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## **Foreword**

I am pleased to present the annual report and summary financial statements for the Irish Blood Transfusion Service for 2024. Our focus in 2024 was predominantly on safety and sustainability of the blood supply and of the organisation.

At the time of writing the IBTS is in the final year of implementation of our five year strategy. Since 'Connections that Count' was developed, the IBTS has undergone significant transformational changes while dealing with some unprecedented challenges. Against that backdrop, the blood supply and the IBTS finances remained stable. We are now working on the development of our next five year strategy in consultation with our many stakeholders and will look forward to sharing that strategy towards the end of 2025.

Our priority in 2024 was, as always, the safety and sustainability of the supply of blood and blood components as well as the safety and sustainability of the organisation. Those themes resonated throughout the organisation with a focus in 2024 on sustainability in a wider context and the development of our sustainability strategy, allied with extensive work on data protection and cybersecurity.

Evolving science requires more sophisticated blood testing and matching and many of the strategic initiatives in 2024 were technical initiatives informed by our continuing aim to ensure the safety and security of the blood supply, as well as the most effective and efficient use of the blood and platelet donations made.

One of the key achievements in implementing our strategy in 2024 related to plasma. The IBTS commenced the supply of recovered plasma for the rapeutic use in October 2024. This means that for the first time in over twenty years, Octaplas made from Irish plasma

became available to the Irish healthcare system. This was a critical step towards allowing Ireland to become self-sufficient in the provision of plasma derived medicinal products and contribute to the pool of plasma required for patients in Europe. I expect that future annual reports will feature many more developments on the use of Irish plasma.

During 2024 we appointed our first Climate and Sustainability Lead to the organisation, recognising the importance of broader sustainability responsibilities in the organisation. As a state body, under the Irish Climate Action Plan we are tasked with operating with increased efficiency with a view to managing our energy use and carbon emissions. After a detailed review of our operations and their impact, in 2024 we approved our first Sustainability Strategy to address the impact of the Irish Blood Transfusion Service on the environment while maintaining the supply of Irish blood and blood products in the most sustainable manner possible. This strategy aligns our energy and carbon targets with other objectives designed to achieve a holistic approach to sustainability.

There was a renewed focus on data protection and cybersecurity in 2024. The IBTS is classified as an essential entity under EU legislation on cybersecurity (NIS2) with a clear onus on the Board of the organisation to ensure compliance with detailed processes and procedures stipulated in the legislation. On behalf of the Board I would like to acknowledge the huge team effort of our staff in working to protect the IBTS systems to achieve NIS2 compliance. Compliance with NIS2 and other related cybersecurity will not be "done" at a point in time and the IBTS is committed to ensuring that cybersecurity continues to get the time and resources required to maintain ongoing compliance.

At board level, during 2024 we said goodbye to Dr Liz Kenny and David Gray and I would like to take this opportunity to thank them both for their service to the organisation. Fresh blood (pardon the pun) is always essential and we were delighted to welcome Noel Beecher to the board.

The Board has been expertly supported by a hardworking and committed management team, led by Orla O'Brien. We look forward to working with Orla in the development of the next strategy in 2025.

Our Medical & Scientific Director Prof Tor Hervig retired from the IBTS in July 2024 and we welcomed Dr Andrew Godfrey to the management team. Andrew joined us at a very interesting time for blood establishments. We are confident that he will steer the IBTS through the medical and scientific opportunities and challenges ahead, including significant changes to the regulatory environment with the introduction of a new EU Regulation on Substances of Human Origin in May 2024.

The IBTS is a unique organisation with truly exceptional staff working the length and breadth of the country. On the complex journey from vein to vein their role is to ensure that each step in the process is carried out to perfection, in pursuit of our core value: We strive for excellence.

As always I conclude by thanking our donors. Over the past two years I've met donors at award ceremonies from Cork to Donegal and several venues in between to thank them personally for their gift of 50 or 100 blood donations. As well as our formal thanks, the recipients at the awards get to hear firsthand from a recipient. It is a real privilege to share the donors' experience of hearing these personal stories, whether told by recipients themselves or their very grateful parents. The stories from the recipients are wide ranging as they emphasise the variety of situations in which they all rely on blood donations. What they have in common is the fact that the blood donations they receive are always life-changing and often life-saving. The IBTS is very grateful to the recipients for sharing their deeply personal experiences with us.

Having had the pleasure of thanking hundreds of donors personally in 2024, I will take this opportunity to thank all blood and platelet donors, whether you have given the gift of one donation or multiples of that. Your generosity and the expertise and commitment of the IBTS staff ensures that the IBTS can continue to provide excellent blood services that improve patients' lives in collaboration with the healthcare community.

#### **Deirdre-Ann Barr**

Chairperson



## **Chairperson's Report**

Report of the Chairperson of the Irish Blood Transfusion Service regarding the assessment of internal controls of a State body for the year ended 31st December 2024 in accordance with Appendix D of the Code of Practice for the Governance of State Bodies 2016, as amended.

- 1. Iacknowledge that the Board is responsible for the Body's system of internal control.
- 2. The IBTS system of internal control can provide only reasonable and not absolute assurance against material error, misstatement or loss.
- 3. The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS. This process is regularly reviewed by the Board via reports from the Chief Executive and updates from the Audit, Risk and Compliance Committee
  - i. Management are responsible for the identification and evaluation of significant risks applicable to their areas of business together with the design and operation of suitable controls. These risks are assessed on a continuing basis and may be associated with a variety of internal or external sources including control breakdowns, disruption in information systems, natural catastrophe and regulatory and compliance requirements.
  - ii. Management meets twice monthly on operational issues and risks and how they are managed. The Executive Management Team's role in this regard is to review on behalf of the Board the key risks inherent in the affairs of the IBTS with the Risk and Resilience Manager and the system of actions necessary to manage such risks and to present their findings on significant matters via the Chief Executive to the Board.
  - iii. The Chief Executive reports to the Board on behalf of executive management on significant changes in the work of the IBTS and on the external environment which affects significant risks. Where areas for improvement in the system

- are identified the Board considers the recommendations made by the Executive Management Team.
- iv. The Director of Finance provides the Finance Committee with monthly financial information, which includes key performance indicators.
- v. An appropriate control framework is in place with clearly defined matters which are reserved for Board approval only or, as delegated by the Board for appropriate Executive approval. The Board has delegated the day-to-day management of the IBTS and established appropriate limits for expenditure authorisation to the Executive. The Chief Executive is responsible for implementation of internal controls, including internal financial controls.
- vi. The system of internal financial control is monitored in general by the processes outlined above. In addition, the Audit, Risk and Compliance Committee of the Board reviews specific areas of internal control as part of its terms of reference.
- vii. The IBTS has outsourced the internal audit function to an independent professional firm, who conduct a programme of work as agreed with the Audit, Risk and Compliance Committee. During 2024 they carried out seven reviews and presented their findings to the Audit, Risk and Compliance Committee. The internal Auditors also meet the Audit, Risk and Compliance Committee without the Executive being present on an annual basis.

The Audit, Risk and Compliance Committee of the Board have satisfactorily reviewed the effectiveness of the system of internal control on behalf of the Board. Following presentation of a report on internal financial controls by the internal auditor, the Audit, Risk and Compliance Committee carried out a formal review of these systems in respect of 2024 at its meeting on the 11th February 2025. The Board approved the report on internal financial controls at its meeting on 17th February 2025.

# Additional Reporting Requirements

# Compliance with the Code of Practice for the Governance of State Bodies

The Board is committed to complying with the relevant provisions of the Code of Practice for the Governance of State Bodies, published by the Department of Public Expenditure and Reform in August 2016 and amended in September 2020.

A code of business conduct for the Board and an employee code of conduct are in place. Both are available on www.giveblood.ie. The Board has adopted a detailed travel and subsistence policy which complies with all aspects of Government travel policy.

The IBTS Board reviewed reports on internal controls during the year along with regular reviews of the reports of the Health Products Regulatory Authority (HPRA) on operational and regulatory compliance controls and risk management. The Board will continue to review these reports and to work closely with the HPRA to ensure the highest international standards.

The IBTS has complied with disposal of assets procedures, as outlined in the 'Code of Practice for the Governance of State Bodies 2016' as amended. The IBTS complies with all relevant obligations as defined under Irish taxation law.

#### **Corporate Governance**

The Board's policy is to maintain the highest standards of corporate governance, in line with generally accepted policies and practices. The Board is accountable to the Minister for Health.

The Board has a manual for Board members. The Board has an agreed timetable for reviewing Terms of Reference for Board Sub-Committees.

#### Workings of the Board

The Board is comprised of twelve members including a non-executive Chairperson appointed by the Minister for Health.

The Board met on six occasions for ordinary meetings during the year. The Board had one unscheduled meeting in October. The Board also held a full day meeting on 22nd May to carry out its annual review of the Strategic Plan 'Connections that Count.'

Attendance by Board members at ordinary Board meetings during the year was as follows:



	Feb	April	June	Sep	Nov	Dec
Ms Deirdre-Ann Barr	✓	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>
Dr Satu Pastila	✓	<b>√</b>	<b>√</b>	<b>✓</b>	<b>✓</b>	<b>√</b>
Ann O'Connor	✓	×	<b>✓</b>	<b>✓</b>	<b>✓</b>	<b>√</b>
Una Clifford	✓	×	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>
David Gray**	✓	✓	<b>√</b>	<b>✓</b>	-	-
Peter Dennehy	✓	<b>√</b>	×	<b>√</b>	<b>✓</b>	X
Kevin Gregory	✓	✓	<b>✓</b>	<b>✓</b>	<b>✓</b>	<b>√</b>
Dr Nina Orfali	✓	<b>√</b>	<b>✓</b>	<b>√</b>	<b>✓</b>	<b>√</b>
Dr Sharon Sheehan	✓	<b>√</b>	<b>✓</b>	<b>√</b>	<b>✓</b>	<b>√</b>
Dr Sarah Doyle#	✓	<b>√</b>	<b>✓</b>	<b>✓</b>	-	-
Stephen O'Hare	✓	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>
Dr Liz Kenny*	✓	<b>√</b>	-	-	-	-
Noel Beecher‡	-	-	-	-	✓	✓

<sup>\*</sup>Dr Liz Kenny - term completed on 20th May

#### **Members of the Board**

Chairperson Deirdre-Ann Barr

Dr Elizabeth Kenny (term completed on 20th May 2024)

Dr Satu Pastila

Dr Sarah Doyle

Mr David Gray (resigned on 6th November 2024)

Prof Sharon Sheehan

Mr Peter Dennehy

Mr Kevin Gregory

Ms Una Clifford

Ms Ann O'Connor

Mr Stephen O'Hare

Dr Nina Orfali

Mr Noel Beecher (appointed on 8th October 2024)

All members receive appropriate and timely information to enable the Board to discharge its duties. The Board takes appropriate independent, professional advice as necessary. Guidelines for the payment of Board member fees and expenses are observed.

<sup>\*\*</sup>David Gray – resigned on 6th November

<sup>#</sup> Mr Noel Beecher – appointed on 8th October ## Dr Sarah Doyle – on sick leave

Ms DA Barr	€11,970
Mr D Gray	€10,957
Ms S Pastila	€11,970
Mr K Gregory	€7,695
Mr P Dennehy	€7,695
Mr S O'Hare	€7,695
Ms U Clifford	€7,695
Ms A O'Connor	€7,695

#### The Public Spending Code

The Board is committed to complying with the provisions of the Public Spending Code and Circular 14/21 Arrangements for Oversight of Digital and ICT related initiatives in the Civil and Public Service.

The IBTS has implemented a project management methodology, suitable for adaptation, depending on the size and complexity of the project in question.

The Board has activated a committee structure to assist in the effective discharge of its responsibilities.

### Performance and Development Committee

Development Performance and Committee deals specifically with matters regarding the performance and development of the Chief Executive. and the Executive Management Team. The Board complies with Government policy on pay for the Chief Executive and employees. The Board also complies with guidelines on the payment of director's fees. The Chief Executive's salary in 2024 was €184,236. The Board Performance and Development Committee consists of 2 Board members and one external independent member. The Performance and Development Committee met three times in 2024.

#### **PD Committee attendance**

	April	Sept	Dec
Ms D-A Barr	✓	<b>√</b>	<b>✓</b>
Ms U Clifford	✓	<b>✓</b>	✓

# Medical & Scientific Advisory Committee

The Medical and Scientific Advisory Committee is comprised of some of the medically qualified members of the Board and the medical consultant staff of the IBTS, as well as a number of external medical consultants and met six times in 2024. Its function is to monitor developments relevant to the field of transfusion medicine and related fields, to inform the Board of any such developments and to advise the Board on appropriate action.



#### **M&SAC** attendance

	Feb	April	June	Sept	Nov	Dec
S Pastila	✓	<b>✓</b>	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>
S Doyle <sup>(1)</sup>	x	×	$\checkmark$	<b>√</b>	X	X
E McSweeney	<b>✓</b>	<b>√</b>	✓	<b>✓</b>	<b>✓</b>	<b>√</b>
N O Flaherty	✓	<b>✓</b>	$\checkmark$	$\checkmark$	X	<b>√</b>
K Morris	×	×	$\checkmark$	×	X	x
S NiLoingsigh	✓	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
B Quill	×	<b>✓</b>	X	×	X	X
R Hagan	✓	×	$\checkmark$	$\checkmark$	<b>✓</b>	x
A Waters	✓	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
C DeGascun	×	×	X	$\checkmark$	X	X
S Thomas	✓	×	<b>✓</b>	✓	$\checkmark$	<b>✓</b>
E Kenny <sup>(2)</sup>	✓	$\checkmark$	-	-	-	-
N Orfali <sup>(3)</sup>	-	<b>√</b>	$\checkmark$	<b>√</b>	<b>✓</b>	✓
Tor Hervig <sup>(4)</sup>	✓	<b>√</b>	<b>√</b>	-	-	-
A Godfrey <sup>(5)</sup>	-	-	$\checkmark$	<b>√</b>	<b>✓</b>	<b>√</b>
D Ó Donghaile <sup>(6)</sup>	✓	<b>✓</b>	X	<b>√</b>	-	-
P Williams <sup>(7)</sup>	-	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>	✓
K Ryan <sup>(8)</sup>	-	-	-	-	<b>√</b>	<b>√</b>
O O'Brien <sup>(9)</sup>	✓	✓	✓	✓	✓	✓

- 1. Dr Sarah Doyle on sick leave
- 2. Dr Elizabeth Kenny Term of Office finished on 20th May 2024
- 3. Dr Nina Orfali was appointed to the M&SAC in February 2024 and her first meeting was in April she took over as Chairperson in June 2024
- 4. Prof Tor Hervig retired from IBTS in July 2024
- 5. Dr Andrew Godfrey was appointed to IBTS in July 2024
- 6. Dr O'Donghaile was no longer a member of the M&SAC from June 2024 in line with the new Medical Model of Care. He deputised for Dr Morris at the September Meeting
- 7. Mr Padraig Williams was appointed to the M&SAC at the February 2024 Board
- 8. Mr Kieran Ryan was appointed to the M&SAC at the September 2024 Board
- 9. Ms Orla O'Brien, CEO is an attendee at the M&SAC

#### **Finance Committee**

The Finance Committee met five times during the year and is comprised of three members of the Board. It is also attended by the Chief Executive, Director of Finance and Management Accountant. The Committee may review any matters relating to the financial affairs of the Board. It reviews the annual capital and operating budgets, Statutory Financial Statements and monthly management accounts, financial KPIs, capital expenditure, working capital and cash flow. It also reviews business planning, costing exercises, procurement, insurance arrangements, contracts, banking, financing arrangements and treasury policy. The Committee also reviews the funding and performance of the Board's pension fund. The Committee reports to the Board on management and financial reports and advises on relevant decision-making. The Finance Committee operates under formal terms of reference, which are reviewed by the Board regularly.

#### **Finance Committee attendance**

	February	May	July	September	November
Mr K Gregory	<b>✓</b>	<b>√</b>	<b>✓</b>	<b>✓</b>	<b>✓</b>
Ms U Clifford	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>	<b>✓</b>
Mr D Gray*	<b>√</b>	<b>√</b>	Х	<b>✓</b>	-

<sup>\*</sup>D Gray resigned from the Board on 6th November 2024.

#### **Audit, Risk & Compliance Committee**

The Audit, Risk and Compliance Committee met five times during the year and is comprised of four members of the Board and two independent external members. It is also attended by the Chief Executive, the Medical & Scientific Director, the Director of Finance, the Director of Donor Services and Logistics, the Director of Quality & Compliance, the Director of Production and Hospital Services, the Chief Information Officer, the Internal Auditor, the Risk and Resilience Manager and the Assistant Accountant or a substitute acts as Secretary to the Committee. The Committee may review any matters relating to the financial, risk, regulatory or compliance affairs of the Board. It reviews the annual Statutory Financial Statements including the accounting policies and notes to the financial statements, compliance with accounting standards and the accounting implications of major transactions, reports of the Internal Auditor, quality reports both internal and from the HPRA, risk management including reviews of the corporate risk register. The external auditors meet the Committee to review the results of the annual audit of the Statutory Financial Statements. The Audit, Risk & Compliance Committee operates under formal terms of reference, which are reviewed by the Board regularly.

