HTA Board meeting, 6 March 2025

Agenda item	**2.4 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: Regulation Risk 2: Sector Risk 3: Staff Risk 4: Financial Risk 5: Digital
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

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HTA Performance report

Purpose of paper

1. This paper informs the Board of the HTA's performance in Quarter 3 (Q3) of 24/25 against our objectives and operational delivery targets.

2. In addition, it provides an early indication of the initial performance in Quarter 4 (Q4).

3. Core operational areas from our Business Plan with formal Key Performance Indicators (KPIs) have been included as topics within this paper, in the same order as that document, to allow the Board easy read across. We have also included some additional operational areas for Board visibility of non-KPI performance where there is something noteworthy to highlight. **Annex A** provides the KPI and Project Data Overview for Q3 (final) and **Annex B** gives the KPI and Project Data Overview for Q4 (latest).

4. The current Strategic Risk Register is provided for information at **Annex C**.

Action required

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

Regulation

6. All Regulation KPIs are green with one exception. That is the KPI to reach a decision on 90% of appropriately completed new licence applications by 90 days. This was at 50% in Quarter 2 and 74% for the business year to date on 31 December 2024. For 2025/26, the Executive team is proposing a more meaningful measure that is less skewed by the inherent volatility arising from highly variable small numbers.

7. Of the Regulation-led projects, none are rated red, and all are on track but with some delays.

Policy and Development

8. During Q3, the Policy and Development team continued to lead the HTA's work on preparing for new SoHO (Substances of Human Origin) Regulations. Given the three-year transition period, we are currently in the scoping phase (first phase) and continue to conduct a gap analysis of the Regulations. This enables us to assess any implications for our licensed establishments as well

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as any impacts for the HTA. We also continued to (a) support the Department in its evaluation of whether changes to existing UK legislation may be required and (b) engage with the Department and other relevant regulators, as needed, to discuss and understand the impact of these regulations.

9. Q3 also saw the team develop processes aligned to its core function, including horizon scanning and a framework for developing Memorandums of Understanding (MoUs). For horizon scanning, the team developed a proportionate and strengthened process, which involves identifying, grading, monitoring, and reporting emerging topics that have the potential to impact the HTA and its regulated sectors. The process has received SMT approval and our first annual horizon scanning report that sets out high priority topics accompanies this pack of papers.

10. To ensure the HTA has a consistent approach to establishing and reviewing MoUs, the team developed a framework. This aims to help ensure MoUs play a role in supporting the working relationship between organisations, as well as fostering collaboration – a key theme underpinning our strategy. The framework has received SMT approval and an MoU with the United Kingdom Accreditation Service (UKAS) was updated.

11. The last quarter also saw the Policy and Development team continue to work closely with NHS England and Sands, the baby loss charity, to update the model perinatal post-mortem consent form. The form was published in November 2024 and has been updated to ensure it is in line with current perinatal post-mortem practice and revised guidelines developed by the Royal College of Pathologists.

Communications

12. The Comms team surveyed all establishments receiving over 300 responses and the findings will be used to prioritise engagement activity in 2025/26. Two online forums were delivered during Q3, with a further two in Q4. We also moved two of these to Q1 due to regulation capacity challenges and in order to align with preparation for changes to SoHO (Substances of Human Origin) regulations.

13. Social media performance continues to exceed expectations, with LinkedIn emerging as our strongest platform for stakeholder engagement. Website metrics are surpassing internal targets. During Q3 and Q4 we have been working on enhancing the security of our website. DHSC approved a plan to remove the front end (previously run by Gatsby) and to run both the front and back ends of the website with Drupal as part of the Cyber Improvement Programme. The changes mean the website will remain secure and be more efficient to maintain. However, an issue within the Website comments page which was quickly identified and mitigated, caused an unforeseen issue with the 'Contact Us' form, which resulted in emails being undelivered to the

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enquiries Team. The impact of this is reflected in the KPIs for the Corporate Services Team.

Information Technology

14.   The KPIs remained consistent against previous months. There were no significant outages or incidents that would adversely affect the KPI, showing that systems were available within KPI expectations.

Corporate Services

15.   The KPIs for responding to enquiries and Freedom of Information requests were both being met by the team until December. However, an issue with our website during December and January resulted in a notable number of enquiries coming through to us several weeks late. This was caused by an unforeseen side-effect of the mitigation works referenced above. After the detection of significant levels of incoming SPAM caused by an issue within the website, the public unknowingly were still able to continue submitting enquiries, but these were not delivered to the enquiries team during the 4-week period. The service has been restored (and lessons learned around mapping which services use the same functionality, and developing options to remove functionality, rather than simply blocking incoming traffic), but there is a backlog of incoming contacts for Corporate Services to work through.

16.   This issue has impacted our enquiries and Freedom of Information turnaround times and whilst the team has been working hard to process responses, it is unlikely we will be able to recover green ratings by the end of the year, which is disappointing for everyone involved.

Finance

17.   This report relates to Q3 of the 204/25 financial year and the table below shows our year-to-date position and our forecast for the year ending at 31 March 2025.

