

HTA Board meeting, 18 September 2025

Agenda item	2.6 HTA Performance Report
Purpose: for information or decision?	Information
Decision making to date?	N/A
Recommendation	The HTA Board is asked to note and comment by exception on the performance recorded and the context provided
Which strategic risks are relevant?	Risk 1: Operational Risk 2: Reputational Risk 3: Financial Risk 4: Strategy Risk 5: People Risk 6: Security
Strategic objective	Efficient and Effective
Core operations / Change activity	Core operations
Business Plan item	Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including risk management and seeking opportunities for ALB collaboration)
Committee oversight?	Board only
Finance and resource implications	Various due to the range of items covered
Timescales	Various due to the range of items covered
Communication(s) (internal/external	N/A
Identified legislative implications	N/A

HTA Performance Report

Purpose of paper

1. This paper informs the Board of the HTA's performance at the end of Quarter 1 (Q1) of 25/26 against our objectives and operational delivery targets.
2. In addition, it provides an early indication of the initial performance in Quarter 2 (Q2) of 25/26.
3. Core operational areas from our Business Plan with Key Performance Indicators (KPIs) have been included as topics within this paper, in the same order as that document. We have also included some additional operational areas for Board visibility of non-KPI performance where there is something noteworthy to highlight.
4. **Annex A** provides the KPI and Project Data Overview as at the end of Q1 (final) and **Annex B** gives the KPI and Project Data Overview for Q2 (latest). The current Strategic Risk Register is provided for information at **Annex C**.

Ask

5. The HTA Board is asked to **note** and comment on the performance recorded and the context provided.

Regulation

6. As shown in **Annex A**, two of the three Regulation KPIs were Green for Quarter 1 - the KPIs for the inspection target and for timeliness of decisions on Living Organ Donation approvals.
7. The KPI for reaching a decision on 70% of new licence applications within 90 days was amber, being just below target at 68%. One of the licence applications on which a decision was not made within 90 days withdrew its application in the first week of July, having determined that they did not need a HTA licence for the activities they were proposing to carry out. Had that happened by the end of June, this KPI would have been Green.
8. Both of the Regulation-led Projects are on-track.
9. The Project to consider how we might further improve our approach to Living Organ Donation work (and related activities) is in a pre-Project discovery

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phase, with the initial Business Case to be considered in Quarter 3. This Project is expected to run into 2025/26.

10. The Innovations in Inspection Project is on track, with a limited trial of a new approach for managing CAPAs (Corrective & Preventative Action Plans) due to be initiated in the second half of the year. Preparation and planning for implementing Evaluated Self Assessments (ESAs) in the Public Display sector were completed in Quarter 1, with implementation now starting in Quarter 2. We plan to carry out ESAs for half the sector this year (25/26) and the other half next year (26/27).

Communications

11. Social media performance was strong, with the post-mortem focus week in May 2025 being our most successful to date. A LinkedIn carousel, this is a post where you can swipe through multiple slides or images, like flipping through pages in a book, achieved 70% engagement (people either liked, commented, shared, or clicked on it) with 177 click-throughs to find out more, whilst video content generated over 20 minutes watch time.
12. In the first Quarter, the Communications team addressed website functionality challenges following the security upgrade. Working closely with the supplier, bug fixes were completed in May and website analytics restored by quarter-end in June.
13. The team promoted HTA's Living Organ Donation role alongside media coverage of the first UK birth following womb transplant and published the LOD data for the previous quarter. We also hosted the ODT stakeholder forum.

Policy and Development

14. In the last Quarter work has included re-developing the Project Initiation Document for the Codes of Practice review and progressing SoHO (Substances of Human Origin) Project delivery, including supporting DHSC and the Food Standards Agency to consider their SoHO regulations impacts.
15. Another key focus for the team centred on completing a comprehensive review of the first year of the Duty to Report arrangements in ODT, shared at the June Board meeting. This review considered how the HTA implemented its responsibilities under the new Regulations using a proportionate, evidence-based approach including quantitative analysis of 12-month report data,

structured discussions with the Living Organ Donation team, and qualitative insights from clinicians, police forces, and Senior Management Team members.

Information Technology and Digital

16. Cyber security is a key strategic priority for the HTA both in respect of protecting sensitive information, including patent data, and in maintaining trust and public confidence in the organisation, without which, we would be unable to conduct our work with credibility. This makes it a particularly challenging area for a small ALB as controls and assurances relating to cyber risk and vulnerabilities do not discriminate between the size of an organisation. In recent years the HTA has worked hard to strengthen security posture and significant improvements have been achieved in relation to increased cyber security, as indicated by the recent independent assessment against the NHS Cyber Assessment Framework (CAF) in June 2025 for the 24/25 year which recorded a high confidence and low risk across our actions and controls based on what was reviewed.
17. There were no major concerns with IT and digital performance during Q1 or more recently. Our operations have remained stable, with no major or minor incidents leading to any wider issues. Overall performance has exceeded the KPIs, demonstrated by consistent 100% service uptime. Indeed, our cyber security posture continues to demonstrate strength and resilience. This is reflected in our Microsoft Defender Exposure Score, which has remained consistently stable around 31. (This is against Microsoft's scoring framework—where 0–29 is considered Low, 30–69 Medium, and 70–100 High—HTA's score places us at the very lower end of the Medium range, bordering on Low). When benchmarked against similar-sized ALBs, HTA's score is significantly better than the average, underpinning our proactive approach and ongoing commitment to safeguarding our systems and data. This achievement is a direct result of our ongoing efforts to reduce exposure, leveraging Microsoft's tailored recommendations to continuously strengthen our defences.

