Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Independent Healthcare Inspection Report (Announced)

Simbec-Orion, Merthyr Tydfil

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Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

We place people at the heart of what we do. We are:

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

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1. 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.

Before the inspection we invited volunteers to complete a HIW questionnaire to tell us about their experience of using the service. We also invited staff to complete a questionnaire to tell us their views on working for the service. A total of 33 questionnaires were completed by volunteers and 31 were completed by staff. Feedback and some of the comments we received appear throughout the report. Where present, quotes in this publication may have been translated from their original language.

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

This (full) report 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 volunteers.

A summary version of the report, which is designed for members of the public can be found on our website.

2. Summary of inspection

Quality of Patient Experience

Overall summary:
Volunteers provided positive feedback about their experiences and rated the service they had received at the clinic as ‘very good’ or ‘good’. 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.

This is what we recommend the service can 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.

This is what the 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.

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.

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.

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.

This is what we recommend the service can improve:

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

This is what the 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 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. 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.

This is what the 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.

3. What we found

Quality of Patient Experience

Patient Feedback

We received positive feedback from the 31 patients (hereafter referred to as volunteers) that completed HIW questionnaires. All volunteers rated the service they had received at the clinic as 'very good' or 'good'.

Some of the comments provided by volunteers on the questionnaires included:

> *"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."*
>
> *"Staff were all very helpful, establishment was clean everywhere I went. Food was good, I felt safe, and checks were regularly carried out."*
>
> *"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."*

Health protection and improvement
We were told that volunteers are provided with health information relevant to the clinical study they are selected for. For example, smoking cessation advice is offered to volunteers participating in clinical trials associated with smoking. Other health protection information was displayed on televisions in the waiting room.

All potential volunteers must undergo physical screening to ensure they are generally fit and healthy before being accepted onto a clinical trial. However, when we reviewed a sample of volunteer records it was not clear what physical examinations had been undertaken on the volunteers by medical staff.

The service must ensure the details of all physical examinations undertaken on volunteers are clearly documented within the volunteer records.

All volunteers who completed a questionnaire told us that they had their medical history checked before taking part in the clinical trial.

Dignity and respect
All but one of the volunteers who completed a questionnaire said that they had been treated with dignity and respect while at the clinic. There were only two volunteers undertaking a clinical trial during the inspection, but we observed staff being kind and respectful.

Three separate consultation rooms were available for staff to speak with volunteers in private. A three-bay examination room was also available for staff to undertake healthcare checks such as weight measurements. The clinic had three eight-bedded wards and two twelve-bedded wards for volunteers to stay when participating in a clinical trial. We saw that the three-bay examination room and beds on all wards had a privacy curtain to preserve the dignity of volunteers. All volunteers who completed a questionnaire confirmed that appropriate measures were taken to protect their privacy while at the clinic. One volunteer provided the following comment:

> *"Privacy is far better with new, thicker curtains."*

We were told that volunteers would sleep in a ward with volunteers of the same sex during each clinical trial. Separate toilets for each gender were also available.

We were told that volunteers could have a chaperone present when being seen by healthcare staff. Information was also displayed in the waiting room to inform volunteers about this. However, there was no evidence within the volunteer records to indicate whether chaperones had been offered to volunteers.

The service must ensure that volunteers are offered the right to have a chaperone, and that the offer is documented within the volunteer records.

Communicating effectively
All volunteers who completed a questionnaire said that staff explained to them what they were doing throughout their stay at the clinic. All volunteers also said that they felt listened to by staff and that all their questions were answered. All staff who completed a questionnaire felt that volunteers are involved in decisions about their care.

We were told that volunteers typically have to be fluent in the English language to participate in clinical trials, to ensure they are able to understand the risks and benefits of the treatment to provide their informed consent. We were told that documents could be translated into Welsh and other languages on request. However, we did not see any information that informed volunteers that they could request documents in other languages.

The service should inform volunteers that key documentation, such as the participant information sheet, can be made available in Welsh or other languages if required.

Patient information and consent
We saw that the statement of purpose and patient information leaflet provided useful information about the clinic, its facilities and staff. Copies of the patient information leaflet were available for volunteers to see on all wards.

Interested volunteers are sent information and then invited to attend the clinic in person to receive a face-to-face consultation and physical screening appointment. During the consultation volunteers are provided with an overview of the clinical trial and are informed about the risks and benefits of the treatment. We saw a copy of the participant information sheet for one of the clinical trials and found it to be comprehensive, and contained all the relevant information volunteers needed to know. All volunteers who completed a questionnaire felt they had received enough information to understand the treatment options and the risks and benefits.