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	Cumulative YTD				2024/25			
	Actual	Budget	Variance		Forecast Outturn	Annual Budget	Variance	
	£	£	£	%	£	£	£	%
INCOME								
Grant in Aid including Non-cash	289,935	475,435	(185,500)	-39.02%	344,638	633,913	(289,275)	-45.63%
Licence Fees	5,411,474	5,309,239	102,235	1.93%	5,411,474	5,309,239	102,235	1.93%
Other	44,627	38,912	5,716	14.69%	60,490	51,882	8,608	16.59%
	5,746,036	5,823,585	(77,549)	-1.33%	5,816,602	5,995,034	(178,432)	-2.98%
Staff Costs							0	
Salaries and Wages	3,085,104	3,224,253	(139,149)	-1.25%	4,158,975	4,299,004	(140,029)	-3.26%
Authority Allowances	92,720	104,299	(11,579)	-17.65%	123,878	139,066	(15,188)	-10.92%
	3,177,824	3,328,553	(150,728)	-4.32%	4,282,853	4,438,070	(155,217)	-3.50%
							0	
Non-salary staff costs							0	
Travel and subsistence	157,768	139,426	18,342	13.16%	204,268	173,500	30,768	17.73%
Other Staff costs[1]	45,427	53,154	(7,727)	-14.54%	63,162	70,150	(6,988)	-9.96%
Recuitment	39,156	30,000	9,156	30.52%	53,485	30,000	23,485	78.28%
Training costs	9,941	23,250	(13,309)	-57.24%	18,941	31,000	(12,059)	-38.90%
	252,292	245,830	6,462	2.63%	339,855	304,650	35,205	11.56%
Other Operating costs							0	
Telecommunication	8,499	7,500	999	13.33%	11,049	10,000	1,049	10.49%
ICT Development[2]	246,897	306,750	(59,853)	-19.51%	335,647	409,000	(73,353)	-17.93%
Legal and Professional (Legal, audit)	110,191	124,875	(14,684)	-11.76%	163,523	166,501	(2,978)	-1.79%
Communications costs	94,703	57,488	37,215	64.74%	105,895	60,500	45,395	75.03%
Living Organ Donation costs	352	1,000	(648)	-64.80%	352	9,000	(8,648)	-96.09%
Shared Service/NHSBT/Projects	109,975	258,375	(148,400)	-57.44%	146,100	294,500	(148,400)	-50.39%
Administration costs	11,170	9,875	1,295	13.11%	13,149	11,500	1,649	14.34%
Accommodation costs	178,246	118,634	59,612	50.25%	167,863	165,000	2,863	1.73%
Non-cash costs	95,136	94,735	402	0.42%	127,912	126,313	1,599	1.27%
	855,170	979,232	(124,062)	-12.67%	1,071,489	1,252,314	(180,825)	-14.44%
Total expenditure	4,285,285	4,553,614	(268,328)	-5.89%	5,694,198	5,995,034	(300,836)	-5.02%
Net surplus/(deficit)	**1,460,750**	**1,269,971**	**190,779**	**15.02%**	**122,404**	**(0)**	**122,404**	

[1]Other Staff costs (all-staff days, subscriptions, conferences, welfare)
[2]ICT Development (including IT Subscriptions, Maintenance, Consultancy)

Below are the explanations for significant variances.

18. **Income** - year to date is under budget by £78k and is represented by grant in aid of £200k which is £185k less than budgeted. A further £100k will be drawn down in February which will be our final tranche. The remainder we agreed to return to centre as part of the savings exercise. The balance of £89k is non-cash income which covers the depreciation/amortisation of our assets.

19. Our licence fee income is above budget by £99k the bulk of which relates to application fees (£86k) which are difficult to budget for and income from HA licences (£44k); these are offset by reductions in three of the four sectors.

20. **Expenditure** – year to date, expenditure is under budget by £268k. Below are explanations for the significant variances to budget.

- Staff costs were underspent by £1,514k which related mainly to on-costs (PAYE and pensions). The budget was set assuming all staff would be in

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the scheme, but the reality is that at least 10 members of staff opted out. There were posts at manager level that were unfilled for a period which has also impacted this variance.

- Non-salary staff costs – are underspent by £8k. Within this variance are underspends within Awayday (£8k) and Venue Hire (£5k). Against this are overspends within other areas such as Staff Welfare (£6k). The balance being smaller overspends across several cost lines.
- Recruitment costs – are over budget by £9k. This reflects the recent appointments made.
- Training costs – underspent by £13k, however there are plans to spend a further £9k in Q4 (see forecast).
- ICT Development – underspent by £60k represented by maintenance costs £37k and General IT consultancy £30k. It is not expected that this position will change in Q4 unless an unplanned event requires a technical consultant.
- Legal and Professional – are also underspending with the majority within legal fees. It is expected that legal costs may increase due to a recent development within the living organ donation sphere. Our audit fees remain in line with last year.
- Shared Services and projects – the significant underspend is due to costs related to the CRM upgrade being categorised as revenue during budget setting but will in fact be capitalised on completion (February or March 2025).
- Accommodation costs – are over budget by £60k which is represented by rent costs that will eventually be capitalised which is necessary under the accounting standard IFRS 16 – accounting for leases.

