DIGITAL INTERVENTION AND DECISION SUPPORT BUILDER SERVICE DEFINITION

TRIAL DECK BY GLOBAL INITIATIVE

1. Service overview

Trial Deck Digital Intervention (DTx) and Decision Support Tool (DST) Builder is a cloud based platform for rapidly designing, validating, and delivering digital therapeutics, decision support tools, and intervention programmes for clinical research and healthcare delivery. It enables multidisciplinary teams to build personalised, data driven therapeutic pathways and guidance without software development, using configurable content modules, participant context variables, and rule based logic.

Decision support is delivered as structured, rule based flows embedded directly within intervention pathways, allowing consistent application of guidance while retaining flexibility across cohorts and individual participants. All changes to content, rules, and pathway configuration are recorded through audit trails, supporting controlled iteration, governance, and traceability throughout delivery.

The service supports both investigational and operational use, including DTx enabled pharmaceutical or care pathways and regulated use cases where formal governance, validation activity, and inspection readiness are required.

2. Service scope

The service supports the configuration and delivery of digital therapeutic interventions and decision support flows, including participant engagement, therapeutic content delivery, and adaptive logic. It is intended for academic, NHS, life sciences, and publicly funded research organisations and is delivered as a managed Software as a Service offering. The service can be used standalone or alongside Trial Deck CTMS for integrated study delivery.

Configuration within the service is performed using built-in tools and components. Bespoke development, novel components, or study-specific extensions beyond the standard service scope are available separately under Cloud Support services.

3. Case Studies

1 Opioids tapering app built in 8 weeks including a custom participant interface (Oxford University Hospitals)

This project delivered a digital therapeutic style opioids tapering programme for Oxford University Hospitals, combining personalised tapering schedules, structured check ins, and rule based decision support to guide participants safely and consistently. The service was designed to support participant confidence and adherence through clear pacing, reminders, tailored guidance, and rapid access to follow up resources.

A key element of the participant experience was a card sorting interface used to capture structured self-reported information in a simple, low friction format. The resulting data was used to drive a clinician facing workflow, enabling clinicians to ask appropriate follow up questions, surface relevant issues, and provide targeted resources and guidance. This created a consistent and auditable interaction pattern while keeping the participant experience straightforward.

The service also supported collaboration with primary care. Trial Deck implemented a single use, time sensitive access code workflow allowing a GP or pharmacist to securely log in and view the relevant participant tapering context within a controlled, role based view. This enabled the GP to gauge tapering progress and support clinical decision making without expanding access beyond what was necessary, while maintaining full audit trails of access and activity.

The end to end solution was delivered in 8 weeks, including a custom participant interface, demonstrating how Trial Deck can accelerate delivery of bespoke DTx experiences while retaining governed configuration and traceable changes.

2 DECIDE TAD decision support tool digitisation and regulated delivery readiness

DECIDE TAD is a mixed methods programme to co-design and evaluate a Decision Support Tool enabling shared decision making for people considering cascade screening for Thoracic Aortic Disease. The programme is led by a UK university sponsor and is designed to progress from tool creation and feasibility testing, through a multi-site clinical trial, and into planning for adoption within NHS care pathways.

Trial Deck was used as the platform foundation to digitise and deliver the DST as an interactive, configurable participant experience. The tool guides people who have been diagnosed with, or are at genetic risk of, Thoracic Aortic Disease through complex decisions such as whether to take a test, how to involve family members, and who to speak to at different stages of the pathway. Delivery required a structured, governed approach with clear version control, auditable change history, and role controlled access to support safe iterative refinement based on user feedback.

The programme is built around staged development and evaluation, including co design and ongoing improvement informed by public and patient involvement and engagement groups. Feedback from these groups has driven measurable improvements in the digital experience and informed refinements to the underlying decision support approach. Global Initiative and the Trial Deck team also supported the study team with regulated delivery readiness, including contributions to documentation required for MHRA facing clinical investigation processes.

4. **Intended users**

The service is designed for use by teams involved in designing and delivering digital therapeutics and decision support, including but not limited to:

- Behavioural scientists and intervention designers
- Clinicians and clinical researchers
- Digital health and DTx product teams
- Trial and study teams delivering therapeutic interventions
- Administrators and governance staff
- CTU Staff
- Clinical operations teams delivering DTx-enabled care or research pathways

5. **Key features**

The following features describe the core capabilities provided by the Trial Deck DTx and DST Builder. Together they support the design, personalisation, and delivery of digital therapeutic programmes and guidance.

- No code creation of digital therapeutics and intervention programmes
- Personalised DTx pathways driven by participant data and behaviour

- Modular therapeutic content blocks for behavioural and clinical use
- Configurable decision support tools embedded within intervention flows
- Participant level tailoring across cohorts subgroups and individuals
- API integration with external systems including IoT devices and wearables
- In platform messaging between participants and authorised support teams
- Audit trails supporting GCP and ALCOA++ compliance requirements
- Regulatory aware design supporting SaMD and clinical investigation submissions
- Seamless integration with Trial Deck CTMS for study delivery
- Decision support logic configurable using rule-based and contextual triggers
- Real-world data ingestion to inform therapeutic logic and decision support
- Inspection-ready audit trails covering intervention delivery and changes
- 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 the service improves working practices for teams delivering digital therapeutics and decision support.

- Rapidly design and deploy digital therapeutics without software development
- Personalise therapeutic experiences at scale across participant populations
- Accelerate intervention iteration through no code configuration and testing
- Reduce delivery burden through automated intervention logic
- Improve consistency of therapeutic delivery across cohorts
- Enable data driven adaptations to interventions during delivery
- Integrate wearable and device data into therapeutic decision making

- Streamline regulatory preparation for SaMD and investigation submissions
- Maintain audit ready records supporting compliance and inspection readiness
- Coordinate therapeutic delivery alongside trial management workflows

7. **Service delivery model**

Trial Deck DTx and DST Builder 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 facing interfaces are designed to meet WCAG 2.2 AA and are tested against WCAG 2.2 AA criteria. Therapeutic content, decision support guidance, and interaction flows can be configured on a per programme or study basis to support different cohorts, conditions, and use cases.

The service supports multi-site and decentralised delivery models, allowing interventions and decision support to be deployed consistently across locations while maintaining centralised oversight, auditability, and governance controls.

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.

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

The service supports data minimisation, separation of participant and study datasets, and controlled access aligned with protocol and consent requirements.

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 validation planning, user acceptance testing, and documentation aligned to regulated or investigational use. Optional services include bespoke data exports, long-term archiving, validation-aligned end-of-study SOPs, and regulated offboarding support.

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 or programme, with optional add-ons for enhanced SLAs, additional support, advanced features, and large-scale delivery.

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

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