



# **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.

<b>Table of contents</b>	<b>2</b>
<b>A. Company information - Non-assessed section</b>	<b>3</b>
<b>B. Value proposition - Non-assessed section</b>	<b>5</b>
<b>C. Technical questions - Assessed sections</b>	<b>7</b>
C1 - Clinical safety	7
C2 - Data protection	14
C3 - Technical security	20
C4 - Interoperability criteria	23
<b>D. Key principles for success</b>	<b>28</b>
D1 - Usability and accessibility - scored section	28
<b>Supporting documentation</b>	<b>36</b>

## A. Company information - Non-assessed section

Information about your organisation and contact details.

Code	Question	Options
A1	Provide the name of your company	Procomp Solutions Ltd
A2	Provide the name of your product	R2 Optimiser
A3	Provide the type of product	App   Wearable   Software as a Service (SaaS)   Other  Procomp: Other - Consulting service
A4	Provide the name and job title of the individual who will be the key contact at your organisation	Mark Russell-Smith Director of International Operations
A5	Provide the key contact's email address	mark.russell-smith@procompglobal.com
A6	Provide the key contact's phone number	07983 627 427
A7	Provide the registered address of your company	Elektroniikkatie 6, 90590 Oulu, Finland

A8	In which country is your organisation registered?	Finland
A9	If you have a Companies House registration in the UK please provide your number	n/a
A10	If applicable, when was your last assessment from the Care Quality Commission (CQC)?	Date   Not applicable Procomp: Not applicable
A11	If applicable, provide your latest CQC report.	Provided Procomp: 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	Who is this product intended to be used for?	Patients   Diagnostics   Clinical Support   Infrastructure   Workforce   Other	<p>Domiciliary Care Strategic Optimisation is a technology-enabled service which is intended to be used by those responsible for Commissioning and Managing Domiciliary Care services.</p> <p>Reporting is delivered to the customer, and all access to Procomp's computing systems is by Procomp personnel.</p>
B2	Provide a clear description of what the product is designed to do and of how it is expected to be used	Free text	<p>It is widely recognised that there are significant pressures on the Domiciliary Care workforce (both in social and health care settings). Deep structural and systemic issues limit overall quality &amp; efficiency and mean that changes are needed to the way Domiciliary Care is organised, commissioned and delivered.</p>

			<p>Despite the strong need for change, meaningful changes are not made because the logistical complexity of Domiciliary Care service delivery makes it extremely difficult to know which changes will have the desired outcomes. Furthermore, many changes would be impractical or impossible to test through live piloting.</p> <p>Domiciliary Care is a logistics problem; the right person needs to be in the right place at the right time. Procomp's roots are in logistics planning &amp; optimisation, and have adapted an approach commonly used in the logistics domain to enable workable solutions to be found to the structural and systemic issues in Domiciliary Care.</p> <p>R2 Domiciliary Care Strategic Optimisation is a technology-enabled service where a snapshot of operational data is taken (from a commissioning authority's and/or provider's ERP or patient management system) and Procomp's advanced, Artificial Intelligence-based planning tool (R2 Optimiser) used to perform detailed modelling of alternative scenarios.</p> <p>The impact of many hypotheses and scenarios can be assessed, many of which would be impractical or impossible to test in the field through trial and error. Domiciliary Care commissioners and managers are then able to make informed decisions regarding which changes to adopt and implement.</p> <p>Scenarios can be modelled to assess the impact of a</p>
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			<p>wide range of potential structural or systemic changes, for example:</p> <ul style="list-style-type: none"> <li>• Changes to care assessment &amp; planning practices</li> <li>• Changes to commissioning and brokerage practices</li> <li>• Changes to roles and shares of responsibility in integrated teams</li> <li>• Changes to work patterns</li> <li>• Outsourcing and insourcing of services</li> <li>• Changes to area structures and team sizes</li> <li>• Effect of taking certain equipment into use</li> </ul> <p>The Strategic Optimisation process typically includes representatives from all stake holders such that all are able to put forward proposals and ensure that their needs are considered. This has the add benefit of making changes easier to take forward and adopt in live use.</p>
B3	Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated	Free text	<p>R2 Domiciliary Care Strategic Optimisation is an established service, with over 60 projects completed in Finland, representing 1/3 of the Domiciliary Care workforce, as well as projects in Belgium and the Netherlands.</p> <p>The primary benefit of the service is that, through detailed modelling of alternative scenarios, Domiciliary Care Commissioners and Managers are able to determine which changes to implement in order to achieve strategic objectives. Typical objectives are to</p>