21. **Forecast** – we are forecasting a surplus of £122k before any accounting adjustments such as IFRS 16 and any write-off of uncollectable debt or increase in our provision.

22. **Position as of January 2025** – as of month 10, our income is under budget by £103k which largely due to the grant in aid which we will not draw down. Total expenditure is under budget by £287k which is a small change from Q2.

23. **Debtors at 31 December 2024** – our debtors at the end of December 2024 were £688k down 81% from September 2024 (£3,597k) but 39% higher than the same period last year. The closing debtors are represented by 140 transactions. A breakdown of total debts by sector compared to 2023/24 is below.

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	2024/25			2023/24		
Sector	No. of est	Value	%	No. of est	Value	%
NHS	67	£391,304	59%	36	£266,183	54%
Government bodies	2	£10,077	1%	5	£45,250	9%
Non-Government bodies	71	£266,732	40%	32	£185,146	37%
Total	**140**	**£668,113**		**73**	**£496,539**	

24. Of the 2024/25 debts, £158k (29 invoices) were due before March 2024. The breakdown by sector is below:

- 12 totalling £45k are NHS
- 17 totalling £113k are Non-NHS

25. Within those outstanding debts that are older than a year there are 12 establishments whose debt will need to be written off for the reasons below:

- 1 Ceased trading
- 2 Dissolved
- 6 have gone into liquidation
- 3 are in administration

26. The 12 total £88k, our current provision is sufficient to cover these and a further review will be conducted in April to establish if our provision should be increased.

Audit and Risk

27. SMT reviewed the Strategic Risk Register at its meeting in December. There were no changes to the residual risk scores. A summary was presented to ARAC in February. The latest version of the HTA's Strategic Risk Register is provided at **Annex C**.

28. The KPI relating to our spend where the target of 1% has been exceeded (5%) is low risk, however, our year end position subject to audit adjustments, may push this a little higher. This however does not impact on the HTAs working capital or cash reserves.

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Human Resources

29. As at 31st January 2025, the annualised staff turnover rate was 26.3%. This continues to be above the 20% KPI. The People Strategy and the incoming HR appointment will be working to address the underlying causes

30. Staff sickness absence was 2%, below the 3% KPI.

Health and Safety

31. As part of Business Planning for 25/26 we have now developed a formal KPI for Health and Safey that we will include in future iterations of this Performance Report: 100% of 'reportable incidents' reported to HSE (Health and Safety Executive) within 10 working days [reported quarterly].

32. As previously reported to Board, we anticipate supplementing this metric with commentary around our activities to manage this important topic. There were no reportable H&S incidents in Q3.

Quarter 4 early insights

33. Details of early Q4 performance are given at **Annex B**:

34. Current overall Business Plan **RAG** rating is **Green**:

35. Core operations: All our KPIs are currently being achieved with three exceptions areas, which are: 1) new licence applications receiving a decision, for which the % is skewed by low numbers; 2) spend within forecast and attrition rate which are both consistent with the performance in previous quarters, and 3) the timeliness of responses to enquiries and Freedom of Information requests, due to a website problem which arose in December / January. The issue has been rectified but it resulted in a backlog of contacts coming through to at the end of Q3 and beginning of Q4.

35. Change activities: *must-do* projects are all on track to deliver / complete as expected by year-end. We have moved the work to review our records management back to 25/26 (under core operations) due to delayed recruitment to the technical Records Management Information Governance Lead role. We continue to engage with the additional project regarding Substances of Human Origin legislation, that we brought online mid-year.

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Recommendation

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

Annex A – Quarterly Board Data Overview, 24/25 Quarter 3 Final Position
Core Operations

Business Plan KPIs

6 On Track	**2** At Risk	**3** Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	24/24 YTD	
	Approach to Regulation											
Regulation	222 compliance assessments across all sectors [reported quarterly against planned allocation]	Reported Quarterly	67	Reported Quarterly	55	Reported Quarterly	57	179	
	99% of panel and non-panel cases actioned within 10 and 5 working days respectively [reported monthly]	100%	100%	100%	100%	100%	100%	99%	100%	100%	100%	
	Support healthcare provision and life-sciences by decisions being reached on 90% of completed new licence applications within 90 days of the application fee being paid [reported quarterly]	Reported Quarterly	80%	Reported Quarterly	50%	Reported Quarterly	71%	74%	
	Trust and Confidence											
DTD	Publish two datasets per year [reported annually]	Reported Annually										
	Publish quarterly incidents data [reported annually]	100%	Reported Annually								100%	
	Use of Information											
DTD	Server downtime less than 3% (within working hours and excluding planned testing) [reported monthly]	0%	0.1%	1.9%	0%	0%	0%	0%	0.5%	0.01%	0.01%	
	100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours [reported monthly]	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	

