



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

# Introduction

**This form is version 2.0 and was last updated on 24 February 2026. Manufacturers must provide this form in lieu of the older v1.0 form from 6 April 2026 when requested by health and care organisations to facilitate assurance of Digital Health Technology products. Prior to this date, care providers should accept whichever version (1.0 or 2.0) is provided by the manufacturer.**

The Digital Technology Assessment Criteria (DTAC) is an assessment framework for digital health technologies (DHTs) bringing together baseline standards and policies that apply to these products. DHTs must be assessed by commissioners and care providers against the standards and policies they are required to meet for them to be considered safe for use in the Health and Social care system in England.

DTAC brings clarity and consistency to the assurance process, which reduces burden on industry and healthcare organisations. DTAC gives confidence to healthcare professionals and patients that products are safe to use.

Digital Health Technologies is software—including mobile or web applications or Software as a Service (SaaS)—provided as a standalone product (or to be used alongside hardware elements) designed or marketed to improve health outcomes, or how the health and care system functions (system services). They may include:

## **In-scope of DTAC**

DHTs to improve health outcomes

- medical devices classed as software or AI as a medical device, or software designed to work alongside a medical device
- software, apps or wearable devices used to help people manage their own health or well-being, or designed to work alongside devices to do so

DHTs to improve how the health and care system functions

- software or apps designed to help deliver, manage, or administrate the provision of care by the health and care system that might influence the care an individual receives: e.g. appointment scheduling or management of digital referrals.
- Software design to release staff time, reduce costs or improve efficiency: e.g. or example systems for managing utilisation of facilities such as bed management.

## **Out of scope of DTAC**

Hardware, onboard software, embedded software in hardware devices

DTAC is not intended to be used to assess onboard software (e.g. firmware) or software embedded in hardware devices, such as in vitro diagnostic (IVD) medical devices (e.g., laboratory equipment) and medical devices used for imaging, diagnosis and treatment (e.g., CT scanners, ECG equipment, radiotherapy equipment). DTAC is also not intended to be applied to products used to support the delivery of care and operation of the health and care system but which are not marketed specifically for a health or care context (e.g. HR or payroll systems). In these cases while elements within DTAC may still apply (e.g. DSPT), but DTAC as a whole is not an appropriate assessment framework.

DTAC forms must be completed by the manufacturer of a DHT in the first instance. If the manufacturer is not the seller of the product, or placing it on the market, the seller must work with the manufacturer to provide a completed DTAC form.

Manufacturers are organisations with the responsibility for the design, manufacturing, packaging or labelling of a DHT product, assembling a system, or adapting a product before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that persons' behalf by a third party.

The assessment criteria are 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 are defined in section C1-C4, and products must meet these criteria to pass assessment. Section D details the key Usability and Accessibility principles and provides a scored element to inform choices between products.

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## A. Company information - Non-assessed section

Information about your organisation and contact details.

Code	Question	Options
A1	Provide the name of your company.	X-on Health Limited
A2	Provide the name of your product.	Surgery Intellect, powered by TORTUS
A3	Provide the version number of your product this form corresponds to	April 2026
A4	State the type of product.	Surgery Intellect, powered by TORTUS is an AI-powered clinical assistant designed to streamline administrative and clinical workflows within primary care. It utilises ambient voice technology (AVT) to assist healthcare professionals to listen, transcribe and code consultations in real time - for both in-person (ambient) and telephone consultations.
A5	Provide the name and job title of the individual who will be the key contact at your organisation.	Daniel Grainge - Product Assurance Officer
A6	Provide the key contact's email address.	governance@x-on.co.uk

A7	Provide the key contact's phone number.	0333 332 0000
A8	Provide the registered address of your company	Glebe Farm, Down Street, Dummer, Basingstoke, Hampshire, RG25 2AD
A9	In which country is your organisation registered?	England
A10	If you have a Companies House registration in the UK, a registered charity number, or any other form of organisational reference, please provide numbers.	02578478
A11	If you are required to register with the <a href="#">Care Quality Commission</a> , please provide the date of your last CQC assessment.	Not applicable
A12	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	Options	Supporting information
B1	What is the intended use of the product?	Patient Support   Clinical Support   Workforce Support or Management	<p>Service features</p> <ul style="list-style-type: none"> <li>• AVT Scribe (for Ambient and Telephone Consultations) generating transcriptions and summaries in the form of a clinical note</li> <li>• Clinical documentation generation: Referral letters and clinical notes in templates applicable for a variety of formatting styles and settings</li> <li>• Automated Clinical Coding: Streamlines the process of clinical coding by identifying and suggesting appropriate codes based on patient interactions</li> <li>• File direct to patient record, following the required review of the generated content</li> </ul>
B2	Provide a clear description of what the product is designed to do and how it is expected to be used		<p><b>Surgery Intellect, powered by TORTUS</b>            Surgery Intellect, powered by TORTUS, uses ambient voice technology (AVT) to listen, transcribe and code consultations via the X-on Phonebar for both in-person (ambient) and telephone consultations. It reduces the cognitive load for GPs</p>

