

## Digital Assessment Questions V2.2

This is a copy of the NHS digital assessment for health apps and digital tools and is currently used to assess products for inclusion on the NHS Apps Library.

Developers of apps and digital tools should review this document to better understand the standards for all products published on the NHS Apps Library. This represents a full list of all possible questions, however not all questions will be relevant to all products.

You can find out more about the assessment process [here](#) and check if your product is [eligible](#).

Any questions or comments relating to this document can be sent to [daq.team@nhs.net](mailto:daq.team@nhs.net).

Last updated: 17/05/19





**Digital**

# Eligibility Questions

Establishing that your product is eligible for full assessment.

Display ID	Question	Response Option	Supporting Information
1.1	Is your product available to the public and can you provide URL(s) to the app store location(s)?	Yes   No	
1.2	Can you confirm that users are able to contact you or your organisation directly via the product, if required?	Yes   No	
1.3	If your product uses any form of NHS Branding, can you confirm that you have permission from the Department of Health & Social Care and that it complies with NHS England's Branding Guidelines?	Yes   No   Not Applicable	<a href="#">Information on NHS branding guidelines</a>
1.4	If your product connects to any of the following services, can you confirm that an appropriate interoperability review and /or a technical review has taken place? * Electronic Referrals Service (eRS) * Electronic Transfer of Prescription Service (ETP) * GP2GP * GP Connect * GPSoC Connection to Primary Care Systems (EMIS, Microtest, TPP, VISION) * Health and Social Care Network * NHS Mail * NHS Pathways * Spine * Summary Care Records	Yes   No   Not Applicable	

1.5	If your product is a medical device as defined within the Medical Device Directive can you provide evidence of: registration with MHRA and self-declaration of conformity, a post market surveillance plan, and a CE certificate from a notified body (class 11a or above)?	Yes   No   Not Applicable	
1.6	If your product constitutes a pharmacy service that requires registration with the General Pharmaceutical Council, can you provide evidence confirming registration?	Yes   No   Not Applicable	
1.7	If your product forms part of a service that requires registered healthcare professionals to operate, can you confirm their registration status and names?	Yes   No   Not Applicable	
1.8	Can you provide a guest login for your product so that assessors can access and evaluate it?	Yes   No   Not Applicable	
1.9	Can you confirm that your organisation is registered as one of the following? * Public Limited Company (Plc) * Private Company Limited By Shares (Ltd) * Company Limited By Guarantee * Unlimited Company (Unltd) * Limited Liability Partnership (Llp) * Community Interest Company * Industrial and Provident Society (Ips) * Royal Charter * Public Body * Charitable Organisation	Yes   No   Not Applicable	
1.10	Can you confirm your organisation is registered with the Care Quality Commission (CQC) if it carries out, or proposes to carry out, any regulated activities in England which require such registration?	Yes   No   Not Applicable	

# Company Registration

Information about your organisation and contact details

Display ID	Answer this question if...	Question	Response Option	Supporting Information
1.1		Provide the name of the individual who will be the key contact at your organisation.	Free Text	
1.2		Provide the key contact's email address.	Free Text	
1.3		Provide the key contact's phone number.	Free Text	
1.4		Provide the name of your company.	Free Text	
1.5		Provide the registered address of your company.	Free Text	
1.6		In which country is your organisation registered?	Free Text	
1.7		Does your organisation carry out, or propose to carry out, any regulated activities in England which require registration with the Care Quality Commission (CQC)?	Yes   No	The CQC is the independent regulator of health and social care in England. Their <a href="#">website</a> provides information on regulated activities that require registration.

1.7.1	Your organisation requires CQC registration	Is your organisation registered with CQC?	Yes   No	
1.7.1.1	Your organisation is registered with the CQC	Provide your organisation's CQC account number.	Free Text	
1.7.1.2	Your organisation is registered with the CQC	Provide the date of your organisation's most recent registration certificate.	Free Text	
1.7.1.3		Provide the date and outcome of your organisation's last CQC inspection. If your organisation has not been inspected, provide the date of your upcoming inspection.	Free Text	
1.7.2	You think that your organisation does not require CQC registration	Have you reviewed the scope of registration for CQC and confirmed your organisation's activities do not require registration?	Yes   No	

# Product Registration

Information about your product and business model

Display ID	Answer this question if...	Question	Response Option	Supporting Information
2.1		Provide a brief description of your product (200 words max).	Free Text	
2.2		Describe all applicable functionality. Include any calculating functions (e.g. body mass index, weight charts for children, calorie counters) and any associated information outputs such as dietary or exercise suggestions.	Free Text	
2.3		Does your product integrate with a website or other software/device?	Yes   No	
2.4		Select the following NHS services your product connects to, or intends to connect to:	Electronic Prescription Service (EPS)   Electronic Referrals Service (eRS)   GP2GP   GP Connect   GPSoC Connection to Primary Care Systems (EMIS, Microtest, TPP & VISION)   Health and Social Care Network   NHS Mail   NHS Pathways   Spine   Summary Care Records   None	
2.4.1	Your product connects to, or intends to connect to any of the NHS Services listed above in 2.4	You must provide evidence that you have permission to connect to and use the services you have selected, for example that your product successfully connects to GPSoC. Describe and upload as a single file any relevant documentation.	File	

2.5		Describe how your product integrates with other systems. If it does not integrate with other systems, put 'N/A'	Free Text	This could include a GP system, a parent system, patient administration or prescribing systems.
2.6		Select all of the following statements that apply to your product:	<p>Your product is a clinical decision support system. It contributes to decisions about treatment and may involve controlling other medical devices   Your product is used as a calculator to provide information which impacts treatment, diagnosis or care. This information is obtained by analysing data entered by the user or collected by the product   Your product is used to provide a psychological intervention to people with a diagnosed condition   Your product is used to facilitate the diagnosis or management of a condition by collecting information. It may include features such as reminders or alerts   Your product is used to facilitate communication with healthcare professionals   Your product is used to influence behavioural change to reduce personal risk factors for a specific condition   Your product enables people to interact with their data or appointments in the NHS or social care systems   Your product enables users to communicate with others   Your product collects information to enable people to</p>	

			keep a personal record. This data is not routinely shared   Your product provides information to promote learning and improve awareness   Your product provides a digital solution to businesses (e.g. appointment booking or staff rotas)   Your product is used as an information or service finder and holds no personal data   Your product is used as an eBook or digital book equivalent	
2.7		Select the health theme(s) that your product aims to address:	Cancer   Child health   Long-term condition   Maternity   Mental health   Patient empowerment   Primary care   Urgent and emergency   Other	
2.7.1	Your product aims to address a health theme not listed above in 2.7	If other, please state.	Free Text	
2.8		In what context do you see your product being used?	Free Text	
2.9		Who are the intended end-users?	Free Text	
2.10		What problem in the health system or to the end-user is your product trying to solve?	Free Text	
2.11		Estimate the number of people who would use the product (per 100,000 of the population).	Free Text	
2.12		Do you think your product could replace a current NHS commissioned service?	Yes   No	
2.12.1	Your product could replace a commissioned NHS service	Provide details about how your product could replace a commissioned service.	Free Text	



2.13		Is your product free to public users?	Yes   No	
2.13.1	If your product is not free to public users	How much does your product cost users?	Free Text	
2.13.2	If your product is free to public users	What is the source of the funding?	Free Text	
2.14		Briefly describe your business model, including any direct costs such as licence cost, purchase cost, subscription for use, etc. If the period of use is less than a year, please indicate this.	Free Text	
2.15		Is your product involved in a pilot or trial with an NHS hospital, Trust, Clinical Commissioning Group (CCG) or in a primary care setting?	Yes, we are live in an area   Almost, we have a go live date   We are in discussions   No	
2.16	If your product is involved in a pilot or trial with an NHS hospital, Trust, CCG or in a primary care setting	Give brief details of the pilot or trial.	Free Text	
2.17		Is your product a medical device as defined within the Medical Device Directive?	Yes   No   Don't know	<a href="#">Information on medical devices regulation and safety</a>
2.17.1	If your product is a medical device	Provide evidence confirming agreement from MHRA or a notified body.	File	
2.17.2	If you don't know whether your product is a medical device	Does your product indicate a diagnosis or treatment, monitor a physiological process or disease, support clinical decisions, perform calculations or indicate individual risk scores for a medical purpose?	Yes   No	

