

**Coronavirus (COVID-19) Workplace Risk Assessment form****Workplace location:** Simbec-Orion - Merthyr Tydfil Industrial Park, Cardiff Road, Pentrebach, Merthyr Tydfil, CF48 4DR, Tel 01443 690977**Lead risk assessor(s):**

Annelize Koch, Senior Medical Director (Tel 01443 694313; annelize.koch@simbecorion.com);

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**Other parties involved in original Risk Assessment:**

Anne Hall, H&amp;S Chair (at the time) (anne.hall@simbecorion.com, Tel 01685 700531);

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Jonathan Finn, Facilities Manager (jonathan.finn@simbecorion.com, Tel 01443 694324), New Facilities manager, Karen Driscoll, joined in September 2020

N.B. Workplace risk assessment and associated COVID-19 policies were also sent to Chris Beadle (External H&amp;S Consultant for review)

**Risk assessment sign-off:** Annelize Koch/Ceri Edwards**Date original risk assessment completed:** 16 June 2020**Subsequent Reviews****Version:** 2.0 (15 July 2020)**Version:** 3.0 (10 September 2020)**Version:** 4.0 (09 November 2020)**Version:** 5.0 (18 January 2021)**Version:** 6.0 (16 June 2021)**Version:** 6.1 (23 June 2021)**Version:** 7.0 (21 February 2022) Please note this Risk Assessment version has been consolidated to include the current risk assessment/status only. Please see previous versions for the history of updates made during the course of the pandemic.