Volunteers are then required to read and sign a form to provide their consent to participate in the clinical trial. All volunteers who completed a questionnaire confirmed that they had signed a consent form before receiving their treatment.

We noted that the participant information sheet informed volunteers that they would receive a full physical examination by one of the study doctors, to confirm that they are in good health before taking part in the clinical trial. However, we noted that consent to receive the full physical examination was not included in the consent form for volunteers to sign.

The service must ensure that volunteers provide their consent before receiving their physical examination and that this is recorded within their volunteer records.

We saw that information was provided to volunteers about aftercare and who to contact should they experience any untoward symptoms after leaving the clinic. The majority of volunteers who completed a questionnaire said they were given adequate aftercare instructions.

Care planning and provision
A clinical protocol is developed for every clinical trial undertaken at the clinic. This provides information on what treatment is being tested and eligibility criteria for volunteers. The protocol is reviewed and must be approved by a Research

Ethics Committee and the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure the clinical trial is safe.

We were told that every volunteer participating in a clinical trial at the clinic is registered on the Over-Volunteering Prevention System (TOPS) database. Every clinic in the UK undertaking Phase I clinical trials has access to this database which ensures that volunteers can be prevented from participating too frequently in trials of new treatments for their own safety.

Equality, diversity and human rights
We saw that the clinic had an equality, diversity and inclusion policy in place and that staff undertake training to ensure they understand their responsibilities.

All but one of the volunteers who completed questionnaires felt they could access the right healthcare at the right time (regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation).

The majority of staff members who completed a questionnaire felt that staff had fair and equal access to workplace opportunities and that the workplace was supportive of equality and diversity.

Citizen engagement and feedback
The service had systems in place to obtain the views and feedback of volunteers. Volunteers are provided with a feedback questionnaire at the end of each clinical trial. We were told that the questionnaires are reviewed by the clinic manager and that key themes are summarised into a monthly report. The report is shared with the senior leadership team to ensure they can monitor the quality of service being provided.

We were provided with copies of completed questionnaires and noted that there was no date on them to indicate when they had been completed. This meant that it may not always be possible for staff to link each questionnaire to the relevant clinical trial. We discussed this with staff who amended the template to include the date of completion going forward.

We were told any negative feedback or issues raised by volunteers on the questionnaires would be followed up and discussed internally to identify any lessons learned. However, any follow up actions or discussions held between staff had not been documented. We spoke with staff who agreed that these should be recorded for audit purposes. We received an update from the service following the inspection which described the steps taken to address this going forward to ensure

that all feedback discussed, and any follow up action taken, would be recorded and shared among the senior leadership team.

Whilst volunteer feedback was encouraged and discussed internally, the setting did not appear to have a process to inform volunteers of the results of this feedback.

The service must implement a process similar to a 'you said, we did' board to inform volunteers of the results of their feedback.

Half of the staff members who completed a questionnaire also told us that they did not receive regular updates on volunteer experience feedback.

The service must ensure that staff are kept informed of volunteer feedback to understand actions taken and any lessons learned.

Delivery of Safe and Effective Care

Managing risk and health and safety
We were assured that suitable processes were in place to manage and review risks to help maintain the health and safety of the volunteers and staff at the clinic. Staff members had their own building passes to access clinical areas of the building which helped to prevent unauthorised access.

The clinical areas and volunteer spaces were well maintained and free from clutter and tripping hazards which provided a comfortable experience for volunteers. One volunteer provided the following comment in the questionnaires:

> *"Plenty of amenities and refurbished rec room, which is a great place to relax and socialise."*

We were told that areas of the building had been refurbished recently. This included new bathrooms and also the provision of new tiltable beds for the volunteers on each ward. The environment was generally in a good state of repair. We saw a couple of areas on Ward 1 and Ward 2 where the roof had been leaking, however we were assured by staff that this was being investigated and scheduled for repair.

The physical screening and consultation areas were located on the ground floor which provided appropriate access for all volunteers. The wards were located upstairs but lifts were available for volunteers with mobility difficulties. The majority of volunteers who completed a questionnaire said that they found the building accessible.

Infection prevention and control (IPC) and decontamination
We found suitable IPC arrangements in place at the clinic to help keep staff and volunteers safe. An up-to-date infection prevention and control policy was available to all staff online. The policy sections included reference to clinical waste, hand hygiene, immunisation and management of blood and bodily fluids.

There was evidence of handwashing audits being undertaken and regular cleaning schedules being maintained. We saw that all staff had completed the relevant IPC training. All volunteers who completed a questionnaire felt the clinic was 'very clean' or 'fairly clean' and most felt infection and prevention control measures were being followed.

