

SNAP TRIAL INTEGRITY SUITE: BACTERIAL ISOLATE SHARING POLICY

DOCUMENT APPROVAL

VERSION NUMBER	DATE	CREATED BY	APPROVED BY	SIGNATURE OF APPROVAL
2.0	15-Oct-2026	GTMG	Steven Tong	eSIGNED by Steven Tong on 16-10-2026
			Joshua Davis	eSIGNED by Joshua Davis on 16-10-2026
			Zoe McQuilten	eSIGNED by Zoe McQuilten on 17-10-2026

Members of the SNAP Trial Global Trial Steering Committee (GTSC) and Regional Trial Management Groups (RTMGs) have had the opportunity to review this document, and it has been signed by the Chief Investigators and the Chair of the GTSC on behalf of the SNAP Trial.

IF ADAPTING THIS DOCUMENT, PLEASE ACKNOWLEDGE US VIA THE FOLLOWING STATEMENT:

"This document has been adapted from the *Staphylococcus Aureus* Network Adaptive Platform (SNAP) Trial Integrity Suite: Isolate Sharing Policy, available from the SNAP Trial website: <https://www.snaptrial.com.au/for-investigators#integrity>.

The SNAP Trial, globally coordinated by the University of Melbourne, is an international adaptive platform trial aimed at identifying the most effective treatments for *Staphylococcus aureus* bloodstream infections."

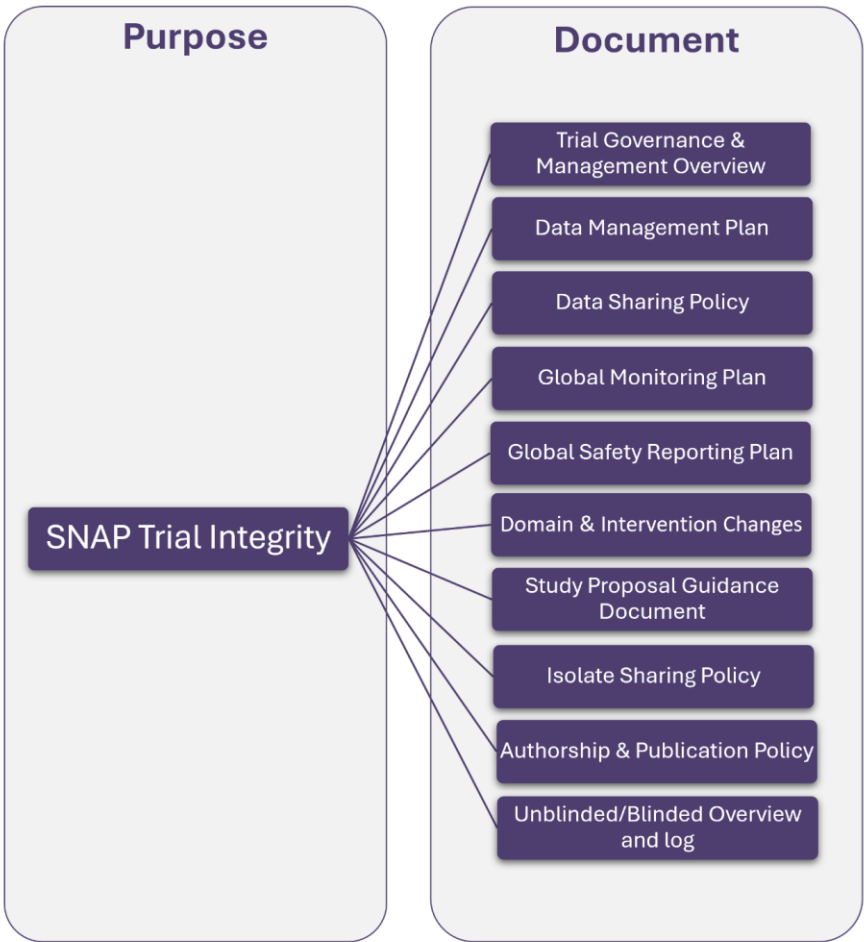
1	<u>CONTENTS</u>	
2	SNAP Trial Integrity Suite	3
3	Introduction	3
3.1	Purpose & Scope.....	3
3.2	Update & Review.....	4
4	Definitions and Responsibilities.....	4
4.1	Isolate Data	4
4.2	Isolate/Isolate Data Requester	4
4.3	Isolate/Isolate Data Provider	5
4.4	Isolate/Isolate Data Owner.....	5
4.5	Isolate/Isolate Data Approver	5
4.6	Isolate/Isolate Data Custodian.....	5
5	SNAP Isolate Sharing Principles	5
5.1	The SNAP Bacterial Biobank	6
5.2	Jurisdictional Ownership & Control.....	6
5.3	Formal Approval for Release	6
5.4	Purpose-Limitation	6
6	SNAP Isolate Data Sharing Principles.....	7
6.1	De-identified Data and Traceability	7
6.2	The SNAP Bacterial Biobank Electronic Data Capture (EDC) System - SNAPTrakka	7
6.3	Mandatory Data Return.....	8
6.4	Appropriate Acknowledgment	8
7	Isolate & Isolate Data Request Overview	8
7.1	Terms & Conditions for Isolate Data Requesters	8
8	Transfer & Security	9
8.1	No Third-Party Transfer	9
8.2	Security and Destruction	9
9	Regulatory Compliance & International Standards.....	9
10	Appendices	10
10.1	Appendix 1: Record of Changes.....	10
10.2	Appendix 2: Flowchart for Requests to Use SNAP Trial Data, Isolates, and Isolate Data	11

