ELECTRONIC DATA CAPTURE SERVICE DEFINITION

TRIAL DECK BY GLOBAL INITIATIVE

1. Service overview

Trial Deck Electronic Data Capture (EDC) is a cloud based service for designing, collecting, and managing structured clinical research data. It supports secure, auditable data capture for multi-site and decentralised studies, enabling research teams to collect high quality datasets in line with regulatory and governance expectations.

The service is provided as a configurable Software as a Service offering. Where buyers require bespoke development, custom components, or enhancements beyond the standard configuration options described in this document, these services are available separately under Global Initiative's Lot 3 Cloud Support offerings and are subject to a separate call off contract.

Trial Deck prioritises configurability and governance over rigid templates, allowing study teams to adapt data capture to protocol needs without custom software development.

2. Service scope

The service provides electronic case report form (eCRF) design, validation, data entry, querying, audit, and export capabilities. It is delivered as a managed Software as a Service offering and may be used as a standalone EDC or alongside other Trial Deck modules.

3. Intended users

Trial Deck EDC is well suited to academic, NHS, and publicly funded research studies requiring secure, auditable electronic data capture. Typical use cases include feasibility studies, single and multi-site trials, decentralised studies, and longitudinal research where data quality, traceability, and inspection readiness are critical.

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

4. **Case Study**

1 SMILE BioResource (NIHR BioResource programme)

SMILE BioResource is a large scale UK research programme designed to build a recontactable cohort within the NIHR BioResource, combining structured participant and clinician recorded data with long term governance and reuse requirements across a wider programme of studies.

Trial Deck is used to provide the Electronic Data Capture layer for SMILE, enabling study teams to design and deliver protocol driven eCRFs and questionnaires with validation at point of entry, controlled query workflows, and complete audit trails. The programme requires consistent data handling across sites and roles, with reliable export and provenance for downstream analysis and governance.

In addition to core EDC capability, Trial Deck was integrated with NIHR systems to support automated transfer of two distinct dataset types into NIHR managed cloud storage. This reduced manual handling and ensured datasets were delivered in the expected structure for the programme's data pipeline. To support repeatability at programme level, reusable default NIHR BioResource questionnaires and standard data dictionaries were created, enabling rapid replication for other studies within the BioResource programme while improving consistency, comparability, and reuse of collected data.

2 GlobalMinds (international scale EDC with planned device and passive mobile data)

GlobalMinds is a large scale international research programme designed to recruit around 50,000 participants. The programme is predominantly remote and digital by design, requiring reliable delivery at scale, consistent governance across partners, and the ability to manage high volume, longitudinal data collection without compromising auditability.

Trial Deck is used to provide the Electronic Data Capture layer for the programme, supporting structured questionnaires and other protocol driven

datasets with validation at point of entry, controlled role based access, complete audit trails, and efficient export of analysis ready datasets. At this scale, the EDC platform must manage large numbers of scheduled activities, reminders, repeated assessments, and data review workflows, while maintaining clear provenance and traceability.

In addition to structured eCRF and questionnaire capture, GlobalMinds includes planned integration with external data sources, including IoT and other connected devices, and large scale passive data collection from participants' mobile phones. These integrations are intended to support secure, controlled ingestion of multiple data streams alongside core study data, enabling combined datasets to be managed under consistent governance controls, with clear separation of responsibilities between data sources, operational partners, and study teams. The result is a scalable, inspection ready approach to high volume data capture and curation for a complex, multi partner research programme.

5. Key features

The features below describe the core EDC capabilities provided by Trial Deck, focused on secure data capture, auditability, and efficient data management.