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1	Social distancing	The attendance of all site staff at the workplace at pre-coronavirus numbers increases the risk of COVID-19 outbreak onsite.	AS of 28 January 2022, Wales is on Alert Level 0 - please see Welsh government website for full details. At Level 0, Welsh government continues to ask those who can work from home to do so as part of Wales' overall efforts to control the spread of the virus. It is the most effective way to minimise exposure to coronavirus at the workplace. We are therefore asking all our staff who can work from home, to continue to follow this Welsh government guidance. Overarching policy has been implemented - Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT), which outlines policy for the Merthyr facility in line with government requirements.	Heads of Departments are implementing minimal staffing levels on site where possible and all other staff are continuing to work from home. Support is provided by the Senior Leadership Team and HR, as required. Host of the Visitors will be responsible for sharing and implementing this policy with Visitors. Managing Director, in conjunction with onsite management team responsible for making site wide decisions on limiting number of staff of site in the event of changes in case numbers/increasing restrictions.	See previous versions of risk assessments and various policies for version history/effective dates.
2	Social distancing	Staff are not provided with suitable support in the workplace to guide them on effective social distancing as they move around the building.	Floor markings added at the external entrances and throughout the building, as appropriate. Designated wait areas added (e.g. at the start of narrower corridors or on a corner). Mirrors added at various locations around the facility to minimise risk of staff bumping into each other on "blind corners".	Overarching policy - Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT), outlines the policy for the Merthyr facility in line with UK government requirements. The Facilities Manager has ensured hand sanitisers, mirrors, floor markings, signage and wait areas throughout building.	Completed w/c 15 June 2020
3	Social distancing	Workstations are not appropriately socially distanced.	Where possible workstations have been socially distanced or workers are placed side by side rather than face to face. Hot desking areas have been limited to retain some social distancing.	Facilities Manager/Coordinator is responsible for rearrangement of workstations to allow for social distancing, as required. If appropriate social distancing is not possible e.g. in Labs, IMP and Clinical areas - Head of Departments responsible for assessing PPE requirements. Staff are responsible for ensuring they follow the policies. Head of Departments are responsible for monitoring policy adherence. Managing Director is responsible for informing Heads of Departments who have departments still working from home (i.e. office based staff) when office space/hot desks are open for regular use (to be reviewed in conjunction with current government guidance on Working from Home where possible).	Completed w/c 15 June 2020 for relevant staff. Ongoing process for office based (administrative) staff who are currently still working from home as standard, as facilities refurbishment is ongoing.
4	Social distancing	Staff on Reception (Main and Enrolment Services) are not suitably socially distanced from people approaching reception.	Due to the layout and size of the reception desks, in general reasonable social distancing can be maintained. As an additional precaution, screens have been implemented at work stations and reception areas	Facilities manager. Facilities coordinator and Head of Enrolment Services responsible for ensure screens utilised.	July 2020.
5	Social distancing	Chairs in the Enrolment Services Reception waiting room are less than two metres apart, preventing effective social distancing	Chairs have been placed at 2 metre social distancing in the Volunteer Reception Area and all other chairs have been removed. Perspex screens (1.2 m by 2 metre) have been purchased to increase Reception area capacity. Trial Participant Site Arrival Instructions During COVID-19 (CV19-POL001-WI-MT-Participants) have been written. Temperature and any symptoms are checked immediately on arrival and subject will only be allowed to proceed with entry/procedures if acceptable. The Instructions also include details of what will be communicated and checked with the volunteers prior to their arrival.	Facilities Manager is responsible for social distancing of Chairs (and then screen installation when needed). Head of Enrolment is responsible for implementation of Trial Participant Site Arrival Instructions During COVID-19 (CV19-POL001-WI-MT-Participants) policy.	Social distancing of Chairs implemented 09 Jun 2020. Screens installed in Volunteer Reception Area on 01 July 2020 and Reception desk screen on 24 July 2020.
6	Social distancing	Beds for the Trial Participants in Clinical Unit are less than two metres apart, preventing effective social distancing	Volunteer Management & Care Policy During COVID-19 – Merthyr Site (CV19-POL005-MT) is in place which documents various housekeeping procedures including bed use. Perspex screens (2 metre by 2 metre) are in place un between the beds as PPE.	Facilities Manager is responsible for screen installation. Clinic Manager and Supervisor team are responsible for implementation of Volunteer Management & Care Policy During COVID-19 – Merthyr Site (CV19-POL005-MT) policy.	Policy in place w/c 15 Jun 2020. Perspex screens installed for all 5 wards by 24 July 2020.
7	Social distancing	Use of Bathroom/shower facilities by trial volunteers	Volunteer Management & Care Policy During COVID-19 – Merthyr Site (CV19-POL005-MT) is in place which documents various housekeeping procedures such as bathroom rota/use.	Clinic Manager and Supervisor team are responsible for implementation of Volunteer Management & Care Policy During COVID-19 – Merthyr Site (CV19-POL005-MT) policy.	Policy in place w/c 15 Jun 2020.