2

SNAP TRIAL INTEGRITY SUITE

The SNAP Trial Integrity Suite is a comprehensive collection of essential documents that provide evidence and guidance for the conduct and oversight of the SNAP Trial globally and sets the minimum standards of compliance for the study.

The SNAP Trial Integrity Suite is comprised of the following documents:



SNAP Trial Integrity Suite v2.3 dated 20-May-26

Figure 1: SNAP Trial Integrity Suite

3

INTRODUCTION

3.1

PURPOSE & SCOPE

The *Staphylococcus aureus* Network Adaptive Platform (SNAP) Trial is committed to responsible sharing of clinical trial bacterial isolates and associated data to serve the dual goals of (1) ensuring the privacy and informed consent of trial participants, and (2) advancing scientific knowledge to improve public health.

The purpose of the Bacterial Isolate Sharing Policy (ISP) is to outline the procedures and principles for sharing isolates and associated data generated in the SNAP Trial.

A goal of the SNAP Trial is to enable researchers to access the SNAP Trial Bacterial Biobank and associated data to maximise the benefits that can be derived from the data. The SNAP Trial acknowledges the importance of making research samples and data publicly accessible, and as such, has developed a comprehensive Isolate Sharing Policy to encourage the re-use of bacterial isolates and associated data. The sharing process maintains trial integrity and ensures appropriate acknowledgment of the contributors, funders, and collaborators, as well as acknowledging the binding nature of participant consent. The SNAP Trial conducts all study procedures with the utmost care and respect for the safety and privacy of its participants.

The ISP applies to all members of the SNAP Trial Group, including trial committees and working groups, trial management groups, the broader SNAP Trial group (site teams and investigators), and all external parties. This policy applies to isolate and associated isolate data requesters.

3.2 UPDATE & REVIEW

This document will be updated throughout the life of the trial to reflect any changes in isolate and isolate data governance and sharing procedures.

This document will be reviewed annually at a minimum, or in the event of the following occurring:

- A substantial amendment to the core protocol documents that impact this document
- Changes to our isolate sharing practices or governance are required

With each update, all members of the Global Trial Steering Committee (GTSC) and Regional Trial Management Groups (RTMGs) will have the opportunity to review and provide feedback on the changes.

Each version of the ISP will be ratified by the GTSC and signed off by the chair on behalf of the committee.

4 DEFINITIONS AND RESPONSIBILITIES

Providers and Requesters of SNAP Trial bacterial isolates and isolate data must obtain all necessary approvals prior to sharing, including from an Ethics Review Body (ERB), and the isolate/isolate data Custodian(s). Providers and Requesters are all responsible for ensuring that sharing is compliant with relevant laws.

4.1 ISOLATE DATA

Genomic and phenotypic data generated from the bacterial isolates collected as part of the SNAP Trial are considered **isolate data** and are not inherently associated with any clinical research data of the participant from which it was derived. Requests for clinical research data related to SNAP Trial participants will require a separate submission of a **Data Access Request Form (DARF)** (see Section 6.1).

4.2 ISOLATE/ISOLATE DATA REQUESTER

The isolate/isolate data requester is the party seeking authorized access to trial isolates/isolate data for a specified purpose. The Requester is responsible for complying with the isolate/isolate data owner's conditions, applicable law, and any contractual or ethical restrictions attached to the isolates/isolate data. The Requester accepts legal, ethical, and contractual obligations to protect participants' privacy and to use the isolates/isolate data only as approved. These obligations include additional duties to respect cross-border isolate/isolate data handling rules, local approvals, and culturally sensitive interpretation of the isolates/isolate data.

