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

**From 5pm, Thursday 22nd December 2022  
until 9am, Tuesday 3rd January 2023**

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

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| **Study** | **Closure Information** |
| **AGILE CST-5** | • **For clinical queries:** please contact Dr Richard FitzGerald by email:  Richard.Fitzgerald@liverpoolft.nhs.uk  **SAE Reporting**  • **Please continue to report SAEs and SUSARs on the RAVE system, or if**  **unable to access, by EMAIL to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) **during this period.** |
| **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 20th December to 2nd January, as our labs will be closed and unable to accept and process your samples |
| **BL13** | **For URGENT clinical queries ONLY** please send an email to the following email address:  S.J.Crabb@southampton.ac.uk (Chief Investigator)  **Please continue to report SAEs or SUSARs in the RAVE database** by completing the eCRF**.** If for any reason you are unable to access the database during this period, please report using either the Canadian Cancer Trials Group FAX No: 1-613-533-2941 or SCTU EMAIL:  [ctu@soton.ac.uk](mailto:ctu@soton.ac.uk).  **Southampton** **Tissue Bank**  Do not send any translational samples between 20th December to 2nd January, as our labs will be closed and unable to accept and process your samples. |
| **CONTRACT 2** | The SCTU will be **closed** between **5pm, Thursday 22nd December 2022 until 9am, Tuesday 3rd 2023**  **For URGENT clinical queries ONLY** please send an email to Nigel Hall [n.j.hall@soton.ac.uk](mailto:n.j.hall@soton.ac.uk)  (Chief Investigator)  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** | **SAE Reporting**   * Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements.   **Sample Shipment**  **UoM MCRC** will be closed **23rd December 2022 to 2nd January 2023 (inclusive) and are not able to receive samples during this time.** You can resume sending samples as usual from **Tuesday, 3rd January 2023**.  For **urgent queries on CRAIN only**, please contact:  Professor Peter Hoskin  Mobile: 02038262445  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 23rd December and 9am on Tuesday 3rd January 2023 and are not able to receive samples during this time.** You can resume sending samples as usual from Tuesday, 3rd January 2023.  Please note that the latest date the samples can be received before Christmas is Friday, 23rd December 2022.  For **urgent queries on ELEVATE only**, please contact:  Dr Elizabeth Smyth  Mobile: 07463717859 Email: [Elizabeth.Smyth@addenbrookes.nhs.uk](mailto:Elizabeth.Smyth@addenbrookes.nhs.uk) |
| **HARE-40** | * For **urgent eligibility or clinical queries** please contact the Chief Investigator, Prof Christian Ottensmeier on **07879 485 676** * **SAE/SUSAR REPORTING** Please e-mail or fax a copy of the SAE form within 24 hours of becoming aware of the event. Fax: : +49 (0) 231 700 118 68 or Email: [pv-biontech@pharmsoft.de](mailto:pv-biontech@pharmsoft.de)   **WISH lab** is closed for the HARE-40 trial during Christmas closure period.  Advance notice of any samples over this period should be sent to Katy McCann [K.J.McCann@soton.ac.uk](mailto:K.J.McCann@soton.ac.uk) and James Pickering  [james.pickering@soton.ac.uk](mailto:james.pickering@soton.ac.uk).  **GCP Lab** is closed for the HARE-40 trial during Christmas closure period.  Advance notice of any samples over this period should be sent to:  GCPLab Liverpool [gcplabs@liverpool.ac.uk](mailto:gcplabs@liverpool.ac.uk) |
| **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) |
| **IELSG 37** | For urgent emails to IESLG, please use their shared inbox - [ielsg@eoc.ch](mailto:ielsg@eoc.ch).   * **For URGENT queries for IELSG 37 only**, please contact:   Dr Andrew Davies  Email:[**a.davies@soton.ac.uk**](mailto:a.davies@soton.ac.uk)  Mobile: **07976815095** |
| **IELSG 42** | For urgent emails to IESLG over the Easter period, please use their shared inbox - [ielsg@eoc.ch](mailto:ielsg@eoc.ch).   * **For URGENT queries for IELSG 32/42 only** please contact:   Dr Kate Cwynarski  Email:[**kate.cwynarski@nhs.net**](mailto:kate.cwynarski@nhs.net)  Mobile: **07870638852**  Please contact IELSG Switzerland for queries regarding IELSG 19, 26 or 32. |
| **MANCAN2** | * **For urgent clinical queries** please contact Chief Investigator, Dr Simon Crabb: [s.j.crabb@soton.ac.uk](mailto:s.j.crabb@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) |
