Selective Antibiotics when symptoms develop versus Universal antibiotic therapy for preterm Neonates At-risk of early-onset sepsis: a multicentric, randomized, controlled, non-inferiority trial (the SAUNA trial)

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Statistical analysis plan

Primary outcome measures

Attribute	Primary noninferiority outcome	Co-primary superiority outcome
Population	Eligible randomized neonates who meet the prespecified PP definition and have an assessable 7-day outcome.	All randomized neonates, analyzed as assigned (ITT).
Treatment	Selective policy versus universal policy under sufficient adherence.	Assignment to selective versus universal policy, regardless of deviations.
Variable	Composite of all-cause death, adjudicated culture-positive sepsis, or adjudicated severe sepsis within 168 hours after randomization.	Composite of all-cause mortality within 168 hours after randomization, or cumulative intravenous antibiotic exposure exceeding 48 hours during those same 168 hours, summed across all antibiotic courses.
Intercurrent events	Major policy deviations/crossover handled by exclusion from PP; rescue therapy after a valid trigger is compatible with the policy.	Treatment deviations and rescue antibiotics handled using a treatment-policy strategy; death incorporated into the composite.
Summary measure	Absolute risk difference (risk in selective minus universal group) Risk ratio supportive.	Absolute risk difference (risk in selective minus universal group) Risk ratio supportive.

Analysis populations

Randomized/ITT population

The ITT population includes every randomized neonate, analyzed in the group assigned by the allocation envelope, irrespective of eligibility errors, treatment received, subsequent withdrawal from treatment, transfer, or protocol deviations. A participant randomized in the wrong gestational-age stratum remains in ITT. Participants randomized in error but with no consent will not be analyzed unless ethics approval and applicable consent provisions permit use; any such case will be documented before unblinding.

Per-protocol population

The PP population is defined without reference to outcome value or treatment effect. It contains randomized participants who satisfy all of the following:

- No major eligibility violation discovered after randomization.
- Randomized using the correct centre-by-gestational-age stratum and correct sequential envelope.
- An assessable 7-day primary noninferiority outcome.
- No crossover to the opposite initial policy.
- Universal arm: first intravenous antibiotic administered within a margin of up to 2 hours after randomization.
- Selective arm: no antibiotic initiated without a valid protocol treatment trigger. When a trigger occurs, the first dose is administered within 2 hours of the documented trigger or availability of the relevant positive result.
- After initiation, antibiotics are not stopped before a sterile culture report is available unless a documented overriding safety reason exists.
- Subsequent management is broadly consistent with the algorithm. A treating-team choice of 5-7 days for sterile-culture treatment or 7-14 days for culture-positive treatment is permissible and is not itself a PP violation.

Borderline cases will be resolved by written consensus using Appendix A.

Safety populations

The primary safety summary will use the safety-as-treated population: participants receiving any intravenous antibiotic within 2 hours after randomization are classified as early-antibiotic exposed; all others are classified as no-early-antibiotic exposure. A secondary safety summary will be as randomized. Valid selective-arm trigger treatment occurring within 2 hours of randomization will be described separately to avoid misinterpreting clinically indicated treatment as nonadherence.

Adjudication population

The adjudication population consists of all randomized participants with any "episode of interest": any sepsis-related investigation, any antibiotic start, any positive baseline culture, or any death. Adjudication completeness and reasons for non-adjudication will be summarized by randomized group before primary outcome derivation.

Population hierarchy in outputs

Analysis	Primary population	Supportive population
Noninferiority composite	PP	ITT
Superiority composite	ITT	PP and as-treated
Secondary efficacy outcomes	ITT	PP where clinically relevant
AEs/SAEs	Safety as treated	As randomized

General analysis conventions

Timing origin and windows

Time zero is the recorded randomization date-time. Unless otherwise specified, an event is in a window when its onset/sample-collection/death time is after randomization and at or before the upper boundary. Exact boundary events are included. The 72-hour and 7-day windows end at 72 and 168 elapsed hours, respectively. Baseline non-contaminant blood-culture positivity is an exception: it is counted as present at time zero because baseline culture is mandated at enrolment and is an explicit trial outcome even if the specimen was collected shortly before envelope opening.