4.3 ISOLATE/ISOLATE DATA PROVIDER

The isolate/isolate data provider is the party that is providing the isolates/isolate data to the Requester (i.e. the party undertaking the isolate transfer process). The Provider is responsible for providing the isolates/isolate data in compliance with the isolate/isolate data owner's conditions, applicable law, and any contractual or ethical restrictions attached to the isolates/isolate data.

4.4 ISOLATE/ISOLATE DATA OWNER

The isolate/isolate data owner is the party with ultimate authority and accountability for SNAP Trial isolates/isolate data. The Owner decides what may be done with the isolates/isolate data, who may access it, and under what conditions. The Owner ensures that processing complies with the protocol, consent, law and ethics approvals.

The Owner is stipulated in formal contracts relating to the SNAP Trial isolates and may be the same party as the Approver.

4.5 ISOLATE/ISOLATE DATA APPROVER

The isolate/isolate data approver is the party who approves the purpose, use, and requirements for an isolate set. The Approver is responsible for formally ratifying or denying requests to access isolates, and to provide formal sign off on releases for isolate sharing.

- RTMGs, on behalf of the International Sponsor Organisations (ISOs) are considered the isolate approvers for the SNAP Trial isolates originating from their region.
- The institution that produced the isolate data is considered the isolate data approver of the isolate data originating specifically from the testing they performed

4.6 ISOLATE/ISOLATE DATA CUSTODIAN

The isolate/isolate data custodian is the party who has an operational and technical role focused on safeguarding the integrity, availability, and confidentiality of the SNAP Trial isolates. The Custodian is responsible for supporting ratified isolate requests by provisioning secure environments (e.g. secure analysis enclaves) and providing isolates per approved processes.

- The Global Trial Steering Committee (GTSC) is considered the isolate custodian for the SNAP Trial Bacterial Biobank. The GTSC is responsible for managing and overseeing all access requests to the SNAP Trial Bacterial Biobank (where isolates from 2 or more countries are being requested). The operational responsibilities of the isolate custodian are delegated by the GTSC to the Global Trial Management Group (GTMG).
- The Regional Trial Steering Committee (RTSC) is considered the isolate custodian for the SNAP Trial regional isolate repository. The RTSC is responsible for managing and overseeing all access requests to the SNAP Trial isolates (where isolates/isolate data are being requested from that country). The operational responsibilities of the isolate custodian are delegated by the RTSC to the Regional Trial Management Group (RTMG) and GTMG (where appropriate).
- The institution that produced the isolate data is considered the custodian for the isolate data originating specifically from the testing they performed. The operational responsibilities of the isolate custodian are delegated by the GTSC to the Global Trial Management Group (GTMG).

5 SNAP ISOLATE SHARING PRINCIPLES

The SNAP Trial recognises that the *Staphylococcus aureus* (*S. aureus*) bacterial isolates are cultured from blood samples obtained from participants of the SNAP Trial. While the blood sample itself and any data relating to the blood sample is considered personal data (and therefore may be considered to

be owned by the participant), the bacterial isolate is a biological material that has been separated from the person's body and does not contain information that can directly identify the individual.

However, it is important to note that if there are any pseudonymised data associated with the isolate that could be linked back to the participant, measures will be implemented to protect the data and ensure compliance with the relevant global and region-specific data protection principles (such as GDPR, ICH-GCP, etc).

5.1 THE SNAP BACTERIAL BIOBANK

As part of this study, for each participant, the index *S. aureus* bacterial isolate is collected and stored. The **index isolate** of a given participant is defined as the first collected blood culture that tests positive for *S. aureus* bacteraemia (SAB).

The SNAP Trial incorporates a comprehensive bacterial biobanking strategy to ensure the preservation and accessibility of its valuable collection of *S. aureus* isolates. The Global Trial Management Group (GTMG), University of Melbourne, houses the SNAP Bacterial Biobank for the SNAP Trial where a copy of each isolate collected during the study will be stored for long-term preservation and the potential for future research.

Given the global nature of SNAP, a network of regional isolate repositories may also be established; however, there will ideally be a single SNAP Bacterial Biobank for all global SNAP Trial isolates.

5.2 JURISDICTIONAL OWNERSHIP & CONTROL

The International Sponsor Organisation (ISO) from which an isolate originated shall retain ownership over that isolate. No isolate copies shall be provided from the SNAP Bacterial Biobank to third parties without explicit, written permission from the Regional Trial Management Group (RTMG), who have designated authority within the country of origin. The SNAP Global Trial Management Group (GTMG) will act on behalf of the GTSC as custodians of all isolates and associated laboratory data contained within the SNAP Bacterial Biobank and SNAPTrakka database (see Section 6.2).

