



The Integrated Support and Assurance Process (ISAP): guidance on assuring novel and complex contracts

Part B: Key Lines of Enquiry

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Contents

1. Integrated Support and Assurance Process: key lines of enquiry for commissioners	4
2. Guidance for early engagement	6
2.1. Aim of the early engagement meeting	6
2.2. Timing.....	6
2.3. Potential sources of evidence	6
2.4. Output.....	6
3. Guidance for Checkpoint 1.....	8
3.1. Aims of Checkpoint 1	8
3.2. Timing.....	8
3.3. Potential sources of evidence	8
3.4. Summary areas of focus for commissioner	10
3.5. Areas of focus for commissioners	12
4. Guidance for Checkpoint 2.....	24
4.1. Aims of Checkpoint 2	24
4.2. Timing.....	24
4.3. Potential sources of evidence	25
4.4. Summary areas of focus for commissioners	26
4.5. Areas of focus for commissioners	28
5. Guidance for Checkpoint 3.....	40
5.1. Aims of Checkpoint 3	40
5.2. Timing.....	40
5.3. Potential sources of evidence	41
5.4. Summary areas of focus for commissioners	42
5.5. Areas of focus for commissioners	44

1. Integrated Support and Assurance Process: key lines of enquiry for commissioners

As set out in Part A of this guidance, the Integrated Support and Assurance Process (ISAP) considers key lines of enquiry (KLOEs). This is the collective term for the areas of focus for NHS England's and NHS Improvement's assurance regimes.

The KLOEs within this document apply to, and need to be answered by, the commissioner. Therefore, procurements must be conducted in a way that enables the commissioner to demonstrate it has assured itself against all the KLOEs. The relevant sub risks that each KLOE is intended to address are listed against each checkpoint stage later in this document.

A description of the KLOEs is included within Table 1.

Table 1: KLOEs

KLOE	Areas of focus for commissioners
Are there clear clinical transformational benefits?	Whether the care model can deliver the clinical transformational benefits envisaged for patients and populations. For example, during the procurement phase the focus will be on whether the documentation is consistent with the stated objectives, benefits and/or delivery model in the case for change.
Have legal risks been identified and mitigated?	Whether the procurement complies with procurement law and whether other legal risks have been considered. For example, during the mobilisation phase the process should confirm that contract variations that may be agreed after the contract is signed will not change the contract in a way that could lead to a breach of procurement laws.
Is the governance and management appropriate?	Whether the commissioner's governance and management are sufficient to deliver the procurement and complex contract successfully. For example, during the strategy phase the focus may be on whether the commissioner has adequately identified and rectified gaps in capacity and capability.
Are the contracted services financially sustainable?	Whether the complex contract is financially sustainable for the local health economy. For example, during the procurement phase the focus may be on whether the provider is financially robust and the assumed risk transfer is therefore realistic.

KLOE	Areas of focus for commissioners
<p>Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?</p>	<p>Whether the commissioner's and/or provider's structure, financial capacity, governance and capability to transform will be able to deliver the care model. For example, during procurement the focus may be on whether the commissioner has requested, or the provider has clearly articulated, the accountabilities, roles and responsibilities during the transition of services. Alternatively, during the mobilisation phase, the focus may be on whether the ongoing management of the contract is robust or able to enforce its intentions.</p>
<p>Is the procurement and contract documentation appropriate?</p>	<p>Whether the complex contract documentation adequately details the agreement between commissioner and provider. For example, is the contract clear on what must be delivered to patients, the commissioner and wider stakeholders? Is it clear that during the mobilisation phase contract variations would not be expected to weaken the levers available to enforce the contract? In respect of mandatory forms of contract (e.g. NHS Standard Contract, MCP/PACS variants), have all proposed derogations, where permitted at all, been agreed with the NHS England Contracts team?</p>
<p>In the event of provider failure, are contingency plans in place?</p>	<p>Whether contingency plans ensure the alternative provision of patients' services and maintain continuity of care in a way that is financially efficient for the taxpayer – and whether these plans are suitably reflected in the contractual terms.</p>

2. Guidance for early engagement

2.1. Aim of the early engagement meeting

The early engagement meeting is a discussion between NHS England and NHS Improvement national and regional representatives and a commissioner that is considering undertaking a procurement that involves a novel and complex contract structures (called 'complex contracts' in this guidance). The aims of this meeting are:

- To determine if the ISAP applies;
- For NHS England and NHS Improvement to understand from the commissioner what the proposed new contractual arrangements are and what the new service model will broadly look like;
- To understand the commissioner's procurement timetable;
- To agree a draft timetable for the ISAP checkpoints; and
- To confirm what sources of evidence and supporting documentation will be required from the commissioner.

2.2. Timing

The early engagement meeting takes place when a commissioner is developing a strategy that involves commissioning a complex contract. It should occur before an engagement Prior Information Notice (PIN) has been issued.

2.3. Potential sources of evidence

Only limited submissions are expected at the early engagement stage. A typical submission would include:

- A prospectus, business case, or similar document containing:
 - The strategic rationale explaining why this may be a good solution for the local health economy in the context of local Sustainability and Transformation Partnership (STP) plans;
 - A description of the care model's scope and scale;
 - The approximate contract value and length;
 - A description of engagement with public, patients, staff (clinical and non-clinical) and providers including the potential impact upon those providers (if known); and
 - An overview of any performance-based income intended to be applied.
- A draft 'engagement PIN' if one is to be issued; and
- An explanation of the intended procurement process, timeline and how the ISAP has been factored into its construction.

2.4. Output

After the early engagement meeting, a panel with members from NHS England and NHS Improvement will jointly decide on:

- Whether ISAP applies;
- Areas for initial feedback; and
- A timetable for Checkpoint 1.

A letter will be sent to the commissioner commenting on each of the KLOEs by exception and describing the next steps.

3. Guidance for Checkpoint 1

3.1. Aims of Checkpoint 1

Key considerations for Checkpoint 1 are:

- To establish whether the proposal represents a good strategic solution for the local economy; and
- To determine if the necessary preparatory work has been completed for the proposed procurement.

It will also be an opportunity to consider any relevant elements for Checkpoint 2, and to determine that the steps that have already been taken are robust. Checkpoint 2 must be completed successfully before any contract can be awarded.

3.2. Timing

Checkpoint 1 takes place just before a formal competitive procurement or other selection process begins.

3.3. Potential sources of evidence

Table 2: Checkpoint 1 sources of evidence

Checkpoint 1: sources of evidence
<p>The documentation forming the evidence will build on the early engagement meeting plus supporting evidence listed below. Most of these documents will already be held. Commissioners should speak to their regional teams if they have concerns about the items listed below.</p> <p>Commissioners should provide all documentation</p> <ul style="list-style-type: none">• Business case• System financial model and analysis• Submission describing gain/loss share and other outcomes based payments arrangements and metrics• Draft procurement strategy• Procurement risk register• Procurement plan / timetable• Evaluation methodology and criteria• Draft contract• Contract notice or PIN being used as a call for competition• Invitation to tender or other invitation to bid• Draft contingency plan in the event of provider failure• Governance strategy plan• Evidence of governing body (or a non-conflicted subset of it) considering key issues and clearing the approach taken

Checkpoint 1: sources of evidence

- Relevant board or other committee minutes
- Reassurance that the commissioner has engaged lawyers who have advised on all relevant matters (including those below), accompanied by a summary of key issues and risks flagged, and confirmation of whether the commissioner has followed the advice received; why, if not and how risks will be mitigated/managed.
 - Anticipated potential evolution of the contract after signature, and after mobilisation
 - Any changes to existing contracts held by the commissioner
 - Conflicts of interest
 - Competition and choice issues
 - Legal issues affecting possible provider forms
 - Tax questions
 - Duties around public engagement and consultation
 - Continued discharge of commissioner duties in the new model and any proposals to transfer commissioner activity to providers
 - Data sharing
 - Workforce/TUPE/pension implications
 - Estates
 - Remedies for poor performance
 - Termination (including any compensation)

