



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

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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.

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A. Company information - Non-assessed section

Information about your organisation and contact details.

Code	Question	Response
A1	Provide the name of your company	Concentric Health Ltd
A2	Provide the name of your product	Concentric
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	Dr Dafydd Loughran, CEO
A5	Provide the key contact's email address	daf@concentric.health
A6	Provide the key contact's phone number	+44 1446 773032
A7	Provide the registered address of your company	Tramshed Tech, Pendyris Street, Cardiff, CF11 6BH
A8	In which country is your organisation registered?	England and Wales
A9	If you have a Companies House registration in the UK please provide your number	10733991
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?	Patients, Clinical Support, and Workforce
B2	Provide a clear description of what the product is designed to do and of how it is expected to be used	Concentric is a digital consent to treatment (aka econsent) application that is used in place of traditional paper consent forms. Concentric supports clinicians and patients with evidence-based information that can be personalised to the individual. Consent information is made available to patients outside their consultation, including the ability to give consent remotely where appropriate.
B3	Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated	<ul style="list-style-type: none"> • Consent process flexibility - Consent process becomes more flexible and adaptable to the needs of the individual and the system, including access over time, access from anywhere, and remote consent functionality through an intuitive application. • Consent information personalisation - Consent information can be easily adapted and personalised to the individual. • Integration delivering joined-up care - Integration of the consent process into other systems to deliver joined-up care, including (where available) a main electronic health record (EHR) and patient held record (PHR). • Trusted content across all specialties - Standardised, evidence-based information and risk profiles - including COVID-19 risks - across over 1,200 operations, procedures and treatments to support use across the organisation as the default mechanism of consent. Trusted across multiple NHS and private sector organisations. • Supporting best practice - Support in meeting best practice consent processes through visibility of process (e.g rate of consent on the day of surgery), and nudges (e.g personalisation of information and documenting personalised notes). • Reduced clinical errors - Reduced risk of wrong site surgery and patient identification errors through legible consent PDFs. • Accessible from anywhere - Cloud-based, integrated system meaning that the clinical consent record can be accessed and amended from anywhere without the need for complex paper logistics.

		<ul style="list-style-type: none"> ● Full audit trail, cryptographically secured - Full audit trail maintained and available for each consent episode, including any customisations, when information was shared, when consent was given etc. Advanced cryptography ensures that the audit trail cannot be tampered with and the state of the episode at each stage can be demonstrated. ● Advanced Electronic Signature - The patient signature recorded within Concentric is classed as an advanced electronic signature by eIDAS UK regulation and is fully admissible in a court of law. ● Improved clinician experience and wellbeing - Improved clinician experience of the consent process, including the ability to deal with complex clinical scenarios (e.g combined procedures). Improved clinician wellbeing due to reduced clinical risk associated with the consent process. ● Saves clinicians time - Reduced consent process administration time due to integration with patient demographics, document storage, and user authentication, an intuitive application and procedure-specific templates. ● Reduced day-of-surgery cancellations and delays - Increased completion of consent prior to the day of surgery (supported by remote consent) and improved visibility of the consent status within Concentric and the EHR reduces day of surgery delays and cancellations. ● Reduced medico-legal risk from lost forms - The risk of losing legal consent forms is removed with a digital process. ● Reduction to near zero use of paper for consent forms and information leaflets - Use of paper, both carbon-copy consent forms and paper information leaflets can be reduced, with paper copies printed only where necessary for a patient without digital access.
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	<p>This page (https://concentric.health/resources/getting-started/#how-concentric-is-used) describes the user flow, and the different ways Concentric is used.</p> <p>This page (https://concentric.health/resources/technical-information-governance/#data-flows) outlines the data flows between clinician, patient, Concentric, and the healthcare organisation's other systems.</p>

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	Concentric clinical risk management system (https://concentric.health/resources/clinical-risk-management-system)
C1.1.2	Please supply your Clinical Safety Case Report and Hazard Log	Clinical safety case report (https://docs.google.com/document/d/e/2PACX-1vRK1nm93UPbM3MzCysCQP5NwyaPPTFzInXOZYb2c_qu2DCKOiheYTzqZLtRv2eucFYpcn3Gn2tG0Anc/pub) Clinical safety hazard log (https://docs.google.com/spreadsheets/d/e/2PACX-1vSan37ua-7Hmky-TLAL2qKaZz9LtyvAU2g0BJTgWPgk gKFI-7auPFR0KKie4ea0-A3KMDtRyuGACPfc/pubhtml)