Corporate Services

18. Performance remained on track against our KPIs for responding to enquiries and to Freedom of Information (Fol) requests which are both Green.

Finance

19. The table below is a summary of our financial position as at 31 July 2025 and our forecast for the year ending at 31 March 2026. An update by the

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components of our year-to-date net surplus is detailed below.

	Cumulative YTD				2025/26			
	Actual	Budget	Variance		Forecast Outturn	Annual Budget	Variance	
	£	£	£	%	£	£	£	%
INCOME								
Grant in Aid including RDEL	190,112	140,111	50,001	35.69%	484,243	419,334	64,909	15.48%
Licence Fees	2,440,346	2,403,098	37,248	1.55%	5,985,386	5,898,098	87,288	1.48%
Other	94,988	75,874	19,114	25.19%	111,827	115,622	(3,795)	-3.28%
Total Income	2,725,446	2,619,083	106,363	4.06%	6,581,456	6,433,054	148,402	2.31%
Staff Costs								
Salaries and Wages	1,497,870	1,522,516	(24,646)	-1.62%	4,666,217	4,567,548	98,669	2.16%
Authority Allowances	46,820	46,355	465	1.00%	144,218	139,066	5,152	3.70%
Total staff costs	1,544,690	1,568,871	(24,181)	-1.54%	4,810,435	4,706,614	103,821	2.21%
Non-salary staff costs								
Travel and subsistence	81,386	53,182	28,204	53.03%	255,544	197,000	58,544	29.72%
Other Staff costs ¹	18,620	13,337	5,283	39.61%	54,053	42,550	11,503	27.03%
Recruitment	8,836	20,000	(11,164)	-55.82%	16,000	35,000	(19,000)	-54.29%
Training costs	25,630	10,250	15,380	150.05%	42,550	45,000	(2,450)	-5.44%
	134,472	96,769	37,703	38.96%	368,147	319,550	48,597	15.21%
Other Operating costs								
Telecommunication	6,947	4,167	2,780	66.71%	11,123	12,500	(1,377)	-11.02%
ICT Development ²	117,761	145,417	(27,656)	-19.02%	453,137	457,000	(3,863)	-0.85%
Legal and Professional (Legal, audit)	80,698	50,967	29,731	58.33%	213,057	167,900	45,157	26.90%
Conference and Project costs	44,292	93,320	(49,028)	-52.54%	285,038	369,655	(84,617)	-22.89%
Shared Service/NHSBT/Projects	23,384	28,998	(5,614)	-19.36%	85,234	90,601	(5,367)	-5.92%
Administration costs	9,954	825	9,129	1106.55%	28,490	15,300	13,190	86.21%
Accommodation costs	57,757	63,684	(5,927)	-9.31%	172,514	168,000	4,514	2.69%
Non-cash costs	52,052	41,511	10,541	25.39%	185,243	125,934	59,309	47.10%
	392,845	428,889	(36,044)	-8.40%	1,433,836	1,406,890	26,946	1.92%
Total expenditure	2,072,007	2,094,529	(22,522)	-1.08%	6,612,418	6,433,054	179,364	2.79%
Net surplus/(deficit)	653,439	524,554	128,885	24.57%	(30,962)	0	(30,962)	

¹Other Staff costs (all-staff days, subscriptions, conferences, welfare)

²ICT Development (including IT Subscriptions, Maintenance, Consultancy)

20. **Income** – the year-to-date position on income is £106k surplus to budget and this is driven by:

- An increase to ring fenced RDEL - £50k more than budgeted due to increased non-cash income which covers the depreciation/amortisation of our assets.

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- Our licence fee income is above budget by £37k the bulk of which relates to application fees (£33k) which have not previously been budgeted for and income from HA licences (£4k).
- Other income is above budget by £19k which relates to a bad debt written off prior year now recovered being offset by the secondee income previously received for the Head of Finance salary.

Half of the total cash grant in aid RDEL drawdown has been received with the remainder due in September 2025.

21. **Expenditure** – year-to-date the expenditure is under budget by £23k. Below are explanations for the significant variances to budget:

- Staff costs are underspent by £24k and recruitment costs by £11k due to some vacant posts that are due to be filled in the Autumn slightly offset by increased employer National Insurance costs for board member salaries.
- Other non-salary staff costs are overspent by £49k relating largely to travel and subsistence (£28k) which is in line with the increased level of inspections taking place and training (£15k) relating to an SMT coaching course.
- ICT development is currently showing a year-to-date underspend of £28k but it can be seen in the forecast outturn that it is anticipated to be spent. The profile of spend will be adjusted for the 2026/27 budget period.
- Conference and project costs are currently underspent by £49k due to a delay in some projects.
- Legal and professional fees are overspent by £30k due to an increase in the external audit fee and ongoing legal cases where costs are unpredictable.

22. Early forecasts on the anticipated outturn have been completed in month 3 and 4 which suggested a significant overspend would materialise, but this has allowed SMT to make early decisions to ensure that we maintain our quality service provision whilst lowering costs to avoid an overspend at year end. We are currently forecasting a modest overspend by £30k at the end of the year, but additional work is in progress to improve this forecast further.

23. The actions we have taken to mitigate the overspend have included rescinding the ability for staff to sell annual leave in September (there will be a further opportunity to do so in March 2026, if affordable), reducing spend on recruitment costs, removing project contingency, savings on the HR shared service contract and doing a deep dive into all budget lines, releasing small amounts that we have determined are not required this year.