3.4. Summary areas of focus for commissioner

Table 3 Checkpoint 1 summary

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	1	Sub-risk: fundamental change in policy.				
1	2	Sub-risk: lack of clarity and consensus on the transformation of delivery and the associated clinical benefits.				
1	3	Sub-risk: procurement documentation is inconsistent with the stated objectives, benefits and/ or delivery model in the case for change.				
1	4	Sub-risk: public consultation (if relevant) changes undermine clinical transformation benefits.				
1	5	Sub-risk: delivery of the stated objectives, benefits and/or delivery model is compromised by considerations elsewhere in the procurement (e.g. affordability, potential bidder negotiating stance).				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Have legal risks been identified and mitigated?						
2	1	Sub-risk: failure to identify and comply with all applicable laws and regulations.				
2	2	Sub-risk: procurement documents and approach breach procurement law.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
3	1	Sub-risk: failure to achieve fully informed governing body/ board approval.				
3	2	Sub-risk: insufficient capacity and capability to deliver the procurement.				
3	3	Sub-risk: failure to plan for capacity and capability required for the mobilisation and service delivery phases.				
3	4	Sub-risk: failure to identify and plan for engaging all stakeholders.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
4	1	Sub-risk: fundamental assumptions about cost, finance and savings are flawed or inconsistent.				

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate entity structure, financial capacity, governance and capability to transform and deliver?						
5	1	Sub-risk: failure to appreciate the potential risks of the novel nature of new structures that could be created and the implications of these for service delivery.				
5	2	Sub-risk: failure to be clear on the risk sharing and its implications.				
5	3	Sub-risk: failure to appreciate the underlying financial health of the existing organisations in the local health economy.				
5	4	Sub-risk: strategy does not address existing and future capacity and capability gaps within the local health economy, or funding needed for them.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the procurement and contract documentation appropriate?						
6	1	Sub-risk: failure to consider the competitive landscape and plan for market engagement.				
6	2	Sub-risk: procurement documentation is inadequate.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
In the event of provider failure, are contingency plans in place?						
7	1	Sub-risk: failure to consider contingency plans for commissioner requested services (CRS) and non-commissioner requested services (non-CRS), if the potential provider(s) fail.				

3.5. Areas of focus for commissioners

Table 4: Checkpoint 1 Q1 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	1	Sub-risk: fundamental change in policy.				
Examples of what good looks like						
<ul style="list-style-type: none"> Commissioners understand the risks/implications of future policy changes and growth in services, and have considered, consulted on and risk-assessed them. 						
1	2	Sub-risk: lack of clarity and consensus on the transformation of delivery and the associated clinical benefits.				
Examples of what good looks like						
<ul style="list-style-type: none"> Expected clinical and financial benefits have been clearly articulated supported by quantified outcome metrics and feasible statements describing how they will be delivered. There is a robust and comprehensive plan for delivering the transformation, including integration and realisation of other benefits. The commissioner has considered the impact of the complex contract on patient choice and competition and there is a plan to mitigate potential risks. It is clear which services are intended to be in scope of the proposed contract and all of the potential parties to the delivery of the transformed service have been identified. A comprehensive list of stakeholders has been identified, for initial dialogue, which includes existing NHS service providers, and local authorities, and independent health and social care providers (where relevant). Potential subcontracting arrangements have been considered. There is a process to consider foreseeable changes to subcontracting. The scope and model of care matches the care model framework. All relevant stakeholders have been identified and engaged about the proposed transformation's clinical benefits. Key stakeholders accept that the clinical benefits are feasible. An independent panel of clinicians has reviewed the intended clinical benefits. The panel represents primary and secondary care and the relevant specialty (such as geriatrics, mental health, general medicine etc.). The panel has constructively challenged the feasibility of the claimed benefits. 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	3	Sub-risk: procurement documentation is inconsistent with the stated objectives, benefits and/ or delivery model in the case for change.				
Examples of what good looks like						
<ul style="list-style-type: none"> • All commissioner board / governing bodies have contributed and provided guidance throughout and have reasonably considered the right level for their review, given the level of change and risk envisaged for their entity. They have requested appropriate evidence from the project and identified skilled members to review the evidence and report. The review has been carried out and exceptions followed up and determined. An amended set of procurement and draft contract documents has been prepared and confirmed, through discussion and formally recorded, as acceptable by each governing body/board. • Clinicians are fully represented through the development phase in drawing up the specification, performance requirements, bidder instructions and evaluation method for the quality submissions. There is senior sign-off of all documents before they are issued to bidders. • The evaluation method has been clearly identified and articulates who this will be undertaken by. • The evaluation method clearly identifies how conflicts of interest will be identified, prevented and remedied. 						
1	4	Sub-risk: public consultation (if relevant) changes undermine clinical transformation benefits.				
Examples of what good looks like						
<ul style="list-style-type: none"> • There is a process for clinical review of updates to the strategy following consultation. These are cross checked with the financial review to establish that the clinical benefits remain within the financial envelope after consultation. 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	5	Sub-risk: delivery of the stated objectives, benefits and/or delivery model is compromised by considerations elsewhere in the procurement (e.g. affordability, potential bidder negotiating stance).				
Examples of what good looks like						
<ul style="list-style-type: none"> • Negotiation strategy and process for finalising the contract are documented with clear mandates, responsibilities, red lines and a regular internal agreement process. Commissioner levers are identified and used when necessary. Issues that affect the stated objectives and/or delivery model are flagged and brought to the internal agreement process for instruction on negotiating stance and any trade-off. Contract drafting is the commissioner's responsibility and this is controlled with material changes discussed and agreed in the internal agreement process. Any derogations from mandatory terms have been discussed and agreed with the NHS England contracts team. 						

Table 5: Checkpoint 1 Q2 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Have legal risks been identified and mitigated?						
2	1	Sub-risk: failure to identify and comply with all applicable laws and regulations.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Appropriately qualified and experienced legal advisers have been engaged. • Legal advisers have identified all the legislation and regulation that apply to the proposed procurement. • Relevant regulators have been involved in an open dialogue about the proposals and the implications for interaction as the contract is delivered. • The commissioner has a full picture of its current contractual landscape including potential future subcontractors under the new contract. Contractual clauses that may affect the new contract’s feasibility have been identified and the risk they pose (likelihood and impact) quantified. Actions to manage and mitigate these risks have been documented. • The commissioner is confident that sufficient legal assurance has been obtained on the legality of the potential options being considered for creating the new delivery structure. 						
2	2	Sub-risk: procurement documents and approach breach procurement law.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Legal advisers have been contracted to provide advice on the compliance of the procurement documentation and process with law and regulation throughout the development and procurement phase. • The commissioner has formal written advice stating that the procurement documents and process are legally compliant. 						

