NHSx

Interweave Connect

The Digital Technology Assessment Criteria for Health and Social Care (DTAC)

Table of contents

The assessment criteria is made up of five core components. Sections A and B will provide the assessors the context required to understand your product and support your evidence. The core assessment criteria is defined in section C1-C4. Section D details the key Usability and Accessibility principles required. Further frequently asked questions are available at the end of the document.

The core criteria in Section C will determine the overall success of the assessment of your product or service. The accompanying score provided from Section D will show the level of adherence to the NHS Service Standard.

A. Company information - Non-assessed section

Information about your organisation and contact details.

Code	Question	Options
A1	Provide the name of your company	Humber Teaching NHS Foundation Trust **(Interweave)**
A2	Provide the name of your product	Interweave – Connect
A3	Provide the type of product	Software as a Service (SaaS)
A4	Provide the name and job title of the individual who will be the key contact at your organisation	Lee Rickles, Yorkshire & Humber Care Record Programme Director & Chief Information Officer
A5	Provide the key contact's email address	lee.rickles@nhs.net
A6	Provide the key contact's phone number	07919 545303
A7	Provide the registered address of your company	Humber Teaching NHS Foundation Trust, Willerby Hill, Beverley Road, Willerby, East Riding of Yorkshire, HU10 6ED

A8	In which country is your organisation registered?	UK
A9	If you have a Companies House registration in the UK please provide your number	Not Applicable – YHCR is hosted by Humber Teaching NHS Foundation Trust
A10	If applicable, when was your last assessment from the Care Quality Commission (CQC)?	Not applicable
A11	If applicable, provide your latest CQC report.	Not applicable

B. Value proposition - Non-assessed section

Please set out the context of the clinical, economic or behavioural benefits of your product to support the review of your technology. This criteria will not be scored but will provide the context of the product undergoing assessment.

Where possible, please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Response
B1	Who is this product intended to be used for?	Clinical Support
B2	Provide a clear description of what the product is designed to do and of how it is expected to be used	Connect is a standards compliant server which, following data mapping procedures, converts existing data into FHIR resources and provides this data to the Exchange to facilitate a shared care record.
B3	Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated	• A complete implementation of a FHIR Server and FHIR Store (fully compliant with FHIR STU 3) • Support for synchronous queries, but also for asynchronous bulk extracts and event-driven subscriptions • Flexible endpoint configuration • Possible to configure dual endpoints for external vs internal access • Entirely configurable choice of listener ports • Options for http or https (including mutual authentication) • Options for message authentication (jwt, api-key, none) • Audit log of all activities (available as FHIR AuditEvent resources) • Option to automate registration of patients with a regional PIX server

		- Runs on Linux or Windows Server 2019, using either Postgres or MSSQL database - Dockerised deployment for ease of installation
B4	Please attach one or more user journeys which were used in the development of this product Where possible please also provide your data flows	Not applicable

C. Technical questions - Assessed sections

C1 - Clinical safety

Establishing that your product is clinically safe to use.

You must provide responses and documentation relating to the specific technology product that is subject to assessment.

The DCB0129 standard applies to organisations that are responsible for the development and maintenance of health IT systems. A health IT system is defined as "product used to provide electronic information for health and social care purposes". DTAC is designed as the assessment criteria for digital health technologies and C1 Clinical Safety Criteria is intended to be applied to all assessments. If a developer considers that the C1 Clinical Safety is not applicable to the product being assessed, rationale must be submitted exceptionally detailing why DCB0129 does not apply.

The DCB0160 standard applies to the organisation in which the health IT is deployed or used. It is a requirement of the standard (2.5.1) that in the procurement of health IT systems the organisation must ensure that the manufacturer and health IT system complies with DCB0129. The organisation must do so in accordance with the requirements and obligations set out in the DCB0160 standard. This includes personnel having the knowledge, experience and competences appropriate to undertaking the clinical risk management tasks assigned to them and organisations should ensure that this is the case when assessing this section of the DTAC.

