S3R RANDOMISATION SERVICE DEFINITION

TRIAL DECK BY GLOBAL INITIATIVE

1. Service overview

Trial Deck S3R Randomisation is a cloud based service for secure, auditable participant allocation in clinical research. It enables study teams to configure randomisation schemes that are reproducible for audit and statistical review, without enabling allocation predictability. The service supports allocation concealment, role based reveals where protocol permits, dry run simulation, and contingency workflows for emergency or offline allocation.

The service is provided as a configurable Software as a Service offering. Where buyers require bespoke statistical development beyond the standard configuration options described in this document, this can be provided under Global Initiative's Lot 3 Cloud Support services and is subject to a separate call off contract.

2. Service scope

The service provides randomisation design configuration, execution, audit, export, and controlled reveal functionality. It can be used as a standalone randomisation service or integrated with other Trial Deck modules such as CTMS, EDC, eConsent, and digital interventions to trigger allocations as part of the participant journey.

3. Intended users & use cases

Trial Deck S3R Randomisation is suited to academic, NHS, and publicly funded research studies requiring traceable, inspection ready allocation. Typical use cases include single and multi site randomised trials, decentralised recruitment, staged randomisation points, and studies requiring role controlled allocation concealment or emergency allocation procedures.

The service is designed for use by clinical research teams and governance functions, including:

- Trial managers
- Data managers
- Researchers and investigators

- Statisticians
- Study coordinators
- Clinical operations and governance staff
- Sponsor representatives requiring oversight Regulatory and compliance teams

4. Key features

S3R is built to translate a trial statistician's randomisation specification into a controlled, testable, auditable implementation. It combines seeded reproducibility, allocation concealment, and role controlled reveal rules with configuration, simulation, and contingency tooling, so randomisation can be run consistently across sites, recruitment patterns, and study phases.

- Seeded randomisation with frozen configuration to support reproducible audit and review
- Configurable methods including simple, block, stratified, and covariate minimisation approaches
- Allocation concealment with role based visibility controls and protocol aligned reveal rules
- Dry run simulation using synthetic participants and test seeds to validate behaviour before go live
- Support for staged randomisation designs including cross over and N of 1 patterns where required
- Contingency workflows including emergency allocation and offline envelope generation where configured
- Full audit trails for configuration, testing, allocation, reveal, and emergency actions
- Versioning of randomisation specifications to support controlled change management Multi-lingual capabilities for Participants, Trial Deck can also support multiple time zones

5. Key benefits

S3R reduces bias risk and operational fragility by removing ad hoc allocation processes and replacing them with a governed randomisation engine that can

be tested, repeated, and reviewed. Study teams gain confidence that the implemented approach matches the protocol, behaves as expected under real recruitment conditions, and remains fully traceable from specification through every allocation decision.

- Enable reproducibility without predictability through frozen, auditable seeds and versioned specifications
- Reduce operational risk by embedding allocation concealment and role controlled reveals into study workflows
- Validate randomisation behaviour before launch using repeatable dry runs and synthetic participants
- Maintain allocation integrity across multi site and asynchronous recruitment
- Provide complete audit traceability from configured specification through every allocation decision
- Support efficient statistical review and governance through exportable, reproducible configuration packages
- Reduce bias risk by preventing ad hoc allocation and preserving a complete, attributable record of actions
- Support trial close out and inspection activities with structured exports suitable for long term retention
- Support long term retention and regulatory inspection of consent evidence

6. **Service delivery model & Accessibility**

Trial Deck S3R Randomisation is delivered as a fully managed SaaS application accessed via a web browser. No local installation is required. Hosting, maintenance, monitoring, security patching, and backups are managed by the supplier using UK based cloud infrastructure.

Researcher facing interfaces are designed for desktop and tablet use. Participant facing components are mobile first where applicable. The service interfaces are designed to meet WCAG 2.2 AA accessibility standards, with ongoing testing and remediation as part of product development.

7. **Security, compliance, and electronic records]**

Trial Deck S3R Randomisation supports delivery aligned to Good Clinical Practice, with allocation concealment, reproducible configuration, and complete auditability. Role based controls ensure only authorised users can configure methods, trigger allocation, or reveal treatment, preserving blinding and minimising bias.

Randomisation designs are defined using controlled, protocol aligned settings, including stratification, blocks, and minimisation. Reproducibility is achieved through frozen, versioned seeds and specifications, allowing deterministic recovery and statistical review without making future allocations predictable. A synthetic participant testing suite supports dry run simulation before go live, including sparse strata and edge case behaviour.

All configuration, allocation, and reveal actions are timestamped and attributable, with immutable audit logging supporting ALCOA++ principles. Emergency offline workflows can be generated in advance and reconciled later, maintaining traceability across contingency scenarios.

Data in transit is protected using TLS 1.2 or above. Data at rest is encrypted using controls provided by the underlying cloud infrastructure. Access to production systems and encryption keys is restricted to authorised personnel. Global Initiative operates an ISO 27001 and ISO 9001 certified management system and is NHS DSPT and Cyber Essentials compliant.

8. Customisation

The service supports configuration without software development. Study teams can configure randomisation methods, stratification factors, covariates and weights, allocation ratios, block settings, concealment rules, reveal controls, and contingency options such as emergency or offline allocation. Configuration is carried out through a secure browser based interface by authorised users. Optional supplier support is available for complex configurations.

Where study designs require novel or highly complex approaches, bespoke randomisation algorithms can be implemented by the supplier in collaboration with the customer's statistician under a separate consultancy arrangement.