Table 6: Checkpoint 1 Q3 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
3	1	Sub-risk: failure to achieve fully informed governing body/ board approval.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The governing body/ board has considered the detailed case for change including clinical and financial benefits, any legal issues and risks, and has been sufficiently briefed on procurement compliance processes and compliance. It has made a fully informed decision to approve the case for change. • The governance arrangements supporting the governing body/ board decision-making have been designed to promote transparency and accountability. 						
3	2	Sub-risk: insufficient capacity and capability to deliver the procurement.				
Examples of what good looks like						
<ul style="list-style-type: none"> • A programme board has been established to oversee the procurement phase with clear terms of reference and membership that has the relevant representation, skills, experience and seniority to make decisions during the procurement phase. • A project team has been established to manage activities in the procurement phase and it has the right skills and experience required to manage a complex procurement. The project team is empowered to make decisions (within agreed delegation limits) and has sufficient capacity to manage all procurement activities efficiently and effectively. • All mandated practice or policy is followed and any exception to this agreed in advance. • A clear and complete project plan describes the key activities in advance of and during the procurement phase. Where a competitive procurement is envisaged, the plan is built around compliance with procurement regulations and best practice at key points such as prior information notice, contract notice, invitation to tender development and issue, tender evaluation and award. The necessary preparations and documents for procurement have been completed, including evaluation criteria and method. Where a single bidder is envisaged, the commissioner is satisfied that this is a lawful approach, and the plan has been changed to reflect a revised procurement process. The plan has a realistic timeframe and highlights interdependencies. The plan identifies, and has secured, the resources needed for it to be implemented effectively and there is a responsible, accountable, consulted and informed (RACI) matrix for these. • The procurement plan includes governance at project level and with the wider commissioner governing body/board. This plan sets out the proposed remit of the procurement governance and delivery teams, when 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
		<p>the various governance activities will be required at each level and the decisions that will need to be made and/or milestones approved. The governance bodies have signed up to the plan and have identified the information they will require and the expertise to engage with it.</p> <ul style="list-style-type: none"> • A process for identifying and remedying conflicts of interests has been considered. • The commissioner understands the capacity and capability it needs to manage the procurement phase and has a fully funded plan to appoint the external support / advisors when required. 				
3	3	Sub-risk: failure to plan for capacity and capability required for the mobilisation and service delivery phases.				
Examples of what good looks like						
		<ul style="list-style-type: none"> • The commissioner has identified its resourcing needs throughout the project and has a clear plan and funding to address any gaps in capacity and capabilities, through mobilisation and commencement of service delivery phases. • The commissioner has considered how it will monitor performance and manage the complex contract. • The draft contract describes remedial action to be taken if standards fall and the trigger point for intervention. 				
3	4	Sub-risk: failure to identify and plan for engaging all stakeholders.				
Examples of what good looks like						
		<ul style="list-style-type: none"> • The commissioner has identified and mapped all stakeholders, carried out an impact assessment, considered reasonable mitigations and has developed an engagement strategy and plan. The plan will describe how and when key stakeholders will be engaged throughout the transformational change. This will include identifying which stakeholders will play a role in the governance structures established to oversee the transformational change project through its various phases. • Public consultation has been confirmed and health overview and scrutiny committee sign-off has been secured. 				

Table 7: Checkpoint 1 Q4 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
4	1	Sub-risk: fundamental assumptions about cost, finance and savings are flawed or inconsistent.				
Examples of what good looks like						
<ul style="list-style-type: none"> • There is an overarching, rational statement of how and why the new contract and delivery model will be financially sustainable. The statement covers the rationale for the new payment approach, the service costs, anticipated savings and commissioner and other third party (e.g. local authority) budget available. The new delivery model's impact on any services that are out of scope of the new contract has been quantified. • Where commissioners intend to use an outcomes-based or payment for performance approach, this has been stated and quantified. • Accurate baseline cost data has been identified for all providers of services within the new care model's scope and signed off by them. • A financial model of the costs and expected benefits from the new care model of care compared to the do-nothing option has been developed. The assumptions underlying the model have been clearly documented and have been checked and challenged by a suitably knowledgeable expert for reasonableness and consistency with the rest of the case for change. Sensitivity analysis has been used to test the impact of varying key assumptions. • A reasonable assessment of the transformation costs has been made. These are based on reasonable assumptions about the likely period over which the transformation will be delivered. The funding source(s) have been identified for these transformation costs. • The commissioner has identified all of its current contracts with providers (and potential subcontractors) that will be within the new care model's scope. The value of these contracts has been reconciled with commissioner budgets and with the providers' statement of costs. • The annual contract value has been appropriately adjusted for anticipated changes in costs of delivering the contract over its duration. • The commissioner has identified services that are part of the new care model but currently funded by another body. It has established their funding source and agreed with the current funders that they will continue funding the services once they transfer to the new contract. The commissioner has agreed lawful and appropriate governance and funding arrangements for those services with the other funding body (for example through a partnership arrangement under section 75 of the NHS Act 2006 and the Partnership Regulations). • Out of scope services and stranded costs have been identified and valued. The health economy is working together to determine how these stranded costs will be managed. • The plans' impact on commissioners and other providers' potential viability 						

Checkpoint 1		Checkpoint 2		Checkpoint 3		
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
<p>has been assessed, and there is a plan to manage this.</p> <ul style="list-style-type: none"> • The commissioner has identified all out of scope services and their prices. It has ensured that sufficient budget has been set aside to continue to fund these services as well as the new care model. • The financial envelope for the new contract has been formally approved by the commissioner chief finance officer (CFO) and signed off by the commissioner governing body/ board. 						

Table 8: Checkpoint 1 Q5 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	1	Sub-risk: failure to appreciate the potential risks of the novel nature of new structures that could be created and the implications of these for service delivery				
Examples of what good looks like						
<ul style="list-style-type: none"> • Through soft market testing, the commissioner has identified potential viable structures that would meet the strategic need. • Sources of finance for the proposed new entity have been considered through market testing. 						
5	2	Sub-risk: failure to be clear on the risk sharing and its implications.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The commissioner has described how the new payment approach allocates financial risk between commissioners and providers and made an initial assessment of whether and how a risk sharing mechanism could help to manage risks that are appropriate for sharing across the system. • Where risk sharing is intended to be used, the commissioner has carried out initial analysis to identify: <ul style="list-style-type: none"> ○ the activities to be included in the arrangement; ○ the organisations to be included and their potential ability and appetite to influence and bear risk; ○ any risks created by the scheme and how they will be mitigated; and ○ that the incentives created by the arrangement will not conflict with those created by other elements of the funding system. • The commissioner has undertaken a system-wide engagement for risk sharing where it is intended to be used. 						
5	3	Sub-risk: failure to appreciate the underlying financial health of the existing organisations in the local health economy.				
Examples of what good looks like						
<ul style="list-style-type: none"> • There is an appreciation of the financial health of all current providers in the local health economy. Where any (or all) of the parties are currently in financial deficit, the case for change describes how (and by how much) the proposed transformational change will help reduce or eliminate existing system deficits. • An approach to testing the financial viability of the potential provider entity has been developed. This includes sensitivity analysis to vary assumptions about the financial health of one or more of the parties involved in order to measure the likely impact on the new provider entity's viability. 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	4	Sub-risk: strategy does not address existing and future capacity and capability gaps within local health economy or funding needed for them.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Detailed analysis has been undertaken to understand the capacity and capabilities required to deliver the new contract. This has been mapped against the current local health economy capacity and capabilities to identify gaps. • There is a plan and funding to address known gaps in capacity and capability within the local health economy, including identifying the specialist skills (such as organisational development, HR, etc.) that will be needed to carry out restructuring, establish the new organisation and deliver the transformational change over time. • The budget to implement the restructuring and transformation has been factored into the financial model or, if not, a separate source of transformation funding has been identified. 						