5.3 FORMAL APPROVAL FOR RELEASE

The SNAP GTMG will manage the process for accessing isolates. Requesters of isolates and/or isolate data must submit a formal request by use of the **Isolate Request Form** detailing the proposed research, including specific isolates required, intended purpose, and planned assays.

Please submit this form, associated Data Access Request Forms (if applicable), and any questions as follows:

- **Requests for singular country/region isolate/isolate data:** submit to the relevant RTMG email address (<https://www.snaptrial.com.au/collaborators>)
- **Requests for 2 or more countries/regions data:** submit to the GTMG email address (snap-trial@unimelb.edu.au)

The SNAP Microbiology Working Group and other working group(s) nominated by the Microbiology Working Group will assess the merit and feasibility of the request. If supported, the application advances to the Global Trial Steering Committee (GTSC) and RTMGs for final review and approval. The GTSC is the highest decision-making body for the SNAP Trial and comprises the lead representatives from all participating SNAP Trial regions, key stakeholders, and expert microbiologists and clinicians. RTMGs and Isolate/Isolate Data Owners must also provide formal, written approval for release of their isolates or lab-generated data as requested.

5.4 PURPOSE-LIMITATION

The use of any isolates provided to an Isolate/Isolate Data Requester is strictly limited to the purpose and assays specified in the approved request that is appended to the relevant Material/Data Transfer Agreements (MDTAs). Any deviation from the stated purpose, or any intention to either use the isolates for additional research or share the isolates with third parties requires a new formal request and approval from the GTSC, Microbiology WG, and relevant RTMGs and laboratories.

The SNAP Trial does not mandate the upload of published data to public registries/databases (e.g. NCBI) but acknowledges that the Requester may be required to do so according to their regional requirements.

6 SNAP ISOLATE DATA SHARING PRINCIPLES

As a general principle, access to the SNAP Trial data is encouraged but highly safeguarded. The SNAP Trial uses the Five Safe principles for guiding decisions around data sharing requests:

- **Safe Projects:** Whether the data is being used for appropriate purposes and is likely to be in accordance with community expectations.
- **Safe People:** The knowledge, skills and trustworthiness of the researcher.
- **Safe Data:** The disclosure risks inherent in the data being shared.
- **Safe Settings:** The access controls in place, such as use of a trusted research environment.
- **Safe Outputs:** Whether any published results could reveal the identity of individuals.

For more information on the use of the Five Safe principles see:
<https://www.abs.gov.au/statistics/understanding-statistics/data-confidentiality-guide/five-safes-framework>

6.1 DE-IDENTIFIED DATA AND TRACEABILITY

Distributed isolates and isolate data from the SNAP Trial will be pseudonymised using a unique anonymised code. This code serves as a secure link between the isolate and its corresponding clinical data in the SNAP Trial database (Spinnaker), protecting participant data integrity and traceability.

The coding system allows for the separation of isolates and isolate data from the corresponding participant clinical trial data, enabling efficient data reconciliation and sharing amongst authorised personnel. This approach ensures participant privacy is maintained while facilitating effective research collaboration and data analysis. Only authorised staff have access to the key that links these codes to participant clinical data.

Requests for linked SNAP Trial clinical data require an additional data request (see Data Access Request Form). Both the isolate and data requests should make clear that linked data is requested. The SNAP Trial acknowledges that requests for isolates and/or isolate data originating from the EU and the UK may be subject to different regulations.

6.2 THE SNAP BACTERIAL BIOBANK ELECTRONIC DATA CAPTURE (EDC) SYSTEM - SNAPTRAKKA

SNAPTrakka is a laboratory data visualisation and analysis EDC platform developed by the Global Trial Management Group (GTMG), in collaboration with the Microbiological Diagnostic Unit, University of Melbourne, to centralise and manage laboratory data generated from isolates collected for the SNAP Trial. This EDC has capacity to store microbiological, genomic, and other laboratory-derived information related to the SNAP Trial, including but not limited to antimicrobial susceptibility profiles, whole genome sequencing (WGS) reads, and derived bioinformatic analyses.

Access to SNAPTrakka is strictly controlled, with different levels assigned based on roles and responsibilities. The system incorporates automated data validation checks, regular audits, and

standardised entry protocols to maintain data quality. SNAPTrakka is developed by the AusTrakka team but operates as an independent platform.