Descriptive summaries

Categorical variables will be reported as n/N (%), including the denominator when it differs from the analysis-set total. Continuous variables will be reported as mean (SD) when approximately symmetric and as median (Q1, Q3) when skewed. Baseline characteristics will not be subjected to null-hypothesis significance tests. Standardized differences may be shown as descriptive indicators of chance imbalance.

Effect estimates and confidence intervals

Binary outcomes: risk difference (selective minus universal) and risk ratio with two-sided 95% CIs.
Primary RD CI: an unconditional score/Newcombe-type interval.
Risk ratio: log-binomial model; if it does not converge, Poisson regression with robust standard errors.
Continuous outcomes: mean difference with 95% CI when a mean is clinically interpretable; otherwise Hodges-Lehmann location shift and Mann-Whitney U p value, plus medians and quartiles.
Counts: incidence rate ratio from negative-binomial regression with log follow-up time as offset when overdispersion is present; otherwise Poisson regression with robust standard errors.

Significance, rounding, and small cells

Except for the gated confirmatory tests, all p values are two-sided and exploratory at 0.05. Effect estimates and CIs will take priority over p values. P values will be reported to three decimals; values below 0.001 as <0.001. Percentages will generally use one decimal, effect estimates two decimals, and p values will not be rounded to 0.000. Exact methods will be used for sparse 2x2 tables where appropriate. No continuity correction will be applied to the primary CI.

Centre and stratification variables

Unadjusted analyses will provide the principal clinical contrast. Adjusted/supportive models will include gestational-age stratum and centre as fixed categorical effects. The randomization stratum actually used will be used in the principal adjusted ITT analysis; actual gestational age will be used in a sensitivity analysis for wrong-stratum cases. Centres with no events in one or both groups may cause instability; if so, centre will be included using a parsimonious stratified or penalized sensitivity model, and the unadjusted result will remain primary.

Analysis software

All planned analyses will be performed in IBM SPSS Statistics version 27 using locked, version-controlled syntax. Any analysis requiring another validated package will be identified, independently reproduced, and documented; SPSS remains the primary analysis platform.

Outcome and variable derivations

General episode rules

Up to four sepsis-like episodes will be recorded during the total period of observation until end of hospital stay or day 30 of life, whichever is later. For binary outcomes, the value will be 1 if at least one qualifying episode occurs in the stated window. Multiple qualifying components or episodes will not increase the binary value. E.g., if there happen to be 2 episodes of adjudicated culture-positive sepsis within the 1st 7 days after randomization, they will count as 1 for the primary outcome.
For episode counts, separate episodes will be counted as recorded and adjudicated. Episode onset will be the recorded episode date-time; culture-positive episode timing will be based on specimen collection, not report date. Changes of antibiotic within one clinical episode will not create a new antibiotic course.

Blinded adjudication variables

Raw clinical and laboratory data will not override a completed adjudication, except to implement the guideline's explicit baseline-culture rule or to correct a documented data-entry error through a formal query before lock.

Culture-positive sepsis (will be adjudicated by an adjudicator blinded to the identifying details and group of randomization of the participant)

A baseline blood culture growing a potential pathogen [other than CoNS (if it meets the NeoKISS criteria for contaminant) or a listed contaminant] will be considered culture-positive sepsis. A later blood or CSF culture growing a potential pathogen requires at least one qualifying clinical sign and no localized infection other than meningitis or pneumonia to be considered culture-positive sepsis. Later CoNS growth requires signs from at least two clinical categories and at least one qualifying laboratory marker (CRP >20 mg/L or PCT >0.5 ng/mL; I:T ratio >0.2 if available; TLC <5000/microlitre without maternal hypertension; or platelets <100,000/microlitre). Baseline asymptomatic CoNS and listed contaminants are classified as no sepsis.

Clinical, probable, and severe sepsis

Clinical sepsis requires signs from at least two NeoKISS clinical categories, treatment for at least 5 days or documented intention to treat for at least 5 days when death/LAMA/transfer prevents completion, no pathogen, no localized infection other than meningitis or pneumonia, and no probable-sepsis laboratory criterion. ***Probable sepsis*** meets the clinical-sepsis clinical/treatment/localization conditions plus at least one laboratory criterion in the adjudication

guideline. ***Severe sepsis*** meets the clinical-sepsis conditions, has either a positive blood culture or qualifying laboratory evidence, and has at least one severity criterion: invasive mechanical ventilation; inotrope above the specified threshold; exchange transfusion; platelet concentrate or fresh-frozen plasma; or meningitis.