Table 9: Checkpoint 1 Q6 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the procurement and contract documentation appropriate?						
6	1	Sub-risk: failure to consider the competitive landscape and plan for market engagement.				
Examples of what good looks like						
<ul style="list-style-type: none"> Research into the entities that may wish to compete as providers has been done. This intelligence has been used to inform a plan for the procurement phase with sufficient resource, documentation and time allowed for a compliant competitive procurement. 						
6	2	Sub-risk: Procurement documentation is inadequate.				
Examples of what good looks like						
<ul style="list-style-type: none"> The bidder submission requirements and evaluation method have been challenged and agreed as appropriate for identifying the bid that best meets the new contract's objectives, while mitigating its risks. The project has considered what could be required to deliver the objectives and what the critical risks to achieving them could be. This has led to specific questions to test the bidder's approach (e.g. "How will you ensure that patient information is available to all providers on an individual's care path given the number of different IT systems currently in place and data protection constraints?" Or "Explain how you have assessed, and allowed for, the risk of delay in your programme".) 						

Table 10: Checkpoint 1 Q7 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
In the event of provider failure, are contingency plans in place?						
7	1	Sub-risk: failure to have considered contingency plans for commissioner requested services (CRS) and non-commissioner requested services (non-CRS), if the potential provider(s) fail.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The draft contract includes sufficient mechanisms and metrics through which to monitor and measure performance and ensure there is early visibility of potential failures. The commissioner has considered whether the contracted services should be designated as CRS (and therefore subject to additional financial oversight by NHS Improvement) or 'essential services' and has provided a clear rationale for the choice. • A contingency plan (for CRS and non-CRS) in the event of provider failure has been considered to ensure the continuity of services is maintained. • Appropriate service delivery arrangements (e.g. an asset register, exit plan/handover pack and communication plan) and financial arrangements have been considered in the event of provider failure for CRS. • Suitable arrangements have also been developed for non-CRS in the event of provider failure. 						

4. Guidance for Checkpoint 2

4.1. Aims of Checkpoint 2

Key considerations for Checkpoint 2 are:

- To establish whether the final contract terms have been agreed and whether these meet the strategic objectives as described at Checkpoint 1;
- To determine whether the commissioner followed the established procurement process; and
- To ensure that the commissioner and preferred provider have the capacity and capability to deliver the complex contract.

Checkpoint 2 provides an opportunity to build on the questions asked at Checkpoint 1 to ensure that the plans and processes set out have been followed.

4.2. Timing

Checkpoint 2 takes place when a preferred bidder has been identified, but before a contract is signed. NHS Improvement will ask the preferred bidder (if it is an NHS trust or foundation trust¹) questions as outlined in Part C of this guidance. Part C of the guidance explains how NHS Improvement's transaction review process applies in the context of the ISAP. NHS Improvement does not have a transaction review process in relation to independent providers and hence only NHS preferred bidders are subject to a transaction review at Checkpoint 2.

¹ This includes subsidiaries and joint ventures wholly or partly owned by a trust.

4.3. Potential sources of evidence

Table 11: Checkpoint 2 sources of evidence

Checkpoint 2: sources of evidence

The documentation forming the evidence, will build on Checkpoint 1 plus supporting evidence listed below. Most of these documents will already be held. Commissioners should speak to their regional teams if they have concerns about the items listed below.

All documentation should be provided by the commissioners

- Selection questionnaire (if applicable)
- Contract notice
- Invitation to tender
- Final contract document set
- Evaluation method and report of evaluation outcome and recommendation for contract award
- Updated procurement risk register
- Updated procurement plan/timetable
- Updated contingency plan
- Summary of key external expert advice with significant issues flagged
- System financial model and analysis
- Governance strategy plan
- Documented changes since the case for change, showing that these have been managed, and an assessment of their impact on procurement and draft contract documents
- Summary of key legal advice on compliance with procurement law with significant issues flagged

4.4. Summary areas of focus for commissioners

Table 12 Checkpoint 2 summary

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	1	Sub-risk: procurement documentation is inconsistent with the stated objectives, benefits and/or delivery model in the case for change.				
1	2	Sub-risk: all governing bodies not fully engaged with procurement process and not aware of issues with procurement or draft contract documents.				
1	3	Sub-risk: contract documentation is inconsistent with the stated clinical objectives and benefits in the case for change.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Have legal risks been identified and mitigated?						
2	1	Sub-risk: breach of public procurement law.				
2	2	Sub-risk: changes to service or provider entity structure made after receiving legal advice do not comply with law or regulation.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
3	1	Sub-risk: insufficient capacity and capability to deliver the procurement plan.				
3	2	Sub-risk: failure to plan for capacity and capability to deliver the mobilisation and transformation.				
3	3	Sub-risk: insufficient capacity and capability to implement the contract in the service delivery phase.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
4	1	Sub-risk: there is not a shared understanding of the risks and their allocation.				
4	2	Sub-risk: financial forecasts are incomplete or inaccurate.				
4	3	Sub-risk: affordability is compromised by other considerations in procurement (e.g. clinical benefits cost more than the amounts in the pricing).				
4	4	Sub-risk: the preferred provider is not financially robust and assumed risk transfer is therefore unrealistic.				
4	5	Sub-risk: unexpected additional cost in bidders' submissions and/or reduction of savings commitment increases price during negotiations.				
4	6	Sub-risk: parties are not fully signed up to the financial envelope and its implications.				

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	1	Sub-risk: failure to appreciate the potential risk of the new entity's novel structure and its implications for service delivery.				
5	2	Sub-risk: failure to discuss and seek all parties' draft agreement to the proposed structure (or options) and its key terms.				
5	3	Sub-risk: failure to consider the proposed new entity's sources of finance.				
5	4	Sub-risk: the preferred provider's corporate structure is not clear or agreed.				
5	5	Sub-risk: the preferred provider's governance is not clear, agreed or appropriate.				
5	6	Sub-risk: the financial implications of the provider structure are not fully considered.				
5	7	Sub-risk: the provider's financial or regulatory deterioration during the procurement is not provided for.				
5	8	Sub-risk: failure to provide for ownership and leadership of the transformation plan with clear accountabilities for roles and responsibilities beneath that.				
5	9	Sub-risk: failure to plan the transformation activities and programme.				
5	10	Sub-risk: failure to plan for capacity and capability to deliver the mobilisation and transformation.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the procurement and contract documentation appropriate?						
6	1	Sub-risk: procurement documentation is inadequate.				
6	2	Sub-risk: the draft contract is inadequate.				
6	3	Sub-risk: agreement between the provider entity members is not adequately documented.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
In the event of provider failure, are contingency plans in place?						
7	1	Sub-risk: failure to have considered continuity of service in the event of provider failure.				
7	2	Sub-risk: failure to consider how services will be designated.				
7	3	Sub-risk: failure to make provision for providers to put in place appropriate financial and non-financial arrangements.				

4.5. Areas of focus for commissioners

Table 13: Checkpoint 2 Q1 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	1	Sub-risk: procurement documentation is inconsistent with the stated objectives, benefits and/or delivery model in the case for change.				
Examples of what good looks like						
<ul style="list-style-type: none"> Contract terms are clear and understood by all parties. All outstanding issues have been resolved. Any changes to demand, service requirements and/or objectives since the case for change have been documented and incorporated in draft contract documents. The process for evaluating quality and financial information, and the interdependencies between quality and finance, has been carried out. Where relevant, clarification questions have been asked of bidders. 						
1	2	Sub-risk: all governing bodies not fully engaged with procurement process and not aware of any issues with procurement or draft contract documents.				
Examples of what good looks like						
<ul style="list-style-type: none"> All commissioner governing bodies have contributed and provided guidance throughout and have reasonably considered the right level for their review, given the level of change and risk envisaged in their entity. They have requested appropriate evidence from the project and identified skilled members to review the evidence and report. Where more than one party to the contract requires the same review, and sharing is used to avoid duplication, cross-cutting duties of care have been agreed. The procurement and draft contract documentation have been reviewed, any exceptions identified at Checkpoint 1 have been followed up and determined. A final amended set of contract documents has been presented and confirmed, through discussion and formally minuted or written approval, as acceptable. 						
1	3	Sub-risk: contract documentation is inconsistent with the stated clinical objectives and benefits in the case for change.				
Examples of what good looks like						
<ul style="list-style-type: none"> Clinicians are fully represented through the evaluation and negotiation phase, with senior clinicians signing off the clinical quality evaluation and any changes to the specification or provider methods and inputs during negotiations. Senior clinicians sign off the clinical aspects of the final draft contract. 						

