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Leadership Insight

A Reflection From the Board Chair and Excutive Director



2024 was a very active year for ICCBBA. The two most significant events were the approval of ICCBBA's strategy 2025-27 and the Forum 30 meeting in Rome, Italy. The strategy discussions offered a framework for the Board of ICCBBA and the office team to think about where we want ICCBBA to be in three years' time. The resulting strategy is ambitious with an increased focus on users in Latin America, India and Africa and more attention placed on accompanying users with implementing and using ISBT 128.



Forum 30 was the second Forum by ICCBBA and brought together over 100 attendees from over 30 countries around the world. We were honoured to count on the Italian national competent authorities for blood, tissues and cells as co-organisers and hosts. Over two days, experts

presented and discussed quality and safety aspects of multiple Medical Products of Human Origin, emphasising the common challenges while highlighting their distinctive characteristics. Forum 30 was also a celebratory occasion marking 30 years since the founding of ICCBBA.

New Board members Jelena Holovati (Canada) and Kathleen Hopping (USA) joined as Tim Pruett (USA) and Martin Hildebrandt (Germany) completed their terms. We are very grateful to all our Board members for their active and constant leadership.

In terms of developing regions, we were very pleased to be present at the African Society for Blood Transfusion (AfSBT) in Kampala, Uganda, the Latin American Tissue Bank Association (ALABAT) in Columbia and TRANSMEDCON (Indian Society of Transfusion Medicine) in Mahabalipuram, India. These experiences informed much of our discussions on strategy. Our educational content continued to grow with new webinars including a joint webinar with AfSBT and our Ask ICCBBA series while we participated in international meetings like ISBT in Barcelona, Spain, ISCT in Vancouver, Cananda and national events like the Italian Tissue Banks Association in Milan. We were also privileged to present a consensus statement on behalf of a group of Non-State Actors in support of the 2024 resolution on access to transplantation at the World Health Assembly in Geneva, Switzerland.

On the regulatory front, we released the revised United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128, and we renewed our status as one of four Unique Device Identifier (UDI) Issuers recognised by the European Union.

We were delighted to be able to increase the allocation for the Enterprise Grant from \$80,000 to \$100,000 for the 2025 process and we welcomed three new staff members - Robin Wilkinson as Deputy Technical Director, Robbie Eich as our Creative Coordinator and Kayla Perez as Education Specialist.

Finally, we would again like to thank our fellow Board members and volunteer experts who make up our Technical Advisory Groups for their time, expertise and enthusiasm. We also acknowledge the critical work done by the ICCBBA office team in developing and maintaining the standard and supporting our users every day.

Zbigniew M Szczepiorkowski

Jas Gezgunden

2024 Board Chair

Eoin McGrathExecutive Director



About ICCBBA

ICCBBA is the international non-state actor that manages, develops, and licenses ISBT 128, the global information standard for the terminology, coding and labeling of medical products of human origin (MPHO). ISBT 128 is designed to best identify MPHO and facilitate efficient, appropriate, and safe use for recipients. ICCBBA also manages the allocation of globally unique identifiers to licensed facilities and maintains the ISBT 128 Standard, international databases for Facility Identification Numbers and Product Description Codes, supporting documentation, and educational materials.

In its efforts to maintain and enhance the ISBT 128 Standard, ICCBBA brings together experts from clinical, scientific, technical, and informatics backgrounds, representatives from scientific and professional societies, and observers from regulatory authorities and industry to review and update the ISBT 128 Standard to ensure it continues to meet the needs of its users.

ICCBBA is a tax-exempt, nonprofit organization as described in Section 501(c)(3) of the US Internal Revenue Code. These regulations stipulate that the organization cannot be organized or operated for the benefit of private interests, and no part of the organization's net earnings may inure to the benefit of any private shareholder or individual. Within its Articles of Association, ICCBBA is required to be organized and operated exclusively for charitable, scientific, and educational purposes.



ICCBBA is ISO 9001:2015 certified.

VISION

Global adoption of ISBT 128 for all medical products of human origin (MPHO).

