1. Background

The Board Assurance Framework (BAF) is a document demonstrating the link between strategy, risk and assurance and is a tool for the Board to hold the organisation to account and gain assurance that the organisation can meet its objectives.

Risks 5A and 5B were discussed at the last Board and discussions with the Assistant Director of Finance have taken place and an action plan to manage these risks has been agreed.

It was agreed that many of the risks outlined in the discussion document were operational, and these will be discussed between a Risk Manager, the Risk Lead for Finance and the Risk Lead for the relevant operational area. So, the financial risk, which is a risk to the operational activity, will be owned within the relevant operating area impacted by that risk, but Finance will be able to oversee these risks.

Some of the risks were, however, considered strategic such as the cross subsidy for Organ Donation, which is contrary to managing public money guidance, and could affect the strategic delivery of both organ donation activity and blood supply, from where the bulk of the cross subsidy is drawn.

2. Update on BAF Risks

Risk 01 (Donor and Patient harm) has increased from a score of 12 to 16. This is associated with TAS-23, lack of digital systems (Therapeutic Apheresis Services). Notes regarding the increase include using a paper-based system, deciphering handwriting, billing errors, ability to print documents, access to clinical documents, data breaches, transcription errors, failure to identify allergy, blood group mistype and inability to measure patient outcomes. This risk needs to be reviewed as it has an inherent score of 12 (suggesting that controls have made the risk worse) and has no target score.

Risk 02a (Internal Disruption) has two risks scoring in the Risk Limit (reduced from three) – TAS-08 (TAS staffing) and DDTS-LSTS-010 (OTDT Critical Services Availability and Resilience). The other risk previously recorded was DDTS-LSTS-011 (Insufficient Technology Services resources). This risk was reviewed 12 January 2023 and the score reduced from 15 down to 12. This was a decision to reduce the likelihood down to a 4. This risk is now in the Judgement Zone and no longer at the Risk Limit.

Risk 03 (Scale and Pace of Change) has increased due to a review of risk PFM-02 (HAV / B19 Sample Screening Time Limit) increasing its score to 15. This is due to delays caused by the failure to appoint a test house; it is almost certain a solution will not be in place before the first samples expire. Focus is now on testing 'in house' and work is ongoing to implement this by July 2023.

Risk 08 (Management Capacity) was increased (although still in the Judgement Zone) 2 February 2023 following a review with People SLT.

3. Risks and Issues for Attention

The last Board Assurance Framework paper highlighted issues concerning the IT infrastructure around Stoke Gifford. An issue has been raised regarding fixed wire testing in the same site. Fixed wire testing is an essential part of maintaining a safe electrical system which is a requirement under the Electricity at work regulations 1989. Failure to test the system increases the risk of fault and therefore fire. Testing the system requires a site-wide power shut-down, which increases the risk of IT failure. A group is being pulled together to advise on the best course of action.

A national alert to NHS organisations regarding reinforced autoclaved aerated concrete (RAAC), which has a lifespan of ~30 years, has resulted in an audit of NHSBT estate. The Southampton site

was surveyed by Kennedy Redford on 10th January 2023, and the report identified that a section of our building was constructed using RAAC planks. A structural Surveyor has been asked to provide a fee bid for a new report, to undertake a full intrusive survey and ascertain the overall condition of the roof. There are several original rooflight openings within the existing RAAC, which have been borded over, these will need to be investigated by the Engineer to determine whether they impact on the integrity of the roof. A short-term issue about accessing the roof to repair air handling units has been resolved by a plan to use scaffolding such that engineers will not have to use the roof for support. The RAAC will need to be replaced, the timing of the replacement again should be based on the new report that the Structural Engineer will prepare. This will impact on the delivery of Hospital Services and Stem Cell services from the Southampton site.