Table 14: Checkpoint 2 Q2 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Have legal risks been identified and mitigated?						
2	1 Sub-risk: breach of public procurement law.					
	Examples of what good looks like					
	<ul style="list-style-type: none"> • Legal advisers have provided input and advice on the compliance of the procurement and negotiation process with law and regulation throughout the procurement phase. • Any circumstances that could trigger changes to previously agreed budget values are specified in documentation. There is confirmation that the scale of the change is allowable under the Public Contract Regulations and within the terms of which the contract was initially advertised. 					
2	2 Sub-risk: changes to service or provider entity structure made after receiving legal advice do not comply with law or regulation.					
	Examples of what good looks like					
	<ul style="list-style-type: none"> • Legal advisers have reviewed any changes made to the service specification and confirmed they still comply. 					

Table 15: Checkpoint 2 Q3 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
3	1	Sub-risk: insufficient capacity and capability to deliver the procurement plan.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Compliance with governance plan developed before Checkpoint 1, reviewed and confirmed. • The procurement team has been fully resourced throughout. The resources cover all the core skills required including clinical requirements, entity transformation, commercial, financial, stakeholder and programme management. Specialist input, e.g. legal, estates, workforce etc. is briefed and available as needed. • All new and evolving practice or policy has been followed and any exception to this agreed in advance. • Any slippage has been analysed and is understood. If the schedule float has been used there are measures to recover lost time. The team and schedule have been revisited to ensure that slippage does not recur and that the remaining float is sufficient to absorb any further risks. • External advisers engaged for advice and support that the commissioner cannot otherwise access from within the commissioner or NHS England. 						
3	2	Sub-risk: failure to plan for capacity and capability to deliver the mobilisation and transformation.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The commissioner is clear on its management role in delivering the mobilisation, managing its risk and meeting its contractual obligations while adhering to the preferred provider's programme and approach. • The commissioner can demonstrate how its statutory duties will be discharged in future. • The commissioner has resourced a clear plan of its activities, integrated with the preferred provider's, so that each meets its contract and statutory obligations, through the mobilisation phase. 						
3	3	Sub-risk: insufficient capacity and capability to implement the contract in the service delivery phase.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Experienced contract managers who could manage the new contract in the future have developed the performance, monitoring, management and reporting requirements • The commissioner's contract management requirement for the new contract has been developed with input from the expertise engaged during the procurement. There are appropriate arrangements and plans in place for the commissioner to manage the contract. 						

Table 16: Checkpoint 2 Q4 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
4	1	Sub-risk: there is not a shared understanding of the risks and their allocation.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The risk register is well categorised, non-duplicative and recognises related risks. Mitigations and contractual allocations have been worked up, but residual risk is still included. • The impact on the contract of the potential viability of commissioners and other providers has been identified and appropriate mitigations made. • The incentives created by the gain/loss sharing agreement have been assessed and mitigations identified where required. • The design of the gain/loss sharing scheme reflects organisations' abilities and appetites to share the agreed risks and this has been tested appropriately 						
4	2	Sub-risk: financial forecasts are incomplete or inaccurate.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The inputs and assumptions of the system financial model are reliable, up to date and reflect the latest assumptions about the transformation of the service as negotiated with the providers, with an appropriate range of scenarios, testing particular outcome based payment scheme with variance in contract income. It remains clear from the financial model that there is a net benefit to the system • Experienced team members have prepared the model, and there is a record of the independent challenge and review it has undergone. • The sources of cost savings have been identified and are tied to the transformation process, its outcomes and the new care model. The forecast savings have been subjected to challenge/diligence by relevant experts/ cost owners/external advisers and agreed as reasonable. • Funds are in place for the transformation plan, including any investment needed, and for the people and additional capacity needed to effect it. Providers of funding have signed off the amounts involved, which have been included in the financial model. • Funds are confirmed as available in budgets from commissioners and other service users, and these cover the forecast costs as shown in the financial model. The commissioner has documented lawful governance and funding arrangements with other commissioners where necessary (for example through a partnership arrangement under section 75 of the NHS Act 2006 and the NHS bodies and Local Authorities Partnership Arrangements Regulations 2000 as amended). 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
						<ul style="list-style-type: none"> The health economy has worked together to understand stranded costs and determine how these will be managed. The impact of plans on the viability of commissioners and other providers, including those providing out of scope services, has been assessed and there is an agreed plan to manage this impact.
4	3	Sub-risk: affordability is compromised by other considerations in procurement (e.g. clinical benefits offered cost more than the amounts in the pricing).				
Examples of what good looks like						
						<ul style="list-style-type: none"> The evaluation process for cross-checking quality proposals against the build-up of inputs and costs has been effectively carried out with any conflicting aspects clarified with bidders as they arise. Any bids where consistency is not achieved have not been taken forward, in line with the evaluation criteria.
4	4	Sub-risk: the preferred provider is not financially robust and assumed risk transfer is therefore unrealistic.				
Examples of what good looks like						
						<ul style="list-style-type: none"> The preferred provider's income and expenditure model, funding structure and back-up funding (from a range of sources) have been confirmed by the commissioner as reasonable and affordable. People with financial expertise have tested the preferred provider's available funding using the modelled value of risk, and found it adequate for the risk allocated to it. The funding adequacy has also been stress-tested for extreme-risk scenarios and the commissioner is aware of the impact of these. The same expertise has reviewed the provider's commitment to the back-up funding and the provisions for its maintenance, and found them acceptable.
4	5	Sub-risk: unexpected additional cost in bidders' submissions and/or reduction of savings commitment increases price during negotiations.				
Examples of what good looks like						
						<ul style="list-style-type: none"> Unforeseen costs do not arise or have been challenged, addressed, mitigated or avoided, e.g. through a change in structure, or special provisions negotiated with say, Department of Health, HM Revenue and Customs etc. – or by requiring the provider to bear them because it would normally be exposed to them.

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
4	6	Sub-risk: parties are not fully signed up to the financial envelope and its implications.				
Examples of what good looks like						
<ul style="list-style-type: none"> Commissioner and preferred provider CFOs have reviewed the financial envelope in the updated, financially assured and agreed version of the financial model. Queries and comments have been addressed, resolved and signed off. Contract terms are clear and understood by all parties. All outstanding issues have been resolved. 						