			<p>and provides accurate, secure patient consultation notes and letters. Once a clinician has reviewed and approved the generated content, Surgery Intellect, powered by TORTUS can file this into the patient record, and back to Surgery Connect's patient contact history, for accurate, joined-up patient records.</p> <p>X-on Health's services can be used as standalone, but they are primarily used as an extension to the core clinical systems used in UK primary care, such as EMIS Web, TPP SystmOne, Vision, and Medicus.</p>
B3	Describe who the intended users are, the intended or proven benefits for users and confirm if / how the benefits have been validated		<p>Clinicians use Surgery Connect to place outbound calls with patients and can generate medical notes following completion of the call, using Surgery Intellect, powered by TORTUS. Users can choose to inform patients about the AVT scribe and gain verbal consent. Transcripts are saved back to Surgery Connect, where the generated medical notes, clinical coding, and patient letters can be reviewed, edited, and saved to the patient record within the clinical system.</p> <p>Face-to-face consultations can also utilise Surgery Intellect, powered by TORTUS to generate the same. Transcripts are saved back to Surgery Connect, where the generated medical notes, clinical coding, and patient letters can be reviewed, edited, and saved to the patient record within the clinical system.</p> <p>The AVT scribe functionality can ease pressures on staff workloads without compromising on patient care. For proven user benefits, see the below case studies:</p> <p><a href="https://tortus.ai/customer/gosh/">https://tortus.ai/customer/gosh/</a></p> <p><a href="https://www.x-on.co.uk/case-studies/better-consultations-via-early-adoption-of-avt/">https://www.x-on.co.uk/case-studies/better-consultations-via-early-adoption-of-avt/</a></p>

B4	<p>Provide information about the flow of data between the product and the Health IT System.</p> <p>Where applicable, provide a user journey map.</p>	Provided	<p>Existing documentation showing data flows and/or user journeys such as deployment diagrams, product installation or user guides etc.</p> <p>GOV.UK provides guidance on <a href="#">how to make a user journey map</a> and what should be included.</p> <p>Data flows enable the assessor to understand how data moves through a product. This may be included within a Data Protection Impact Assessment. If this is the case, please provide a separate attachment for ease of review.</p> <p>User journey diagrams are accessible via <a href="#">Journey diagrams</a></p> <p>User guides: <a href="https://help.x-onweb.com/en/">https://help.x-onweb.com/en/</a></p>

## C. Technical questions - Assessed sections

### C1 - Clinical safety

Establishing that your product is clinically safe to use. Suppliers must provide responses and documentation relating to the specific version of the DHT product that is subject to assessment.

[DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems](#) applies to the manufacturers of Health IT systems. A Health IT system is defined as “product used to provide electronic information for health and social care purposes” meaning it can “influence, support or manage real time or near real time direct care of patients/service users”.

Suppliers should note that while DTAC applies to DHTs which cover software products, Health IT systems subject to DCB0129 may include hardware elements provided alongside the software. If the DHT product under assessment is being provided as part of a Health IT system with

hardware elements, the DCB0129 documentation requested should cover the full scope of the Health IT system being offered, including any hardware elements. If a manufacturer considers that the C1 Clinical Safety is not applicable to the product being assessed, rationale must be submitted detailing why DCB0129 does not apply.

Health and care organisations should note that the [DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems](#) standard applies to organisations in which the health IT is deployed or used. It is a requirement of the standard (2.5.1) that prior to deploying Health IT systems the organisation must ensure that the manufacturer and Health IT system complies with DCB0129. Health and care organisations must do so in accordance with the requirements and obligations set out in the standard, which includes that personnel involved have the knowledge, experience and competences appropriate to undertaking the clinical risk management, such as a qualified Clinical Safety Officer. Health and care organisations should ensure that all questions in this section of DTAC is assessed by the same personnel.

If the Clinical Safety Officer or any other individual in the health and care organisation 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 \(www.gov.uk\)](#). For DHT products that are not a medical device, any event which impacts upon the safety of one or more patients accessing NHS services should be recorded to the Learn from patient safety events (LFPSE) service, in order to support both national learning and local responses. Use your organisation's LFPSE-connected LRMS software where possible, or else record the event using LFPSE's online service: [Learn from patient safety events](#).

Code	Question	Options	Supporting information	Scoring criteria
C1.1.1	Does your DHT product, or any component within it, qualify as Software or Artificial Intelligence as a Medical Device under the UK Medical Devices Regulations 2002?	Yes	<p>If you have answered Yes, then please complete a <a href="#">Pre-acquisition questionnaire (PAQ form)</a> for medical devices in respect of the product or its component, and provide this alongside the DTAC form. Then proceed to Question C.1.1.2</p> <p>Surgery Intellect, which is powered by TORTUS AI, our third party strategic partner, is registered as a medical device with the Medicines and Healthcare products Regulatory</p>	To pass, the manufacturer is required to provide a completed PAQ form if they have answered Yes

