CLINICAL TRIAL MANAGEMENT SYSTEM SERVICE DEFINITION

TRIAL DECK BY GLOBAL INITIATIVE

1. Service overview

Trial Deck CTMS is a cloud based clinical trial management system supporting the design, implementation, and management of clinical studies, including decentralised, digital, hybrid, and multi-site trials. The service provides a central operational platform for study teams to design and release a study protocol, coordinate activity, monitor progress, and maintain governance throughout the study lifecycle.

Trial Deck CTMS is designed for complex, regulated research environments, with a strong focus on governance, auditability, and operational oversight. It supports operational trial management functions including study setup, participant tracking, scheduling, oversight, and reporting. It focuses on operational management rather than statistical analysis or source data verification, and can incorporate EDC, digital intervention, and external systems where required while maintaining clear separation of responsibilities across study systems.

The service is delivered as a fully managed SaaS application accessed via a web browser, with UK based hosting, monitoring, security patching, and backups managed by the supplier. Participant access is provided through a mobile first interface designed to meet WCAG 2.2 AA

2. Service scope

The service supports operational trial management functions including study design & setup, participant tracking, scheduling, oversight, and reporting. It is intended for academic, NHS, and publicly funded research organisations and is delivered as a managed Software as a Service offering.

Trial Deck CTMS focuses on operational management rather than statistical analysis or source data verification. It incorporates Electronic Data Capture, Digital Intervention, and external systems where required, while maintaining a clear separation of responsibilities across study systems.

3. Case Study

1 Case study: GlobalMinds, international scale digital research programme

GlobalMinds is a large scale international research programme designed to recruit around 50,000 participants, with delivery spanning multiple organisations, jurisdictions, and operational partners. It is predominantly remote and digital by design, combining high volume participant recruitment with robust governance and oversight requirements.

The programme is complex in both delivery and data. It brings together digital screening and eligibility workflows, electronic consent, repeated longitudinal questionnaires, and permission based linkage to external health records. It also includes biological sample workflows, requiring coordination with specialist logistics and laboratory partners, and reliable tracking of sample collection and status at participant level.

At this scale, the volume and variety of data generated is substantial. The study must handle large numbers of participant events, scheduled activities, reminders, questionnaires, and support interactions, as well as maintaining a complete operational audit trail. It also requires clear separation of roles and responsibilities across sponsors, study teams, and external partners, while preserving confidentiality and ensuring access is appropriately controlled.

Trial Deck is used to provide the CTMS backbone for programme delivery, enabling structured study operations at scale, consistent participant lifecycle management, controlled workflows, and inspection ready audit trails, while supporting integration with external systems through documented APIs where required. GlobalMinds leverages every service offering from Trial Deck.

2 Case study: DISCA (SleepBuddy), Southampton Clinical Trials Unit

DISCA (SleepBuddy) is a UK multicentre randomised controlled trial evaluating a digital, parent guided sleep intervention for children aged 6 to 12 with ADHD and chronic insomnia. The study is sponsored by University Hospital Southampton NHS Foundation Trust and is NIHR funded.

The trial is designed for remote participation, with baseline and follow up assessments at 3 and 6 months. The primary outcome is sleep onset latency at 3 months, measured using a caregiver completed sleep diary, with a wider

set of secondary outcomes and a process evaluation to understand acceptability and use.

Trial Deck supports trial operations through a secure, auditable online platform approach. Public trial materials describe randomisation being conducted as part of the online platform, using 1:1 allocation with stratification, with allocation managed through the platform rather than manual processes. A public recruitment flyer also directs participants to a Trial Deck hosted study URL, supporting a consistent participant entry point and reducing dependence on local site specific systems.

DISCA recruits across multiple NHS sites in England, enabling consistent study delivery across locations while maintaining clear operational oversight and governance for the central trial team.

4. Intended users

The service is designed for use by the full clinical study team, including but not limited to:

- Trial managers
- Data managers
- Researchers and investigators
- Statisticians
- Study coordinators
- Clinical operations and governance staff
- Sponsors and sponsor representatives requiring operational oversight

5. Key features

The following features describe the core capabilities provided by Trial Deck CTMS. Together they support end to end operational management of clinical studies, enabling study teams to configure, coordinate, monitor, and govern trial activity across sites and roles.

- Study and protocol design and configuration
- Participant status and lifecycle tracking
- Visit, milestone, and notification scheduling

- Role based access control and permissions, including blinding
- Audit trails and activity logging
- CRF creation with configurable logic flows
- Multi-site and decentralised study oversight
- Participant randomisation and allocation
- Serious Adverse Event reporting workflows
- API access for external system integrations
- Centralised oversight of multi-site and decentralised trial operations
- Inspection-ready audit trails across operational workflows
- Configurable governance controls aligned with protocol requirements
- Multi-lingual capabilities for Participants, Trial Deck can also support multiple time zones

6. **Key benefits**

Working with Global Initiative's Trial Deck platform mean taking advantage of nearly three decades of experience in software development focused on data integrity and industry-leading data governance principles.. They focus on reducing operational burden, improving oversight and compliance, and enabling faster, more consistent delivery of clinical research.

- Rapid configuration and deployment of studies
- Simplified trial management through intuitive workflows
- Audit ready operational records
- Support for ALCOA++ aligned data governance
- Reduced setup time for multi site studies
- Clear operational oversight throughout delivery
- Consistent processes across study teams
- Reduced risk of operational error
- Faster decision making during study delivery
- Improve inspection readiness through traceable, auditable operational records

7. **Service delivery model**

Trial Deck CTMS 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.

Participant access is provided through a mobile first, WCAG 2.2 AA compliant interface. The participant interface and experience can be configured on a per study basis, allowing study teams to tailor content, flows, and interactions to meet the needs of different cohorts and study designs.

The service supports decentralised and hybrid delivery models, enabling central coordination of study activity while allowing sites, participants, and supporters to interact remotely under controlled governance and audit conditions.

8. Accessibility

Trial Deck Digital Intervention and Decision Support Builder is designed to be accessible to a wide range of users, including participants, supporters, and study teams. Participant-facing interfaces are designed to meet WCAG 2.2 AA standards, including support for keyboard navigation, screen readers, colour contrast, and responsive layouts across devices.

Accessibility is considered throughout design and development, with testing carried out using browser accessibility tools and assistive technologies. Identified accessibility issues are logged, prioritised, and addressed as part of ongoing product improvement.

Study teams can configure content, language, timing, and presentation to support accessibility needs across different cohorts, languages, and time zones. Where studies have specific accessibility requirements, the supplier can provide guidance or additional support as part of onboarding or optional services.

9. 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.

10. 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.

10.1 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.

11. Onboarding and support

Onboarding includes online training for new researchers, access to online documentation, and a dedicated delivery manager. Ongoing support is provided through a service management portal during UK business hours.

Where required, onboarding can include support for operational readiness, validation planning, and user acceptance testing.

12. Data management and exit

Study teams can export data using self-service tools in open formats, supporting ALCOA++ principles and data integrity checking. At contract end, data is securely deleted in line with agreed retention policies. Optional services include bespoke data exports, long-term archiving, validation-aligned end of study SOPs, and regulated offboarding support. Participants have the option to be informed of other studies relevant to their profiles on Trial Deck; these data are separate to study-related, collected data.

13. Free self-service version

A time limited self-service version is available for evaluation, supporting up to 50 participants for six months. It excludes advanced features such as audit trail search, SAE workflows, custom roles, localisation, SMS, API access, and production SLAs. Please contact Global Initiative to validate your study's eligibility.

14. 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.