MISSION

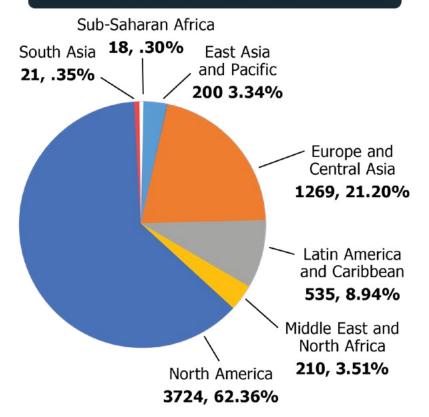
Enhancing patienty safety by promoting and managing the ISBT 128 international information standard for use with MPHOs.

Facility Distribution

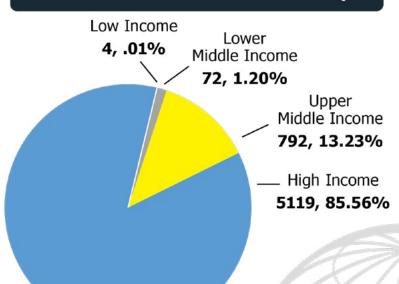
New Registered Facilities 2024

Grand Total	184
Uruguay	1
United States	83
United Kingdom	2
United Arab Emirates	5
Taiwan, China	2
Switzerland	1
Sweden	1
Spain	1
Slovenia	1
Singapore	1
Saudi Arabia	8
Qatar	2
Poland	13
Peru	1
Mexico	1
Kuwait	1
Japan	1
Israel	6
India	1
Hungary	12
Greece	2
Germany	1
Cyprus	1
Costa Rica	2
China	12
Canada	12
Brazil	8
Belgium	1
Argentina	1

2024 Distribution of FINs by World Bank Region



2024 ISBT 128 Registrations by World Bank Income Class Groups



Board of Directors

Positions as of May 2024



Zbigniew Szczepiorkowski Chair United States Cellular therapy, clinical use of apheresis products, pathology, transfusion medicine.



Egypt
Blood transfusion, human tissues and cells, injury prevention, patient blood management, research methodologies.

Mohammed Farouk

Vice Chair



TreasurerUnited States
Adverse events in transfusion and transplantation, biovigilance, infectious diseases, internal medicine.

Matthew Kuehnert



Kelly Tilleman
Secretary
Belgium
Assisted reproduction, fertility preservation, genetic testing, human reproduction and embryology, in vitro maturation of oocytes starting from ovarian cervical tissue, lab quality, proteomics, quality and safety of tissues and cells, reproductive tissues and cells.



Joy Mammen
India
Blood transfusion, medicine,
hematology, laboratory informatics,
pathology, transfusion medicine.



United Kingdom/Singapore

Cell therapy, transfusion, clinical hematology, clinical trials, collaborative research, blood transfusion, regenerative medicine, stem cell transplantation.



Diletta TrojanItaly
Tissue banking, colon cancer research, mouse models, genetic tests.

Welcome



Farewell

Mickey Koh



Martin Hildebrandt Germany

2024 ICCBBA Staff



Eoin McGrath Executive Director



Karen Moniz Technical Director



Erwin Cabana Technical Manager



Alex Weston Controller



Mónica Freire Standards Documentation Manager



Chris Salinas Global Development Manager



Betty Perez Executive Assistant



Ryan Ruiz Information Standards Specialist II



Alex Garlets Information Standards Specialist



Allison Hiebert Administrative Assistant II - Accounting



Cristina Villegas Administrative Assistant - Accounting



Wendy Becerra Administrative Assistant II - Global Development

Farewell





Robin Wilkinson Deputy Technical Director

Welcome



Robbie Eich Creative Services Coordinator



Kayla Perez **Education Specialist**

Forging Excellence

Development of Standards and Product Codes

ISBT 128 Standards and Implementation Guides undergo periodic review and revision to incorporate new information, accommodate developments in practice, and maintain alignment with current technical specifications. Each document includes a summary highlighting major updates to assist users in readily identifying and evaluating updated content. In 2024, several Standards and Implementation Guides were revised, including the following:

ST-003 Version 1.2.0

ISBT 128 Standard Labeling of Human Tissues

This document is intended to help facilities and software developers design appropriate ISBT 128 labels for tissue products.



ST-011 Version 1.9.0

ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128

The purpose of this document is to provide requirements and guidance for the labeling of medical devices containing a human tissue or cellular component using the ISBT 128 Standard. The document addresses US regulations for medical device identification.