			<ul style="list-style-type: none"> <li>• Improve service quality</li> <li>• Improve care worker satisfaction</li> <li>• Improve workforce utilisation (and hence reduce cost)</li> </ul> <p>Realised benefits have been measured in a number of ways, such as through before and after KPI reporting from ERP systems, and subjective reporting by care workers.</p> <p>The Finnish Nurses' and care workers' union have been involved in many cases and have noted the improvement in the working lives of their members, writing positive articles about Procomp's achievements in two issues of their monthly magazine.</p> <p>Realised benefits include</p> <ul style="list-style-type: none"> <li>• The customer gains an understanding of the structural and systemic factors involved and how they affect Domiciliary Care service delivery and utilisation of the workforce</li> <li>• The customer is able to identify the structural and systemic changes which will have the desired outcomes on Domiciliary Care service quality and workforce utilisation</li> <li>• Improved work patterns for care workers <ul style="list-style-type: none"> <li>○ More compact schedules with less time spent waiting and less travelling</li> </ul> </li> <li>• Improved care workforce utilisation</li> <li>• Reduced mileage</li> <li>• Improved reconciliation of demand and supply</li> <li>• Increased capacity</li> </ul>
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			<ul style="list-style-type: none"> <li>Improved quality metrics <ul style="list-style-type: none"> <li>Continuity</li> <li>Improved delivered vs. planned service time</li> </ul> </li> </ul>
B4	<p>Please attach one or more user journeys which were used in the development of this product</p> <p>Where possible please also provide your data flows</p>	Provided   Not available	<p>This question is a context question, and it is expected that existing documentation will be provided.</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 as a separate attachment for ease of review.</p> <p>Procomp User Journey for strategic optimisation:</p> <ul style="list-style-type: none"> <li>Please see high level 'Customer Journey Strategic Optimisation' attached</li> </ul> <p>Procomp Data Sharing:</p> <ul style="list-style-type: none"> <li>For strategic optimisation the data is imported from a spreadsheet or txt file directly to the R2 Optimiser database</li> <li>Please see detailed Data Protection Impact assessment (C.2.3.2)</li> <li>A high-level data flow is available in the "R2 Optimisation Service Description" which can be provided as extra information if needed</li> </ul>

## 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	Options	Supporting information	Scoring criteria
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with DCB0129?	Yes   No	The <a href="#">DCB0129</a> 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”.	<p>To pass, the developer is required to confirm that they have undertaken Clinical Risk Management activities in compliance with DCB0129.</p> <p>We work with SafeHand, a qualified consultancy, on Clinical Risk Management (DCB0129) and Information Governance compliance.</p> <p>We are proceeding with DTAC with a specialist consultant in two stages:</p> <ul style="list-style-type: none"> <li>- Phase one for Strategic Optimisation Service (the subject of this DTAC)</li> <li>- Phase two for Operational Optimisation (to be the subject of a separate DETAC)</li> </ul> <p>Strategic Optimisation is a Service provided by Procomp personnel - User access to the system is not needed or provided</p> <ul style="list-style-type: none"> <li>- An Optimisation Specialist from Procomp imports data and runs all simulations in the R2 Optimiser during the Strategic Optimisation project</li> <li>- Some views of the application will</li> </ul>

				<p>be demoed to the customer and the customer will be provided with reports but will not have actual access to the application during the project</p> <ul style="list-style-type: none"> <li>- Please see more details under section B</li> </ul> <p>DCB0129 sets a standard for clinical safety of software, that is used within the health and care environment.</p> <p>The Strategic Optimisation Service gives rise to no clinical risk falling under DCB0129 for the following reasons:</p> <ul style="list-style-type: none"> <li>• no user access is needed or provided for the Strategic Optimisation Service</li> <li>• Procomp software is used to model and simulate different kinds of scenarios for planning of domiciliary care visits with anonymised data (no actual visits are planned)</li> </ul> <p>Please see more information about the data security measures under section C2.1.</p> <p>DCB0129 will be needed for Procomp's Operational Optimisation product (user access needed and actual domiciliary care visits are planned). We will produce a separate DTAC with DCB0129 for</p>
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				Operational Optimisation, to be completed during 2021.
C1.1.1	Please detail your clinical risk management system	Provided   No evidence available	<p>DCB0129 sets out the activities that must and should be undertaken for health IT systems.</p> <p>An example <a href="#">clinical risk management system template</a> can be downloaded from the NHS Digital website.</p>	<p>To pass, the developer is required to evidence that a clinical risk management system is in place and that it is compliant with the requirements set out in DCB0129.</p> <p>This should include:</p> <ul style="list-style-type: none"> <li>• The clinical risk management governance arrangements that are in place</li> <li>• The clinical risk management activities</li> <li>• Clinical safety competence and training</li> <li>• Audits</li> </ul> <p>Procomp: Not applicable for Strategic Optimisation. Please see C1.1 for more info.</p>
C1.1.2	Please supply your Clinical Safety Case Report and Hazard Log	Provided   No evidence available	<p>Specifically, your DTAC submission should include:</p> <ul style="list-style-type: none"> <li>• A summary of the product and its intended use</li> <li>• A summary of clinical risk management activities</li> <li>• A summary of hazards identified which you have been</li> </ul>	<p>To pass, the developer is required to submit the Clinical Safety Case Report and Hazard Log that is compliant with the requirements set out in DCB0129. This 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>unable to mitigate to as low as it is reasonably practicable</p> <ul style="list-style-type: none"> <li>• 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>It should not include the hazard log in the body of the document - this should be supplied separately.</p> <p>Example <a href="#">Clinical Safety Case Report and Hazard Log templates</a> can be downloaded from the NHS Digital website.</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 products 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 which may have a clinical safety</li> </ul>
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				<p>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 developer 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> <p><b>Procomp:</b> Not applicable for Strategic Optimisation. Please see C1.1 for more info.</p>
C1.2	Please provide the name of your Clinical Safety Officer (CSO), their profession and registration details	Free Text	<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</li> </ul>	<p>To pass, the developer must have a named CSO which can be 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>