#### **Audit, Risk & Compliance Committee attendance**

	February	April	June	September	December
Mr D Gray*	✓	<b>✓</b>	<b>√</b>	<b>✓</b>	-
Prof S Sheehan	<b>✓</b>	<b>√</b>	<b>√</b>	<b>✓</b>	<b>√</b>
Mr P Dennehy	<b>√</b>	<b>√</b>	Х	<b>✓</b>	<b>√</b>
Ms A O'Connor	✓	<b>√</b>	✓	<b>√</b>	<b>√</b>

<sup>\*</sup>D Gray resigned from the Board on 6th November.



# Research & Development Committee

The Research and Development Committee met three times during the year to oversee the implementation of the IBTS Research and Development Strategy. The Committee is comprised of two members of the Board and three independent external members. The Research and Development Committee is attended by the Chief Executive, the Medical and Scientific Director, the Finance Director and the Research and Development Lead Facilitator.

## Research & Development Committee attendance

	April	Aug	Nov
Mr S O'Hare	✓	$\checkmark$	$\checkmark$
Mr P Dennehy	×	<b>√</b>	×

## **Risk Register**

The risk register identifies various types of risks including strategic, reputational, clinical, IT, cyber security, financial and operational risks to the organisation and the existing controls and further actions necessary to minimise the impact on the organisation, in the event of the risk occurring.

Globally the risk associated with cyber-attacks continues to increase and has compelled the organisation to put plans in place to improve cyber security resilience. This is an ongoing process, led by the Chief Information Officer and dedicated Project Manager and is overseen by the Audit, Risk and Compliance Committee.

A Risk and Resilience Manager has responsibility for overseeing the risk register and business contingency arrangements. A set of inherent risks have been identified which are monitored by the Audit, Risk and

Compliance Committee and the Board on a regular basis. At present the risk register is reviewed and updated by the Executive Management Team. The Board has full access to the Risk Register in real time.

This monitoring ensures that the identified risks and controls are current and that new and emerging risks are identified and control measures put in place.

#### **Going Concern**

After making reasonable enquiries, the Board Members have a reasonable expectation that the IBTS has adequate resources to continue in operational existence for the immediate future. For this reason, they continue to adopt the going concern basis in preparing financial statements. In light of the pension deficit and the potential for further post reporting date changes in the value of the pension scheme's assets and liabilities, the Board in evaluating the appropriateness of the going concern concept to the current set of Financial Statements considered all of the pension fund valuations and cash flow for the twelve months from the date of approval of the financial statements and is of the opinion that the Board can meet all its liabilities including funding of the IBTS pension scheme as they fall due. In these circumstances the Board considers the going concern concept appropriate to the preparation of the Financial Statements.

#### **Internal Control**

The Board is responsible for internal controls in the IBTS and for reviewing their effectiveness. The Board's system of internal financial control comprises those controls established in order to provide reasonable assurance of:

- The safeguarding of assets against unauthorised use or disposition; and
- The maintenance of proper accounting records and reliable financial information used within the organisation.

The key elements of the Board's system of internal financial control are as follows:

- A comprehensive system of financial reporting
- Annual budget prepared and presented to both the Finance Committee and the Board
- Monthly monitoring of performance against budgets by Finance Committee and Board
- Sign off by budget holders on individual budgets
- Budget reviews with budget holders
- Clearly defined finance structure
- Appropriate segregation of duties
- Clear authorisation limits for capital and recurring expenditure approved by the Finance Committee
- Key financial processes are fully documented in written procedures
- Regular stock takes and reconciliations carried out by staff independent of stores staff
- Financial system possesses verification checks and password controls
- Issues of products are reconciled to ensure all of the Board's activities are fully billed
- Regular monitoring of credit control function
- Purchase orders signed by Procurement and Supplier Relationship Manager or authorised substitute
- Stock items are requisitioned by means of automatic ordering
- All non stock invoices signed and coded by budget managers or their authorised signatories
- All stock invoices are independently matched with stores Goods Received Notes (GRN) and purchase orders
- Payment verification checks of supplier invoices by staff independent of accounts payable staff

The Board is aware that the system of internal control is designed to manage rather than eliminate the risk of failure to achieve business objectives. Internal control can only provide reasonable and not absolute assurance against material misstatement or loss.

The Financial Statements for the year ended 31st December 2024 have been prepared under FRS102.

# Statement of Board Members' Responsibilities

The Board is required by the Blood Transfusion Service Board (Establishment) Order 1965, to prepare financial statements for each financial year which, in accordance with applicable Irish law and accounting standards, give a true and fair view of the state of affairs of the Irish Blood Transfusion Service and of its income and expenditure for that year. In preparing those financial statements, the Board is required to:

- Select suitable accounting policies and then apply them consistently;
- Make judgements and estimates that are reasonable and prudent;
- Disclose and explain any material departure from applicable accounting standards:
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Irish Blood Transfusion Service will continue in business.

The Board is responsible for keeping proper books of account, which disclose with reasonable accuracy at any time, the financial position of the Irish Blood Transfusion Service and to enable it to ensure that the financial statements comply with the Order. It is also responsible for safeguarding the assets of the Irish Blood Transfusion Service and hence taking reasonable steps for the prevention and the detection of fraud and other irregularities.



#### **Procurement**

The IBTS is in compliance with current procurement rules and guidelines as set out by the Office of Government Procurement.

### **Asset Disposal**

There were a number of vehicle disposals during 2024. They were sold by means of public auction.

#### **Protected Disclosures**

The IBTS complies with the requirements under the Protected Disclosures Act 2014 as updated by the Protected Disclosures (Amendment) Act 2022 and confirms that procedures are in place for the making of protected disclosures in accordance with section 21(1) of the Protected Disclosures Act 2014. There were no protected disclosures in 2024.

# Official Languages Act (as amended)

The IBTS complies with the requirements under the Irish Language (Amendment) Act 2021. In 2024, IBTS met its obligations of 20.89% of all advertising in Irish, with 5.16% spend of all advertising on Irish media only.

# Commercially significant developments

#### **Plasma**

The IBTS commenced the supply of recovered plasma for fractionation to a third party for processing in December 2024. This means that for the first time in over twenty years Octaplas made from Irish plasma will become available to the Irish healthcare system.

#### **Selective HTLV Testing**

Selective testing for HTLV was introduced in February 2024. This evidence-informed and risk assessed change in testing practice means that only 1st time donors and donors not previously tested for HTLV (i.e. donated prior to 1997) will be tested for HTLV saving the IBTS approximately €120,000 per annum.

#### **HEV Testing**

Grant income of €538,400 was received in 2024 by the IBTS from the Department of Health to carry out HEV testing. The grant funding from the Department of Health for HEV testing ceased on 31st December 2024. The IBTS continues HEV testing of all donations and has absorbed the cost within its cost base.

#### **Deirdre-Ann Barr**

Chairperson



## **Chief Executive's Report**

Once again, I am proud to present the 2024 annual report for the Irish Blood Transfusion Service (IBTS) sharing our performance during the penultimate year of our strategy, Connections that Count: Developing the IBTS 2021 – 2025.

## Our core purpose – safe and sustainable blood supply

In line with our core purpose, we successfully managed the national blood supply with increased demand for Red Cells (128,471 units issued in 2024; 2.9% higher than 2023) and Platelets (23,471 units issued in 2024; 3.6% higherthan 2023). While supply was strong and stable for RhD Positive blood, demand for RhD Negative blood outstripped supply at times throughout the year. We ran three national appeals to sustain the blood supply with a magnificent response from our donors and the public. With any blood supply challenges, preventing any adverse impact on patient care is always our priority. Instead of restricting supply to hospitals, we collaborated with other blood establishments to share these precious resources and optimise stock management as is best practice across Europe.

Our blood supply is dependent on the generosity of our voluntary non-remunerated donors. Over the course of the year our donor services teams succeeded in recruiting over 11,500 new donors. Working collaboratively with relevant advocacy and community groups, we also sought to diversify our donor base to reflect the diversity of our population; this is essential to enable us to better match blood to the needs of specific patients.

#### Our strategic developments

In addition to delivering our essential services every day, we sustained our focus on delivering key strategic initiatives. We strive to support better healthcare by exploring options for introducing new products and services designed to meet emerging healthcare needs. During 2024, we engaged our hospital partners to assess the clinical need for implementation of new or modified blood components for treatment of patients with major haemorrhage and/or other conditions. In parallel, we completed the validation of a whole blood product for use in trauma and/or massive haemorrhage situations in both prehospital and in hospital settings.

One of our most significant achievements was the re-introduction of recovered Irish plasma for therapeutic use. This initiative enabled the use of recovered plasma from whole blood donors in the form of Fresh Frozen Plasma and for the production of plasma derived medicinal products. This is a significant development for the IBTS and a first step in enabling Ireland to contribute to the pool of plasma in Europe to support the production of critical medicines for patients.

In line with our objective to achieve operational excellence, we introduced an evidence-based and risk-assessed change to blood sample testing by introducing selective testing for HTLV. We now only test samples from our first time donors and those from donors whose last donation was prior to 1997. This change in testing practice ensures value and efficiency, while prioritising quality and safety.



We also completed a comprehensive review of our current donor services and collections operating model to identify improvements to ensure it is sustainable, fit for purpose for the future, and puts the needs of our donors to the fore. This review will guide how we develop our service over the years to come.

In parallel, we progressed initiatives to enhance our donors' experience. We worked towards enabling our donors to complete their self-assessed health history digitally using a tablet in clinics to streamline their clinic experience and enable more personalised risk assessment. This project will continue to progress as a priority in 2025.

Good progress was made this year on our multi-year capital project to redevelop the IBTS Centre on the grounds of St Finbarr's Hospital in Cork. In 2024, the Board approved the Design Brief and the tender for the single point Design Team was issued. We look forward to progressing this significant project with the Department and our stakeholders in the years ahead.

Further achievements from our Corporate Strategy, People and Culture Strategy, Research and Development Strategy and IT Strategy are reported on throughout this annual report.

# Our responsiveness to changes in regulation and legislation

Alongside our operational service delivery and strategic progress, the IBTS continues to adapt and respond to changes in our regulatory and legislative environment.

In July 2024, the new Regulation on standards of quality and safety for substances of human origin intended for human application were published. Substances of human origin (SoHO) means any substance collected from the human body. These new rules (SoHO Regulation) will replace the current rules for blood (Directive 2002/98/EC) and tissues and cells (Directive 2004/23/EC) and will apply from

7 August 2027. The SoHO Regulation aims to improve the safety and quality of all substances of human origin for human application. This regulation includes technical rules on quality and safety that can adapt to emerging risks and new technologies, strengthened protections for donors and patients, harmonisation across Europe, introduction of measures to prevent shortages of blood, tissues and cells, and supporting innovation. This will bring significant change for the IBTS and early scoping work is underway.

We also worked to strengthen governance arrangements between the IBTS, the National Haemovigilance Office and the Health Products Regulatory Authority. We completed the tender for a new haemovigiliance reporting system and a project team are now working to progress implementation of the system nationally in 2025.

We made a concerted effort to enhance our cyber resilience during 2024 with a dedicated Project Manager and a detailed programme of work to deliver specific outcomes to enhance IBTS cyber risk posture and thereby improve cyber resilience. Progress has been made on the foundations identified for 2024. This foundation will be built upon and cyber resilience will remain a priority area of focus for us in 2025.

In 2024, we appointed our first Climate and Sustainability Lead and developed our first Sustainability Strategy, which was approved by the Board in November. This strategy provides a framework for the IBTS to positively impact on the Sustainable Development Goals. The aligned Climate Action Roadmap provides the specific actions necessary for us to deliver on our mandate to achieve targets set out in the Public Sector Climate Action Mandate (CAM) 2024 and the Government's Climate Action Plan (CAP) 2024.

We are privileged to have a highly trained and professional workforce. Attracting and retaining specialist staff continued to be challenging in 2024. We made every effort and implemented many initiatives to support recruitment and retention in this competitive market and will continue to focus on this in 2025 to reverse this trend and bring more stability in our workforce.

#### **Acknowledgements**

We are continually grateful to the 87,619 donors who attended our clinics one or more times in 2024. We acknowledged our whole blood and platelet donors at the seven Donor Award ceremonies that took place across the country in 2024, the first of which was held in Carlow in March. However, our donors deserve repeated thanks for their continued loyalty and tremendous response to the three appeals during the year. In 2024, we celebrated 931 donors who reached their 50-donation milestone, and 214 donors who reached their 100-donation milestone. It is a highlight of our year to meet and personally thank our donors at these ceremonies for their extraordinary commitment to blood and platelet donation.

We can only do what we do because of the expertise and commitment of our people. I would like to express my sincere gratitude to the Board, and Chairperson Deirdre-Ann Barr, for their guidance and support throughout the year. I am grateful to the Executive Management Team and all of our staff for their exceptional commitment and never failing to step up when needed. I would like to acknowledge our staff who retired or moved on during the year for their loyal and dedicated

service to the organisation. In July, we said goodbye to our colleague, Prof Tor Hervig who retired from his role as Medical and Scientific Director and welcomed Dr Andrew Godfrey. We look forward to working with Dr Godfrey to shape our future over the years ahead.

Building strong collaborative relationships with our key stakeholders is important to us. I want to acknowledge the continued support of the Ministers and staff of the Department of Health and the Health Products Regulatory Authority. Our colleagues in European counterparts and the European Blood Alliance remain key partners in the mutual sharing of best practice and expertise.

Our core purpose remains constant. We remain committed to providing excellent blood and tissue services that improve patients' lives. We can only do this with the generosity of our donors, the expertise of our people, the collaboration of our healthcare partners and the trust of the public. The work we do is unique and it is a privilege and responsibility that all of us in the Irish Blood Transfusion Service take seriously. I am proud of the organisation's ambition and achievements in 2024. In 2025, we will reflect on our learnings, build on our successes and continue to strive for excellence with our donors at the heart of all we do.

#### Orla O'Brien

Chief Executive



# Medical & Scientific Director's Report

I am delighted to be writing my first Medical and Scientific report for the IBTS. I joined the IBTS in July 2024 and the first six months of my time here have been an amazing experience with opportunities to build new relationships within the organisation. I would like to acknowledge Professor Tor Hervig, our previous Medical and Scientific Director, for the invaluable assistance he has offered before, during and after our handover period.

#### **Blood Supply**

Demand for blood over the past year has been strong, with increases in novel cancer and haematological therapies driving the majority of this change. This has placed the blood supply under strain across the year.

This challenge has brought us as an organisation much closer to our end users. We have engaged with clinical teams across the country to optimise the use of our rare blood groups, the group O RhD negative and the rare RhD type R0 blood needed for some treatments.

# Optimising the Use of RhD negative blood

In light of the significant change in the demand for blood, in particular Group O RhD negative blood, we reviewed the strategies employed across Europe to conserve this rare resource. We talked to some larger hospitals already engaging with many of these initiatives and we have implemented changes to our policy to permit the expanded use of RhD positive red cells throughout hospitals. This has changed our message to our hospital users and is awaiting final approval by National Transfusion Advisory Group (NTAG) before national adoption.

#### **Diversifying the Donor Base**

As demand for rare blood increases, in particular the RhD type RO, we have been aware for some years that there is a need to increase the ethnic diversity of our donor base. In 2023, we introduced malarial antibody testing for donors of African heritage. This has seen us welcome more than 300 new donors of African heritage over the past 18 months. There is a great deal of work still to be done in order to increase the number of these donors who continue to donate, and we are looking at the testing performed in other blood establishments across Europe to expand our criteria for donation to include as many people from as many backgrounds as possible.

# Donor Selection Criteria and the Individual Donor Risk Assessment (IDRA)

The end of 2023 saw us introduce IDRA, and we have this year taken part in the FAIR Study led by NHSBT looking at how our donors complete these assessments. This will give us a better picture of how accurate the risk assessments are, and this will offer us a robust way to increase the diversity of our donor base without compromising safety for the recipients of these blood products.

We have throughout the year reviewed the efficacy of IDRA with an IDRA Safety Monitoring Group (ISMG) and the data we have seen suggests that the introduction of this approach to donor selection has been of massive benefit to our donor base and to the organisation.

We continue to monitor our donor selection criteria, with a particular focus on novel and emerging infectious diseases through our Infection Steering Group (ISG).

#### Research

The Research and Development team continue to engage with more research which is focused on the needs of donors and recipients of blood in Ireland.

We have a total of 18 ongoing research projects, with a further 4 completed and published in 2024. This represents a year-on-year increase in the activity within the research department. We have also supplied more than 1,500 blood components for use in research around Ireland.