			<p>Agency (MHRA). The MHRA number is Tortus AI - 30011. TORTUS AI's listing can be found here:  <a href="https://pard.mhra.gov.uk/manufacturer-details/115018">https://pard.mhra.gov.uk/manufacturer-details/115018</a></p> <p>The Pre-acquisition questionnaire can be found within the TORTUS Trust Centre:  <a href="https://trust.tortus.ai/">https://trust.tortus.ai/</a></p>	
C1.1.2	Is your product classified as a standalone medical device?	No	<p>Before responding to this question, please read <a href="#">guidance on applicability</a> of the DCB0129 and DCB0160 clinical safety standards found on NHS England's website.</p> <p>This question is intended to determine whether your product is a standalone medical device, or whether it forms part of or integrates with a Health IT System that your organisation places on market (e.g. an EPR incorporating a SaMD or AlaMD module).</p> <p>In the latter case, the product as a whole may have non-medical intended-uses not covered by medical device regulations; but may still pose clinical risks and as such are subject to the DCB0129 standard.</p> <p>If you have answered Yes, you may proceed to Section C2. Otherwise, proceed to question C1.2.</p>	

C1.2	Is your product designed to provide electronic information to influence, support or manage the real time or near real time direct care of patients/service users?	Yes	<p>This question determines whether your product is either itself or part of a Health IT System subject to <a href="#">DCB0129</a>. A Health IT system is defined as a product used to provide electronic information for health and social care purposes, meaning it may influence, support or manage real time or near real time direct care of patients/service users. Further <a href="#">guidance on applicability</a> can be found on NHS England's website.</p> <p>If you have answered Yes, you may skip question C1.2.1 and proceed to C1.2.2</p> <p>If you have answered No, please provide a justification in C1.2.1. You may then skip the following questions and proceed to question C2.</p> <p>All documentation in relation to DCB0129 can be found within the Trust Centre:  <a href="https://surgeryconnect.academy/trust-centre/">https://surgeryconnect.academy/trust-centre/</a></p>	
C1.2.1	Please provide a justification for why your product does not fall in scope of DCB0129	N/A	<p>Where a manufacturer believes their product is not in scope, they must provide their reasons justifying this.</p> <p>This justification should be provided by the manufacturer considering the</p>	

			<p>terms as defined in the DCB0129 standard and applicability guidance linked previously.</p> <p>Please note commissioning organisations can challenge the determination if not in agreement.</p>	
C1.2.2	<p>Have you undertaken Clinical Risk Management activities for this product which comply with DCB0129?</p>	Yes	<p>The <a href="#">DCB0129</a> standard applies to manufacturers of Health IT system.</p> <p>If your software product is placed on the market as part of a system including hardware components, please provide DCB0129 documentation for the whole Health IT system, including hardware elements.</p>	<p>To pass, the manufacturer is required to confirm that they have undertaken Clinical Risk Management activities in compliance with DCB0129.</p>
C1.2.3	<p>Please detail your clinical risk management system</p>	Provided	<p>All documentation in relation to Clinical Risk Management systems can be found within the Trust Centre:</p> <p>X-on <a href="https://surgeryconnect.academy/trust-centre/">https://surgeryconnect.academy/trust-centre/</a></p>	<p>To pass, the manufacturer must demonstrate that a clinical risk management system, compliant with DCB 0129, is in place and that it was adhered to throughout product development.</p> <p>This must include evidence that clinical safety risks have been identified, evaluated and mitigated throughout the lifecycle of the product.</p>
C1.2.4	<p>Please supply your Clinical Safety Case Report and Hazard Log</p>	Provided	<p>Specifically, your DTAC submission should include:</p> <ul style="list-style-type: none"> <li>• A definition of the scope of</li> </ul>	<p>To pass, the manufacturer is required to submit the Clinical Safety Case Report and Hazard Log that is compliant with the requirements set out in DCB0129. This</p>