If the Clinical Safety Officer or any other individual has concerns relating to safety of a medical device including software and apps, this should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting system: Report a problem with a medicine or medical device - GOV.UK (www.gov.uk).

Code	Question	Response
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with DCB0129?	Yes
C1.1.1	Please detail your clinical risk management system	Available upon request
C1.1.2	Please supply your Clinical Safety Case Report and Hazard Log	Available upon request
C1.2	Please provide the name of your Clinical Safety Officer (CSO), their profession and registration details	Paul Warwick, Registered Nurse (Mental Health) RN (MH), NMC Pin Number 90J1496E
C1.3	If your product falls within the UK Medical Devices Regulations 2002, is it registered with	Not applicable

	the Medicines and Healthcare products Regulatory Agency (MHRA)?	
C1.3.1	If yes, please provide your MHRA registration number	Not applicable
C1.3.2	If the UK Medical Device Regulations 2002 are applicable, please provide your Declaration of Conformity and, if applicable, certificate of conformity issued by a Notified Body / UK Approved Body	Not Applicable
C1.4	Do you use or connect to any third-party products?	YES - Further details of the technical design is found on: https://interweavedigital.com/technical
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	Available upon request

C2 - Data protection

Establishing that your product collects, stores and uses data (including personally identifiable data) compliantly.

This section applies to the majority of digital health technology products however there may be some products that do not process any NHS held patient data or any identifiable data. If this is the case, the Data Protection Officer, or other suitably authorised individual should authorise this data protection section being omitted from the assessment.

Code	Question	Response
C2.1	If you are required to register with the Information Commissioner, please attach evidence of a current registration. If you are not required to register, please attach a completed self-assessment showing the outcome from the Information Commissioner and your responses which support this determination.	Provided – Ref No: **Z477113X** valid until **19 June 2024** Humber Foundation NHS Trust is a Data Processor only, as is processing data only on behalf of other data controllers of the initiative.
C2.2	Do you have a nominated Data Protection Officer (DPO)?	Yes

C2.2.1	If you are required to have a nominated Data Protection Officer, please provide their name.	Johnny Chagger, Head of Information Governance & Data Protection Officer, johnny.chagger@nhs.net
C2.3	Does your product have access to any personally identifiable data or NHS held patient data?	Yes
C2.3.1	Please confirm you are compliant (having standards met or exceeded status) with the annual Data Security and Protection Toolkit Assessment.	Confirmed – Humber Foundation NHS Trust - Standards met – **29/02/2024**
C2.3.2	Please attach the Data Protection Impact Assessment (DPIA) relating to the product.	Available upon request
C2.4	Please confirm your risk assessments and mitigations / access controls / system level security policies have been signed-off by your Data Protection Officer (if	Confirmed

	one is in place) or an accountable officer where exempt in question C2.2.	
C2.5	Please confirm where you store and process data (including any third-party products your product uses)	UK only INTERWEAVE does not store or process data outside the UK. DATA is contractually stored within a Geofenced UK Based data Centre
C2.5.1	If you process store or process data outside of the UK, please name the country and set out how the arrangements are compliant with current legislation	Not Applicable – UK Only data centres are used

C3 - Technical security

Establishing that your product meets industry best practice security standards and that the product is stable.

Dependent on the digital health technology being procured, it is recommended that appropriate contractual arrangements are put in place for problem identification and resolution, incident management and response planning and disaster recovery.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Response
C3.1	Please attach your Cyber Essentials Certificate	Cyber Essentials: Certificate No: dc41c9fe-585d-4446-a481-68071b26c5de Cyber Essentials PLUS : 1b3462a2-76e9-4763-9466-d4526809b88b https://iasme.co.uk/certified-organisations/
C3.2	Please provide the summary report of an external penetration test of the product that included Open Web Application Security Project (OWASP) Top 10 vulnerabilities from within the previous 12-month period.	Latest results available upon request due to rolling Pen Test schedule

C3.3	Please confirm whether all custom code had a security review.	Yes - Internal code review
C3.4	Please confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?	Yes – MFA is in place for all developers, Admins, and users.
C3.5	Please confirm whether logging and reporting requirements have been clearly defined.	Yes logging and reporting is established via Google Cloud Platform
C3.6	Please confirm whether the product has been load tested	Yes

C4 - Interoperability criteria

Establishing how well your product exchanges data with other systems.