We continue to expand our presence in the International community, with poster presentations at major international haematology events and engagement in multicentre projects with Science Foundation Ireland, the Royal College of Surgeons in Ireland and Trinity College Dublin.

We held our second BlooDHIT Blood Donation Haematology, Infection and Transfusion conference on November 14th and 15th in Dublin. This conference brings together much of the research we have in Ireland with international experts in the field and helps inform our vision for the next five years. The conference was extremely well attended, by more than 170 scientists, clinicians and health professionals with an interest in transfusion.

#### Tissue activities

The demand for tissue and serum eye drops continued to increase this year. 2024 has also seen significant progress in our project to open an Irish Eye Bank for corneal transplants, and this remains our strategic priority. There is great demand for this tissue as currently the only other source is from other countries. We are completing our final agreements with the other involved healthcare providers in Ireland and completing the laboratory validation for cadaveric samples. We will be aiming to harvest and transplant our first corneal tissue in 2025.

#### Laboratories

We continue to commit resources to the National Donor Screening Laboratory project to upskill our current staff base to allow cross cover and permit more flexible working patterns for our staff.

#### Haemovigilance

The pilot for the planned IT system for haemovigilance continues to progress with an expected implementation date of H2 2025. We are aiming to have the governance structure and the medical director position of the National Haemovigilance Office (NHO) completed prior to implementation of the new electronic system in late 2025.

## The Irish Unrelated Bone Marrow Register (IUBMR)

The need for stem cell transplantation in Ireland is increasing and the workload for the registry personnel has grown correspondingly. It is impressive to witness the service level the IBTS staff provide to the clinicians.

Our efforts to recruit more young donors to the registry during the donation process has been successful and we are now conducting an increasing number of international requests.

#### Global Health Initiative -Collaboration with the National Blood Transfusion Service of Tanzania

This year we reviewed the partnership with the National Tanzanian Blood Transfusion Service (NBTS) and unfortunately, for many reasons we have concluded that at the current time, we could not enter into a formal partnership with the NBTS. We still have many opportunities with Tanzania outstanding, including educational and research options and we will be pursuing this through a research project rather than a formal partnership.

#### **Final Remarks**

This year has been an exciting development for me and for IBTS as a whole with our ongoing programmes in both the operational and research spaces. I am looking forward to the potential of our next 5-year-strategy cycle which will be developed in 2025.

#### **Dr Andrew Godfrey**

Medical & Scientific Director



## **Donor Services and Logistics**

#### **Donor Awards**

	50s	100s	Ceremonies
Carlow	104	13	1
Limerick	182	9	1
Ardee	102	17	1
Cork	161	40	1
Tuam	128	23	1
Dublin	254	112	2

### **National Advertising 'Lifeline' Campaign**

Following its launch in 2023, we further developed the national "Lifeline" campaign, incorporating advertising across TV, radio, social media, on-demand video, podcasts, and billboards. Additionally, we introduced cinema ads and digital display advertising. The campaign is a balance between encouraging existing donors to help us maintain the blood supply, while increasing awareness among potential new donors.



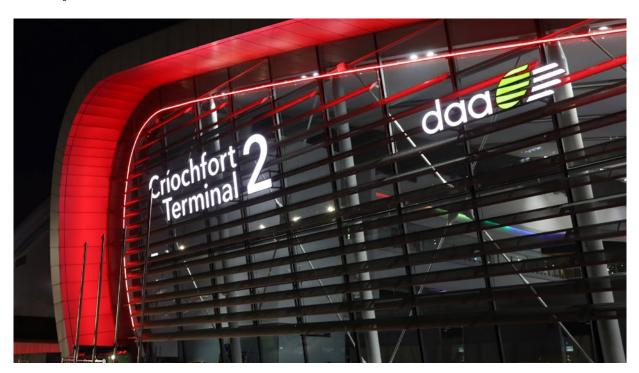
### Oisín's Campaign – GAA

Our GAA campaign, "Every Drop Counts, I Know," honours the late Oisín Kelly, a young inspirational sportsman who advocated passionately for blood donation following his experience of the benefit of many blood and platelets transfusions while being treated for cancer. With Oisín's family and friends support, the campaign was launched initially in Oisín's home county, Carlow, in late 2024. The launch was attended by many GAA figures including An Uachtaráin GAA Jarlath Burns, with the campaign set to roll out nationally during 2025, encouraging particularly young people who play sports, to consider giving blood.



#### World Blood Donor Day - Light Up Red

To mark World Blood Donor Day on June 14, the IBTS worked closely with a wide range of partners and organisations to light up their landmark buildings red for the day. Over 20 major sites participated nationwide, including the GPO, Mansion House, the Department of Health. Kilkenny Castle and the Rock of Cashel.



### **Vodafone Partnership**

Vodafone has long been an important partner of the IBTS, supplying all our text messaging for free. In 2024, Vodafone ran their 'Every Connection Counts' campaign featuring the IBTS in billboards and digital and social media ads, highlighting our use of their texting services to help reach our goal of 3,000 donations per week.

### **Liberty Hall Halloween Billboard**

The IBTS was delighted to partner with SIPTU who provided very prominent advertising space on Liberty Hall in October, where we displayed a Halloween message prominently for over two weeks.

#### **First-Time Donors**

In 2024 over 11,500 new donors were welcomed. New onboarding communications and information packs were introduced to foster a sense of community and encouragement to continue to give blood into the future.

Additionally, many of these new donors also signed up to the online appointments portal with nearly 53,000 donors now registered to make appointments online for upcoming clinics.



### **Community engagement**

The IBTS were present at national events like the National Ploughing Championships, Dublin Pride, and Africa Day, which will support the campaign to diversify the donor panel and make it better matched with Ireland's changing patient base.

The regional teams also participated in many various activities, including local sports club meetings, promotions in shopping centres, and corporate business networking and presentation events.

### Platelets advertising

The IBTS also ran a cinema advertising campaign to recruit more platelets donors, and a short social media campaign, gaining insights that will inform future recruitment.

# Irish language advertising obligations

For Irish language advertising requirements, IBTS achieved its obligations in 2024 (20.89% of all advertising in Irish, with 5.16% spend of all advertising on Irish media only).\*

\* these are submitted figures with indicative outcomes from the commissioners portal pre audit.





Figure 1. Whole Blood Donors by Gender

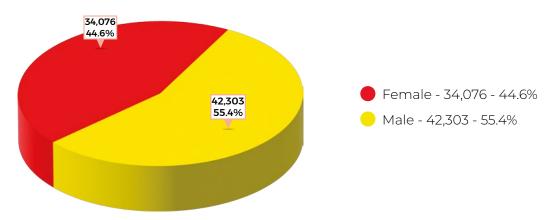


Figure 2. Whole Blood Donors by Bloodgroup

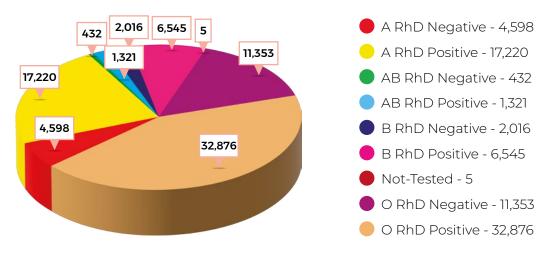
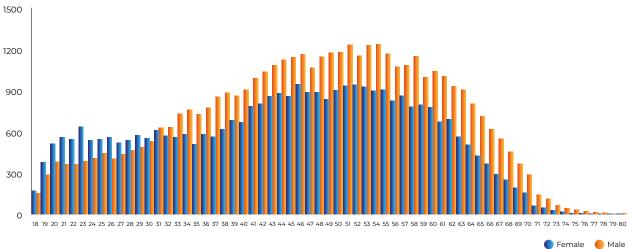


Figure 3. Whole Blood Donors by Age and Gender



## **Production and Hospital Services**

### Production, Hospital Services, Supply Chain, Transport & Logistics, Scientific Support and Component Development

#### Key achievements:

- Re-introduced whole blood derived plasma for therapeutic use and made first shipment of plasma for fractionation to make plasma derived medicinal products.
- Completed replacement of temperaturecontrolled blood collection vehicles with HVO fuel compatible vehicles.
- Completed initial validation testing on a potential new product - whole blood containing platelets for use in trauma.
- Maintained blood stocks across the supply chain, ensuring blood and blood product availability to meet patients' needs.
- Worked with internal and external healthcare partners to maximise and optimise the use of blood components for all patient groups.
- Continued replacement of critical blood processing equipment to maintain state of the art processing capability and operational best practice in both centres in the NBC and Cork.
- Worked with internal and external research partners to advance the development of improved blood components. Presented research findings at national and international conferences.

The Components production function is responsible for processing, labelling and banking of all whole blood donations, platelet pools and platelet apheresis donations nationally.

The Hospital Services function is responsible for inventory management, receipt and issuing of blood and blood product orders from hospitals.

The Supply Chain, Transport & Logistics functions are responsible for supporting internal and external business needs.

The Scientific Support and Component Development team are responsible for the management of all platelet products, nonroutine whole blood and red cell products issued from the NBC. This team also provides day to day scientific support for numerous departments and encompasses the product development function.

#### **Blood Component Activity**

There was an increase in red cells (+2.9%) and platelets (+3.6%) issued to hospitals in 2024, compared to 2023.

#### **Medicinal Product Activity**

There was a decrease in LG-Octaplas issued in 2024 (-6.3%) and an increase in fibrinogen concentrate issued in 2024 (+2.1%), compared to 2023. There was a transition of fibrinogen concentrate product from Riastap to Fibryga during the year.



Figure 4. Red Cell Issues 2020 to 2024

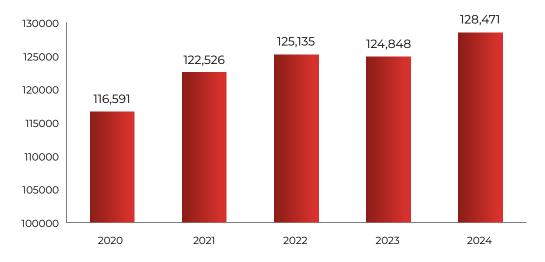


Figure 5. Platelet Issues 2020 to 2024

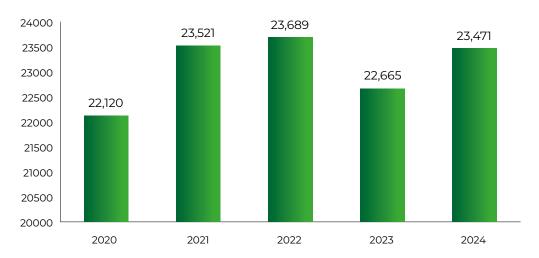
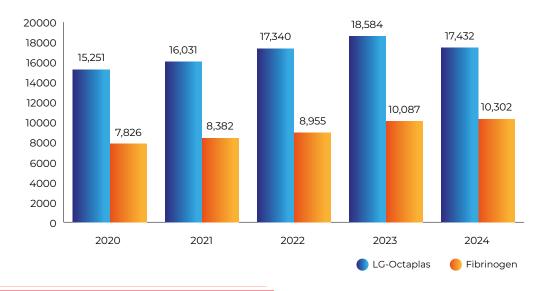


Figure 6. LG-Octaplas and Fibrinogen Issues 2020 to 2024



#### **Plasma For Medicine**

Plasma is the liquid part of your blood that carries red cells, platelets and white blood cells around the body. It contains clotting factors that help to stop bleeding, and antibodies, known as immunoglobulins, which fight infection.

Plasma can be transfused as liquid plasma, processed into other plasma products, such as cryopreciptate or used as a source of important medicinal products known as Plasma Derived Medicinal Products (PDMPs). These are therapeutic agents essential to lifesaving healthcare, which are obtained by a combination of large-scale processing steps called fractionation.

PDMPs are used for the treatment of a variety of conditions including immune disorders, neurological disorders, blood disorders and infectious diseases.

Since 2001, the IBTS have been importing plasma for therapeutic use to reduce the risk of transmission of vCJD. However, in 2024 the IBTS re-introduced whole blood derived plasma for large scale human therapeutic use. It has been a significant undertaking encompassing all aspects of the organisation from donation clinics to product distribution.

The project entailed infrastructure changes in blood processing, the implementation of industrial freezing technology and a suite of electronic system changes to enable the management of plasma product and data. The IBTS has now introduced plasma handling, freezing and storage processes compliant with industry regulations for medicinal products and the first shipment of plasma for fractionation took place in December 2024.

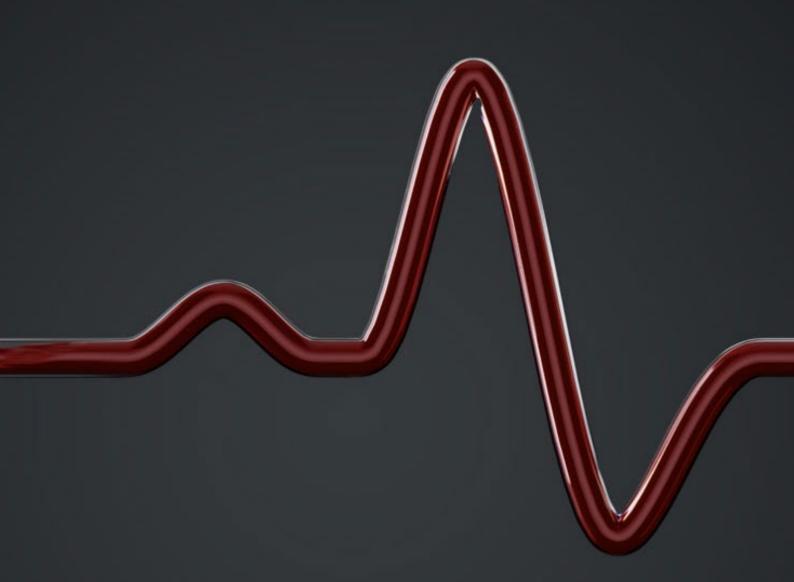
Medicinal plasma will be returned for use in Irish hospitals and any plasma that is surplus to the requirements of the Irish healthcare system will be used in the manufacture of other PDMPs such as immunoglobulin. This ensures that we make best use of every donation for patients in Ireland as well as contributing to the European pool of plasma.

There is a significant deficit in the volume of plasma currently being collected in Europe and there is a drive to achieve self-sufficiency for PDMP production.

Europe is heavily reliant on the United States and the EU is seeking greater security and control of its plasma collection and PDMP availability. Optimising the plasma collection supply chain is essential to removing the vulnerability and reliance on outside sources of PDMPs.

To ensure the future needs of patients in Ireland are met and become fully self-sufficient, additional plasma must be collected directly from donors in a process called plasmapheresis. This is where blood is removed from the donor, plasma is separated and the red cells returned to the donor. This is known as source plasma and the IBTS is well placed to commence this as platelet donations are already collected in a similar way.

Most European countries collect source plasma to supplement the plasma supply. Following the removal of restrictions relating to vCJD, source plasma collection is now possible in Ireland and the IBTS are in the early stages of scoping what this strategic development might look like.



TABHAIR FUIL CHUN LÁMH THARRTHÁLA A THABHAIRT DO DUINE.

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TÁIMID AG BRATH ORT.

## **Testing**

# National Donor Screening Laboratory (NDSL)

The NDSL encompasses the three donor testing laboratories: Automated Donor Grouping (ADG), Virology, and Nucleic Acid Testing (NAT). This extensive collaboration between the three donor testing laboratories allows for optimum workflow analysis, strategic utilisation of key scientific personnel, up skilling of scientific personnel in multiple scientific disciplines, increased research and development in all areas and the increase of testing services available to the IBTS.

# Key achievements of the NDSL in 2024 included:

- The Virology Laboratory continued its partnership with the Seroepidemiology Unit (SEU) in the Health Protection Surveillance Centre (HPSC) in relation to the ongoing Covid 19 National Serosurveillance Programme in 2024.
- The Virology Laboratory introduced selective HTLV testing for first time and lapsed donors, moving away from the universal testing of all donors in 2024.
- ADG has continued to develop a rare donor screening programme. In 2024 the department identified 2 Kpb- donors (prevalence 0.0001%) and 29 Lub- donors (prevalence 0.2%).
- ADG identified an additional 3 U- and 57
  Fya-b- donors. These antigen negative
  types are only present in an African
  ancestry donor population.
- Training and participation in an internal audit team based on ISO (International Organisation for Standardisation) requirements.

- The maintenance and advancement of the cross-training programme with support from the Training and Education Officer provided cross functional support between staff in the three departments which has contributed to developing a cohesive and collaborative team in the NDSI
- The NDSL has continued to promote sustainabilityandenvironmentalinitiatives in line with its My Green Lab Green certification.