C1.2	Please provide the name of your Clinical Safety Officer (CSO), their profession and registration details	Dr Dafydd Loughran GMC 7265351 CSO training completed (NHS Digital)
C1.3	If your product falls within the UK Medical Devices Regulations 2002, is it registered with the Medicines and Healthcare products Regulatory Agency (MHRA)?	Not applicable, outside of the scope of the UK Medical Devices Regulations 2002.
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
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	Google Cloud Platform (cloud hosting). Google Cloud Platform data processing and security terms Postmark (patient and clinician emails). Postmark / Concentric Health data processing addendum Twilio (patient SMS). Twilio data processing addendum

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.	<p>Not required to be registered with the Information Commissioner. As an organisation which is only a data processor, not a data controller, there is no expectation to be registered with the Information Commissioner (ICO).</p> <p>ICO Self-assessment questionnaire: Do you use CCTV for the purposes of crime prevention? No Are you processing personal information? Yes Do you process the information electronically? Yes Is your organisation responsible for deciding how the information is processed? No</p> <p>ICO Self-assessment outcome: No requirement for registration to pay a fee</p>
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.	Martyn Loughran CTO martyn@concentric.health
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 (https://www.dsptoolkit.nhs.uk/OrganisationSearch/8WH16)
C2.3.2	Please attach the Data Protection Impact Assessment (DPIA) relating to the product.	Different integrations mean that organisations put in place slightly different DPIA's based on the data flows occurring within the organisation. This is the template DPIA used.
C2.4	Please confirm your risk assessments and mitigations /	Confirmed

	access controls / system level security policies have been signed-off by your Data Protection Officer (if 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 (for UK healthcare organisations)
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

C3 - Technical security

Establishing that your product meets industry best practice security standards and that the product is stable. Depending 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	Attached (https://drive.google.com/file/d/1gDO7hkCQVoscGe-6O4WJTKJcZiIY-wCS/view?usp=sharing) (valid until 28 June 2022)
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.	Summary from Sapphire Web Application Vulnerability Assessment conducted between the 15th and 18th November 2021: Sapphire conducted a web application assessment against the defined scope, in order to find vulnerabilities that could be remotely exploited and lead to financial or reputational losses. Overall, the security posture was found to be in a good state backed up by the fact there were no critical or serious risk vulnerabilities found. The issues discovered range from medium to low, based on threats posed.
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
C3.5	Please confirm whether logging and reporting requirements have been clearly defined.	Yes
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
C4.1.1	<p>If yes, please provide detail and evidence:</p> <ul style="list-style-type: none"> - 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 - Confirm they are documented and freely available - Third parties have reasonable access to connect 	<p>Details relating to our integrations, including FHIR integrations are found within this publicly available documentation (https://concentric.health/resources/technical-information-governance/#integration).</p>
C4.2	Do you use NHS numbers to identify patient record data?	Yes

C4.2.1	<p>If yes, please confirm whether it uses NHS Login to establish a user's verified NHS number.</p> <p>If no, please set out the rationale, how your product establishes NHS number and the associated security measures in place.</p>	<p>No</p> <p>Secure integrations are put in place between Concentric and the PAS database for the healthcare organisation, including search by NHS number where available. For patient access, a secure link is shared with the patient and authenticated with the patient's date of birth. Read more about our authentication (https://concentric.health/resources/technical-information-governance/#authentication)</p>
C4.3	<p>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, TLS 1.2)</p>	<p>Yes.</p>
C4.3.1	<p>If yes, please detail the standard</p>	<p>Industry standard approaches for secure interoperability are preferred, such as FHIR API's for patient demographics and document storage. Regarding data security in transit, web and API servers only allow requests made using TLS version 1.2 or above, which provides protection against snooping and man in the middle attacks on data. Non-HTTPS requests are denied by API servers.</p>
C4.3.2	<p>If no, please state the reasons and mitigations, methodology and security measures.</p>	<p>Not applicable</p>
C4.4	<p>Is your product a wearable or device, or does it integrate with them?</p>	<p>No</p>
C4.4.1	<p>If yes, provide evidence of how it complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards.</p>	<p>Not applicable</p>