24. We have, however, identified the need to increase the forecast outturn in two areas, for legal costs due to enhanced activity in-year and for travel and subsistence costs in order to be more in line with the outturn from the

previous year. We will continue to review and refine the need for legal opinion as we move through the coming months, and we have taken mitigating action to keep travel and subsistence costs affordable.

25. In addition to internal pressures, DHSC has issued an in-year moratorium for 25/26 on new uncommitted spending in relation to grant funded activities. While our GIA (Grant in Aid) is only a small part of our funding, as the majority of our funding is raised from licence fees, we have agreed that we will review other spending decisions which are not already committed and consider alternative approaches where this is feasible without our essential activity suffering.
26. **Debtors at 31 July 2025** – our debtors at the end of July 2025 stood at £91k represented by 15 establishments. Of this, £85k was from the current financial year, 2025/26, with the remainder being older debt. Of the current year overdue invoices, three related to licence holders going through revocation, and another licence holder has queried charges with the Licensing Team. A breakdown of total debts by sector (at the end of July) compared to the same period last year is below.

	2025/6			2024/5		
Sector	Number of establishments	Value	%	Number of establishments	Value	%
NHS	9	£49,555	54%	36	£247,993	46%
Government bodies	0	£0	0%	3	£89,903	17%
Non-Government bodies	6	£41,840	46%	35	£196,059	37%
Total	15	£91,395		74	£533,955	

Audit and Risk

27. The latest version HTA Strategic Risk Register is provided at [**Annex C**](#).
28. The People Risk remains above tolerance, although SMT consider the risk is lower than in previous quarters due to the work flowing from the people strategy and the positive pulse survey.
29. The Finance Risk has increased in its likelihood and stems from the Q1 forecast outturn position. Much work has been done to mitigate that position and the overall forecast outturn is greatly improved. However, there are also pressures arising from the overall picture for DHSC. As result, the DHSC Finance DG has issued a moratorium around uncommitted spending, although, there are exceptions such as H&S, travel, subsistence, pay settlements and in-year awards, and learning & development. As we don't have as much certainty

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in our financial position going forward into Q2 due to the external pressures faced, we have moved the risk to above tolerance.

30. We also moved down to slightly below tolerance the assessment of the risk assigned to the possibility of a successful cyber-attack or a data loss. Whilst we believe this to be a more accurate reflection of the current status of the risk, given the significant improvements achieved to reduce exposure and continuously strengthen our defences, there is no complacency on the part of HTA personnel in continuing to take a proactive approach to safeguarding our systems and data, and we continue to review this risk regularly.
31. All other risks have been reviewed but remain stable.

Health and Safety

32. There were no new Health and Safety incidents reported in Q1 (nor in Q2 to-date). We have been supported by colleagues from the CQC Health & Safety Team in completing risk assessments and in reviewing H&S related policy such as the Driving at Work Policy.
33. A new Service Level Agreement is currently with the CQC legal team and allows HTA to benefit from a wide range of Health and Safety advice and support.
34. The new quarterly Health and Safety Committee held their first meeting with representatives across all business areas in attendance.

Human Resources

35. While our attrition rate remains unchanged, a pulse survey conducted at the end of Q1 and suggests that the direction of travel coming from the People Strategy work is positive.
36. Our staff sickness remains low and below target, and the current managing absence policy is being updated.

Quarter 1 summary

37. At the end of Q1 the overall Business Plan **RAG** rating is **Green**:
38. Core operations: 11 of our 14 KPIs are either Green or necessarily nil returns at this point in the year. 1 is Amber (new licence decisions) and 2 (both in the same area of focus – attrition) are Red and the performance levels for these 3 items are broadly as anticipated.

39. Change activities: we are on track to deliver all the *must-do* Projects that we have committed to for 25/26.

Quarter 2 early insights

40. Details of early Q2 performance are given at **Annex B**:
41. The *current* overall Business Plan **RAG** rating remains **Green**:
42. Core operations: our KPI performance remains positive and has not materially changed at the start of Q2.
43. Change activities: we remain on track, with our final 25/26 Projects still to bring online being progressed through early discovery conversations.
44. On the debt front, the picture has further improved during August and the outstanding debt has been reduced to a total of £76k with only £2k (from one invoice) unpaid from the prior periods (i.e. before April 2025).

Recommendation

45. The HTA Board is asked to **note** and comment on the performance recorded and the context provided.

Annex A – Quarterly Board Data Overview, 25/26 Quarter 1 Final Position

Core Operations

Business Plan KPIs

7
On Track

1
At Risk

2[^]
Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	25/26 YTD	
	Approach to Regulation														
Regulation	[1] 222 compliance assessments across all sectors [reported quarterly against planned allocation]	Reported Quarterly		73	Reported Quarterly		XX	Reported Quarterly		XX	Reported Quarterly		XX	73	
	[2] Decisions reached on 70% of new licence applications within 90 days of the application fee being paid (rolling annual average) [reported quarterly]	Reported Quarterly		68%	Reported Quarterly		XX	Reported Quarterly		XX	Reported Quarterly		XX	68%	
	[3] 99% of panel and non-panel cases actioned within 10 and 5 working days respectively [reported monthly]	96%	100%	100%	XX	XX	XX	XX	XX	XX	XX	XX	XX	100%	
	Trust and Confidence														
N/A	N/A	N/A													
	Use of Information														
DTD	[4] 99% system availability across our core essential functions, outside of scheduled maintenance routines and system patching [reported monthly]	100%	100%	100%	XX	XX	XX	XX	XX	XX	XX	XX	XX	100%	
	[5] Bi-annual open datasets are assessed, validated and published within 10 weeks of quarter end [reported annually]	Reported Annually											XX	XX	

