

Southampton CTU Easter Closure Notice 2023

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

From 5pm, Wednesday 5th April 2023
until 9am, Wednesday 12th April 2023

Individual trial arrangements including Patient Registration and Randomisation listed below.

| Study | Closure Information |
|-------------|---|
| AGILE CST-8 | <ul style="list-style-type: none"> • For clinical queries: please contact Professor Saye Khoo by email at: khoo@liv.ac.uk <p>SAE Reporting</p> <ul style="list-style-type: none"> • Please continue to report SAEs and SUSARs on the RAVE system, or if unable to access, by EMAIL to ctu@soton.ac.uk during this period. |
| ALCOCHANGE | <ul style="list-style-type: none"> • 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 | <p>Clinical queries - for urgent clinical queries only, please contact Prof Simon Crabb (AURORA Chief Investigator) via S.J.Crabb@southampton.ac.uk</p> <p>SAE Reporting</p> <p>Please continue to report SAEs and SUSARs by EMAIL to ctu@soton.ac.uk during this period.</p> <p>Translational Samples</p> <p>Do not send any translational samples between 5th April - 11th April, as our labs will be closed and unable to accept and process your samples (unless arrangements have been made)</p> |

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| <p>BL13</p> | <p>For URGENT clinical queries ONLY please send an email to <u>the following email address</u>: S.J.Crabb@southampton.ac.uk (Chief Investigator)</p> <p>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.</p> <p>Southampton Tissue Bank Do not send any translational samples between 4th to 12th April, as our labs will be closed and unable to accept and process your samples.</p> |
| <p>CADET</p> | <ul style="list-style-type: none"> • Please continue to report SAEs by EMAIL during this period to 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 and they will be dealt with on our return. |
| <p>CONTRACT 2</p> | <p>For URGENT clinical queries ONLY please send an email to Nigel Hall n.j.hall@soton.ac.uk (Chief Investigator)</p> <p>For issues with iMedidata please contact the helpdesk on; helpdesk@mdsol.com or by telephone on 0800 001 5212</p> <p>SAE Reporting</p> <p>Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Christmas break.</p> |
| <p>CRAIN</p> | <p>SAE Reporting</p> <ul style="list-style-type: none"> • Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements. <p>Sample Shipment UoM MCRC will be closed 7th April 2023 to 10th April 2023 (inclusive) and are not able to receive samples during this time. You can resume sending samples as usual from Tuesday, 11th April 2023.</p> <p>For urgent queries on CRAIN only, please contact: Professor Peter Hoskin Mobile: 02038262445</p> |

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| | <p>Email: peterhoskin@nhs.net</p> |
| <p>ELECTRA</p> | <p>For URGENT QUERIES ONLY, please contact the chief investigator Prof Alex Mirnezami at Alex.Mirnezami@uhs.nhs.uk or A.H.Mirnezami@soton.ac.uk</p> <p>SAE Reporting Please continue to report SAEs and SUSARs by EMAIL during this period to ctu@soton.ac.uk</p> |
| <p>ELEVATE</p> | <p>SAE Reporting</p> <ul style="list-style-type: none"> Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements. <p>CMDL will be closed between 5pm on Thurs 6th April and 9am on Tuesday 11th April 2023 and are not able to receive samples during this time. You can resume sending samples as usual from Tuesday, 11th April 2023.</p> <p>For urgent queries on ELEVATE only, please contact:</p> <p>Dr Elizabeth Smyth Mobile: 07463717859 Email: Elizabeth.Smyth@addenbrookes.nhs.uk</p> |
| <p>HARE-40</p> | <ul style="list-style-type: none"> For urgent eligibility or clinical queries please contact the Chief Investigator, Prof Christian Ottensmeier on 07879 485 676 SAE/SUSAR REPORTING Please e-mail a copy of the SAE form within 24 hours of becoming aware of the event to BioNTech: Email: SAEalerts@biontech.de <p>WISH lab is closed for the HARE-40 trial during Easter closure period 6th-11th April 2023.</p> <p>Advance notice of any samples over this period should be sent to Katy McCann K.J.McCann@soton.ac.uk and James Pickering james.pickering@soton.ac.uk.</p> <p>GCP Lab is closed for the HARE-40 trial during 7th -10th April 2023 - Easter closure period.</p> |

