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Insights from Our Leadership

BOARD CHAIR REFLECTION



Greetings and Welcome to the ICCBBA Annual Report of 2022. It is with great pleasure and a sense of accomplishment that we present to you this comprehensive overview of our organization's endeavors, achievements, and progress throughout the past year. As the Chairs of the Board (current and immediate past), we are honored to reflect upon our collective journey and the remarkable contributions that have brought us to where we stand today.



The last year was filled with significant changes to our operations. We said good bye to Mr. Paul Ashford after 17 years

of his dedicated service to ICCBBA, and said welcome to our new Executive Director, Mr. Eoin McGrath. This change in leadership, as expected, resulted in changes in our structure and operations. We are looking forward to new initiatives which such major change invariably brings, and are very hopeful that the execution of these new projects will propel our organization to the next level of excellence and bring additional value to our customers and stakeholders.

In the following pages, you will find a detailed account of the initiatives, partnerships, and advancements that have defined our year. It is our sincere hope that as you read through these pages, you will share in the enthusiasm and pride that we feel as we recount our shared accomplishments and look ahead to the opportunities that lie on the horizon.

Thank you for your unwavering support, dedication, and commitment to ICCBBA. Together, we continue to shape the landscape of our field and create a lasting impact on the lives of individuals around the world.

Zbigniew M Szczepiorkowski

Zbigniew M Szczepiorkowski 2023 Board Chair

Timoty L. Tim Pruett

2022 Board Chair

EXECUTIVE DIRECTOR REFLECTION

2022 was my first year as the new Executive Director. I took on the role with some trepidation considering the "shoes" I had to fill. Paul Ashford who retired in December 2021 had led ICCBBA for 17 years. His legacy is a highly flexible, robust and widely accepted international information standard. I inherited an expert team with a mix of long-serving and more newly arrived staff and a financially solvent organisation with solid governance structures in place.

While I was already very familiar with ICCBBA from my work at JACIE and EBMT, as I embarked on my steep learning curve, I saw how ICCBBA had garnered widespread endorsements from across the professional MPHO communities and how it really is part of the solution to some of the challenges in safety and efficiency.



During 2022, we have introduced some changes to our internal processes building on work already begun in previous years. The team moved to a hybrid work model. We moved to 100% electronic invoicing saving time and effort over mailed paper invoices. We introduced the Objectives and Key Results (OKR) framework as a means of translating high-level strategic goals into tangible actions and outcomes. We started to seek more one-to-one networking opportunities at conferences to supplement the more traditional booth-based format. The long-standing relationship with ISBT was formalised through a Memorandum of Understanding. Our status as a Non-State Actor with WHO was renewed with a new work-plan and we celebrated 15 years of collaboration with GS1. The Chain of Identity Identifier standard was published, providing an essential element for delivering novel MPHO therapies to patients.

I am fortunate to have been entrusted with the reins of an organisation with solid foundations, a tremendous history and above all, excited for what the future will bring as we continue to make transfusion and transplantation safer and more efficient for patients, donors and healthcare professionals.





About ICCBBA

ICCBBA is an international non-state actor that manages, develops, and licenses ISBT 128, the international 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.

Argentina Australia 5 Austria 2 Bahrain Brazil 8 Canada 15 Chile China 9 Czech Republic 2 France Greece 3 Hungary India Italy 92 Jordan Mexico 3 Netherlands Oman Pakistan 2 Poland 7 Saudi Arabia 8 Spain United Kingdom 11 **United States** 76