Primary noninferiority composite

The composite primary noninferiority outcome is present if any of the following occurs by 168 hours after randomization: (a) all-cause mortality; (b) at least one adjudicated culture-positive sepsis episode; or (c) at least one adjudicated severe sepsis episode. The composite is absent when complete follow-up and adjudication establishes that none occurred. If any component is known positive, the composite is present even when another component is missing. If no component is positive but at least one necessary component cannot be determined, the composite is missing. The component definition is non-mutually exclusive: severe sepsis may also be culture positive.

Co-primary superiority composite

The composite coprimary superiority outcome is: "all-cause mortality within 7 days (i.e. 168 hours) after randomization, or cumulative intravenous antibiotic exposure exceeding 48 hours during those same 168 hours, summed across all antibiotic courses."

Duration will be derived from recorded date-times. Death is included to avoid classifying early death as a favorable antibiotic-exposure outcome. Its inclusion in both primary composites is acceptable: in the noninferiority composite it protects safety; in the superiority composite it prevents a competing terminal event from appearing as reduced antibiotic exposure.

Transfer, LAMA, and withdrawal for the antibiotic composite

If death is known within 7 days, the composite is present. If cumulative antibiotic courses exceeding 48 hours is documented, it is present regardless of later transfer or withdrawal. If neither is documented and complete records through 7 days establish that no qualifying course occurred, it is absent. Otherwise, it is missing. Participants with missing co-primary outcomes remain in ITT and are handled by multiple imputation and sensitivity analyses; they are excluded from PP by definition when the 7-day outcome is unassessable.

Secondary outcomes

Outcome	Operational derivation	Window(s)
Primary composite components	All-cause death; >=1 culture-positive sepsis; >=1 severe sepsis, each binary.	72 h after randomization, 7 d after randomization, hospital stay*, and day 30 as specified
NEC	Modified Bell stage II or III	Hospital stay; day 30
Sepsis-related mortality	Death with adjudicator adjudicating it as related to sepsis	72 h after randomization, 7 d after randomization, hospital stay, day 30
Clinical sepsis	>=1 episode adjudicated to be clinical sepsis	72 h after randomization, 7 d after randomization, hospital stay, day 30
Probable sepsis	>=1 episode adjudicated to be probable sepsis	72 h after randomization and 7 d after randomization
Asymptomatic proven EONS	Asymptomatic baseline non-contaminant pathogen-positive blood culture.	72 h after randomization

Sepsis work-up	Any CBC, CRP, PCT, or blood culture performed for a suspected episode.	72 h after randomization, 7 d after randomization, hospital stay, day 30
Any antibiotic	At least one administered systemic IV antibiotic dose.	72 h after randomization, 7 d after randomization, hospital stay
Cumulative antibiotic exposure	Sum of covered days of antibiotics across all courses. Days will be calculated from calendar dates rather than hours, because exact time of start and stop of antibiotics will be recorded only up to day 7; thereafter it will be recorded only as dates.	72 h after randomization, 7 d after randomization, hospital stay, day 30
Hospitalization duration	Elapsed days from birth/admission to final discharge; capped at 100 days. Death, LAMA, and transfer are not treated as routine discharge in time-to-discharge analyses.	Hospital
Healthcare-associated infection	Culture-positive sepsis with specimen collected after 72 h after randomization OR any culture-positive episode after a sterile baseline culture.	Hospital stay
AEs/SAEs	Recorded event, maximum NAESS grade, seriousness, action, outcome, and WHO-UMC causality.	Randomization to day 30 or hospital stay, later of the two

*Hospital stay will be capped at a maximum of 100 days

Day 30 and hospital windows

Day-30 outcomes will be assessed through completion of 30 days of chronological age, using the recorded date of birth where available. Hospital-stay outcomes include documented inpatient events through final hospital exit or 100 days after randomization, whichever occurs first. For transferred neonates, records from the receiving hospital are included when obtained. Outcomes after LAMA/transfer are missing if adequate records cannot be obtained. Death is never censored merely because it occurs after transfer when reliable follow-up establishes it.

Primary noninferiority analysis

Primary analysis

In the PP population, the event proportion in each randomized group risk difference will be estimated. The two-sided 95% unconditional score/Newcombe-type CI will be calculated. Noninferiority is established if the upper CI limit is <0.07. The risk ratio with 95% CI will be supportive and does not determine noninferiority.