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| | <p>Advance notice of any samples over this period should be sent to:</p> <p>GCPLab Liverpool gcplabs@liverpool.ac.uk</p> |
| iDx Lung | <p>For URGENT clinical queries ONLY please send an email to Peter Johnson johnsonp@soton.ac.uk (Chief Investigator)</p> |
| IELSG 37 | <p>For urgent emails to IESLG, please use their shared inbox - ielsg@ior.usi.ch.</p> <ul style="list-style-type: none"> • For URGENT queries for IELSG 37 only, please contact: Dr Andrew Davies <p>Email: a.davies@soton.ac.uk Mobile: 07976815095</p> |
| IELSG 42 | <p>For urgent emails to IESLG over the Easter period, please use their shared inbox - ielsg@ior.usi.ch.</p> <ul style="list-style-type: none"> • For URGENT queries for IELSG 32/42 only please contact: Dr Kate Cwynarski <p>Email: kate.cwynarski@nhs.net Mobile: 07870638852</p> <p>Please contact IESLG Switzerland for queries regarding IELSG 19, 26 or 32.</p> |
| MANCAN2 | <ul style="list-style-type: none"> • For urgent clinical queries please contact Chief Investigator, Dr Simon Crabb: s.j.crabb@soton.ac.uk <p>SAE Reporting</p> <ul style="list-style-type: none"> • Please continue to report SAEs and SUSARs by EMAIL during this period to ctu@soton.ac.uk |
| MaPLE | <p>SAE Reporting</p> <ul style="list-style-type: none"> • 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, otherwise we will respond to your email on our return. |
| NERO | <p>Patient enrolment is open as usual during this time.</p> |

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| | <p>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 / df132@le.ac.uk</p> <p>**Please note on 10 – 11th April, Prof Fennell will be unavailable. In his absence, for clinical queries, please contact Dr Sean Dullo on his mobile 07950465731 or via email sean.dullo@uhl-tr.nhs.uk</p> <p>SAE Reporting - Please continue to report SAEs and SUSARs by EMAIL during this period to ctu@soton.ac.uk</p> | | | | | | | | | | | | | | | | | | | | | |
|--------------------------|--|--------------------------|------------------------|--------------------------|-------------|------------------|-----|-------------|-------------------|-----|-------------|-------------------|-----|-------------|------------------|-----|-------------|----------------|------------------|-------------|----------------|------------------|
| <p>OptiMATE</p> | <p style="text-align: center;"><u>Recruitment is open as usual during this time.</u></p> <ul style="list-style-type: none"> For urgent Medical or Eligibility queries only, please contact the on-call Investigator as below: <table border="1" data-bbox="424 1003 1369 1261"> <thead> <tr> <th><u>Date</u></th> <th><u>Primary Contact</u></th> <th><u>Secondary Contact</u></th> </tr> </thead> <tbody> <tr> <td>06-Apr-2023</td> <td>Prof Andy Davies</td> <td>N/A</td> </tr> <tr> <td>07-Apr-2023</td> <td>Dr Kate Cwynarski</td> <td>N/A</td> </tr> <tr> <td>08-Apr-2023</td> <td>Dr Kate Cwynarski</td> <td>N/A</td> </tr> <tr> <td>09-Apr-2023</td> <td>Prof Andy Davies</td> <td>N/A</td> </tr> <tr> <td>10-Apr-2023</td> <td>Prof Chris Fox</td> <td>Dr Beth Phillips</td> </tr> <tr> <td>11-Apr-2023</td> <td>Prof Chris Fox</td> <td>Dr Beth Phillips</td> </tr> </tbody> </table> <ul style="list-style-type: none"> Prof Chris Fox - Nottingham Hospital Switchboard (please ask to be connected to Prof Chris Fox): 0115 969 1169 Dr Kate Cwynarski: 07870 638852 Prof Andy Davies: 023 8120 8639, or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639. Dr Beth Phillips: 07776 071715 Please continue to report SAEs and SUSARs by email over this period to zks.pv@list.uniklinik-freiburg.de HMDS will be closed on Friday 7th April and Monday 10th April for the Easter Bank Holidays. <ul style="list-style-type: none"> The last day for sending samples will be Wednesday 5th April. | <u>Date</u> | <u>Primary Contact</u> | <u>Secondary Contact</u> | 06-Apr-2023 | Prof Andy Davies | N/A | 07-Apr-2023 | Dr Kate Cwynarski | N/A | 08-Apr-2023 | Dr Kate Cwynarski | N/A | 09-Apr-2023 | Prof Andy Davies | N/A | 10-Apr-2023 | Prof Chris Fox | Dr Beth Phillips | 11-Apr-2023 | Prof Chris Fox | Dr Beth Phillips |
| <u>Date</u> | <u>Primary Contact</u> | <u>Secondary Contact</u> | | | | | | | | | | | | | | | | | | | | |
| 06-Apr-2023 | Prof Andy Davies | N/A | | | | | | | | | | | | | | | | | | | | |
| 07-Apr-2023 | Dr Kate Cwynarski | N/A | | | | | | | | | | | | | | | | | | | | |
| 08-Apr-2023 | Dr Kate Cwynarski | N/A | | | | | | | | | | | | | | | | | | | | |
| 09-Apr-2023 | Prof Andy Davies | N/A | | | | | | | | | | | | | | | | | | | | |
| 10-Apr-2023 | Prof Chris Fox | Dr Beth Phillips | | | | | | | | | | | | | | | | | | | | |
| 11-Apr-2023 | Prof Chris Fox | Dr Beth Phillips | | | | | | | | | | | | | | | | | | | | |
| <p>Pola-R-ICE</p> | <ul style="list-style-type: none"> Patient enrolment is open as usual during this time. For clinical queries please contact the study sponsor GWT. e-mail: 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. Tel: direct line 023 8120 8639 or mobile 07976 815095. | | | | | | | | | | | | | | | | | | | | | |