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 the context of health and social care. Do you engage users in the development of the product?	Yes
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?	<p>User research: Throughout development and live use, user research insights - both patient and clinician - have driven development decisions. Patient and clinician insights from Autumn 2020 user interviews are described in this summary document (https://drive.google.com/file/d/1-z73LKZjSrN1GmgFHjAFAYTK9Gos6rPL/view?usp=sharing).</p> <p>Patient feedback: If wished by the healthcare organisation (as the data controller) a digital patient feedback survey is sent to all patients 2 weeks following consent to get their feedback on experience, ease of use, quality of information, and areas for improvement. Approximately 2000 patient feedback responses have been received in the past 12 months (average overall experience = 9/10), and directly input into sprint planning. Patient feedback can also be shared within the application at any time.</p> <p>Clinician feedback: Collected within the application and feedback survey sent out at intervals, asking for feedback on overall experience, preference compared to paper process, perceived quality of consent process compared to paper process, and any areas of improvement.</p> <p>Publications: The Concentric team, alongside academics, have published findings relating to the problems of traditional paper-based consent processes, and early work demonstrating the impact of introducing digital consent. Examples include:</p>

		<ul style="list-style-type: none"> • Assessment of the introduction of semi-digital consent into surgical practice - BJS • Completion of hand-written surgical consent forms is frequently suboptimal and could be improved by using electronically generated, procedure-specific forms - Surgeon • Surgical consent: the world's largest Chinese Whisper? A review of current surgical consent practices - BMJ Medical Ethics <p>Search data and analytics: Real world use of the product is monitored to guide improvements in product, content, and process. Examples include:</p> <ul style="list-style-type: none"> • Consent statistics demonstrating use of 'on the day' consent, guiding quality improvement programmes. • Custom modifications to templates allowing content review based on real-world use. • 'No treatment search results' allowing addition of missing but required content.
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, and is it 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 the product fits into a user pathway or journey	Concentric has a clear role in the treatment pathway, with consent being a required step prior to undergoing invasive treatment. Clinicians initiate a Concentric episode for patients, and share the information with patients during or following a consultation. A system map was developed during development to ensure consideration of all key user journeys (https://concentric.health/img/resources/system-map.png)
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.	<p>Patients are routinely asked at 2 weeks post consent for their feedback on usability of the system. The following are usability testing results from patients at one healthcare organisation over the past 12 months.</p> <p>https://concentric.health/img/resources/patient-usability-feedback.png</p> <p>Quality assurance testing is undertaken on all common browsers prior to each release.</p> <p>Responsive web application with all functionality available across all screen sizes.</p>

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.	https://concentric.health/resources/accessibility-statement
D1.5	Create a team that includes multi-disciplinary skills and perspectives. Does your team contain multidisciplinary skills?	Yes, the Concentric web application is developed by a multidisciplinary team including developers, clinicians, designers, and service users.
D1.6	Use agile ways of working. Do you use agile ways of working to deliver your product?	Yes, product development is undertaken in two week sprints in response to user requirements and research insights.
D1.7	Iterate and improve frequently. Do you continuously develop your product?	Yes, continuous updates are released approximately every 2 weeks. 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.
D1.8	Define what success looks like and be open about how your service is performing. Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	Yes, this can be found here (https://docs.google.com/spreadsheets/d/e/2PACX-1vSp9ERLoXzadRh18dO8e0tMwqeHApwrvKWHvDrAJ4EHF8uD6m-YxSXhVSOQ93dDSbiNOkeKPQ_JKVV5/pubhtml?gid=674014414&single=true).
D1.9	Choose the right tools and technology. Does this product meet with NHS Cloud First Strategy?	Yes. Concentric Health advocates a cloud first approach (all current deployments are cloud deployments).
D1.9.1	Does this product meet the NHS Internet First Policy?	Yes. Concentric Health advocates a cloud first approach (all current deployments are cloud deployments).
D1.10	Use and contribute to open standards, common components and patterns. Are common components and patterns in use?	Yes. Common components such as the Common User Interface patient banner are used, and data patterns such as the FHIR patient demographic lookup. Integration of further common components such as the NHS FHIR PDS and NHS Login are currently in progress.

D1.10.1	If yes, which common components and patterns have been used?	Common components such as the Common User Interface patient banner are used, and data patterns such as the FHIR patient demographic lookup. Integration of further common components such as the NHS FHIR PDS and NHS Login are currently in progress.
D1.11	Operate a reliable service. Do you provide a Service Level Agreement to all customers purchasing the product?	Yes, a service level agreement of 99.9% uptime or above is offered to all healthcare organisations.
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	Uptime reporting is made available to customers. A template report is shown here (https://docs.google.com/document/d/e/2PACX-1vSKruuKfu8vayhBTJHD9oReamDqXD8VZI68DCT416k9gQoH1mCLMZv3L6nxRQIOFz88LgNzoWBLK4JN/pub).
D1.12.2	Please provide your average service availability for the past 12 months, as a percentage to two decimal places.	>99.95%. Status page with latest uptime data available here (https://concentric.statuspage.io/).