2.18	If your product is a medical device	<p>If defined as a medical device your product should be 'CE' marked to show the manufacturer's declaration that it complies with the EU Medical device directives.</p> <p>Please provide the following evidence:</p> <p>Class 1 devices</p> <ul style="list-style-type: none"> <li>- your evidence of registration with MHRA and self-declaration of conformity, or</li> </ul> <p>Class 11a and above devices</p> <ul style="list-style-type: none"> <li>- your CE certificate from a Notified Body</li> </ul> <p>All</p> <ul style="list-style-type: none"> <li>- Your post market surveillance plan.</li> </ul>	File	<a href="#">Guidance on CE marking</a>
2.19		Does your product form part of a service that requires registered healthcare professionals to operate?	Yes   No	
2.19.1	If your product forms part of a service that requires healthcare professionals to operate it	Confirm their registration status, names and fitness to practice in England as well as appropriate identifiers/codes.	Free Text	
2.20		Does your product process (e.g. store) the personal data of NHS or Social Care patient/client/service users?	Yes   No	
2.20.1	If your product processes personal data of NHS or Social Care users	Where does the product process (e.g. store) the personal data of NHS or Social Care patient/client/service users?	In the UK   In the European Economic Area   In a country deemed 'adequate' i.e. recognised by the EU Commission to have an adequate level of protection   In the USA under a Privacy Shield arrangement   Other	
2.20.2	If your product processes personal data outside of regions listed above in 2.20.1	If other, where does your product process (e.g. store) the personal data of NHS or Social Care patient/client/service users?	Free Text	

2.21		Are registration or login details required for full use of your product?	Yes   No	
2.21.1	If login details are required for full use of your product	Please provide guest login details.	Free Text	
2.22		Select which platforms your product is available on and provide version numbers.	A. iOS   B. Android   C. Windows Mobile   D. OS X   E. Linux   F. Other	
2.22.1	If your product is available on iOS	Provide the iOS version number.	Free Text	
2.22.2	If your product is available on Android	Provide the Android version number.	Free Text	
2.22.3	If your product is available on Windows Mobile	Provide the Windows Mobile version number.	Free Text	
2.22.4	If your product is available on OS X	Provide the OS X version number.	Free Text	
2.22.5	If your product is available on Linux	Provide the Linux version number.	Free Text	
2.22.6	If your product is available on a platform not listed above in 2.22	Provide the 'other type' version number.	Free Text	
2.23		Provide the URL(s) to the app store location(s).	Free Text	
2.24		Does your product use any form of NHS Branding?	Yes   No	<a href="#">Information on NHS identity guidelines</a>
2.24.1	If your product uses any form of NHS branding	Confirm you have permission from the Department of Health & Social Care to use NHS Branding.	Yes   No	

2.24.2	If your product uses any form of NHS branding and you have permission from the Department of Health & Social Care	Provide confirmation of permission from the Department of Health and Social Care.	File	
2.24.3	If your product uses any form of NHS branding	Confirm the branding complies with NHS England's Branding Guidelines.	Yes   No	<a href="#">Information on NHS identity guidelines</a>
2.25		Does your product constitute a pharmacy service that requires registration with the General Pharmaceutical Council?	Yes   No	<a href="#">Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet</a>
2.25.1	If your product requires registration with the General Pharmaceutical Council	Provide evidence confirming registration with the General Pharmaceutical Council.	File	
2.26		If your product directly provides or facilitates access to registered pharmacy services, indicate which services these are:	A. Dispensing directly via Electronic Prescription Service (EPS) nominated pharmacies   B. Dispensing directly via pharmacies where a prescription is not sent directly via EPS   C. Any other pharmacy service (advanced, enhanced, locally commissioned, private)   D. None	
2.26.1	If you answered A or B or C listed above in 2.30	Are users informed of the geographical location of the pharmacy/dispenser?	Yes   No	
2.26.2	If you answered A or B or C listed above in 2.30	Is the type of pharmacy (online/physical/other) clearly stated prior to the beginning of any sign up process?	Yes   No	

2.26.2.1	If the type of pharmacy is clearly stated prior to the beginning of any sign up process	Describe how the type of pharmacy is presented to the user.	Free Text	
2.26.3	If you answered A or B or C listed above in 2.30	Are access, collection and/or delivery options explicitly stated prior to any engagement with offered services, such as opening times?	Yes   No	
2.26.4	If you answered A or B or C listed above in 2.30	Is the choice of pharmacy offered to the user restricted in any way?	Yes   No	
2.26.4.1	If the choice of pharmacy offered to the user is restricted in any way	Confirm how and where this and subsequent restrictions are presented to the user.	Free Text	
2.26.5	If you answered A or B or C listed above in 2.30	Is Electronic Prescription Service (EPS) nomination included within the product?	Yes   No	
2.26.5.1	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Are users provided with clear information about EPS within the product before any of their personal details are captured for the purpose of nomination?	Yes   No	<a href="#">Information on Electronic Prescription Services</a>
2.26.5.2	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Is the information provided in line with the information on EPS published by nhs.uk?	Yes   No	<a href="#">Information on Electronic Prescription Services</a>
2.26.5.3	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Is the nomination clearly distinct from any other sign up process within the product?	Yes   No	

2.26.5.4	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Is the nomination clearly communicated in plain English?	Yes   No	
2.26.5.5	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Does the nomination require proactive patient consent? (a pre-ticked box is not sufficient).	Yes   No	
2.26.5.6	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Is the ability and process required to change a nominated pharmacy at any time made explicit and clear?	Yes   No	
2.26.5.7	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Is it explicit that withdrawal from EPS is not possible once signed up, but that this does not restrict future pharmacy choices?	Yes   No	
2.26.5.8	If you answered A or B or C listed above in 2.30 and if EPS nomination is included within your product	Is this information available for the user to refer back to at any point during their use of the service?	Yes   No	
2.26.6	If you answered C listed above in 2.30	Please list potential services offered and whether these are free at the point of care or if an additional cost is incurred by the user or commissioner above and beyond standard NHS contract reimbursement.	Free Text	

Display ID	Answer this question if...	Question	Response Option	Supporting Information
1.1		Are there any clinical benefits to using your product? For example, will it improve symptom control or clinical outcomes?	Yes   No	
1.1.1	Your product provides any clinical benefits	Describe what clinical benefits and the timeframe for success.	Free Text	
1.1.2	Your product provides any clinical benefits	Do you have any evidence to show success of the clinical benefits? For example, published articles, pilot studies or user research.	Yes   No	<a href="#">Information on levels of medical evidence</a>
1.1.2.1	You can provide evidence demonstrating the clinical benefits of your product	Select all relevant evidence type(s) from the following:	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"   Case series (and poor-quality cohort and case-control studies)   Individual case-control study   Systematic review (with homogeneity) of case-control studies   "Outcomes" Research; ecological studies   Individual cohort study or low quality randomized controlled trials (e.g. <80% follow-up)   Systematic reviews (with homogeneity) of cohort studies   All or none randomized controlled trials   Individual randomized controlled trials (with narrow confidence interval)   Systematic reviews (with homogeneity) of randomized controlled trials	
1.1.2.2	You can provide evidence demonstrating the clinical benefits of your product	Upload a relevant document or provide relevant URLs. Please indicate how you would like to provide this information:	Text   File   Text and File	
1.1.2.3		Provide relevant URLs.	Free Text	

1.1.2.4		Upload relevant document.	File	
1.1.3	Your product does not provide any clinical benefits or if you cannot provide evidence of any clinical benefits.	Give the reason why not.	Free Text	
1.2		Are there any behavioural benefits to using your product? For example, will it improve patient reported outcomes or experience measures?	Yes   No	
1.2.1	If your product provides any behavioural benefits	Describe the improvements to psychological or social motivation, patient reported outcomes or experience measures.	Free Text	
1.2.2	If your product provides any behavioural benefits	Do you have any evidence to show success of the behavioural benefits? For example, published articles, pilot studies or user research.	Yes   No	
1.2.2.1	You can provide evidence demonstrating the behavioural benefits of your product	Select all relevant evidence types from the following:	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"   Case series (and poor-quality cohort and case-control studies)   Individual case-control study   Systematic review (with homogeneity) of case-control studies   "Outcomes" Research; ecological studies   Individual cohort study or low quality randomized controlled trials (e.g. <80% follow-up)   Systematic reviews (with homogeneity) of cohort studies   All or none randomized controlled trials   Individual randomized controlled trials (with narrow confidence interval)   Systematic reviews (with homogeneity) of randomized controlled trials	<a href="#">Information on levels of medical evidence</a>
1.2.2.2	You can provide evidence demonstrating the behavioural benefits of your product	Upload a relevant document or provide relevant URLs. Please indicate how you would like to provide this information:	Text   File   Text and File	
1.2.2.3		Provide relevant URLs.	Free Text	



