracy of information detailed in the patient's medical records and on any other essential GCP documentation to ensure that all clinical information is recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified. In addition, all changes made to any trial documents must be attributable, legible, contemporaneous, original, and accurate.

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).

You are required to put measures in place within 21 days of the date of this letter to ensure that these breaches do not re-occur. You are also required to notify us of your compliance within 28 days of the date of this letter explaining how these measures will be implemented for any future clinical trials in the UK. If you fail to comply further action against you, including criminal prosecution, will be considered.

You should also note that this Notice, plus any responses, will be provided to the European Medicines Agency (for notification to the competent authorities of each EEA State and the European Commission), and the Health Research Authority (for distribution to the relevant ethics committees) and will be published on the MHRA website.

Yours sincerely

[redacted]

Bernadette Sinclair-Jenkins
A person authorised to sign on behalf of The Secretary of State for Health

Email: [redacted]