ST-015 Version 3.3.0

ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules



The purpose of this document is to provide specifications for the structure of the Global Registration Identifier for Donors (GRID) and the Issuing Organization Number (ION); information on how to obtain and update an ION; and, rules on the use of the GRID. **Note:** A tool for calculating the checksum based on the Issuing Organization Number (ION) and Registration Donor Identifier (RDI) entries can be found in the Lookup Tools section of the website. <u>Click here to access the GRID Checksum Calculator.</u>

ST-017 Version 1.0.1

ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO

This document is intended to help facilities with labeling medical devices that contain Medical Products of Human Origin (MPHO) that are regulated as medical devices. It focuses on Unique Device Identification (UDI) labeling.

Forging Excellence cont.

Development of Standards and Product Codes

IG-002 Version 4.0.0

United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128

The purpose of this document is to provide guidance on labeling requirements in the US for blood and blood components.



IG-025 Version 1.1.0

IMPLEMENTATION GUIDE: US Guidance on Printing Text Associated with Red Cell Antigens

The purpose of this document is to provide guidance for the printing of text and the coding of Red Blood Cell antigen test results on the affixed blood label.



IG-045 Version 1.1.0

IMPLEMENTATION GUIDE: Applying ISBT 128 Labels to Collection Products for Further Manufacture

The purpose of this document is to provide guidance to help users implementing standardized labeling of collection products for further manufacture in compliance with the ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing (ST-018).



IG-047 Version 1.0.1

IMPLEMENTATION GUIDE: ISBT 128 Implementation Toolbox

The purpose of this document is to provide a toolbox of commonly used items essential for implementing ISBT 128. It also provides guidance and recommended steps for consideration when planning out one's ISBT 128 implementation.



IG-048 Version 1.0.1

IMPLEMENTATION GUIDE: MPHO Unique Identifier

The purpose of this document is to provide guidance on creating and using the MPHO Unique Identifier in compliance with the ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier.

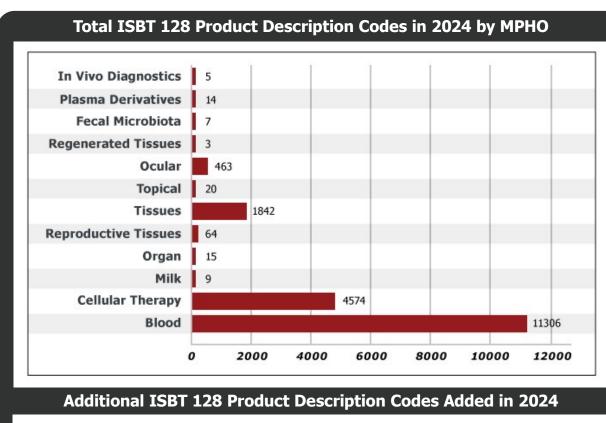


Forging Excellence cont.

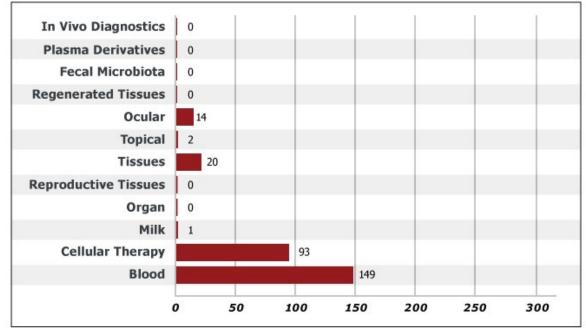
Development of Standards and Product Codes

In 2024, requests for blood product description codes were the most active, followed by requests for cellular therapy codes.

ISBT 128 Product Description Code requests are reviewed by ICCBBA's technical department.







Forging Excellence cont.