1.2.2.4		Upload relevant document.	File	
1.2.3	Your product does not provide any behavioural benefits or if you cannot provide evidence of any behavioural benefits.	Give the reason why not.	Free Text	
1.3		Are there any economic benefits to using your product?	Yes   No	
1.3.1	There are established economic benefits to using your product	Describe what economic benefits and the timeframe for success.	Free Text	
1.3.2	There are established economic benefits to using your product	Do you have any evidence to show success of the economic benefits? For example, published articles, pilot studies or user research.	Yes   No	
1.3.2.1	If you can provide evidence demonstrating the economic benefits of your product	Select all relevant evidence types from the following:	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"   Case series (and poor-quality cohort and case-control studies)   Individual case-control study   Systematic review (with homogeneity) of case	
1.3.2.2	You can provide evidence demonstrating the economic benefits of your product	Upload a relevant document or provide relevant URLs. Please indicate how you would like to provide this information:	Text   File   Text and File	
1.3.2.3		Provide relevant URLs.	Free Text	
1.3.2.4		Upload relevant document.	File	
1.3.3	There are no established economic benefits to using your product or if you	Give the reason why not.	Free Text	

	cannot provide evidence of economic benefits.			
1.4		Are there any other outcomes that you have measured?	Yes   No	
1.4.1	There are any other outcomes that you have measured	Describe what other outcomes and the timeframe for success.	Free Text	
1.4.2	There are any other outcomes that you have measured	Has your product been evaluated in any way for these other outcomes?	Yes   No	
1.4.2.1	You can provide evidence demonstrating the evaluation of these outcomes	Select all relevant evidence types from the following:	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"   Case series (and poor-quality cohort and case-control studies)   Individual case-control study   Systematic review (with homogeneity) of case-control studies   "Outcomes" Research; ecological studies   Individual cohort study or low quality randomized controlled trials (e.g. <80% follow-up)   Systematic reviews (with homogeneity) of cohort studies   All or none randomized controlled trials   Individual randomized controlled trials (with narrow confidence interval)   Systematic reviews (with homogeneity) of randomized controlled trials	
1.4.2.2		Upload a relevant document or provide relevant URLs. Please indicate how you would like to provide this information:	Text   File   Text and File	
1.4.2.3		Provide relevant URLs.	Free Text	
1.4.2.4		Upload relevant document.	File	
1.4.3	There are no outcomes that you have measured which have been evaluated	Give the reason why not.	Free Text	

1.5		Describe any resource costs associated with running your service, any indirect costs of facilitating its use, or any activities assumed to be undertaken by healthcare staff. If directly replacing a process, provide details of the resources needed and the comparative service costs being replaced.	Free Text	
1.6		Based on your business model and associated costs to the NHS or its users, are there resource impact benefits associated with your product?	Yes   No	
1.6.1	There are any resource impact benefits associated with your product	Provide details of resource impact benefits.	Free Text	
1.7		Is there cost and resource impact data available to demonstrate the claimed economic benefits of your product?	Yes   No	
1.7.1	There is any cost and impact data available for your product	Provide details of cost and resource impact data.	Free Text	

The National Institute for Health and Care Excellence (NICE) and their partner organisations recently published a set of [evidence standards](#) for digital health technologies. We are working to incorporate these standards into future versions of these questions.

You will need to answer the current set of questions, but you should familiarise yourself with the evidence requirements for later versions of this assessment.

# Technical Assessment – Clinical Safety

Establishing that your product is clinically safe to use

Display ID	Answer this question if...	Question	Response Option	Supporting Information
2.1		Does your product fall within the scope of the NHS England mandated Safety Standard DCB0129?	Yes   No	<a href="#">Information on clinical risk management standard DCB0129</a>
2.1.1	Your product falls within the scope of DCB0129	Provide a copy of your Safety Case and Hazard Log.	File	Safety Case and Hazard Log templates can be found <a href="#">here</a>
2.1.2	Your product does not fall within the scope of DCB0129	Provide a brief explanation as to why your product does not fall within the scope of the NHS England mandated Safety Standard DCB0129.	Free Text	<a href="#">Information on clinical risk management standard DCB0129</a>
2.2		Is it possible for users to experience adverse effects as a result of using your product?	Yes   No	For example, think about what may happen if the information displayed within your product is missing, incorrect or displayed in a confusing manner. Could this have an effect on the user or the care/treatment they receive?
2.2.1	If it is possible for users to experience adverse effects as a result of using your product	List all of the possible adverse effects of using your product.	Free Text	
2.3		List any adverse events associated with your product reported to a notified body, regulatory authority, or known to you from other sources.	Free Text	
2.4		Provide details of the measures that have been put in place to prevent a recurrence of any reported events, including any proof of their effectiveness.	Free Text	
2.5		Has the safety assessment for your product and its impact on interfacing systems been reviewed and approved by a suitably qualified clinician or other healthcare professional?	Yes   No	
2.5.1	If the safety assessment for your product has been approved by a qualified clinician	Provide the name and job title of the reviewer.	Free Text	

# Technical Assessment – Data Protection

Establishing that your product handles personal information in a safe, fair and lawful way.

Display ID	Answer this question if...	Question	Response Option	Supporting Information
3.1		<p>Using your product causes personal data to be processed (e.g. collected /used/stored/analysed transmitted). This could be processing carried out by you/your organisation, another organisation on your behalf or by the users themselves.</p> <p>The definition of personal data can be found on <a href="#">ICO's website</a> examples are listed in the supporting information.</p> <p>This includes any processing of personal data that is:</p> <ul style="list-style-type: none"> <li>• Carried out by a third party e.g. user analytics, user surveys, bulk emailers, tracker software (meant to collect data about the user or their online actions whether used for marketing or not)</li> <li>• Caused by allowing 'permissions' your product requests to access or perform actions on existing personal data e.g. the user's mobile phone photo library, contact lists, address books</li> </ul>	True   False	
3.1.1	Your product processes personal data	Provide details of any other personal data items being processed by your product that are not listed in the supporting information.	Free Text	
<b>Sensitive Personal Data</b>				

3.2		<p>Using your product causes sensitive personal data to be processed (e.g. collected/used/stored/analysed/transmitted). This could be processing carried out by you/your organisation, another organisation on your behalf or the users themselves.</p> <p>The definition of sensitive personal data can be found on the <a href="#">ICO's website</a> and examples are listed in the supporting information.</p> <p>This includes any processing of sensitive personal data that is:</p> <ul style="list-style-type: none"> <li>• Carried out by a third party e.g. user analytics, user surveys, bulk emailers, tracker software (meant to collect data about the user or their online actions whether used for marketing or not)</li> <li>• Caused by allowing 'permissions' your product requests to access or perform actions on existing sensitive personal data (e.g. the user's mobile phone photo library, contact lists, address books)</li> </ul>	True   False	<p>This includes:</p> <ol style="list-style-type: none"> <li>1. Physical / mental health or condition (past, current or future status) including: <ol style="list-style-type: none"> <li>a. Medical data – data that are inherently/clearly medical data</li> <li>b. Raw sensor data – data that can be used in itself or in combination with other data to draw a conclusion about the actual health status or health risk of a person</li> <li>c. Conclusions data – data where conclusions are drawn about a person's health status or health risk, irrespective of whether these conclusions are accurate, or otherwise adequate</li> </ol> </li> <li>2. Sexual life / orientation</li> <li>3. Family / lifestyle / social circumstance</li> <li>4. Political opinion</li> <li>5. Offences committed / alleged to have committed / criminal proceedings / outcomes / sentence*</li> <li>6. Financial data (that might be used for payment fraud)</li> <li>7. Religion or other beliefs</li> <li>8. Trade Union membership</li> <li>9. Racial / ethnic origin</li> <li>10. Biometric data (e.g. fingerprints / facial recognition) for the purpose of uniquely identifying a person</li> <li>11. Genetic data for the purpose of uniquely identifying a person</li> <li>12. Other sensitive personal data</li> </ol>
3.2.1	Your product processes sensitive personal data	Provide details of any other sensitive personal data items being processed by your product that are not listed in the supporting information.	Free Text	
3.3	Your product processes personal OR sensitive personal data	The personal data (and/or sensitive personal data) includes NHS or Social Care Data e.g. patient or client information).	True   False	