We saw that sharps bins were being used appropriately and disposed of safely. Guidance was available for staff outlining their responsibilities to ensure the safe management of sharps and what to do in the event of a sharps injury.

Safeguarding children and safeguarding vulnerable adults
We looked at the safeguarding arrangements in place at the clinic. The clinic co-ordinator was the designated safeguarding lead. We saw that staff had been suitably trained in safeguarding of vulnerable adults. The staff we spoke with during the inspection showed a good understanding of their safeguarding responsibilities and appropriately described how they would raise any safeguarding concerns should they need to.

We were told that mental health assessments are undertaken during the consultation and screening stages to ensure volunteers have the capacity to understand the risks and benefits of participating in a clinical trial.

However, we were told that the service did not have a safeguarding policy in place that captured all the safeguarding procedures and processes currently being followed at the clinic.

The service must develop a safeguarding policy to provide guidance to staff on how to identify and raise any safeguarding concerns, and to outline the current processes in place at the clinic. The policy should also include the relevant contact details for local safeguarding teams.

Medical devices, equipment and diagnostic systems
The service had the relevant equipment and medical devices to meet the needs of the volunteers. Equipment was maintained initially by staff and any faults would be escalated as necessary. We saw evidence that equipment had been recently serviced and calibrated in line with the manufacturer's guidelines.

Safe and clinically effective care
The service has achieved MHRA Phase I accreditation to help ensure clinical trials are conducted as safely as possible. We saw a standard operating procedure in place that defined the processes for the identification and management of risks for undertaking clinical trials. This helped to meet MHRA requirements for ensuring the safety of participating volunteers.

We saw that medication currently being used in a clinical trial was being stored securely and that staff had to sign when removing any medication. Regular stock checks were also being carried out.

A range of standard operating procedures were in place that set out the arrangements to safely store and administer medication at the clinic. The clinical protocols also set out how medication and treatment should be stored and administered for each specific study.

We saw that emergency resuscitation equipment was available throughout the clinic. All items were stored appropriately and easily accessible for use in an emergency situation. Checks were being undertaken on stock levels and to ensure that they remained in date and safe to use.

All staff members who completed a questionnaire felt that care of the volunteers is the organisation's top priority, and that they were content with the efforts of the organisation to keep themselves and volunteers safe.

Participating in quality improvement activities
We were told that the service has recently invested in upgrading its facilities, and we noted that building work was being undertaken at the site during the inspection.

We were also told about an upcoming quality improvement project to purchase and implement eSource at the clinic, which is a clinical management system that will help the service become more efficient at collecting volunteer and clinical trial data and remove duplication.

Records management
During the inspection we looked at a sample of four volunteer records and notes. The information was legible and mainly documented the screening and risk assessments undertaken on each volunteer to determine their eligibility suitability for each clinical trial. We were not permitted by the service to look at the records being maintained during the clinical trial that was being undertaken at the time of the inspection. We were told that records would be updated in line with the clinical protocol as set by the sponsor for each clinical trial.

Volunteer records and notes appeared to be stored in a variety of places, including electronically and on paper. This did not make it easy to navigate and review the records during the inspection. The purchase of the eSource clinical management system may help to resolve this issue once it has been implemented and embedded as standard practice.

Quality of Management and Leadership

Staff Feedback

We received mostly positive feedback from staff members who completed a HIW questionnaire. All staff members were satisfied with the quality of care and support provided to volunteers, and all but one member of staff would recommend the clinic as a place to work.

All staff members felt that they can meet the conflicting demands of their work and most staff felt there are enough staff at the clinic for them to do their job properly.

Governance and accountability framework
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. However, 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.

The majority of staff members who completed a questionnaire told us that senior managers are visible and that communication between senior management and staff is effective. Staff also felt that senior managers were committed to the care of volunteers.

During the inspection there was good presence from the senior leadership team. We saw evidence that the responsible individual had been visiting the setting every six months to produce a written report on the standard of treatment and services being provided at the clinic. This included an overview of recent volunteer feedback and staff feedback from a recent engagement survey. It was positive to see the report included an action plan to demonstrate what actions had been taken in response to potential improvements suggested by staff.

Staff members who completed a questionnaire provided positive feedback about their immediate line managers. The majority of staff felt their manager asks for their opinion before making decisions that affect their work and that their manager could be counted on to help me with a difficult task at work.

Dealing with concerns and managing incidents
Information was available on display in the waiting room to inform volunteers how they could make a complaint or raise a concern should they wish to do so. This information was also included in the participant information sheet. Volunteers were told that they could contact HIW if they were not satisfied with their response from the service.