YTD CALCULATION

CUMULATIVE

AVERAGE

LATEST MONTH

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Business Plan KPIs

7
On Track1
At Risk2[^]
Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	25/26 YTD	
	Efficient and Effective														
P&CG	[6] 90% of enquiries answered within 10 working days [reported monthly]	97.9%	96.8%	97.1%	XX	XX	XX	XX	XX	XX	XX	XX	XX	97.3%	
	[7] 100% of FOIs (Freedom of Information requests) responded to within 20 working days [reported quarterly]	Reported Quarterly		100%		Reported Quarterly	XX		Reported Quarterly	XX		Reported Quarterly	XX	100%	
Resources	[8] Actual spend within 3% of budget [reported quarterly]	Reported Quarterly		1.2%		Reported Quarterly	XX		Reported Quarterly	XX		Reported Quarterly	XX	1.2%	
	[9] Debt no more than 5% of income at year end [reported annually]	Reported Annually											XX	XX	
	[10] Unqualified external audit opinion received [reported annually]	Reported Annually											*	*	
	[11] 100% of 'reportable incidents' reported to HSE (Health and Safety Executive) within 10 working days [reported quarterly]	Reported Quarterly		N/A		Reported Quarterly	XX		Reported Quarterly	XX		Reported Quarterly	XX	N/A	
	[12] Staff sickness no more than 3% [reported monthly]	2.1%**	2.2%**	1.6%	XX	XX	XX	XX	XX	XX	XX	XX	XX	1.6%	
	[13 a] Attrition rate excluding planned exits (Fixed Term Contracts) no more than 18% [reported monthly]	24.1%	24.1%	24.1%	XX	XX	XX	XX	XX	XX	XX	XX	XX	24.1%	
	[13 b] Total attrition rate no more than 20% [reported monthly]	31%	31%	29.3%	XX	XX	XX	XX	XX	XX	XX	XX	XX	29.3%	

*Not due for reporting until May / June 2026

**April and May Sickness KPI data re-stated retrospectively

^NB our performance in terms of staff attrition is scrutinised by x2 KPIs for 25/26 (with and without fixed term contracts, 13 a / b) but represents x1 area of performance

Change Activities

Project Summary Status – Overall RAG Heatmap for Board Review

	Project	Sponsor	Apr 25	May 25	Jun 25	Commentary for Board Review
Activities	Innovation in inspection <i>[Must do]</i>	Nicky Harrison	A	A	A	The Project remains at Amber due to ongoing resource limitations. While CAPA review and trial modelling continue to progress, the upcoming final report for FII Phase 2 - anticipated in July - may influence the overall delivery schedule <i>[Project expected to run into 26/27, albeit with a new scope / structure]</i>
	Living Organ Donation approvals <i>[Must do]</i>	Nicky Harrison	W	W	W	Not started (although pre-Project discovery is already taking place, including Board discussions) <i>[Project expected to run into 26/27]</i>
	Substances of Human Origin <i>[Must do]</i>	Louise Dineley	A	A	A	The Project remains on track, with an Amber rating due to potential Resource constraints and an unconfirmed budget. In June, progress continued on Products mapping, with further cross-business engagement underway ahead of a Q2 progress update <i>[Project expected to run into 26/27]</i>
	Review of Codes of Practice <i>[Should do]</i>	Louise Dineley	G	G	G	Phase 1 progressing through a high-level review of relevant Codes and processes, including documentation from the 2017 substantive Review <i>[Project expected to run into 26/27, subject to May PSMT Change Control]</i>
	Implement Change Authority Board process within Information Technology <i>[Could do]</i>	Louise Dineley	A	A	G	The Project is progressing well, with a documented Delivery approach, process map, and defined Stage Gates. Following CAF submission, Resources have been secured - returning the Project to a Green status <i>[Project expected to complete in 25/26]</i>
	Replace our current finance system <i>[Could do]</i>	Katrina Leighton-Hearn	W	W	W	Not started <i>[Project expected to complete in 25/26]</i>
	Implement our People strategy <i>[Should do]</i>	Katrina Leighton-Hearn	G	G	G	The People Strategy launched to drive organisational improvement, with the Implementation Plan and Q1 progress presented to the Remuneration Committee in June 2025 <i>[Project expected to run into 26/27]</i>
All	Project delivery	All SMT	G	G	G	On track to deliver all <i>must do</i> items as planned

Annex B – Quarterly Board Data Overview, 25/26 Quarter 2 Latest Position**Core Operations**

Business Plan KPIs

7

On Track

1

At Risk

2^

Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	25/26 YTD					
	Approach to Regulation																		
Regulation	[1] 222 compliance assessments across all sectors [reported quarterly against planned allocation]	Reported Quarterly		73		Reported Quarterly		XX		Reported Quarterly		XX		Reported Quarterly		XX	73		
	[2] Decisions reached on 70% of new licence applications within 90 days of the application fee being paid (rolling annual average) [reported quarterly]	Reported Quarterly		68%		Reported Quarterly		XX		Reported Quarterly		XX		Reported Quarterly		XX	68%		
	[3] 99% of panel and non-panel cases actioned within 10 and 5 working days respectively [reported monthly]	96%	100%	100%	100%		XX		XX		XX		XX		XX		XX	100%	
	Trust and Confidence																		
N/A	N/A	N/A																	
	Use of Information																		
DTD	[4] 99% system availability across our core essential functions, outside of scheduled maintenance routines and system patching [reported monthly]	100%	100%	100%	100%		XX		XX		XX		XX		XX		XX	100%	
	[5] Bi-annual open datasets are assessed, validated and published within 10 weeks of quarter end [reported annually]	Reported Annually													XX		XX		