3.3.1	Your product processes personal or sensitive personal data AND this data includes NHS or Social Care Data	You/your organisation complies with NHS national guidance on offshoring and the use of public cloud services.	True   False	NHS and Social Care providers may use cloud computing services for NHS data, but personal and sensitive personal data should only be hosted within the UK, European Economic Area (EEA), a country deemed adequate by the European Commission, or in the US where covered by Privacy Shield. Click <a href="#">here</a> for more information on cloud services and data offshoring.
3.4	Your product does not process personal or sensitive personal data	<p>You have indicated that the use of your product will not cause any personal or sensitive personal data to be processed.</p> <p>Please confirm that:</p> <ul style="list-style-type: none"> <li>• You have read and fully understood the definitions of personal sensitive personal data provided by the Information Commissioner’s Office</li> <li>• You have read and fully understood the supporting information and examples</li> <li>• You have fully considered all the data including that processed by placing and retrieving information through a cookie or similar technology</li> <li>• Should there be an intention to process such data, you accept that a reassessment will be required before the data processing begins in order to remain on the NHS Apps Library</li> </ul> <p>I confirm</p>	True   False	
<b>Organisation Status</b>		<p>Understanding you/your organisation’s role in the processing is crucial. The following questions will help identify your data protection responsibilities by finding out if you/your organisation is a:</p> <ul style="list-style-type: none"> <li>• 'Controller'</li> <li>• 'Controller' and 'manufacturer/designer' of the product)</li> <li>• 'Processor' only or</li> <li>• Product 'manufacturer/designer' only.</li> </ul>		Please also read the guidance available on the UK <a href="#">Information Commissioners website</a>

3.5	Your product processes personal OR sensitive personal data	<p>You/your organisation (does not need to actually possess the data) but STILL, alone or jointly with another organisation, decides:</p> <ul style="list-style-type: none"> <li>• to collect the data in the first place and the legal basis for doing so;</li> <li>• which items of data to collect (e.g. the content of the data);</li> <li>• the purpose or purposes the data are to be used for;</li> <li>• which individuals to collect data about;</li> <li>• whether to disclose the data, and if so, who to;</li> <li>• whether subject access and other individuals' rights apply (e.g. the application of exemptions); and</li> <li>• how long to retain the data or whether to make non-routine amendments to the data.</li> </ul> <p>If your answer to these statements is 'True', this indicates that your organisation is a 'Controller' (you may also be the designer/manufacturer, but your role as a 'Controller' dictates your data protection liabilities).</p>	True   False	
3.6	Your product processes personal OR sensitive personal data AND your organisation is not a Controller	<p>You/your organisation processes personal data on behalf of another organisation and the other organisation (the 'Controller') makes the decisions described above.</p> <p>If your answer to this is 'Yes', then you / your organisation is a 'Processor'.</p>	Yes   No	<p>A 'Controller' is required to ensure a contract / written binding agreement is in place that sets out clear instructions to the 'Processor' and establishes the liabilities of the 'Controller' and its 'Processor'.</p> <p>'Processing' means any operation or set of operations performed on personal data, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.</p>



3.6.1	Your product processes personal OR sensitive personal data AND your organisation is a Processor (and not a Controller)	Please provide the details of the 'Controller' organisation on whose behalf you are processing personal data.	Free Text	
3.7	Your product processes personal OR sensitive personal data AND your organisation is neither a Controller nor Processor	<p>You/your organisation is developing, or has developed, a product but you will not control or process the personal data because:</p> <ul style="list-style-type: none"> <li>• the individual user who downloads your product controls their own data entirely OR</li> <li>• the client (organisation) which buys your product is the 'Controller' and will make the decisions described earlier regarding what personal data is processed when using your product).</li> </ul> <p>If your answer to this is 'Yes', then you/your organisation is a manufacturer or designer (neither a 'Controller' nor 'Processor'). Your app must be designed and configurable to meet the potential clients' (the 'Controller') legal requirements or safeguard the privacy rights of users who individually download the product you make available.</p>	Yes   No	<p>If you are developing a product which will be taken into use by another organisation, for example a health or care organisation/professional to process personal data, then the health or care organisation/professional will be the 'Controller' of the personal data processed by the product and will be accountable for evidencing compliance with relevant:</p> <ul style="list-style-type: none"> <li>• Legislation (e.g. Data Protection legislation)</li> <li>• Policies (e.g. <a href="#">Information on cloud services and data offshoring</a>)</li> </ul> <p>As part of your development process, you, as a 'maufacturer/designer', should ensure that you can evidence that your product meets your customer/client's expectations e.g. it meets the data protection principle 'Data Protection by design and default', which means embedding data privacy features and data privacy enhancing technologies into the design at an early stage.</p> <p>To evidence compliance with this principle, you should complete <a href="#">a Data Protection Impact Assessment</a> (which is included later in this section). If you are not a 'Controller', then you should not complete the 'Controller' questions.</p> <p>Available Mobile Health (mHealth) product</p>

				<p>guidance includes:</p> <ul style="list-style-type: none"> <li>• The <a href="#">privacy code of conduct</a> for mHealth apps which is being developed under the initiative of the European Commission submitted for comments to the Article 29 Data Protection Working Party in June 2016</li> <li>• The <a href="#">code of practice standard (PAS 277)</a> developed by the British Standards Institution (BSI);</li> <li>• The <a href="#">international Standard IEC 82304-1</a>, which is being prepared by a Joint Working Group of IEC subcommittee 62A (Common aspects of electrical equipment used in medical practice) and ISO technical committee 215: Health Informatics.</li> <li>• The UK ICO describes this situation in an article: <a href="#">Six reasons you need to be thinking about data protection.</a></li> </ul>
<b>Application of legislation</b>				<p>European and UK data protection laws apply to 'Controllers' that are:</p> <ul style="list-style-type: none"> <li>• Established in the EU/UK</li> <li>• Established outside of EU/UK but offers goods or services to EU/UK residents or monitors the behaviour of EU/UK residents</li> </ul> <p>Many organisations that were not subject to existing EU/UK data protection law before May 2018 will now be subject to the GDPR, especially online businesses.</p>
3.8	Your product processes personal OR sensitive personal data AND is a Controller	You/your organisation is subject to European/UK Data Protection laws.	True   False	

<b>Data Protection Registration and Annual Fee</b>				
3.9	Your product processes personal OR sensitive personal data AND your organisation is a Controller AND is subject to European/UK Data Protection Laws	You/your organisation has a registration number in the Data Protection Register	True   False	<p>If you/your organisation is subject to UK/EU data protection law, you must register and pay a data protection fee - in the UK this is paid to the Information Commissioner's Office (ICO).</p> <p>See <a href="#">data protection fee</a>, which includes a Registration self-assessment 'Not sure if you need to pay a fee to the ICO?'</p>
3.10	Your product processes personal OR sensitive personal data AND your organisation is a Controller AND is subject to European/UK Data Protection Laws and if your organisation has a registration number in the Data Protection Register	What is your registration number in the appropriate European/UK Data Protection Register?	Free Text	
3.11	Your product processes personal OR sensitive personal data AND your organisation is a Controller AND is subject to European/UK Data Protection Laws and if your organisation does not have a registration number in the Data Protection Register	If you do not have a registration number in the Data Protection Register, explain why	Free Text	
<b>Answer this section if your product processes personal OR sensitive personal data AND if your organisation is a Controller</b>		<b>ICO Data Protection Self Assessment – Controllers Checklist</b>		

3.12		Complete the 'Controllers' checklist and tell us your overall grading (which must achieve Green or Amber to be considered for the NHS Apps Library). You will be asked to provide us with a copy in a subsequent question. See the supporting information for details of the 'Controllers' checklist.	Red   Amber   Green	The UK Information Commissioner's Office provides a <a href="#">Data Protection checklist</a> to help 'Controllers' assess the general level of data protection compliance.
3.13		Provide the name and title of a senior manager in the 'Controller' organisation who verifies the grading is accurate.	Free Text	
3.14		What date was this checklist completed on? (this should be within a month of your application)		
3.15		Please supply a copy of the completed ICO Checklist.	File	
	<b>Answer this section if your product processes personal OR sensitive personal data AND if your organisation is a Controller OR a Manufacturer</b>	Data Protection Impact Assessment Report (DPIA)		<p>Under Data Protection legislation, organisations must be able to demonstrate (evidence) that their processing of personal and sensitive personal data complies with the Data Protection Principle of 'Data Protection by Design'.</p> <p>A DPIA is a tool that enables organisations to identify and mitigate risks inherent in proposed data processing activities before the processing begins.</p> <p>A comprehensive DPIA is required which covers the criteria set out in <a href="#">European guidelines (Annex 2)</a> and additionally covers trackers and permissions (described in later questions).</p> <ul style="list-style-type: none"> <li>You may use your own equivalent documentation or you may use the DPIA template available from the UK ICO website: <ul style="list-style-type: none"> <li><a href="#">DPIA template: WORD version</a></li> <li><a href="#">DPIA template: PDF version</a></li> </ul> </li> </ul>