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8	Social distancing	Use of canteen	The canteen is open with a maximum number of people specified per table, screens and wipes provided for clean down after use. The canteen food is to be pre-ordered to minimise any queues. Facemasks are worn until seated. Where possible and appropriate windows in the canteen can be opened to enable a fresh air flow/circulation. In the event of a significant case rise or variant of concern, the canteen maybe closed and return to takeaway service only (this would be communicated clearly with staff).	Facilities Coordinator responsible for working with Catering staff to ensure signage, policies in place. All staff to follow policies on use of canteen.	From 2021
9	Working patterns	Commuting, particularly if it involves public transport, raises the risk of staff catching and spreading the virus.	For those needing to come into the office/Unit and commute on public transport, the Welsh government made facemasks mandatory on public transport on 27 July 2020 and this remains in place at Level 0. At Level 0, Welsh government continues to ask those who can work from home to do so as part of Wales' overall efforts to control the spread of the virus. We are therefore continuing to ask all our staff who can work from home, to continue to follow this Welsh government guidance - therefore keeping commutes on public transport to a minimum.	All staff responsible for following relevant policies and Welsh government requirements. Head of Departments responsible for supporting their team to work from home where possible.	From w/c 15 Jun 2020.
10	Working patterns	Arrangements whereby staff work in close proximity to multiple colleagues during the working day/shifts raise the risk of the virus spreading.	Due to the nature of the work being performed on site, in general "fixed teams or partnering" (so each worker works with only a few others) is not possible.	Heads of Departments have considered whether their staff can work in "fixed teams or partnering" and this has not been possible, however close proximity working has been kept to a minimum.	From w/c 15 Jun 2020.
11	Hygiene and cleanliness	A lack of hand hygiene among staff raises the risk of virus transmission.	Cleaning facilities and hand sanitisers provided throughout the facility. Particular attention has been given to the clinical / enrolment and laboratory areas where trial volunteers are present and/or equipment is in use. Additional hand sanitisers installed / supplied in communal areas (reception areas/entrances/exits / lift entries / canteen area to further increase ease of use and visibility. Posters are up throughout the Facility to remind of hygiene/handwashing procedures. Training on the Virus and the importance of handwashing has been provided company wide and the training is available "on demand" on Staff Workplace site.	Facilities Manager for the installation of additional hand sanitisers in the workplace, including at entrances, to further complement the existing ones. Research Physician has provided training on importance of effective handwashing.	June 2020.
12	Hygiene and cleanliness	Contaminated surfaces raise the risk of virus transmission.	Enhanced cleaning of the facility has been ongoing during the pandemic. An Enhanced Cleaning Policy During COVID-19 (CV19-POL004-MT) for the Merthyr Site is in place. Staff using technical/clinical equipment are aware of importance of equipment cleaning. Clean wipes for desk surfaces are available to staff to clean down their areas/shared equipment/hot desks.	Facilities Manager/Site Coordinator managing external cleaning provider for cleaning of work areas and equipment, as per enhanced cleaning policy requirements.	w/c 15 Jun 2020
13	Hygiene and cleanliness	Contaminated surfaces raise the risk of virus transmission.	Hot desking areas are required due to the facility layout and need to return to work. However, booking is limited to reduced number of desks to maintain some social distancing. Staff using the newly created areas will be given their own keyboard and mouse, where possible. Cleaning wipes to be placed on each hot desk for clean down after use.	Facilities Coordinator will be responsible for administering the hot desk booking system. Managing Director to advise on hot desk numbers. BSG responsible for providing keyboards and mouse.	From 28 February 2022
14	Hygiene and cleanliness	Contamination through shared buffets or utensils raises the risk of virus transmission.	Staff and visitors are given individual lunchboxes during meetings. The option of communal buffets with shared utensils have been removed.	Facilities Coordinator responsible for working with Catering staff on catering requirements.	From Q4 2021
15	Workers with possible or confirmed coronavirus infection	Workers with coronavirus symptoms may come to work and risk passing the virus on to their colleagues and contaminating the workplace.	Working Safely at Merthyr Site During COVID-19 (CV19-POL001-UK-MT), outlines policy for the Merthyr Facility. The arrival instructions are included in Employee Site Arrival Instructions During COVID-19 – Merthyr Site (CV19-POL001-WI-MT-Employee). Staff Awareness around symptom checking will continue to be raised through Education and Notices, and Reminders. Implemented Site Measures - including Maintained Social Distancing Measures, PPE and Enhanced Cleaning. Staff with any symptoms requested to follow Simbec-Orion staff sickness policy (e.g. contact Line Manager) and contact NHS Wales online (for Test and Trace) and follow self-isolation advice. Clinic General Risk Assessment to Re-Start Clinical Trial Activity (No.2) reviews risk specifically related to re-starting clinical trial activities in the Clinical Pharmacology Unit. Policy for the handling of a suspected COVID-19 case in the clinical pharmacology unit (CV19-POL006-MT) in place, including reference to cleaning procedures in the event of a suspected/confirmed case. A full site attendance log is kept to aid contact tracing in the event of a case.	HR and Managing Director, Clinical Pharmacology have implemented the overarching policy - Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT), outlines the policy for the Merthyr facility in line with UK government requirements. Medical team have implemented Policy for the handling of a suspected COVID-19 case in the clinical pharmacology unit (CV19-POL006-MT).	w/c 15 Jun 2020