To provide a seamless care journey, it is important that relevant technologies in the health and social care system are interoperable, in terms of hardware, software and the data contained within. For example, it is important that data from a patient's ambulatory blood glucose monitor can be downloaded onto an appropriate clinical system without being restricted to one type. Those technologies that need to interface within clinical record systems must also be interoperable. Application Programme Interfaces (APIs) should follow the Government Digital Services Open API Best Practices, be documented and freely available and third parties should have reasonable access in order to integrate

technologies.

Good interoperability reduces expenditure, complexity and delivery times on local system integration projects by standardising technology and interface specifications and simplifying integration. It allows it to be replicated and scaled up and opens the market for innovation by defining the standards to develop upfront.

This section should be tailored to the specific use case of the product and the needs of the buyer however it should reflect the standards used within the NHS and social care and direction of travel.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Response
C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	Yes – this is documented within the **Interoperability Cookbook Abstract 2nd Edition v.1.1**
C4.1.1	If yes, please provide detail and evidence: ● The API's (e.g., what they connect to) set out the healthcare standards of data interoperability e.g., Health Level Seven International (HL7) / Fast Healthcare Interoperability Resources (FHIR) ● Confirm that they follow Government Digital Services Open API Best Practice	Restful FHIR APIs, exposing FHIR resources from numerous data providers in the region using UK Care Connect profiles Fully documented and freely available. Connection via Onboarding Process to assure security / clinical safety / information governance

	● Confirm they are documented and freely available ● Third parties have reasonable access to connect If no, please set out why your product does not have APIs.	
C4.2	Do you use NHS number to identify patient record data?	Yes
C4.2.1	If yes, please confirm whether it uses NHS Login to establish a user's verified NHS number. If no, please set out the rationale, how your product established NHS number and the associated security measures in place.	No, secure integration is in place between INTERWEAVE and end-point EPR systems Further information can be obtained via the technical documents - https://www.interweavedigital.com/customer-support/technical/
C4.3	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0,	Yes

	TLS 1.2)	
C4.3.1	If yes, please detail the standard	Yes There are two options: 1) Automated extraction via the Interweave Exchange. This connects using TLS 1.2 with mutual authentication and OAuth2 (JWT tokens) 2) Custom bulk extract. The details would be specific to each extract, but would use appropriate industry standards such as TLS 1.2 to secure the data transfer
C4.3.2	If no, please state the reasons and mitigations, methodology and security measures.	Not Applicable
C4.4	Is your product a wearable or device, or does it integrate with them?	No
C4.4.1	If yes, provide evidence of how it complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards.	Not Applicable

D. Key principles for success

The core elements defined in this section will form part of the overall review of the product or service and is a key part to ensuring that the product or service is suitable for use. The assessment will set a compliance rating and where a product or developer is not compliant highlight areas that the organisation could improve on with regards to following the core principles.

This section will be scored in relation to the [NHS service standard](#). This will not contribute to the overall Assessment Criteria as set out in Section C.

D1 - Usability and accessibility - scored section

Establishing that your product has followed best practice.

Please note that not all sections of the NHS Service Standard are included where they are assessed elsewhere within DTAC, for example clinical safety.