- Electronic case report form creation with configurable validation rules
- Real time data validation and consistency checks at point of entry
- Full audit trails for all data creation, edits, and access
- Role based access controls for secure data entry and review
- Query management workflows for data clarification and resolution
- Integration with wearable and IoT platforms through secure integrations, including APIs where required
- Data integrity controls aligned with ALCOA++ principles
- Secure data storage with encryption in transit and at rest
- Configurable inter form and intra form logic
- Self service exports for monitoring, review, and downstream analysis

Trial Deck EDC is designed to support inspection ready research operations. Built in auditability, controlled access, and traceable data workflows enable study teams to demonstrate compliance with Good Clinical Practice,

ALCOA++ principles, and sponsor or regulator expectations without additional tooling. The platform supports consistent data handling across sites, roles, and study phases.

6. Key benefits

Trial Deck EDC focuses on reducing operational risk, improving data quality, and simplifying oversight for research sponsors and study teams. Benefits emphasise efficiency, governance, and confidence at every stage of the study lifecycle.

The benefits below describe how the service improves research delivery and data quality.

- Reduce data entry errors through real time validation
- Accelerate database lock with structured query management workflows
- Improve inspection readiness with complete, searchable audit trails
- Ensure data integrity aligned with ALCOA plus principles
- Streamline multi site data collection using consistent electronic forms
- Enable faster issue resolution through controlled data clarification queries
- Maintain secure access using role based permissions
- Support decentralised data capture without compromising governance
- Export clean datasets quickly for analysis and reporting
- Demonstrate inspection readiness through complete, traceable, auditable study datasets
- Support confident sponsor, ethics, and regulatory review through transparent data governance

7. Service delivery model

Trial Deck EDC 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.

The service supports both centralised and distributed study delivery models, including multi-site and decentralised research. Study teams can manage data consistently across sites while maintaining clear oversight, role separation, and auditability.

Participant data entry interfaces are designed to be accessible and usable across devices, with mobile friendly support where required. Researcher and data management interfaces are optimised for desktop and tablet use.

The service interfaces are designed to meet WCAG 2.2 AA accessibility standards, with ongoing testing and remediation as part of product development.

8. Accessibility

Trial Deck EDC service 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 plus principles.

Data in transit is protected using TLS 1.2 or above. Data at rest is encrypted using strong encryption mechanisms provided by the underlying cloud infrastructure. Access to encryption keys and production systems is restricted to authorised personnel only.

All production data is hosted and processed within the United Kingdom.

Global Initiative operates an ISO 27001 and ISO 9001 certified management system and is NHS DSPT and Cyber Essentials compliant.

Security and compliance controls are embedded into platform design rather than applied retrospectively, reducing operational burden on study teams and supporting consistent, repeatable governance across studies.

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
Service credits may be applied only where explicitly agreed in the call off contract.

11. Customisation

The service supports configuration without software development. Study teams can customise eCRFs, validation rules, inter form and intra form logic, mandatory fields, visit schedules, query workflows, reporting exports, and role based access permissions. Configuration is carried out through a secure browser based interface by authorised users. Optional supplier support is available for complex configurations.

12. API Access and Integration

Trial Deck EDC provides a documented REST API to support controlled integration and data exchange with external systems. API access is managed through secure token based authentication and exposes endpoints focused on participant identifiers and context variables. The API supports integration with laboratories, logistics providers, wearable and IoT platforms, and other external data sources relevant to data capture. Administrative configuration, CRF design, and workflow management are performed through the web interface.

13. Onboarding and support

Onboarding includes online training for study teams, access to comprehensive documentation, and a service management portal for support requests. Each customer is assigned a delivery manager to support onboarding and early study configuration. Additional services such as protocol validation and testing are available at additional cost.

14. 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, archiving, and end of study SOPs.

Participants may opt in to be informed of future and other studies. Participant profile data is logically separated from study datasets and managed under separate consent and access controls.

These processes are designed to support sponsor obligations for data retention, inspection, and future reuse in line with consent, protocol, and applicable regulations.

15. 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.

16. Pricing model

Pricing follows the standard Trial Deck pricing structure and is based on study size, duration, enabled modules, and required support services. Full pricing details are provided in the G Cloud service listing.

Pricing for bespoke development, custom components, or specialist enhancements is not included in the SaaS pricing and is provided separately under Lot 3 Cloud Support.