SNAP Reporting Implementation Guide
Planned release of trial results
Version 2.0

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Contents

1 Introduction

The statistical analysis plans (hereafter known as the *SAPs*) set out how the data for each SNAP domain, and if appropriate silo within the domain, will be analysed and reported. This may occur when recruitment to any domain intervention is ceased for any subgroup due to exceeding decision thresholds for superiority or futility, or reaching maximum domain or subgroup recruitment or following recommendation(s) from the DSMC. Therefore, analyses may be required at different time points for either the interventions and/or subgroups, despite being specified in the same SAP. For example, if recruitment to the adult subgroup for the (flu)cloxacillin intervention arms is ceased for the backbone domain. These distinct events, pre-specified in the protocol or documented in DSMC meetings and or/correspondence, trigger the analyses and reporting of the accumulated trial data. The SNAP Reporting Implementation Guide (hereafter known as the *RIG*), specifies participant eligibility for inclusion in each trial report and explicitly defines which trial results will be released (i.e. unblinded). This is an integral part of the trial integrity documentation. Each SNAP report generated will be sequentially numbered and will include:

- the reason for the report and an outline of what has previously been reported for the SNAP platform;
- the date and participant eligibility for when the last adjunctive-domain randomisation-revealed participant completed follow-up, including the date that the last report-eligible participant was recruited;
- the combinations of silos (PSSA, MSSA, MRSA), subgroups (adult, paediatric, etc.) and interventions for which results will be included in the report, i.e. which results are being unblinded and which will remain blinded to maintain trial integrity in the other silos/subgroups/intervention combinations;
- CONSORT flowchart indicating all SNAP participants that may contribute to the primary analysis.
- version control

The *RIG* is designed to be updated over the life-course of the SNAP platform and provides a summary of the trial results unblinded by date. It is the responsibility of the chair of the SNAP statistical subcommittee or their delegate to maintain the *RIG*, including version control.

2 Report 1: Backbone domain for the MSSA and PSSA silos, adult subgroup and paediatric penicillin intervention arm

Reference documentation:
SNAP Backbone Domain for PSSA and MSSA silos Statistical Analysis Plan Version 1.0
SNAP Derived variables Version 1.0
SNAP SIG Version 6.0

2.1 Previously reported SNAP results

None.

2.2 Reason for reporting

The DSMC on 6 August 2024 recommended ceasing recruitment of adults to the (flu)cloxacillin (control) arms in both the PSSA and MSSA silos due to safety concerns about the adult rate of acute kidney injury (hereafter known as *AKI*). The DSMC recommendation did not extend to paediatric participants as there were too few events [of special interest] in this subgroup. The letter on 6 August 2024 was following an extraordinary meeting of the DSMC on 5 August 2024, informed by:

- a previous DSMC recommendation on 18 June 2024 to pause adult recruitment to the (flu)cloxacillin (control) arms in both the PSSA and MSSA silos;
- a DSMC requested unscheduled analysis of the primary estimand performed in July 2024, where the decision threshold was exceeded for non-inferiority between (flu)cloxacillin and cefazolin in the backbone domain for the MSSA silo alone.

The cessation of recruitment to the (flu)cloxacillin arms in the MSSA and PSSA silos results in a deterministic allocation procedure to the single remaining arm (i.e. randomisation unnecessary), therefore, the GTSC paused all recruitment to the backbone domain for PSSA and MSSA silos in both adult and paediatric subgroups on 21 June 2024. Total adult and paediatric recruitment into the backbone domain for the MSSA silo was 1341 and 87, respectively, and for the PSSA silo was 281 and 14, respectively, by 21 June 2024.

A decision was made by the GTSC on 7 August 2024 to close the backbone domain for the PSSA and MSSA silos for both adults and paediatrics and report the results for the backbone domain for the PSSA and MSSA silos for all subgroups. However, the Paediatric Working Group proposed continued paediatric recruitment into the backbone domain for the PSSA and MSSA silos on 6 September 2024, given the low number of paediatric participants already recruited and the lack of evidence of any safety concerns in this age group. This was endorsed by the GTSC on 9 September 2024, and the decision to close the PSSA and MSSA silos for the backbone domain for paediatrics was over-turned. Recruitment to these silos for paediatric participants is anticipated to start in 1Q2025.

2.3 Eligible participants and data extraction

All SNAP participants who were recruited to the platform (i.e. had randomisations generated but not necessarily revealed) on or before 21 June 2024 (site local date and time) are eligible for this report. Data cleaning and consistency checks relevant to this report will be performed prior to the data extraction, which will occur on 29 November 2024 (Australian Eastern Standard time). Complete data will be provided to the Analytic Team, although not all participants and data items will be required for the report; the Analytic Team is responsible for the selection of eligible participants and data items for the report.

