

Domain 1: The technology and its value

What does SHTG need to see?	Your responses
An overview of the technology.	
What does this look like?	
<ul style="list-style-type: none">• A clear description of the technology.<ul style="list-style-type: none">○ What is the purpose of the technology?○ What is the stage of development of the technology?○ Is the technology already in use?○ In what context and to what extent is it in use?○ What geographical variations are there in its use?	

What does SHTG need to see?	Your responses
An overview of the technology.	
What does this look like?	
<ul style="list-style-type: none"> • A description of the health condition (if applicable). <ul style="list-style-type: none"> ○ What are the symptoms of the health condition? ○ What impact does the health condition have on the service user? ○ What is the impact of the health condition for the health and care sector? 	

What does SHTG need to see?	Your responses
An overview of the technology.	
What does this look like?	
<ul style="list-style-type: none"> • A description of the target population. <ul style="list-style-type: none"> ○ What is the size of the target population? This could be a description of the prevalence and incidence of the relevant health problem, or experts' estimates if this is not available. ○ Are there populations that are disproportionately affected by the health condition? ○ Why would a person want to use the health technology? ○ Are there any groups of people who cannot or should not use the health technology? 	

What does SHTG need to see?	Your responses
A description of the pathway of care, that is, before the introduction of the new technology.	
What does this look like?	
<ul style="list-style-type: none"> • What are the current technologies (comparators) within the existing pathway of care(s)? <ul style="list-style-type: none"> ○ Describe them all, if there is more than one ○ Describe the existing pathway(s). ○ It can be helpful to provide a flow chart or diagram. • What if there is no existing pathway of care or system processes? <ul style="list-style-type: none"> ○ Describe the potential impact of introducing the health technology on existing healthcare systems. 	

What does SHTG need to see?	Your responses
<p>A description of the proposed pathway of care based on the introduction of the technology.</p>	
<p>What does this look like?</p>	
<ul style="list-style-type: none"> • A description of the proposed pathway. <ul style="list-style-type: none"> ○ Will the technology replace an existing technology or step in current practice? ○ Will the technology complement current practice or be in addition to current practice? ○ At what stage of the care pathway will the technology be used? <ul style="list-style-type: none"> ▪ For example, will it be used in primary care and/or secondary care? 	

What does SHTG need to see?	Your responses
A description of the proposed pathway of care based on the introduction of the technology.	
What does this look like?	
<ul style="list-style-type: none"> • Changes to current pathways or practice. <ul style="list-style-type: none"> ○ What changes would need to be made to infrastructure, service provision and workforce to adopt the technology? ○ What changes will be needed to operate and maintain the proposed pathway or process using the technology? ○ Will there be a need for training and education for health and care professionals or the target population? ○ What are the barriers and enablers to the use of the technology? 	

What does SHTG need to see?	Your responses
A description of the value proposition of the technology.	
What does this look like?	
<ul style="list-style-type: none"> • The health benefits and other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with current practice. • The anticipated health benefits and impact on other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with the technology. 	

What does SHTG need to see?	Your responses
A description of the value proposition of the technology.	
What does this look like?	
<ul style="list-style-type: none"> • The costs and resource use associated with current practice. • The expected costs and resource use associated with the new technology. 	

What does SHTG need to see?	Your responses
A description of the clinical need for the technology.	
What does this look like?	
<ul style="list-style-type: none"> • Does the technology address a current priority area for the health and care in Scotland? <ul style="list-style-type: none"> ○ For example, does it fit with national strategy? • What is the evidence for the clinical need for this technology? • Is there evidence of the support and interest for this intervention in the health and care community? • Does the technology fix a problem applicable to a small number of health boards, or is it applicable to all boards? 	

Domain 2: Safety, acceptability and credibility

What does SHTG need to see?	Your responses
<p>A description of how the technology complies with relevant regulatory standards.</p>	
<p>What does this look like?</p>	
<ul style="list-style-type: none"> • Does the technology have regulatory approval (that is, UKCA or CE marking)? • Is documentation that all safety and quality standards (relevant to the device classification) have been met provided? 	

