**The Southampton Clinical Trials Unit will be closed for trial enquiries over the Christmas period as follows:**

**From 5pm, Thursday 21st December 2023   
until 9am, Tuesday 2nd January 2024**

**Individual trial arrangements including Patient Registration and Randomisation listed below.**

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| **Study** | **Closure Information** |
| **ALCOCHANGE** | * **For clinical queries: please contact Dr Gautam Mehta by email: gautam.mehta@ucl.ac.uk** * **Please report SAEs and SUSARs by EMAIL during this period to: ctu@soton.ac.uk** |
| **AURORA** | **Clinical queries -** for **urgent** clinical queries only, please contact Prof Simon Crabb (AURORA Chief Investigator) via [S.J.Crabb@southampton.ac.uk](mailto:S.J.Crabb@southampton.ac.uk)  **SAE Reporting**  Please continue to report SAEs and SUSARs by EMAIL to [ctu@soton.ac.uk](mailto:ctu@soton.ac.uk) during this period.  **Translational Samples**  Do not send any translational samples between 19th December – 2nd January, as our labs will be closed and unable to accept and process your samples.  **IMP Deliveries**  Please note Roche’s offices are closed on Christmas Bank Holidays and there is only a skeleton service on 27th, 28th, & 29th Dec.   |  |  | | --- | --- | | **Order Placed** | **Products Delivered** | | Wednesday 20th December | Friday 22nd December | | Thursday 21st December | Wednesday 27th December | | **Office Closed Monday 25th & Tuesday 26th Dec** | | | Wednesday 27th December | Friday 29th December | | Thursday 28th  December | Tuesday 2nd January | | Friday 29th December (Orders placed before 12 noon) | Wednesday 3rd January | | **Office Closed Monday 1st January** | | | Tuesday 2nd January | Thursday 4th January | | **Normal opening hours apply thereafter.** | | |
| **BL13** | All BL13 patients have now completed treatment and are in standard of care follow-up. Any clinical decisions should be made at the site level during this closure period.  For urgent queries ONLY, please email Simon Crabb, CI, on S.J.Crabb@southampton.ac.uk . The trial team will deal with all emails promptly on our return. |
| **BRITISH** | **Patient enrolment is open as usual during this time.**  **For clinical queries and urgent eligibility queries**: please contact the Chief Investigator Dr Andrew Flett. In the first instance, please call mobile number: **07717 715757*.*** If unable to reach by mobile, or if an email follow up is needed, please use: [andrew.flett@uhs.nhs.uk](mailto:andrew.flett@uhs.nhs.uk).  **SAE Reporting - Please continue to report SAEs by EMAIL during this period to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) |
| **CADET** | * **Please continue to report SAEs by EMAIL during this period to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) * **For urgent clinical queries:** please contact Chief Investigator Dr Cathy Murphy **c.murphy@soton.ac.uk** * **For all other queries** please email [cadet@soton.ac.uk](mailto:cadet@soton.ac.uk) and they will be dealt with on our return. |
| **COAT** | * **For all urgent queries during the Christmas closure period:** please email the SCTU: [ctu@soton.ac.uk](mailto:ctu@soton.ac.uk) * **For all routine queries:** please email [coat@soton.ac.uk](mailto:coat@soton.ac.uk) * **Please do not recruit anyone between the 20th December 2023 – 1st January 2024.** |
| **CONTRACT 2** | **For URGENT clinical queries ONLY** please send an email to Harriet Corbett (Harriet.Corbett@alderhey.nhs.uk)  For issues with iMedidata please contact the helpdesk on;  [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com) or by telephone on 0800 001 5212  **SAE Reporting**  Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Christmas break. |
| **CRAIN** | **Dose Slot Allocation**  If there is a potential patient and a dose slot needs to be held or confirmed during this closure period then please email [crain@soton.ac.uk](mailto:crain@soton.ac.uk) **and** [ctu@soton.ac.uk](mailto:ctu@soton.ac.uk) as per the dose slot allocation instructions. The CTU mailbox will be being monitored during the closure period and the CRAIN team will be informed of any emails requiring our attention. As per the standard allocation instructions please allow up to one working day for confirmation.  **SAE Reporting**  Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements.  **Sample Shipment**  **UoM MCRC** will be closed from 20th December 2023 to 2nd January 2024 (inclusive). You can resume sending samples as usual from Wednesday 3rd January 2024. If any EDTA or urine samples are scheduled to be taken and shipped during this closure period then please contact SCTU in advance to discuss arrangements.  **CRUK Manchester Institute** will be closed from 12:00 21st December 2023 to 1st January 2024 (inclusive). You can resume sending samples as usual from Tuesday 2nd January 2024. If any cfDNA samples are scheduled to be taken and shipped during this closure period then please contact SCTU in advance to discuss arrangements.  For **urgent queries on CRAIN only**, please contact:  Professor Peter Hoskin  Mobile: 02038262136  Email: [peterhoskin@nhs.net](mailto:peterhoskin@nhs.net) |
| **ELECTRA** | For **URGENT QUERIES ONLY,** please contact the chief investigator Prof Alex Mirnezami at [Alex.Mirnezami@uhs.nhs.uk](mailto:Alex.Mirnezami@uhs.nhs.uk) or [A.H.Mirnezami@soton.ac.uk](mailto:A.H.Mirnezami@soton.ac.uk)  **SAE Reporting**  **Please continue to report SAEs and SUSARs by EMAIL during this period to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) |
| **ELEVATE** | **SAE Reporting**  • Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements.  **CMDL** will be closed between 5pm on Friday, 22nd December 2023 and 9am on Tuesday, 2nd January 2024 and are not able to receive samples during this time. You can resume sending samples as usual from Tuesday, 2nd January 2024.  **For URGENT CLINICAL QUERIES ONLY on ELEVATE, please contact:**  Dr Elizabeth Smyth  Email: elizabeth.smyth2@nhs.net |
| **iDx Lung** | **For URGENT clinical queries ONLY** please send an email to Peter Johnson [johnsonp@soton.ac.uk](mailto:johnsonp@soton.ac.uk) (Chief Investigator)  **For all other queries** please email [idxlung@soton.ac.uk](mailto:idxlung@soton.ac.uk) and they will be dealt with on our return. |
| **IELSG 37 and IELSG 42** | For urgent emails to IESLG, please use their shared inbox - [ielsg@ior.usi.ch](mailto:ielsg@ior.usi.ch).  Please contact IELSG Switzerland for queries regarding IELSG 19, 26 or 32. |
| **MecROX** | **For URGENT clinical queries ONLY** please send an email to Ahilanandan Dushianthan [A.Dushianthan@soton.ac.uk](mailto:A.Dushianthan@soton.ac.uk) (Chief Investigator)  **For all other queries** please email [mecrox@soton.ac.uk](mailto:mecrox@soton.ac.uk) and they will be dealt with on our return. |
| **NERO** | **For clinical queries, urgent eligibility queries** **and medical emergencies**: please contact the chief investigator Prof Dean Fennell. In the first instance, please call Prof Fennell’s mobile **07870370708**.  If unable to reach by mobile, or if an email follow up is needed, please use: [dean.fennell@nhs.net](mailto:dean.fennell@nhs.net) / [df132@leicester.ac.uk](mailto:df132@leicester.ac.uk)  **SAE Reporting - Please continue to report SAEs and SUSARs by EMAIL during this period to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) |
| **OptiMATe** | Recruitment is open as usual during this time.   * For **urgent Medical or Eligibility queries only**, please contact the on-call Investigator as below:  |  |  |  | | --- | --- | --- | | **Date** | **Contact Name** | **Contact Number** | | 22-Dec-2023 | Prof Chris Fox | Nottingham Hospital Switchboard (please ask to be connected to Prof Chris Fox):  0115 969 1169 | | 23-Dec-2023 | Prof Chris Fox | | 24-Dec-2023 | Prof Chris Fox | | 25-Dec-2023 | Prof Chris Fox | | 26-Dec-2023 | Prof Chris Fox | | 27-Dec-2023 | Prof Chris Fox | | 28-Dec-2023 | Prof Chris Fox | | 29-Dec-2023 | Dr Jeff Smith | Clatterbridge Hospital Switchboard (please ask to be connected to Dr Jeff Smith):  0151 556 5000 | | 30-Dec-2023 | Dr Jeff Smith | | 31-Dec-2023 | Dr Jeff Smith | | 01-Jan-2024 | Dr Jeff Smith |  * Please continue to report SAEs and SUSARs by email over this period to [zks.pv@list.uniklinik-freiburg.de](mailto:zks.pv@list.uniklinik-freiburg.de) * There will be no back-up randomization service on Monday 25th or Tuesday 26th December due to German National Holidays. * HMDS will have minimal cover in place over the Christmas period.   + There may be delays to post sent via Royal Mail. If possible, please do not send any samples between 21st and 27th December 2023. |