Table 17: Checkpoint 2 Q5 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	1	Sub-risk: failure to appreciate the potential risk of the new entity's novel structure that could be created and its implications for service delivery.				
Examples of what good looks like						
<ul style="list-style-type: none"> Providers have indicated their preferred structure, the type of organisation they propose and how the new entity is aligned to the objectives in the case for change. Commissioners are satisfied that this statement was reached by assessing alternative options for their likely legal, financial and service delivery implications as well as the extent to which they would meet the overarching objectives, care model and financial rationale outlined in the case for change. There is a clear statement of how the options address the NHS Five Year Forward View and applicable frameworks and how they are aligned to relevant STP plans. There is a clear statement of why the model is the preferred option. 						
5	2	Sub-risk: failure to discuss and seek all parties' draft agreement to the proposed structure (or options) and its key terms.				
Examples of what good looks like						
<ul style="list-style-type: none"> Draft memoranda of understanding or heads of terms have been prepared and shared with commissioners. These describe the key terms on which the organisations will work together to create the new structure, including governance arrangements, decision-making and dispute resolution processes. 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	3	Sub-risk: failure to consider the proposed new entity's sources of finance.				
Examples of what good looks like						
Commissioners are satisfied that: <ul style="list-style-type: none"> • The proposed new entity's sources of finance have been considered and agreement sought from potential funders. • Where financing from the private sector is involved, legal and financial advice has been obtained to confirm that the terms and assumptions of the financing are reasonable. 						
5	4	Sub-risk: the preferred provider's structure is not clear or agreed.				
Examples of what good looks like						
<ul style="list-style-type: none"> • A joint briefing has been given to each of the preferred provider's boards describing the preferred provider entity's corporate structure and the rationale for it from commercial, financial, legal, risk and operational perspectives, for the providers collectively and individually. Each individual provider's relationship with the preferred provider entity is clearly described and the provider's team has assessed it as reasonable in the light of the activities and risk the provider is responsible for. 						
5	5	Sub-risk: the preferred provider's governance is not clear, agreed or appropriate.				
Examples of what good looks like						
Commissioners are satisfied that: <ul style="list-style-type: none"> • Governance, reporting and decision-making processes have been drawn up and there is evidence that they have been designed in the light of the roles and risks involved in the new entity, the transformation and the new delivery model. All the provider members have agreed the arrangements, which include a dispute resolution procedure. • There has been appropriate scrutiny and challenge by the preferred provider's board. • The preferred provider's plan demonstrates clear arrangements for the quality of care to be delivered, including who is accountable for its delivery. • There is a draft of the planned legal arrangements between the bidding partners and any subcontractors which covers the key legal terms needed (e.g. liability, funding, who bears costs, employment etc.) and agreement in principle has been obtained. 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	6	Sub-risk: the financial implications of the provider structure are not fully considered.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The commissioners have received advice on the financial implications and risks of the preferred provider's structure. This advice demonstrates the proposed structure is viable. • Where relevant, both procurement and draft contract have terms that provide for a parent company guarantee, for its minimum amount and duration, for credit/covenant checks on the provider with a minimum threshold included, and for credit maintenance. These provisions reflect the envisaged multiparty ownership of the provider entity. • Any structure changes have been incorporated and reviewed in the light of the original structure rationale and from commercial, financial, legal, risk and operational perspectives for the providers collectively and individually. 						
5	7	Sub-risk: the provider's financial or regulatory deterioration during the procurement is not provided for.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The original financial strength tests are monitored throughout the procurement so that measures can be taken to provide additional back up funding if needed. 						
5	8	Sub-risk: failure to provide for ownership and leadership of the transformation plan with clear accountabilities for roles and responsibilities beneath that.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The composition, skills profile and remit of the leadership team are identified, and formal appointments are either made or in the final stages of being made. At least some of the team have been leading on bidding and negotiations, and work well with the commissioner. 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	9	Sub-risk: failure to plan the transformation activities and programme.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The preferred provider’s approach and overarching programme are clear on the beginning, interim and end states at a high level. There is demonstrated understanding of the high level activities required to transition. Other options have been considered with the chosen approach being preferred. • The plan has been developed to a reasonable level of detail and its assumptions are tested and supportable. It meets the contract milestones and incorporates the risks. It has been used to generate the resourcing requirement in terms of capabilities and capacity. • There are appropriate plans and contingencies to ensure clinical service continuity through any transition. 						
5	10	Sub-risk: failure to plan for capacity and capability to deliver the mobilisation and transformation.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The provider has demonstrated that it has used its transformation plan and programme of activities to identify the capacity and capability it will need to deliver and to manage the risks allocated to it. This has been compared to existing resources and gaps are filled or will be filled when required. • The budget required to implement the restructuring and transformation has been factored into the financial model or, if not, a separate source of transformation funding has been identified. 						

Table 18: Checkpoint 2 Q6 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the procurement and contract documentation appropriate?						
6	1	Sub-risk: procurement documentation is inadequate.				
Examples of what good looks like						
<ul style="list-style-type: none"> • A review process of the invitation to tender commercial proposition, the evaluation method and draft contract has been undertaken. Where standard form documents exist, these have been confirmed as appropriate for this particular project and followed with permissible derogations only. The overall consistency and coherence have been reviewed, the bid submission requirements and evaluation cross-checked and external advice sought on at least the legal aspects and the financial data, submission requirements and bidder pricing. 						
6	2	Sub-risk: inadequate draft contract.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The contract is clear on what must be delivered to both patients and service users and to the commissioner and wider stakeholders in their management and oversight role. Any constraints and standards that apply to delivery methods are definitive. There are provisions for volumes and changes in these. • Where standard form documents exist, they have been confirmed as appropriate for this particular project and followed with permissible derogations only. • The deliverables and performance standards are all objective and measurable by the commissioner. The payment mechanism and contract terms are aligned to them. • The nature and impact of performance failure has been considered. Appropriate remedial actions, proportionate sanctions and payment deductions are attached to specific key performance indicators. These escalate if performance continues to fall short, with the interventions, sanctions and incentives remaining realistic, proportionate and practical to effect. Termination is provided for both in terms of financial and practical effect. Consequences of termination have been considered and provided for. • The drafting and definition of pricing is clear. The contract makes it clear what is included, and what is excluded and will be billed separately. Where payments are on a per-unit basis, it is clear what constitutes a unit and how volume bands are calculated. Escalation and re-pricing arrangements are clear. • There is a clear and workable payment mechanism which covers the process from assessing the performance and volumes delivered, linking to the price and performance schedule and through to issuing of invoices. • A dispute resolution procedure provides for arbitration/determination, resolution, cost apportionment, any rights of appeal and ultimately 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the procurement and contract documentation appropriate?						
						<p>termination for failure to agree.</p> <ul style="list-style-type: none"> • Legal/commercial advisers have provided a complete analysis of the mechanisms by which price can vary under the contract from the amounts shown in the full business case model. The analysis describes the controls and protections around these potential variations. • Legal/commercial advisers' analysis has confirmed no major inconsistency with the invitation to tender. • Final review of the entirety of the contract as drafted. • All provider financial support is duly executed. The risk and impact of this falling short have been assessed and provided for or agreed as acceptable/manageable. • The preferred bidder has appropriate assurances with their proposed subcontractors. • The cap has been confirmed as still allowing the provider to absorb a reasonable range of risk, and as not undermining the stated risk allocation in the invitation to tender. The residual risk borne by the commissioner as a result of the cap has been assessed and, if material, included in the financial model and risk register. • Compensation on termination follows market practice. The principles in the contract are clear and a calculation formula is included. The provisions have been checked for any perverse incentive for either party.
6	3	Sub-risk: agreement between the provider entity members is not adequately documented.				
Examples of what good looks like						
						<ul style="list-style-type: none"> • Commissioners are satisfied that the key terms of parties' contractual arrangements are summarised in a document/agreement for the provider entity so that all members are clear about the terms on which they are participating. The commissioner (or its adviser) has reviewed this and confirmed it enables the preferred provider to deliver the requirements and deal with risks.