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16	Workers with possible or confirmed coronavirus infection	Workers who have someone in their household with coronavirus symptoms or have been in close contact with someone who has been diagnosed with coronavirus may come to work and risk passing the virus on to their colleagues and contaminating the workplace.	Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT) policy implemented, which includes guidance for workers who have been in close contact with someone with suspected/confirmed COVID-19. Working Safely policy requires wearing of face covering in all communal areas of the building. Enhanced cleaning policy in place.	HR and Managing Director, Clinical Pharmacology have implemented the overarching policy - Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT). This outlines the policy for the Merthyr facility in line with UK government requirements, including the policy and responsibilities of Workers if they have been in close contact with someone with suspected/confirmed COVID-19.	w/c 15 June 2020
17	Visitors with possible or confirmed coronavirus infection	Visitors with coronavirus symptoms may come to work and risk passing the virus on to their colleagues and contaminating the workplace.	Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT) policy implemented, which includes guidance for visitors who have been in close contact with someone with suspected/confirmed COVID-19. Working Safely policy requires wearing of face covering in all communal areas of the building. This is further supplemented by Visitor Policy During COVID-19 – Merthyr Site (CV19POL002-MT). Enhanced cleaning policy in place.	HR and Managing Director, Clinical Pharmacology have implemented the overarching policy - Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT). This outlines the policy for the Merthyr facility in line with UK government requirements, including the policy and responsibilities of Visitors. Managing Director, Clinical Pharmacology has implemented Visitor Policy During COVID-19 – Merthyr Site (CV19POL002-MT). Visitor hosts will be responsible for sharing the policy prior to access to site.	w/c 15 June 2020
18	Trial Participants with possible or confirmed coronavirus infection.	Trial Participants with coronavirus symptoms may come to the Site and risk passing the virus on to other trial participants or staff and contaminating the workplace.	Trial Participant Site Arrival Instructions During COVID-19 (CV19-POL001-WI-MT-Participants) which includes the requirement for symptom checking and temperature screening. Individual Risk Management Plan sections/addendums with specific COVID-19 considerations implemented for each clinical trial being conducted in the unit. Policy for the handling of a suspected COVID-19 case in the clinical pharmacology unit (CV19-POL006-MT) in place, including reference to cleaning procedures in the event of a suspected/confirmed case. Risks further mitigated by social distancing, PPE and enhanced cleaning (policies are in place). All trial participants receive LFT at the start of any inpatient stay.	HR and Managing Director, Clinical Pharmacology have implemented the overarching policy - Working Safely at the Merthyr Tydfil Site During COVID-19 (CV19-POL001-UK-MT). Medical team have implemented Policy for the handling of a suspected COVID-19 case in the clinical pharmacology unit (CV19-POL006-MT). Head of Enrolment is responsible for implementation of Trial Participant Site Arrival Instructions During COVID-19 (CV19-POL001-WI-MT-Participants) policy. Clinic Manager and Supervisor team are responsible for implementation of PPE and Volunteer Management & Care Policy During COVID-19 – Merthyr Site (CV19-POL005-MT) policies in the Clinical Unit. Facilities Manager is responsible for implementing the Enhanced Cleaning Policy During COVID-19 – Merthyr Site (CV19POL004-MT).	Policies in place from w/c 15 June 2020 (since restarting trial activities)
19	Vulnerable workers	Workers who are classed as "clinically vulnerable", such as pregnant workers and those aged 70 or over, are at higher risk of severe illness if they contract coronavirus.	Vulnerable workers able to visit site in line with Welsh government guidance. Full support is offered to any vulnerable workers who need to work from home.	Line managers/the HR department to discuss with "clinically vulnerable" workers their circumstances, consulting with them about potential adaptations to their role in advance of their return to work.	Ongoing as needs dictate.