YTD CALCULATION	
	CUMULATIVE
	AVERAGE
	LATEST MONTH

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Business Plan KPIs

	6 On Track	2 At Risk	3 Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	24/24 YTD	
Efficient and Effective												
Perf & Corp Gov	95% of enquiries are answered within 10 working days [reported monthly]*	99%	89.6%	91.8%	96.0%	97.3%	96.5%	97.4%	96.5%	74.7%	93.2%	
	100% of FOIs responded to within 20 working days [reported quarterly]*	Reported Quarterly		100%	Reported Quarterly		100%	Reported Quarterly		83.3%	98.2%	
Resources	Actual spend within 1% of forecast [reported quarterly]	Reported Quarterly		4%	Reported Quarterly		11%	Reported Quarterly		5%	5%	
	Debt no more than 3% of income at year end [reported annually]	Reported Annually										
	Unqualified external audit opinion received [reported annually]	Reported Annually										
	Attrition rate no more than 20% [reported monthly]	31.4%	33.3%	29.7%	34.5%	33.9%	30.4%	28.6%	27.8%	26.3%	26.3%	
	Staff sickness no more than 3% [reported monthly] **	2%	2.2%	2.4%	2.1%	2.4%	1.8%	1.7%	2.5%	1.8%	1.8%	

* Performance for December has been restated

** Performance for November and December has been restated

YTD CALCULATION	
	CUMULATIVE
	AVERAGE
	LATEST MONTH

Change Activities

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Project Summary Status – Overall RAG Heatmap for *Board Review*

Project	Sponsor	Oct 24	Nov 24	Dec 24	Commentary for Board Review
Fuller Independent Inquiry [Must do]	Nicky Harrison	A	A	A	Live work packages - continue to maintain, respond and support as required *[Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations]*
Innovation in inspection [Should do]	Nicky Harrison	A	A	A	Workstream 'Security Standards' focused on PM sector, in-play: rolling out activities aligned to outlined security enforcement strategy and piloting evidence -based assurance programme *[Project expected to run into 25/26]*
Substances of Human Origin [Must do]	Louise Dineley	W	A	A	The Project Team are undertaking the SoHO gap analysis to produce a response for SaBTO by the end of March 2025. This gap analysis will also form the foundation work required for phase two of the Project, including forming the supporting documentation and groups *[Project expected to run into 25/26]*
Public Bodies Review [Must do** if notified]	Louise Dineley	W	W	W	Not started *[Start Date N/A]*
Facilitate an in-person event [Must do]	Louise Dineley	C	C	C	Project completed
Establish a horizon scanning and insight process [Could do]	Louise Dineley	G	G	G	Following a review of previous horizon logs, consultation with Heads of Regulation and Comms, and review of media/literature a list of horizon topics has been created. In the creation of the Board paper due to be presented at the March Board meeting, this list will be prioritised and shortlisted. *[Project expected to complete in 24/25]*
Publish a 2023/24 review [Must do]	Louise Dineley	C	C	C	Project completed
Data and Technology strategy [Must do]	Louise Dineley	C	C	C	Project completed

Activities

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Project Summary Status – Overall RAG Heatmap for *Board Review*

	Project	Sponsor	Oct 24	Nov 24	Dec 24	Commentary for Board Review
Activities	Complete backlog updates to CRM *[Must do]*	Louise Dineley	G	G	G	BCC have been asked to provide a concise breakdown of the works required. Project Initiation Document approved. BCC provided with Purchase Order and work has started *[Project expected to complete in 24/25]*
	Regulatory Insight Model and Index *[Must do]*	Louise Dineley	A	A	G	Trustmarque have been awarded the contract to develop an incremental RIMI Service Catalogue and a User Guide starting from 06 Jan 25Work has progressed in readiness for UAT commencing 13 Jan 25, ahead of the RIMI pilot *[Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations]*
	Review records management *[Should do]*	Louise Dineley	W	W	W	Not started *[Start Date Jan 24, slipped – Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations]*
	Replace our current finance system *[Should do]*	Katrina Leighton-Hearn	W	W	W	Not started *[Removed from 24/25 – Project expected to be progressed in 25/26]*
	Outsource of Human Resources *[Must do]*	Katrina Leighton-Hearn	G	G	G	HR was effectively outsourced as per the SLA between HTA and CQC as at April 2024. The relationship is now BAU, but there remains some work to drive improvements in the HR service and close / complete the Project governance *[Project expected to complete in 24/25]*
	Develop a People strategy *[Must do]*	Katrina Leighton-Hearn	G	G	A	Delivered themed workshops for the People Strategy strands *[Project expected to complete in 24/25]*
All	Project delivery	All SMT	G	G	G	Broadly on track to deliver all *must do* items as planned

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<u>Annex B</u> – Quarterly Board Data Overview, 24/25 Quarter 4 Latest Position