Supportive ITT analysis

The same unadjusted RD and CI will be estimated in ITT using the missing-data strategy mentioned later. The PP result is the formal decision analysis specified by the protocol. The ITT result will be interpreted for consistency, recognizing that nonadherence may bias an ITT noninferiority comparison toward no difference. Any material discordance between PP and ITT will be explicitly discussed; the ITT result does not replace the PP decision criterion.

Adjusted supportive analysis

A multivariable logistic regression will include randomized group, gestational-age stratum, centre, maternal intrapartum-antibiotic duration (0 to <4 versus >=4 hours), any transient symptoms before enrolment, CPAP at enrolment, 5-minute Apgar score (<7 versus >=7). All covariates are forced into the model; automated selection will not be used. Adjusted odds ratio and 95% CI will be reported.

Model-based standardized risks and an adjusted RD will be produced when estimable; this analysis is supportive and cannot override the unadjusted PP decision.
Collinearity will be assessed using eigenvalues/condition indices and variance-inflation factors. Sparse categorical levels will not be collapsed using outcome information. If separation occurs, penalized logistic regression or a prespecified reduced model retaining treatment and randomization strata will be used as sensitivity analysis and labeled accordingly.

Component and timing analyses

Each component will be displayed by group at 72 hours and 7 days, with RD and RR. A participant may appear in multiple component rows. Kaplan-Meier curves for time to first composite event may be shown descriptively, with baseline positive cultures assigned time zero. Because death is already a component, competing-risk methods are not needed for the composite; for nonfatal components, death before the component will be treated as a competing event in exploratory cumulative-incidence displays.

Gated co-primary superiority analysis

Gatekeeping rule

The co-primary superiority analysis becomes confirmatory only after noninferiority established. If the gate is not passed, the same estimate and CI will be reported as descriptive, and its nominal p value will be labeled nonconfirmatory.

Primary ITT analysis

In ITT, the composite event proportion, RD, RR, two-sided 95% CIs, and two-sided test of equality will be reported. Superiority of selective treatment is declared when the gate is open, $p<0.05$. The primary effect is the absolute percentage-point reduction of 50%; number needed to treat to prevent one death-or-prolonged-antibiotic composite event will be reported as $1/|RD|$ when RD is significantly below zero, with a CI obtained by inversion of the RD CI where interpretable.

Supportive analyses

PP analysis using the same definition. As-treated analysis based on early antibiotic exposure. Separate display of death and cumulative antibiotic courses >48 hours; these components are not separately confirmatory.

Secondary and safety analyses

Binary secondary outcomes

Binary outcomes will be analyzed in ITT using RD and RR with 95% CIs. Chi-square or Fisher exact p values may accompany the estimates. No formal adjustment for multiplicity will be made for secondary outcomes, their individual components, repeated assessment windows, subgroup analyses, or sensitivity analyses. These analyses will be considered supportive or exploratory. Effect estimates will be presented with two-sided 95% confidence intervals and, where appropriate, nominal two-sided p-values. The confidence intervals and p-values for these analyses will not provide simultaneous family-wise error control and will not be used to make definitive confirmatory claims.

Antibiotic exposure

Any-antibiotic exposure and course-duration thresholds will be summarized as binary outcomes. Cumulative therapy days will include zero for participants receiving no antibiotics and will be summarized by mean (SD) and median (Q1, Q3). Between-group comparisons will report mean difference and a bootstrap 95% CI plus a Mann-Whitney U comparison. Agent-days, number of courses, time from valid trigger to first dose, and premature discontinuation before sterile culture will be descriptive. Antibiotics administered for non-sepsis indications will be included in total exposure and categorized by indication when available.

Hospitalization

Length of hospitalization is expected to be skewed. Median and quartiles, Hodges-Lehmann shift, and Mann-Whitney U p value will be reported. Death, transfer, and LAMA can be a competing variable for

ordinary discharge; therefore, time to discharge alive will additionally be described using cumulative incidence with death as a competing event.

Recurrent sepsis and healthcare-associated infection

The proportion with at least one HAI will be analyzed as binary. Episode counts per participant will be summarized and compared using negative-binomial regression with follow-up time as offset if adequate events exist. Organism and resistance summaries will be descriptive. Analyses by Gram-positive/Gram-negative organism are conditioned on post-randomization infection and are exploratory.