			<ul style="list-style-type: none"> <li>application to clinical domains</li> <li>• Be suitably trained and qualified in risk management or have an understanding in principles of risk and safety as applied to Health IT</li> <li>• Have completed appropriate training</li> </ul> <p>The work of the CSO can be undertaken by an outsourced third party.</p>	<p><b>Procomp:</b> Not applicable for Strategic Optimisation.</p> <p>Please see C1.1 for more info.</p>
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)?	Yes   No   Not applicable	<p>If this question is not applicable, because your product does not fall within the UK Medical Devices Regulations 2002, continue to question C1.4.</p> <p>If No, but the product falls within the UK Medical Devices Regulations 2002, continue to question C.1.3.2.</p> <p>The MHRA provides guidance on medical devices to place them on the market in Great Britain and Northern Ireland, <a href="#">regulatory requirements</a> for all medical devices to be placed on the UK market, <a href="#">conformity assessment</a> and the UK Conformity Assessed (UKCA) mark, <a href="#">classification of stand-alone medical device software</a> (including apps) and <a href="#">how to tell if your</a></p>	<p>To pass, if the product falls within the UK Medical Device Regulations 2002 and is required to be registered with the MHRA, the product must have a valid registration.</p> <p>It is currently possible that products do fall within the UK Medical Devices Regulations 2002 but are not yet required to be registered with the MHRA.</p> <p><b>Procomp:</b></p> <p>The Strategic Optimisation Service is not a medical device due to the following:</p> <ul style="list-style-type: none"> <li>- There is no user access to the application during a Strategic Optimisation project</li> <li>- No actual domiciliary care visits are planned during a Strategic</li> </ul>



			<a href="#">product falls within the UK Medical Devices Regulations 2002.</a>	<p>Optimisation project; different planning scenarios are modelled with anonymised data</p> <ul style="list-style-type: none"> <li>- Findings and recommendations from Strategic Optimisation will be reviewed by the customer prior to adoption and implementation</li> </ul>
C1.3.1	If yes, please provide your MHRA registration number	Free text		<p>To pass, the registration number must be valid.</p> <p>Procomp: Not applicable for Strategic Optimisation</p>
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	Provided   No evidence available	<p>Medical device manufacturers must ensure that their device complies with the relevant Essential Requirements of the legislation and draw up a Declaration of Conformity to declare this.</p> <p>Class I devices with a measuring function and devices in Class IIa, IIb and III must undergo conformity assessment from an EU Notified Body</p>	<p>To pass, valid documentation appropriate to the risk classification of the device must be provided.</p> <p>Procomp: Not applicable for Strategic Optimisation</p>

			or UK Approved Body which has been designated for medical devices, and be issued a certificate of conformity (commonly referred to as a “CE certificate” or “UKCA certificate”).	
C1.4	Do you use or connect to any third-party products?	Yes I No	<p>If no, continue to section C2.</p> <p><a href="#">DCB0129</a> contains the requirements in relation to third party products.</p>	<p><b>Procomp:</b></p> <p>Procomp’s software utilises a 3<sup>rd</sup> party mapping service (e.g. TomTom) which is used to visualise data and scenarios on a map.</p> <p><b>Strategic Optimisation:</b> Connecting to a 3<sup>rd</sup> party product for map visualisation does not bring any clinical risk to a patient because</p> <ul style="list-style-type: none"> <li>- The data that is used in the Strategic Optimisation is anonymised</li> <li>- No actual patient visits will be planned during Strategic Optimisation</li> <li>- No user access is needed for Strategic Optimisation (see description B1 and B2)</li> </ul> <p>The risk analysis for the 3<sup>rd</sup> party map product will be done in the second phase as part of DCB0129 for operational</p>

				optimisation (see detailed plan under C1.1)
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	Provided   No evidence available		<p>To pass, a valid conformity certificate must be provided. The Clinical Risk Management documentation must meet the requirements detailed in question C1.1.</p> <p><b>Procomp:</b></p> <p><b>Strategic Optimisation:</b> See above: Not applicable for Strategic optimisation.</p> <p>The risk analysis for the 3<sup>rd</sup> party map application will be done as part of the DCB0129 for Operational Optimisation (see more information under C1.1)</p>