Core Operations

Business Plan KPIs

	6 On Track	1 At Risk	3 Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	24/25 YTD	
Approach to Regulation													
Regulation	222 compliance assessments across all sectors [reported quarterly against planned allocation]	Reported Quarterly		67	Reported Quarterly		55	Reported Quarterly		57		179	
	99% of panel and non-panel cases actioned within 10 and 5 working days respectively [reported monthly]	100%	100%	100%	100%	100%	100%	99%	100%	100%	100%	100%	
	Support healthcare provision and life-sciences by decisions being reached on 90% of completed new licence applications within 90 days of the application fee being paid [reported quarterly]	Reported Quarterly		80%	Reported Quarterly		50%	Reported Quarterly		71%		74%	
Trust and Confidence													
DTD	Publish two datasets per year [reported annually]	Reported Annually											
	Publish quarterly incidents data [reported annually]	100%	Reported Annually									100%	
Use of Information													
DTD	Server downtime less than 3% (within working hours and excluding planned testing) [reported monthly]	0%	0.1%	1.9%	0%	0%	0%	0%	0.5%	0.01%	0.04%	0.04%	
	100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours [reported monthly]	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	

YTD CALCULATION
CUMULATIVE
AVERAGE
LATEST MONTH

Business Plan KPIs

6 On Track	1 At Risk	3 Off Track

		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	24/25 YTD	
Efficient and Effective													
Perf & Corp Gov	95% of enquiries are answered within 10 working days [reported monthly] *	99%	89.6%	91.8%	96.0%	97.3%	96.5%	97.4%	96.5%	74.7%*	Awaiting Data	TBC	
	100% of FOIs responded to within 20 working days [reported quarterly] *	Reported Quarterly		100%	Reported Quarterly		100%	Reported Quarterly		83.3%*		98.3%	
Resources	Actual spend within 1% of forecast [reported quarterly]	Reported Quarterly		4%	Reported Quarterly		11%	Reported Quarterly		5%		5%	
	Debt no more than 3% of income at year end [reported annually]	Reported Annually											
	Unqualified external audit opinion received [reported annually]	Reported Annually											
	Attrition rate no more than 20% [reported monthly]	31.4%	33.3%	29.7%	34.5%	33.9%	30.4%	28.6%	27.8%	26.3%	25%	25%	
	Staff sickness no more than 3% [reported monthly] *	2%	2.2%	2.4%	2.1%	2.4%	1.8%	1.7%	2.5%	1.8%*	1.9%	1.9%	

YTD CALCULATION
CUMULATIVE
AVERAGE
LATEST MONTH

*Restated for Dec

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Project Summary Status – Overall RAG Heatmap for *Board Review*

	Project	Sponsor	Nov 24	Dec 24	Jan 25	Commentary for Board Review
Activities	Fuller Independent Inquiry [Must do]	Nicky Harrison	A	A	A	Live work packages - continue to maintain, respond and support as required *[Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations].*
	Innovation in inspection [Should do]	Nicky Harrison	A	A	A	Workstream 'Security Standards' focused on PM sector, in-play: rolling out activities aligned to outlined security enforcement strategy and piloting evidence -based assurance programme *[Project expected to run into 25/26]*
	Substances of Human Origin [Must do]	Louise Dineley	A	A	A	The Project Team are undertaking the SoHO gap analysis to produce a response for SaBTO by the end of March 2025. This gap analysis will also form the foundation work required for phase two of the Project, including forming the supporting documentation and groups *[Project expected to run into 25/26].*
	Public Bodies Review [Must do** if notified]	Louise Dineley	W	W	W	Not started *[Start Date N/A].*
	Facilitate an in-person event [Must do]	Louise Dineley	C	C	C	Project completed
	Establish a horizon scanning and insight process [Could do]	Louise Dineley	G	G	A	Following a review of previous horizon logs, consultation with Heads of Regulation and Comms, and review of media/literature a list of horizon topics has been created. In the creation of the Board paper due to be presented at the March Board meeting, this list will be prioritised and shortlisted *[Project expected to complete in 24/25].*
	Publish a 2023/24 review [Must do]	Louise Dineley	C	C	C	Project completed
	Data and Technology strategy [Must do]	Louise Dineley	C	C	C	Project completed

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Project Summary Status – Overall RAG Heatmap for *Board Review*

	Project	Sponsor	Nov 24	Dec 24	Jan 25	Commentary for Board Review
Activities	Complete backlog updates to CRM *[Must do]*	Louise Dineley	G	G	G	BCC have been asked to provide a concise breakdown of the works required. Project Initiation Document approved. BCC provided with Purchase Order and work has started *[Project expected to complete in 24/25]*
	Regulatory Insight Model and Index *[Must do]*	Louise Dineley	A	G	G	Trustmarque have been awarded the contract to develop an incremental RIMI Service Catalogue and a User Guide starting from 06 Jan 25Work has progressed in readiness for UAT commencing 13 Jan 25, ahead of the RIMI pilot *[Project expected to complete in 24/25, but work will continue into 25/26 as part of core operations]*
	Review records management *[Should do]*	Louise Dineley	W	W	W	Not started *[Removed from 24/25 – Project expected to be progressed in 25/26 as part of core operations]*
	Replace our current finance system *[Should do]*	Katrina Leighton-Hearn	W	W	W	Not started *[Removed from 24/25 – Project expected to be progressed in 25/26]*
	Outsource of Human Resources *[Must do]*	Katrina Leighton-Hearn	G	G	C	Project completed
	Develop a People strategy *[Must do]*	Katrina Leighton-Hearn	G	A	G	Project is on track to deliver as expected – final output to be approved by Board in March *[Project expected to complete in 24/25]*
All	Project delivery	All SMT	G	G	G	Broadly on track to deliver all *must do* items as planned.