NEW REGISTRATIONS IN 2022



EUROPEAN REGISTRATIONS IN 2022

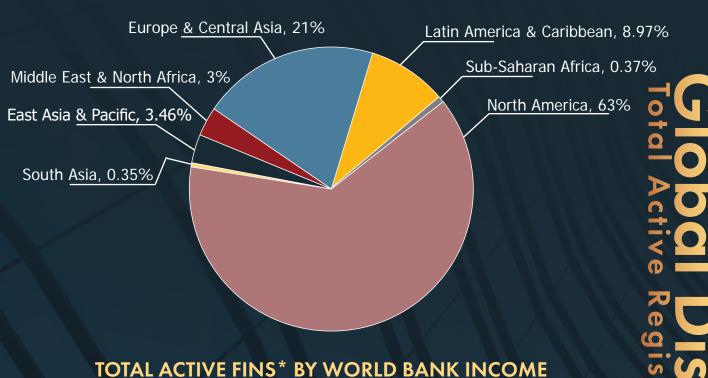


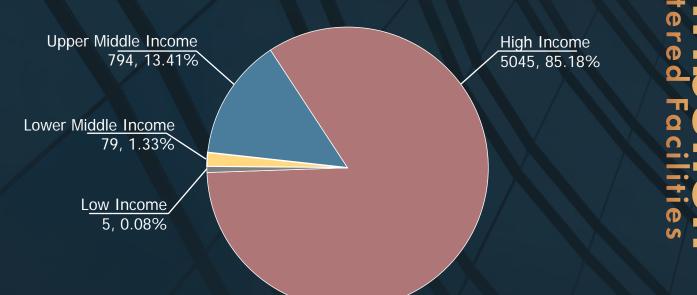
92 Italian cell therapy facilities with the support of the Centro Nazionale de Trapianti, the national competent authority, have been given the possibility to fully implement ISBT 128 as coding and labelling cellular therapy system for their products. This represents a significant step towards harmonisation across the multiple regions that make up the Italian healthcare system.

TOTAL ACTIVE FACILITY DISTRIBUTION WORLDWIDE



TOTAL ACTIVE FINS* BY WORLD BANK REGION





*Facility Identification Numbers

ADDITIONAL INFORMATION



254 total registrations worldwide in 2022.



Almost 70% of new registrations in 2022 were outside the U.S., largely due to 92 Italian facilities.

2022 Staff



EOIN MCGRATH Executive Director



KAREN MONIZ
Technical Director



MATT DELGADO Business Director



ERWIN CABANA Technical Manager



ALEX WESTON
Accounting Manager



MÓNICA FREIRE Standards Documentation Manager



BETTY PEREZ
Executive Assistant



WENDY BECERRA Administrative Assistant II - Global Development



ALLISON HIEBERT
Administrative
Assistant II Accounting



RYAN RUIZ
Information Standards
Specialist II



CRISTINA VILLEGAS
Administrative
Assistant Accounting



ALEX GARLETS Information Standards Specialist



BRIANA RICE Education Specialist



JOHNNY TSAI Creative Services Coordinator Departed



ANDREW PRICE Creative Services Coordinator Joined

Board of Directors

positions as of April 2022



Tim Pruett Chair United States General surgery, infectious diseases, internal medicine, transplantation



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



Diane Wilson Treasurer United States Tissue banking, tissue engineered products, nursing and health administration



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



Matthew Kuehnert United States Adverse events in transfusion and transplantation, biovigilance, infectious diseases, internal medicine



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



Martin Hildebrandt Internal medicine, hematology and oncology cell-based gene therapies, transfusion medicine

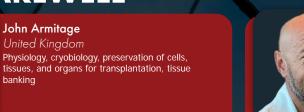


Michey Koh United Kingdom/Singapore Cell therapy, transfusion, clinical hematology, clinical trials, collaborative research, blood transfusion, regenerative medicine, stem cell transplantation



Mohammed Farouk Blood transfusion, human tissues and cells, injury prevention, patient blood management, research methodologies







Diego Ponzin Clinical interest in ocular surface and corneal diseases, cornea biology, eye banking, ocular transplantation, ophthalmology

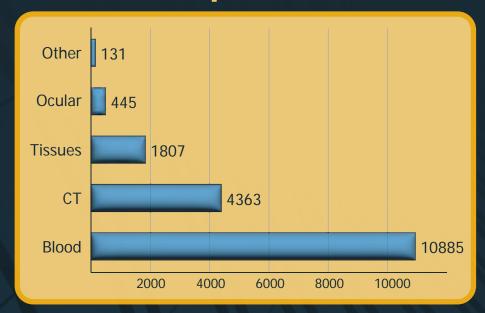
ISBT 128 Product Description Codes







In 2022, the most requested product description codes were for blood products. Requests for cellular therapy codes were the second most active category.



