

European Medicines Agency

EudraCT registration team

12 September 2019

Dear EudraCT registration desk,

Re: Confirmation of a lack of results for a specific trial

The sponsor representative of the below named clinical trial would like to notify to the MHRA and EMA that no results will be uploaded to the EudraCT record for the clinical trial.

The trial is sponsored by The Royal Marsden, with a single centre for participant activity (The Royal Marsden). The trial officially ended on 15 September 2018, representing a premature closure due to repeated failure of FDHT tracer supply by the vendor Alliance and the unacceptable consequences for participants (needless additional appointments and associated anxiety) and clinical staff (having to delay treatment and explaining the reasons for the delay).

The trial was also prematurely closed due to a lack of confidence in the ability of Alliance to supply future specialist tracer or adopt their processes to improve reliable supply of the tracer.

Whilst open to recruitment, only 2 patients were recruited at The Royal Marsden and completed imaging procedures. As such, insufficient data was collected to undertake a statistical analysis.

Clinical trial details as follows:

- EudraCT reference: 2014-005684-32
- Protocol title: (18F) dihydro-testosterone (FDHT) PET imaging in patients with progressive prostate cancer
- Sponsor: The Royal Marsden NHS Foundation Trust
- Chief Investigator: Professor Wim Oyen

We kindly request that the MHRA and EMA make note of this situation.

Yours sincerely,



Sponsor representative

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