**Short PeRiod IncideNce sTudy of Severe Acute Respiratory Infection**

Frequently Asked Questions

(FAQs)

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| **Study Management** | |
|  | ***What is the Management Committee?*** |
|  | The Management Committee is the overarching governance committee for SPRINT-SARI. This committee will conduct teleconferences 2-4 times a year. |
|  | ***Who are members of the Management Committee?*** |
|  | The Management Committee is made up of the SPRINT-SARI investigators listed on page 1 of the study protocol and a representative of each informal and formal Network participating in SPRINT-SARI. If you are part of a Network, your Network will nominate a representative for the Management Committee. A list the Network leads can be found on the SPRINT-SARI website ([www.sprintsari.org](http://www.sprintsari.org)). |
|  | ***I am a member of the Management Committee, what do I need to do?*** |
|  | The Network representative on the Management Committee responsibilities include:   * Liaising with the project manager and chief investigator on all study related issues; * Identifying and encouraging sites to participate in SPRINT-SARI; * Identifying research co-ordinators and/or principal investigators at each site; * Coordinating the study for participating sites; * Assisting your participating sties to obtain IRB (ethical) approval; * Notifying the project manager and chief investigator when all participating sites have obtained IRB (ethical) approval as per your local requirements; * Completing the network level component of EARL activities; * Providing assistance to all sites within your country and/or network region; * Reviewing, providing feedback on and approving all study related documents; * When possible, attend the Management Committee teleconferences. |
|  | ***What is the SPRINT-SARI Working Group, and what does it do?*** |
|  | The working group is comprised of members of the Management Committee. This group meets frequently to discuss the study in detail, create study documents and implement decisions related to how the study is managed.  The Management Committee are responsible for all major decisions including those related to the Protocol and Case Record Form. |

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| **IRB/Ethics Applications** | |
|  | ***What support is available with IRB/Ethics applications?*** |
|  | A master generic IRB/Ethics application has been created to support you in your SPRINT-SARI IRB/Ethics application. This application (SPRINT-SARI IRB\_Ethics Application Master Guide) can be found on the SPRINT-SARI website ([www.sprintsari.org](http://www.sprintsari.org)). |
|  | ***What level of consent should we request?*** |
|  | The SPRINT-SARI Management Committees consent preference is:   1. Waiver of Consent; 2. Opt Out Consent; followed by 3. Informed Consent (with Waiver of Consent in the event of a pandemic). |
|  | ***The IRB/Ethics Committee has requested we re-submit our application with informed consent, what should we do?*** |
|  | The working group is currently writing a generic letter for you to send to your local IRB/Ethics committee. The letter will explain and justify why waiver of consent has been requested for SPRINT-SARI. Once complete this letter will be available on the SPRINT-SARI website. |

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| **Outbreak Response** | |
|  | ***What do we do during an outbreak/ pandemic?*** |
|  | With this CRF and Protocol you can respond to an outbreak in accordance with your sites priorities and ability. You can collect data at any tier and use the SPRINT-SARI database.  Because you applied for ethics approval with all the SPRINT-SARI data collection tiers you are not limited by the CRF tier you used during the SPRINT-SARI study period. |
|  | ***How long do we collect data for during an outbreak/ pandemic?*** |
|  | You can collect data for as long as you think it is required, your institution/hospital would like to or you have agreed to with ISARIC. You are not limited to the 5 to 7 day SPRINT-SARI study period. You can collect for up to as long as new cases are occurring. |
|  | ***How do we ensure we have the ability to collect data during an outbreak/ pandemic?*** |
|  | In your Institute Review Board (IRB) or Ethics application you will need to specify that this CRF and Protocol will be activated in the event of a local or global respiratory pandemic or outbreak.  You should request the longest possible period for approval in your IRB or Ethics application and renew/ re-submit the IRB or Ethics application before your approval expires. This will ensure you are able to collect data in the event of an outbreak/ pandemic. |
|  | ***What will the data be used for between outbreak/pandemic?*** |
|  | Between pandemics /outbreak the data analyses will be stratified according to available data every year SPRINT-SARI is conducted.  Sites/investigators interested in conducting an ancillary study with data collected for SPRINT-SARI should refer to the Protocol section on ancillary studies for more information. |
|  | ***In the event of an outbreak/ pandemic, how will data collection change?*** |
|  | In order to participate in SPRINT-SARI sites should obtain ethics approval for **ALL** tiers; this will allow sites to conduct observational research at any tier in the event of a pandemic / outbreak according to their research priorities, infrastructure and interests.  Choosing to change tiers or collect data in the event of a pandemic will be up to the individual site and Network. |