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HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the HTA Board meeting

HTA 04-25

Category	Red	Amber	Green
KPI / PI	• If performance is >10% below target	• If performance is = 1%-10% of target	• If performance is = target

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

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HTA 04-25 ANNEX C - STRATEGIC RISK REGISTER

1 Regulation risk

Updated by	Nicolette Harrison						Updated date		27/02/2025	
Risk name	**Risk 1: Notable regulation failure leading to public harm and/or loss of public/professional confidence in the HTA**									

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		↔

Cause	- Failure to identify notable regulatory non-compliance - Regulation is not transparent, accountable, proportionate, consistent and targeted - Regulation is not sufficiently agile to respond to changes in sectors - Insufficient capacity and/or capability. This includes insufficient expertise, reductions in staffing from attrition, inadequate contingency planning, recruitment difficulties (including Independent Assessors [IAs]), inadequate adherence to agreed policies and procedures (especially in relation to decision-making)) - Poor quality or out of date policies and procedures - Failure to fully follow-up on identified risks and issues - Inability to access relevant technical expertise; for example, to support the assessment of regulated activities or premises
Effect	- Patient safety compromised - Loss of public confidence - Loss of professional confidence - Loss of trust and respect from people in regulated sectors, potentially leading to greater non-compliance and challenging of decisions - Reputational damage - Technical regulatory decisions re process or risk management that turn out to be incorrect
Existing controls	- Regulatory model that provides a range of proactive and targeted regulatory assessments - Well-established processes supporting our core business; Regulatory decision-making framework including police referral policy and process - Range of assessment models to support sector-specific inspection approaches that can be adapted quickly according to risk - Training and development: Structured induction for new staff; Directorate training / away days; Regulation budget includes provision for conference attendance and staff training - Specialist expertise identified and recruited to ensure a broad range of knowledge across sectors and developing areas - In exceptional circumstances, scope for limited reallocation of resource to priority areas - Access to specialist legal advice for novel or complex matters
Actions to improve mitigation	Although this risk is currently at a tolerable level, the following actions have been identified as ways of bringing the residual risk level closer to optimal. 1. Invest resource in cross-organisational work to develop operational policy positions on new or complex areas eg new SoHO Regulations [CURRENTLY PAUSED] 2. Establish HTA Insight Network to facilitate horizon scanning [CURRENTLY UNDER DISCUSSION] 3. Identify and establish HTA access to suitable expert groups to assist with advice on complex PPD authorisations and SAEARs/HTARI cases [CURRENTLY PAUSED] 4. HTA to reconvene internal Quality Forum meetings and associated processes for governance document review [COMPLETE] 5. Undertake a critical evaluation of the activities aimed at strengthening the Living Organ Donation approval process over the past couple of years to assess their effectiveness and impact. [FOR 2025/26 BUSINESS PLAN]
Owners / Status	Nicolette Harrison

2 Sector risk

Updated by	Nicolette Harrison						Updated date	27/02/2025	
Risk name	**Risk 2: Misperception of the HTA's role and reach or poor external relationships leading to gaps in sectoral risk management**								

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	4	8	**At tolerance**

Risk owner	Nicolette Harrison	Link to strategy	Trust & confidence	Trend since last update	↔

Cause	- Low levels of not approving proposed LOD cases may lead to a risk that the framework, or HTA's operation of the framework, is ineffective [NEW] - Complex regulatory landscape creates risk of misperception of the HTA's role and remit and challenges in managing regulatory intersections - HTA's formal regulatory framework, including legislation, may not keep pace with sector developments and so may not be able to effectively manage emerging risks - Lack of clarity about changes in responsibilities e.g. following any legislative changes - Lack of HTA insight into broader pressures and issues affecting our sectors that may be indicators of new or emerging risks - Lack of suitable engagement or information or intelligence-sharing mechanisms between the HTA and other regulators, relevant agencies or law enforcement impedes the HTA's ability to share and escalate concerns or to refer concerns or issues to other more appropriate agencies, where relevant
Effect	- Diminished professional confidence in the adequacy of the legislation and/or the regulatory framework operated by HTA - Reduced public confidence in regulation of matters relating to human tissue - Reputational damage
Existing controls	- Horizon scanning process; Communications and Engagement Strategy; Formal and informal engagement with, and feedback from, our sectors and stakeholders - Effective management of HTA's public profile to maintain awareness and professionalism and deal with media enquiries, including developing HTA lines and positions - Active management of professional stakeholders, in our sectors, other bodies, other Government Departments and Devolved Administrations, including providing advice - Regular engagement with DHSC sponsorship team and Substances of Human Origin (SoHO) team on matters which might impact public and professional confidence - Identifying and taking action on issues where we believe these will support public and professional confidence - HTA representation on relevant multi-agency groups and forums, including particularly those dealing with new and emerging issues or innovative practice - Maintaining and utilising existing Memoranda of Understanding (MOUs) and Information Sharing Agreements with other relevant bodies e.g. other regulators - Maintaining, utilising and periodically updating relevant HTA policies and processes (e.g. the Police Referral and Warrants Policy)
Actions to improve mitigation	Although this risk is currently at a tolerable level, the following actions have been identified as ways of bringing the residual risk level closer to optimal. 1. Undertake a programme of wider awareness-raising activities following the sentencing of private healthcare group for licensing breach in 2023/24 [CURRENTLY PAUSED] 2. Review and update existing Memoranda of Understanding (MOUs) and Information Sharing Agreements (ISAs), especially with CQC and other health regulators [IN PROGRESS] 3. Join the NHSE-led 'Mortuary Oversight Group' as an observer [COMPLETE] 4. Join the Health and Social Care Regulators Forum and Emerging Concerns Protocol [COMPLETE] 5. Revise the HTA's horizon scanning processes to ensure they are fit for purpose and proportionate [IN PROGRESS] 6. Business Plan for 2025/26 to include a repeat of the publication of an HTA Annual Review of 2024/25 and a stakeholder event [IN PROGRESS] 7. Business Plan for 2025/26 to include an intention to further strengthen the LOD approvals process [INCLUDED IN 2025/26 DRAFT BUSINESS PLAN].
Owners / Status	Nicolette Harrison