Code	Question	Options
D1.1	**Understand users and their needs in context of health and social care** Do you engage users	Yes

	in the development of the product?	
D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods do you use to engage users and understand their needs?	A user-centric approach is central to the design thinking philosophy of our new Product Manager. We have commissioned a design agency to provide the expertise required to undertake effective user research and have recently commenced a programme of user interviews and workshops aimed at producing persona definitions, user journeys, prototypes and usability testing.
D1.2	**Work towards solving a whole problem for users** Are all key user journeys mapped to ensure that the whole user problem is solved, or it is clear to users how it fits into their pathway or journey?	Yes
D1.2.1	If yes or working towards it, please attach the user journeys and/or how	Yes, various forums, working groups, and public consultation forums are in place. Transparency is provide via the website.

	the product fits into a user pathway or journey	
D1.3	**Make the service simple to use** Do you undertake user acceptance testing to validate usability of the system?	Yes
D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	Provided – DXW YHCR Report, MYHT Test-Report, Test Script HUTH Resources
D1.4	**Make sure everyone can use the service** Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?	Yes

D1.4.1	Provide a link to your published accessibility statement.	Under review
D1.5	**Create a team that includes multi-disciplinary skills and perspectives** Does your team contain multidisciplinary skills?	Yes – the team includes multiple disciplines including governance, technical, and clinical areas.
D1.6	**Use agile ways of working** Do you use agile ways of working to deliver your product?	Yes, product development is undertaken in sprints in response to user requirements and research insights, and enhancements.
D1.7	**Iterate and improve frequently** Do you continuously develop your product?	Yes, continuous updates are released. Updates may include new features, bug fixes, security patches, and other changes in response to feedback and changes in user needs, clinical evidence, or policy. There are mechanisms and appropriate resources in place to identify and respond to feedback, review content, and understand user priorities. All releases are subject to Change Management reviews.
D1.8	**Define what success looks like and be open about how your service is performing**	**Yes** •Interweave complete the Benefits Analysis and Realisation Tool (BART) and submit to NHSE quarterly. •Each ICS completes and returns a set of metrics to us, we coordinate returns to NHSE •Interweave complete a Shared Care Record Assurance report (slide) which is

	Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	approved at the YHCR Delivery Board and submitted to NHSE on a monthly basis. Interweave also join a number of meetings and forums for NHSE assurance
D1.9	**Choose the right tools and technology** Does this product meet with NHS Cloud First Strategy?	Yes – the product suite is built on the Cloud First strategy.
D1.9.1	Does this product meet the NHS Internet First Policy?	Yes
D1.10	**Use and contribute to open standards, common components and patterns**	Yes
D1.10.1	If yes, which common components and patterns have been used?	Please refer to the Technical Design Documents: https://www.interweavedigital.com/customer-support/technical/

D1.11	**Operate a reliable service** Do you provide a Service Level Agreement to all customers purchasing the product?	Yes
D1.12	Do you report to customers on your performance with respect to support, system performance (response times) and availability (uptime) at a frequency required by your customers?	Yes
D1.12.1	Please attach a copy of the information provided to customers	Available upon request for up to date reports
D1.12.2	Please provide your average service availability for the past 12 months, as a percentage to two decimal places	99.67%

Supporting documentation

Please ensure that when providing evidence, documents are clearly labelled with the name of your company, the question number and the date of submission.

Possible documents to be provided are:
- A11 - CQC Report
- B4 - User journeys and data flows
- C1.1.1 - Clinical Risk Management System
- C1.1.2 - Clinical Safety Case Report
- C1.1.2 - Hazard Log
- C1.3.2 - UK Medical Device Regulations 2002 Declaration of Conformity and if applicable Certificate of Conformity
- C1.4.1 - Clinical Risk Management documentation and Conformity certificate for third party suppliers
- C2.1 - Information Commissioner's registration or completed Self-assessment Outcome Tool
- C2.2.1 Completed Information Commissioner's Self-Assessment Outcome Tool
- C2.3.2 - Data Protection Impact Assessment (DPIA)
- C3.1 - Cyber Essentials Certification
- C3.2 - External Penetration Test Summary Report
- C4.4.1 - If a wearable, evidence of how the product complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards
- D1.2.1 - User Journeys and/or how the product fits into a user pathway or journey
- D1.3.1 - Supporting information showing user acceptance testing to validate usability
- D1.13.2 - Customer Performance Report