## NDSL Publications and Presentations:

- Infectious Disease Screening: A Key Step in Diversifying the Irish Donor Population was presented at the second Blood Donation, Haematology, Infection and Transfusion Conference – BlooDHIT 2024.
- The Introduction of Malaria Antibody Testing at the Irish Blood Transfusion Service. Poster presentation at ISBT Barcelona.
- Cytomegalovirus Seroprevalence in Irish Blood Donors. Poster presentation at BlooDHIT conference.
- SARS-CoV-2 Surveillance Study in Irish Blood Donors. Poster presentation at BlooDHIT conference.
- Journey to Sustainability at the IBTS.
   Poster presentation at BBTS and BlooDHIT conference
- Beckman Coulter PK7400 Primary Blood Group Analyser is suitable for phenotyping and screening Irish Blood Donors. Poster presentation at BlooDHIT conference.
- The Creation and Development of the Irish Rare Donor Programme. Poster presentation at ISBT and oral presentation at BlooDHIT conference.
- Diversity of Blood Antigen Phenotypes in Irish Blood Donors. Poster presentation at Faculty of Public Health Medicine Conference.



#### **NDSL Laboratory Activity:**

In 2024 the NDSL tested 140,767 donations, with 132,718 coming from repeat donors (94%) and 8,049 (6%) of these donations coming from first time donors. In addition, 2,032 sample only new donors were also tested.

All donations were tested for:

- ADG: ABO/Rh, extended Rh phenotype (CcEe), donor antibody screen and high titre A/B
- **Virology:** The presence of antibody to Human Immunodeficiency viruses (anti-HIV1/2), antibody to Hepatitis C virus (anti-HCV), antibody to Human T-Lymphotropic virus type I and II (anti-HTLV-I/II), antibody to Hepatitis B core (anti-HBc), Hepatitis B surface Antigen (HBsAg), antibody to Treponema Pallidum (Syphilis).
- NAT: Human Immunodeficiency Virustype 1 and 2 (HIV-1/2), Hepatitis C virus (HCV) and Hepatitis B virus (HBV) and Hepatitis E Virus (HEV)

Selected donations were tested for:

- ADG: Extended antigen types, haemoglobin S, neonatal antibody screen. Donors are typed for extended antigen types (Fya/b, Jka/b, M, S/s, k) for routine hospital orders and to identify rarer phenotypes or combinations of antigen negative types. These are typically for patients with complex transfusion requirements such as sickle cell disease or multiple red cell antibodies and for prophylactically antigen-matched blood for intrauterine transfusions and certain patients who are known red cell antibody producers.
- Virology: Selected donations are tested for Cytomegalovirus (CMV) (approx. 80% of donations) in order to have a supply of CMV negative donations for those patients who are at risk of the complications of CMV infection e.g. immunocompromised patients. Selected donations are also

tested for Malaria antibodies. Selective testing for HTLV was introduced in 2024 for all first time and lapsed donors only.

for West Nile Virus (WNV) from May to December 2024. This testing was performed for donors who had travelled to a WNV at risk area within the past 28 days.

ADG have two instruments in use: PK7400 as the primary blood group analyser and Ortho Vision as the secondary blood group analyser. Both instruments are immunohaematology systems and utilise both hemagglutination and sensitisation techniques. The PK7400 is a high-throughput microplate system and the Ortho Vision tests using column agglutination technology. Manual techniques are used for antibody identification and sickle cell trait testing.

The Virology laboratory performs screening on the Abbott Alinity's System, which is a high-throughput, fully-automated immunoassay analyser designed to determine the presence of specific antigens and antibodies using chemiluminescent immunoassay (CMIA) technology. Malaria antibody screening is performed on the Dynex DS2 instrument.

The NAT laboratory performs Individual Donation testing (ID-NAT) using the Panther testing instruments with the Ultrio Elite (UE), HEV and WNV assays. The Panther instrument is a fully automated closed system for NAT testing. The Procleix UE assay is a multiplex Transcription Mediated Amplification (TMA) assay for the detection of HIV-1/2 RNA, HCV RNA and HBV DNA in human plasma. The Procleix HEV assay detects HEV RNA. The WNV assay reliably detects low level WNV RNA (lineage 1 and 2) in blood donations.

The laboratory also performs screening tests for viral markers for various departments within the IBTS, including stem cell donors, heart valve tissue donors and samples from recipient tracing testing programmes.

## Participation in External Quality Assessment Schemes (EQAS):

NDSL participate in several EQAS. All departments within the NDSL had satisfactory results for their relevant EQA.

In 2024 ADG participated in 3 NEQAS schemes. This consisted of 18 separate serology exercises and 6 abnormal haemoglobin exercises.

The Virology Laboratory participates in three proficiency programmes: one circulated by the United Kingdom National External Quality Assessment Service (UK NEQAS) for Microbiology, the second by the NRL, Australia and one by the European Directorate for the Quality of Medicines and HealthCare (EDQMNAT). Overall, 25 proficiency exercises were completed in 2024 in Virology, assessing all virology markers tested in the laboratory.

The NAT laboratory participated in seven proficiency programmes: two provided by the NRL, Australia, one by the European Directorate for the Quality of Medicines and HealthCare (EDQM), two by Quality Control for Molecular Diagnostics (QCMD), UK and two by the National Centre for the Control and Evaluation of Medicines (CNCF), Italy. Overall, 16 proficiency exercises were completed in 2024 in the NAT laboratory.

The laboratory also participates in the surveillance programme run by National Health Service Blood and Transplant (NHSBT) Epidemiology Unit/Health Protection Agency UK. The repeat reactive rates and the confirmed positive rates for testing kits using various lot numbers of reagents with the NHSBT are monitored. A notifying report is generated which details assay performance and trends in reactive rates.

#### **NDSL Contingency Testing:**

As the NDSL is a national testing facility, the IBTS has an external testing plan with the Scottish National Blood Transfusion Service in case of a critical failure of instruments or site. The NDSL succeeded in participating in 2 exercises in 2024 which involved sending samples from 24 donors for testing. This plan has not had to be activated in a 'live' situation since the consolidation of testing at the National Blood Centre in 2010

#### **NDSL Audits:**

The Laboratory also participates in several internal and external audit programmes to ensure compliance within the Quality Management System (QMS). This auditing of the NDSL processes and procedures are undertaken by the Health Products Regulatory Authority (HPRA), the IBTS Quality Assurance (QA) department and the NDSL Laboratory.

#### Red Cell Immunohaematology (RCI) Laboratory

The RCI Laboratory provides comprehensive pre-transfusion and antenatal referral services to hospitals across the country.



#### **Key Achievements 2024:**

#### **Research and Educational Achievements**

RCI staff actively contributed to the scientific communitythroughconference presentations and research initiatives, including:

- BBTS Conference: Enhancing the Delivery of Services and Fostering Collaboration in the Transfusion Field

   Formation of the UK and Ireland Red
   Cell Immunohaematology Working Group
- ISBT Conference: Blood Provision for a Patient with Anti-IH and Subsequent Laboratory Improvements
- **BloodHIT Conference:** Combining Serological and Molecular Methods
- Undergraduate research project:
  - In February 2024, a Medical Science student from ATU, commenced her final-year undergraduate research project at RCI.
  - > **Project Title:** Evaluating Reagents for the Use of Enzyme Treatment of Adsorption Cells in Reference Serology

## Advancements in laboratory testing

- Developed a standardised approach for testing patients receiving Anti-CD47 treatment.
- Finalised a process to distinguish between anti-M IgM and anti-M IgG.

#### Laboratory achievements

Key achievements include:

- Successfully retained ISO 15189 accreditation following an inspection in May 2024.
- Conducted a review of the reporting process in collaboration with Medlab Partners
- Completed a comprehensive review of stock management to enhance efficiency.
- Improved turnaround times for antibody titration reporting in pregnancy, ensuring timely clinical decision-making.
- Expanded electronic reporting capabilities for hospitals nationwide through Sharefile and email integration.
- Developed and implemented a transition plan for ISO 15189:2022 compliance.
- Adopted a risk-based audit schedule, ensuring all audits conducted in 2024 adhered to this framework.

#### Laboratory activity

The RCI Laboratory provides a comprehensive range of specialised immunohaematology services, including:

- Crossmatched blood provision for patients with complex antibodies.
- Investigation of red cell antibodies, including serologically complex cases.
- Investigation of haemolytic transfusion reactions to ensure patient safety.
- ABO/Rh typing, including the resolution of blood group anomalies.
- Assessment of patients with positive direct antiglobulin tests to identify underlying causes.
- Investigation of autoimmune haemolytic anaemia, supporting accurate diagnosis and treatment.
- Detection of monoclonal antibody interference, ensuring accurate transfusion compatibility testing.
- Diagnosis and management of haemolytic disease of the foetus and newborn (HDFN).

- Antenatal screening for red cell antibodies to identify at-risk pregnancies, including antibody quantitation and titration.
- Provision of suitable blood at delivery for at-risk pregnancies to optimize neonatal outcomes.
- Extended phenotyping for transfusiondependent patients and those with complex red cell antibodies.
- Phenotyping of donor red cells upon request to support transfusion compatibility.
- Provision of clinical and scientific advice to hospital colleagues.
- Importation of rare blood for named patients requiring specialised transfusion support.
- Out-of-hours emergency on-call service to ensure urgent transfusion needs are met.
- Provision of hospital blood bank services for Blackrock Hospice, Our Lady's Hospice, and the Royal Victoria Eye and Ear Hospital.

#### **Activity metrics**

In 2024, the RCI Laboratory tested a total of 2,553 samples, reflecting a 1.74% decrease compared to 2023.

	Total No. of Samples tested	RhD Type Workup	Antibody ID	Anti-D Quant	Anti-c Quant	Monoclonal Interference	Total Compatibility Test	On-call Samples
2023	2598	6	2453	384	153	384	1184	267
2024	2553	2	2343	275	154	341	1102	294
(%)	-1.74	-66.7	-4.5	-28.4	+0.65	-11.2	-6.9	+9.2



#### **Key observations**

- Anti-D Quantitation referrals decreased by 28.4%, likely due to the success of the Routine Antenatal Anti-D Prophylaxis (RAADP) programme and a declining birth rate in Ireland.
- Since November 2023, RCI mandated a clinical request for all crossmatch referrals, filtering out inappropriate requests. This led to a 6.9% decrease in compatibility test requests in 2024.
- A further decrease in referrals for patients receiving monoclonal drug anti-CD38 was observed, reflecting hospitals implementing their own monoclonal interference testing strategies, such as DaraEx.

#### Sample complexity

RCI continued to receive highly complex serological cases, with a 40% increase in serologically difficult or rare samples referred in 2024. A significant portion of these were antenatal cases, where identification of red cell antibodies was crucial in assessing the risk of haemolytic disease of the foetus and newborn (HDFN) and determining blood requirements for mother and baby. All cases managed to date have resulted in successful outcomes.

#### Antibody trends (2023 Vs 2024)

Antibody	2023	2024	% difference
Anti-G	49	60	+18.3
Anti-Ch/Rg	25	37	+32.4
System Specific	23	18	-21.7
HTLA-type Antibodies	22	12	-45.5
Anti-Wra	18	39	+53.8
Anti-Lua	11	17	+35.3
Anti-Kpb	8	11	+27.3
Anti-Lea	8	21	+62
Anti-P1	6	10	+40
Anti-Leb	5	21	+76.2
Anti-Yta	4	1	-75
Anti-IH	4	4	0
Immune Anti-B	2	0	-200
Anti-k	2	2	0
Anti-H	1	0	-100
Anti-Kna	1	0	-100
Anti-Vw	1	3	66.7
Anti-Ce	1	0	100
Anti-f	1	1	0
Anti-Coa	1	0	100
Anti-PP1Pk	1	6	83.3
CR1-Related antibody	0	7	700
JMH	0	3	+300
Yka	0	2	+200
Lub	0	2	+200
JK3	0	2	+200
Fy3	0	1	+100
Mia	0	1	+100
Total	194	281	+40%

# SCARF (Serum, Cell, and Rare Fluid Exchange Network)

The RCI Laboratory continued to expand its inventory of Rare Reference Cells and Antisera through participation in the International SCARF Exchange Network and the UK Cell Exchange. Testing methodologies were further optimised to accommodate Ireland's evolving population demographics.

## Importation of rare blood and products

In 2024, a total of 15 red cell units were imported for named patients, representing a 73.3% increase compared to 2023 (4 units). These imports were facilitated on seven occasions from the following countries:

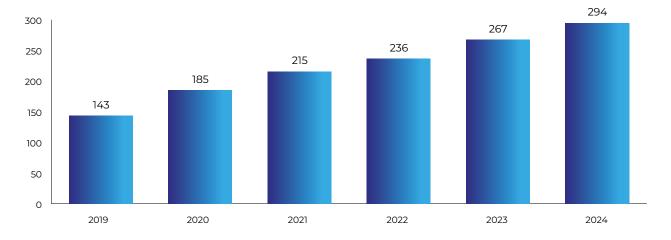
- United Kingdom (n=4)
- Canada (n=1)
- Spain (n=1)
- Sweden (n=1)

Additionally, RCI assisted in the importation of 12 platelet units, marking a 75% increase from 2023 (3 units). From September 2024, SSCD assumed responsibility for platelet importation.

#### **Out-of-Hours Requests**

Demand for out-of-hours services continued to rise, with a 9.2% increase in referrals in 2024. The graph below illustrates the steady increase in out-of-hours referrals from 2019 to 2024.

Figure 7. On-call requests 2019 - 2024





## Participation in External Quality Assurance Schemes

The RCI Laboratory actively participates in multiple external quality assurance (EQA) schemes, including; IEQAS, AQQAS, NEQAS and WASPS. Additionally, RCI participates in inter-laboratory comparison schemes for various specialised techniques, including:

- Elution techniques
- Antibody titration
- Adsorption techniques
- DTT treatment
- Neutralisation techniques

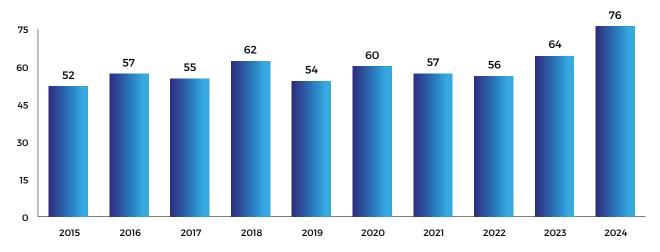
All results obtained were satisfactory; however, three data entry errors were identified and subsequently raised as incident reports. These were managed in accordance with IBTS policies and procedures to ensure continued quality improvement.

### National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)

The National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL) provides a comprehensive range of clinical testing services designed to support the allogeneic haematopoietic stem cell transplantation (HSCT) programmes at St. James's Hospital and Our Lady's Children's Hospital, Crumlin. HSCT can be used in the treatment of leukaemias, bone marrow failure syndromes and inherited metabolic disorders.

The laboratory determines the human leucocyte antigen (HLA) type of all patients and donors (related or unrelated) prior to transplantation to aid donor selection. The laboratory uses exclusively molecular methods based on the polymerase chain reaction (PCR) to define the genes that encode the HLA molecules. This technology can achieve a high level of resolution that distinguishes between individual alleles of the HLA genes. Since the 15th June 2020 the NHIRL performs high resolution HLA typing for 11 HLA loci (HLA-A, B, C, DRB1/3/4/5, DQA1, DQB1, DPA1, DPB1) by Next Generation Sequencing (NGS) using the Illumina MiSeq platforms.

Figure 8. Number of Irish Patients receiving a HSCT from an Unrelated Donor 2015 - 2024



The laboratory has an extensive quality assurance programme including participation in both internal and external proficiency testing programmes for HLA typing, human platelet antigen (HPA) genotyping and HLA antibody investigations. The NHIRL has been accredited by the European Federation for Immunogenetics (EFI) since 2001.

In 2024 samples from 317 Irish patients for potential haematopoietic stem cell transplants and 371 family members were HLA typed by the NHIRL. For those patients without a suitable family donor, an unrelated donor may be identified from the registry of volunteer unrelated donors. A total of 464 samples from possible unrelated donors were HLA typed for Irish patients in 2024. The NHIRL provides an immunogenetics support service for the Irish Unrelated Bone Marrow Registry (IUBMR). From October 2019 the blood donor Health and Lifestyle Questionnaire (HLQ) included a question for donors aged between 18-25 asking if they would like to join the bone marrow registry. This has resulted in a very significant increase in the number of donors registering, with 2,266 new donors joining in 2024.

In 2024 a total of 76 unrelated donor transplants were performed. In the last 10 years the IUBMR has facilitated 593 unrelated donor transplants for Irish patients (Figure 8).

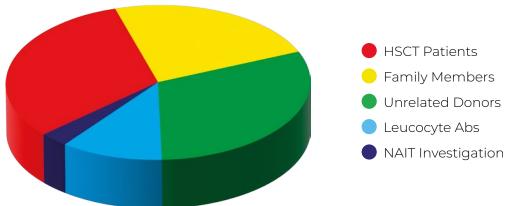
In addition, a total of 331 platelet donors were HLA-A, -B typed and included on the panel of platelet donors to support the provision of an optimal platelet product to the hospitals.