## 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	Options	Supporting information	Scoring criteria
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C2.1	<p>If you are required to register with the Information Commissioner, please attach evidence of a current registration.</p> <p>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>	<p>Provided   Not provided</p>	<p>There are some instances where organisations are not required to register with the Information Commissioner. This includes where no personal information is being processed.</p> <p>The Information Commissioner has a <a href="#">registration self-assessment tool</a> to support this decision making.</p>	<p>To pass, the developer is required to submit evidence that they have a current registration with the Information Commissioner. This can be validated against the <a href="#">Information Commissioner's Register of Fee Payers</a>.</p> <p>Alternatively, if the developer confirms they are not registered with the Information Commissioner because they are not required to do so, then a self-assessment from the Information Commissioner's self-assessment tool should be attached which aligns to the product.</p> <p>Procomp Registration reference: <b>ZB192933</b></p>
C2.2	<p>Do you have a nominated Data Protection Officer (DPO)?</p>	<p>Yes   No   We do not need one</p>	<p>Not all organisations are required to have a <a href="#">Data Protection Officer</a> (DPO). This is determined by the type of organisation and core activities. The most common reason for organisations providing digital health technologies to have a DPO is due to the core activities involving processing health data (being a special category).</p> <p>The Information Commissioner has a <a href="#">self-assessment tool</a> to determine whether you must appoint a DPO.</p>	<p>Procomp: Yes</p>

C2.2.1	<p>If you are required to have a nominated Data Protection Officer, please provide their name.</p> <p>If you are not required to have a DPO please attach a completed self-assessment showing the outcome from the Information Commissioner and your responses which support this determination.</p>	Free text   Provided		<p>To pass, the developer is required to confirm they have a DPO in place where this is mandated. Where a DPO one is in place if it is not required by the Information Commissioner then this will also constitute a pass.</p> <p>Alternatively, if the developer confirms they do not have a DPO because they are not required to do so, then a self-assessment from the Information Commissioners self-assessment tool should be attached which confirms this and aligns to the product.</p> <p>Procomp: Phil Walker (Safehand)</p>
C2.3	Does your product have access to any personally identifiable data or NHS held patient data?	Yes   No	<p>The UK General Data Protection Regulation (GDPR) applies to the processing of <a href="#">personal data</a>.</p> <p>If no, continue to question C2.4</p>	<p>Procomp:</p> <p>Yes, for Strategic Optimisation: Postcode</p>
C2.3.1	<p>Please confirm you are compliant (having standards met or exceeded status) with the annual Data Security and Protection Toolkit Assessment.</p> <p>If you have not completed the current year's</p>	Confirmed   Unable to confirm	The <a href="#">Data Security and Protection Toolkit</a> allows organisations to measure performance against the National Data Guardian's 10 data security standards.	<p>To pass, the developer must confirm that they are compliant with the Data Security and Protection Toolkit Assessment. This should be validated against the <a href="#">Data Security and Protection Toolkit database</a> and achieve Standards Met or Exceeded status.</p> <p>Dependent on the date of the assessment versus the opening of the annual assessment period, it may be that a developer has not yet</p>

	assessment and the deadline has not yet passed, please confirm that you intend to complete this ahead of the deadline and that there are no material changes from your previous years submission that would affect your compliance.			<p>completed the toolkit. The developer is asked to confirm that they will complete the assessment and that they will maintain their compliance versus the previous year.</p> <p>Procomp: DSP toolkit completed and confirmed online in September 2021. An explanatory DSP toolkit Portfolio with more details can be shared in confidence upon request.</p>
C2.3.2	Please attach the Data Protection Impact Assessment (DPIA) relating to the product.	Provided   Not provided	<p><a href="#">DPIA's</a> are a key part of the accountability obligations under the UK GDPR, and when done properly help organisations assess and demonstrate how they comply with data protection obligations.</p> <p>The Information Commissioner has provided guidance on <a href="#">how to complete a DPIA</a> and a <a href="#">sample DPIA template</a>.</p>	<p>To pass, the developer must provide a DPIA that is compliant with the requirements set out under the General Data Protection Regulations. It should ensure that risks to the rights and freedoms of natural persons are managed to an acceptable level.</p> <p>The DPIA should:</p> <ul style="list-style-type: none"> <li>• Establish the context; taking into account the nature, scope, context and purposes and processing and the sources of the risk</li> <li>• Assess the risks; considering the particular likelihood and severity of high risks</li> <li>• Treat the risks; through mitigation and ensuring the protection of personal data and demonstrating compliance with the GDPR</li> </ul>

				<p>It should include:</p> <ul style="list-style-type: none"> <li>• A description of the envisaged processing operations and the purposes of the processing</li> <li>• An assessment of the necessity and proportionality of the processing</li> <li>• An assessment of the risks to the rights and freedoms of data subjects</li> <li>• The measures envisaged to address the risks and to demonstrate compliance with the GDPR</li> </ul> <p>Procomp: Please find DPIA attached</p>
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 one is in place) or an accountable officer where exempt in question C2.2.	Confirm   Cannot confirm		<p>To pass, the developer must confirm that their Data Protection Officer or accountable officer has signed-off the risk assessments and mitigations / access controls and system level security policies.</p> <p>Procomp: Signed-off by DPO Phil Walker (Safehand)</p>