2.4 Maintaining trial integrity

2.4.1 CONSORT flowchart and baseline summaries

A CONSORT flowchart will be produced that documents the total number of participants in each domain that contribute to the reported analyses. The total number of participants allocated to each intervention will only be provided for:

- Backbone PSSA silo (flu)cloxacillin arm **adult subgroup only**

- Backbone PSSA silo penicillin arm **adult subgroup only**
- Backbone PSSA silo penicillin arm **paediatric subgroup only**
- Backbone MSSA silo (flu)cloxacillin **adult subgroup only**
- Backbone MSSA silo cefazolin **adult subgroup only**

No further recruitment or randomisation revealed totals will be reported for any interventions or domains.

Similarly, baseline characteristics will be summarised and reported for only for the interventions and subgroups defined above.

2.4.2 Reporting descriptive summaries of the endpoints

The report will include **selected** subgroup-specific descriptive summaries of trial endpoints by revealed backbone domain interventions for the PSSA and MSSA silos. **Only** the following subgroup-silo-intervention summaries will be included in the report, to maintain trial integrity:

- Adult, PSSA, (flu)cloxacillin
- Adult, PSSA, penicillin
- Paediatric, PSSA, penicillin
- Adult, MSSA, (flu)cloxacillin
- Adult, MSSA, cefazolin

2.4.3 Reporting statistical model parameters for the estimands

The report will include **selected** summeries of the subgroup-specific posterior distributions for the revealed backbone domain intervention compared to control for the PSSA and MSSA silos. **Only** the posterior distributions for the statistical model parameters detailed below will be included in the report, to maintain trial integrity (priority results are highlighted in red).

Core estimands

Estimand	Adult-PSSA	Adult-MSSA	Paediatric-PSSA	Paediatric-MSSA
1	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
2* (A1.1)	—	—	—	—
3	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
4	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
5	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
6	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
7	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
8	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
9	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
10	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
11	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
12	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
13* (A1.9)	—	—	—	—
14	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
15* (A1.10)	—	—	—	—
16* (A1.11)	—	—	—	—
17#	—	—	—	—
18#	—	—	—	—

* : Analysis performed as a backbone domain silo-specific estimand.
\# : No statistical analysis defined.

Silo-specific backbone estimands

Estimand	Adult-PSSA	Adult-MSSA	Paediatric-PSSA	Paediatric-MSSA
A1.1	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.2	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.3	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.4	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.5	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.6	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.7	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.8	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.9	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.10	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—
A1.11*	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	—	—
Backbone.1	$\beta_{Adult,PSSA,d_{13}}$	$\beta_{Adult,MSSA,d_{12}}$	$\beta_{Paed,PSSA,d_{13}}$	—

* : Endpoint not available for paediatric subgroup.

PRE-SPECIFIED SUBGROUPS

1. Paediatric subgroup

Estimand	Adult-PSSA	Adult-MSSA	Paediatric-PSSA	Paediatric-MSSA
14.P	—	—	$\beta_{Paed,PSSA,d_{13}}$	—
15.P (A1.10)	—	—	—	—
16.P	—	—	$\beta_{Paed,PSSA,d_{13}}$	—
P.1	—	—	$\beta_{Paed,PSSA,d_{13}}$	—

2. PWID

Data linkage is not available at this point in time, therefore, it is not possible to perform the analysis for estimand PWID.2.

Estimand	Adult-PWID-PSSA	Adult-nonPWID-PSSA	Paediatric-PSSA
1	$\beta_{Adult-PWID,PSSA,d_{13}}$	$\beta_{Adult-nonPWID,PSSA,d_{13}}$	—
PWID.1	$\beta_{Adult-PWID,PSSA,d_{13}}$	$\beta_{Adult-nonPWID,PSSA,d_{13}}$	—
PWID.2	—	—	—

Estimand	Adult-PWID-MSSA	Adult-nonPWID-MSSA	Paediatric-MSSA
1	$\beta_{Adult-PWID,PSSA,d_{12}}$	$\beta_{Adult-nonPWID,PSSA,d_{12}}$	—
PWID.1	$\beta_{Adult-PWID,PSSA,d_{12}}$	$\beta_{Adult-nonPWID,PSSA,d_{12}}$	—
PWID.2	—	—	—