Education and Training

ICCBBA Webinars



Unlocking Opportunities: Explore ICCBBA's Enterprise Grant

February 2024

Ask ICCBBA 2024 May 2024



ISBT 128 Vendor Workshop

August 2024

Forging Strong Links for Patient Safety: The Power of the ISBT 128 CoI Identifier September 2024

isbt128.org/presentations

Joint Webinars

AfSBT Webinar on ISBT 128

February 2024

NMDP Webinar: Cell Therapy Labeling Standards

to Ensure Patient Safety

February 2024

FACT Webinar: ISBT 128 Split-Label Webinar

March 2024

forum30

The MPHO Safety and Traceability Summit

The International Council for Commonality in Blood Banking Automation ("ICCBBA"), in partnership with the Italian national competent authority for blood Centro Nazionale Sangue ("CNS") and for cells/ tissues Centro Nazionale Trapianti ("CNT"), hosted Forum 30 The MPHO Safety and Traceability Summit on 14-15 November 2024. The event convened over 100 health professionals, patients, regulators, and other stakeholders from 34 countries around the world. They addressed critical challenges and opportunities concerning safety and traceability of Medical Products of Human Origin (MPHO). Key discussions highlighted the importance of global cooperation to safeguard patients and foster innovation in the application of these therapies. Celebrating ICCBBA's 30th anniversary, the event reaffirmed the transformative role of the ISBT 128 Standard in ensuring the safety and traceability of MPHOs worldwide.

The event emphasized the life-saving and life-changing nature of MPHO, common characteristics of otherwise diverse therapeutic products and the importance of nurturing global cooperation in safeguarding patients receiving MPHO.

Discussions also emphasized technical interoperability to ensure safe management of MPHO and the need to address challenges through global regulatory alignment. Experience was shared of investigations of MPHO-related adverse events and how harm to recipients and healthcare professionals could be minimized.

The conference also celebrated the 30th anniversary of the founding of ICCBBA in 1995 and the continued evolution of the globally recognized ISBT 128 Standard, which provides unique coding and traceability standards for MPHOs.

Highlights and Action Steps

A diverse group of international experts presented on

- The need for traceability to support MPHO safety and efficiency in their management
- How technical innovation and informational interoperability supports safe access to MPHO
- The need for global regulatory alignment to address evolving challenges in the therapeutic application of MPHO

Key announcements included the preparation by the World Health Organization (WHO) of a global strategy for transplantation including regional consultations with member states. The goal is to present the strategy for adoption at the 2026 World Health Assembly.

Events like Forum 30 help strengthen international collaboration among standards development organizations, professional associations and governmental organizations to enhance implementation and global impact. Participants called for similar multi-stakeholder events like Forum 30 to be repeated at national or regional levels.

Technical Advisory Groups

TAG Information

ICCBBA Technical Advisory Groups (TAGs) advise on the ongoing development of the ISBT 128 Standard to support new developments in various fields of transfusion and transplantation. TAG groups comprise volunteer members from different geographical areas who are experts in various fields of MPHO. TAG members represent a variety of medical societies, standards-setting bodies, national health organizations, regulatory agencies, and software developers.

TAG Operations and Processes

ICCBBA TAGs focus on standardizing terminology and identification for specific areas of MPHO. Volunteers contribute to generating, reviewing, and commenting on proposed changes to the Standard and supporting documents. TAG members also contribute to ISBT 128 educational content and provide guidance and support to facilities implementing the Standard. Volunteers contribute to the global adoption of the Standard by promoting implementation of the ISBT 128 Standard in facilities worldwide.

For more information on ICCBBA Technical Advisory Groups, please visit our Committees webpage: <u>ISBT 128 | ICCBBA | Committees</u>

2024 TAG Chairs

Standards Committee, APTAG, and TAG-IT

Wayne Bolton – Australia

ATAG

Kathleen Hopping — United States

ARTTAG
Kelly Tilleman — Belgium

CTCLAG

Indresh Kaur – United States

EBTAG

Kristin Mathes – United States

EMATAG

Jolanta Antoniewicz-Papis — Poland

ETTAG and ITTAG

Izabela Uhrynowska-Tyszkiewicz – Poland

MBTAG **Debbie Barnett – United Kingdom**

NATTAG

Jelena Holovati – Canada

RMTAG

Martin Hildebrandt – Germany

Chair Terms Concluding 2023

Special thanks to the contributions of: **Zbigniew Szczepiorkowski – CTCLAG**

TAG Activities

Assisted Reproductive Technology Technical Advisory Group

ARTTAG

In 2024, the group continued discussions on renaming ARTTAG to MARTAG (Medically Assisted Reproduction Technical Advisory Group) to reflect its broader scope, as medically assisted reproduction (MAR) encompasses all assisted reproductive technology (ART) procedures as well as assisted insemination. Members also highlighted the importance of broadening the membership base—particularly by including members from countries such as Poland, where ISBT 128 implementation is mandated—to strengthen collaboration and expertise, and to help inform future strategies for supporting users.