4. Conclusion and Next Steps

The Board seminar on risk management is awaiting dates. The risk team continues to rationalise the links between child and parent risks, and aligning risk by strategic, operational and compliance groupings. To move forward the team will:

- Engage with work undertaken by the General Counsel, Company Secretary and their team on governance, to ensure that risk flow though governance committees to Board is comprehensive and robust.
- Work with the Finance risk lead and operational risk leads to appropriately align operational risk with financial causes.
- Work with the Chief Financial Officer and Assistant Director of Finance to appropriately describe the cross subsidy risks.

Board Assurance Framework February 2023 - Summary page

No.	Risk Title (full description in the detail pages)	Current risk score Feb 2023	Against Risk Appetite	Last review Jan 2023	
				Change	Prev. Score*
01	Donor / Patient Safety	**16**	Risk Limit	↑	**12**
02A	Service Disruption (Internal)	**16**	Risk Limit	↔	**16**
02B	Service Disruption (External)	**16**	Risk Limit	↔	**16**
03	Change Programme scale & pace	**15**	Tolerance Range	↑	**12**
04	Number and diversity of donors	**16**	Judgement Zone	↔	**16**
05A	Financial Shortfall (sudden policy changes)	**12**	Tolerance Range	↔	**12**
05B	Stakeholder and partner support for strategic objectives	**15**	Tolerance Range	↔	**15**
06	Inability to access data sets	**12**	Tolerance Range	↔	**12**
07	Staff Capacity and Capability	**16**	Judgement Zone	↔	**16**
08	Manager's Skills and Capability	**16**	Judgement Zone	↑	**9**
09	Regulatory Compliance	**12**	Judgement Zone	↔	**12**

Ref	Risk Title / Owner	Date of last change / last review	Appetite Category / Level	Risk Score against Appetite (● = Current Residual Score, ○ = Residual Score at last change)
BAF-01	Donor & Patient Safety / Clinical Director	26 Jan 2022 / - 13 Jan 2023	Clinical / Minimal	1 2 3 4 5 6 7 8 9 10 11 ○12 13 14 15 ●16 17 18 19 20 21 22 23 24 25
TAS-23	*Lack of Digital Systems*	*15-Dec-22*	*Disruption / Minimal*	○12 ●16
BAF-02a	Service Disruption (Internal) / Director of Quality	26 Jan 2022 / 12 May 2022	Disruption / Minimal	●16 ○20
TAS-08	*Staffing and Skill-mix / Head of Operations - Therapeutic Apheresis Services*	*10 Mar 2022 / 15 Dec 2022*	*Disruption / Minimal*	○12 ●16
DDTS-LSTS-010	*Stoke Gifford Infrastructure / Assistant Director Live Services*	*22/11/2022 / -*	*Disruption / Minimal*	●15
BAF-02b	Service Disruption (External) / Director of Quality	26 Jan 2022 / 12 May 2022	Disruption / Minimal	○12 ●16
CMT-29	*Consumables / National Operations Manager - CMT*	*29 Apr 2022 / 26 Jul 2022*	*Disruption / Minimal*	○12 ●16
RCI-R-03	*Supply Chain Failure / Head of Reagents*	*4 Oct 2022 / 4 Oct 2022*	*Disruption / Minimal*	●16
BAF-03	Change Programme scale & pace / Chief Digital Officer	26 Jan 2022 / -	Programme / Open	1 2 3 4 5 6 7 8 9 10 11 ○12 13 14 ●15 16 17 18 19 20 21 22 23 24 25