			<ul style="list-style-type: none"> <li>• your assessment</li> <li>• A summary of your approach to clinical risk management and the activities you followed</li> <li>• A summary of the hazard assessment undertaken, including identified risks, their evaluation and mitigation strategies considered and implemented.</li> <li>• A Test Summary section that demonstrates that the product has been appropriately (Functionally &amp; Non-functionally) tested</li> <li>• A summary of any perceived Test Issues (Defects) The clear identification of hazards which will require user or commissioner action to reach acceptable mitigation (for example, training and business process change)</li> </ul> <p>The hazard log can be appended at the end of this document.</p> <p>Example <a href="#">Clinical Safety Case Report and Hazard Log templates</a> can be downloaded from the NHS England website.</p> <p>Please note that in relation to the Hazard Log, there is no system for quantifying and stratifying risk that specified for universal use in the NHS.</p>	<p>should be commensurate with the scale and clinical functionality of the product and address the clinical risk management activities specified with the standard.</p> <p>The Clinical Safety Case Report should present the arguments and supporting evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment at the defined point in the product's lifecycle. It should provide the reader with a summary of all the relevant knowledge that has been acquired relating to the clinical risks associated with the product at that point in the life cycle:</p> <ul style="list-style-type: none"> <li>• A clear and concise record of the process that has been applied to determine the clinical safety of the product</li> <li>• A summary of the outcomes of the assessment procedures applied</li> <li>• A clear listing of any residual clinical risks that have been identified and the related operational constraints and limitations that are applicable</li> <li>• A clear listing of any hazards and associated clinical risks that have been transferred, together with any declared risk control measures, that are to be addressed as part of the clinical risk management process in the organisation where the product is being deployed</li> <li>• A listing of outstanding test issues / defects associated with the product</li> </ul>
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			<p>The manufacturer must declare, in the Clinical Safety Case Report, the scheme they have used.</p> <p>Commissioning organisations will evaluate this scheme in the context of their own tolerance for risk.</p> <p>All documentation in relation to Clinical Safety Case Report and Hazard Log can be found within the Trust Centre:</p> <p>X-on  <a href="https://surgeryconnect.academy/trust-centre/">https://surgeryconnect.academy/trust-centre/</a></p> <p>TORTUS (for the purposes of our third-party integration for Surgery Intellect)  <a href="https://trust.tortus.ai/">https://trust.tortus.ai/</a></p>	<p>which may have a clinical safety impact.</p> <p>The Hazard Log should record and communicate the on-going identification and resolution of hazards associated with the product. All foreseeable hazards should be identified, and the risk of such hazards should be reduced to acceptable levels.</p> <p>A summary should also be provided to the assessor of identified hazards that the manufacturer has been unable to mitigate to as low as it is reasonably practicable. It should also clearly identify the hazards which will require user or commissioner action to reach acceptable mitigation.</p>
C1.2.5	Please provide the name of your Clinical Safety Officer (CSO), their profession and registration details	Provided	<p>The CSO must:</p> <ul style="list-style-type: none"> <li>• Be a suitably qualified and experienced clinician</li> <li>• Hold a current registration with an appropriate professional body relevant to their training and experience</li> <li>• Be knowledgeable in risk management and its application to clinical domains</li> <li>• Have sufficient responsibility to be able to ensure processes</li> </ul>	<p>To pass, the manufacturer must have a named CSO, which may be provided through an outsourced arrangement.</p> <p>They must be a suitably qualified and experienced clinician and hold a current registration with an appropriate professional body relevant to their training and experience.</p>

			<p>defined in DCB0129 are followed</p> <p><b><u>To note: the requirement for the Clinical Safety Officer to have undergone NHS training is no longer applicable. The requirements of the role are summarised above; with full details of expected responsibilities and competencies found in the standard's documentation and implementation guidance.</u></b></p> <p>Dr. Imran Khan GP, Clinical Safety Officer, and Clinical Informatician.</p> <p>Imran.khan15@nhs.net Imran@khanclinicalinformatics.net</p> <p>GMC Reg. 7278705 <a href="https://www.khanclinicalinformatics.net/">https://www.khanclinicalinformatics.net</a> /</p>	
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## C2 - Data protection

Establishing that your product collects, stores and uses personal data) in compliance with the UK General Data Protection Regulation (UK GDPR) and other relevant legislation.

Code	Question	Options	Supporting information	Scoring criteria
C2.1	<p>If your organisation has or will have direct or remote access to any patient data or NHS systems, please confirm you are compliant (having standards met or exceeded status) with the annual Data Security and Protection Toolkit (DSPT) assessment for the current year if new to market, or previous year if you have yet to provide a return for the current year.</p>	Confirmed	<p>The DSP Toolkit has been completed (Standards Exceeded) and compliance is maintained.            Organisation Code 8JM42            Link:  <a href="https://www.dsptoolkit.nhs.uk/OrganisationSearch/8JM42">https://www.dsptoolkit.nhs.uk/OrganisationSearch/8JM42</a></p>	<p>To pass, the manufacturer must confirm that they are compliant with the DSPT assessment and achieve Standards Met or Exceeded status for the current year, or previous year. This should be validated by assessors against the <a href="#">DSPT database</a>.</p>
C2.2	<p>Does the product or service <a href="#">process</a> any personal data or data about deceased individuals?</p> <p>This includes any personal data processed by a sub processor.</p>	Yes	<p>If Yes, please continue to the following questions. If No, you may skip the following questions and proceed to question C3.</p> <p>If your organisation has no role in operating or hosting the product or service (e.g. products designed to be hosted on the care providers infrastructure) and with no means of accessing information contained within it (including remote access for support and maintenance</p>	

			<p>purposes) then you may answer No to this question.</p> <p>Please note that the UK General Data Protection Regulation (UK GDPR) applies to the processing of <a href="#">personal data</a>.</p> <p>While it does not apply to deceased individuals, there are additional legal considerations under the <a href="#">common law duty of confidentiality for health and care data</a>, including for data of deceased individuals.</p>	
C2.2.1	Please attach evidence of a current registration with the Information Commissioner's Office (ICO).	Provided	<p>ICO registration Z8221333  <a href="#">ICO Certificate</a></p>	To pass, the manufacturer is required to submit evidence that they have a current registration with the ICO, which may be a screenshot of their registration number that includes details of the expiration date. This should be validated by the assessor against the <a href="#">ICO's Register of Fee Payers</a> .
C2.2.2	Please attach the Data Protection Impact Assessment (DPIA) relating to the product.	Provided	<p>DPIAs are available for all our Product components, and can be found within the Trust Centre:</p> <p>X-on  <a href="https://surgeryconnect.academy/trust-centre/">https://surgeryconnect.academy/trust-centre/</a></p>	To pass, the manufacturer must provide a DPIA that provides sufficient detail for the assessing organisation to understand how the technology will use personal data and then determine whether it agrees that it is UK GDPR compliant and/or accepts any risks.