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| **Inclusion Criteria** | |
|  | ***Can we enrol patients of any age?*** |
|  | Yes, SPRINT-SARI has no age inclusion or exclusion criteria. If a patient meets the inclusion criteria the patient should be enrolled in SPRINT-SARI irrespective of age. |
|  | ***In the inclusion criteria it says “For children and adults who are able to report dyspnoea, the presence of either dyspnoea or tachypnoea can be used to meet entry criteria.” What does this mean?*** |
|  | For children and adults who are able to report dyspnoea, the presence of either dyspnoea or tachypnoea can be used to meet entry criteria. For children and adults who are NOT able to report dyspnoea, ONLY tachypnoea can be used to meet the inclusion criteria. |
|  | ***In the inclusion criteria it says “New admission with symptom onset within the previous 14 days (required for inclusion)” what does the 14 days refer to?*** |
|  | If the patient is admitted to the hospital within 14 days of the first symptom onset, which you believes is attributable to this proven or suspected acute respiratory infection the patient is eligible to be enrolled in SPRINT-SARI.  If the patient has had symptoms for longer than 14 days they are not eligible to be enrolled in SPRINT-SARI. |
|  | ***The patient was admitted to a different unit/ward within our hospital not participating in SPRINT-SARI, can we enrol the patient once they get to our unit/ward and retrospectively complete data collected prior to admission in our unit/ward?*** |
|  | Yes, if the patient met the inclusion criteria at the time of admission to your hospital you can enrol these patients in SPRINT-SARI and retrospectively collect any data required prior to your ward/units admission. |
|  | ***A patient was previously admitted to hospital for a separate hospital admission. Can we enrol this patient in SPRINT-SARI?*** |
|  | If a patient was discharged from hospital ≥14 day prior to this admission the patient can be enrolled in SPRINT-SARI.  If a patient was discharged from hospital within the last 14 days weeks and/or this admission is considered to be directly related to the previous admission this patient does should not be enrolled in SPRINT-SARI. |
|  | ***If a patient is re-admitted to our unit/ward on the same hospital admission they were enrolled in SPRINT-SARI does this mean we continue to collect SPRINT-SARI data?*** |
|  | Yes, please complete data as per the tier you are completing. Tier 2 & 3 are the only tiers that require continued data collection past the first day of ICU and/or hospital admission. |