What does SHTG need to see?	Your responses
A description of any safety considerations.	
What does this look like?	
<ul style="list-style-type: none"> • What are the safety concerns? <ul style="list-style-type: none"> ○ Related to the technology or comparator. ○ How do these safety concerns compare with current practice? ○ Does the frequency or severity of harms change over time or in different settings? ○ What are the risks for the public and the environment that when using the technology? ○ Are there any harms related to dosage or frequency of applying the technology? 	

What does SHTG need to see?	Your responses
A description of any safety considerations.	
What does this look like?	
<ul style="list-style-type: none"> • Managing the risks. <ul style="list-style-type: none"> ○ How can the safety risks for service users, professionals and the environment be reduced? ○ Are there any service user groups that are more likely to be harmed through the use of the technology? ○ Are there any safety risks to staff when using the technology compared with current practice? 	

What does SHTG need to see?	Your responses
A description of any safety considerations.	
What does this look like?	
<ul style="list-style-type: none"> • Screening and diagnosis technologies. <ul style="list-style-type: none"> ○ What is the impact of false positive, false negative and incidental findings, from the viewpoint of service user safety? 	

What does SHTG need to see?	Your responses
<p>A description of how intended service user groups were involved in the development of the technology.</p>	
<p>What does this look like?</p>	
<ul style="list-style-type: none"> • How were representatives from intended service user groups involved in the design, development or testing of the technology? 	

What does SHTG need to see?	Your responses
A description of inequalities.	
What does this look like?	
<ul style="list-style-type: none"> • How have health inequalities been considered in the design of the technology? • Are there any positive impacts of the technology on health inequalities? <ul style="list-style-type: none"> ○ Is there evidence that the technology challenges health inequalities in the UK health and social care system? ○ Is there evidence that the technology improves access to care among hard-to-reach populations? ○ Is there evidence that the technology promotes equality and eliminates unlawful discrimination? ○ Is there evidence that the technology fosters good relations between people with protected characteristics (as described in the Equalities Act 2010) and others? ○ Are there any efforts to reduce the negative impacts of the technology on health inequalities? 	

What does SHTG need to see?	Your responses
A description of the environmental sustainability considerations.	
What does this look like?	
<ul style="list-style-type: none"> • What are the expected environmental sustainability benefits and negative impacts from using the technology? • Is an analysis of the environmental outcomes available (for example, comparative CO2e estimates)? 	

What does SHTG need to see?	Your responses
A description of the credibility of the technology with UK health and care professionals, and service users or the public.	
What does this look like?	
<ul style="list-style-type: none"> • Is there evidence that relevant health or care professional(s) working in the UK health and social care system have been involved in designing, developing or testing the technology, or given their support to the deployment of the technology? • Is there evidence that the technology is viewed as useful by professional experts or expert groups? 	

Domain 3: Demonstrating the performance of the technology

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> • Demonstrating benefits. <ul style="list-style-type: none"> ○ Are there high quality, relevant studies available? ○ Were these studies done in a setting relevant to the Scottish health and social care system? ○ Did the studies show improvements in relevant outcomes? 	

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> • For technologies that treat a specific condition. <ul style="list-style-type: none"> ○ Are there interventional studies (experimental or quasi-experimental design) that support the claimed benefits of the technology? <ul style="list-style-type: none"> ▪ Did they show improvements in relevant outcomes? ▪ Is the comparator a care option that reflects the current NHSScotland care pathway? ▪ In a novel, innovative or transformative technology, the setting may not reflect the Scottish pathway, but it should still be able to demonstrate excellent performance and high value. 	

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> • For technologies that diagnose a specific condition. <ul style="list-style-type: none"> ○ Do they support the claimed benefits of the test? ○ This may include test accuracy studies, using an appropriate reference standard, or a concordance study to show agreement with current practice. 	

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> • When it is not possible, ethical or relevant to conduct an interventional study. <ul style="list-style-type: none"> ○ Are there observational studies? 	