Ref	Risk Title / Owner	Date of last change / last review	Appetite Category / Level	Risk Score against Appetite (● = Current Residual Score, ○ = Residual Score at last change)
BAF-04	Donor Numbers & Diversity / Director of Donor Experience	26 Jan 2022 / 12 Jan 2023	Operational / Open	○ 12, ● 16
BAF-05a	Financial Shortfall (sudden policy changes) /Chief Finance Officer	26 Jan 2022 / 12 Jan 2023	Finance / Open	● 12
BAF-05b	Stakeholder and partner support for strategic objectives / Chief Digital Officer	26 Jan 2022 / 12 Jan 2023	Finance / Open	○ 12, ● 15
BAF-06	Inability to access data sets / Chief Medical Officer	26 Jan 2022 / -	Innovation / Open	● 12
BAF-07	Staff Capacity and Capability / Chief People Officer	26 Jan 2022 / 13 Oct 2022	People / Open	● 16
BAF-08	Managers Skills and Capability / Chief People Officer	13 Oct 2022 / 02 Feb 2023	People / Open	○ 9, ● 16
BAF-09	Regulatory Compliance / Director of Quality	26 Jan 2022 / 7 July 2022	Legal, Regulatory & Compliance / Cautious	● 12

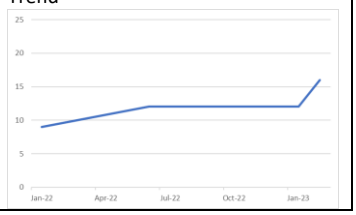
BAF Risk	01	There is a risk that harm occurs to a donor or patient, caused by one of the following (i) Failure of NHSBT processes to mitigate a known risk (a serious incident) (ii) Failure to scan for emerging infections (iii) A known complication of transfusion or transplantation that we cannot currently mitigate (iv) Complications occurring in the wider health system where NHSBT is responsible for advice and education resulting in a loss of confidence and goodwill from our organisational stakeholders and the wider public.

Linked Strategic Priority
Modernise our operations to improve safety, resilience and efficiency

Lead Executives	Chief Medical Officer
Board or Executive Committee	CARE

Risk Limit

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**4**	**4**	**16**
Target	4	2	8

Current score	Change since last review	Trend
16	↑	

Controls
C1. Quality Management System including MPD772 management of serious incidents C2. Investigation and learning from reported incidents/events C3. Learning from Excellence Group (OTDT) C4. JPAC and SaBTO Safety Policy Committees including Donor Organ Risk Assessment Group (SaBTO) C5. Donor Vigilance Annual Report (Joint NHSBT / UKHSA Epidemiology Team) C6. Emerging Infections Surveillance Process C7. Haemovigilance and Biovigilance Systems C8. Education and training programmes in transfusion and solid organ transplantation C9. 24-hour advice available from NHSBT Consultant on call rotas and Laboratories

Assurances
A1. Management Quality Review and MHRA Audit Reports A2. Annual Safe Supplies Report (Joint NHSBT / UKHSA Epidemiology Team) A3. UK Blood Services Horizon Scanning Reports (JPAC) A3a. Internal Audit on Horizon Scanning Processes (GIAA 2021) A4. ABO Horizon Scanning report A4. Annual SHOT Report A5. Annual solid organ transplantation Biovigilance Report (SaBTO) A6. Hospital customer services surveys and reports

Gaps in control
GC1. Processes span whole of NHS including UKHSA and Trusts. Gaps are not always easy to see GC2.The detection of new infections is inherently difficult with usual involvement of other species

Gaps in assurance
GA1. No annual stem cell transplantation biovigilance report

Actions to address gaps in control or assurance	Due date
1. Establish data system for improved knowledge of patient outcomes for stem cell transplantation ‡	April 22- UK SCSF report
2. Introduction of Automated results transfer project ‡	June 2022
3. CRM and outcomes database for NHSBT TAS treated patients ‡	22/23
4. Implementation of new NHSE PSIRF framework as rolled out ‡	Oct 2022
5. NHSBT Education strategy defined ‡	22/23
6. Review of Consultant on call rotas as part of operating model review to ensure remain fit for purpose ‡	Q1 2022

Child Risks		**Inherent**	**Residual**	**Target**
ODT-02	Delays or errors in offering process	16	12	8
RCI-08	Patient Harm	20	12	4
TAS-23	Lack of Digital Systems	12	16	Not given

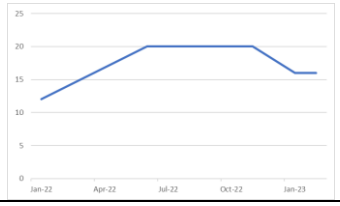
BAF Risk	02A	There is a risk of interruption to the effective operation of one or more of NHSBTs business function(s), caused by disruption to one or more essential (internal) resources, including equipment, IT, staff, loss of access to data and estate / facilities, resulting in delay or failure to continued supply of safe and effective products and services.