Adverse events and serious adverse events

AEs and SAEs will be summarized by safety-as-treated group and as randomized. Outputs will include participants with >=1 event, number and name of events (as per NAESS), maximum NAESS grade, seriousness criterion, suspected relationship, discontinuation/modification, outcome. Deaths are shown both in mortality outcomes and SAE summaries without making these categories mutually exclusive. Safety testing will be descriptive; rare-event CIs will use exact methods.

Covariate-adjusted and subgroup analyses

Prespecified adjusted covariates

Covariate	**Coding**
Treatment group	Selective vs universal
Gestational-age stratum	$26^{0/7}$ to $31^{6/7}$ vs $32^{0/7}$ to $34^{6/7}$ weeks
Centre	Nine fixed categorical levels
Maternal intrapartum antibiotics	0 to <4 h vs >=4 h before delivery
Transient symptoms before enrolment	Any vs none
CPAP at enrolment	Yes vs no
5-minute Apgar	<7 vs >=7

Subgroups

Subgroup analyses are exploratory and will use treatment-by-subgroup interaction terms. Subgroup-specific RDs/RRs and 95% CIs will be shown in a forest plot. Interaction $p<0.01$ is a cautious signal, not proof of heterogeneity. No subgroup will redefine the primary conclusion.

Subgroup	**Status and interpretation**
Gestational-age stratum	Prespecified, pre-randomization; principal subgroup.
Centre	Prespecified; shown only where events and both groups permit estimation.
Gram-positive vs Gram-negative infection	Prespecified but post-randomization and restricted to infected participants; descriptive/exploratory, not a causal effect modifier.
Radiographic pneumonia present vs absent	Prespecified but post-randomization; descriptive/exploratory.

Missing data and sensitivity analyses

Extent and reasons

Missingness will be tabulated by group for outcomes and covariates, with timing and reason: withdrawal of consent, LAMA, transfer, lost contact, incomplete adjudication, source unavailable, test not performed, or technical/data error. Patterns of missingness will be reviewed blinded to treatment labels before locking.

PP primary analysis

The PP primary analysis is complete case by definition because missing 7-day outcome is a PP exclusion. The number and percentage excluded for missing outcome will be displayed by group. No outcome imputation will be used to create PP membership.

ITT multiple imputation

For ITT primary and co-primary analyses, multiple imputation by fully conditional specification will be used missingness is sufficient to affect inference. Fifty imputed datasets will be created, increasing the number if the fraction of missing information makes Monte Carlo error material. The imputation model will include randomized group, the three noninferiority components, co-primary components, centre, gestational-age stratum, prespecified adjusted covariates, baseline culture status, treatment received/adherence indicators, hospital outcome, follow-up duration, and predictors/reasons for missingness. Binary variables will use logistic imputation and continuous variables predictive mean matching or an appropriate transformed model. Imputation will be performed separately by randomized group if convergence and sample size permit; otherwise treatment and relevant interactions will be included. Rubin's rules will pool model parameters; pooled risks/RDs will use validated combination procedures documented in the syntax.

Primary sensitivity analyses

Sensitivity analysis	**Rule**
Complete-case ITT	Analyze participants with observed composite status.
Conservative noninferiority worst-case scenario	Missing selective outcomes = event; missing universal outcomes = no event.
Noninferiority best case scenario	Missing selective = no event; missing universal = event.
Co-primary conservative case	Missing selective = event and missing universal = no event, plus the reverse case.
Wrong-stratum ITT	Adjusted model using actual gestational-age category instead of envelope stratum.

Missing secondary outcomes

Secondary outcomes will generally use available cases with explicit denominators. Multiple imputation may be used for a key secondary outcome when missingness exceeds 5% or differs materially by group, but such analyses will be labeled supportive. No imputation will be used for AE occurrence in the absence of adequate follow-up; observed safety follow-up time will be shown.

Interim monitoring

Two interim analyses are planned at approximately 33% and 66% of the target sample or expected primary events, whichever occurs first. Information fractions about 1/3, 2/3 and 1 include the final look.