3.16		<p>To be considered for the NHS Apps Library, a DPIA report must be provided for any product that causes personal or sensitive personal data to be accessed/processed.</p> <p>Complete and attach a dated and signed DPIA Report (see supporting information), ensuring that it:</p> <ul style="list-style-type: none"> <li>• Meets the criteria set out in <a href="#">European guidelines (Annex 2)</a></li> <li>AND</li> <li>• Includes details of trackers (software meant to collect data about the user or their online actions) with a justification why each is required, what the purpose of each is and the legal basis (e.g. consent for such processing)</li> <li>• Includes details of permissions (actions the product can do on user's device) with a justification why each is required, what the purpose of each is and the legal basis (if necessary e.g. consent for such processing)</li> </ul>	File	
3.17		Your DPIA meets the criteria set in Annex 2 of Guidelines on Data Protection Impact Assessment (DPIA).	True   False   Partially	Information on <a href="#">European guidelines (Annex 2)</a>
3.17.1	AND If your product partially meets the criteria set out in Annex 2 of Guidelines of DPIA	Provide details of any criteria set out in Annex 2 that are not met in the DPIA.	Free Text	
3.18		Your DPIA includes details of trackers and permissions used by your product along with the justification for why each is required and their purpose. If there are no trackers or permissions used by your product, this is clearly stated in the DPIA.	True   False	
3.18.1	AND If your DPIA includes details of trackers and permissions used by your product	If these trackers comprise personal data (e.g. allow a user to be tracked), users are made adequately aware of the trackers/permissions in the product's privacy notice.	True   False	
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller</b>		<b>Legal Basis for Processing Personal Data (Excluding Cookies)</b>		

3.19	AND If your product processes personal data AND your organisation is a Controller	The legal basis for each processing purpose of the personal data is clearly described to the individual.	True   False	
3.20		The legal basis for the processing of personal data is:	Consent   Other legal basis	
3.20.1	AND If there is an 'other legal basis' for the processing of personal data	As you have selected 'other legal basis', please describe the basis here:	Free Text	
3.21	AND If your product processes sensitive personal data and if your organisation is a Controller	The legal basis for each processing purpose of sensitive personal data is ALSO clearly described to the individual.	True   False   Not Applicable	
3.22	AND If your product processes sensitive personal data and if your organisation is a Controller	The legal basis for the processing of sensitive personal data is:	Consent   Other legal basis	
3.22.1	AND If there is an 'other legal basis' for the processing of sensitive personal data	As you have selected 'other legal basis', please describe the basis here:	Free Text	
		<b>Controllers Obligations - Personal Data Breach Actions</b>		
3.23	If your product processes personal OR sensitive personal data AND your organisation is a Controller	<p>You/your organisation has a documented plan showing your intended reactions to a data breach <b>before</b> a breach occurs. This plan includes assessing:</p> <ul style="list-style-type: none"> <li>• whether personal data, and what personal data, is involved</li> <li>• need to notify the appropriate Data Protection Authority (in UK the ICO) without undue delay and, not later than 72 hours after discovering the breach</li> <li>• the existing technical and organisational protection</li> </ul>	True   False	

		<p>measures in place / your subsequent measures to ensure that the high risk to the rights and freedoms of users is no longer likely</p> <ul style="list-style-type: none"> <li>• notifying the affected individuals, without undue delay, of the appropriate details, for example likely consequences</li> <li>• your measures to mitigate possible adverse effects</li> </ul>		
<p><b>If your product processes personal OR sensitive personal data AND your organisation is a Controller</b></p>		<p><b>Controllers Obligations - Individuals' Rights are Upheld</b></p>		
3.24		You/your organisation has developed measures to treat risks and to protect the applicable rights of the data subjects.	True   False	
3.24.1	AND If your organisation has developed measures to protect the applicable rights of the data subjects	The rights of the data subjects include providing transparency/fair processing information to data subjects.	True   False	
3.24.2	AND If your organisation has developed measures to protect the applicable rights of the data subjects	The rights of data subjects include the right of data portability (which only applies where consent or contract with the data subject is the legal basis and personal data are / knowingly and actively provided by the data subject / generated by and collected from the use of the service or device e.g. 'observed' such as search history, traffic data, location data, other raw data such as heartbeat tracked by fitness and health trackers).	True   False   Not Applicable	
3.24.3	AND If your organisation has developed measures to protect the applicable rights of the data subjects	The rights of the data subjects include the right to erase (or the "right to be forgotten").	True   False   Not Applicable	
3.24.4	AND If your organisation has developed measures to protect the applicable rights of the data subjects	The rights of the data subjects include the right to rectify, object, restrict processing.	True   False	
3.25		You/your organisation use all reasonable measures to verify the identity of an individual who exercises these rights.	True   False	

<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller AND allows your users personal data to be processed by a third party</b>		<b>Controllers Obligations – Processing Contracts e.g. Cloud or Network/Communications Providers</b>		
3.26		You/your organisation allows or causes your users' personal data to be processed by a third party (e.g. hosts the data, manages your website, provides user research or analytics services, user survey tools, bulk email providers that manage your client email lists).	True   False	
3.26.1		The third party provides technical services (e.g. maintains personal data backups or stores personal data in a cloud).	True   False	
3.26.2		The third party accesses/uses personal data (for which you are the 'Controller').	True   False	
3.26.3		A written binding agreement (e.g. contract) is in place between you/your organisation and each third party ('Processor').	True   False	
3.26.4		No contract clauses indemnify 'Processors' against fines or claims under UK/EU data protection law.	True   False	
3.26.5		All contracts clearly set out the subject matter and duration of the processing.	True   False	
3.26.6		All contracts clearly set out the nature and purpose of the processing.	True   False	
3.26.7		All contracts clearly set out the type of personal data and categories of data subject.	True   False	
3.26.8		All contracts clearly set out the obligations and rights of the 'Controller'.	True   False	
3.26.9		All contracts require the 'Processor' to only act on the written instructions of the 'Controller'.	True   False	
3.26.10		All contracts require the 'Processor' to ensure that their employees processing the data are subject to a duty of confidence.	True   False	



3.26.11		All contracts require the 'Processor' to take appropriate measures to ensure the security of processing.	True   False	
3.26.12		All contracts require the 'Processor' to only engage 'Sub-Processors' with the prior consent of the 'Controller' and under the same conditions as the processing written contract.	True   False	
3.26.13		All contracts require the 'Processor' to assist the 'Controller' in providing subject access and allowing data subjects to exercise their rights under the UK/EU law.	True   False	
3.26.14		All contracts require the 'Processor' to assist the 'Controller' in meeting its UK/EU data protection law obligations in relation to: <ul style="list-style-type: none"> <li>• the security of processing</li> <li>• the notification of personal data breaches, and</li> <li>• data protection impact assessments</li> </ul>	True   False	
3.26.15		All contracts require the 'Processor' to tell the 'Controller' immediately if it is asked to do something infringing UK/EU data protection law.	True   False	
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller</b>		<b>Fair Processing Information</b>  The next set of questions firstly identify from whom the data is obtained, the content to be included in the fair processing information, and when this information should be provided. The requirements differ depending upon whether the personal data is obtained from the data subject directly or from a third party.  Individuals have the right to be informed about the collection and use of their personal data. This is a key transparency requirement under data protection legislation. Guidance is available on the <a href="#">ICO's website</a>		
3.27		How is the personal data obtained?	The personal data is obtained directly from the individual   The personal data is obtained from a third party	
3.27.1	AND if the personal data is obtained directly from the individual	Fair processing information is provided at the time the personal data is obtained.	True   False	