Linked Strategic Priority
Modernise our operations to improve safety, resilience and efficiency

Lead Executive	Director of Quality
Board or Executive Committee	Risk Management Committee

Risk Limit

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**4**	**4**	**16**
Target	3	3	9

Current score	Change since last review	Trend
16	↔	

Controls
C1. Business Continuity Management System and BC Plans
C2. Supply contingency and risk arrangements
C3. Resilience in IT arrangements
C4. Operational Development Group
C5. National Fire Safety Group
C6. Electrical Group
C7. National Water Safety Group
C8. Security Governance Board
C9. IPC
C10. Asbestos Group
C11. Estates Internal Cryogenic Group
C12. Estates Risk Management Group
C13. Estates Training Group
C14. Hazop Group
C15. Clean Room Advisory Group
C16. Software development lifecycle
C17. Change control process
C18. IT Monitoring capabilities
C19. Test Assurance Process
C20. Firewalls and other IT security measures

Assurances
A1. ISO22301 certification and audit
A2. Internal and External Audit programme
A3. BC Exercise programme
A4. Statutory Compliance Dashboard
A5. BC report to RMC

Gaps in control
GC1. BC Plan for Pulse Failure
GC2.BC Plan for Microbiology Services

Gaps in assurance
GA1. BC Exercise plan paused due to Covid

Actions to address gaps in control or assurance	Due date
GC1. BCP review and Single point of failure identification	Q2 2022/23
GA2. Exercise programme to improve coverage and identify gaps in plans	Q1 2022/23
GA3. Data Centre migration project	Q3 2022/23

Child Risks		**Inherent**	**Residual**	**Target**
TAS-08	Staffing and Skill-mix	16	16	9
DDTS-LSTS-010	Stoke Gifford Infrastructure	20	15	8

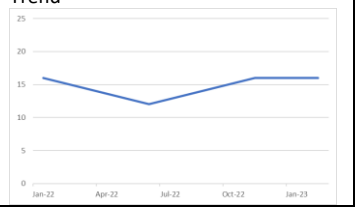
BAF Risk	02B	There is a risk NHSBT fails to meet the demand for essential products and services, caused by disruption and/or variability of external factors, such as donor behaviour, fluctuations in hospital demand, third party supplier shortages, adverse weather, resulting in NHSBT being unable to continue to deliver safe and effective products and services.

Linked Strategic Priority
Modernise our operations to improve safety, resilience and efficiency

Lead Executive	Director of Quality
Board or Executive Committee	Risk Management Committee

Risk Limit

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**4**	**4**	**16**
Target	4	1	4

Current score	Change since last review	Trend
16	↔	

Controls
C1. Business Continuity Management System
C2. Supply contingency and risk arrangements
C3. Demand management process
C4. Donor demographic data analysis and action
C5. Donor Marketing activities
C6. Customer Services intelligence gathering

Assurances
A1. ISO22301 certification and audit
A2. Supply report to RMC
A3. Internal and External Audit programme
A4. BC Exercise programme
A5. BC report to RMC

Gaps in control

Gaps in assurance
GA1. BC Exercise Programme paused due to Covid

Actions to address gaps in control or assurance	Due date
GC1. Exercise programme development	Q1 2022/23
GC2. Actions to address RO demand gap	
GC3. Appointment Grid Trial and new Donor Appeal	
GC4. Review of supplier resilience and border arrangements	

Child Risks		**Inherent**	**Residual**	**Target**
CMT-29	Consumables	16	16	4
RCI-R-03	Supply Chain Failure	12	16	4