Development of Standards

ST-019

ISBT 128 STANDARD LABELING OF REPRODUCTIVE TISSUE AND CELL PRODUCTS

ST-019 is intended to help facilities and software developers design appropriate ISBT 128 labels for reproductive tissue and cell products.



isbt 128.org/ST-019



isbt 128.org/ST-026

ST-026

ISBT 128 STANDARD FOR THE MPHO UNIQUE IDENTIFIER

ST-026 exists for the coding of the MPHO Unique Identifier. It provides the rules for the construction of the MPHO Unique Identifier, a single data item providing globally unique instance identification and designed to optimize the electronic capture of critical MPHO traceability information.

ST-027

ISBT 128 DICTIONARY OF STANDARD DATA ELEMENTS

ST-027 describes the data elements defined within ISBT 128 and identifies the corresponding unique resource identifier for each element. These data elements are for use in electronic messages.



isbt128.org/ST-027



isbt 128.org/ST-028

ST-028

ISBT 128 STANDARD
CHAIN OF IDENTIFIER

ST-028 provides specifications for the structure of the Chain of Identity (CoI) Identifier, information on how to obtain and update a Facility Identification Number (FIN), and rules on the use of the ISBT 128 CoI Identifier.



ICCBBA Education

STANDARDIZATION OF CELLULAR THERAPY TERMINOLOGY, CODING AND LABELING:
A REVIEW

Published in: Cytotherapy - International Society of Cell and Gene Therapy (ISCT)

Topic: ISBT 128; cellular therapy; labeling; standard terminology; traceability.

Publish date: March 31, 2022

Citation: Cytotherapy. 2022 Jun;24(6):577-582. doi:10.1016/j.jcyt.2022.02.009.

https://pubmed.ncbi.nlm.nih.gov/35370094/



OVERVIEW OF THE ISBT 128 STANDARD

Recognizing the need to create educational content on the purpose and importance of the ISBT 128 Standard, ICCBBA published a video that explains how the ISBT 128 Standard supports product traceability through the global harmonization and identification of MPHO.

https://youtu.be/rv--jZOBDIs



Technical Advisory Groups

ICCBBA Technical Advisory Groups (TAGs) are essential to the ongoing development of the ISBT 128 Standard. These groups provide stakeholder input and educational and technical support to facilities implementing ISBT 128. TAG groups advise on the ongoing development of the ISBT 128 Information Standard to support new developments in various fields of transfusion and transplantation.

TAG OPERATIONS

Each year, TAGs will have one face-to-face meeting and will meet via conference calls in accordance with their needs. Technical discussions are organized by means of online discussion forums. TAG volunteers represent a variety of medical societies, standards setting bodies, national health organizations, regulatory agencies, and software developers. Participants are experts in various MPHO fields from different parts of the world.

TAGs operate through consensus decision-making to ensure the best possible solutions are utilized for the ISBT 128 Standard and MPHO product identification, focusing on standardization of terminology and product names for MPHO. TAGs also provide advice and support to facilities introducing ISBT 128 and help to prepare educational materials and tools to support the implementation of ISBT 128. TAG members also promote the adoption of the ISBT 128 Standard in facilities around the world.

THANK YOU, TAG MEMBERS!

A special thank you to all TAG volunteers for their invaluable contributions! In addition, ICCBBA recognizes the many long-term volunteers who have contributed to ISBT 128's growth.



