

Inspection Summary Report

Simbec-Orion, Merthyr Tydfil

Inspection date: 19 October 2023

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This summary document provides an overview of the outcome of the inspection

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Volunteers provided positive feedback about their experiences and rated the service they had received at the clinic as 'very good' or 'good'.

Strict clinical protocols were in place to provide information on what treatment is being tested and the eligibility criteria for volunteers. Each clinical trial is reviewed and approved by relevant governing bodies to ensure they are conducted as safely as possible.

We were assured that there were appropriate governance processes and systems in place at the clinic to help identify risks and improvements to the service. We received positive feedback from staff members who completed a HIW questionnaire.

Note the inspection findings relate to the point in time that the inspection was undertaken.



What we did

Full details on how we inspect the NHS and regulate independent healthcare providers in Wales can be found on our [website](#).

Healthcare Inspectorate Wales (HIW) completed an announced inspection of Simbec-Orion (registered with HIW as Simbec Research), Merthyr Tydfil Industrial Park, Pentrebach, Merthyr Tydfil, CF48 4DR on 19 October 2023. The service undertakes licenced clinical trials of new and existing medication or treatment with patients aged 18 and over.

Our team, for the inspection comprised of one HIW inspector and one clinical peer reviewer. The inspection was led by a HIW inspection manager. This summary version of the report is designed for members of the public.

A full report, which is designed for the setting, and describes all findings relating to the provision of high quality, safe and reliable care that is centred on individual patients can be found on our [website](#).



Quality of Patient Experience



Overall Summary

Appropriate measures were being taken to protect the privacy and dignity of volunteers throughout all stages of the process. We saw evidence that volunteers signed a consent form before participating and receiving treatment. Volunteers received a physical screening examination to ensure they were fit and healthy before being accepted onto a clinical trial. However, the service must improve its recording of the details of such physical screening examinations within the volunteer records. The service must also ensure that volunteers provide their consent before receiving their physical examination.

Where the service could improve

- The service must ensure that volunteers are offered the right to have a chaperone, and that the offer is documented within the volunteer records
- Volunteers should be informed that they can request key documentation, such as the participant information sheet, in Welsh or other languages
- The service must ensure that volunteers and staff are kept informed of feedback to understand actions taken and any lessons learned.

What we found this service did well

- Comprehensive information was being provided to volunteers to ensure they understood the risks and benefits of each clinical trial
- The service had systems in place to obtain the views and feedback of volunteers.

Patients told us:

“An excellent facility with engaging and attentive staff. Professionally run studies where you are kept up to date on all aspects of the study. Good facilities. A real team spirit and fun environment that puts you at ease during overnight stay.”

“Really impressed from the treatment of the staff being very friendly and always making you feel comfortable and confident in their work. I will always highly recommend this place.”

Delivery of Safe and Effective Care



Overall Summary

Suitable processes were in place to help maintain the health and safety of the volunteers and staff at the clinic. The clinical areas and volunteer spaces were well maintained and provided a comfortable experience for volunteers.

Volunteer records documented the screening undertaken on each volunteer to determine their eligibility suitability for each clinical trial. Mental health assessments are undertaken to ensure volunteers have the capacity to understand the risks and benefits of participating in a clinical trial.

Where the service could improve

- A safeguarding policy must be developed to provide guidance to staff on how to identify and raise any safeguarding concerns.

What we found this service did well

- Emergency resuscitation equipment was available throughout the clinic with all items stored appropriately and easily accessible for use in an emergency situation
- The staff we spoke with during the inspection showed a good understanding of their safeguarding responsibilities.

Quality of Management and Leadership



Overall Summary

We saw evidence that staff had completed their mandatory training as required and other training relevant to their roles. We found a positive approach in place to promote the wellbeing of staff, and staff felt they have a good work-life balance.

During the inspection we noted the service did not have some essential policies in place as required by the Independent Health Care (Wales) Regulations 2011. The service must review its library of policies and procedures to ensure it complies with the relevant national minimum standards and regulations.

What we found this service did well

- Staff members told us that the service encourages staff to report errors, near misses or incidents and agreed that staff involved are treated fairly
- Robust arrangements to undertake checks on new employees to ensure they are fit to work at the clinic.

Next steps

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the appendices of the full inspection report.

When we identify concerns that pose an immediate risk to patient safety we ask the service to undertake urgent action. These concerns are outlined in the appendices and outline the action taken by the service to protect patient safety and approved by us. We also provide a detailed table of improvements identified during the inspection where we require the service to tell us about the actions they are taking to address these areas and improve the quality and safety of healthcare services. In addition we outline concerns raised and acknowledge those resolved during the inspection.

At the appropriate time HIW asks the service to confirm action has been taken in line with management responses documented in the improvement plan. We also ask services to provide documented evidence of action taken and/or progress made.