3.27.2	AND if the personal data is obtained from a third party	Fair processing information is provided within one month of having obtained the data from a third party OR, if the personal data is used to communicate with the individual, at the latest, when the first communication takes place.	True   False	
3.27.3		You/your organisation's fair processing information is provided to individuals free of charge.	True   False	
<b>Answer this section if your product processes personal OR sensitive personal data AND is a Controller</b>		<b>You/your organisation's fair processing information includes the following:</b>		
3.27.4		The identity and the contact details of the 'Controller' and where applicable, the 'Controller's' representative.	True   False	
3.27.5		The purposes and the legal basis for each purpose.	True   False	
3.27.6		The recipients, or categories of recipients, of the personal data.	True   False	
3.27.7		The details of data transfers outside the European Economic Area, including how the data will be protected. For example: <ul style="list-style-type: none"> <li>• The recipient is in an 'adequate' country (e.g. recognised by the EU Commission to have an adequate level of protection)</li> <li>• Binding Corporate Rules (BCR) or</li> <li>• Model Contract Clauses</li> </ul> and you have made the individual aware of how they may obtain a copy of the safeguards, or where they can be seen.	True   False   Not Applicable	
3.27.8		The retention period or, if no fixed retention period can be provided, the criteria used to determine that period.	True   False	
3.27.9		The right to lodge a complaint with a supervisory authority (in the UK this would be the Information Commissioner's Office (ICO)).	True   False	

3.27.10		Whether the provision of personal data is part of a statutory or contractual requirement or obligation and possible consequences of failing to provide the personal data.	True   False   Not Applicable	
3.27.11		The existence of automated decision making including profiling and information about how decisions are made, the significance and the consequences.	True   False   Not Applicable	
3.27.12		The existence of the data subject's right to access/obtain a copy of their personal data.	True   False	
3.27.13		The existence of the data subject's rights to rectify, erase and restrict their personal data.	True   False	
3.27.14		The existence of the data subject's rights to object to the processing.	True   False   Not Applicable	
3.27.15		The existence of the data subject's rights to withdraw consent (if consent is the legal basis).	True   False   Not Applicable	
3.27.16		The existence of the data subject's rights to data portability (provide the personal data in machine readable form).	True   False   Not Applicable	
3.27.17		The existence of the data subject's rights to object to decisions based solely on automated processing (which could include profiling), if the decisions produce legal effects or similarly significantly affects the data subject.	True   False   Not Applicable	
3.27.18		If the personal data is to be used later for a new purpose which was not adequately described in the initial transparency information and is 'incompatible' with the original purpose, you will provide users with updated transparency information which may mean re-obtaining consent (if consent was the legal basis).	True   False	
3.27.19		Users are notified of substantial changes to the existing transparency information (and consent obtained again unless the consent obtained previously remains valid).	True   False   Not Applicable	

3.27.20	AND if personal data is obtained from a third party	The categories of personal data (what types of personal data you have obtained about the data subject).	Yes   No	
3.27.21	AND if personal data is obtained from a third party	The source the personal data originates from (if not the data subject) and whether it came from publicly accessible sources.	Yes   No   Not Applicable	
3.27.22	AND if personal data is obtained from a third party	The right to object to processing of their personal data is communicated to the data subject no later than the time of the first communication with the data subject and the information is provided clearly and separately from any other information provided to the data subject.	Yes   No	
3.27.23	AND if personal data is obtained from a third party	If disclosure to another recipient is envisaged, the fair processing information is provided, at the latest, before the data is disclosed.	Yes   No   Not Applicable	
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if the legal basis for processing personal data is consent</b>		<b>Consent</b>		Valid consent is defined as 'any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.' You can find guidance on consent on the <a href="#">ICO's website</a> .
3.28.1		Consent is freely given, specific for each separate purpose and informed.	True   False	
3.28.2		Consent is not a precondition of signing up to a service unless it is necessary for that service.	True   False	
3.28.3		Consent is requested separately from the terms and conditions.	True   False	
3.28.4		At the time consent is requested, the individual is provided with the relevant fair processing information.	True   False	

3.28.5		The individual can withdraw consent as easily as it was given (e.g. via the same electronic interface, an unsubscribe link; instructions in emails contained in all communications).	True   False	
3.28.6		Consent (granular consent) is obtained separately for every type of purpose foreseen, for example marketing.	True   False	
3.28.7		If a future additional purpose is envisaged after consent was obtained and the new purpose is incompatible with the original purpose, then additional consent will be obtained before processing for the new purpose begins.	True   False	
3.28.8		Consent is recorded.	Yes, for the current consent only   Yes, for current and previous consents   No, consent is not recorded	
3.28.9		You/your organisation can evidence that the individual gave their valid consent to the processing (e.g. how and when consent was obtained and the information provided to the individual (data subject) at the time).	True   False	
3.28.10		The individual is required to provide a clear affirmative action to signify consent to the processing of personal data for each purpose.	Yes, by an opt button or link online   Yes, by selecting from equally prominent yes/no options   Yes, by responding to an email requesting consent   Yes, by filling optional fields in a form   Yes, other   No, a clear affirmative action is not required	
3.28.11		You/your organisation does NOT use pre-ticked opt-in boxes.	True   False	
3.28.12		You/your organisation does NOT use blank opt-out boxes.	True   False	
3.28.13		You/your organisation does NOT use default settings.	True   False	
3.28.14		You/your organisation confirms it does NOT use a blanket acceptance of your terms and conditions.	True   False	
3.28.15		You/your organisation ensures that an individual who refuses or withdraws consent can do so without detriment to the service provided (e.g. an individual is not unfairly penalised - though it is acceptable to offer additional	True   False	

		incentives to those who do consent, for example for marketing purposes).		
3.28.16		You/your organisation does NOT penalise individuals who withdraw consent.	True   False	
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller</b>		<b>Children's Personal Data</b>		
3.29		You/your organisation's product are particularly: <ul style="list-style-type: none"> <li>• Aimed at children OR</li> <li>• Likely to be used by children</li> </ul>	True   False	
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if your product is likely to be used by children</b>		<b>Children's Personal Data - Rights</b>  <b>You/your organisation:</b>		
3.29.1		Design processes by which a child can exercise their data protection rights with the child in mind, and make them easy for children to access and understand.	True   False	
3.29.2		Allow competent children to exercise their own data protection rights.	True   False	
3.29.3		If your original processing was based on consent provided when the individual was a child, then you comply with requests for personal data to be erased whenever you can.	True   False	
3.29.4		Design your processes so that, as far as possible, it is as easy for a child to get their personal data erased as it was for them to provide it in the first place.	True   False	

<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if your product is likely to be used by children</b>		<b>Children's Personal Data - General</b>  <b>You/your organisation:</b>		
3.30.1		Complies with all the requirements of the UK/EU data protection legislation, not just those specifically relating to children and included in this checklist.	True   False	
3.30.2		Designs your processing with children in mind from the outset and uses a data protection by design and by default approach.	True   False	
3.30.3		Makes sure that your processing is fair and complies with the data protection principles.	True   False	
3.30.4		As a matter of good practice, you use Data Protection Impact Assessments (DPIAs) to help you assess and mitigate the risks to children.	True   False	
3.30.5		If your processing is likely to result in a high risk to the rights and freedom of children, then you always complete a DPIA.	True   False	
3.30.6		As a matter of good practice, you consult with children as appropriate when designing our processing.	True   False	
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if your product is likely to be used by children</b>		<b>Children's Personal Data - Fair Processing Information</b>  <b>You/your organisation:</b>		
3.31.1		Provide privacy notices which are clear, and written in plain, age-appropriate language.	True   False	

3.31.2		Use child friendly ways of presenting privacy information, such as diagrams, cartoons, graphics and videos, dashboards, layered and just-in-time notices, icons and symbols.	True   False	
3.31.3		Explain to children why you require the personal data you have asked for, and what you will do with it, in a way which they can understand.	True   False	
3.31.4		Explain the risks inherent in the processing, and how you intend to safeguard against them, in a child friendly way, so that children (and their parents) understand the implications of sharing their personal data.	True   False	
3.31.5		Tell children what rights they have over their personal data in language they can understand.	True   False	
3.31.6		As a matter of good practice, if relying upon parental consent then you offer two different versions of your privacy notices; one aimed at the holder of parental responsibility and one aimed at the child.	Yes   No   Not Applicable	
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if your product is likely to be used by children</b>		<b>Children's Personal Data - Lawful Basis for Processing a Child's Personal Data</b>  <b>You/your organisation:</b>		
3.32.1		If relying on consent, you will make sure that the child understands what they are consenting to, and you do not exploit any imbalance in power in the relationship between you and the child.	True   False	
3.32.2		If relying on 'necessary for the performance of a contract', you will consider the child's competence to understand what they are agreeing to, and to enter into a contract.	True   False	
3.32.3		If relying upon 'legitimate interests', you will take responsibility for identifying the risks and consequences of the processing, and put age appropriate safeguards in place.	True   False	