3 Staff risk

Updated by	Kate Towner					Updated date		27/02/2025		
Risk name	Risk 3: Inability to progress core activities due to insufficient staff capacity and capability to deliver organisational goals									

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**	4	4	**16**	**9**		**9**		**Above tolerance**
Risk owner	Katrina Leighton-Hearn		Link to strategy	Efficient & effective			Trend since last update				↔

Cause	- General high staff turnover putting recruitment pressure on managers and capacity pressures on broader teams to cover gaps - Turnover of staff in key roles that are 'single points of failure', leading to gaps in essential capability - Poor leadership and line management practices, including unclear objectives. Also poor job design and recruitment techniques and/or poor support from HR. - Poor prioritisation or insufficiency of resources - Poor H&S and risk assessment and monitoring of staff safety - Insufficient focus on staff culture or health and well-being due to lack of resource or SMT/CEO focus to organise and support effectively
Effect	- Lack of key expertise leading to organisational inability to deliver key objectives or to effectively manage risk - Insufficient staff capacity to manage the extent of the HTA's core duties and corporate responsibilities. - Poor deployment of staff leading to inefficient working and increasingly pressured staff leading to further loss of staff - Reduction in staff resilience, or inability to protect staff in the workplace, leading to sickness absence and staff loss. Poor advice from HR not resolving issues. - Poor culture and engagement and general lack of motivation amongst staff; HTA becomes a less attractive place to work.
Existing controls	- Recruitment to vacancies and skills gaps ongoing, with use of agencies where needed. Good engagement with HR on JDs and recruitment approach. - Prioritisation of organisational tasks and objectives to ensure pinch points are recognised and staff not overloaded, including reducing workloads where necessary - Creation by teams of SOPs and clear role descriptions for quick induction of staff on recruitment or whilst covering roles due to absence. Cross-team training. - Development of a staff forum to support networking and a focus on social / organisation culture and to have a stronger staff voice in the organisation. [Q2 2024] - Staff survey and review of HR MI to ensure there is a clearer senior understanding of staffs' feelings and situations [Q2 2024] - Revision of people policies and procedures that protect staff -Health and Safety, risk assessments completed [Q3 2024]
Actions to improve mitigation	- People Strategy for the period 2025 - 2028, starting with the staff survey, that focuses on valuing and supporting employees to deliver effectively. Final report to the Board 6 March 2025 [Q4 2024] - Monitoring of the implementation of the People Strategy tracking measurable actions [from Q1 2025] - Revision of people policies and procedures that protect staff, including sickness management [throughout 2024/25 and 2025/26] - Development of the HTA leadership team and managers, and improvements to how we manage performance. [Ongoing] - 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 [throughout 24/25]
Owners	Katrina Leighton-Hearn, SMT, BDT

4 Financial risk

Updated by	Kate Towner			Updated date		27/02/2025	
Risk name	Risk 4: There is a risk that the HTA has insufficient or ineffective management of its financial resources						

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**	2	3	**6**	**6**	**9**	**Below tolerance**
Risk owner	Katrina Leighton-Hearn		Link to strategy	Efficient & effective		Trend since last update			↑