3. Endocarditis

Estimand	Adult-None-PSSA	Adult-Left-PSSA	Adult-Right-PSSA	Adult-Both-PSSA	Paediatric-PSSA
1	$\beta_{A-None,PSSA,d_{13}}$	$\beta_{A-Left,PSSA,d_{13}}$	$\beta_{A-Right,PSSA,d_{13}}$	$\beta_{A-Both,PSSA,d_{13}}$	$\beta_{Paed,PSSA,d_{13}}$

Estimand	Adult-None-MSSA	Adult-Left-MSSA	Adult-Right-MSSA	Adult-Both-MSSA	Paediatric-MSSA
1	$\beta_{A-None,MSSA,d_{12}}$	$\beta_{A-Left,MSSA,d_{12}}$	$\beta_{A-Right,MSSA,d_{12}}$	$\beta_{A-Both,MSSA,d_{12}}$	—

4. blaZ

Not available at this point in time. Only reported for PSSA silo.

Estimand	Adult-noblaZ-PSSA	Adult-blaZ-PSSA	Adult-unkblaZ-PSSA	Paediatric-PSSA
1	—	—	—	—

Estimand	Adult-noblaZ-MSSA	Adult-blaZ-MSSA	Adult-unkblaZ-MSSA	Paediatric-MSSA
1	—	—	—	—

5. Cefazolin inoculum effect

Not available at this point in time. Only reported for MSSA silo.

Estimand	Adult-nocefinoc-PSSA	Adult-cefinoc-PSSA	Adult-unkcefinoc-PSSA	Paediatric-PSSA
1	—	—	—	—

Estimand	Adult-nocefinoc-MSSA	Adult-cefinoc-MSSA	Adult-unkcefinoc-MSSA	Paediatric-MSSA
1	—	—	—	—

6. (flu)cloxacillin inoculum effect

Not available at this point in time. Only reported for MSSA silo.

Estimand	Adult-nocloxinoc-PSSA	Adult-cloxinoc-PSSA	Adult-unkcloxinoc-PSSA	Paediatric-PSSA
1	—	—	—	—

Estimand	Adult-nocloxinoc-MSSA	Adult-cloxinoc-MSSA	Adult-unkcloxinoc-MSSA	Paediatric-MSSA
1	—	—	—	—

7. type A beta-lactamase

Not available at this point in time. Only reported for MSSA silo.

Estimand	Adult-noblacinoc-PSSA	Adult-blacinoc-PSSA	Adult-unkblacinoc-PSSA	Paediatric-PSSA
1	—	—	—	—

Estimand	Adult-noblacinoc-MSSA	Adult-blacinoc-MSSA	Adult-unkblacinoc-MSSA	Paediatric-MSSA
1	—	—	—	—

8. CNS focus of infection

Only reported for MSSA silo.

Estimand	Adult-NoCNS-PSSA	Adult-CNS-PSSA	Paediatric-PSSA
1	—	—	—

Estimand	Adult-NoCNS-MSSA	Adult-CNS-MSSA	Paediatric-MSSA
1	$\beta_{A-NoCNS,MSSA,d_{12}}$	$\beta_{A-CNS,MSSA,d_{12}}$	—

9. Ethnicity

Reported for NZ ethnicity only.

Estimand	Adult-Maori-PSSA	Adult-SPacI-PSSA	Adult-othNZ-PSSA	Adult-ntNZ-PSSA	Paediatric-PSSA
1	$\beta_{A-Mao,PSSA,d_{13}}$	$\beta_{A-SPI,PSSA,d_{13}}$	$\beta_{A-oNZ,PSSA,d_{13}}$	$\beta_{A-ntNZ,PSSA,d_{13}}$	$\beta_{Paed,PSSA,d_{13}}$

Estimand	Adult-Maori-MSSA	Adult-SPacI-MSSA	Adult-oNZ-MSSA	Adult-ntNZ-PSSA	Paediatric-MSSA
1	$\beta_{A-Mao,MSSA,d_{12}}$	$\beta_{A-SPI,MSSA,d_{12}}$	$\beta_{A-oNZ,MSSA,d_{12}}$	$\beta_{A-ntNZ,MSSA,d_{12}}$	$\beta_{Paed,MSSA,d_{12}}$

2.4.4 Reporting SAR/SAE data

SAR are recorded at all SNAP sites and are a priority result. The report will include **selected** subgroup-specific summaries of SAR that are either definitely, probably or possibly related to one of the revealed backbone domain interventions for the PSSA or MSSA silos, irrespective of whether the same SAR is also attributed to another revealed intervention in another domain. **Only** the following subgroup-silo-intervention summaries will be included in the report, to maintain trial integrity:

- Adult, PSSA, (flu)cloxacillin
- Adult, PSSA, penicillin
- Paediatric, PSSA, penicillin
- Adult, MSSA, (flu)cloxacillin
- Adult, MSSA, cefazolin

The report will not include information nor summaries of SAE as these are only recorded and reported in selected countries for regulatory purposes. Details of SAE are provided to the DSMC in open and closed DSMC reports.