<p><b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if your product is likely to be used by children</b></p>		<p><b>Children's Personal Data - Solely Automated Decision-Making (Including Profiling)</b></p> <p><b>You/your organisation:</b></p>		
3.33.1		Do not usually use children's personal data to make solely automated decisions about them if these will have a legal, or a similarly significant, effect upon them.	True   False	
3.33.2		If you do use children's personal data to make such decisions, then you make sure that one of the exceptions applies and that suitable, child appropriate measures are in place to safeguard the child's rights, freedoms and legitimate interests.	True   False	
3.33.3		In the context of behavioural advertising, when deciding whether a solely automated decision has a similarly significant effect upon a child, you take into account: the choices and behaviours that you are seeking to influence; the way in which these might affect the child; and the child's increased vulnerability to this form of advertising; using wider evidence on these matters to support our assessment.	True   False   Not Applicable	
3.33.4		Stop any profiling of a child that is related to direct marketing if they ask you to.	True   False   Not Applicable	
<p><b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if your product is likely to be used by children</b></p>		<p><b>Children's Personal Data - Marketing</b></p> <p><b>You/your organisation:</b></p>		
3.34.1		When considering marketing to children, you take into account their reduced ability to recognise and critically assess the purposes behind the processing and the potential consequences of providing their personal data.	True   False   Not Applicable	

3.34.2		Take into account sector specific guidance on marketing to make sure that children’s personal data is not used in a way that might lead to their exploitation.	True   False   Not Applicable
3.34.3		Stop processing a child’s personal data for the purposes of direct marketing if they ask you to.	True   False   Not Applicable
3.34.4		Comply with the direct marketing requirements of the Privacy and Electronic Communications Regulations (PECR).	True   False   Not Applicable
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if your product is likely to be used by children</b>		<b>Children's Personal Data - Information Society Services (ISS) directly to a child, on the basis of consent</b>  <b>You/your organisation:</b>	
3.35.1		If you decide not to offer your ISS (online service) directly to children, then you mitigate the risk of them gaining access, using measures that are proportionate to the risks inherent in the processing.	True   False   Not Applicable
3.35.2		When offering ISS to UK children on the basis of consent, you make reasonable efforts (taking into account the available technology and the risks inherent in the processing) to ensure that anyone who provides their own consent is at least 13 years old.	True   False   Not Applicable
3.35.3		When offering ISS to UK children on the basis of consent, you obtain parental consent to the processing for children who are under the age of 13, and make reasonable efforts (taking into account the available technology and risks inherent in the processing) to verify that the person providing consent holds parental responsibility for the child.	True   False   Not Applicable
<b>Answer this section if your product processes personal OR sensitive personal data AND your organisation is a Controller and if</b>		<b>Children's Personal Data - Age</b>	

<b>your product is likely to be used by children</b>				
3.36.1		When targeting wider European (non UK) markets you comply with the age limits applicable in each member state.	True   False   Not Applicable	
3.36.2		You regularly review available age verification and parental responsibility verification mechanisms to ensure you are using appropriate current technology.	True   False   Not Applicable	
3.36.3		You do NOT seek parental consent when offering online preventive or counselling services to a child.	True   False   Not Applicable	
<b>If your product processes personal data OR sensitive personal data AND is a Controller</b>		<b>Cookies</b>		
3.37		You/your organisation use cookies, web beacons or similar technologies.	True   False	
<b>Answer this section if your product processes personal data OR sensitive personal data AND your organisation is a Controller and uses cookies, web beacons or similar technologies</b>		<b>Cookies - Policy</b>		
3.38.1		You/your organisation provides users with a cookie policy.	True   False	
3.38.2		The cookie policy explains that consent is being requested for the storage and access of cookies in and from the users' terminal equipment.	True   False	

3.38.3		The cookie policy ensures consent is valid by requiring a clear affirmative action from the user (e.g. pre-ticked boxes or inactivity do not constitute valid consent).	True   False	
3.38.4		The cookie policy fully explains the purpose, in plain language, of each cookie type being used.	True   False	
<b>Answer this section if your product processes personal data OR sensitive personal data AND your organisation is a Controller and uses cookies, web beacons or similar technologies</b>		Cookies - 'Strictly Necessary' Cookies		
3.38.5		You/your organisation use 'strictly necessary' cookies (without which the end user would be unable to use the specific service explicitly requested).	True   False   Not Applicable	
3.38.6		Although consent is not required, is the end user made aware that 'strictly necessary' cookies are being used?	True   False   Not Applicable	
<b>Answer this section if your product processes personal data OR sensitive personal data AND your organisation is a Controller and uses cookies, web beacons or similar technologies</b>		Cookies - Consent for Non-Essential Cookies		
3.38.7		Excluding 'strictly necessary' cookies, is consent obtained for each separate cookie purpose?	True   False   Not Applicable	
3.38.8		You/your organisation can evidence that the individual gave their valid consent to the processing (e.g. how and when consent was obtained and the information provided to the individual (data subject) at the time).	True   False   Not Applicable	
3.38.9		Consent can be withdrawn as easily as it was given (e.g. via the same electronic interface).	True   False	

<p><b>Answer this section if your product processes personal data OR sensitive personal data AND your organisation is a Controller</b></p>	<p><b>Usage/Bug Reporting and Online Tracking</b></p>	<p><b>First Party</b>  A first party cookie can only be created and viewed by the operator of a website a user is visiting. These cookies are often used so that a website recognises the user and automatically applies the user’s desired settings (e.g. which language to display). Website owners may also use the data gathered for analytics or their own online marketing.</p> <p><b>Third Party</b>  Third party web tracking refers to cookies (and other methods that perform the same function e.g. Flash cookie, Server log: Web beacons, tracking pixels) that are generated by external sites and track a user’s journey across different websites. This information may be used for analytics, but more commonly it is used for targeted marketing (e.g. to direct and display advertisements to the individual as a potential customer).  Under EU/UK Data Protection legislation, tracking may only take place if the individual has given their valid consent (e.g. the user has been made aware of any party that may collect, receive, or use the end users’ personal data as a consequence of your use of a tracker. You must also provide users with prominent and easily accessible information about the third party’s use of users’ personal data.  Tracking is not anonymous. A tracker may not have the individual’s name but is able to identify the user (e.g. in order to deliver targeted advertising). Consent is therefore required before this personal data is collected.</p>		
3.39		You collect usage or bug report data (e.g. Google/Adobe Analytics).	True   False	
3.39.1	AND if your organisation collects usage/bug report data	It is collected with informed and valid consent of the user	True   False	
3.39.2	AND if your organisation collects usage/bug report data	It is collected using fully anonymised data (e.g. no personal data, such as tracking data, is collected by you/your organisation or any third party)	True   False	

<p><b>Answer this section if your product processes personal data OR sensitive personal data AND your organisation is a Controller</b></p>	<p>Appointment of a Data Protection Officer</p>	<p>Controllers (and processors) of personal data are required to designate (or recruit/engage) a Data Protection Officer DPO when the organisation:</p> <ul style="list-style-type: none"> <li>• carries out large scale processing of sensitive personal data (also known as special categories of data) e.g. health data</li> <li>• carries out large scale systematic monitoring of individuals (for example, online behaviour tracking) or</li> <li>• is a public authority (except for courts acting in their judicial capacity)</li> </ul>		
<p>3.40</p>		<p>You/your organisation has a designated Data Protection Officer who is formally tasked with ensuring that you/your organisation is aware of, and complies with, its data protection responsibilities.</p>	<p>True   False   Not Applicable</p>	
		<p>Comments and confirmation</p>		
<p>3.41</p>		<p>Use the text box below if you need to clarify any of your responses (please indicate which question(s) you are referring to). If you believe none of your responses require clarification, you must confirm this as the box cannot be left blank.</p>	<p>Free Text</p>	

Display ID	Answer this question if...	Question	Response Option	Supporting Information
4.1		Select all the following components applicable to your product:	1. Application for smartphone or tablet   2. Medical Device   3.Website   4. Wearable   5. Other	
4.1.1	If your product is an application for a smartphone or tablet	Does your product access, process or store personal or sensitive personal data?	Yes   No	
4.1.2	If your product is an application for a smartphone or tablet AND accesses, processes or stores personal or sensitive personal data	Is sensitive personal data persisted to the mobile device?	Yes   No	
4.1.3	If your product is a Medical Device, Website, Wearable or Other	Does your product access, process or store personal or sensitive data?	Yes   No	
4.2		Has a code-level security assessment been undertaken?	Yes   No	<a href="#">OWASP Mobile Security Testing Guide</a>  <a href="#">OWASP Application Security Verification Standard (ASVS)</a>
4.2.1	If a code-level security assessment has been undertaken for your product	Provide evidence of the assessment report.	File	
4.2.2	If a code-level security assessment has been undertaken for your product	Has the security assessment been undertaken by an external body?	Yes   No	<a href="#">Information on CREST accredited companies</a>

