

Date: 26th January 2026.
Ref: CORP 25/26 - 231

Dear xxx

Freedom of Information request: Clinical Trial Information for IRAS 320034 (CORP 25/26 – 231)

Thank you for your request for information which the Trust received on 7th January 2026.

Your Request:

According to data obtained from the UK Health Research Authority, your institution has not communicated a clinical trial registry ID number to the Health Research Authority for the following study sponsored by your institution that received REC ethics approval during the year 2023.

IRAS number plus study title:

IRAS 320034 A pilot study investigating environmental contamination when handling Bolus Systemic Anti-Cancer Therapy (SACT): the use of a closed system device versus standard administration

Request for information:

- 1. Please provide the registration number (e.g. ISRCTN, NCT, CTIS) for this study*
- 2. Please state the date on which the first participant was enrolled into this study*
- 3. If the study has not been registered, please briefly explain why it was not registered.*

Background:

According to the global Declaration of Helsinki, every clinical trial has to be registered before enrolment of the first participant. Within the UK, clinical trial registration is mandatory for all clinical trials as per HRA rules. (Additional UK registration requirements apply to a subset of clinical trials known as CTIMPs.)

Please find the Trust's response below:

- 1. Please provide the registration number (e.g. ISRCTN, NCT, CTIS) for this study**

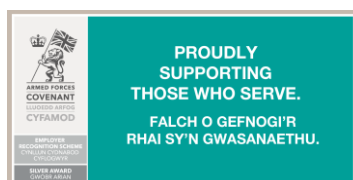
This study was not registered on an external public clinical trial registry.

- 2. Please state the date on which the first participant was enrolled into this study**

No participants were enrolled into this feasibility/pilot study.

The study opened on 05 September 2023 and closed on 30 May 2024 without recruitment.

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Velindre University NHS Trust is happy to receive communication in Welsh or English.



3. If the study has not been registered, please briefly explain why it was not registered.

This was a single-centre feasibility/pilot medical device study, classified as a Clinical investigation or other study of a medical device study.

I trust this answers your request for information, however, should you not be satisfied with the information supplied or the process of supplying it, you have a right to complain and request a review. Please note that you must submit a request for a review within 40 days of the date of this letter.

You should forward your complaint to:

Mr Ian Bevan via FOI.VUNHST@wales.nhs.uk
Head of Information Governance
Velindre University NHS Trust
2, Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff, CF15 7QZ

Should you wish to take your complaint further, if you are still unhappy with the decision after review, you can contact the:

Information Commissioner's Office - Wales
2nd Floor, Churchill House,
Churchill Way,
Cardiff, CF10 2HH
Telephone: 0330 414 6421
email: wales@ico.org.uk

Yours sincerely

Non Gwilym
Interim Director of Corporate Governance
Velindre University NHS Trust
2 Charnwood Court
Heol Billingsley
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Cardiff
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