We saw that a complaints log was being maintained to capture formal and informal complaints. We noted that there were no recent or current complaints.

We found appropriate arrangements in place to deal with any incidents that may occur at the clinic. The registered manager described the processes in place to investigate incidents and identify and share any lessons learned.

All staff members who completed a questionnaire agreed that the service encourages staff to report errors, near misses or incidents and agreed that staff involved are treated fairly. Staff also agreed that the service takes action to ensure that errors, near misses or incidents do not reoccur and said that they receive feedback following such events.

Workforce planning, training and organisational development
Staffing levels were appropriate to maintain volunteer safety within the clinic at the time of our inspection.

Suitable processes were in place for the registered manager to monitor compliance with mandatory training. We saw evidence that staff had completed their mandatory training as required and other training relevant to their roles. The majority of staff members who completed a questionnaire felt that they had received appropriate training to undertake their role.

We were told that all staff receive a mid-year performance review and annual appraisal. We saw evidence that staff had received their annual appraisals in a timely manner.

Workforce recruitment and employment practices
Staff described the checks undertaken on new employees to ensure they are fit to work at the clinic. This included requesting references for their previous five years of employment, checking professional clinical qualifications and carrying out a Disclosure and Baring Service (DBS) check. However, we noted that a recruitment policy setting out these procedures was not in place.

The service must develop a recruitment policy to ensure the safe recruitment of staff in line with the Independent Health Care (Wales) Regulations 2011.

Newly appointed permanent staff receive a period of induction to learn about the clinic, read policies and complete mandatory training.

The majority of staff members who completed a questionnaire felt that the service takes positive action on health and wellbeing and that they can achieve a good work-life balance from their current working pattern.

4. 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 following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns Identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection.			

Appendix B - Immediate improvement plan

Service: Simbec-Orion

Date of inspection: 19 October 2023

The table below includes any immediate non-compliance concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
No immediate non-compliance concerns were identified on this inspection.				

Appendix C - Improvement plan

Service: Simbec-Orion

Date of inspection: 19 October 2023

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
The service must ensure the details of all physical examinations undertaken on volunteers are clearly documented within the volunteer records.	Health Protection and Improvement	Our current method of documenting physical examination is done as per protocol is acceptable from a Good Clinical Practice (GCP)/regulatory perspective. However, to address HIW's improvement request, going forward, the electronic Case Report Form (eCRF) template will be updated to include all body systems for the physical examination for new studies. (The eCRF is where all trial data is collected). Furthermore, for all ongoing studies, the study specific Information sheet and Informed Consent Form has been	Ross Herbert, Clinic Coordinator – for the eCRF update Gabrielle Brill, Regulatory Affairs Specialist, Clinical Pharmacology – for the Study Information Sheet and Consent template update	eCRF Global Library template has been updated on the 20 October 2023. When the eCRF is being updated for ongoing studies, these changes are also made to current studies. (N.B. There will be a period where legacy studies will have the previous method of

		updated to detail the relevant body systems per protocol which may be evaluated under a physical examination. The Information Sheet and Informed Consent Form template will also be updated to list the body systems for the physical examination for new studies.		documenting physical examination.) The study Information Sheet and Informed Consent Form template will be updated and released by 31 March 2024.
The service must ensure that volunteers are offered the right to have a chaperone, and that the offer is documented within the volunteer records.	Dignity and respect	Our current process allows for Chaperones and this is highlighted in posters in Enrolment Services Reception. The study Information Sheet template will be updated to make it clear that chaperones are available at any time during the study. The study Informed Consent form template will be updated to include specific documentation to confirm volunteer's consent/offer around chaperones and that chaperone can be requested at any time during the study.	Gabrielle Brill, Regulatory Affairs Specialist, Clinical Pharmacology – for the Study Information Sheet and Consent template update Deborah Evans, Clinic Manager – for the Additional Chaperone Posters in the Clinic	Information Sheet template update – 31 March 2024 Additional Chaperone Posters in Clinic – 31 March 2024

		We will also put Chaperone posters up throughout the Clinic floor (in addition to Enrolment Services reception).		
The service should inform volunteers that key documentation, such as the participant information sheet, can be made available in Welsh or other languages if required.	Communicating effectively	We have reviewed our approach to Welsh translations and believe we have a pragmatic proportionate approach for the needs of our volunteer population. The geographical location of the Unit, based upon the latest census records, has less than 10% of the local population identify as Welsh speaking (either as a first or second language). In addition, our overall volunteer demographic is not exclusive to individuals living in Wales, we have a recruitment pool which extends into various cross border regions in the UK. For participant care and safety, as per the required principles of our informed consent, it is essential that the clinical trials consent process is conducted in a language which is mutually spoken and understood by	Gabrielle Brill, Regulatory Affairs Specialist, Clinical Pharmacology	The study Information Sheet and Informed Consent Form template will be updated and released by 31 March 2024.