Blood Technical Advisory Groups

<u> Americas Technical Advisory Group (ATAG)</u> Europe, Middle East, and Africa Technical Advisory Group (EMATAG) Asia Pacific Technical Advisory Group (APTAG)

The blood TAGs contributed to the new version of the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 v4.0.0 (IG-002) document, which was published in January 2024. ICCBBA thanks the US Consensus Standard Subcommittee members for contributing to this document and the ATAG members for their valuable input. The document Implementation Guide: US Guidance on Printing Text Associated with Red Cell Antigen (IG-025) was also published in February 2024. IG-025 provides guidance for the printing of text and the coding of Red Blood Cell antigen test results on the affixed blood label.

Blood TAGs are actively contributing to the development of standardized inventory status and adverse event codes using ISBT 128. These codes are intended to support product status information across health IT systems.

Cellular Therapy Coding and Labeling Advisory Group

CTCLAG

In 2024, the CTCLAG committee contributed to education efforts for the ISBT 128 Chain of Identity (CoI) Identifier. The group is also working with ISCT, ISEV, and ICCBBA to develop a standardized nomenclature for extracellular vesicles. The CTCLAG IG-003 subcommittee is working on the next version of the United States Consensus Guidance for the Uniform Labeling of Cellular Therapy Products Using ISBT 128 (IG-003).

The group held its first face-to-face meeting since 2016 in Houston, TX, USA.

Technical Advisory Group for Information Technology

TAG-IT

TAG-IT meets asynchronously via forum to review IT-related standards. In 2024, the group contributed to updating the ISBT 128 Standard for XML Electronic Messaging - Standardized XML Elements for Medical Products of Human Origin (ST-020). Additionally, the group is helping to establish a publication for utilizing HL7® FHIR® messages for ISBT 128 MPHO Information.

TAG Activities cont.

Regenerative Medicine Technical Advisory Group

RMTAG

Following input from the RMTAG, ICCBBA continued its work on developing a labeling standard for tissue-engineered products (TEPs). This standard aims to support the uniform electronic encoding of key product information, help minimize manual transcription errors, promote the use of internationally standardized terminology, and enhance global traceability and biovigilance of TEPs. The standard is currently under review and is pending publication.

Milk Banking Technical Advisory Group

MBTAG

In late 2024, MBTAG finalized revised definitions for the attributes Pre-Term, Term, and Colostrum and introduced two new attributes—Premature Colostrum and Transitional Milk—to enhance the international applicability of the standard. Final approval of the updated terminology was deferred to 2025. The group also agreed to expand the scope of the ISBT 128 Standard Labeling of Human Milk Banking Products (ST-013) to include unpasteurized milk.

Tissue Technical Advisory Groups

Eye Bank Technical Advisory Group (EBTAG)

European Tissue Technical Advisory Group (ETTAG)

International Tissue Technical Advisory Group (ITTAG)

North America Tissue Technical Advisory Group (NATTAG)

The Tissue TAGs play a crucial role in developing the ISBT 128 tissue terminology, which supports global harmonization and enhances the traceability and safety of tissue products. The tissue groups contributed to the updated ISBT 128 Standard Labeling of Human Tissues (ST-003) document, which was published in February 2024. The TAGs also discussed various terminology requests for new tissue classes and attributes in 2024.

Closing Notes:

ICCBBA's Technical Advisory Groups play a crucial role in expanding and improving standardized terminology within the ISBT 128 Standard. By offering expert insights, collaborations, and recommendations, these groups help ensure that ISBT 128 harmonized terminology meets the changing needs of the transfusion and transplantation communities. ICCBBA sincerely thanks its committees for their valuable contributions to enhancing patient safety through the implementation of the ISBT 128 Standard.