The NHIRL received 1,962 samples as part of clinical investigations in 2024 (Figure 9). As well as supporting the stem cell transplant programmes the NHIRL provides a platelet immunology service for the serological investigation of neonatal alloimmune thrombocytopenia (NAIT), post transfusion (PTP), purpura platelet refractoriness, alloimmune thrombocytopenias adverse transfusion reactions. The number of investigations for NAIT in 2024 (n=57).

#### **Disease Association**

The NHIRL provides a routine disease association HLA typing service. This service represented 4,119 (45.2%) of the 9,105 samples received for testing by the NHIRL in 2024. The majority (83%) of disease association samples are referred for determining the presence or absence of HLA-B27 which is associated with Ankylosing Spondylitis; a painful, progressive rheumatic disease mainly affecting the spine and sacroiliac joints. The service also provides HLA typing for Coeliac Disease (DQ2/DQ8, 3.4%), Behcet's Disease (B\*51, 5%), Abacavir-induced hypersensitivity reaction (B\*57:01, 9%) Narcolepsy (DQB1\*06:02, 0.85%), Birdshot retinochoroidopathy (A\*29, 1.4%), Acute severe Hepatitis in children (DRB1\*04, 0.5%) and Metastatic Uveal Melanoma (A\*02:01, 0.4%).







### Blood Group Genetics Laboratory (BGGL)

Molecular Blood Group typing is performed by the Blood Group Genetics Laboratory of the Molecular Biology and Genetics Department at the National Blood Centre, with the purpose of providing a molecular diagnostic service for blood group determination.

The Blood Group Genetics Laboratory provides a service for:

- Foetal RhD Screen
- Weak D Genotype investigation
- RhD Variant investigation
- Full RBC Genotype investigation
- RHCE Variant investigation

DNA-based testing is increasingly being used to predict a blood group phenotype to improve practices in transfusion medicine. Red blood cells carrying a particular antigen, if introduced into the circulation (through transfusion or pregnancy) of an individual who lacks that antigen, can elicit an immune response. The resultant production of antibodies can have a significant effect on the patient's morbidity and even mortality.

Sensitive methods, such as quantitative polymerase chain reaction (qPCR), offer the ability to detect very low levels of DNA and are particularly applicable for the detection of fetal blood group genes in cell-free DNA extracted from maternal blood.

In 2024 over 5100 samples were received by the Blood Group Genetics Laboratory for foetal RhD screening from 13 different hospitals nationally. The electronic transmission of foetal RhD screening results through Medibridge is available to referring hospitals.

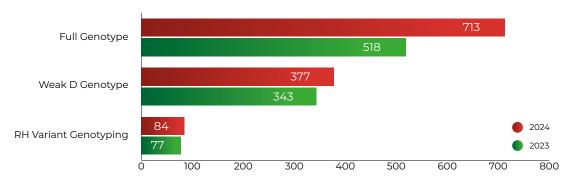
Since the development of the BGG laboratory and the implementation of foetal RhD screening in 2018/19, over 7500 women have avoided unnecessary prophylactic anti-D.

Molecular determination of blood groups offers a powerful method that overcomes many of the limitations of, and often offers higher resolution blood group typing than serological methods (e.g. RhD and RHCE variants, FYGATA mutation).

Currently 44 Human Blood Group Systems have been identified, their genes cloned and the molecular basis associated with individual antigens determined; there are 354 red cell antigens represented in the 44 Blood Group Systems.

The Blood Group Genetics Laboratory continues to provide an extensive red cell genotyping service for the resolution of serological ambiguities (weak D, RhD investigation, extended genotyping for anti-CD38 monoclonal antibody therapies) and to compliment haemoglobinopathy patient workups for the investigation of complex RHCE variant alleles.





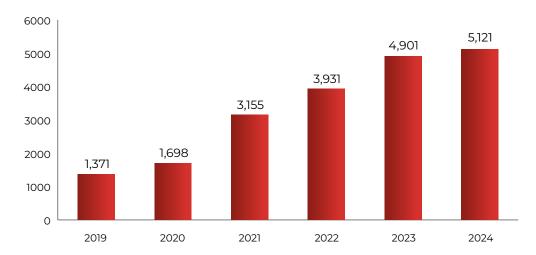


Figure 11. Foetal RhD Screen

#### **Diagnostics/Crossmatch Cork**

The diagnostics laboratory at the IBTS Cork Centre provides both routine and reference immunohaematology and laboratory services. The former to South Infirmary University Hospital (SIVUH), St. Finbarrs', and Marymount University Hospital and Hospice, and reference immunohaematology and laboratory Services to the Munster region. Medical scientists and despatch officers are on-site 24/7 supported by specialist medical staff and a Consultant Haematologist.

The Laboratory provide the services below;

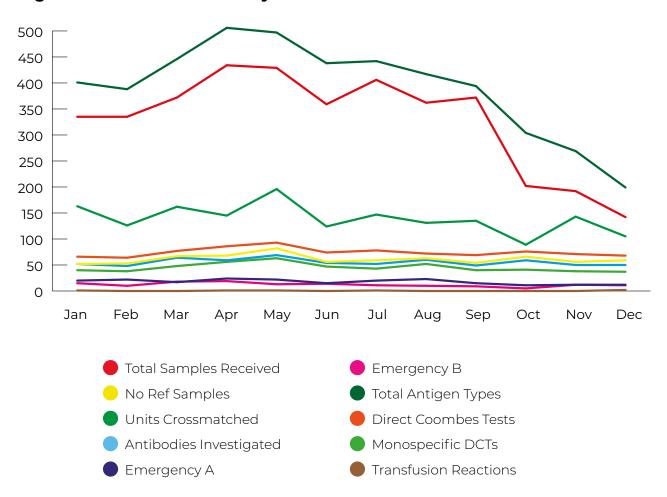
- As hospital Blood Bank for several city hospitals, the laboratory undertakes blood grouping, antibody screening, provides cross-matched red cells and other components for individual patients.
- Provides laboratory and clinical advice for these patients. Investigates possible transfusion reactions, participates in patient blood management and transfusion practice planning and review through the hospital transfusion committees and audit, and manages component traceability.
- Investigates complex or anomolous red cell typing, extended typing for transfusion dependent patients, positive direct antiglobulin tests, auto-immune haemolytic anaemia, haemolytic disease of the foetus/newborn, and complex antibodies providing extended matched (phenotyped) and crossmatched red cells for these patients. Individual samples in these cases may take several hours to investigate fully and may require donation screening where matching red cells are not available on the shelf. Four patient samples required further specialist referral to the international blood group reference laboratory (IBGRL) Bristol, and a further 135 samples were sent to the NBC for genotyping. Advice is provided to colleagues in the region.
- Investigates ante-natal patients with red cell antibodies and tracks their care through the pregnancy to plan availability of matched blood for mother and baby at delivery.



- The Diagnostics laboratory staff manage special component stock for the region. This includes all platelet components and all orders received by the electronic order system (EOS) for antigen typed red cells, irradiated blood components and blood components for babies.
- As the scientist is on duty out of hours, the diagnostics laboratory contributes to the service by undertaking secondary processing of blood components and are the first point of contact for clinical queries which are referred on to the medical staff.
- Performance in External Quality Assessment Schemes was satisfactory throughout the year.

Total samples received 2024: 3940 (2023: 4130). The decrease in sample numbers is owing to cessation of hospital blood bank services to Mater Private Cork on 30/09/2024.

Figure 12. Crossmatch Activity 2024



### Other Services

#### Tissue

The IBTS Tissue Bank is located at the National Blood Centre, where it operates as a licensed tissue establishment. It also holds a Good Manufacturing Practice (GMP) license for the production of serum eye drops, which are classified as an exempt medicinal product.

The facility features several clean rooms that are crucial for the processing and testing of human tissue intended for clinical use, as well as for the production of serum eye drops. The Tissue Bank provides human tissue to hospitals nationwide. While some of the tissue comes from Irish donors, other tissues are sourced from tissue banks across Europe or imported from the United States. The range of tissue products offered includes ocular, cardiovascular, musculoskeletal, and skin.

In 2024, the production of serum eye drops saw a significant increase of 30%. These eye drops are prescribed as a last-resort treatment when other options have failed. They are available by prescription from an ophthalmic consultant. Demand for other types of human tissue remained consistent with previous years.

The project to restart cornea collection from Irish donors gained momentum in 2024, and it is expected that in 2025, the Tissue Bank will once again be able to retrieve corneas from Irish donors.

#### Therapeutic Apheresis Service

The Therapeutic Apheresis Service (TAS) in the IBTS Cork Centre provides therapeutic apheresis for patients in the Munster region at Cork University Hospital (CUH) and Mercy University Hospital (MUH).

TAS is led by IBTS Consultants, supported by Therapeutic Apheresis Nurses, Specialist Medical Officers (SpMO) and Specialist Haematology Registrars (SpR) on rotation. Procedures are carried out at the patients' bedside using mobile apheresis equipment; Optia. Terumo Spectra Individualised apheresis protocols are prepared for each patient in conjunction with the requesting clinical hospital team, guided by the American Society for Apheresis 'Guidelines and Indications for Treatment' (ASFA, 2019-2023), and cognisant of the other guidelines including those from the British Society of Haematology (BSH, 2015).

TAS operates within the IBTS quality management system, with trained personnel, controlled documentation, standard operating procedures (SOPs), validated technology and adverse event monitoring. Adverse events are subject to ongoing review and changes are incorporated into the IBTS Therapeutic SOPs.

TAS staff attend national and international meetings and comply with continuing professional development (CPD) including audits. This includes contributing to a report on activity and indications for apheresis in three centres over a 5-year period: 'A Retrospective Analysis of Therapeutic Apheresis in Ireland' that was presented in Belfast at the Haematology Association of Ireland 2024 Annual Conference.



28 patients were treated from 31 referrals. 25 of 28 patients were therapeutic apheresis (PLEX) patients, 2 of 28 were Red Blood Cell Exchange (RBCX). 157 procedures were undertaken. This included Therapeutic Plasma Exchange (TPE) 148 procedures, RBCX 9 procedures. TAS also attended on 13 other occasions when procedures were cancelled following pre procedure patient assessment, for reasons such as change in clinical status or line failure.

As displayed in the following tables and figures, the demand for TAS is varied and unpredictable. The trend in increasing neurology referrals is balanced by a reduction in haematology and to a lesser extent, renal referrals over recent years.

The below table summarises the breakdown of patients' and procedures in 2024:

	Patients	Procedures
Neurology	20	109
Renal, Oncology, Haematology	8	48
Other	0	0
Total	28	157

#### **Service Demand Trend**

CUH had the greatest demand for TAS in 2024. Variability in service demand is captured below by 'requesting hospital', 'clinical specialities', 'referring consultants', 'degree of urgency', 'ASFA category', and 'service trends by month, 'weekend, bank holidays and out of hours'.

Our service from 2017 to date typically provides 97 to 181 procedures per annum, with an average amount of 132 procedures per year. 157 procedures were performed in 2024, not including cancelled procedures.

Trends and variability in service demand in recent years shown in figures 13 and 14.

### Weekend, Bank Holiday and Out of Hours Service

Emergency apheresis may be required in acute life or organ threatening cases. Daily/ alternate day protocols may also require weekend service. Of the procedures carried out in 2024, 3 (<2%) were performed at the weekend and there were very few procedures carried out of hours compared to previous years (23% in 2023). The trend in demand (by quarter year) for weekend/bank holiday service is set out in Figure 15.

Figure 13. Total Annual Procedures 2017 - 2024

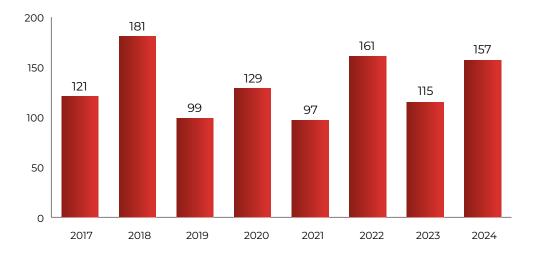


Figure 14. Service Demand 2017 - 2024 by month

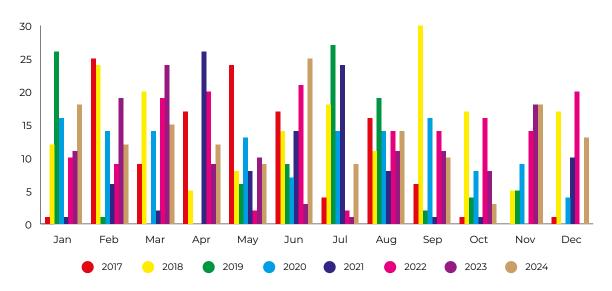
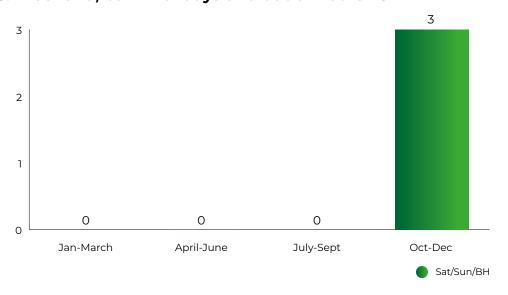


Figure 15. Weekend, bank holidays and out of hours 2024





#### Sickle Cell Disease

TAS continued the elective Red Cell Exchange (RBCX) programme which had commenced in 2020. In 2024 a total of 9 RBCX were performed. It is anticipated that this demand may increase as the regional paediatric patient cohort matures into adulthood.

### Degree of urgency of Therapeutic Apheresis Service required

Depending upon the clinical presentation of the patient, the available resources (eg. personnel and equipment), and other treatment available options, Emergent, Urgent and Routine has been classified by IBTS with reference to ASFA guidance as follows:

**Emergent:** Immediate/out of hours TAS

required – "life or limb" threatening eg. TTP, Red Cell Exchange Acute Crisis, Symptomatic Hyperviscosity.

**Urgent:** TAS required, however can

wait until the next working day –Case dependant. Not immediately "life or limb" threatening and if TAS delayed, there is no rapid deterioration of patient's condition. Likely no permanent harm on patient if delayed 24/48 hours and treatment will not immediately

reverse disease process.

**Routine:** TAS provided the next suitable

working day or planned/ routine TAS. Not imminently "life or limb" threatening and delay in TAS causes no rapid deterioration of patient's condition. No permanent harm on patient if delayed and treatment will not immediately reverse disease

process.

Figure 17: Out of **28** patients who received Therapeutic Apheresis in 2024, 26 patients presented as urgent.

### Vascular access for patients and procedures

Therapeutic Apheresis requires excellent blood flow which, especially for an intensive programme over a short number of days, may require support by the placement of Central Venous Catheters (CVC) by anaesthesiology or radiology services at the referring hospital.

In 2024 most patients required a central line for Plasma Exchange. CVC allowed apheresis to be performed at higher rates with an ease of use, as well as consistent availability to vascular access without regular venepuncture to the patient. Peripheral lines are particularly suited for apheresis treatment plans for which the anticipated therapy is elective day case or short term, such as RBCX. There was a noted increase in CVC line issues in 2024 and a Line Issue Database was started at the end of May.

#### **Quality Framework**

A quality management system is defined as a formalised system that documents processes, procedures and responsibilities for achieving quality policies and objectives. The TAS is compliant with the American Society for Apheresis (ASFA) guidelines (2019/2023). TAS undertakes internal audits and continuous professional development to assure good practice. Communication with other apheresis services and attendance at UK and international conferences also ensures that the service is evidence based.

**Training:** The TAS team are licensed medical practitioners and registered general nurses who undertake all mandatory training and continuous professional development to ensure practice is current and evidence based.

#### Facilities and technology:

The TAS uses two Spectra Optia machines which are stored in the CUH and can be transported to the MUH, as required. The machines are validated and have a bi-annual routine preventative maintenance.

#### **Outcome communication:**

The clinical outcome of apheresis procedures should be documented in compliance with the British Society for Haematology guidelines. TAS records the outcome at time of treatment along with relevant clinical data collection days or weeks after the apheresis procedure. Additionally, TAS requests outcome details from service users.



### National Haemovigilance Office (NHO)

Haemovigilance is internationally recognised as essential to the development of safe clinical transfusion practice. It collects and assesses information on unexpected or undesirable effects resulting from blood transfusion, and develops strategies and systems to prevent their occurrence or recurrence. Haemovigilance in Ireland is co-ordinated by the National Haemovigilance Office (NHO), based at the Irish Blood Transfusion Service (IBTS). Since the programme commenced in 1999 a total of 9583 serious adverse transfusion reactions and events have been reported. All figures in this report are correct on day of submission.

The NHO liaises with and supports hospital based Haemovigilance Officers (HVO) throughout Ireland and also Medical Consultants with Haemovigilance responsibilities. In addition, the NHO maintainslinkswith colleagues internationally through the International Haemovigilance Network (IHN) and the UK and Ireland Blood Transfusion Network (UK & IBTN).