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Business Plan KPIs

7
On Track

1
At Risk

2^
Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	25/26 YTD	
	Efficient and Effective														
P&CG	[6] 90% of enquiries answered within 10 working days [reported monthly]	97.9%	96.8%	97.1%	98.2%	XX	XX	XX	XX	XX	XX	XX	XX	97.5%	
	[7] 100% of FOIs (Freedom of Information requests) responded to within 20 working days [reported quarterly]	Reported Quarterly		100%	Reported Quarterly		XX	Reported Quarterly		XX	Reported Quarterly		XX	100%	
Resources	[8] Actual spend within 3% of budget [reported quarterly]	Reported Quarterly		1.2%	Reported Quarterly		XX	Reported Quarterly		XX	Reported Quarterly		XX	1.2%	
	[9] Debt no more than 5% of income at year end [reported annually]	Reported Annually												XX	XX
	[10] Unqualified external audit opinion received [reported annually]	Reported Annually												*	*
	[11] 100% of 'reportable incidents' reported to HSE (Health and Safety Executive) within 10 working days [reported quarterly]	Reported Quarterly		N/A	Reported Quarterly		XX	Reported Quarterly		XX	Reported Quarterly		XX	N/A	
	[12] Staff sickness no more than 3% [reported monthly]	2.1%	2.2%	1.6%	0.7%	XX	XX	XX	XX	XX	XX	XX	XX	0.7%	
	[13 a] Attrition rate excluding planned exits (Fixed Term Contracts) no more than 18% [reported monthly]	24.1%	24.1%	24.1%	24.1%	XX	XX	XX	XX	XX	XX	XX	XX	24.1%	
	[13 b] Total attrition rate no more than 20% [reported monthly]	31%	31%	29.3%	29.3%	XX	XX	XX	XX	XX	XX	XX	XX	29.3%	

*Not due for reporting until May / June 2026

^NB our performance in terms of staff attrition is scrutinised by x2 KPIs for 25/26 (with and without fixed term contracts, 13 a / b) but represents x1 area of performance

Change Activities

Project Summary Status – Overall RAG Heatmap for Board Review

	Project	Sponsor	May 25	Jun 25	Jul 25	Commentary for Board Review
Activities	Innovation in inspection <i>[Must do]</i>	Nicky Harrison	A	A	A	The Project remains at Amber due to ongoing Resource capacity constraints. Progress continues with the CAPA review as well as trial modelling. However, the publication of the FII Phase 2 report impacted progress in July; trial expected to commence in Q3 <i>[Project expected to run into 26/27, albeit with a new scope / structure]</i>
	Living Organ Donation approvals <i>[Must do]</i>	Nicky Harrison	W	W	W	Not started (although pre-Project discovery is already taking place, including Board discussions) <i>[Project expected to run into 26/27]</i>
	Substances of Human Origin <i>[Must do]</i>	Louise Dineley	A	A	A	The Project remains on track, though potential Resource constraints and an unconfirmed budget continue to present Risks, reflected in the Amber rating. In July, the team continued development of Products mapping. <i>[Project expected to run into 26/27]</i>
	Review of Codes of Practice <i>[Should do]</i>	Louise Dineley	G	G	G	The Project is on track. Phase 1 has been completed, resulting in a systematic review paper that outlines the findings and proposed next steps. The paper is scheduled to be presented at August's PSMT. <i>[Project expected to run into 26/27]</i>
	Implement Change Authority Board process within Information Technology <i>[Could do]</i>	Louise Dineley	A	G	G	The Project is progressing smoothly. Key advancements include the development of the Change Management Process and Policy, alongside the integration of Secure-by-Design principles. <i>[Project expected to complete in 25/26]</i>
	Replace our current finance system <i>[Could do]</i>	Katrina Leighton-Hearn	W	W	W	Not started (although pre-Project discovery is already taking place, including Benefits discussions) <i>[Project expected to complete in 25/26]</i>
	Implement our People strategy <i>[Should do]</i>	Katrina Leighton-Hearn	G	G	G	The Project remains on track. The Q1 pulse survey has been completed, and current efforts are focused on delivering Key Milestones <i>[Project expected to run into 26/27]</i>
All	Total Project cohort	All SMT	G	G	G	On track to deliver all <i>must do</i> items for 25/26 as planned

Category	Red	Amber	Green
KPI / PI	<ul style="list-style-type: none"> If performance is >10% below target 	<ul style="list-style-type: none"> If performance is = 1%-10% of target 	<ul style="list-style-type: none"> If performance is = target

Category	Red	Amber	Green	Blue	White
Overall Project RAG	<ul style="list-style-type: none"> If one or more of the Plan, Benefits, Cost and Resources RAGs are RED 	<ul style="list-style-type: none"> If one or more of the Plan, Benefits, Cost and Resources RAGs is AMBER and none are RED 	<ul style="list-style-type: none"> If all of the Plan, Benefits, Cost and Resources RAGs are GREEN 	<ul style="list-style-type: none"> Project complete 	<ul style="list-style-type: none"> Project not live
Plan	<ul style="list-style-type: none"> If more than one Key Date or Milestone is off-track 	<ul style="list-style-type: none"> If one Key Date or Milestone is off-track 	<ul style="list-style-type: none"> If no Key Dates or Milestone are off-track 		
Benefits	<ul style="list-style-type: none"> If more than one Benefit is off-track 	<ul style="list-style-type: none"> If one Benefit is off-track 	<ul style="list-style-type: none"> If no Benefits are off-track 		
Cost	<ul style="list-style-type: none"> If Spend is >3% over / under forecast 	<ul style="list-style-type: none"> If Spend is 1%-3% over / under forecast 	<ul style="list-style-type: none"> If Spend is within 1% of forecast 		
Resource	<ul style="list-style-type: none"> If more than one identified Role has no assigned Resource 	<ul style="list-style-type: none"> If one identified Role has no assigned Resource 	<ul style="list-style-type: none"> If all identified Roles have assigned Resource 		