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| **Data Storage and Management** | |
|  | ***When will the data collection period begin?*** |
|  | In coordination with representatives of each geographic location the Management Committee will specify a 6 (to 8) week period. Sites and/or networks will choose which 5-7 day study period during the 6 (to 8) weeks they will enrol patients in SPRINT-SARI. Sites are responsible for informing the study Management Committee (via The central SPRINT-SARI project manager) of your study enrolment dates at least 4 weeks prior to commencement.  The 2016 study periods are:  **Northern Hemisphere**: 8-week window, 4th January to 6th March 2016  **Southern Hemisphere:** 8-week window to be confirmed, commencing in July/August 2016  **Tropic Regions:** at any time during or between the study periods above. |
|  | ***What are the database options?*** |
|  | 1. *Central database*: Fully anonymised and de-identified data will be entered into an online eCRF database built on the CliRes Data Management System software is hosted in the UK. For information email Laura Merson (Database Coordinator), email [laura.merson@ndm.ox.ac.uk](mailto:laura.merson@ndm.ox.ac.uk) The database is found here: <https://www.cliresdms.org> 2. *National/Internet based database:* In Countries unable to upload data on a centralised database the right to retain a local database on a national server is available with aggregated completely anonymised data exported centrally for analysis. ISARIC/CliRes Data Management System will send you a copy of the software, which you host on an internet based server. You control the access and assign permissions for your staff to access the database. Your study staff can enter data from any computer/device that has an internet browser and connection. |
|  | ***Who owns the data?*** |
|  | The data belongs entirely to you. If it is hosted on the centralised database in the UK, the data you entre is controlled/accessed by the CLiRes Team only for maintenance purposes and the study team for data analysis. Your data is stored separately from any other data, and accessible only to those granted access by the “site owner” (your authorized data manager). If you use a National database the owner of the data will depend on your national/local data agreements. For more information please refer to the Data Terms of Submission document stored on the SPRINT-SARI website ([www.sprintsari.org](http://www.sprintsari.org)). |
|  | ***Where will the data be stored?*** |
|  | The central database, built on the CliRes Data Management System software is hosted in the UK. For information email Laura Merson, (Database Coordinator), email [laura.merson@ndm.ox.ac.uk](mailto:laura.merson@ndm.ox.ac.uk).  For information on where your national database is stored please contact your network lead investigator. If you don’t know who to contact email the central project manager, email [mnhs-sprint.sari@monash.edu](mailto:mnhs-sprint.sari@monash.edu) or Laura Merson (Database Coordinator), email [laura.merson@ndm.ox.ac.uk](mailto:laura.merson@ndm.ox.ac.uk) |
|  | ***Is there an eCRF available?*** |
|  | 1. Centralised database: There is an eCRF, coordinated by ISARIC, run by CliRes Data Management System (<https://www.cliresdms.org>). The centralised database is in the United Kingdom (UK). To access this database you will need a device with an internet browser and an internet connection. 2. *National/Internet based database:* an eCRF will be available, the internet address will be published on the SPRINT-SARI website. To access this database you will need a device with an internet browser and an internet connection. |
|  | ***National Databases and SPRINT-SARI study data analysis*** |
|  | In countries unable to upload data to the centralised database aggregated completely anonymised data will be exported centrally for analysis at the completion of the SPRINT-SARI study period. |
|  | ***I am having difficulties navigating the CliRes database, where can I go to get help?*** |
|  | A step by step database instruction guide is available on the SPRINT-SARI website ([www.sprintsari.org](http://www.sprintsari.org)) and the CliRes database FAQ page. If you have any questions or difficulties not included in the step by step guide please contact the CliRes team using the database contact tab or contact ISARIC via email ([data@iddo.org](mailto:data@iddo.org)). |
|  | ***Should I complete the paper CRF before entering the data in the eCRF, or can I enter the data directly into the eCRF to save time?*** |
|  | The paper CRF is a tool for data collection. It is up to the site and your available resources if you will collect data on the paper and then enter the data from the paper CRF to eCRF or enter data direct into the eCRF. |
|  | ***How quickly should the data be entered into the eCRF? Do we have a timeline?*** |
|  | A timeline for data entry into the eCRF is not given however, best practice is to enter data as soon as possible.  At certain points we will ask that all data on patients be entered. If a site is getting very behind on data entry we will ask for this to be caught up.  The important thing is to ensure you have data for all the data points’ relevant to the tier you are completing which may be difficult to collect later.  These are:  RAPID CRF:   * 3.1 Symptom onset date of first/earliest symptom;   CORE CRF:   * 1.11 Ethnic Group; * 1.14 & 1.14.1 Travel in the 14 days prior to first symptom onset; * 1.15 Contact with animals, raw meat or insect bites in the 14 days prior to first symptom onset; * 2.2 Recurrent fever prior to admission; * 2.4 Treatment with immunosuppressants (including inhaled/oral corticosteroids) prior to admission; * 2.5 Treatment with anti-infectives (antibiotics and anti-virals) for this illness episode prior to admission; * 2.7.1 Birth weight of infant <1 years old (only applicable if patient is < 1years old); * 2.7.3 & 2.7.4 Breastfed; * 2.7.5 Appropriate development for age; * 2.7.6 Vaccinations appropriate for age/country; * 3.1 Symptom onset date;   SUPPLEMENTARY TO CORE CRF:   * Section 1. Travel: Did the patient travel in the 14 days prior to first symptom onset? (if the patient travelled to more than 1 location; this data point is associated with the CORE CRF data points 1.14, 1.14.1); * Section 1. ANIMAL EXPOSURES: Did the patient have contact with live/dead animals, raw meat or insect bites In the 14 days prior to first symptom onset? (If the patient has more than 1 animal exposure; this data point is associated with the CORE CRF data points 1.15); * Section 2. ADMISSION IMMUNOSUPPRESSANT: Receiving immunosuppressants (including inhaled/oral corticosteroids) prior to admission (if you answered YES to the CORE CRF data point 2.4 this section need to be completed); * Section 2. ADMISSION ANTI-INFECTIVES: Treated with anti-infectives (antibodies and anti-virals) for this illness episode prior to admission (if you answered YES to the CORE CRF data point 2.5 this section need to be completed);   EPIDEMIOLOGY CRF   * All data points in this CRF (Sections 1-3). |