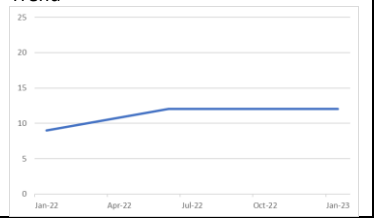
BAF Risk	03	There is a risk that the scale and pace of the NHSBT change programme will adversely impact our core functions or our ability to deliver our strategy caused by poor prioritisation, forecasting, change control and risk evaluation resulting in an impact on the provision of products and services

Linked Strategic Priority
Grow and diversify our donor base Modernise our operations Collaborate with partners

Lead Executive	Chief Digital and Information Officer
Board or Executive Committee	Executive Committee supported by portfolio oversight group

Tolerance Range

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**3**	**5**	**15**
Target	1	1	1

Current score	Change since last review	Trend
15	↑	

Controls
C1. Portfolio prioritisation and regular review C2. Appropriate assignment of qualified SROs and PPM staff C3. Business cases include optimism bias, contingency and are approved at appropriate levels C4. Scale of change investment fund C5. Change control system operated by QA C6. Change control system operated by IT

Assurances
A1. MHRA licences and audit reports A2. Programme and project status reporting A3. Programme/Project internal assurance reviews A4. Independent Gateway reviews A5. NHSBT performance reporting A6. Business plan quarterly reviews A7. GIAA Audit

Gaps in control
GC1. Qualified SROs and PPM staff *GC2. Understanding of delivery capacity and change dependencies*

Gaps in assurance
GA1. Portfolio level MI on changes to time, cost and quality

Actions to address gaps in control or assurance	Due date
GC1. SRO and PPM continuous learning plan	
GA2. Mature and embed Portfolio Oversight Group performance and management information	
GA3. Improve scheduling, demand and capacity planning at portfolio level	

Child Risks		**Inherent**	**Residual**	**Target**
PFM-02	HAV / B19 Sample Screening Time Limit	16	15	1

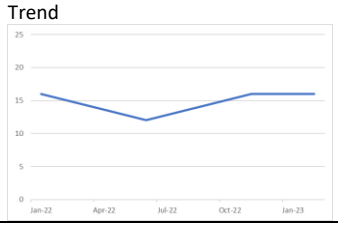
BAF Risk	04	There is a risk that we do not attract the right number and diversity of donors due to failure to engage the public effectively, resulting in the worsening of the supply demand gap for our products.

Linked Strategic Priority
Grow and diversify our donor base to meet clinical demand and reduce health inequalities

Lead Executive	Director of Donor Experience
Board or Executive Committee	BOLT, OTDT SMT, Plasma Board, DX QPR

Judgement Zone

	Impact	Likelihood	Total
Inherent	4	5	20
Current	**4**	**3**	**12**
Target	3	2	6

Current score	Change since last review	Trend
16	↔	

Controls
C1. Blood stock oversight activity C2. GCS PASS and Business Case C3. Agency Procurement Process (Media) C4. Quarterly survey

Assurances
A1. Consensus Review at BOLT A2. Quarterly Reporting / DHSC and Cab Office PASS Form A3. Cab Office Contract Management of Media Buying A4. Donor Metrics (satisfaction, sentiment, propensity to donate etc.)

Gaps in control
GC1. Stem cell strategy *GC2. Ro Strategy* *GC3. Visibility at Exec level* *GC4: Cross-DX Marketing and Campaigns Governance*

Gaps in assurance
GA1. National Stem cell operational reporting *GA2. Black donor metrics* *GA3. Campaign and communication content* *GA4: Consistent and regular Donor feedback*

Actions to address gaps in control or assurance	Due date
GC1&2: Development of dedicated plans and strategy for controls	By Apr2022
GC3&GA3. Marketing plan visibility and Quarterly updates to the ET	By Apr2022
GC4: New Cross-DX Marketing and Communication Governance framework	By Apr2022
GA1&GA2: Updated KPIs and metrics aligned to plans and strategy	By Jul2022
GA4: Quarterly 'hot topic' reporting to ET and Board, from 'voice of the donor'	By Apr2022