2.5 Documents provided to analytic team

The following documents will be provided to the Analytic Team where required:

- SNAP Backbone Domain for PSSA and MSSA silos Statistical Analysis Plan (SAP) Version 1.0
- SNAP Derived Variables (SDV) Version 1.0
- Additional data and documentation as required

3 Report 2: Adjunctive domain, all silos and available subgroups

Reference documentation:
SNAP Adjunctive Domain Statistical Analysis Plan Version 1.0
SNAP Derived variables Version 2.0
SNAP SIG Version 10.0

3.1 Previously reported SNAP results

Previously reported results are outlined above. In brief, all trial summaries, estimands and pre-specified subgroups are reported for the following interventions:

- Adult, PSSA, (flu)cloxacillin
- Adult, PSSA, penicillin
- Paediatric, PSSA, penicillin
- Adult, MSSA, (flu)cloxacillin
- Adult, MSSA, cefazolin

With the except of estimands that involve data linkage and subgroups *blaZ, (flu)cloxacillin inoculum effect, cefazolin inoculum effect, type A beta-lactamase subgroup.*

3.2 Reason for reporting

The DSMC on 10 July 2025 recommended ceasing recruitment to the adjunctive domain due to the threshold for futility [of superiority] being reached. Recruitment was ceased across all sites on 16 July 2025. The total number of adult and paediatric randomisations revealed for the adjunctive domain was 3,934 and 187, respectively.

3.3 Eligible participants and data extraction

All SNAP participants who were recruited to the platform (i.e. had randomisations generated but not necessarily revealed) on or before 16 July 2025 (site local date and time) are eligible for this report. Data cleaning and consistency checks relevant to this report will be performed prior to the data extraction, which is expected to occur in January 2026. Data will be provided to the Analytic Team, although not all participants and data items will be required for the report; the Analytic Team is responsible for the selection of eligible participants and data items for the report.

3.4 Maintaining trial integrity

3.4.1 CONSORT flowchart and baseline summaries

A CONSORT flowchart will be produced that documents the total number of participants in each domain that contribute to the reported analyses. The total number of participants allocated to each intervention will only be provided for:

- Adjunctive control arm (no clindamycin) **adult subgroup**

- Adjunctive clindamycin arm **adult subgroup**
- Adjunctive control arm (no clindamycin) **paediatric subgroup**
- Adjunctive clindamycin arm **paediatric subgroup**

The number of treatment allocations for previously reported domains/interventions may be summarised under baseline characteristics: these include adult-PSSA (flu)cloxacillin, adult-PSSA penicillin, paediatric-PSSA penicillin, adult-MSSA (flu)cloxacillin, adult-MSSA cefazolin. No further recruitment or randomisation revealed totals will be reported for any other interventions or domains. Adult participants with PSSA or MSSA infections who enrolled to the SNAP platform after the Backbone domain for PSSA and MSSA silos had ceased recruitment are recorded as ineligible for the backbone domain.

Baseline characteristics will be summarised and reported only for the adjunctive interventions and subgroups defined above. In the baseline table, the previously reported Backbone domain interventions will be summarised as frequency (%) separately for each adjunctive domain intervention, including the frequency (%) of those participants not eligible for the backbone domain randomisation reveal (i.e. a combination of those that do not meet the backbone domain-specific criteria and those recruited after recruitment has ceased).

3.4.2 Reporting descriptive summaries of the endpoints

The report will include subgroup-specific descriptive summaries of trial endpoints by revealed Adjunctive domain interventions. The following subgroup-intervention summaries will be included in the report, to maintain trial integrity:

- Adult, control (no clindamycin)
- Adult, clindamycin
- Paediatric, control (no clindamycin)
- Paediatric, clindamycin

For other subgroup-domain-silo combinations where the estimands have previously been reported, no further summaries will be reported on the accumulated data.

3.4.3 Reporting statistical model parameters for the estimands

The report will include summaries of the subgroup-specific posterior distributions for the revealed Adjunctive domain intervention compared to control. **Only** the posterior distributions for the statistical model parameters detailed below will be included in the report, to maintain trial integrity (priority results are highlighted in red).

Model parameters previously reported will not be reported again on the accumulated data.

