ECONSENT SERVICE DEFINITION

TRIAL DECK BY GLOBAL INITIATIVE

1. Service overview

Trial Deck eConsent is a cloud based electronic consent service supporting secure, auditable participant consent for clinical research. It enables digital presentation of consent materials, mandatory step enforcement, electronic signature capture, consent versioning and reconsent, and locked consent records with complete audit trails. The service supports regulatory aligned workflows, including alignment with 21 CFR Part 11 principles where applicable, and integrates with Trial Deck CTMS, EDC, and digital interventions or may be deployed standalone. Study teams can validate consent workflows before go live using a synthetic participant testing suite, supporting controlled review and sign off without exposing real participant data.

2. Service scope

The service supports the full electronic consent lifecycle, including consent content management, participant information presentation, electronic signature capture, consent versioning, withdrawal handling, audit logging, and export for inspection or archiving. It is delivered as a managed Software as a Service offering and may be used independently or as part of an end to end Trial Deck study platform.

3. Case Studies

1 SMILE BioResource (hybrid consent with digital confirmation and long term governance)

SMILE BioResource is a large scale research programme combining in person participant engagement with robust digital record keeping and long term retention requirements. Consent is obtained in a controlled setting and then confirmed digitally to ensure consent evidence is captured consistently, retained securely, and remains accessible for audit and future governance needs.

Trial Deck eConsent supports the digital presentation of consent materials, electronic confirmation, and generation of read only signed consent documents. Consent records are locked after submission and are supported by complete audit trails for creation, access, and version history. Role based

access controls ensure only authorised study staff can view or export consent records, aligned to protocol requirements.

The service supports a hybrid operating model where participant engagement may occur in person, but the definitive consent evidence is managed digitally, improving traceability, reducing reliance on paper, and simplifying export for archiving and inspection focused review.

2 Anonymised perinatal digital intervention (time sensitive consent with supported participation)

This study is a digitally delivered intervention supporting young parents aged 16 to 24 experiencing post-partum depression. Recruitment and onboarding are time sensitive, and the consent process must be clear, supportive, and auditable while remaining accessible for participants who may be distressed, time constrained, or engaging on a mobile device.

Trial Deck eConsent is used to present participant information and consent steps in a structured, mandatory sequence, reducing the risk of incomplete consent and ensuring a consistent process across the cohort. The service captures electronic signatures with traceable metadata, generates locked consent records, and maintains complete audit trails to support governance and inspection readiness.

The study also incorporates supporters with lived experience who provide guidance to participants during onboarding and engagement. Trial Deck role based access controls support clear separation between participant and supporter permissions, allowing supporters to help without granting access to consent record administration. The outcome is a consent process that is sensitive to participant needs, robust under time pressure, and demonstrably auditable throughout delivery.

3 GlobalMinds (consent evolution for new data streams at scale)

GlobalMinds is an international scale research programme designed to recruit around 50,000 participants and to expand over time as additional data streams are introduced. As the programme evolves, the consent model must support clear version control, transparent presentation of new consent elements, and reconsent where required, while maintaining a complete audit trail of what each participant consented to and when.

Trial Deck eConsent provides structured consent delivery with mandatory steps, electronic signature capture, locked consent records, and full audit

trails. Consent versioning supports controlled updates as new modules or data streams are added, enabling the programme to introduce additional consent components without losing traceability of earlier consent states.

At this scale, the service must support high volume participant onboarding and reconsent events, reliable export of consent packs and audit logs, and secure role based access for teams operating across multiple partners and responsibilities. The result is a consent framework that remains auditable and manageable as study scope expands.

4. Intended users

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

- Trial managers
- Research nurses and study coordinators
- Investigators and principal investigators
- Data managers
- Governance, QA, and monitoring staff
- Regulatory and compliance teams

5. Key features

The features below describe the core capabilities of Trial Deck eConsent, focused on secure consent capture, auditability, and regulatory aligned evidence generation.