Child Risks		**Inherent**	**Residual**	**Target**
OTDT-06	Inadequate tissue donation activity	20	16	4

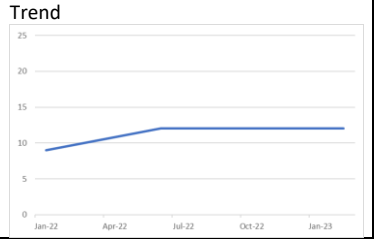
BAF Risk	05A	There is a risk that a sudden and unexpected change in government finances, health policy and associated commissioning arrangements for our services results in a significant shortfall in income

Linked Strategic Priority
Develop and scale new services to provide additional support to the NHS

Lead Executive	Director of Finance
Board or Executive Committee	ARGC

Tolerance Range

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**4**	**3**	**12**
Target	3	3	9

Current score	Change since last review	Trend
12	↔	

Controls
C1. National Commissioning Group C2. Annual accountability and budget setting C3. Business Planning and Performance Management

Assurances
A1. NCG Outcome letters to NHS Trusts A2. Business plans A3. Performance Reports Audit performance reporting

Gaps in control

Gaps in assurance

Actions to address gaps in control or assurance	Due date
GC1. Diversifying income sources	

Child Risks	**Inherent**	**Residual**	**Target**
Exists only at Strategic Level (Agreed ARGC July 2022)			

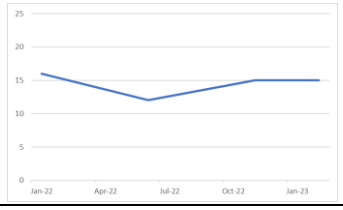
BAF Risk	05B	There is a risk that failure to gain support from UK Health Departments, our commissioners and partners for our strategic priorities, and associated funding, results in constrained strategic objectives that do not deliver the increase in lives saved and improved that we seek

Linked Strategic Priority
Develop and scale new services to provide additional support to the NHS

Lead Executive	TBA
Board or Executive Committee	ARGC

Tolerance Range

	Impact	Likelihood	Total
Inherent	5	4	20
Current	**5**	**3**	**15**
Target	5	2	10

Current score	Change since last review	Trend
15	↔	

Controls
C1. TBA

Assurances
A1. TBA

Gaps in control

Gaps in assurance

Actions to address gaps in control or assurance	Due date
GC1. TBA	

Child Risks		**Inherent**	**Residual**	**Target**
ODT-29	Shortfall in Programme/ GIA funding	20	15	10

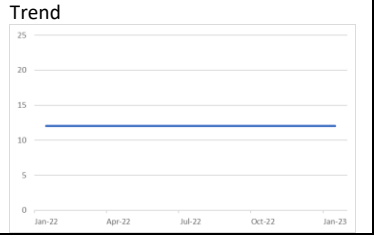
BAF Risk	06	There is a risk that NHSBT will be unaware and fail to monitor clinical outcomes in patients receiving our products and services caused by an inability to access data sets in a timely manner due to incompatibility of information systems and lack of engagement with Trusts and other bodies holding significant datasets, preventing us from identifying and driving forward opportunities for improvement

Linked Strategic Priority
Innovate to improve patient outcomes

Tolerance Range

Lead Executive	Chief Medical Officer and Director of Clinical Services Chief Digital and Information Officer
Board or Executive Committee	RMC or CARE (TBC)

	Impact	Likelihood	Total
Inherent			
Current	**4**	**3**	**12**
Target			

Current score	Change since last review	Trend
12	↔	

Controls
C1. Established processes between solid organ transplant centres and NHSBT C2. Funded transformation plans to establish pilot in multi-transfused patients C3. Priority with UK Stem Cell Strategic Forum deliverables (in publication) C4. NHSBT's membership of the Data Alliance Partnership C5. IT Security and Governance C6. Industrialising our Data Supply Chain