Global Relationships

2024 Meetings and Events

January 16-19	Florida, United States	Advanced Therapies
March 01-04	Kampala, Uganda	African Society for Blood Transfusion
March 15-16	Texas, United States	Human Milk Banking Association of North America
April 17-19	Nevada, United States	American Society for Apheresis
April 24-25	Saudi Arabia (virtual)	Scientific Conference of the Saudi Blood Bank Friends Organization (SCBBFC)
May 07-09	Virginia, United States	19th Annual FDA and the Changing Paradigm for HCT/P Regulation conference
May 29 - June 01	Vancouver, Canada	International Society for Cell and Gene Therapy
June 23 - 27	Texas, United States	Eye Bank Association of America
June 24	Brussels, Belgium	EU Conference on the new regulation on Substances of Human Origin
June 25 - 28	Washington, United States	TERMIS World
September 09	Washington, United States	WHO-NOTIFY project biovigilance meeting
September 19	Brussels, Belgium	Roundtable on Ensuring the security of supply of blood and blood products
September 26-29	Mahabalipuram, India	National Conference of the Indian Society of Transfusion Medicine
September 30-October 03	Colorado, United States	American Association of Tissue Banks
October 02	Llafranc, Spain	ESACT Bioprocessing and Manufacturing of Gene and Cell Therapy Products Course
October 19 - 22	Texas, United States	Association for the Advancement of Blood and Biotherapies
October 24	Milan, Italy	Associazione Italiana Banche dei Tessuti
November 05-07	Hybrid	GS1 Healthcare (hybrid)
November 6-8	Bogotá, Colombia	Congreso de la Asociación Latinoamericana de Bancos de Tejidos
November 28 - 29	Barcelona, Spain	European Association of Tissue and Cell Banks

Global Relationships cont.

Endorsements



ICCBBA is a Non-State Actor in Official Relations with the WHO.

Global Relationships cont.

Collaborations



Association for the Advancement of Blood & Biotherapies

ICCBBA is represented on the AABB IS Committee, Blood Bank and Transfusion Service Standards Committee, Cell Therapy Standards Committee, and the Cell Therapy Circular of Information Task Force. AABB is represented on ICCBBA's CTCLAG and ATAG Committees.



ICCBBA has been a member of the Alliance for Regenerative Medicine since 2022 under Foundations, Associations, and Patient Advocates.



ICCBBA has an agreement with the European Commission to provide product codes for use in the Tissue Establishments compendium supporting the Single European Code for tissues and cells.



ICCBBA is recognized as a UDI issuing agency by FDA (USA), SFDA (Saudi Arabia) and the EU.



ICCBBA has a Memorandum of Understanding with GMDNA, the organization responsible for the Global Medical Device Nomenclature (GMDN) used to identify medical devices.



ICCBBA has collaborated with GS1 since 2007 with a Memorandum of Understanding in place and regularly renewed since then.



ICCBBA is an active participant in the HL7 FHIR Orders and Observations Healthcare Product group impacting the enhanced BiologicallyDerivedProduct resource.



ICCBBA has Memorandums of Understanding with ISBT and WMDA.



ICCBBA sits on the ISO US TAG to TC 215 Committee.



ICCBBA joined the Joint Initiative Council in December 2022.



ICCBBA is one of several Standards Development Organizations collaborating within the Standards Coordinating Body network SDOs and Other Organizations Developing Standards — Standards Coordinating Body.



The integration of ISBT 128 coding into the USCDI under Biologically Derived Product Interoperability Standards Advisory (ISA) (healthit. gov) has garnered increasing support over the last three years.



ICCBBA is a member society of the Worldwide Network of Bone Marrow Transplantation.

Enterprise Grant

In 2024, ICCBBA continued its commitment to advancing patient safety and strengthening transfusion and transplantation systems worldwide through the **Enterprise Grant Program**. This year's awards recognized three exemplary organizations in Africa whose innovative projects are improving the safety, efficiency, and traceability of Medical Products of Human Origin (MPHO) in resource-constrained settings.

ICCBBA **doubled the available funding** for the 2024 program, reflecting its ongoing dedication to supporting sustainable, high-impact initiatives that enhance global health outcomes.

2024 Grant Recipients:

Safe Blood for Africa Foundation (Cameroon)

Prof. Claude Tayou Tagny, Project Coordinator

Grant Amount: \$20,000

Implementing a blood safety informatics system and quality management framework at the Yaoundé University Teaching Hospital to prepare for AfSBT accreditation and serve as a regional training hub.

Ethiopian Blood and Tissue Bank Service (Ethiopia)

Dr. Ashenafi Tazebew Amare, Director General

Grant Amount: \$38,683.04

Expanding the Blood Safety Information System (BSIS) to regional centers to ensure full traceability of blood collections and transfusions nationwide, strengthening patient safety and system efficiency.