C2.5	Please confirm where you store and process data (including any third-party products your product uses)	UK only   In EU   Outside of EU	Individual organisations within the Health and Social Care system are accountable for the risk-based decisions that they must take.	<p>Individual organisations within the Health and Social Care system are accountable for the risk-based decisions that they must take.</p> <p>Due consideration should be taken where data is processed outside of the UK.</p> <p>Please note: It is a contractual requirement under the new GP IT Futures (GPITF) framework as it was in the GP System of Choice (GPSoc) framework, to host all data in England.</p> <p>Procomp: Stored and processed in EU. Strategic Optimisation is not a GPITF system.</p>
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	Free text	<p>From 1 January 2021, the UK GDPR applies in the UK in place of the “EU GDPR”. The UK GDPR will carry across much of the existing EU GDPR legislation. The Department for Digital, Culture, Media &amp; Sport has published two <a href="#">Keeling Schedules</a> which show the changes to the Data Protection Act 2019 and EU GDPR.</p> <p>The Information Commissioner has published guidance on</p>	<p>Individual organisations within the Health and Social Care system are accountable for the risk-based decisions that they must take.</p> <p>Due consideration should be taken where data is processed outside of the UK and should only be hosted within the European Economic Area (EEA) or a country deemed as adequate by the European Commission.</p> <p>To pass, the developer must demonstrate that the country in which data is processed or stored is compliant with current legislation or the organisation's policy (should this differ).</p>



			<a href="#">international data transfers</a> after the UK exit from the EU Implementation Period.	PROCOMP: Data is stored in Finland. Finland is part of EEA. Finland is compliant with the legislation.
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### 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	Options	Supporting information	Scoring criteria
C3.1	Please attach your Cyber Essentials Certificate	Provided   No evidence available	<p><a href="#">Cyber Essentials</a> helps organisations guard against the most common cyber threats.</p> <p>The National Cyber Security Centre (NCSC) have published <a href="#">cyber security guidance for small to medium enterprises</a> (SME's).</p>	<p>To pass, developers must have a valid Cyber Essentials certificate. 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> <p>NHS organisations are required to have Cyber Essentials in place (and is now incorporated into the NHS Digital Data Security and Protection Toolkit (DSPT) for NHS Trusts and Foundation Trusts in 2021-22 assessments) and to mitigate risk within the supply chain, suppliers should hold Cyber Essentials.</p>

				<p>Procomp: Cyber Essentials Certificate attached</p>  <p>Procomp Cyber Essentials Certificate.p</p>
C3.2	<p>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.</p>	<p>Provided   No evidence available</p>	<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>To pass, the developer must evidence that the product has undergone an external penetration test 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</a> (CVSS).</p> <p>Procomp:</p> <p>The last penetration test (with F-secure Elements Vulnerability Management Solution) was run on the 14<sup>th</sup> of September 2021. The results can be shared in confidence upon request.</p>
C3.3	<p>Please confirm whether all custom code had a security review.</p>	<p>Yes - Internal code review   Yes - External code review   No   No</p>	<p>The NCSC provides guidance on <a href="#">producing clean and maintainable code</a>.</p>	<p>To pass, the developer must confirm that an internal or an external custom code security review has been undertaken. An external review is preferable; however an internal code review would meet the</p>

		because there is no custom code		baseline requirement.  Procomp: Yes - Internal code review
C3.4	Please confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?	Yes   No	The NCSC provides guidance on <a href="#">Multi-Factor Authentication</a> .	To pass, the developer must confirm yes that all privileged accounts have MFA.  Procomp: Yes  <b>Strategic Optimisation:</b> Strategic Optimisation is not an online service no user access is needed to the software (please see description in B1 and B2).  Nevertheless, Procomp does utilise MFA for accessing its systems.
C3.5	Please confirm whether logging and reporting requirements have been clearly defined.	Yes   No	The NCSC provides guidance on <a href="#">logging and protective monitoring</a> .  To confirm yes to this question, logging (e.g., audit trails of all access) must be in place. It is acknowledged that not all developers will have advanced audit capabilities.	To pass, the developer must confirm yes that logging and reporting requirements have been clearly defined.  Procomp:  Yes.  Logs are recorded on multiple levels: - Firewalls logs all connections made to the servers (including failed attempts).

				<ul style="list-style-type: none"> <li>- Server's event log logs all logIn's and logOut's to the rdp server.</li> <li>- The R2 application records an audit trail of users' logins, logouts, and other actions, including viewing service user data.</li> </ul>
C3.6	Please confirm whether the product has been load tested	Yes   No	Load testing should be performed.	<p>To pass, the developer must confirm yes that load testing has been performed.</p> <p>Procomp: Yes</p> <p>Load testing is not relevant for <b>Strategic Optimisation</b> as there is no user access and the system is only used by one user to model the scenarios.</p> <p>Nevertheless, the interface service (REST API) and the optimisation core have been load tested.</p>

## 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	Options	Supporting information	Scoring criteria
C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	Yes   No	<p>The NHS website developer portal provides guidance on <a href="#">APIs and the NHS</a>.</p> <p>Government Digital Services provide guidance on <a href="#">Open API best practice</a>.</p>	<p>To pass, developers must demonstrate that they have API's that are relevant to the use case for the product, follow Government Digital Services Open API Best Practice, are documented and freely available and that third parties have reasonable access to connect.</p> <p>APIs should adopt generally accepted standards of data interoperability for the NHS or social care dependent on the use case for the product.</p>