- Digital presentation of participant information and consent materials
- Mandatory step enforcement to ensure informed completion
- Electronic signature capture with timestamp, IP address, and participant metadata
- Automatic generation of read only signed consent documents
- Tamper evident locking of consent records after submission
- Full audit trails for consent creation, access, and updates
- Role based access control for consent records and audit data

- Consent versioning and re consent workflows
- Configurable consent workflows by study, site, or cohort
- Secure APIs for consent status synchronisation with external systems
- Participant facing content can be configured in multiple languages. Studies can be configured to support participants across multiple time zones.

6. Key benefits

The benefits below describe how Trial Deck eConsent improves study delivery, governance, and inspection readiness.

- Reduce consent errors through enforced completion and validation
- Accelerate study startup with rapid digital consent deployment
- Provide clear, attributable evidence of informed consent
- Improve inspection readiness with complete, auditable consent records
- Support protocol amendments through controlled re consent workflows
- Simplify monitoring with centralised consent review and export
- Maintain governance using role controlled access to consent data
- Reduce operational burden through automated consent documentation
- Enable decentralised consent without compromising auditability
- Support long term retention and regulatory inspection of consent evidence

7. Service delivery model

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

Participant facing consent interfaces are mobile first and designed to meet WCAG 2.2 AA and tested against WCAG 2.2 AA criteria, supporting use across smartphones, tablets, and desktops. Researcher and governance interfaces are optimised for desktop and tablet use, supporting efficient review, oversight, and export of consent records.

8. Security, compliance, and electronic records

Trial Deck eConsent is designed to support delivery in line with Good Clinical Practice principles and applicable electronic records and signatures guidance.

Controls including role based access, consent record locking, audit logging, and traceable metadata support ALCOA++ principles and help ensure consent records are attributable, legible, contemporaneous, original, and accurate. Electronic signatures are captured in a manner aligned with 21 CFR Part 11 principles where applicable.

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. Access to production systems and encryption keys is restricted to authorised personnel only. Controls support data minimisation, separation of participant and study datasets, and protocol aligned access restrictions.

Participant facing consent interfaces are designed to meet WCAG 2.2 AA accessibility standards, including support for keyboard navigation, screen readers, colour contrast, and responsive layouts. Accessibility testing is carried out as part of ongoing product development, and identified issues are tracked and addressed through the standard change management process.

Global Initiative operates an ISO 27001 and ISO 9001 certified management system and is NHS DSPT and Cyber Essentials compliant, with annual penetration testing carried out.

9. Customisation

The service supports configuration of consent processes without software development. Study teams can customise consent content, participant information sheets, completion rules, consent versions, re consent triggers, withdrawal handling, and role based access permissions.

Customisation is carried out through a secure browser based configuration interface by authorised users. Configuration options are designed to maintain auditability, traceability, and regulatory integrity. Optional supplier support is available for complex consent workflows or governance aligned configurations.

10. Testing and validation

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

In addition to standard unit, integration, regression, and security testing, Trial Deck provides a comprehensive built-in testing suite that allows study teams to validate consent workflows using synthetic participants. This enables users to simulate participant journeys end to end, including consent presentation, completion rules, electronic signature capture, version changes, re-consent events, and withdrawal scenarios, without exposing real participant data.

Synthetic participant testing allows teams to verify user experience, logic, access controls, audit behaviour, and downstream integrations before a study goes live. Testing outputs are visible to authorised users and support controlled review and sign off.

Where required, Global Initiative can support study specific validation activities, including configuration verification, user acceptance testing, and inspection focused documentation, provided as an optional service. This supports risk based validation approaches aligned with Good Clinical Practice and electronic records expectations.

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

Onboarding includes consent specific training for study teams, covering consent configuration, version management, audit access, and inspection readiness, alongside access to comprehensive documentation and a service management portal. 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.

13. Data management and exit

Study teams can export consent data using self service tools in open formats, including signed consent documents, associated metadata, timestamps, version history, and full audit trails. Exports support ALCOA++ principles and long term retention requirements. Metadata captured is configurable and applied in line with protocol requirements and data minimisation principles.

At contract end, consent data is securely deleted or archived in line with agreed retention policies and regulatory obligations. Optional services include bespoke exports, validation aligned archiving, and end of study or inspection focused SOPs.

14. 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.

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.