20	Mental health	Workers face an anxious time when they are attending work, whether they fear the risk of infection, are facing difficulties away from work (for example with family illness or bereavement), or fears for the future (for example financial worries).	Simbec-Orion has a mental health support program (including the Calm support and trained Mental Health First Aiders), so that staff have a first point of contact if they need to reach out to someone, or need guidance on where to get further support from within the organisation. Regular webinars and posts on Workplace to support mental health wellbeing.	HR department producing posts on Workplace forum and arranging regular mental health wellbeing seminar/zoom sessions.	Ongoing since before the start of pandemic with increased frequency of guidance/posts/webinars for mental health wellbeing during pandemic.
21	Local ICU support in the event of a medical emergency arising from clinical trial activity	Simbec-Orion has an agreement in place with Cwm Taf University Health Board for Prince Charles Hospital (PCH) for supporting emergencies arising from the clinical trials performed by the unit, as part of MHRA Phase I Accreditation Requirements. The Local ICU at PCH may be busy with COVID-19 patients in the NHS which may impact their ability to cope with an emergency admittance (related to the trial drug) from Simbec-Orion.	We have remained in contact with the Local Health board and representatives from the Intensive Care Unit (ICU), Prince Charles Hospital (PCH) throughout the pandemic and all communication and decisions are documented in the Clinic Restart Risk Assessment.	Senior Medical Director discussed with appropriate Health board representatives .	03 June 2020 and ongoing communication throughout the pandemic.
22	Ability for Simbec-Orion staff to travel with trial participant in the ambulance in the event of an emergency transfer requirement to local ICU	Simbec-Orion has an agreement in place with Welsh Ambulance Services Trust (WAST) for transfer of subjects to the local ICU at PCH. During the COVID-19 pandemic, WAST has advised that it will not be possible for a member of Simbec-Orion team to travel in the ambulance with the trial participant if an emergency transfer is required (which is part of our SOP).	Overarching clinical risk assessment for restarting trials post peak of the COVID-19 pandemic outlines the requirement during this period for the relevant trial paperwork to be sent in the ambulance with the patient and the staff member will follow the ambulance by car and remain at the hospital until the A&E/ICU team member advises they are no longer required. The trial specific COVID-19 RMP addendums/sections also include this requirement.	Overarching Clinical Risk Assessment for Re-Starting trials - Ceri Edwards, Managing Director, Clinical Pharmacology; Annelize Koch, Senior Medical Director and Deborah Evans, Clinic Manager. Study Specific RMP addendums - the individual Project Managers, overseen by Nadine Aawar, Senior Director of Project Management.	15 July 2020 for the Overarching Clinic Re-Start Risk Assessment. Inclusion in RMP addendums for trials in set up stage will be an ongoing process, as needed.

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23	Sample Receipt	Sample received from patients with known or unknown COVID 19 infection	Standard PPE (Lab Coat, Gloves, Lab Specs) and handling processes (wiping vials with spillages, COBAS cleans) are implemented with the risk of specimens containing pathogens. Routine daily cleaning twice a day (end of AM, end of PM) minimum to reduce the risk of contamination between people handling samples in Sample Receipt.	Lab Services, Director	Combination of ongoing standard practice. Additional measures; 15 Jun 2020
24	Sample Receipt	Internal On site Transfer	It is standard practice that all specimens are transported from one lab to another using a secondary container e.g. Sample transport bag.	Lab Services, Director	Ongoing standard practice

Risk Assessment Sign-Off:

DocuSigned by:  
  
 Signer Name: Annelize Koch  
 Signing Reason: I approve this document  
 Signing Time: 23-Feb-2022 | 19:10 GMT  
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Annelize Koch, Senior Medical Director

Risk Assessment Sign-Off:

DocuSigned by:  
  
 Signer Name: Ceri Edwards  
 Signing Reason: I approve this document  
 Signing Time: 23-Feb-2022 | 19:05 GMT  
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Ceri Edwards, Managing Director, Clinical Pharmacology