				<p>If the product does not have API's and there is a legitimate rationale for this considering the use case of the product then the buyer can accept this rationale.</p> <p>Procomp:</p> <p><b>Strategic optimisation:</b></p> <ul style="list-style-type: none"> <li>- API's not needed</li> <li>- Data import is handled via file import (spreadsheet or txt files)</li> <li>- More information about the data import is available in the "R2 Optimisation Service Description" which can be shared in confidence upon request.</li> </ul>
C4.1.1	<p>If yes, please provide detail and evidence:</p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• Confirm that they follow Government Digital Services Open API Best Practice</li> <li>• Confirm they are documented and</li> </ul>	Free text		

	<p>freely available</p> <ul style="list-style-type: none"> <li>• Third parties have reasonable access to connect</li> </ul> <p>If no, please set out why your product does not have APIs.</p>			
C4.2	Do you use NHS number to identify patient record data?	Yes   No   No because product does not identify patient record data	NHS Digital provides guidance on <a href="#">NHS Login for partners and developers</a> .	<p>To pass, developers should confirm that if a product uses an NHS number to identify a patient record, that it uses NHS Login. NHS Digital provides a list of all current <a href="#">digital health and social care services that integrate with NHS Login</a>.</p>
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 established NHS number and the associated security measures in place.</p>	Free text		<p>If a product does not use NHS Login to establish a verified NHS number, then a legitimate rationale should be set out and the security and appropriateness of the methodology should be considered.</p> <p>Procomp:</p> <p><b>Strategic optimisation:</b> NHS number is not used to identify patient record data in Strategic Optimisation. The data is anonymised. Please see more information in the description under B1 and B2)</p>

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, TLS 1.2)	Yes   No   No because the product does not read/ write into EHRs		<p>To pass, developers should confirm that the product has the capability to read/write into EHRs using industry standards for secure interoperability.</p> <p>If a product does not use industry standards, then a legitimate rationale should be set out and the security, usability and appropriateness of the methodology should be considered.</p> <p>Procomp: No because the product does not read/write into EHRs</p>
C4.3.1	If yes, please detail the standard	Free text		
C4.3.2	If no, please state the reasons and mitigations, methodology and security measures.	Free text		
C4.4	Is your product a wearable or device, or does it integrate with them?	Yes   No	If no, continue to section D.	<p>To pass, the developer must evidence compliance with ISO/IEEE 10073</p> <p>Procomp: The product is not a wearable device, and it does not integrate with a wearable device.</p>
C4.4.1	If yes, provide evidence of how it complies with ISO/IEEE 11073 Personal	Provided   No evidence available	<a href="#">Access the ISO Standard</a> . This is a paid-for	



	Health Data (PHD) Standards.		document.
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## 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	Supporting information	Weighted score	Scoring criteria
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D1.1	<b>Understand users and their needs in context of health and social care</b>  Do you engage users in the development of the product?	Yes   No   Working towards it	<a href="#">NHS Service Standard Point 1</a>	10%	<p>Developers should be awarded 10% if they demonstrate that user need has been taken in account through user research, search data, analytics or other data to understand the problem.</p> <p>The submission should confirm that the developer has considered, and tested user needs with appropriate stakeholders (stakeholders will differ depending on the product) and that as the product continues to iterate user engagement has continued.</p> <p>If the developer selects working towards it and/or can only partially evidence the requirement, for example user need has only partially been considered or it is not considered on an ongoing basis they should be awarded 5%.</p> <p>If the developer selects no to this question or cannot provide evidence that user need has been considered, they should be awarded 0%.</p> <p>Procomp:</p> <p>Yes</p> <p>Most development for new features or functionality is triggered by</p> <ul style="list-style-type: none"> <li>- a request from a current user</li> </ul>
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?	Free text			

					<ul style="list-style-type: none"> <li>- follow up of user behavior by the Optimisation Specialist (who is also the contact person with the customer)</li> <li>- Development need of new clients</li> </ul> <p>The user is consulted during the development process and the new feature or functionality is demoed to the user during implementation. Please see the overall process 'R2 Optimiser new functionality &amp; feature flow' attached.</p> <p>For Strategic Optimisation the flow mainly has to do with discussing the details of existing or new reports and the design of the reports produced in R2.</p> <p>See more information about the multidisciplinary development team under D1.5. The members of the team (including the Product Owner) know the product through and through and consider the whole application environment when new features and functionalities are added.</p>
D1.2	<p><b>Work towards solving a whole problem for users</b></p> <p>Are all key user journeys</p>	Yes   No   Working towards it	<a href="#">NHS Service Standard Point 2 and Point 3</a> are often dealt with by	10%	<p>Developers should be awarded 10% if they attach supporting information showing that the product solves a whole user problem or that it is clear to users</p>