Cause	- Under-recovery of income / poor debt recovery (including regulated establishment inability to pay) or inability to forecast variable income accurately - Failure in setting a robust operating budget or to effectively prioritise work and / or manage costs / efficiencies - Unexpected significant cost pressures (e.g. legal, urgent infrastructure investment, etc) or budget change requests from DHSC or HMT arising in year - Inability to robustly control expenditure / manage operating budgets or failure to adhere to HMT and Cabinet Office Standards (finance and commercial) - System of control unable to prevent fraud / error or adapt to new risks - Insufficient finance resource to manage transactions or support sound financial management / finance system no longer fit for purpose
Effect	- Late or non-payment of HTA debt leading to reputational damage / pressures on suppliers / staff - Resources lost due to fraud, error or avoidable fees/charges - Inability to stay within budget leading to leading to the need to stop work or to lose the confidence of DHSC. - Inability to manage costs over the longer term leading to unreasonable increases in licence fees or requests for further public funding. - Reputational risk to the Accounting Officer, increased scrutiny (including the PAC) and difficulties in gaining business case approval
Existing controls	- 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 reserves. - 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
Actions to improve mitigation	- Improved internal financial monitoring and management and teach-ins for SMT, including a focus on resource use. [Q3 2024] moved to [Q2 2025] - Action plan to move from rudimentary to basic level of maturity on the GovS:013 Counter Fraud Functional Standards [throughout 2024/25] - Develop plans to improve structure, systems and processes across HTA and HFEA finance teams to improve efficiency and staff development [throughout 2024/25 and 2025/26] - Focus on financial and commercial skills and awareness of HTA managers. [throughout 2024/25 and beyond]
Owners	Katrina Leighton-Hearn, Colin Sullivan (AO)

5 Digital risk

Updated by	Louise Dineley			Updated date	27/02/2025	
Risk name	**Risk 5: Failure to make use of available data, digital and technology to ensure systems are kept up to date and support the delivery of business activities.**					

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	5	4	**20**	2	4	**8**	**9**	**9**	**Below tolerance**

Risk owner	Louise Dineley	Link to strategy	Use of Information	Trend since last update	↔

Cause	- Core systems identified as either approaching or out of support in the event of an incident - Data management is inconsistent across the business limiting opportunities to optimise and make use of information and intelligence. - Ageing business technology systems that have evolved rather than be designed limit alignment to business needs and / or opportunities for digital developments. - Staff confidence and capability in data and digital services can limit developments - Cyber Security changes in compliance requirements and standards not aligned to business capabilities - Knowledge and intellectual property of HTA systems is held by third party supplier - Inconsistency in data and information management practices is a limiting factor in our ability to make better use of information held.
Effect	- IT breach and/or loss of sensitive data - Increased risk of system and process vulnerabilities being exploited by third parties resulting in restricted access or system failure - Loss of core IT systems required by HTA staff to deliver their work - Options that make use of existing technology and digital developments need to be adopted to address inefficient ways of working and reduce manual work-arounds - Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed - Reliance on manual processes and single points of contact to bridge digital gaps - Large volume of data and records held beyond designated retention schedules impacting on storage, records management, data quality and information governance - Digital ambition such as the use or consideration of AI in regulated activities is constrained and / or not understood to determine compliance with standards - Limited internal resourcing capacity risks maintaining a reliance on third party supplier support
Existing controls	- Polices, processes and practices covering all aspects of system security and data management have been reviewed, revised and or updated on a 12 month schedule. - Data relating to establishments securely stored with the Customer Relationship Management System (CRM) - Appropriate procedures to manage personal data including GDPR compliance. - Staff training in key business systems and mandatory annual training on policies and required controls - Training and development of professional competence part of annual PDPs and performance reviews - IT systems protected and assurances received from 3rd party suppliers that protection is up to date - System performance analytics available and reported monthly - Business Planning to map out anticipated Information Technology and Data work and Portfolio Management to track / support / report delivery for example 2024/25 Business plans and identified projects covering updates and data development (including AI) - Ongoing knowledge gathering and transfer from third party suppliers and wider health system partners - Compliance with DSPT 2024 assessment and forward look to Cyber Assessment Framework
Actions to improve mitigation	- Agreed Digital and IT Strategy 2024-27 sets the direction of travel through a defined vision, mission and priorities. - Plans in place to communicate and embed the strategy from early Q2 2024/25.These priorities will inform projects delivered through the annual business planning process to drive change, improvement and identify opportunities to strengthen and or / exploit the use of current systems and data holdings. - Priorities identified for 2024/25 aim to establish a strong foundation through supported systems, resourcing and developments to strengthen future digital capacity and capability. These include: CRM update (phase 2) - Q4 2024/25. Status: On track, UAT scheduled; Pilot of AI - Q3 & 4 2024/25. Status: On track; RIMI - initial build to agreed indicators Q4 2024/25. Status : On track for a mvp. UAT completed and preparing for "go live"; Data publications - Q2 2024/25 and Q4 2024/25. Status: Q2 completed, preparing for Q4 publication. - The increased and continued threat posed through cyber security is key under continual review with formal assurance reported on a quarterly basis. Reports to ARAC -Mitigation of the risk through controls and actions is dependent on an ongoing commitment and prioritisation of resources relative to the risk. It is anticipated that the risk will move to within tolerance on commencement and progress of the CRM update in Q3 that is underway. B15
Owners	Louise Dineley 27/2/2025

Tolerance movement

This dashboard provides a trend in changes in risk and tolerance

Team	Tolerance (June-24)	Oct-24	Nov-24
Regulation	8	⟷	⟷
Sector	8	⟷	⟷
Staff	9	⟷	⟷
Financial	9	⬆	⟷
Digital	9	⟷	⟷