<u>Uganda UK Health Alliance</u> (Uganda)

Dr. Philip Lugoloobi, Health Innovation Fellow, Africa Oxford Initiative

Grant Amount: \$20,000

Developing a digital Blood Alarm System to improve accountability, traceability, and timely utilization of blood products, reducing delays in critical transfusions.

Grant Objectives:

- Build technical capacity in transfusion and transplantation systems.
- Achieve reliable traceability of MPHO.
- Strengthen organizational infrastructure for safety and efficiency.

"Since 2023, ICCBBA has more directly linked income earned from our reserves to our mission. This allowed us to double the funding available for the 2024 call. This increase reflects our continued commitment to enhancing patient safety and expanding the reach and impact of our grant program."

Eoin McGrath

Executive Director, ICCBBA

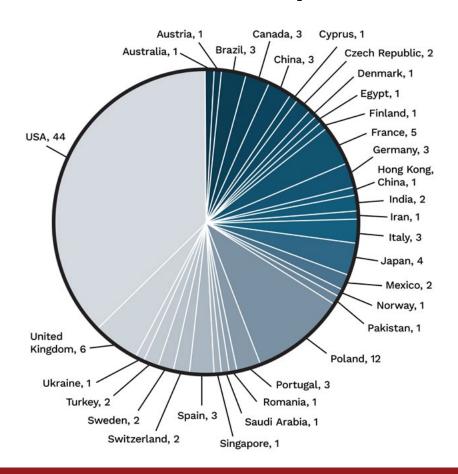
Vendors

The ISBT 128 Information Standard and its accompanying databases, software, reference tables, and documentation are protected by copyright. The use of the ISBT 128 Standard is limited to vendors who are registered and licensed with ICCBBA. Registration with ICCBBA not only provides Licensed ISBT 128 Vendors with the benefits outlined on the Vendor Benefits page but also provides the licensed organization with access to the password-protected areas of the ICCBBA website. These copyrighted files are updated regularly; thus, it is highly recommended that Licensed ISBT 128 Vendors download the most recent publications of these copyrighted files to ensure that their products/services adhere to the most up-to-date ISBT 128 information.

In 2024, ICCBBA continued to enhance the licensed ISBT 128 Vendor Profiles presented within the ISBT 128 Vendor Lookup Tool.

A breakdown of the country in which the ISBT 128 Licensed Vendors are headquartered is as follows:

ISBT 128 Licensed Vendor Headquarters Country



2024 ended with a total of **118 actively licensed ISBT 128 vendors**. Of these, 6 were newly licensed in 2024: Circulate, LLC, S.C. Info World S.R.L., Print Slawomir Szemiczek, Saftu Tecnologias Sapi de CV, Arcos, Inc., and Bluecord, Inc.

2024 Balance Sheet

Accoto

Total liabilities and net assets

Assets	
Current Assets	
Cash and cash equivalents	\$ 279,661
Investments	4,877,718
Accounts receivable, net	73,850
Prepaids	23,198
Total current assets	5,254,427
Noncurrent Assets	
Property and equiptment, net	10,845
Operating lease right-of-use assets	171,817
Deposits	6,254
Total noncurrent assets	<u> 188,916</u>
Total assets	<u>\$ 5,443,343</u>
Liabilities and Net Assets	
Current Liabilities	
Accounts payable	\$ 40,349
Accrued wages and benefits	160,633
Operating lease liabilities	84,139
Deferred revenue	26,439
Total current liabilities	311,560
Noncurrent liabilities	
Operating lease liabilities, net of current portion	90,314
Total liabilities	401,874
Net assets	
Without donor restrictions	
Undesignated	2,232,792
Designated	2,808,677
Total net assets	<u>5,041,469</u>

\$ 5,443,343

Statement of Cash Flows

Year Ended December 31, 2024

Cash flows from operating activities		
Change in net assets	\$	320,706
Adjustments to reconcile change in net assets		
to net cash provided by operating activities:		
Bad debt		115,289
Depreciation		7,246
Noncash operating lease expense (benefit)		80,919
Net realized and unrealized gain on investments		(648,082)
Change in operating assets and liabilities:		
Accounts receivable		(48,491)
Prepaids		(3,487)
Accounts payable		7,077
Accrued wages and benefits		41,355
Operating lease liabilities		(78,283)
Deferred revenue		(5,701)
Net cash provided by (used in) operating activities		(211,452)
Cash flows from investing activities		
Proceeds from sale of investments		3,361,077
Purchase of investments		(3,303,737)
Net cash provided by (used in) investing activities	_	57,340
Net change in cash		(154,112)
Cash, beginning of year		433,773
Cash, end of year	<u>\$</u>	279,661