For more information on ICCBBA Technical Advisory Groups, please visit our Committees webpage: https://www.isbt128.org/committees

Technical Advisory Groups

BLOOD TECHNICAL ADVISORY GROUPS ATAG, EMATAG, APTAG

The Blood Technical Advisory Groups collaborate to create new blood terminology. The groups are considering collaborating on an external project to develop standardized inventory status codes and uniform definitions to support traceability and hemovigilance, and the role in which the ISBT 128 Standard could play in establishing it. The groups discussed the updates needed to the IG-002 United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 v4.0.0 document. The groups also discussed the updates needed on the IG-025 Implementation Guide: US Guidance on Printing Text Associated with Red Cell Antigen as a result of the new FDA Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results.



CHAIRS

ATAG Incoming: Kathleen Hopping Ŭnited States Outgoing: Suzanne Butch

EMATAG

Incoming: Jolanta Antoniewicz-Papis | Poland Outgoing: Mario Muon

APTAG Wayne Bolton Åustralia



EBTAG CHAIR Diego Ponzin Italy

ETTAG AND ITTAG CHAIR

Izabela Uhrynowska-Tyszkiewicz Poland

NATTAG CHAIR Jelena Holovati Canada

TISSUE TECHNICAL ADVISORY GROUPS EBTAG, ETTAG, ITTAG, NATTAG

The Tissue Technical Advisory Groups collaborated towards the publishing of the ISBT 128 Standard Labeling of Ocular Tissue. This document is intended to help facilities and software developers design appropriate ISBT 128 labels for ocular tissue products. Document link: https://www. isbt128.org/ST-009. Eye banking societies have reaffirmed their endorsement of ISBT 128 as the global standard for the terminology, coding, and labeling of human donor ocular tissue and recommend its international adoption in the Second Joint Statement on Terminology, Coding, and Labeling of Human Donor Ocular Tissue. These societies include the Eye Bank Association of America (EBAA), the Eye Bank Association of Australia (EBAANZ), and the European Eye Bank Association (EEBA).

CELLULAR THERAPY CODING AND LABELING ADVISORY GROUP **CTCLAG**

The CTCLAG held meetings on a monthly basis to align the ISBT 128 Standard with the rapidly evolving nature of the cell therapy field. In 2022, the group contributed to the development of new cell therapy codes and terminology within the ISBT 128 Standard. The group initiated discussions with the International Society of Extracellular Vesicles (ISEV) and the ISCT Exosomes Committee on the potential need for standardized terminology and codes for exosomes. The group also contributed to the ongoing improvement of the IG-003 US Consensus Standard for Cell Therapy document. The document is being updated to align with the changes made to ST-001 ISBT 128 Standard Technical Specification such as the expanded reference tables and new terms. CTCLAG participated in important discussions during the development of the ST-028 ISBT 128 Standard Chain of Identity Identifier document.



CHAIRS

CTCLAG CHAIR

Zbigniew Szczepiorkowski **United States**

Technical Advisory Groups

ASSISTED REPRODUCTIVE TECHNOLOGY TECHNICAL ADIVSORY GROUP ARTTAG

The ARTTAG group made important contributions to the development of the ISBT 128 Standard Labeling of Reproductive Tissue and Cell Products. This standard is intended to help facilities and software developers design appropriate ISBT 128 labels for reproductive tissue and cell products.



CHAIRS

ARTTAG CHAIR
Kelly Tilleman - Belgium



CHAIRS

MBTAG CHAIR

Debbie Barnett - United Kingdom

MILK BANKING TECHNICAL ADVISORY GROUP MBTAG

In 2022, the MBTAG contributed to the ISBT 128 Standard Labeling of Human Milk Banking Products. The group will continue to work with ICCBBA to develop an implementation guide to complement the ISBT 128 Standard for Labeling Human Milk Bank Products. Additionally, acknowledging the pressing worldwide need for biovigilance in human milk banking, the MBTAG is discussing the necessity for a new international consensus on the terminology, coding, and labeling of human milk donations.

REGENERATIVE MEDICINE TECHNICAL ADVISORY GROUP RMTAG

The RMTAG worked on developing a labeling standard for tissue-engineered products to support uniform electronic encoding of key product information, help minimize manual transcription errors, use internationally standardized terminology, and enable global traceability and exchange. The group participated in a survey, "Development of a global standard for the labeling of tissue-engineered products." The survey was circulated in October 2022 and intended to gather input from key stakeholders on the label design to ensure users benefit fully from the resulting standard. A proposal has been developed to provide a data structure to allow the Product Description Codes (PDCs) of the constituent elements of a final product to be made available to the end user.