HTA 27-25 Annex C

Risk Dashboard

This dashboard provides a total count of risks against risk categories

Team	Current risk?	Residual risk	Tolerance levels	Tolerance level
Operational	Yes	8	-	8
Reputational	Yes	9	-	9
Financial	Yes	12	▲	9
Strategy	Yes	9	-	9
People	Yes	12	▲	9
Security	Yes	8	▼	9
HTA Total	6			

Operational risks

Updated by		Nicolette Harrison					Updated date		August 2025	
Risk name		We have a major regulatory failure with negative consequences for members of the public, broader stakeholders and staff								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	3	5	15	2	4	8	5	8	At tolerance	
Risk owner	Nicolette Harrison			Link to strategy	Approach to regulation		Trend since last update		↔	
Management commentary - on current live risks	A significant regulatory failure could be due to people or process (or a combination). - 'People' failure could be due to competence (relevant factors - training, expertise, experience) or capacity (individual or collective) - 'Process' failure could be due to systems, policies or procedures. This could include reference to inspection models which deploy fewer inspectors and a greater use of remote or self-assessment methodologies. Length of existence of HTA and increasing cumulative volume and complexity of regulated activities may also increase the chances of a failure Failure to seek legal advice where appropriate could lead to decisions being taken without full consideration of all relevant regulatory legal risks									
Management commentary - views on mitigation	- Well-established core regulatory processes eg Regulatory decision-making framework including police referral policy and process; evidenced by Internal Audits - Training and development: Structured induction for new staff; Directorate training / away days; provision for conference attendance; corporate staff training - Recruitment exercises are used positively to seek a broad range of suitable knowledge, skills and experience across sectors - Regulatory priorities by sector are re-assessed annually as part of business planning, with some (limited) capacity to reallocate resource in-year - Whilst specialist legal advice is sought for novel or complex matters, a risk remains that any potential successful legal action or claim relating to an isolated regulatory failure could be perceived externally as systemic and negatively impact the HTA's reputation - Sir Jonathan Michael's extensive Phase 2 report into the handling of the deceased in various settings reflected well on the HTA's actions to further strengthen our activities, with only one minor operational recommendation for the HTA to formalise current informal incident reporting arrangements for the Anatomy sector.									
Risk external interdependencies			Control arrangements						Owner	
Changes in the legislative framework Legal challenge			Control arrangements are considered effective with a regulatory function that provides an increasingly wide range of proactive and targeted regulatory assessments to modernise and strengthen the HTA's approach to fulfilling its core regulatory functions that are responsive to emerging risks. Examples from recent years include the developments of Virtual Regulatory Assessment, Evaluated Self-Assessment, Evidential Compliance Assessment and the revised Data Collection Exercise. As such, the HTA continues to modernise and evolve its control arrangements, including through a significant increase in inspections.						Nicolette Harrison (Director of Regulation)	

Reputational risks

Updated by		Louise Dineley					Updated date		August 2025	
Risk name		Our reputation as a trusted expert authority is at risk if misunderstanding about human tissue use and regulation overshadows our expert guidance, potentially undermining public confidence and regulatory compliance across sectors we regulate.								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	4	4	16	3	3	9	9	9	At tolerance	
Risk owner	Louise Dineley			Link to strategy	Trust and confidence		Trend since last update		↔	
Management commentary - on current live risks	<p>The 20-year existence of the HTA (Human Tissue Act 2004) coupled with "a quickening of the pace of change, innovation and improvements in all sectors" creates increasing complexity. HTA regulates over 800 premises across 6 sectors, with growing technical complexity creating more opportunities for misinformation to emerge. Professionals working in the establishments we licence demonstrate knowledge gaps in HTA regulations with limited training capacity to keep staff current on complex and evolving issues in the regulation of tissue</p> <p>HTA is "a lean organisation" with high attrition rate and limited resources for rapid response to misinformation or misunderstanding of the HTA's role. The increased use of AI has the potential to add to misunderstandings and misconceptions of teh HTA's role.</p> <p>Website search functionality improvements explicitly deprioritised as "won't do for 25/26" couple with digital infrastructure gaps limit ability to analyse and leverage "wealth of information, data and insight"</p> <p>Stakeholder feedback indicates guidance is inconsistent and difficult to locate on digital platforms and implementation of "remote or self-assessment methodologies" creates distance between regulator and regulated bodies, which could create more opportunities for misinformation to spread.</p>									
Management commentary - views on mitigation	<p>HTA communication plan for 2025/26 will focus on 6 themed weeks to shine a light on key areas, developing 10 external case studies and news stories and converting key documents to HTML, improving accessibility and findability.</p> <p>HTA stakeholder engagement approach should help prioritise engagement with high-influence stakeholders, improve information sharing across HTA to ensure consistent messaging and continue to deliver quarterly engagement preferred by stakeholders.</p> <p>HTA has a critical incident response plan, which includes a critical incident response plan tested annually (April 2025). The Head of Comms has completed Government Communication Service training on misinformation and disinformation and crisis communications.</p> <p>The combined activity will continue to help build understanding of the HTA.</p> <p>Advice & Guidance is continually reviewed by the HTA to reflect to provide direction and supported through our response to enquiries.</p>									
Risk external interdependencies			Control arrangements						Owner	
Externally published narrative and interpretation of the HTA's role			Delivery of the HTA communication plan for 2025/26 to support proactive comms related to the activities delivered. Ongoing publication of open data sets with focus on highlight an insight offer through the Annual Review of the impact of HTA activities. Increased and targeted use of communication channels such as targeted social media weeks to extend the reach and understanding of the HTA's work						Director of Data, Technology & Development	