				<p>It must cover:</p> <ul style="list-style-type: none"><li>- A summary of the product, including how it processes data</li><li>- A list of the data fields required</li><li>- How data flows into, within and out of the product</li><li>- What security controls are in place in relation to end users (on/off boarding users; what limits their access within the product)</li><li>- the technical and organisational measures in place, which must cover data in transit and at rest, and be proportionate to the risk of the processing</li><li>- details of which countries the data will be stored in or flow through</li><li>- whether the manufacturer's staff will be able to access any personal data, which must be proportionate and have an identified legal basis for doing so</li><li>- who will be the controller for all elements of the processing</li><li>- arrangements for retention and disposal of data</li><li>- details of any processors or sub processors used for any part of the technology, and confirmation that there is a legally binding agreement to cover this processing</li><li>- the confidentiality, availability and integrity risks associated with processing the personal data within its product, and how it</li></ul>
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				<p>mitigates these</p> <ul style="list-style-type: none"> <li>- how the product supports data subject rights</li> </ul> <p>The manufacturer's DPIA should be used by the NHS organisation when completing their own DPIA, as controller.</p>
C2.2.3	<p>Provide a copy or link to your product's <a href="#">transparency information</a></p>	Provided	<p>X-on's Privacy Notice can be found using the below links:</p> <p><a href="https://www.x-on.co.uk/privacy-notice/">https://www.x-on.co.uk/privacy-notice/</a></p> <p><a href="https://help.x-onweb.com/en/articles/83518-privacy-policy">https://help.x-onweb.com/en/articles/83518-privacy-policy</a></p> <p>NHS England has developed a template <a href="#">privacy notice</a> and <a href="#">guidance</a>.</p>	<p>To pass, the manufacturer must demonstrate that it has transparency materials relating to the product available to the buyer that helps meet <a href="#">transparency requirements</a> under UK GDPR. This may be published DPIAs or other documentation that explains how the product processes information.</p> <p>The controller can use this content to inform its own transparency materials for the product.</p>
C2.2.4	<p>Provide the relevant product terms and conditions regarding use of user data, end user licence agreement or equivalent.</p> <p>If this does not apply to your product, state this and explain why.</p>	Not provided	<p>UK GDPR principles set a legal requirement for health and care organisations to only engage in processing that it has <a href="#">assessed as fair</a>.</p> <p>Our Surgery Intellect, powered by TORTUS, uses Surgery Connect as the core platform. All Surgery Connect contracts are issued in a standard form by the NHS Commercial Hub under the rules of the Better Purchasing Framework for advanced cloud based telephony. The contract was negotiated by the Hub and uses the NHS Terms and Conditions for</p>	<p>To pass, the manufacturer must demonstrate that its terms and conditions are clear and fair with regard to privacy and use of data.</p> <p>This could be provided through the relevant clauses in the products contract or a separate terms and conditions of use document for end users.</p>

			<p>the Supply of Goods and the Provision of Services. Schedule 3 (Contract Version) (August 2022). Schedule 3 sets out the detailed provisions for Information and Data Provisions. .</p> <p>A copy of this contract is available: <a href="#">NHS Contract Template Surgery Connect</a></p> <p>Or from the Hub on request.</p> <p>Surgery Intellect, powered by TORTUS, has its own Information and Data Provision schedule order to address the user data issues specific to that service:</p> <p><a href="#">Surgery Intellect Data Schedule</a></p>	
C2.2.5	Please confirm where your product (including any third-party components) store and process data.	UK only	If UK only, skip to C3.	
C2.2.6	If you store or process data outside of the UK, please name the country and set out how the arrangements are compliant with current legislation.	N/A	<p>UK GDPR requires safeguards to be applied to personal data processed (including storage or transfer through of data) in any country outside of the UK. The UK government maintains a <a href="#">list of countries</a> that it has granted adequacy status, which effectively means that personal data can flow freely to that country. To process data in any other country, an alternative legal mechanism compliant with UK GDPR such as an</p>	<p>To pass, the manufacturer must provide a statement to confirm that any data shared or stored outside the UK is compliant with current legislation. This could be that the country is considered adequate by the ICO. If not, the processing must be covered by an appropriate safeguard such as an IDTA; or binding corporate rules, which must also have an accompanying transfer risk assessment.</p>

			<a href="#">Internation Data Transfer Agreement (IDTA)</a> is required. The manufacturer must ensure it has an appropriate safeguard in place if any personal data within its product leaves the UK.	
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### C3 - Technical security

Establishing that your product meets industry best practice security standards.

Dependent on the DHT 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 product under assessment, and not generally for your organisation.