| **MaPLE** | The Southampton Clinical Trials Unit will be closed for trial enquiries over the Christmas period from 5pm on Thursday 22nd December 2022 until 9am,  Tuesday 3rd January 2023.  **SAE Reporting**   * Please continue to report SAEs and SUSARs by EMAIL during this period to **ctu@soton.ac.uk** * For urgent MaPLe queries, please contact: Professor Peter Johnson –[johnsonp@soton.ac.uk](mailto:johnsonp@soton.ac.uk,%20otherwise), otherwise we will respond to your email on our return. |
| **NERO** | * Patient enrolment is open as usual during this time. * **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@le.ac.uk](mailto:df132@le.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** | **Primary Contact** | **Secondary Contact** | | 23-Dec-2022 | Dr Kate Cwynarski | Dr Jeff Smith | | 24-Dec-2022 | Dr Jeff Smith | N/A | | 25-Dec-2022 | Dr Jeff Smith | N/A | | 26-Dec-2022 | Prof Chris Fox | N/A | | 27-Dec-2022 | Dr Jeff Smith | N/A | | 28-Dec-2022 | Dr Jeff Smith | N/A | | 29-Dec-2022 | Prof Chris Fox | Dr Kate Cwynarski | | 30-Dec-2022 | Prof Chris Fox | Dr Kate Cwynarski | | 31-Dec-2022 | Prof Chris Fox | N/A | | 01-Jan-2022 | Prof Chris Fox | N/A | | 02-Jan-2022 | Prof Chris Fox | N/A |  * Prof Chris Fox - Nottingham Hospital Switchboard (please ask to be connected to Prof Chris Fox): 0115 969 1169 * Dr Kate Cwynarski - 07870 638852 * Dr Jeff Smith - 07901 321079 * 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) * HMDS will be closed from 26-DEC-2022 to 27-DEC-2022, and again on 02-JAN-2022.   + Please do not send any samples via Royal Mail after 15-DEC-2022.   + Samples due between 15th and 23rd December may be sent via courier. This must be arranged by the site for the sample to be delivered directly to the department. HMDS are unable to reimburse for the use of a courier.   + Samples may be sent per usual arrangements from 28-DEC-2022 onwards. * MRI Imaging - Please do not send CDs containing Images to SCTU via the post between 19-DEC-2022 and 02-JAN-2023. | |
| **Pola-R-ICE** | * Patient enrolment is open as usual during this time. * **For clinical queries,**: please contact the study sponsor GWT. The sponsor office will be closed from 23 Dec 2022 to 2 Jan 2023   e-mail: [polarice@g-wt.de](mailto:polarice@g-wt.de)  Tel: 49 (0) 351 25933 171 (Dr Anna Polowinski).   * **For urgent eligibility queries** **and medical emergencies:** please contact the 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). The office will be closed from 23 Dec 2022 to 2 Jan 2023. * **Laboratory, HMDS** will be closed on Monday 26th December, Tuesday 27th December and Monday 2nd January. In addition, if an urgent sample needs to be processed between the 28th and 30th of December 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:** please continue to report SAEs and SUSARs by email to [pharmacovigilance@zks.uni-leipzig.de](mailto:pharcovigilance@zks.uni-leipzig.de)   **IMP from Roche** no IMP orders will be processed between 16 Dec 2022 and 2 Jan 2023 |
| **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 (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 **26th - 27th December and 2nd January**. HMDS have asked for sites not to send any samples after Thursday 15th December via Royal Mail. For samples due between 15th and 23rd December, please consider a courier (HMDS nor SCTU will be unable to reimburse for this). Samples may be sent Wednesday 28th December and Thursday 29th December as per usual arrangements.  The SCTU must be notified in advance of any ctDNA samples due to arrive at HMDS between **28th – 30th December.**  **WISH**  The WISH Laboratory will be closed from **5pm on Thursday 22nd December 2022 – Monday 2nd January inclusive**. Sites are asked not to send samples after **20th December** and to resume shipping on 3rd January.  The SCTU must be notified in advance of any Flow samples due to arrive at WISH between 20th December and the 3rd January. |
| **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).   ALMAC  ALMAC will be closed **26th ‐ 27th December, and 2nd January**. The last date for shipping acalabrutinib will be **22nd December**. Therefore, **any**  **drug orders will need to be placed by 15th December** to ensure delivery.  HMDS  HMDS will be closed on  **26th - 27th December and 2nd January**.  Please ensure that any blocks due for genetic profiling between 22nd Dec – 6th Jan reach the lab by **16th December.**  The SCTU must be notified in advance of any ctDNA samples due to arrive at HMDS between 28th – 30th December. |
| **ReMODL-B** | The Southampton Clinical Trials Unit will be closed for trial enquiries over the Christmas period from 5pm on Thursday 22nd December 2022 until 9am,  Tuesday 3rd January 2023. |

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| **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 staff of the SCTU would like to thank everyone   
for their kind assistance and hard work.