6.3 MANDATORY DATA RETURN

The Requester of any isolates and/or isolate data is expected to share all results, data, and findings from any assays or analyses conducted on the isolates to the SNAP Trial as outlined in the terms of the contractual agreement(s) attached to the request (e.g. an MDTA). In cases where SNAP isolates and/or isolate data are presented as part of a publication, results are expected to be shared with the SNAP Trial within three months of publication (unless otherwise stated in the MDTA). This ensures that the clinical trial has a complete record of all data generated from its biological materials, a critical contributor to increasing its scientific and clinical value. Access to data generated by the Requester is governed by this isolate sharing policy (i.e. anyone requesting to use this data must obtain approval from the data generator).

6.4 APPROPRIATE ACKNOWLEDGMENT

The Requester of any isolates and/or isolate data must appropriately acknowledge the contributing countries and laboratories in any academic output, publication, or presentation using the isolates or derived data. The acknowledgment format, outlined in the **SNAP Authorship and Publication Policy**, should be agreed upon by all parties prior to transfer of isolates and must conform to international attribution standards.

7 ISOLATE & ISOLATE DATA REQUEST OVERVIEW

Requests for isolates and isolate data must be made formally by submission of the Isolate Request Form (IRF). Before proceeding, please carefully review these other SNAP Trial Integrity Documents (available on the [SNAP Trial Website](#)):

- Data Sharing Policy (DSP)
- Authorship & Publication Policy

The Requester may incur a fee to cover costs of isolate and isolate data request reviews and processing requirements.

7.1 TERMS & CONDITIONS FOR ISOLATE DATA REQUESTERS

The Requester must be familiar with the ISP, and adhere to the terms and conditions outlined below:

- The isolates/isolate data provided are confidential and will only be used and disseminated according to the approved request. Any scope to use isolates/isolate data beyond the approved purposes will need to be approved with a new or amended data request.
- The Requester will ensure all isolates/isolate data received are stored securely, as per the storage conditions approved in the IRF, and in line with relevant ethical and regulatory guidelines.
- The Requester will ensure that any isolates/isolate data received are kept strictly confidential and are accessible only to those approved in the IRF. Any additional persons requiring access to the isolates/isolate data will be approved with a new or amended request.
- The Requester must refrain from making any attempts to personally identify individuals from the provided isolates/isolate data. If the Requester inadvertently identifies an individual, they are strictly prohibited from recording such identifiable information, disclosing the identification to

others, or attempting to contact the individual. Any instances of accidental identification must be promptly reported to SNAP Trial.

- The Requester will provide information about the funding sources (if applicable) for their proposed work, including updates on subsequent funding secured after receiving the shared isolates/isolate data.
- The Requester will acknowledge the SNAP Trial and the relevant parties as the source in any publications or presentations of the research, according to the SNAP Trial Authorship & Publication Policy. The Requester will share and accept input on authorship by the SNAP Trial prior to publication.
- The Requester will forward a copy of any publication or presentation to the SNAP Trial for ratification prior to public dissemination
- Once the purpose of the isolate/isolate data request is completed, the Requester may be asked to destroy all copies of the provided isolates/isolate data, as per the terms set out in any MDTAs.

8 TRANSFER & SECURITY

8.1 NO THIRD-PARTY TRANSFER

The Requester of any isolates and/or isolate data is prohibited from transferring, sharing, or otherwise providing any isolates or related data to a third party without first obtaining explicit, written permission from the SNAP Trial GTSC and the relevant RTMGs.

8.2 SECURITY AND DESTRUCTION

The Requester is responsible for the secure storage and handling of all isolates/isolate data. If requested by the SNAP Trial and/or the relevant RTMGs, the Requester must destroy and dispose of the isolates/isolate data in a manner that complies with relevant biosafety and ethical guidelines and provide written confirmation of this destruction. The SNAP Trial retains custodianship of all isolates/isolate associated data collected under the trial umbrella.

9 REGULATORY COMPLIANCE & INTERNATIONAL STANDARDS

The SNAP Bacterial Biobank will comply with international regulatory standards relating to the collection, storage, shipment, sharing, and use of bacterial isolates collected for research purposes. All associated international repositories that are part of the SNAP Trial network are advised of these standards and best practices. However, it is understood and expected that these international partners operate under their own regional guidelines and standards, specific to their geographical locations and jurisdictions.

10 APPENDICES

10.1 APPENDIX 1: RECORD OF CHANGES

VERSION NUMBER	VERSION DATE	SECTIONS AFFECTED	SUMMARY OF CHANGES	LEAD AUTHOR
1.0	10-Oct-23	-	-	Vi Nguyen
2.0	15-Oct-26	All	Updated all sections to bring in line with the Data Sharing Policy.	Samuel de Jong