	mapped to ensure that the whole user problem is solved, or it is clear to users how it fits into their pathway or journey?		teams together.		<p>how it fits into their pathway or journey.</p> <p>If the developer selects working towards it and can provide evidence that goes some way to explaining how the whole user problem is solved or only partially explains how the product fits a user journey, they should be awarded 5%.</p> <p>If the developer selects no to this question or cannot provide evidence that shows the user journey or how the product fits into the pathway or journeys, they should be awarded 0%.</p> <p><b>Procomp:</b></p> <p><b>Strategic Optimisation:</b> Yes - Please see the high-level user journey for Strategic Optimisation attached.</p>
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	Provided   No evidence available			
D1.3	<p><b>Make the service simple to use</b></p> <p>Do you undertake user acceptance testing to validate usability of the system?</p>	Yes   No   Working towards it	<a href="#">NHS Service Standard Point 4</a>	10%	<p>Developers should be awarded 10% if they attach supporting information showing user acceptance testing to validate usability of the product.</p> <p>If the developer selects working towards it and can provide evidence that goes</p>

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   No evidence available			<p>some way to demonstrate that user acceptance testing is being used to validate usability of the system, they should be awarded 5%.</p> <p>If the developer selects no to this question or cannot provide evidence that shows user acceptance testing to validate usability of the system, they should be awarded 0%.</p> <p>Procomp: Yes</p> <p>Please see the overall process 'R2 Optimiser new functionality &amp; feature flow' attached → the steps for testing are described in the flow.</p> <p>For Strategic Optimisation the testing mainly has to do with validating the reports that have been developed and produced in R2 user interface.</p> <p>For larger Operational Optimisation projects with several new features, the customer/user is required to carry out full UAT. This is specified in the Project Initiation Document in the beginning of a project, Procomp provides a frame for a test plan.</p> <p>Please see example of a base test plan</p>
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					in attachment 'Domiciliary care planning_Testcases_Base_Example'. Please note that this is an example only (most of the testcases have been hidden due to business confidentiality).
D1.4	<p><b>Make sure everyone can use the service</b></p> <p>Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?</p>	Yes   No   Working towards it	<p><a href="#">NHS Service Standard Point 5</a></p> <p>The Service Manual provides information on <a href="#">WCAG 2.1</a> level AA.</p> <p>The Government Digital Service provides guidance on <a href="#">accessibility and accessibility statements</a>, including a sample template.</p>	20%	<p>Developers should be awarded 20% for WCAG 2.1 level AA compliance.</p> <p>Developers should be awarded 5% for working towards it.</p> <p>If the developer selects no to this question, they should be awarded 0%.</p> <p>Procomp:</p> <p><b>Strategic Optimisation</b> Not applicable for Strategic Optimisation – no user access needed (see description under B1 and B2)</p> <p>The product is not a patient facing application. Reports are provided for Commissioners and Managers of Domiciliary Care services.</p>
D1.4.1	Provide a link to your published accessibility statement.	Free text		10%	Developers should be awarded 10% for a published accessibility statement that includes the information below:

					<ul style="list-style-type: none"> <li>• Whether the website or app is 'fully', 'partially' or 'not' compliant with accessibility standards</li> <li>• If it is not fully compliant, which parts do not currently meet accessibility standards and why</li> <li>• How people can get alternatives to content that is not accessible to them</li> <li>• How to contact you to report accessibility problems and a link to the website that they can use if they are not happy with your response</li> </ul> <p>If an accessibility statement is not included or it does not contain the required information listed above the developer should be awarded 0%.</p> <p>Procomp:</p> <p><b>Strategic Optimisation</b> Not applicable for Strategic Optimisation – no user access needed (see description under B1 and B2)</p> <p>The product is not a patient facing application. Reports are provided for Commissioners and Managers of Domiciliary Care services.</p>
D1.5	Create a team that	Yes   No	<a href="#">NHS Service</a>	2.5%	Developers should be awarded 2.5% for

	<p><b>includes multi-disciplinary skills and perspectives</b></p> <p>Does your team contain multidisciplinary skills?</p>	Working towards it	<a href="#">Standard Point 6</a>		<p>confirming they have a multi-disciplinary team.</p> <p>If the developer selects working towards it or no to this question, they should be awarded 0%.</p> <p>PROCOMP: Yes</p> <p>The development team of the Domiciliary Care part of the software is a compact team with experienced individuals with a variety of skills and who understand the substance of domiciliary care.</p> <p>Please find the description of the team roles in “Procomp R2 Optimiser – Multi disciplinary team” attached.</p>
D1.6	<p><b>Use agile ways of working</b></p> <p>Do you use agile ways of working to deliver your product?</p>	Yes   No   Working towards it	<a href="#">NHS Service Standard Point 7</a>	2.5%	<p>Developers should be awarded 2.5 % if they confirm they use agile ways of working.</p> <p>If the developer selects working towards it or no to this question, they should be awarded 0%.</p> <p>PROCOMP: Yes</p> <p>We have used many agile ways of working in the development team for several years. The user need has always been the main trigger for development. Since the beginning of 2020 we have</p>