Code	Question	Options	Supporting information	Scoring criteria
C3.1	Please attach your Cyber Essentials Certificate	Provided	<p>Cyber Essentials and Cyber Essentials Plus Certificates can be found on the company Trust Centres:</p> <p><a href="https://surgeryconnect.academy/trust-centre/#compliance">https://surgeryconnect.academy/trust-centre/#compliance</a></p>	<p>To pass, the manufacturer must have a valid Cyber Essentials certificate.</p> <p>Certification lasts for a period of 12 months so the certificate should be within date. This should be validated against the <a href="#">IASME database</a>.</p>

C3.2	Please confirm whether you have signed the <a href="#">Cyber Security Charter for Suppliers to the NHS?</a>	Yes	<p>If you have responded 'Yes' please skip remaining questions within the C3 section.</p> <p>If you have responded 'No' please continue to respond to all remaining questions within this section.</p>	
C3.3	If the product is internet based (e.g., website) or is provided as a service accessible from the internet (e.g., Mobile App, server-side software), 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”	Provided	<p>The NCSC provides guidance on <a href="#">penetration testing</a>. The OWASP Foundation provides guidance on the <a href="#">OWASP top 10 vulnerabilities</a>.</p> <p><a href="#">X-on Health Ltd Penetration Test 2026</a></p>	<p>To pass, the manufacturer must evidence that the product has undergone penetration testing by a third party that included the OWASP top 10 vulnerabilities.</p> <p>The penetration testing / summary report must demonstrate there are no vulnerabilities that score 7.0 or above using the <a href="#">Common Vulnerability Scoring System (CVSS)</a>.</p>
C3.4	Please confirm that software has been produced in adherence to the Department for Science, Innovation and Technology (DSIT) / National Cyber Security Centre (NCSC) <a href="#">Software Security Code of Practice</a> and commits to meeting the principles of secure design and development, secure build environment, secure deployment and maintenance and communication with customers.	Yes	DIST publishes a <a href="#">Software Security Code of Practice</a> . Software provided to the NHS should be produced in adherence to this code of practice and principles.	To pass, the manufacturer must confirm that their development process aligns to the Software Security Code of Practice and that they commit to the principles.

C3.5	Please confirm you have a plan for implementing multi-factor authentication for all account types, preferably through identity federation.	N/A	The NCSC provides guidance on <a href="#">Multi-Factor Authentication</a> .	To pass the manufacturer must confirm they have a plan in place.
C3.5.1	If applicable, please confirm that all supplier accounts with privileged access to the product (e.g. for provision of support) have multi-factor authentication (MFA) enabled or equivalent MFA is applied at the remote end when accessing the product?	N/A	The NCSC provides guidance on <a href="#">Multi-Factor Authentication</a> .	<p>To pass, the manufacturer must confirm all supplier accounts with privileged access to the product have MFA enabled; or that this is not applicable.</p> <p>MFA must be enforced on all privileged access connections to the product, and on all remote access connections to the product, but does not necessarily need to be enforced on the product itself (for example MFA may be applied to initial connectivity to a network from which the product can be accessed directly).</p>
C3.6	Please confirm whether logging and reporting requirements have been defined.	N/A	<p>The NCSC provides guidance on <a href="#">logging and protective monitoring</a>.</p> <p>To confirm yes to this question, logging (e.g., audit trails of all access) must be in place. It is acknowledged that not all manufacturers will have advanced audit capabilities.</p> <p>We can confirm that logging and reporting requirements have been defined - there are audit trails of all actions and levels of access</p>	To pass, the manufacturer must confirm that logging and reporting requirements have been defined.

			within the product.	
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## C4 - Interoperability criteria

Establishing how well your product exchanges data with other systems.

It is important that relevant technologies in the health and social care system are interoperable in terms of hardware, software and data contained within in order for health and social care providers to deliver integrated care. 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 Program 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	Options	Supporting information	Scoring criteria
C4.1	Does your product expose any Application Program Interfaces (API) or integration channels	No	If No, you may skip the following questions and proceed to C4.2	

	for other products relevant to the provision or administration of health or social care?		If Yes, please continue to C4.1.1.	
C4.1.1	If yes, please confirm that these APIs use appropriate international or industry standards for interoperability appropriate for the use case. Please list these and explain why they are appropriate.	N/A	The NHS England <a href="#">Standards Directory</a> allows manufacturers to identify standards relevant for their products use case.  NHS England website <a href="#">Developer and integration</a> hub provides guidance on national APIs and API standards.	To pass, manufacturers must list and justify the relevant interoperability standards used.
C4.1.2	Please confirm these APIs both: <ul style="list-style-type: none"> <li>• follow GDS Open API Best practice guidance, and</li> <li>• are openly documented and freely available to third parties.</li> </ul>	N/A	See Government Digital Services provide guidance on <a href="#">Open API best practice</a> , including <a href="#">open documentation</a> .  If you are unable to confirm the above, please complete Question 4.1.3, otherwise proceed to question 4.2	To pass the manufacturer must confirm this criteria is met, or set out their approach to making API's available to third parties in C4.1.3
C4.1.3	If you are unable to confirm your APIs meet the previous criteria, please set out the basis on which your APIs are documented and made available to third parties.	N/A		To pass, the manufacturer must set out the basis on which their APIs can be made available to third parties to develop integrations.
C4.2	Is your product intended to	Yes	If No, proceed to C4.3, otherwise	