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> • Understanding service users' and healthcare professionals' views of the technology. <ul style="list-style-type: none"> ○ Are there qualitative studies or surveys available? 	

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> • When it's important to know how technology works in the real world. <ul style="list-style-type: none"> ○ Real-world evidence may help to reduce uncertainty. <ul style="list-style-type: none"> ▪ For example, is the technology expected to have high costs or large system impacts, such as requiring significant service redesign? 	

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> Is any published evidence described of real-world benefits transferable to the Scottish population? 	

What does SHTG need to see?	Your responses
Evidence of clinical benefits.	
What does this look like?	
<ul style="list-style-type: none"> Is there evidence that the technology has been evaluated in the Scottish health and social care system? (see Real-world evaluation section). 	

What does SHTG need to see?	Your responses
Real-world evaluation.	
What does this look like?	
<ul style="list-style-type: none"> • Is there evidence that the technology has been evaluated in the Scottish health and social care system? <ul style="list-style-type: none"> ○ Was the technology acceptable to service users (including clinicians, service users and caregivers)? ○ Did the technology perform its intended purpose to the expected level? ○ Did the technology successfully integrated into current service provision or current best practice? ○ Did the technology cause any unintended negative impacts on service users or services? ○ Did the technology show improvements in outcomes (costs saved, efficiencies achieved and health and care improvements)? ○ Was the technology used in line with expectation (who, how, for how long)? 	

Domain 4: Capturing the cost and value for money of the technology

What does SHTG need to see?	Your responses
A budget impact analysis.	
What does this look like?	
<ul style="list-style-type: none">Is there agreement around the size of target population and estimates on the uptake of the technology?	

What does SHTG need to see?	Your responses
A budget impact analysis.	
What does this look like?	
<ul style="list-style-type: none"> • What are all direct costs of the technology and its implementation? <ul style="list-style-type: none"> ○ What is the cost of the technology, including cost of the technology (purchasing, updating and maintenance)? ○ What are the costs of staffing and training? ○ What are the costs of the supportive IT infrastructure needed to implement the technology? 	

What does SHTG need to see?	Your responses
<p>A budget impact analysis.</p>	
<p>What does this look like?</p>	
<ul style="list-style-type: none"> • What are all the direct costs associated with the comparator (current practice)? 	

What does SHTG need to see?	Your responses
<p>A budget impact analysis.</p>	
<p>What does this look like?</p>	
<ul style="list-style-type: none"> • What are the relevant indirect costs associated with the technology and the comparator, reference test or current practice? 	

What does SHTG need to see?	Your responses
<p>A budget impact analysis.</p>	
<p>What does this look like?</p>	
<ul style="list-style-type: none"> • Is there an exploration of the uncertainty of the estimate obtained from the budget impact analysis by varying the assumptions used, to investigate how these variations impact the analysis? 	

What does SHTG need to see?	Your responses
<p>An economic evaluation.</p>	
<p>What does this look like?</p>	
<ul style="list-style-type: none"> • A cost effectiveness analysis. For example: <ul style="list-style-type: none"> ○ a cost-utility analysis ○ a cost-consequence analysis, and ○ an exploration of the uncertainty of the obtained estimate by using sensitivity and scenario analyses. 	

Additional domain 1: Digital Technology Assessment Criteria (DTAC)

Additional information required for digital technologies.

What does SHTG need to see?	Your responses
<p>A completed NHS Digital Technology Assessment Criteria (DTAC).</p>	
<p>What does this look like?</p> <ul style="list-style-type: none"> • The NHS DTAC sets out specific standards for digital healthcare technologies. If you want your technology to be used in the NHS and social care, it should meet these standards. The DTAC focuses on five core areas: <ul style="list-style-type: none"> ○ clinical safety ○ data protection ○ technical assurance ○ interoperability, and ○ usability and accessibility. • Using the DTAC will give staff, service users and the public confidence that the digital technology they use meets national minimum standards across the core areas. • Completing the DTAC will help technology developers to prepare for assessment. The assessments may be conducted by SHTG, or by local health and care organisations. • This helpful YouTube video provides an overview of the DTAC. 	