Independence and information control

An independent statistician will prepare closed unblinded reports for the DSMB. Investigators, participating sites, sponsor/funder, outcome adjudicator, and final blinded statistician will not receive comparative interim results. The DSMB may recommend continuation, modification, or termination after considering statistical evidence, deaths, SAEs, data quality, recruitment, external evidence, and feasibility.

Statistical boundaries

Analysis	**Planned total patients (per arm)**	**Information fraction**	**Noninferiority Z boundary**	**Noninferiority one-sided P threshold**	**Harm Z boundary***	**Harm one-sided P threshold***
First interim	500 (250)	1/3	≥3.7103	≤0.0001035	≥2.2895	≤0.0110258

Second interim	1,000 (500)	2/3	≥2.5114	≤0.0060122	≥2.2895	≤0.0110258
Final	1,500 (750)	1	≥1.9930	≤0.0231281	≥2.2895	≤0.0110258

Sample-size re-estimation

Sample-size may be re-estimated at the first interim review. Any blinded re-estimation based on pooled nuisance quantities will preserve the 7-percentage-point margin and the type-I error, and will be fully documented.

Data review, quality control, and reproducibility

Blinded data review

Before lock, a blinded review will reconcile screening, consent, eligibility, randomization, treatment start/stop, culture dates and results, episode dates, adjudication completeness, death, transfer/LAMA, and follow-up. Randomized groups will be masked as A/B. No outcome-driven recoding, exclusion, covariate transformation, subgroup creation, or model choice will be made after treatment identity is known.

Derived-variable validation

A programming specification will list each source field, permissible code, date-time conversion, derivation, missing-value rule, and output. Primary/co-primary variables will be independently derived twice or checked against a second program. A blinded 10% sample and every primary event will be traced to CRF/adjudication source.

Database lock and audit trail

The final analysis dataset will be read-only, de-identified, and versioned. The data dictionary, query log, adjudication log, PP-deviation decisions, randomization reconciliation, frozen SAP, SPSS syntax, output log, and final tables will be archived. Any correction after lock requires a documented unlock, reason, approval, relock, and rerun of affected outputs.

Presentation of results

Participant flow

A CONSORT flow diagram adapted for noninferiority trials will show screened, excluded with reasons, randomized, allocated, received assigned initial policy, crossovers, follow-up status, missing primary outcomes, PP exclusions by reason, and numbers analyzed in ITT, PP, and safety populations.

Main result table

Outcome/population	**Selective n/N (%)**	**Universal n/N (%)**	**RD (95% CI)**	**RR (95% CI)**
Primary NI composite - PP				
Primary NI composite - ITT				
Death or cumulative antibiotic courses >48 h composite - ITT				
Co-primary - PP				

Interpretation rules

Result	**Permitted conclusion**
NI passes; (gated) superiority passes in favorable direction	Selective policy is noninferior for safety and superior for the death/prolonged-antibiotic composite.
NI passes; (gated) superiority does not pass	Selective policy is noninferior; superiority for the stewardship composite is not established.
NI fails	Noninferiority is not established. Superiority result is descriptive

	only, even if nominally significant.
NI estimate suggests benefit but upper CI >=7%	Do not claim noninferiority; uncertainty includes the prespecified unacceptable harm margin.

Appendix A. Major protocol deviations and PP classification

Domain	Major deviation (exclude from PP)	Not automatically major
Eligibility	Any protocol exclusion present at randomization; mandatory inclusion criterion absent; no valid consent.	Minor documentation error with eligibility confirmed from source.
Stratum/allocation	Wrong centre or gestational-age stratum; wrong/nonsequential envelope; allocation not verifiable.	Clerical transcription corrected against envelope log.
Universal initiation	No antibiotic or first dose >2 h after randomization without documented overriding reason.	Drug choice/dose changed according to local policy or susceptibility.
Selective initiation	Antibiotic started without valid trigger; valid trigger not treated within 2 h without documented overriding reason.	Treatment started after a valid trigger; drug changes according to clinical need.
Course continuation	Stopped before sterile culture report without documented adverse reaction/overriding safety reason.	Treating-team choice of 5-7 d sterile-culture or 7-14 d culture-positive course.
Crossover	Initial policy changed to the opposite policy without a valid trigger/safety justification.	Clinically mandated rescue treatment compatible with assigned policy.
Outcome	7-day primary outcome not assessable; required adjudication unavailable after all queries.	A component missing but composite known positive from another component.