					<p>effectively been integrating agile tools and techniques for analysis and daily work within the development team.</p> <p>New development for R2 Optimiser is almost always triggered by a user need. Either a current user asks for a new feature or the Procomp contact person (Optimisation specialist or Customer support specialist) notices a user need while monitoring the user doing his/her daily tasks. The new features or functionalities are discussed with the user before development. For Strategic Optimisation new features mainly have to do with creating or modifying reports.</p> <p>Please find the process “R2 Optimiser – Process for new functionality and feature” attached.</p> <p>Last year (2020) we mapped all the major processes for Strategic Optimisation (and for Operational Optimisation) and started to map the user stories and customer journeys to make sure that we are adding value for the user and customer.</p> <p>We work in sprints of 4 weeks. See more information about the sprints under D1.7.</p> <p>We have set up a process to map and</p>
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					<p>check that the current features and functionalities in the software are up to date; what is still un use or needed and what can be removed from the software all together. These are checked in a weekly meeting with the development team.</p>
D1.7	<p><b>Iterate and improve frequently</b></p> <p>Do you continuously develop your product?</p>	<p>Yes   No   Working towards it</p>	<p><a href="#">NHS Service Standard Point 8</a></p>	<p>5%</p>	<p>Developers should be awarded 5% if they confirm they continually develop their product.</p> <p>If the developer selects working towards it or no to this question, they should be awarded 0%.</p> <p><b>PROCOMP: Yes</b></p> <p>We work in sprints of 4 weeks. Therefore, usually a new version of the software is released every 4 weeks but we can release urgent features/bug fixes more frequently if needed and if UAT is done.</p> <p>There is a sprint planning/sprint follow up meeting every week. The tasks for the sprint are prioritised and followed up in Jira tool (prioritising is led by the Product Owner).</p> <p>The development team meets shortly in a daily stand up to discuss issues. Urgent</p>

					matters are prioritised immediately and escalated to project manager if necessary.
D1.8	<p><b>Define what success looks like and be open about how your service is performing</b></p> <p>Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?</p>	Yes   No  Working towards it	<a href="#">NHS Service Standard Point 10</a>	10%	<p>Developers should be awarded 10% for confirming that the benefit case includes objectives and metrics that can be tracked.</p> <p>If the developer selects working towards it or no to this question, they should be awarded 0%.</p> <p>Procomp:</p> <p>As a result of a successful project the customer is able to identify the structural and systemic changes which will have the desired outcomes on Domiciliary Care service quality and workforce utilisation.</p> <p>As a result of implementing the identified changed, the following measurable benefits are achieved:</p> <ul style="list-style-type: none"> <li>Improved care workforce utilisation <ul style="list-style-type: none"> <li>Reduced mileage and time spent travelling</li> <li>Reduced gap time</li> <li>Carers spend increased time with service users</li> </ul> </li> <li>Increased capacity of the provider market</li> </ul>

					<ul style="list-style-type: none"> <li>Improved quality metrics                             <ul style="list-style-type: none"> <li>Continuity</li> <li>Improved delivered vs. planned service time</li> </ul> </li> </ul>
D1.9	<b>Choose the right tools and technology</b>  Does this product meet with NHS Cloud First Strategy?	Yes   No   No because it is not applicable	<a href="#">NHS Service Standard Point 11</a>  <a href="#">NHS Internet First Policy</a> .	5%	Developers should be awarded 5% for confirming the product meets cloud first and / or internet first.  If the developer selects working towards it or no to this question, they should be awarded 0%.  <b>PROCOMP:</b>  Not applicable for Strategic Optimisation (see description under B1 and B2)
D1.9.1	Does this product meet the NHS Internet First Policy?	Yes   No   No because it is not applicable			
D1.10	<b>Use and contribute to open standards, common components and patterns</b>  Are common components and patterns in use?	Yes   No   Working towards it	<a href="#">NHS Service Standard Point 13</a>	5%	Developers should be awarded 5% for confirming common components and patterns are used.  If the developer selects working towards it or no to this question, they should be awarded 0%.  <b>PROCOMP:</b>  Not applicable for Strategic Optimisation
D1.10.1	If yes, which common components and patterns have been used?	Free text			

D1.11	<b>Operate a reliable service</b>  Do you provide a Service Level Agreement to all customers purchasing the product?	Yes   No	<a href="#">NHS Service Standard Point 14</a>	10%	<p>Developers should be awarded 10% offering a service level agreement, reporting on performance and having an uptime of 99.9% or above.</p> <p>If the developer does not provide a service level agreement and / or reporting on performance, they should be awarded but has an uptime of 99.9% or above they should be awarded 5%.</p> <p>If the developer has an uptime of 99% or above, they should be awarded 2.5%.</p> <p>If the developer has an uptime of less than 99%, they should be awarded 0%.</p> <p><b>PROCOMP:</b></p> <p>Not applicable for Strategic Optimisation as there is no user access and therefore no uptime for Strategic Optimisation service.</p>
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   No			
D1.12.1	Please attach a copy of the information provided to customers	Provided   No evidence available			
D1.12.2	Please provide your average service availability for the past 12 months, as a percentage to two decimal places	Free text			

## 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