	share or receive data from national or local systems for managing or delivering patient care (e.g. clinical record systems, patient administration systems etc.) or for other administrative purposes where a patient identity is relevant (e.g. license management of a digital therapeutic)?		continue to C4.2.1	
C4.2.1	Is your product capable of using the NHS number to identify patient data when exchanging data?	No	The NHS number is the <a href="#">mandated standard identifier</a> for patients. Further guidance can be found <a href="#">here</a> .  If No, proceed to C 4.2.3, otherwise continue to C4.2.2	To pass the manufacturer must answer yes, or set out an alternative approach for ensuring data quality.
C4.2.2	Does your product integrate to either the NHS Personal Demographics Service, or to other local record systems to establish/validate the patient NHS number?	Yes - we are onboarded with NHS Personal Demographics Service (PDS FHIR API) but we do not use PDS to identify patient data for Surgery Intellect, powered by TORTUS.	The <a href="#">Personal Demographics Service</a> is used as the national master database for all NHS patients in England.  In process of onboarding to PDS but have not completed, please set out the current situation in your response to C4.2.3  If Yes, please skip C4.2.3 and proceed to C4.2.4	To pass the manufacturer must answer yes or set out an alternative approach for ensuring data quality.

C4.2.3	If you have answered No to either C4.2.1 or C4.2.2 please set out the approach taken to identify patient records that ensures correct identification and data quality	We integrate directly with Optum (EMIS Web), TPP SystemOne, Medicus, and Vision, for the purpose of identifying patient records to ensure correct identification and data quality.		To pass the manufacturer must set out how patient data is correctly identified, and how data accuracy is to be maintained when integrating with other local or national systems
C4.2.4	If the product is to be used directly by patients, do you use NHS login to verify the identity of and authenticate the user?	No	<p>NHS England provides guidance on <a href="#">NHS login for partners and developers</a>.</p> <p>NHS England provides a list of all current <a href="#">digital health and social care services that integrate with NHS Login</a>.</p> <p>If you have answered No to this question, please proceed to C4.2.5, otherwise you may skip the following questions and move to Section D.</p>	If applicable, to pass, the manufacturer must answer yes, or set out adequate data protection measures in C4.2.6
C4.2.5	If the product is to be used by public health or adult social care organisations as part of	Yes	Where DHT products are used by Health and Care provider organisations to deliver services, the product must enable the care	If applicable, to pass, the supplier must answer yes.

	<p>their delivery of care services (e.g. booking platform, patient access gateway) does your product support compliance with DAPB3051 standard for identity verification and authentication?</p>		<p>provider organisation to comply with <a href="#">DAPB3051 Identity Verification and Authentication Standard for Digital Health and Care Services</a>.</p> <p>If you have answered Yes, you may skip the following question and proceed to Section D.</p> <p>If you have answered Not Applicable, please complete section C4.2.6</p>	
C4.2.6	<p>If you are not using NHS login to authenticate the user, please set out your approach to authenticating the user and what data protection measures are in place.</p>	<p><a href="#">Yes - We are not using NHS login.</a></p>	<p>Any product that is to be used directly by the patient should have a robust approach to identity verification and authentication sufficient to ensure data protection.</p> <p><b>User Authentication Approach and Data Protection Measures</b></p> <p>X-on Health does not currently support NHS Login for user authentication. Instead, we utilise a robust multi-layered authentication strategy:</p> <p>Clinical System Integration &amp; MFA: Multi-Factor Authentication (MFA) is applied to the initial network connectivity. Users must authenticate via their primary clinical system using a NHS</p>	<p>To pass, the manufacturer must set out their approach to authenticating the user in a way that ensures users privacy is protected.</p>

			<p>Smartcard or equivalent MFA method. This serves as a prerequisite to accessing the restricted functionality of Surgery Connect and Surgery Intellect.</p> <p>Single Sign-On (SSO): In addition to clinical system authentication, users are required to sign on via X-on SSO to gain access to the Phonebar interface. This dual-layer authentication protocol is applicable to all user accounts.</p> <p>Role-Based Access Control (RBAC): The platform employs granular RBAC to ensure that staff, including administrative, clinical, and reporting personnel, access only the specific data required for their professional duties.</p> <p>Data Protection Measures To ensure the security of patient and citizen data, X-on Health employs the following technical and organisational safeguards:</p> <p>Audit Trails: The system maintains comprehensive, tamper-resistant, and time-stamped audit logs. These logs record all user logins, data queries, and access to patient records, ensuring full accountability for every action taken within the system.</p>	
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			<p>Encryption Standards: All data at rest is encrypted using AES-256. Data in transit is secured using TLS 1.2+ with certificates signed using 2048-bit RSA/SHA-256.</p> <p>UK-Based Sovereignty: All patient data is processed and stored exclusively within secure, UK-based Tier 3 data centres.</p> <p>Compliance &amp; Assurance: Our security framework is validated by ISO 27001 certification, Cyber Essentials Plus, and annual CREST-approved penetration testing. We consistently maintain an "Standard Exceeded" status on the Data Security and Protection Toolkit (DSPT) (ODS code: 8JM42).</p>	
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## D. Key principles for success

The elements defined in this section provide a comparative indication of the products fit for use in the NHS in England and in public Adult Social care. The assessment is not intended to result in pass or failure. It provides insight on the accessibility and usability of a product and highlights areas that the manufacturer could improve on, and may also inform buyers decisions on product selection based on comparison between products.

This will not contribute to the overall Assessment Criteria as set out in Section C.