Table 19: Checkpoint 2 Q7 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
In the event of provider failure, are contingency plans in place?						
7	1	Sub-risk: failure to have considered continuity of service in the event of provider failure.				
Examples of what good looks like						
<ul style="list-style-type: none"> • A contingency plan has been fully developed. • This plan demonstrates understanding of the impact of failure on service users and the critical services that would need to be maintained. • It contains plans for alternative provision in the event that essential services (both CRS and non-CRS) need to be re-commissioned, including potential gaps, mitigations and the assets required to secure continuity of services. 						
7	2	Sub-risk: failure to consider how services will be designated.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The contract clearly indicates which services are designated as CRS (and therefore subject to additional financial oversight by NHS Improvement). 						
7	3	Sub-risk: failure to make provision for providers to put in place appropriate financial and non-financial arrangements.				
Examples of what good looks like						
<ul style="list-style-type: none"> • A guarantee (as appropriate) that covers the provider's liability if it fails to fulfil its contractual obligations and liabilities to the commissioner for the cost of providing the services under the terms of the contract. • Financial strength tests have been conducted on the guarantor to determine whether it is able to cover the liabilities and where this is at risk additional mitigations have been included. • An asset register (including subcontractors) that is regularly maintained and agreed and submitted to the commissioner. • There is an agreed exit plan/handover pack, which could be given to a new/alternative provider where required, describing key contracts, insurance, liabilities, asset location, systems, access information and suppliers. • There is an agreed communications plan. • The provider must allow the commissioner's nominee to be present at board meetings in the event of failure to help shape remedial plans and take corrective action. 						

5. Guidance for Checkpoint 3

5.1. Aims of Checkpoint 3

The key considerations for Checkpoint 3 are:

- To establish whether there have been any changes since the contract was awarded;
- To establish that the mobilisation plans are being successfully implemented; and
- To ensure that the provider and commissioner are prepared for service delivery.

5.2. Timing

Checkpoint 3 takes place just prior to the service commencement. NHS Improvement will ask the successful provider (if it is an NHS trust or foundation trust) the questions outlined in Part C of this guidance and will follow up on any recommendations made at Checkpoint 2.

5.3. Potential sources of evidence

Table 20: Checkpoint 3 Sources of evidence

Checkpoint 3: sources of evidence
<p>The documentation forming the evidence, will build on Checkpoint 2 plus supporting evidence listed below. Most of these documents will already be held. Commissioners should speak to their regional teams if they have concerns about the items listed below.</p>
<p>For commissioners</p>
<p>Contract documents, arrangements, plans and licensing:</p>
<ul style="list-style-type: none">• Contract management plan (which includes management resource requirements and governance arrangements)• Initial contract performance information• Contract mobilisation and management arrangements• Summary of key legal advice related to mobilisation or implementation• Integration plan• Evidence of pathway redesign, workforce, IT and estates arrangements and plans• Evidence of clinical oversight and final sign off to confirm the service is safe to go live• Licensing and registration documents
<p>Governing body/board oversight and performance arrangements:</p>
<ul style="list-style-type: none">• Minutes of governing body/board and/or programme board meetings and papers; updated analysis papers, clinical and financial review including clinical and financial sign off (where relevant) of significant changes to original clinical, financial and delivery assumptions• Evidence of progress updates to programme board/governing body/board• Risk register, governing body/board and programme board minutes demonstrating mitigation of key risks and processes established for the continued management of post-transaction risks• Patient complaints procedure• Details of any new information that has come to light indicating material impacts on providers or commissioners• Information requested pre-mobilisation as part of Checkpoint 2.

5.4. Summary areas of focus for commissioners

Table 21 Checkpoint 3 Summary

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	1	Sub-risk: clinical feasibility compromised because, after the contract has been signed, clinical assumptions are identified as flawed.				
1	2	Sub-risk: clinical feasibility compromised because, after the contract has been signed, financial assumptions are identified as flawed.				
1	3	Sub-risk: clinical feasibility compromised because, after the contract has been signed, delivery assumptions are identified as flawed.				
1	4	Sub-risk: the service is not safe to go live.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Have legal risks been identified and mitigated?						
2	1	Sub-risk: contract variations agreed after the contract has been signed make fundamental changes to the contract, leading to breach of laws and/ or regulatory compliance.				
2	2	Sub-risk: the implications for the commissioner of contract variations agreed after the contract has been signed (e.g. changes to exit clauses, gain/loss clauses) are not fully understood before they are agreed.				
2	3	Sub-risk: the new structure is not licensed or registered with the required regulatory bodies.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
3	1	Sub-risk: insufficient capacity and capability to implement the contract after it has been awarded.				
3	2	Sub-risk: lack of definition of contract management roles and responsibilities.				
3	3	Sub-risk: contract management arrangements are not established and operating effectively.				
3	4	Sub-risk: corporate knowledge (and contract intent) is lost in the transition between the procurement and delivery teams.				
3	5	Sub-risk: the implications for the commissioner of contract variations agreed after the contract has been signed (e.g. changes to exit clauses, gain/loss clauses) are not fully understood before they are agreed.				
3	6	Sub-risk: mobilisation timetable is not adhered to; delays during mobilisation phase lead to deadline pressure and decision-making/ governance challenges.				

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
4	1	Sub-risk: financial feasibility compromised because, after the contract has been signed, clinical assumptions are identified as flawed.				
4	2	Sub-risk: financial feasibility compromised because, after the contract is signed, financial assumptions are identified as flawed.				
4	3	Sub-risk: financial feasibility compromised because after the contract has been signed, delivery assumptions are identified as flawed.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	1	Sub-risk: financial feasibility compromised because of financial challenges experienced by providers after the contract has been signed.				
5	2	Sub-risk: provider entity fails to operate effectively; management challenges within the provider entity/entities compromise the delivery of transformational change.				
5	3	Sub-risk: financial or clinical feasibility compromised because of financial or clinical challenges experienced by providers or commissioners after the contract has been signed.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the procurement and contract documentation appropriate?						
6	1	Sub-risk: contract variations weaken the levers available to the commissioner to enforce the contract.				
6	2	Sub-risk: failure to have suitable subcontracting arrangements, where relevant.				
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
In the event of provider failure, are contingency plans in place?						
7	1	Sub-risk: failure to have contingency plans for CRS and non-CRS, if the preferred provider fails.				
7	2	Sub-risk: failure to have appropriate service delivery arrangements for CRS, in the event of provider failure.				
7	3	Sub-risk: failure to have appropriate financial arrangements for CRS, in the event of provider failure.				
7	4	Sub-risk: failure to obtain the commissioner's consent to a change in control.				

5.5. Areas of focus for commissioners

Table 22: Checkpoint 3 Q1 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are there clear clinical transformational benefits?						
1	1	Sub-risk: clinical feasibility compromised because, after the contract has been signed, clinical assumptions are identified as flawed.				
Examples of what good looks like						
<ul style="list-style-type: none"> Clinical review and oversight retained throughout mobilisation and impact of changes identified, analysed and mitigated appropriately. 						
1	2	Sub-risk: clinical feasibility compromised because, after the contract has been signed, financial assumptions are identified as flawed.				
Examples of what good looks like						
<ul style="list-style-type: none"> Financial review and oversight retained throughout mobilisation and impact of changes identified, analysed and mitigated appropriately. 						
1	3	Sub-risk: clinical feasibility compromised because, after the contract is signed, delivery assumptions are identified as flawed.				
Examples of what good looks like						
<ul style="list-style-type: none"> Delivery assumptions, including estates, workforce, IT and transport are kept under review throughout mobilisation and impact of changes identified, analysed and mitigated appropriately. 						
1	4	Sub-risk: the service is not safe to go live.				
Examples of what good looks like						
<ul style="list-style-type: none"> The service is safe to go live and signed off by all relevant stakeholders. 						