Core estimands

Estimand	Adult-Adjunctive	Paediatric-Adjunctive
1	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
2	see estimand B.1	see estimand B.1
3	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
4	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
5	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
6	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
7	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
8	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
9	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
10	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
11	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
12	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
13	see estimand B.7	see estimand B.7
14	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
15	see estimand B.8	see estimand B.8
16	see estimand B.9	see estimand B.9
17 #	no analysis	no analysis
18 #	no analysis	no analysis

: No statistical analysis defined.

Domain-specific adjunctive estimands

Estimand	Adult-Adjunctive	Paediatric-Adjunctive
B.1	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.2	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.3	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.4	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.5	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.6	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.7	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.8	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$
B.9	$\beta_{Adult,d_{22}}$	$\beta_{Paed,d_{22}}$

PRE-SPECIFIED SUBGROUPS

1. Paediatric subgroup

Estimand	Adult	Paediatric
14.P	—	$\beta_{Paed,d_{22}}$
15.P	—	see estimand B.8
16.P	—	$\beta_{Paed,d_{22}}$
P.1	—	$\beta_{Paed,d_{22}}$

2. PWID

Data linkage is not available at this point in time, therefore, it is not possible to perform the analysis for estimand PWID.2.

Estimand	Adult-PWID	Adult-nonPWID	Paediatric
1	$\beta_{Adult-PWID,d_{22}}$	$\beta_{Adult-nonPWID,d_{22}}$	—
PWID.1	$\beta_{Adult-PWID,d_{22}}$	$\beta_{Adult-nonPWID,d_{22}}$	—
PWID.2	—	—	—

3. Clindamycin resistance

Data will be pooled across adult and paediatric subgroups. Statistical model will collapse adult

and paediatric strata, but is adjusted for age group.

Estimand	No resistance	Inducible resistance	Constitutive resistance
1	$\beta_{NoRes,d_{22}}$	$\beta_{IndRes,d_{22}}$	$\beta_{ConRes,d_{22}}$

4. Severe disease phenotype

Data will be pooled across adult and paediatric subgroups. Statistical model will collapse adult and paediatric strata, but is adjusted for age group.

Estimand	ICU/HDU admission at entry	No ICU/HDU admission at entry
1	$\beta_{ICU,d_{22}}$	$\beta_{NoICU,d_{22}}$

5. Panton valentine leucocidin (PVL) positive isolate

Data will be pooled across adult and paediatric subgroups. Statistical model will collapse adult and paediatric strata, but is adjusted for age group.

Estimand	PVL positive isolate	PVL negative isolate
1	$\beta_{PVLpos,d_{22}}$	$\beta_{PVLneg,d_{22}}$

6. Antibiotic susceptibility silo

Data will be pooled across adult and paediatric subgroups. Statistical model will collapse adult and paediatric strata, but is adjusted for age group. Note that this subgroup analysis was not specified in the core protocol or appendices.

Estimand	MSSA	PSSA	MRSA
1	$\beta_{MSSA,d_{22}}$	$\beta_{PSSA,d_{22}}$	$\beta_{MRSA,d_{22}}$

7. Pregnancy

For the primary estimand, separate summaries (frequency (%)) for pregnant and non-pregnant subgroups (females aged 13-59 years) by adjunctive intervention arm.

8. Ethnicity

Reported for NZ ethnicity only.

Estimand	Adult-Maori	Adult-SPacI	Adult-othNZ	Adult-ntNZ	Paediatric
1	$\beta_{A-Mao,d_{22}}$	$\beta_{A-SPI,d_{22}}$	$\beta_{A-oNZ,d_{22}}$	$\beta_{A-ntNZ,d_{22}}$	$\beta_{Paed,d_{22}}$

3.4.4 Reporting SAR/SAE data

SAR are recorded at all SNAP sites and are a priority result. The report will include **selected** subgroup-specific summaries of SAR that are either definitely, probably or possibly related to one of the revealed adjunctive domain interventions, irrespective of whether the same SAR is also attributed to another revealed intervention in another domain. **Only** the following subgroup-silo-intervention summaries will be included in the report, to maintain trial integrity:

- Adult, control (no clindamycin)
- Adult, clindamycin
- Paediatric, control (no clindamycin)
- Paediatric, clindamycin

The report will not include information nor summaries of SAE as these are only recorded and reported in selected countries for regulatory purposes. Details of SAE are provided to the DSMC in open and closed DSMC reports.

3.5 Documents provided to analytic team

The following documents will be provided to the Analytic Team where required:

- SNAP Adjunctive Domain Statistical Analysis Plan (SAP) Version 1.0
- SNAP Derived Variables (SDV) Version 2.0
- Additional data and documentation as required