| **Pola-R-ICE** | * Patient enrolment is open as usual during this time. * **Clinical and Eligibility queries,** study sponsor, GWT- note: minimal cover 25-29 Dec. e-mail: [polarice@g-wt.de](mailto:polarice@g-wt.de) Tel: 49 (0) 351 25933 171 (Dr Anna Polowinski). * **Urgent medical emergencies,** UK Chief Investigator, Prof. Andy Davies. e-mail: [a.davies@soton.ac.uk](mailto:a.davies@soton.ac.uk). Tel: direct line 023 8120 8639 or mobile 07976 815095. * **Data Management,** ZKS Leipzig**:** e-mail [dm\_polarice@zks.uni-leipzig.de](mailto:dm_polarice@zks.uni-leipzig.de). * **Central Laboratory,** HMDSwill be closed on Monday 25th and Tuesday 26th December for the Christmas bank holidays. Please be aware of potential postal delays due to the Christmas period. If an urgent sample needs to be processed please arrange this with HMDS in advance. e-mail: [leedsth-tr.pola-r-ice@nhs.net](mailto:leedsth-tr.pola-r-ice@nhs.net) * **SAE reporting,** ZKS Leipzig**:** please continue to report SAEs and SUSARs by email to [pharmacovigilance@zks.uni-leipzig.de](mailto:pharcovigilance@zks.uni-leipzig.de) * **IMP,** Rocheno IMP orders will be processed between 25-Dec 23-1 Jan 2024. |
| **P+R-ICE** | * Patient enrolment is open as usual during this time. * **For clinical queries**: please contact Prof. Andy Davies (direct line 023 8120 8639), email: [a.davies@soton.ac.uk](mailto:a.davies@soton.ac.uk) or call Southampton General Hospital Switchboard on 023 8077 7222 and ask for extension 8639. * **For urgent eligibility queries** **and medical emergencies**: please ring Prof. Andy Davies (07976 815095). * **For SAE reporting:** please continue to report SAEs and SUSARs by email to [ctu@soton.ac.uk](mailto:ctu@soton.ac.uk).   **HMDS**  The HMDS laboratory will be closed on Monday 25th and Tuesday 26th December. Due to potential postal delays during the Christmas period, please avoid sending blood samples between **21st – 27th December** if possible. The SCTU must be notified in advance of any ctDNA or tumour samples due to arrive at HMDS between this timeperiod.  **WISH**  WISH laboratory will be closed from Friday 22nd December and will reopen Tuesday 2nd January 2024. The last day for sending samples will be **Wednesday 20th December**. If there are exceptional circumstances, then the team may be able to accommodate samples coming into the lab after this date. The SCTU must be notified in advance of any Flow samples due to arrive at WISH between 22nd December and the 2nd January 2024. |
| **REMoDL-A** | * Patient enrolment is open as usual during this time. * **For clinical queries**: please contact Prof. Andy Davies (direct line 023 8120 8639), email: [a.davies@soton.ac.uk](mailto:a.davies@soton.ac.uk) or call Southampton General Hospital Switchboard on 023 8077 7222 and ask for extension 8639. * **For urgent eligibility queries** **and medical emergencies**: please ring Prof. Andy Davies (07976815095). * **For SAE reporting:** please continue to report SAEs and SUSARs by email to [ctu@soton.ac.uk](mailto:ctu@soton.ac.uk).   HMDS  HMDS will be closed on Monday 25th and Tuesday 26th December.  **Blood samples**: please avoid sending blood samples between 21st – 27th Dec if possible. In the case that samples need to be sent during this time, there will be staff at the lab 27th – 29th Dec to process them. Please bear in mind that there may be postal delays during this time period.  **Tumour blocks**: blocks may be sent anytime throughout the Christmas and New Year period. Due to the timing and availability of the GEP analysis runs, any patients registered with a cycle 2 date due 21st Dec – 5th Jan will need their block to arrive at the HMDS lab by 17th Dec at the latest.  Please be aware of these dates and if you have any questions, please email HMDS directly - [leedsth-tr.remodl-a@nhs.net](mailto:leedsth-tr.remodl-a@nhs.net).  ALMAC  The ALMAC closures over the Christmas and New Year period are listed below. |
| **UNIVERSAL** | * **Please continue to report SAEs by EMAIL during this period to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) * **For urgent clinical queries:** please contact Professor Tom Wilkinson at [t.wilkinson@soton.ac.uk](mailto:t.wilkinson@soton.ac.uk) (Chief Investigator) * **For all other queries** please email [universal@soton.ac.uk](mailto:universal@soton.ac.uk) and they will be dealt with on our return. |

All of the staff at SCTU would like to thank everyone for their kind assistance and hard work and we wish you all a relaxing Christmas break.



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