Assurances
A1. ODT Annual Reports A2. National Comparative Audit Reports A3. SHOT Annual Report A4. EBMT and BSBMTCT Annual Reports A5. NHSBT Internal Clinical Audit Reports

Gaps in control
GC1. No systemised mechanism to capture and understand outcomes in the patients we serve *GC2. No data sharing SLA in place between NHSBT and Trusts / other agencies*

Gaps in assurance
GA2. Outcome of transfusion recipients *GA2. Full and timely outcomes of Stem Cell recipients* *GA3. Outcomes in NHSBT TAS patients* *GA4. Limited patient related outcome or experience measures (PROMs and PREMs) in any directorate*

Actions to address gaps in control or assurance	Due date
GA1. Data mapping information flows in stem cell transplantation	
GA2. Setting up database for clinical outcomes in TAS	
GA3. TAS setting up CRM	
GA4. The full adoption, endorsement, and funding of the data strategy to give greater influence	
GA5. Developing standard APIs to NHS Digital Guidance	

Child Risks		**Inherent**	**Residual**	**Target**
	No Child Risks in the System (no inherent or target scores as a result)			

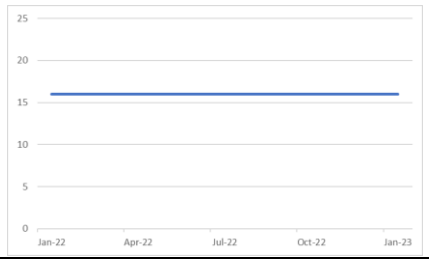
BAF Risk	07	There is a risk that a lack of capacity, capability and / or flexibility in our workforce, caused by challenges in our attraction, recruitment and retention strategies, prevent us from delivering our strategic priorities or core functions.

Linked Strategic Priority
Invest in people and culture to ensure a high performing and inclusive organisation

Lead Executive	Chief People Officer
Board or Executive Committee	People Committee

Judgement Zone

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**4**	**4**	**16**
Target	4	2	8

Current score	Change since last review	Trend
16	↔	

Controls
C1. Recruitment process C2. Organisational Development C3. Strategic advice from People and Culture Teams C4. HR Policies in place

Assurances
A1. People Tracker in Performance Report A2. Directorate People Scorecards A3. Audit of Recruitment (GIAA) A4. Staff Partnership Council reports

Gaps in control

Gaps in assurance
GA2. Audit of People Data for validation

Actions to address gaps in control or assurance	Due date
GC1. Workforce planning and succession planning	High Level Approach – Q3 22/23 Socialisation & Agreement Q4 22/23 Mobilise Year 1 version 23/24 Refine Q1 24/25 onwards
GA2. Applicant tracker system for recruitment (PETS Project)	April 2022
GA3. Attraction Strategy (completed and expanded to all roles)	March 2023
GA4. Refresh of people development strategy	End Q4 2022/23
GA5. Establish the Academy	End Q4 2021/22
GA6. People Strategy	End Q3 2022/23
GA7. Education and Training Strategy	End Q3 2022/3

Code	Title	Inherent	Residual	Target
CSPPM-06	Lack of resource prevents delivery of Clinical Services portfolio	16	16	8
PEOPLE-06	Staff Capacity / Capability / Recruitment / Retention	20	16	6
PEOPLE-09	Workforce Information	20	16	9

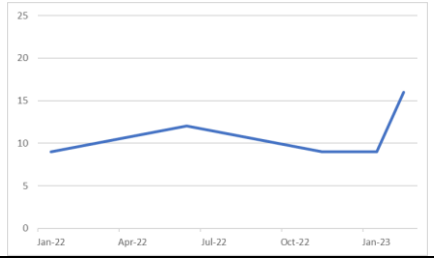
BAF Risk	08	There is a risk that our leaders and managers lack the skills and capabilities required in today's NHS to create a high-performing, inclusive environment, and to deliver our strategic priorities