## D1 - Usability and accessibility

Establishing that your product has followed best practice.

Code	Question	Options	Supporting information
D1.1	Provide information about how the product is used or fits into existing systems (e.g., care pathways). For example, by providing a user journey demonstrating how the product is intended to fit into their care pathway or clinicians or other staff's user journey, or providing information about how product use (e.g., provide a copy of the instructions for use).	Provided	<p>Understanding intended use case in context of user journey is important to help Health and Care providers to design accessible, usable digital care pathways.</p> <p>User journey diagrams are accessible via <a href="#">Journey diagrams</a></p> <p>Extensive video demos are accessible via our online help centre. <a href="#">X-on Health Help Centre</a></p> <p>We also have a learning platform, the Academy, which provides access to a diverse range of interactive training resources that provide users with lots of information about product use. Our CPD-accredited training courses help to engage users with their understanding on how to optimise their use of X-on software and services in an innovative way, with access to interactive expert knowledge through a mapped learning plan.</p>
D1.2	Do you undertake testing with intended users to validate the product's usability?	Yes	<p>Usability of software by the intended users is a key factor in ensuring efficiency, efficacy and safety.</p> <p>The product is mature and deployed extensively within the NHS.</p> <p>In addition to formal acceptance during deployment an extensive set of customer references is available on the web site and through the Practice Index referral system. These include appraisals of usability.</p>

			We also conduct pilots of all our major products and features, following an extensive Quality Assurance testing process and subject to relevant approvals, before deployment in order to validate the product's usability.
D1.3	Please confirm that you have read the Accessible Information Standard and considered how its requirements should be reflected in the design of your product.	Confirm	<p>The <a href="#">Accessible Information Standard</a> is a set of requirements regarding accessibility and other elements necessary for NHS bodies compliance with the Equalities Act (2010).</p> <p>While it is not binding on IT suppliers, providers' duty to conform may create requirements for DHTs used in the provision of Health and Adult Social Care in the UK.</p>
D1.4	Is your product a web or mobile application?	Yes	<p>Please refer to the WCAG to determine if your product is a web or mobile application.</p> <p>If yes, complete the following questions. If not, Section D is now complete.</p>
D1.4.1	If your product is a web or mobile application, does it comply with the Web Content Accessibility Guidelines (WCAG) 2.2 scoring AA or higher?	No, but a plan and timeline for achieving WCAG 2.2 AA is in place	<p>It is UK <a href="#">Government policy</a> that from October 2024 digital public services should achieve AA or higher on the Web Content Accessibility Guidelines (WCAG) 2.2 as a means of demonstrating compliance with The Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018.</p> <p>While this may not apply directly to third party products in all situations, meeting these requirements remains an important factor for digital products used in the Health and Adult Social Care System.</p> <p>If your product does not currently meet WCAG 2.2 AA, but have a plan in place for doing so, please answer D1.3.2.</p> <p>Otherwise proceed to D1.3.3</p>

			Commitment to creating documentation with WCAG 2.2 Level AA accessibility regulations in mind (high colour contrast, text alternatives for images, full keyboard navigation, clear language).
D1.4.2	Please set out the timescale by which you plan to obtain WCAG 2.2 AA	Yes	Surgery Intellect, powered by TORTUS, is partially conformant with WCAG 2.2 level AA. This means that some parts of our content do not fully conform to the accessibility standard. We are always striving to improve the accessibility of our products and services. If you have encountered any issues with using any of our products, please call us on 0333 332 6633. We plan to work towards obtaining WCAG 2.2 AA where possible, and the standard is actively involved in our product design process.
D1.4.3	Provide a link to your published accessibility statement.	Provided	The Government Digital Service provides guidance on <a href="#">accessibility and accessibility statements</a> , including a sample template.  X-on accessibility statement can be found on the website <a href="https://help.x-onweb.com/en/articles/83525-accessibility-statement">https://help.x-onweb.com/en/articles/83525-accessibility-statement</a>
D1.5	Please provide your average service availability for the past 12 months, as a percentage to two decimal places	99.99%	Provision of reliable, high availability services is a requirement for digital services in the public sector  A service agreement is part of the contract with customers. All customers have access to the support portal which displays service availability and allows reporting of any issues.  Service availability over the past 12 months has been 99.99% to 2 decimal places.

## 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 - N/A
- B4 - User journeys and data flows - [Journey diagrams](#)
- C1.1 - Pre-Acquisition Questionnaire Form - TORTUS AI Trust Centre
- C1.2.3 - Clinical Safety Case Report - X-on Health Trust Centre
- C1.3.4 - Hazard Log - X-on Health Trust Centre
- C2.2.1 - Information Commissioner's registration - [ICO Certificate](#)
- C2.2.2 - Data Protection Impact Assessment (DPIA) - X-on Health Trust Centre
- C2.2.4 Products terms and conditions regarding use of user data, end user licence agreement or equivalent - X-on Health Trust Centre
- C3.1 - Cyber Essentials Certification - X-on Health Trust Centre
- C3.2 - External Penetration Test Summary Report - [Penetration Test 2026](#)
- D1.1 - User Journeys and/or how the product fits into at user pathway or journey - [Journey diagrams](#)