### Serious Adverse Events (SAEs) – mandatory and non-mandatory

Mandatory SAEs relating to the quality and safety of blood under EU Blood Directive 2002/98/EC and non-mandatory SAEs relating to the clinical aspect of blood transfusion are reviewed by the NHO. These reports come from blood establishments, hospital blood banks and facilities. During 2024, 314 SAEs were reported to the NHO. 134 of all SAEs were deemed mandatory (43% of all SAEs). In addition, 180 non-mandatory SAEs, (57% of all SAEs) primarily relating to errors in clinical areas, were also reported. This figure includes Wrong Blood in Tube events (WBIT) (n=86) which were collected by the NHO.

### Serious Adverse Reactions (SARs) - mandatory and non-mandatory

At the time of writing, a total of 161 SARs that meet the criteria have been reported in 2024. Mandatory SAR (103) reported to date is an increase on those recorded in 2023 (67). A notable increase was evident in relation to Transfusion Associated Circulatory Overload (TACO) (2023 n=32, 2024 n=45) leading to the NHO issuing a safety notice to the hospitals...



#### Annual Notification of Serious Adverse Reactions and Events (ANSARE)

In compliance with Commission Directive 2005/61/ EC Annex II D and III C, all hospitals transfusing blood together with all blood establishments must complete and return an ANSARE form to the NHO. 266 mandatory reports were reported by the NHO in 2024 (for the reporting year 2023), with the compilation of 2024 ANSARE report ongoing at time of writing.

### Health Products Regulatory Authority (HPRA)

The Competent Authority for implementation of all aspects of the EU Blood Directive is the HPRA and, as in previous years regular case review meetings were held with the NHO to discuss reported incidents.

### Education, promotion and developments

The NHO supports the ongoing development of hospital in-service training programmes by working closely with hospital based HVOs. Ongoing education of undergraduate and post graduates medical scientist and specialists registrars also continued during the year.

#### e-Learning

In 2024 the NHO moved their eLearning Platform from LearnPro NHS to HSeLand. The transition has been successful with 7 modules currently available and ongoing partnership with the UK and Ireland Blood Transfusion Network (UK & I BTN).

The majority of Irish hospitals and a number of third level institutions are registered on the programme. This includes hospital staff and health care undergraduates in several universities undertaking the modules as a mandatory course requirement.

### Irish Unrelated Bone Marrow Registry

2024 Key achievements:

- Addition of 3,625 donors onto the registry in 2024
- Transformation of donor recruitment, enriching the registry with younger donors

Haematopoietic progenitor cell transplantation is a lifesaving therapy for certain patients with leukaemia, bone marrow failure syndromes, and for particular inherited metabolic disorders. For the many patients who do not have the preferred option of a fully matched sibling, an unrelated donor from one of the forty-two million volunteer donors available worldwide can provide a suitable alternative.

To meet the need for haematopoietic progenitor cell donors for both Irish and international patients, the Irish Unrelated Bone Marrow Registry (IUBMR) was set up in 1989.

The Irish Registry searches and selects donors for patients in need of a transplant in Ireland. It also hosts a database of donors in Ireland who are willing to donate blood stem cells.

Tissue typing of donors registered on the unrelated panel is performed by the National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL). The registry is licenced by the HPRA under the EU Tissue Directive 2004/23/EC.

#### **National Activities**

The IUBMR searches for suitable donors on the Irish Panel and through the World Marrow Donor Association (WMDA) database, on behalf of the Irish transplant centres at St. James's Hospital, Dublin and Children's Health Ireland at Crumlin.

In 2024, the number of patients referred to the IUBMR for unrelated searches was 154.

74 Irish patients received stem cell transplants from an unrelated donor in 2024. The majority of these were from international donors. 4 of these patients received two transplants during 2024 – two of these patients received PBSC and DLI from their donors, and one patient received a bone marrow product and a PBSC product, and one patient received a bone marrow product and a cord product.

Of the **78** transplants performed:

20 were of bone marrow,

55 were peripheral blood stem cells,

**2** patients received DLI products (donor lymphocyte infusions), and

1 patient received a cord product.

#### **International Activities**

The IUBMR is connected to European Marrow Donor Information System (EMDIS), a communication system which allows international registries to search each other's panels and select donors for extended testing with ease.

**204** IUBMR donors were selected for national and international patients.

Of these, **78** IUBMR donors were selected for additional testing in 2024.

11 of these donors were selected for Workup requests which resulted in 6 transplant donations – 2 bone marrow, 3 PBSC, 1 DLI.

#### **Irish Donor Recruitment**

In 2024, 2,266 new volunteers gave blood samples to join the IUBMR, which will be added to the current registry of over **30,000** potential donors.



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### **Quality & Compliance**

Throughout 2024 the Quality and Compliance functional areas continued to implement and support a culture of quality to enable the organisation to meet its objective of delivering the highest value to donors and patients. A Quality Management System is essential for the organisation to consistently deliver high quality products and services, improve operational efficiency and maintain a customer centric approach.

Quality Achievements for 2024 are outlined for each functional area. These were delivered under our key strategic objectives:

- Support IBTS medical laboratories and other departments in meeting international standards
- Improve efficiencies across a range of quality activities
- Introduce a flexible risk based approach.

### Health Products Regulatory Authority (HPRA)

The Health Products Regulatory Authority (HPRA) is the main regulatory body who authorise the IBTS to manufacture blood and tissue products. It is responsible for administering the provisions under relevant EU Directives and legislation for blood and tissue products. During 2024 the HPRA continued their comprehensive inspection programme with the following areas completed:

#### **HPRA Inspections**

Authorisation Type	Inspection Site/ Area	Inspection Days	Compliance Actions
Wholesaling Distribution	Good Distribution Practice (GDP) NBC	2	<b>F</b> 2]
Authorisations	Good Distribution Practice (GDP) MRTC	1	– 52¹
	MRTC Cork Mobile	1	1
	Dublin Mobile Clinic	1	6
	D'Olier Street Clinic	1	5
Blood Establishment	Stillorgan Clinic	1	4
Authorisation	Munster Regional Transfusion Centre (MRTC)	2	2
	National Blood Centre (NBC)	8	12
Totals		17	82



#### **HPRA Variations and Derogations**

Variation Number	Authorisation reference(s)	Date submitted to HPRA	Date Authorisation recieved
V24 / 1294-1296	Wholesaling Distribution Authorisation W00011-00001	25/07/2024	02/01/2025
V24 / 1294-1296	Wholesaling Distribution Authorisation W00011-00001	25/07/2024	02/01/2025
V24 / 2229-2231	Blood Establishment Authorisation BE-002		06/12/2024
V24 / 1130	Tissue establishment TE 012	11/06/2024	07/03/2025

Derogation Number	Description	Date of application	Date Authorisation received
A5955671	Continue to use MedHem Science Cardiac bags in the interim whilst MedHem Science work towards their CE certification	14/05/2024	25/11/2024

#### New EU Regulation for the IBTS

On 17 July 2024 the new Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation) was published by the EU. This new SoHO Regulation (EU) 2024/1938 will merge the existing human blood, tissues and cells legislation (BTC Legislation) that were previously split between the Blood Directive 2002/98/EC and the Tissues and Cells Directive 2004/23/EC and their implementing acts (the specificities of these regulated substances will be taken into account in the technical standards issued by expert bodies).

After around 20 years in place, the BTC Legislation was deemed no longer sufficient to meet the scientific and technical state of the art and was in need of an update.

The SoHO Regulation will apply to all Substances of Human Origin (SoHO) intended for human application, as well as those used to manufacture medical devices and medicinal products. It will also regulate SoHO activities from the early steps of donor registration and history review, testing and collection, to distribution, human application and outcome monitoring. Provisions for the protection of SoHO donors, SoHO recipients and offspring from medically assisted reproduction are also included.

In addition to improving quality and safety, the regulation aims to increase harmonisation and facilitate cross-border exchanges and access to SoHO and strengthen existing levels of health protection. The new regulation also sets out to facilitate innovation and the implementation of digital readiness.

Learning lessons from the COVID-19 pandemic, the SoHO Regulation also sets out new rules on supply continuity, including the establishment of national emergency plans and certain obligations for entities dealing with critical SoHO.

Over the coming years the IBTS will work closely with Regulatory Authorities and the Department of Health to ensure full transition is achieved.

The SoHO Regulation (EU) 2024/1938 will apply as from 7 August 2027.

### Irish National Accreditation Board (INAB)

The Irish National Accreditation Board (INAB) is the national body with responsibility for the accreditation of laboratories in Ireland to ISO 15189:2022. During 2024 the IBTS Red Cell Immunohaematology Laboratory received its second surveillance visit following award of accreditation in 2022<sup>2</sup>.

#### **Quality Assurance (QA)**

Over the last year the Quality Department supported all teams across the organisation to ensure the IBTS continues to maintain the highest standard in blood collection, production and testing systems and services. The Quality Assurance (QA) team provide a support service to all departments in the organisation working closely with each department across all quality system elements to ensure compliance.

During 2024 the QA team held >50 meetings throughout the year on various quality system elements with departments for their internal investigation into non-conformances and to support in controlled changes which impact their areas. This also included preparation and participation in 10 regulatory inspections and biovigilance reporting for both the Blood and Tissue Establishments.

The QA team also engaged in pilot IBTS Values workshops as part of ongoing team development.

#### **Quality Assurance Activity**

Quality System	Total
Incident Reports	7403
	740
Quality Complaints	8144
Recalls	356
Change Controls	474
Change Orders (Document changes)	550
Serious Adverse Events	100
Serious Adverse Reactions	127
Tissue Vigilance (including IUBMR)	30

#### **INAB Assessments**

Assessment Date	Major Findings	Status	Minor Findings	Status	Total Assessment Days
31/05/2024	1	CLOSED	19	CLOSED	3 (3 assessors 1 day)
12/07/2024	-	-	1	CLOSED	1.5 (3 assessors 0.5 day)

<sup>2.</sup> Accreditation 405MT voluntarily suspended on 24/02/2025

<sup>3.</sup> Includes audit findings and quality complaints

<sup>4. &</sup>gt;60% post donation notification and DAT+



#### **Validation**

2024 was again a very busy year for the validation department with the support and close out of 48 validations across the organisation covering collections, testing and processing, products, IT and medical. This included supporting significant projects such as the re-introduction of Irish Plasma for therapeutic use and qualification of replacement weigher mixers and heat sealers on clinics.

A new system for managing GMP assets was also introduced for the Validation function in early 2024.

#### Validation activity

2024	Change Control Plans Raised	Preventative Maintenance / Calibration		Requalification	Supplier Level Agreements
Total Number	243	2015	309	570	35

### Quality Systems Development (QSD)

The Quality Systems Development team continued to provide ongoing support to the Quality function and wider organisation during 2024 in the areas of systems support, document management and systems training. Key achievements delivered in 2024 by this team were:

- Successful tender awarded to implement an Electronic Quality Management System (EQMS). A significant milestone which moves the organisation a step closer to having a full electronic solution for all elements of the quality system.
- Successful tender awarded and commencement of implementation of a new National Haemovigilance registry for the National Haemovigilance Office (NHO), in consultation with multi agency stakeholders. This is on track to be in place by end 2025.

- A pilot of a revised Quality Management Review and KPI framework was approved by the Quality Regulatory and Safety Governance Group, with further activities planned in this area in 2025.
- Continued provision of support to all areas with significant revision and training of IBTS document management processes, namely in response to meet INAB assessment requirements.

#### **Quality Testing**

During 2024 continued support was provided by the Quality testing teams. This area comprises of the following laboratories:

- Material Management Laboratory
- Bacterial Testing Laboratory
- Quality Control Laboratory (Dublin and Cork)

In 2024 the Quality testing laboratories underwent assessment for MyGreenLab assessment, achieving a final assessment score of 89%, and receiving a Green Award accreditation.

#### **Material Management Laboratory**

The Material Management Laboratory performs a range of essential functions for the IBTS, working closely with RCI Laboratory, SSCD Laboratory, Tissue Bank, Inventory Control, Practice Development and Quality Control. The main responsibilities and activities of the laboratory in 2024 included:

- Management and batch acceptance of critical consumables such as blood packs, platelet sets, critical labels, reagents and solutions.
- Investigating, reporting and trending of material defects and validation of material related changes
- Inspection and controlled release of IBTS medicinal products and management of related medicinal product recalls.
- Participation in External Quality Assurance programmes.
- Review and optimisation of the critical material procedure and related defect trending and tracking.
- Key stakeholder in the implementation of Plasma for Medicine project at the IBTS.
- Key stakeholder in the changeover from RiastaptoFibryga(fibrinogenconcentrate).
- Validation of non-DEHP citrate solution for apheresis collection.
- Validation of software to allow compliance with the Falsified Medicines Directive for Medicinal Products.

#### **Material Management Activity**

		Potential Defects Investigated				
Year	Critical Materials Batch Accepted⁵	Blood Packs	Platelet Sets	GMP Items	Medicinal Products	
2024	1,017	224	20	26	18	
2023	>900	178	23	15	3	



#### **Bacterial Testing Laboratory**

The Bacterial Testing Laboratory performs a range of essential functions for the IBTS, working closely with the Tissue Bank in the IBTS as well as the Cryobiology Laboratory (SJH). The main responsibilities and activities of the laboratory in 2024 included:

- Screening all IBTS platelet products for the presence of bacteria, reducing the risk of transfusion-transmitted bacterial infection
- Environmental Monitoring of IBTS Clinics, Production and Hospital Service Despatch areas

- Environmental Monitoring of IBTS cleanrooms to GMP Annex I requirements
- Investigation of Suspected Transfusion Reactions (STRs) referred by customer hospitals
- Participation in External Quality Assurance programmes
- Introduction of new Spectrophotometer instrument for media growth promotion testing
- Validation of new Sporicidal Disinfectant for use in IBTS Cleanrooms.

#### Platelet testing activity

Year	Pooled Platelets	Apheresis Platelets	Total <sup>6</sup>	Pooled Platelets expired	Apheresis Platelets expired	Total expired
2024	10,116	7,854	17,970	688	2,008	2,696
2023	8,854	8,165	17,019	694	2,250	2,944

#### **Environmental Monitoring Activity**

Year	Clinics	Equipment	CNC Area <sup>7</sup>		Grade A/B/C Cleanroom <sup>8</sup>	Biosafety Cabinets	Total
2024	1,957	1,702	3,418	2,090	11,976	1,163	22,306
2023	992	994	968	1265	12,144	690	17,053

#### **Quality Control Laboratory**

The Quality Control Laboratories (Dublin and Cork) perform a range of essential functions for the IBTS, working closely with the Apheresis Clinics, Production, Components Laboratory, Medical and Quality Assurance.

The main responsibilities and activities of the laboratory in 2024 included:

- Quality Monitoring testing of platelets, red cells and plasma products in line with requirements set out by the European Directorate for the Quality of Medicines and HealthCare (EDQM), confirming platelet count (PLT), haemoglobin (HB), haematocrit (HCT) and leucodepletion (residual white cell count (rWCC)) in relevant products.
- Management of recalls for donor-related or product-related reasons.
- Management of HemoCue 301 blood testing instruments for IBTS Blood donation clinics.
- Providing testing support for SSCD and Material Management driven validation Projects.

- Introduction of a new blood gas analyser to allow testing blood products for pH, potassium, lactate and glucose.
- Introduction of a new coagulation instrument to allow testing of Plasma for Medicine for Factor VIII, Fibrinogen and Von Willebrand factor.
- Batch acceptance of >150 deliveries of reagents for use by Diagnostics Laboratory in Cork.
- Validation testing for Low Titre Group O Whole Blood (LTOWB) development.
- Validation of non-DEHP citrate solution for Apheresis collection.
- Validation testing for reconstituted WB, pre-split paedipack, new G5 Compomats in the production laboratory and plasma project (BAT plasma).
- HemoCue 301 venous haemoglobin reevaluation.

#### **Quality Control Testing Activity**

Product	Platelet Apheresis	Platelet pools	Red Cells	Specialised Red cells <sup>9</sup>
2024	7,947	2,021	2,712	350
2023	8,165	1,978	2,681	243



#### **Risk and Resilience**

During 2024 the IBTS monitored and identified the risks and potential threats to business continuity and the risks were continually managed through the corporate risk register and quarterly risk reporting to the Executive Management Team (EMT), Audit, Risk and Compliance Committee (ARCC) and the IBTS Board. Some of the key achievements and activities for the Risk and Resilience function were:

- The Emergency Blood Management (EBM) Group founded in 2021 continued to utilise the IBTS Emergency Blood Management (EBM) Plan for Managing Shortages of Red Cell Components. This plan dovetails with the National Transfusion Advisory Group (NTAG) Plan for IBTS, HSE and Hospitals in the Republic of Ireland to address red cell shortages. The IBTS utilised national appeals and importation of stock in 2024 to assist with the national blood stock.
- The IBTS participated in a series of meetings in the UK as part of the National Health Service Blood Transfusion (NHSBT) Business Continuity forum and in Europe with the European Blood Alliance (EBA) aimed at assessing and managing various risks. These meetings were part of an ongoing effort to ensure that the IBTS stays ahead of potential challenges and continues to thrive in an increasingly complex environment.