Linked Strategic Priority
Invest in people and culture to ensure a high performing and inclusive organisation

Lead Executive	Chief People Officer
Board or Executive Committee	People Committee

Judgement Zone

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**4**	**4**	**16**
Target	2	2	4

Current score	Change since last review	Trend
16	↑	

Controls
C1. D&I Embedded in Policy C2. PDPR Processes (inc. Training Gateway review) C3. Clear expectations included in PDPR C4. Development Policy C5. Tracking professional development / revalidation C6. Freedom to Speak Up Guardian C7. Workforce Race Equality Standard Plan C8. Workforce Disability Equality Standard Plan

Assurances
A1. Training reporting A2. D&I Programme Board and EDI Consultative Council A3. Reports on workforce profile characteristics A4. Code of Conduct A5. Staff Survey A6. Staff Network

Gaps in control

Gaps in assurance
GA1. Comprehensive Training Reporting *GA2. Audit of PDPR Process* *GA3. Gaps in staff network coverage*

Actions to address gaps in control or assurance	Due date
GC1. Introduction of career conversations	End Q4 2022/23
GA2. New resolution framework (most inclusive and fair way of resolving problems)	Jan 2023
GA3. People Strategy	End Q3 2022/23
GA4. Education and Training Strategy	End Q3 2022/3
GA5. Cultural Audit	End Q4 2022/3
GA6. Leadership Development Programme	End Q4 2022/3

Child Risks		**Inherent**	**Residual**	**Target**
PEOPLE-05	Leaders and managers lack the skills and capabilities	16	16	4

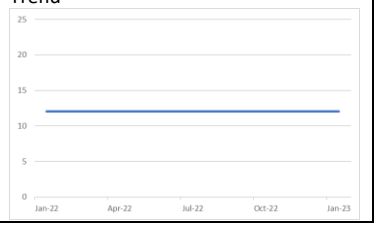
BAF Risk	09	There is a risk that the organisation will become non-compliant with current or emerging regulations which could result in NHSBT being subject to significant regulatory action and/or licences being revoked. This would impact on the ability of NHSBT to provide critical services and products and/or have a serious impact on patient safety. It also has the potential to significantly, and detrimentally, affect the reputation of the organisation

Linked Strategic Priority
Modernise our operations to improve safety, resilience and efficiency Innovate to improve patient outcomes Collaborate with partners to develop and scale new services for the NHS

Lead Executive	Director of Quality
Board or Executive Committee	Risk Management Committee

Judgement Zone

	Impact	Likelihood	Total
Inherent	4	4	16
Current	**4**	**3**	**12**
Target	3	2	6

Current score	Change since last review	Trend
12	↔	

Controls
C1. Quality Management System C2. Regulatory and Legislative Change Management C3. Regulatory Affairs and Licencing C4. Training, Education, Competency and Development

Assurances
A1. Management Quality Review A2. Regulatory Radar A3. External Audit Reports from MHRA/HTA A4. Internal Audit vie GIAA

Gaps in control
GC1. Lack of formal demand planning process for QA. *GC2. Lack of control over Data Integrity (non-conformance identified through MHRA Audit).* *GC3. CQC Registration process is outside of QA scope (i.e. separate to licensing).*

Gaps in assurance
GA1 – no prior audits of CQC Well Led compliance

Actions to address gaps in control or assurance	Due date
GC1. Design of a demand planning process for QA.	TBC
GC2. Data Integrity plan (CoreStream DI pilot for Clinical Services Q3 21/22).	Q1 22/23 (organisation wide roll out)
GC3: CQC registration to be included in the Regulatory Affairs team scope.	Q4 21/22
GC4. Well Led Project and GGI review	January 2022

Child Risks		**Inherent**	**Residual**	**Target**
PFM-11	Units Unsuitable for PFM due to Non-Compliance with Fractionator Requirements	16	12	8