9. Testing and validation

Trial Deck S3R Randomisation is developed and operated under a controlled software lifecycle aligned with ISO 9001 and ISO 27001 principles. The service undergoes structured testing to support reliability, security, and inspection readiness prior to release.

In addition to standard unit, integration, regression, and security testing, Trial Deck provides a dedicated randomisation testing suite that allows study

teams to validate randomisation behaviour using synthetic participants. This enables users to run repeatable dry runs end to end, including stratification, blocks, minimisation rules, allocation ratios, concealment settings, reveal permissions, and staged or multi point randomisation, without exposing real participant data.

Synthetic participant testing allows teams to explore expected allocation behaviour, sparse strata edge cases, operational workflows, role based access controls, audit behaviour, and downstream integrations before a study goes live. Outputs are visible to authorised users and support controlled review and sign off by the study statistician and sponsor where required.

Annual penetration testing is performed, alongside continuous vulnerability monitoring and controlled release pipelines with versioning and rollback. Where required, Global Initiative can support study specific validation activities, including configuration verification against the statistical specification, user acceptance testing support, and inspection focused documentation, provided as an optional service.

10. Security and compliance

The service is designed to support delivery in line with Good Clinical Practice principles. Controls including role based access, audit logging, and data integrity checks support ALCOA++ principles.

Data is protected using industry standard encryption controls. Data in transit is secured using TLS 1.2 or above. Data at rest is encrypted using strong encryption mechanisms provided by the underlying cloud infrastructure. Encryption key management and access controls are restricted to authorised personnel only. Controls support data minimisation, separation of participant and study datasets, and protocol-aligned access restrictions.

Global Initiative operates an ISO 27001 and ISO 9001 certified management system and is NHS DSPT compliant. Global Initiative carry out annual penetration tests.

11. Availability and service levels

A standard SLA is included within the annual licence fee, operating on a best efforts basis during UK business hours. An extended SLA is available at additional cost, providing enhanced response targets and a 99.9 percent uptime commitment. All SLAs are subject to the call off contract.

11.1 Uptime service level agreement

Uptime commitment

The extended SLA includes a target of 99.9 percent uptime for operational aspects of the service, measured over each three month cycle.

Definition of uptime

Uptime is defined as the percentage of total minutes in a three month cycle during which the service is fully operational and able to perform its intended functions under normal operating conditions.

Exclusions

The following are excluded from uptime calculations: scheduled maintenance notified in advance; emergency maintenance required to address critical issues; customer induced downtime including misconfiguration, unsupported software, or excessive demand; external network or third party service issues; force majeure events; and security related downtime required for threat response or emergency patching.

Best efforts

Global Initiative will use reasonable best efforts to achieve the stated uptime target. Factors outside the supplier's direct control may affect availability.

Service credits

The extended SLA does not include financial reimbursements, discounts, or incentives in the event of downtime. Service credits for hosting may be awarded at the supplier's discretion.

12. Onboarding and support

Trial Deck S3R is designed for study teams to configure and operate randomisation directly, using an interface that mirrors how randomisation is specified in protocols and statistical analysis plans.

Onboarding includes a structured setup process led by a delivery manager, with online training for trial managers and statisticians, supported by documentation and a service management portal for support requests. The onboarding process covers method selection, stratification factors and covariates, allocation ratios and block settings, concealment and reveal rules, emergency and offline procedures, and reproducibility controls including seed management and versioning.

Before go live, teams can use a dedicated testing area with synthetic participants to run dry runs, review allocation behaviour, check edge cases such as sparse strata, and confirm that results are reproducible across

repeated simulations. Outputs can be reviewed and signed off by the study statistician or sponsor as part of routine governance.

Support is provided via email or ticketing, with phone support available during UK business hours. Standard and extended SLAs apply as per the call off contract. Where required, Global Initiative can provide a technical fit for purpose statement confirming that the implemented configuration matches the supplied statistical specification. For bespoke or highly complex designs, we can work directly with the study statistician under a separate consultancy arrangement.

13. Data management and exit

Study teams can export randomisation records using a self-service export capability within the S3R module. Exports can include the full randomisation specification, allocation method, stratification factors, covariates and weights, allocation ratios, block settings, concealment and reveal rules, emergency and offline procedures, frozen seed values, version history, and complete audit trails. Where permitted by role and protocol, exports also include participant level allocation outputs with timestamps and status, clearly identifying any emergency or offline allocations.

Export packages are provided in open, commonly used formats suitable for archiving, inspection, and statistical review. Records preserve traceability, reproducibility, and provenance, supporting ALCOA++ principles and long term regulatory expectations.

At contract end, customers retain access for an agreed exit period to complete exports. Following successful data extraction, access to the S3R module is withdrawn and randomisation data is securely archived, retained, or destroyed in line with the agreed retention period and contractual arrangements. Optional services include bespoke export packs for inspection readiness, managed archiving support, extended access periods, and documented close out procedures where required.

14. Free self-service version

A time limited self-service version is available for evaluation. All studies, including evaluation ones, have the option to use the simple “coin-flip” randomisation algorithm for free.

15. Pricing model

Pricing is based on an annual licence per study, with optional add-ons for enhanced SLAs, additional support, and specialist services.

Where customers require bespoke functionality, novel integrations, or study-specific development beyond standard service configuration, these services are available separately under Cloud Support (Lot 3).

Full pricing details are provided in the G Cloud service listing.