Financial risks

Updated by		Katrina Leighton-Hearn					Updated date		August 2025	
Risk name		Failure to be financially sustainable and/or to meet efficiency expectations of the Spending Review and other requirements								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	4	5	20	3	4	12				8
Risk owner	Katrina Leighton-Hearn			Link to strategy	Whole Strategy			Trend since last update		↑
Management commentary - on current live risks	<p>The HTA are facing uncertainty both due to ALB review and the Spending Review (SR). There is also a moratorium in place now for uncommitted spend. The reduction in GIA means that our reliance on variable fee income has increased from around 80% of total income to around 95%. The risk that fee activity will fluctuate from budgeted levels is now greater than in previous years. That, alongside greater variability in inflation, means there is an increased risk of both over and underspend in expenditure.</p> <p>The nature of the regulatory work of the HTA is such that it could attract legal challenge, which in itself will pose a financial risk to the organisation. We have one such legal challenge and our legal costs are expected to be overbudget because of it.</p> <p>The experienced long standing Head of Finance left at the end of June 2025, and the new substantive starts on 1st September.</p> <p>There are potential financial implications stemming from the people strategy.</p> <p>Q1 Finance Forecast is showing a potential overspend of c£300k but sufficient mitigation has taken place and we anticipate that this will be £30k forecast overspend at month 5, with more work ongoing.</p>									
Management commentary - views on mitigation	<p>Director of Finance attends regular DHSC Finance meetings and we have a dedicated Finance Business Partner at DHSC who keeps us abreast of developments particularly around the current SR.</p> <p>Fee model in place and is reviewed periodically. The model gives flexibility around increasing fees where we experience possible future reductions in our grant-in-aid, coupled with the annual financial planning that takes a bottom up approach and includes detailed staff budgeting.</p> <p>An interim Head of Finance is in place to cover until end of September.</p> <p>There are sufficient reserves in place to cover any unforeseen circumstances, in addition to being underwritten by the Department should the HTA find itself in litigation.</p> <p>Have raised the legal pressure with DHSC to ensure the ball in rolling for conversations with Treasury, awaiting form.</p> <p>SMT have discussed the month 4 forecast outturn and agreed a number of mitigating actions.</p> <p>Am discussing our GIA with Dept of Health</p>									
Risk external interdependencies			Control arrangements						Owner	
DHSC - further efficiency pressures on GIA budgets (RDEL and CDEL) DHSC - inability to secure sufficient funding in upcoming Spending Reviews			Budget management framework to control and review spend and take early action when diverging from budget Close engagement with DHSC sponsors and finance, with timely openness about financial position and pressures to allow amendments to budget/access Cash reserves ensure that there are no short or medium term pressures on meeting financial liabilities and would allow sufficient time to approach our sponsor Department to provide cover in extremis. Financial projections, cash flow forecasting and monitoring, good communications between finance and operational teams allows robust financial management. - Robust licence fee modelling and rigorous debt recovery procedure ensures income comes in as expected. - Annual external audit and internal audits of financial processes and control environment to identify weaknesses in procedure. - Horizon scanning for changes to DHSC funding and networking with DHSC and ALB FDs regarding Spending Reviews, etc to ensure we can engage effectively - Fully staffed finance team allows recovery of the debt backlog						Katrina Leighton-Hearn	

Strategy risks

Updated by		Louise Dineley					Updated date		August 2025	
Risk name		We fail to keep pace and adapt to innovation, growth and reform.								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	4	4	16	3	3	9	9	9	At tolerance	
Risk owner	Louise Dineley			Link to strategy	Whole Strategy		Trend since last update			
Management commentary - on current live risks	The start of 2025/26 has already identified a number of areas for potential change including a review of ALBs, regulatory reform, opportunities for digital and tech developments as part of a drive for greater efficiencies and the growth of different areas of life sciences either through emerging technologies or innovations in practice that are not currently regulated. In addition to opportunities for growth and development, the HTA is also preparing for the introduction of the Substances of Human Origins regulations. This level of change is significant and it is essential that the HTA has capacity to engage with the system and contribute to the changing shape of regulation through the lens of safe use of human tissue. The HTA is acutely aware that the phase 2 report from the Fuller Independent Inquiry may make recommendations that inform and makes changes to the management of the deceased across a range of settings (regulated and those not currently regulated). The HTA coordinates its modernisation as part of a phased and prioritised programme. The pace of change at scale to supplement the existing strategic vision will be informed by the Spending Review (June 2025) and any centrally directed wholesale system change.									
Management commentary - views on mitigation	The priorities of the HTA's Strategy 2024-27 set out a strategic vision that embraces, change, innovation and reform, and aims to support the central mission through the framed delivery of its activities. The 4 priorities (approach to regulation; use of information, efficient & effective and trust and confidence) set out an ambition to be realised over the three year period with the support of delivery via the annual business plan. This phased delivery supports continual review and responsiveness to any changes in the landscape or to operating practices. Looking forward we need to consider and promote the wider contribution that the HTA offers to the wider health and life sciences systems, an example of this is the SoHO regulations programme over the next 2 years.									
Risk external interdependencies			Control arrangements						Owner	
Extensive change and reform to the system			Continued engagement and contribution to changes. Use of insight gained through regulation to strengthen the HTA's authoritative voice to proactively and positively inform opportunities for reform and change, whilst continuing to promote and safeguard the existing use of tissues and cells.						Director of Data, Technology & Development	