		Investigator and participant alike to ensure full understanding and clarity. Therefore, all processes surrounding this are conducted in the English language only. With respect to our process for facilitation of access to Welsh language documents, we have a standard external translation vendor which if required, would be able to provide the documentation in a certified Welsh translation if a participant were to request this. However, due to practical and logistical considerations we do not translate in advance. Our local Wales Research Ethics Committee are also satisfied with this approach. The general Participant/Patient guide, Chaperone posters, Fire and emergency procedures/posters and various other signs in the Unit are provided in both Welsh and English. We believe that our current process and procedures are sufficiently robust		

		and have further discussed these with the Healthcare Inspector Wales post inspection report. We will implement a further improvement by including specific mention in the study Information sheet and Informed Consent template that we can provide a Welsh translation on request.		
The service must ensure that volunteers provide their consent before receiving their physical examination and that this is recorded within their volunteer records.	Patient information and consent	With respect to the timing of informed consent versus the performance of the physical examinations, the participant Information sheet and Informed Consent form template is clear within Section 5 that informed consent is the first step conducted within a clinical trial. Further to this, the timing of the signature of informed consent is documented with a timestamp on the actual consent form which may be crosschecked against source documentation / eCRF in order to confirm that the physical examination occurred following receipt of informed consent. The completion of informed consent is also documented within the	Gabrielle Brill, Regulatory Affairs Specialist, Clinical Pharmacology	Not applicable – no further action to be taken

		volunteer records for each clinical trial.		
The service must implement a process similar to a 'you said, we did' board to inform volunteers of the results of their feedback.	Citizen engagement and feedback	Volunteer feedback information from last quarter of 2023 is currently available (next to our 'who's who' notice board on the clinic floor). However, we do recognise further improvements could be made to presentation. Further meetings are to be held to decide how this information will be better presented to volunteers going forward, including actions taken.	Deborah Evans, Clinic Manager	30 April 2024
The service must ensure that staff are kept informed of volunteer feedback to understand actions taken and any lessons learned.	Citizen engagement and feedback	Whilst the volunteer feedback information from last quarter of 2023 is currently available and is displayed in the Clinic corridor (next to our 'who's who' notice board on the clinic floor), we acknowledge that further improvements can be made. Since November 2023, a summary of feedback has been shared at our monthly MHRA Phase I Accreditation	Deborah Evans, Clinic Manager	30 April 2024

		committee meetings with the clinic management team. Further meetings will be held to decide further improvements in terms of keeping the wider staff team informed, including actions taken and lessons learned.		
The service must develop a safeguarding policy to provide guidance to staff on how to identify and raise any safeguarding concerns, and to outline the current processes in place at the clinic. The policy should also include the relevant contact details for local safeguarding teams.	Safeguarding children and safeguarding vulnerable adults	Our Participant Safeguarding Policy (POL-00193) was made effective on 26 January 2024 in our electronic Quality Management System (eQMS) and includes contact details for local safeguarding teams. Relevant staff members will be required to read and document training within the system. (Clinical, Medical and Enrolment staff)	Deborah Evans, Clinic Manager	Completed - Effective from 26 January 2024
The service must review its library of policies and procedures to ensure it complies with the relevant national minimum standards and regulations.	Governance and accountability framework	Simbec-Orion SOPs and policies were reviewed against the Independent Healthcare (Wales) 2011 Regulation in 2023. We will perform a further review against the following to further ensure our Quality Management system	Deborah Evans, Clinic Manager Josh Ursell, Head of Enrolment Services	31 May 2024

		complies: The National Minimum Standards for Independent Healthcare Services in Wales.	Annelize Koch, Senior Medical Director Ceri Edwards, Managing Director, Clinical Pharmacology	
The service must develop a recruitment policy to ensure the safe recruitment of staff in line with the Independent Health Care (Wales) Regulations 2011.	Workforce recruitment and employment practices	A Recruitment policy is currently under development to formally document the requirements of the regulations.	Tom Skelton, Head of Talent Acquisition	31 March 2024

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative

Name (print): Ceri Edwards

Job role: Managing Director, Clinical Pharmacology

Date: 08 February 2024