- In response to red weather alerts issued across Ireland, the IBTS managed the schedule of critical staff members who needed to be on site and offered remote work options where possible to staff or asked staff to stay home until conditions improved. Updates of contact details were made to the Emergency Bulk Text Messaging System to ensure text alert notifications reach our teams.
- A project plan for the upgrade of the electrical infrastructure at the National Blood Centre (NBC) was completed successfully, thus reducing the risk score of loss of electrical power at the NBC.
- The IBTS further embedded cyber security risk management based on the existing risk and resilience framework.
- Updates to the IBTS Corporate Risk Management Policy and Procedure were also completed in 2024.
- An Internal Audit of Business Continuity and Disaster Recovery Processes at the IBTS was conducted in 2024. There was an improvement in our performance from the previous audit conducted in 2021 and the rating was satisfactory with two important findings (Amber). An action plan was developed to address the findings.

## Academic Activities, Research and Innovation

#### **Key achievements 2024**

- Contributed to a total of 8 peer-reviewed academic publications and gave 23 presentations at numerous national and international conferences.
- Hosted the second Blood Donation Haematology Infection and Transfusion Conference – BlooDHIT 2024.
- Launched our Research Strategy Addendum 2024 -2025.
- Helped tackle the various issues impacting blood and tissue services through ongoing representation at European Blood Alliance (EBA), Biomedical Excellence for Safer Transfusion (BEST), International Society for Blood Transfusion (ISBT) and European Haematology Association (EHA) working groups.
- Continued our contribution to academia through participation in undergraduate and postgraduate university medical and scientific courses.

### Research Activities & Strategic Initiatives

The IBTS Research programme is committed to providing the research evidence for improving and developing blood and tissue services to patients. This is done through collaboration with academic researchers, staff, clinical colleagues and donors. The Research Strategy addendum 2024-2025 identified 4 priorities – Capacity, Capability, Culture and Key research.

#### **BlooDHIT 2024**

The second BlooDHIT – Blood Donation Haematology Infection and Transfusion Conference was held on November 14th and 15th in Dublin. The BlooDHIT conference enabled the IBTS to truly live its organisational values of 'improving patients' lives, together' and 'striving for excellence'. BlooDHIT aimed to:

- (1) Highlight key research areas throughout the vein-to-vein process
- (2) Learn from the experience and opinion from national and International experts
- (3) Communicate IBTS-led research

#### **Key research:**

CRIMSON Centre for Research In Major haemorrhage and transfuSiON (CRIMSON) research programme (Joint initiative with Royal College of Surgeons in Ireland).

The aims of this joint initiative are to understand the underlying biological mechanisms that impact platelet function, storage and ultimately their capacity to prevent bleeding. The first project aims to assess the impact of storage conditions platelet function and clearance. Preventing GPIb clustering may improve the haemostatic function and circulation of coldstored platelets. The second project aims to understand the role of ABO blood group in regulating primary haemostasis and the clinical relevance in the context of major bleeding. ABO blood group impacts multiple aspects of primary haemostasis, however, the biological mechanisms underpinning this ABO effect remains poorly understood.



### Irish Medicines centre for Personalised Advanced Cellular Therapeutics (IMPACT).

The IBTS is one of the collaborating organisations of the IMPACT consortium. Throughout 2024, a large multi-centre grant funding application has continued to progress. If successful, the funding will enable the creation of a new centre to support the provision of advanced therapeutic medicinal products (ATMPs) to Irish patients. IBTS research, as part of the IMPACT programme. will focus on understanding the role that the blood services will play in the provision of ATMPs in Ireland. The outcomes of this work will directly impact future IBTS strategic direction. In addition, the IMPACT consortium will support partnership with patient advocacy groups and provide research opportunities to explore the following; (i) requirements for allogeneic donation, (ii) protocols for ATMP donor recruitment and screening, (iii) Leucophoresis collection model, (iv) GMP requirements for ATMP production, (v) Usage of by-products of blood donation in ATMP production and (vi) ATMP quality control, regulation and licencing.

#### Component Development

Ongoing development of current, new, and emerging blood components is critical to ensuring the direct application of research findings. Currently, ongoing research is attempting to characterise the role of Platelet-derived Extracellular vesicles (PEVs) in transfusion. PEVs are inherently cotransfused alongside platelets into patients, but the specific role that they play in not currently understood. In addition, the IBTS provided unused blood components to Irish researchers. A total of 1,590 blood components were issued for research purposes in 2024, the majority of which were buffy coats for immunology or cell biology-based research. This service is an essential source of cellular material for researchers.

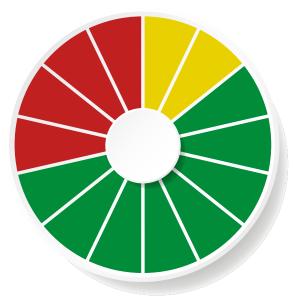
### **Strategy**

2024 was the fourth year of delivering the strategic objectives outlined in our statement of strategy, *Connections that Count – Developing the IBTS 2021 to 2025*.

There were fourteen strategic initiatives prioritised for delivery in 2024. The image below provides an overview of the progress made in 2024. Green indicates the initiative was successfully completed at year end, yellow indicates the initiative was significantly progressed with completion scheduled in Q1 of 2025, while red indicates the initiative was delayed with the delivery scheduled in Q2-Q4 2025.

Many of the successfully delivered initiatives had organisation-wide impact or involved significant cross-functional collaborative effort.

### Figure 19. Status of 2024 Strategic Initiatives



Key successes in 2024 include:

- The introduction of selective testing for HTLV in Q1 2024 - an evidence-based and risk-assessed change to donor sample testing to ensure value and efficiency while prioritising quality and safety;
- The validation of whole blood components for issue to patients with massive haemorrhage in Q2 2024;
- The restructuring and cross-training of qualitycontrol and materials management was completed in Q2 2024. This change enables a more flexible model of service delivery, which is dynamic and adaptable, removing single points of dependency and leading to process and quality improvements;
- The enhancement of our IT and HR infrastructure, with the roll out of Windows 10 in Q3 2024 and the optimisation of the CoreHR online platform for staff in Q4 2024;
- The first shipment of Irish plasma which was sent for fractionation in Q4 2024. This is a key milestone towards the reintroduction of Irish plasma for the rapeutic use;
- The completion of a review of our donor services and collections operating model in Q4 2024. This review includes recommendations for how we can strengthen and future-proof our service for donors; and
- The development of a Sustainability Strategy and Climate Action Roadmap for the IBTS to improve our environmental impact (Q4 2024). This strategy and roadmap will enable the IBTS to achieve government mandated efficiency targets.



#### **Human Resources**

#### **People and Culture**

Aligned with ONEHR strategic priorities detailed in 'Transforming Together - People: Culture: Connections' the IBTS Strategic Workforce plan presented to the Department of Health was sanctioned in December 2024. The operational workforce planning progressed through the Strategic Workforce and Financial Planning Governance Group to ensure that the IBTS had the necessary talent to enable the successful delivery of our service and support the achievement of our overall strategic ambitions.

The market for talent across health care and administrative domains remains competitive. We saw a total staff turnover rate of 11.6% and a voluntary turnover rate of 7.9%. A total of 108 recruitment campaigns were activated in 2024.

#### **Recruitment / Turnover**









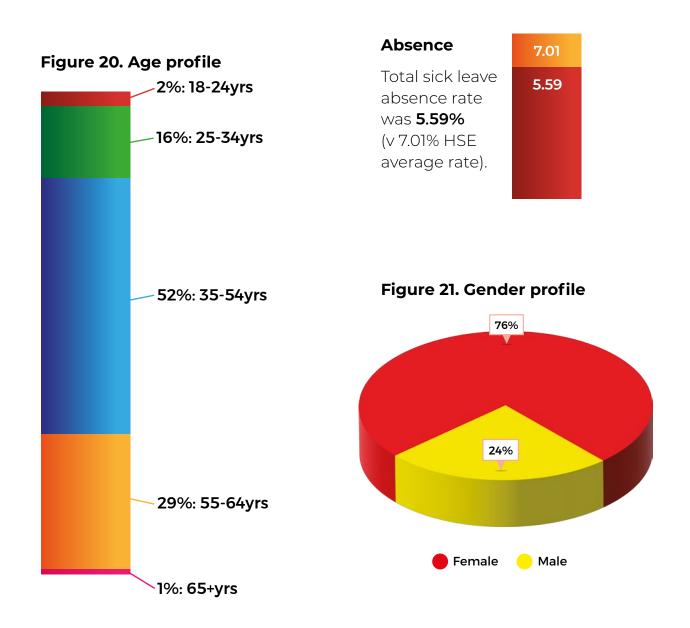


#### **Long Service Awards**



In 2024;

1 staff member celebrated **50** years of service 1 staff member celebrated 30 years of service 11 staff celebrated **20** years of service and **8** staff celebrated **10** years of service.



#### **Gender Pay Gap**

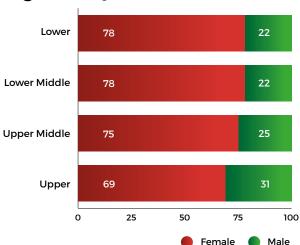
The gender pay gap reflects underlying systemic inequalities and discrimination in the workplace, affecting women's financial wellbeing and reinforcing gender disparities. Tackling this gap is essential for fostering fairness, diversity, and economic empowerment. The gender pay gap report measures the difference in the average gross hourly pay between women and men within an organisation, expressed as a percentage. It is important to note that this is distinct from equal pay, which ensures that individuals receive the same compensation for work of equal value, irrespective of gender.

The IBTS gender pay gap results show that, on average, females in fulltime permanent employment and those in temporary employment earn 8.8% less per hour than their male counterparts. This trend is reversed slightly for part-time employees with almost no gender pay gap in this domain, -0.5%.

The median hourly remuneration is less across all categories for females when compared with males.

There are more females across all quartiles in all categories which is representative of the demographics of the organisation (76% F, 24% M). 69% of females occupy the fulltime upper quartile while 78% of females occupy the lower quartile.

#### Figure 22. Quartiles



IBTS membership in the IMI 30% Club continued with participation in the IMI mentorship programme, demonstrating our commitment to incorporating diversity ambitions within our ONEHR strategy.

#### **Organisational Structure Review**

The Organisational Structure Review Implementation Work Plan that commenced in June 2022 was successfully completed as planned in March 2024 with the approval of the Performance Development Committee, a subcommittee of the Board.

#### Implementing Public Sector Equality & Human Rights Duty 2024



#### **Training Programmes**

New training modules relating to equality and inclusion were made available to staff in 2024:

- Recognising and Responding to Domestic Abuse (in partnership with Women's Aid)
- Menopause Awareness (in partnership with Menopause Hub)



#### **Engagement at Work**

Organisation-wide celebrations were held in recognition of significant events, including International Women's Day, Neurodiversity Celebration Week, and Pride 2024, fostering an inclusive and supportive workplace environment for all. Additionally, modules on Women's Health and Neurodiversity were updated in our Employee Assistance Portal to provide enhanced resources and support for our employees' wellbeing.

#### **Inclusion Programme**

The IBTS secured committee membership for another term with the Department of Health Disability Monitoring Committee, continuing our commitment to advocating for disability rights and inclusion. We achieved a 4.6% representation of staff identifying as having a disability in our 2024 NDA-related staff census, surpassing the 3% minimum target.

We partnered with Vision Ireland and AHEAD regarding supportive technology to enable people with disabilities to work in the IBTS and we continue to partner with community group, Festina Lente to provide paid work placements for people with learning difficulties.

Gender-biasdecodinganddiversityandinclusion tracking technology is implemented on our jobs' vacancy advertising and communications hosted on Irish Jobs ie and LinkedIn

#### **Shaping our Future Workforce**

The IBTS remains committed to nurturing the formation and growth of leaders across all areas of the organisation and supports a culture that is open and encourages everyone to act as a leader. An ongoing partnership with the University of Limerick (UL) continued in 2024. We invested in the iLEAD programme, and a cross section of staff participated in phase one of the leadership formation programme. The next level of the LEAD programme is being reviewed to ensure that the IBTS is providing leadership development that meets the evolving needs of our people and our service. This will go live in 2025.

#### **Talent Management**

#### **Succession Planning**

Ongoing investment in succession planning across the organisation occurred in 2024. All Directorates engaged in the succession planning process to review and identify critical roles and assess potential talent risks across the service. By implementing new ways to capture data pertaining to succession planning and talent, L&D have been able to gain deeper insight into the areas that require focused attention and continue to work with relevant Directors to develop and implement targeted action plans for those key positions. This proactive approach has allowed the organisation to make informed decisions about talent development and to prepare for future needs while minimising potential disruptions. Continuous collaboration between L&D and senior management remains essential to refining and evolving these plans to meet the services evolving demands.

#### **Embed Continuous Learning**

#### **Technology Enablement**

Providing the tools and technology to improve the employee experience and embed continuous learning was a key focus area for L&D in 2024. Implementing the Health eLearning Management (HeLM) in partnership with the HSE involved significant workto configure, integrate and plan, allowing for go live in early 2025.

#### Compliance

A significant amount of effort was targeted towards strengthening our mandatory compliance rates across the organisation in 2024. Managers played a critical role in this process by acting as champions for the initiative, reinforcing the key messages in team meetings, one-on-one discussions, and through regular follow-ups. This ensured that employees understood not only the "what" and "why" of compliance but also the consequences of non-compliance, helping to foster a culture of accountability. The collaboration with stakeholders also helped identify potential gaps in understanding or areas of resistance, allowing us to tailor messaging and resources to address specific concerns. This collaborative approach ensured that the message was not just topdown but also reflected the perspectives and needs of those directly involved in day-to-day operations.

As a result, compliance rates improved, and there was a noticeable shift in attitudes toward mandatory compliance training, with employees becoming more engaged and proactive in fulfilling these requirements. It also led to a stronger sense of ownership and responsibility in ensuring that the IBTS adheres to necessary regulations and standards.

More specifically cyber security and data protection awareness knowledge improved through targeted online training modules that were supported in partnership with the IT department. These modules equipped employees with the knowledge to recognise and respond to threats, reducing the risk of cyber and data incidents.

L&D continued to prioritise health and safety training, ensuring all employees remain informed, prepared, and compliant with regulatory requirements. Our strong compliance rate for our online health and safety modules across the organisation reflects a shared commitment to creating a safe working environment for everyone.

By delivering the IBTS Code of Conduct training to all employees, we reinforced our commitment to maintaining the highest professional and ethical standards within the organisation. This training not only set clear expectations for behaviour but also played a crucial role in shaping the workplace culture. It helped employees understand the importance of fostering a respectful, inclusive, and accountable environment where everyone is treated with dignity and fairness. Through the training, employees were equipped with the knowledge and practical skills needed to handle complex ethical dilemmas and situations with integrity, ensuring that they could make well-informed decisions that align with the organisation's values.

The impact of this initiative went beyond compliance. It also served as a proactive tool for preventing misconduct, promoting open communication, and ensuring that all employees felt empowered to speak up when necessary. By creating a shared understanding of what is expected in terms of ethical conduct, we solidified the foundation for a positive and supportive workplace culture.



#### **Performance Development**

Performance Development remained a priority in 2024 and the need for continuous improvement drove the emphasis on clear, actionable goals within the Performance Development process. L&D worked closely with managers to ensure that employees understood how to set SMART (Specific, Measurable, Achievable, Relevant, Timebound) goals that aligned with both individual growth and organisational objectives.

Additionally, there was a concerted effort to integrate feedback loops throughout the year, ensuring that performance conversations were not just annual reviews, but ongoing discussions that were meaningful and productive. This helped create a culture of continuous improvement, where employees could track their progress, adjust their goals as needed, and feel supported by their managers.

The direct engagement of L&D with teams allowed for a more personalised approach, ensuring that the unique needs of different departments were addressed while maintaining consistency across the organisation. External drivers and the operational context of our service, in particular blood supply shortages and adverse weather events, created challenges in maintaining high engagement levels across the organisation.

#### **Enriching Our Culture**

#### **LEAN Services**

2024 saw the appointment of LEAN service providers to successfully establish, implement and embed LEAN as a self-sufficient practice in the organisation through a three-year programme of work. This is a significant undertaking for the IBTS focusing on data-driven, strategically aligned and culturally aligned improvements that build internal capability and sustainability.

### Putting Safety and Wellbeing First

### Health and Safety Management System

Supporting the IBTS People and Culture Statement of Strategy 2021 to 2025 in regard to monitoring 'our health and safety performance to guide decision making' and building 'on internal compliance, competency and engagement standards', the IBTS completed a public procurement process to deliver an enterprise-wide cloud based Electronic Health and Safety solution. This solution was successfully implemented and launched in 2024, with its rollout supported by one-on-one, departmental, and group training across the service. This demonstrates our commitment to enhancing employee experiences and providing supportive technologies for our staff.

The technology supports the organisation and departments across the following key areas.