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| | <ul style="list-style-type: none"> • Data Management, ZKS Leipzig: e-mail dm_polarice@zks.uni-leipzig.de. • Laboratory, HMDS will be closed on Friday 7th and Monday 10th April for the Easter bank holidays. Therefore the last date for sending samples will be Wednesday 5th April. If an urgent sample needs to be processed please arrange this with HMDS in advance. e-mail: leedsth-tr.polarice@nhs.net • SAE reporting: please continue to report SAEs and SUSARs by email to pharmacovigilance@zks.uni-leipzig.de • IMP from Roche no IMP orders will be processed between 7-10 April 2023. |
| <p>P+R-ICE</p> | <ul style="list-style-type: none"> • 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 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. <p>HMDS The HMDS laboratory will be closed on Friday 7th April and Monday 10th for the Easter bank holidays. Therefore the last date for sending samples will be Wednesday 5th April. The SCTU must be notified in advance of any ctDNA samples due to arrive at HMDS between 6th and the 10th April.</p> <p>WISH WISH laboratory will be closed from Thursday 6th April and will reopen Wednesday 12th April 2023. The last day for sending samples will be Tuesday 4th April. If there are exceptional circumstances, then the team may be able to accommodate samples coming into the lab. The SCTU must be notified in advance of any Flow samples due to arrive at WISH between 4th and the 12th April.</p> |
| <p>REMoDL-A</p> | <ul style="list-style-type: none"> • 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 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. <p><u>HMDS</u></p> |

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| | <p>HMDS will be closed on Friday 7th April and Monday 10th April. Any blood samples need to be sent by Wednesday the 5th so that they are received on Thursday 6th.</p> <p>Tumour blocks may be sent anytime throughout the Easter period. If your patient is due to be randomised for cycle 2 prior to 20th April, their tumour block must have been received by the HMDS lab by 31st March, as no analyses will be conducted over the Easter period. Any patients requiring randomisation after 20th April will not be impacted by the lab closure.</p> <p>Please be aware of these dates and if you have any questions, please email HMDS directly - leedsth-tr.remocl-a@nhs.net.</p> <p><u>ALMAC</u></p> <p>ALMAC will be closed during the Easter period, please ensure that this is taken into consideration when submitting IMP orders at this time.</p> |
| REMoDL-B | For any urgent queries, please email ctu@soton.ac.uk . |
| UNIVERSAL | <ul style="list-style-type: none"> • Please continue to report SAEs by EMAIL during this period to ctu@soton.ac.uk • For urgent clinical queries: please contact Professor Tom Wilkinson at t.wilkinson@soton.ac.uk (Chief Investigator) • For all other queries please email universal@soton.ac.uk and they will be dealt with on our return. |

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