Updated by		Katrina Leighton-Hearn					Updated date		August 2025	
Risk name		Not having the people we need who are trained properly and well-motivated to do all the things we need to deliver								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	4	5	20	3	4	12	9	9	Above tolerance	
Risk owner	Katrina Leighton-Hearn			Link to strategy	Efficient and effective		Trend since last update		↓	
Management commentary - on current live risks	<p>We currently have 60 employees at the HTA, with approximately half of these in the regulation space.</p> <p>Our current KPI shows stable attrition rates that we hope will come down by the end of the year, suggesting that the work being done is aligning culture to our values - we must also recognise that attrition is also linked to the size of the organisation and the lack of opportunity for advancement.</p> <p>Staff Survey in 2024/25 suggested there were pockets of discontentment in regards to motivation, morale and commitment to the HTA.</p> <p>There is a combined risk with financial sustainability because areas to explore in the people strategy may have financial implications such as training, use of new performance systems and a potential change to the HTA pay structure in 2026.</p>									
Management commentary - views on mitigation	<p>A People Strategy has been written to address all areas of concern, significant work to date has already been undertaken and verbal feedback suggests that we are beginning to influence change in the culture of the organisation. Quarterly reviews will begin to assess impact of changes and start to highlight the areas of most concern that will need to be addressed. The People Strategy will maintain a flexibility to adjust according to priorities.</p> <p>A pulse survey has taken place to test the impact that the work to date has been having on the organisation, and it appears positive.</p>									
Risk external interdependencies			Control arrangements						Owner	
CQC, DHSC			<ul style="list-style-type: none">- Board Approved People Strategy for the period 2025 - 2028 that focuses on valuing and supporting employees to deliver effectively.- Monitoring and reporting of the progress in the implementation of the People Strategy tracking measurable actions [from Q1 2025]- Revision of people policies and procedures that protect staff, including sickness management 2025/26- Strengthen L&D and induction processes to ensure staff are equipped to succeed in their roles [included in People Strategy]- Leavers / handover process formalised via a checklist to ensure corporate knowledge is retained and encourage staff to complete exit interviews- SLA in place with CQC for HR services						Katrina Leighton-Hearn	

Security risks

Updated by		Louise Dineley					Updated date		August 2025	
Risk name		Failure to invest, maintain and use IT systems in line with business needs and security standards could result in a successful cyber attack or data loss								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	4	5	20	2	4	8	9	9	Below tolerance	
Risk owner	Louise Dineley			Link to strategy	Use of information		Trend since last update		↔	
Management commentary - on current live risks	Over the last 12 months the HTA has targeted development activity to strengthen its IT security posture and resilience of its systems to minimise data loss or downtime of our systems. This resilience and reliability is critical for day to day remote working and increasing level of mobile working. The increased and continued threat from cyber attacks means that our systems and controls (policies, processes and people) are subject to continuous improvement and updating. An immediate priority is to ensure our systems are maintained, kept up to date and are supported. Currently there is one system that is not supported although there are plans to replace this in 2025/26. This risk is currently accepted and is being managed locally. The threat posed from cyber crime is increasing and requires controls to be continually reviewed. In addition to focusing on controls we also need to mitigate the potential impact of a successful attack. The impact and disruption to the business and its delivery of effective regulation has the potential to be significant. The speed of any recovery and its completeness determined by continuing exposure to known vulnerabilities, data and information loss.									
Management commentary - views on mitigation	Our Digital and IT Strategy provides a roadmap for achieving the ambition and the required resilience against the risk. The Strategy is a three year strategy with significant progress made in year 1 to provide a foundation for further developments subject to ongoing and planned investment in core systems and interfaces. There are plans in 2025/26 (from Q3 onwards) to start the work to bring any remaining systems back into support . This is expected to extend into 2026/27Q3 onwards). A work programme to strengthen our information and records management is currently being drafted. This will help manage our information and recovery through clear storage and retention protocols. It is anticipated that this programme will commence in late Q2 / early Q3 prioritised to meeting external requirements. Ongoing strengthening of our security performance is part of our commitment to continual improvement. In June we submitted the HTA's assessment against the Cyber Assessment Framework. Our assessment was independently validated in part with an overall positive rating and outcome. In September the HTA will begin its preparation for the 2025/26 CAF									
Risk external interdependencies			Control arrangements						Owner	
Impact of Spending Review on the HTA's ability to maintain an ongoing level of investment			The improvement programme to support continued development of our systems and controls through prioritised an annual investment . Our ambition is one of continual improvement to ensure we remain responsive to the changing presentation of risks and threats. As far as possible cyber security and data loss will be mitigated by secure designs, with the reliance on human behaviours as a last line of defence. Monitoring of our systems and their performance is a standing item at each ARAC meeting with operational reports provided to the Director of DTD on a monthly basis.						Director of Data, Technology & Development	

IMPACT	Risk Scoring Matrix					
	5. Very High	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
	Likelihood					
Risk score = Impact x Likelihood		1. Rare (≤3%)	2. Unlikely (3%-10%)	3. Possible (10%-50%)	4. Likely (50%-90%)	5. Almost certain (≥90%)