#### **Inspection & audit**

Inspection and audit scheduler with action/task workflow management

Policy, Forms & Checklists

#### Incident

End to end incident management, for all incidents including accidents, near misses and dangerous occurrences

#### **Data**

Real time Health and Safety data, analytics and Reporting including dashboards

#### Risk

Facilitation of health and safety risk assessment with action/ task workflow management

#### **Health and Wellbeing**

The IBTS partnered with the Irish Heart Foundation and their Slí@work programme. "Slí@Work aims to encourage people to incorporate walking into their working day", for example, walking short distances for transport and during break times and includes motivational signage and specially designed walking routes. Over the course of 2025, the IBTS will continue work with a Coordinator from the Irish Heart Foundation to establish further circular walking routes in the vicinity of IBTS centres.

In honour of National Workplace Wellbeing Day on Friday, April 26th, we curated an organisational Wellbeing Week schedule, offering staff a range of resources focused on financial, physical, and mental wellbeing. Additional information and resources were promoted and shared with staff throughout the year via staff bulletins.



### Information Communication Technology

#### Key achievements 2024

- Maintaining secure, stable operations remained the top priority for the IBTS' IT Function in 2024. Significant focus and resources were assigned to a variety of initiatives aimed at improving our resilience and maintaining operational stability.
- Preparations for the forthcoming EUwide NIS-2 Directive took priority through much of the year, with updates to policies and procedures, as well as technical improvements being implemented.
- During 2024, we completed an organisation-wide desktop refresh and approximately 460 devices were replaced across the organisation. The project also included re-validating all of our GMP applications, and several business applications were upgraded during the project.

- The IT Function was also heavily involved in the re-introduction of Irish Plasma, including supporting infrastructural changes that were required within Components, making configuration changes to our key Business Systems and developing electronic files and reports to be exchanged with our plasma fractionator, and ensuring compliance.
- Work was initiated in late 2024 on a project to replace our hospital online ordering system, with a more modern version, which is better integrated into other Blood Establishment systems. Work also continued on projects to extend use of our online booking portal for donors, and enhancing technologies used in clinics countrywide.

### Sustainability

### IBTS Climate Action Roadmap & Sustainability Strategy

As a Public Service Organisation (PSO), the Irish Blood Transfusion Service is mandated to meet energy and carbon emissions reduction, along with several other quantitative and qualitative targets, by 2030.

As a centre for innovation, education, and development in the field of healthcare, the IBTS understands why it is necessary to do so. The IBTS is committed to the acceleration of its sustainability journey with the completion and Board approval of its Climate Action Roadmap and Sustainability Strategy.

The Climate Action Roadmap will be reviewed and updated annually, to address gaps and to implement any new guidance from Government. The Climate Action Roadmap contains major energy efficiency projects scoped for introduction to the IBTS, and the data on these projects will be updated with each iteration to ensure that it accurately reflects progress.

The Sustainability Strategy sets out objectives for the organisation between 2025-2030 which will work in tandem with and are additional to the mandated targets for the IBTS. Focus areas for the strategy include, but are not limited to, commuting, waste production, biodiversity, education, and social aspects.

#### IBTS Energy Related Greenhouse Gas Emissions

The IBTS has had success in the reduction of emissions from buildings and vehicles. The IBTS is required to reduce fossil fuel related emissions by 51% and total emissions also by 51% by 2030.

Due to the cycle of the verification process by the Sustainable Energy Authority of Ireland's (SEAI) Monitoring & Reporting (M&R) mechanism, the data for the IBTS for 2024 has been submitted but will not all be verified prior to the publication of the Annual Report for 2024. The data for road diesel and gas oil has been reported and calculated directly by the M&R system. Electricity and natural gas data is provided by the SEAI through meters. In 2024, there were significant reductions in electricity and road diesel usage, and an increase in natural gas usage due to the colder temperatures in 2024 compared to previous years. The increase in gas oil in 2024 was because this was retrospectively added to the system.

The IBTS undertook an energy audit to better understand the impacts and main opportunities for improvement, which provided the data for the projects included in the Climate Action Plan.

Projects scoped within the Climate Action Roadmap outline plans to further reduce emissions produced from our activities while still delivering vital services. These will require significant investment to ensure that the projects are fully scoped, meeting all required criteria for plant equipment and guaranteeing that the IBTS is procuring using Green Public Procurement Criteria.



Emission Group	CO <sub>2</sub> Emissions	Ghg Baseline (2016-18) (Tonnes CO₂)	2024 (Tonnes CO <sub>2</sub> ) <sup>10</sup>	2030 Target (Tonnes CO₂)
Fossil	Gas oil <sup>11</sup>	4	7	583
	Natural Gas	938	735	_
	Road Diesel	247	191	
Electricity	Net Electricity Imports	2,015	1,008	431
Total	Total	3,204	1,941	1,013

CO<sub>2</sub>e Emissions generated within the IBTS buildings and vehicles.<sup>12</sup>

The projects envisioned for the IBTS include LED lighting upgrades, heating and cooling improvements, plant equipment efficiency retrofits/replacements, and fuel transitions. The provision of this project pipeline through the Climate Action Roadmap will ensure that the IBTS stays on target to achieve our 2030 emissions targets as a public service organisation. The majority of the projects are specifically focused on the National Blood Centre, as this building accounts for 81% of the energy use within the organisation.

Emissions within the IBTS estate are associated with heating (natural gas and electricity) and power supply (electricity) to our buildings, along with the fuel used within the IBTS fleet (road diesel). Gas oil within the IBTS estate is used for the contingency power supply in our generators at the National Blood Centre and Cork Centre.

For energy use within the organisation, the IBTS is required to increase our energy performance by 50% from the baseline (2006-2008) by 2030. This is currently on track to be achieved due to energy efficiency upgrades and proactive energy management within the organisation during that period.

Figure 23. 2024 Energy Use in IBTS Buildings & Fleet (kWh)

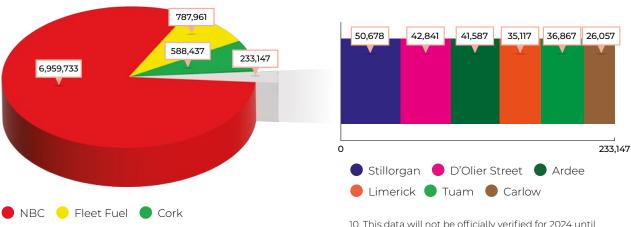


Figure 23 - Breakdown of total energy used (Electricity, Natural Gas, Gas Oil, Fleet Diesel in kWh) across IBTS buildings and fleet.

10. This data will not be officially verified for 2024 until 29th August 2025. This data contains extrapolations. 11. Gas Oil was not previously reported within the IBTS. In 2024, estimations were made based on use retroactively, by the Standard Operating Procedures in place for their usage. 2024 data is based on these estimations with the actual usage for 2 non-emergency procedures that occurred in 2024.

12. All values within the table have been rounded to the nearest tonne CO<sub>2</sub>e.

IBTS Energy Source	2024 Natural Gas (kWh)	2024 Electricity (kWh)	2024 Road Diesel (kWh)	2024 Gasoil (kWh)	2024 Total (kWh)
NBC	3,849,440	3,087,821	-	22,473	6,959,733
Fleet Fuel	-	-	787,961	-	787,961
Cork	255,560	329,817	-	3,060	588,437
Stillorgan	28,543	22,135	-	-	50,678
D'Olier Street	-	42,841	-	-	42,841
Ardee	27,394	14,193	-	-	41,587
Limerick	18,226	16,891	-	-	35,117
Tuam	-	36,867	-	-	36,867
Carlow	14,891	11,166	-	-	26,057
Total Energy (kWh)	4,131,443	3,561,730	787,961	25,533	8,506,667
Total Associated Emissions (tonnes CO₂e)	735	1,008	191	7	1,941

The breakdown of energy usage within the IBTS buildings and fleet in 2024. 13,14

### Implementation of the Mandate

The IBTS is committed to enacting the Climate Action Mandate within its activities and has made good progress between 2023 and 2024 to improve implementation across the organisation.

The table below outlines the improvement from 52% implementation in 2023 to 75% implementation in 2024. Plans are in place to address the gap in implementation and to be proactive in addressing additional requirements within the annual update to the Mandate.

The IBTS is committed to creating a robust system for the management of energy and environmental impacts and ensuring a practice of continual improvement for the IBTS

Implementation Level	2023	2024
Implemented	9	20
Partially Implemented/ Partially Complete	7	8
Not Implemented	8	4
Not Applicable	6	9
Implementation Rate (%) <sup>15, 16</sup>	52%	75%

Level of implementation of the Climate Action Mandate within the IBTS between 2023 and 2024

<sup>13.</sup> As detailed previously, data in this table has extrapolation (Electricity & Natural Gas). Data has not been verified by the SEAI.

<sup>14.</sup> Values rounded to the nearest whole kWh/Tonne CO<sub>2</sub>. 15. Calculated by assigning 100% scoring to Complete Implementation, 50% to Partially Implemented, and 0% to Not Implemented, and taking an average of the overall score. Not Applicable returns are discounted. 16. Rounded to nearest whole %.



#### **Circular 01/2020**

As a public service organisation, the IBTS is mandated to address the emissions arising from official air travel and has been compliant with Circular 01/2020 since its introduction.

In line with the most recent Climate Action Mandate (2024), the IBTS has made a payment as required to the Climate Action Fund. The payment made was to cover 32.52 tonnes of  $CO_2e$  generated over 407,783 km of flights for official business in 2024.

The IBTS is committed to limiting air travel to necessary purposes only, and all official air travel is reviewed at the highest level for requirements before approval.

Flight Type	Cabin Class	2023	2024	
One-Way	Economy	170	106	
Return	Economy	41	58	
Total Flight Legs <sup>17, 18</sup>	Economy	252	222	

Flights taken by the IBTS for official business, addressing adherence to Circular 01/2020

### **Sustainability Activities & Initiatives**

The IBTS engaged with several sustainability initiatives and activities in 2024.

 In 2024, the IBTS officially launched the Sustainability Steering Group which helped to develop the Sustainability Strategy and will drive other sustainable initiatives from 2025 onwards.

- The IBTS achieved the Bronze Smarter Travel Mark for the National Blood Centre in 2024, and this will be expanded to the whole organisation in 2025.
- The IBTS added a Monthly Sustainability Update to the internal communication newsletter, to inform staff on IBTS data and some guidance and helpful information for home.
- A module for Climate & Sustainability was added to the IBTS Corporate Orientation Programme, providing guidance to new joiners on targets and how they can play their role.
- Held a climate action focused Waste Awareness Workshop with a waste service provider, to give staff an opportunity to ask questions about their impacts and for guidance.
- The IBTS began a detailed Waste Management Strategy assessment, with the development of a robust waste register to track the segregation of waste within the organisation and highlight areas for improvement. Ambitious targets to increase recycling of core streams to 55% by the end of 2025, and to 60% by 2030 have been agreed.
- There has been an improvement in the recycling rate from 51% from January to August, to 58% from September to December following implementation.
- In the National Blood Centre Apheresis Clinic, the IBTS have begun to donate deposit return items to the Re-Turn for Children Scheme, donating DRS cans/bottles to 6 of the largest children's charities in Ireland.
- In 2024, the IBTS signed up as a Business Supporter of the All-Ireland Pollinator Plan and will endeavour to improve and track our progress year on year.

<sup>17.</sup> Flights deemed to be returns if they involved direct flight returns i.e. Dublin to Manchester and Manchester to Dublin with no layovers.

<sup>18.</sup> Flight legs total is all calculated by all one-way flights equalling 1 leg, and all return flights equalling 2 legs.



#### My Green Lab Certification



Recognised by the United Nations Race to Zero campaign as a key measure of progress towards a zero-carbon future, My Green Lab (MGL) Certification is considered the gold standard for laboratory sustainability best practices around the world.

As the IBTS represents excellence in our field, being exemplar in terms of a commitment to sustainable science, while continuing to provide vital services, is of huge importance to us. The aim of engaging with MGL is to educate and engage IBTS laboratory staff on laboratory sustainability best practice in order to actively contribute to minimising the environmental impact of their laboratory operations and thereby assist the IBTS to meet it's 2030 Climate Action Plan targets of improving energy efficiency and reducing carbon emissions.

Between May 2023 - September 2024. MGL certification was expanded to other laboratories in the IBTS. The Tissue Department, Scientific Support Component Development Laboratory, Red Cell Immunohaematology Laboratory, NBC and Cork Centre Quality Control Laboratory, Molecular Biology and Genetics Department developed action plans to meet the MGL sustainability targets. In December 2024 the Irish Blood Transfusion Service laboratories became MGL Certified. Three of the laboratories achieved Green Certification, the highest level of accreditation offered by the programme.

We are committed to continuous improvement within the organisation and will collaborate on best practices to ensure that all laboratories are in the best position to achieve the highest levels of accreditation possible.

Many of the developments in 2024/25 around waste management, energy efficiency, and data availability will assist the laboratory teams in progressing My Green Labs certification in 2025 and beyond.



### **Finance**

#### Summary Accounts for the year ended 31st December 2024

	2024 €'000	2023 €'000
Income		
Recurring income	84,590	81,835
Non-recurring income	3,223	2,467
Total Income	87,813	84,302
Expenditure		
Total expenditure	85,151	80,966
Surplus / (Deficit) for year	2,662	3,336
Actuarial gain / (loss) on pension schemes	6,330	(2,071)
Transfer to Capital Reserves	(111)	(90)
Transfer to Research Reserve	(80)	(192)
Accumulated Surplus / (Deficit) at 1st January	(4,078)	(5,061)
Accumulated Surplus / (Deficit) at 31st December	4,723	(4,078)

#### Income

The Board's total income for 2024 of €87.8 million (2023 €84.3 million) is analysed into recurring and non-recurring income. Recurring income consists of revenue generated from sales of products and services provided to hospitals of €84.6 million (2023 €81.8 million). Non-recurring income of €3.2 million (2023 €2.5 million) includes a grant from the Department of Health in respect of HEV testing and deferred funding for the single public service pension scheme. The increase in recurring income is due to increased issues of both red cell and platelets during the year and also an increase in testing volumes on the previous year. Income also includes the revenue from the first shipment of Irish plasma for fractionation in over 20 years and will also see the re-introduction of Irish plasma for therapeutic use in 2025.

#### **Expenditure**

Expenditure for 2024 amounted to €85 million (2023 €81 million). There was a reduced pension charge under FRS102 in 2024 but higher pay costs as a result of the pay awards under the national public service pay agreement. There was also higher expenditure in terms of repairs and renewals and with the increase on the income side comes higher costs in terms of bought in products.

#### **Reserves**

The Board has a Capital reserve for the development of new facilities in Cork. The balance in the fund at the year ended 31st December 2024 was €10.79 million (2023 €10.68 million).

At the 31st December 2023 the balance of research funds was €3.4 million (2023 €3.3 million).



#### **Capital Expenditure**

The Board invested €2.5 million in capital projects and equipment during 2024 (€2.1 million 2023).

The main capital investments during the year included an X-Ray irradiation machine, upgrades to our laboratory fridges and freezers and various pieces of equipment for our Research and Tissue laboratories.

#### **Prompt Payment Legislation**

The Board complies with the requirements of Prompt Payment Legislation except where noted below. The Board's standard credit taken, unless otherwise specified in specific contractual arrangements, are 30 days from receipt of the invoice or confirmation of acceptance of the goods or services which are subject to payment. It is the Board's policy to ensure that all accounts are paid promptly.

During the year ended 31st December 2024, under the terms of applicable legislation, invoices to the value of  $\in$ 179,523 were late, by an average of 8.94 days. These invoices constituted 0.76% by number and 0.38% by value of all payments to suppliers for goods and services during the year. Total interest and fines paid in respect of all late payments amounted to  $\in$ 4,179.43

The Board continuously reviews its administrative procedures in order to assist in minimising the time taken for invoice query and resolution and the approval and payment process.

#### **Contact Details**

#### **Auditors**

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#### **Solicitors**

Philip Lee LLP Connaught House One Burlington Road Dublin 4 D04 C5Y6

#### **Bankers**

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#### **Irish Blood Transfusion Service**

#### **National Blood Centre**

James's Street, Dublin 8 D08 NH5R t: 01/4322800 e: contactus@ibts.ie

www.giveblood.ie Donor infoline 1800731137 www.facebook.com/giveblood www.x.com/giveblood\_ie

#### **Cork Centre**

St Finbarr's Hospital Douglas Road Cork t: 021/4807400 T12 Y319

#### **Dublin Blood Donor Clinic**

2-5 D'Olier Street Dublin 2 t: 01/4745000 DO2 TK51

#### **Stillorgan Blood Donation Clinic**

6 Old Dublin Road Stillorgan Co Dublin t: 1850 808 808 A94 NX47

#### **Ardee Centre**

John Street Ardee Co Louth t: 041/6859994 A92 HCP4

#### **Carlow Centre**

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#### **Tuam Centre**

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