Table 23: Checkpoint 3 Q2 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Have legal risks been identified and mitigated?						
2	1	Sub-risk: contract variations agreed after the contract has been signed make fundamental changes to the contract, leading to breach of laws and/ or regulatory compliance.				
Examples of what good looks like						
<ul style="list-style-type: none"> Legal advisers are retained and used throughout mobilisation; advice relating to potential contract variations is communicated to decision-makers, with the opportunity for question/ debate before decisions are made. Advice on risk around variations (particularly regarding procurement challenges) received and understood. 						
2	2	Sub-risk: the implications for the commissioner of contract variations agreed after the contract has been signed (e.g. changes to exit clauses, gain/loss clauses) are not fully understood before they are agreed.				
Examples of what good looks like						
<ul style="list-style-type: none"> Legal advisers are retained and used throughout mobilisation; advice relating to potential contract variations is communicated to decision-makers, with the opportunity for question/ debate before decisions are made. Advice on risk around variations (particularly regarding procurement challenges) received and understood. 						
2	3	Sub-risk: the new structure is not licenced or registered with the required regulatory bodies.				
Examples of what good looks like						
<ul style="list-style-type: none"> There is appropriate licensing and registration. 						

Table 24: Checkpoint 3 Q3 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
3	1	Sub-risk: insufficient capacity and capability to implement the contract after it has been awarded.				
Examples of what good looks like						
<ul style="list-style-type: none"> Contract management resources assigned according to the contract's complexity and risk. 						
3	2	Sub-risk: lack of definition of contract management roles and responsibilities.				
Examples of what good looks like						
<ul style="list-style-type: none"> Team structure aligned to experience, knowledge and authority. Clearly defined roles and responsibilities for key areas such as: <ul style="list-style-type: none"> Managing the administration of any changes to the contract. Managing the supplier's performance throughout the term of the contract. Ensuring the commissioner continues to comply with the terms of the contract. 						
3	3	Sub-risk: contract management arrangements are not established and operating effectively.				
Examples of what good looks like						
<ul style="list-style-type: none"> A contract management team with appropriate capacity and capability is involved in the mobilisation phase alongside the procurement project team. Detailed contract performance information metrics, reporting format and reporting cycle are defined/ designed. A contract management handbook and plan have been written to enable the contract management team to perform its role. A patient complaints process has been set up. 						
3	4	Sub-risk: corporate knowledge (and contract intent) is lost in the transition between the procurement and delivery teams.				
Examples of what good looks like						
<ul style="list-style-type: none"> Evidence of integration between procurement resources responsible for contract creation, and delivery resource responsible for managing the contract. 						

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the governance and management appropriate?						
3	5	Sub-risk: the implications for the commissioner of contract variations agreed after the contract has been signed (e.g. changes to exit clauses, gain/loss clauses) are not fully understood before they are agreed.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Legal advisers are retained and used throughout mobilisation; advice relating to potential contract variations is communicated to decision makers, with the opportunity for question/ debate before decisions are made. 						
3	6	Sub-risk: mobilisation timetable is not adhered to; delays during mobilisation phase lead to deadline pressure and decision-making/ governance challenges.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Any possible delays in the mobilisation timetable are reflected in deferring the date the service commences, or are appropriately mitigated in other ways. 						

Table 25: Checkpoint 3 Q4 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Are the contracted services financially sustainable?						
4	1	Sub-risk: financial feasibility compromised because, after the contract has been signed, clinical assumptions are identified as flawed.				
Examples of what good looks like						
<ul style="list-style-type: none"> Clinicians are fully represented throughout mobilisation, assessing the quality of service delivery and any changes to the specification or provider methods and inputs. 						
4	2	Sub-risk: financial feasibility compromised because after the contract is signed, financial assumptions are identified as flawed.				
Examples of what good looks like						
<ul style="list-style-type: none"> The financial inputs and assumptions are up to date and reflect the latest assumptions about transformation of the service as negotiated with the providers. All parties have agreed the rules of the gain/loss sharing scheme and processes for implementing and operationalising the scheme have been agreed by all key stakeholder party to the scheme and are clearly documented 						
4	3	Sub-risk: financial feasibility compromised because after the contract is signed, delivery assumptions are identified as flawed.				
Examples of what good looks like						
<ul style="list-style-type: none"> The sources of cost savings have been identified and tracked to changes in the delivery model. These savings are being compared to the assumptions made during the procurement phase and any differences accounted for. 						

Table 26: Checkpoint 3 Q5 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is there an appropriate provider entity structure, financial capacity, governance and capability to transform and deliver?						
5	1	Sub-risk: financial feasibility compromised because of financial challenges experienced by providers after the contract has been signed.				
Examples of what good looks like						
<ul style="list-style-type: none"> Financial review and oversight retained throughout mobilisation and impact of changes identified, analysed and mitigated appropriately. The financial plan demonstrates post-contract financial viability. 						
5	2	Sub-risk: provider entity fails to operate effectively; management challenges within the provider entity/entities compromise the delivery of transformational change.				
Examples of what good looks like						
<ul style="list-style-type: none"> Delivery assumptions around the capacity and capability of the provider entity/entities are kept under review throughout mobilisation and impact of changes identified, analysed and mitigated appropriately. There are appropriate arrangements for pathway redesign, IT, workforce and other enablers. There are appropriate arrangements relating to estates. 						
5	3	Sub-risk: financial or clinical feasibility compromised because of financial or clinical challenges experienced by providers or commissioners after the contract has been signed.				
Examples of what good looks like						
<ul style="list-style-type: none"> No new information demonstrates a material impact on the provider or commissioner that could affect the contract's feasibility. 						

Table 27: Checkpoint 3 Q6 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
Is the procurement and contract documentation appropriate?						
6	1	Sub-risk: contract variations weaken the levers available to the commissioner to enforce the contract.				
Examples of what good looks like						
<ul style="list-style-type: none"> Legal advisers are retained and used throughout mobilisation; advice on potential contract variations is communicated to decision-makers, with the opportunity for question/debate before decisions are made. Advice on risk around variations (particularly regarding procurement challenges) received and understood. 						
6	2	Sub-risk: failure to have suitable subcontracting arrangements, where relevant.				
Examples of what good looks like						
<ul style="list-style-type: none"> There are robust subcontracting arrangements, with risks appropriately shared. 						

Table 28: Checkpoint 3 Q7 KLOE commissioner assurance

Checkpoint 1		Checkpoint 2			Checkpoint 3	
KLOE 1	KLOE 2	KLOE 3	KLOE 4	KLOE 5	KLOE 6	KLOE 7
In the event of provider failure, are contingency plans in place?						
7	1	Sub-risk: failure to have contingency plans for CRS and non-CRS, if the preferred provider fails.				
Examples of what good looks like						
<ul style="list-style-type: none"> • A contingency plan has been fully developed, for CRS and non-CRS to maintain continuity of services, where required, in the event of provider failure. • The commissioner has been regularly monitoring the provider's circumstances to assess whether a contingency plan should be deployed. 						
7	2	Sub-risk: failure to have appropriate service delivery arrangements in place for CRS, in the event of provider failure.				
Examples of what good looks like						
<ul style="list-style-type: none"> • For CRS, an up-to-date asset register regularly maintained with an agreed exit plan/handover pack describing key contracts, insurance, liabilities, asset location, systems, access and suppliers. • There is a communication plan. 						
7	3	Sub-risk: failure to have appropriate financial arrangements in place for CRS, in the event of provider failure.				
Examples of what good looks like						
<ul style="list-style-type: none"> • Financial strength tests have been regularly conducted on the guarantor to determine whether it can cover the liabilities and where this is at risk additional mitigations have been included. 						
7	4	Sub-risk: failure to obtain the commissioner's consent to a change in control.				
Examples of what good looks like						
<ul style="list-style-type: none"> • The provider has sought the commissioner's consent to a change in control (i.e. it is to be acquired by another provider/organisation). 						