# Technical Assessment – Usability and Accessibility

Establishing that your product is easy to use and accessible to all users

Display ID	Answer this question if...	Question	Response Option	Supporting Information
5.1		Does the colour contrast of the text on your native app comply with WCAG 2.0 AA level requirements? All text in your product must have a contrast ratio of at least 4.5 : 1.	Yes   No	<a href="#">Information on the WCAG 2.0 guidelines.</a>
5.2		Did you follow the 6 key principles under the human-centred design process that conforms to the ISO 9241-210 Standard?	Yes   No	<a href="#">Information on the ISO Standard.</a> This is a paid-for document.
5.3		What phases did your human-centred design process go through? For example discovery, alpha, beta, go live.	Free Text	
5.4		What user demographics were defined at the outset of your product's development?	Free Text	
5.5		What user research informed your user needs?	Free Text	
5.6		List each user need your product addresses, and the acceptance criteria for each need.		
5.7		How many times were versions of your product tested with users?	0   1   2   3   4+	
5.7.1	If versions of your product were tested with users	Please list the type(s) of research conducted. For example lab testing, remote testing, popup testing, questionnaires, etc.	Free Text	



5.8		Before release, was your product evaluated for usability and accessibility with a representative sample of the user demographic?	Yes   No	
5.8.1	If your product was evaluated for usability and accessibility before release	Throughout the evaluation of early versions and pre-release versions, what changes were made to your product in light of the user feedback? Please provide examples/evidence.	Free Text	
5.8.2	If your product was evaluated for usability and accessibility before release	Post-release, how do you continue to collect feedback from users and make changes to your product based on this feedback?	Free Text	
5.8.3	If your product was evaluated for usability and accessibility before release	What is your post-release schedule of improvements to your product?	Free Text	
5.9		What platform(s) does your product use?	1. Native iOS or Android app   2. Progressive web app   3. Website	
<b>If your product is a native iOS or Android app</b>		<b>Native App</b>		
5.9.1	If your product is a native iOS or Android app	What device OS accessibility features does your product use? For example VoiceOver (iOS), Dynamic Type (iOS), TalkBack (Android) or Select To Speak (Android).	Free Text	
<b>If your product is a progressive web app</b>		<b>Progressive Web App</b>		
5.10.1	If your product is a progressive web app	Does your product comply with the baseline checklist for progressive web apps, as defined by Google?	Yes   No	<a href="#">Information on the progressive web app checklist</a>
5.10.1.1	If your product is a progressive web app	List any items on this checklist, which your progressive web app does not meet.	Free Text	

5.11	If your product is a progressive web app	Have you conducted accessibility testing on your progressive web app?	Yes   No	
5.11.1	If your product is a progressive web app and accessibility testing has been conducted	Provide evidence of this testing, including outcomes and any planned further changes to improve accessibility.	Free Text	
<b>Websites</b>				
5.12.1	If your product is a website	Is your website responsive?	Yes   No	
5.12.2	If your product is a website	Does your website accessibility conform to WCAG 2.1 level AA?	Yes   No	<a href="#">Information Web Content Accessibility Guidelines 2.0</a>
5.12.3	If your product is a website	Does your website provide text equivalents for every non-text element within the product?	Yes   No	
5.12.4	If your product is a website	Does your website provide an accessibility statement?	Yes   No	<a href="#">Information on how to write and accessibility statement</a>
5.12.4.1	If your product is a website and provides an accessibility statement	Provide a link to your accessibility statement.	Free Text	<a href="#">Information on how to write and accessibility statement</a>
5.12.5	If your product is a website	Have you conducted accessibility testing on your web service?	Yes   No	
5.12.5.1	If your product is a website and if you have conducted accessibility testing on your web service	Provide evidence of this testing, including outcomes and any planned further changes to improve accessibility.	File	
5.12.6	If your product is a website	Can your product be used with keyboard-only control, and with assistive technologies, such as screen readers and screen magnifiers?	Yes   No	

# Technical Assessment – Interoperability

Establishing how well your product exchanges data with other systems

Display ID	Answer this question if...	Question	Response Option	Supporting Information
6.1		Does your product expose any Application Programming Interfaces (APIs) or integration channels for other consumers?	Yes   No   Not Applicable	
6.1.1	Your product exposes any APIs for other consumers	Does your API adhere to the Government Digital Services (GDS) Open API Best Practices?	Yes   No   Partially   Not Applicable	<a href="#">Information on API technical and data standards</a>
6.1.2	Your product exposes any APIs for other consumers and 'Partially' adheres to GDS Open API best practices	For specific areas where best practices are not followed, list the rationale and relevant mitigations put in place.	Free Text	
6.1.3	Your product exposes any APIs for other consumers and GDS Open API best practices are 'Not Applicable'	State the reasons and why they are not applicable.	Free Text	
6.2		Is your product capable of exporting data in a standard format?	Yes   No	
6.2.1	Your product does not export data in a standard format	State the reasons and relevant mitigations if it does not.	Free Text	
6.3		Is your product a wearable or device, or does it integrate with them?	Yes   No	
6.3.1	Your product is a wearable or device or integrates with them	Provide evidence of how it complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards.	Free Text	<a href="#">Access the ISO Standard</a> . This is a paid-for document

# Technical Assessment – Technical Stability

Establishing that the required level of testing has been carried out for your product

Display ID	Answer this question if...	Question	Response Option	Supporting Information
7.1		Are the source code and any configuration items for your product version controlled with all changes audited?	Yes   No	
7.1.1	Your product version controlled with all changes audited	Provide details of your version control processes.	Free Text	
7.2		Do you have accreditation to any industry wide testing standards such as ISO 9001, ISO 29119 etc?	Yes   No	<a href="#">Information on ISO standards.</a> These are paid-for standards.
7.2.1	You have accreditation to any industry wide testing standards	What testing accreditation(s) do you have or are in the process of acquiring (including completion dates)?	Free Text	
7.3		Do you do any testing?	Yes   No	
7.3.1	You do any testing	What types of testing are being executed for your product?	1. Non-Functional   2. Functional   3. Regression	
<b>Answer this section if you do functional or non-functional testing</b>		<b>Non-Functional or Functional testing</b>		
7.3.2		Are all significant issues identified in all test phases resolved prior to release?	Yes   No	
7.3.3		Briefly describe all of your testing activities and provide documentation to support them.	Free Text and File	

<b>Answer this section if you do regression testing</b>		<b>Regression testing</b>		
7.3.4		Briefly describe all of your testing activities and provide documentation to support them.	Free Text and File	
7.3.5	You do not do testing	Provide a reason why no testing is being executed.	Free Text	
7.4		Describe your processes for accepting and responding to technical faults from end users and provide documentation to support this.	Free Text and File	
7.5		Do you have the capacity to rollback to previous versions of your product as and when required?	Yes   No	
7.5.1	You can rollback to previous versions of your product	Provide a brief outline of your rollback process and provide documentation to support this.	Free Text and File	
7.6		Do you proactively monitor running of systems and system components to automatically identify faults and technical issues?	Yes   No	
7.6.1	You proactively monitor systems to automatically identify faults and technical issues	Describe your monitoring processes and procedures.	Free Text	
7.7		Do you have a documented roadmap for the future development of your product?	Yes   No	
7.7.1	You have a documented roadmap for the future development of your product	Provide details of planned development, technical updates and potential release dates.	Free Text	

7.7.2	If you have a documented roadmap for the future development of your product	Provide details of how you will ensure the continued availability of your product.		
7.8		Do you have a plan for decommissioning your product?	Yes   No	
7.8.1	You have a plan for decommissioning your product	Describe your processes for decommissioning your product and dealing with any retained identifiable data.	Free Text	
7.9		Do you have a plan for dealing with any retained identifiable data in the event that an individual stops using your product? For example by uninstalling or unsubscribing.	Yes   No   N/A	
7.9.1	You have a plan for dealing with retained identifiable data if an individual stops using your product	Describe your processes for dealing with any retained identifiable data in the event that an individual stops using your product?	Free Text	