Statement of Functional Expenses

	Program Services	General and Administrative	Total
Salaries and benefits	\$ 1,124,566	\$ 313,353	\$ 1,437,919
Management consultant	124,790	41,597	166,387
Program, conferences, and meetings	308,052	9,786	317,838
Rent	79,080	26,360	105,440
Professional fees	122,837	79,017	201,854
Insurance	-	35,871	35,871
Bank and credit card fees	-	67,059	67,059
Donations	75,901	6,211	82,112
Depreciation	-	7,246	7,246
Education and promotion	118,303	11,045	129,348
Staff business travel	7,044	20,233	27,277
Office supplies	8,195	8,781	16,976
Dues and subscriptions	-	10,772	10,772
Telephone	5,296	1,324	6,620
Internet services	26,446	6,611	33,057
Postage	1,283	321	1,604
Other	17,622	22,170	39,792
Staff training	2,626	3,527	6,153
Printing	63	-	63
Bad debt	115,289		115,289
	<u>\$2,137,393</u>	\$671,284	\$2,808,677

2024 Income Statement

(US Dollars)

Revenue	
Registration and license fees	<u>\$ 2,342,919</u>
Expenses	
Program services	2,137,393
General and administrative	671,284
Total expenses	<u> 2,808,677</u>
Net income from operations	(465,677)
Investment income (loss)	<u>786,464</u>
Change in net assets without donor restrictions	320,706
Net assets without donor restrictions, beginning of year	4,720,7634
Net assets without donor restrictions, end of year	<u>\$ 5,041,469</u>

Goals and Stategic Plans

ICCBBA is Working on Three Main Strategic Lines

ICCBBA's strategic goal since its inception has been global adoption of a single traceability standard for all Medical Products of Human Origin (MPHO)—ISBT 128. However, despite issuing over 6,000 Facility Identification Numbers (FINs) to more than 3,000 organizations in 76 countries, ISBT 128 remains underutilized, particularly in low- and middle-income countries. Challenges include facilities becoming inactive due to license fee issues, poorly understood implementation, dependence on costly IT solutions and insufficient localized communication e.g., lack of translated documents.

To address these challenges, ICCBBA's strategy will be to enhance user support by understanding needs, improving messaging, and facilitating implementation through training and translation. The organization will globalize efforts by creating regional networks, engaging local regulators, and providing training materials and content in multiple languages.

The primary focus regions will be South America, India, and Africa, leveraging linguistic commonalities and existing contacts. Regions with high ISBT 128 take-up such as North America, Europe and Australasia will continue to receive our support in maintaining their knowledge and expertise up-to-date.

The main features proposed are summed up through the following three action areas or pillars:

01. Support

- Increase our support to the users through active implementation support, education and training, and an increased presence at regional events
- Better package our messaging in terms of what the standard does and what the benefits are to the end-user and ultimately the patient
- Proactively approach users and create channels to inform and receive feedback
- Keep our licensing model as accessible as possible for all users

Goals and Strategic Plans Cont.

02. Globalise

- Appoint local/regional development officers in target regions and countries to build networks and engage with the local users, regulators and other stakeholders in getting buy-in to ISBT 128.
- Localise more of our content through translation and using technology to communicate in the language of the user

03. Stay Relevant

- Adapt the standard to new therapeutic uses of MPHO as they emerge
- Pursue interoperability across health information systems
- Leverage technology to efficiently deliver services

The transversal areas of Communications, Governance and Management and Technology will provide the foundations for our actions. We will ensure effective internal and external communication. By maintaining strong governance and management practices, we will ensure effective implementation of the strategic plan. We will leverage technology to enhance the delivery and adoption of ISBT 128 and all ICCBBA's services.

By having the strategy in place for the coming three years, ICCBBA has equipped itself with a framework for making choices and taking decisions. We look forward to report on progress in the coming years.



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