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| **Data Entry** | |
|  | ***In the CORE CRF data points, 1.11 1.14, 1.14.1, 1.15, 2.2, 2.4, 2.5, 2.7.1, 2.7.3-6 & 3.1 and the EPIDEMIOLOGICAL CRF, why do we need this information? Sometimes I forget to ask the patient and/ or family these questions or the time is not suitable to ask such questions, what do I do?*** |
|  | These data points were included on the CRF as they have the potential to have a major association with the definition of SARI and long term outcomes.  Therefore, if this study finds a difference in the relationship between exposure and outcome, we might show baseline data for equivalence.  We recommend that this data is collected at the time of enrolment into SPRINT-SARI and included on your study checklist or other documents. |
|  | ***Can you complete the eCRF as you go?*** |
|  | Yes, you can complete the eCRF as you go, you don’t need to enter all data points into the eCRF as once. When data points are recorded at the same time you will need to enter all the data points at the same time. You can complete sections of the eCRF as the information is gathered. |
|  | ***CORE CRF data point, section 8- outcome. Sometimes the patients cause of death is more than one cause, what do I do?*** |
|  | In CORE CRF section 8.4 enter the data for the primary cause of death (only select one primary cause). If the patient had other contributory cause(s) of death please check any that apply and/or specify if not included as a data point in CORE CRF section 9.5. |
|  | ***In the CRF version 21 JULY 15 SUPPLEMENTARY TO CORE CRF section 2 asks about admission immunosuppressents, including oral/inhaled corticosteroids however in the CORE CRF it excludes inhaled corticosteroids. Do we include the inhaled corticosteroids?*** |
|  | No, please complete the SUPPLEMENTARY CRF following the CORE CRF guidelines. We would like all inhaled corticosteroids EXCLUDED from the data collected. |

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| **IT database requirments** | |
| Information relevant for September 2015 | |
|  | ***What are the IT system requirements for the different database options?*** |
|  | 1. **Centralised database:** Entering data to the centralised server via[**www.cliresdms.org**](http://www.cliresdms.org/)**.**   *Hardware/software requirements:* any device with an internet browser and an internet connection   1. **Local/Institutional database:** Entering data to a local server   Hardware requirements:   |  |  | | --- | --- | | **Item** | **Recommended Minimum** | | Processor | x64 Processor 2.0GHz or faster | | RAM | At least 4 GB and should be increased as database size increases to ensure optimal performance. | | Disk space | At least 40GB and should be increased as database size increases. |   Software requirements:   |  |  | | --- | --- | | **Item** | **Supported platform** | | Operating System | Windows Server 2008 (64-bit edition)  Windows Server 2012 (64-bit edition). | | Databases | Microsoft SQL Server 2008 (x64) Express Edition, Standard Edition and Enterprise Edition. | | Internet Information Services (IIS) | 6.0  7.0  7.5 | | Microsoft .NET Framework | 2.0  4.0 | |  |  |  1. **National/Internet based database:** Entering data to a locally hosted internet based server   *Hardware/software requirements: The same as per the local/institutional database*, **PLUS** these items below:   |  |  | | --- | --- | | **Items** | **Quantity** | | Domain name | 1 | | SSL certificate | 1 | | High speed internet connection  Internet Protocols | 1  HTTP (standard internet) or HTTPS (secure internet) | |
|  | ***What are the offline data capture device requirements for the above databases?*** |
|  | All database options require the same device requirements:   |  |  | | --- | --- | | **Item** | **Recommended Minimum** | | Device type | Tablet, Laptop and PC | | Software | Windows 8.1 or  Windows 10 | | Display size | 7 inches or above  Touchscreen recommended | | Processor | x64 Processor 1.0GHz or faster | | RAM | At least 1 GB | | Disk space | At least 20GB | | Wireless | Optional. It is used to synchronize the data | | Ports | Memory slot  USB | | Memory stick | Optional. It is used for daily back up of data | |

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| If you have a question that is not covered on this document please contact ***The central SPRINT-SARI project manager*** via email, [mnhs-sprint.sari@monash.edu](mailto:mnhs-sprint.sari@monash.edu) |