CHAIRS

RMTAG CHAIR Martin Hildebrandt - Germany



CHAIRS

SC CHAIR

Wayne Bolton - Australia

STANDARDS COMMITTEE

SC

The Standards Committee consists of TAG Chairs along with experienced technical experts. Representatives and technical experts attended a face-to-face meeting in Sao Paolo, Brazil with the ICCBBA Board in May 2023. In 2022, the Standards Committee worked with the TAGs to ensure that effective and efficient developments were made to the ISBT 128 Standard.

Meetings and Events in 2022

Foundation for The Accreditation of Cellular Therapy (FACT) - 3rd Regenerative Medicine InterCHANGE Virtual Event | 25 January





3rd Supply Chain and Logistics for Cell & GTx Summit Boston, Massachusetts | 25 - 27 April

International Society for Cell & Gene Therapy (ISCT) Annual Meeting San Francisco, California | 4 - 7 May





WHO Notify Project Technical Meeting Rome, Italy | 20 - 21 June

Phacilitate - Advanced
Therapies Europe
London, England | 31 August - 1 September





American Association of Tissue Banks
(AATB) Annual Meeting
San Antonio, Texas | 19 - 22 September

10th African Society for Blood Transfusion (AfSBT) International Congress Dakar, Senegal | 19 - 22 September





Azenta Cryo Symposium
Boston, Massachusetts | 17 - 19 October

37th GS1 Healthcare Global Conference Paris, France | 15 - 17 November



Collaborations



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 Memoranda of Understanding with GMDNA, the organization responsible for the Global Medical Device 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** HL7 FHIR 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 STANDARDS within the Standards Coordinating Body network SDOs & 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 has been a member of the Alliance for Regenerative Medicine since 2022 under Foundations, Associations, & Patient Advocates.



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



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.





















































Global Advisory Panel

on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies





ICCBBA recognizes that successful implementation of the ISBT 128 Standard requires an underlying organizational infrastructure that is well developed and quality driven. ICCBBA's Enterprise Grant was started in 2017 to build capacity and know-how in transfusion and transplantation, particularly in low-resource settings. Go to https://www.isbt128.org/grants-and-awards for information.

2022 GRANT RECIPIENT



The 2022 grant went to the International Coalition for Safe Plasma Proteins (ICSPP). ICCBBA awarded \$20,000 to help address the global insufficiency of plasma-derived medicinal products that are unavailable or unaffordable in many low- and middle- income countries (LMIC) and the consequent suffering and early mortality of patients with bleeding disorders and immune deficiencies who lack adequate treatments.

DONATION



ICCBBA continued its annual \$20,000 donation to the International Society for Blood Transfusion (ISBT). ICCBBA's longstanding relationship with ISBT was formalised through a Memorandum of Understanding signed in late 2022.

rants and Donations

Vendors

Every individual or entity intending to utilize the ISBT 128 Standard must register with ICCBBA. This requirement extends to vendors, regardless of whether their products involve the reading, interpretation, printing, or transmission of ISBT 128 information. The ICCBBA website offers a licensed vendor lookup tool that permits users to search for ICCBBA-licensed vendors based on their name, category, and/or region. These vendors offer a wide array of products, ranging from pre-printed Donation Identification Number sets to laboratory supplies and equipment, as well as software solutions.

There were 119 active vendors licensed with ICCBBA as of December 31, 2022.

LICENSED VENDORS SEARCHABLE DATABASE



https://www.isbt128.org/vendor-lookup-tool

LICENSED VENDOR MARKS





SAMPLE VENDOR PROFILE

Vendor Name:

Futuristic Technological Solutions

Zuturistic Zechnological

Website:

www.futuristictech.com

Contact Name:

Steven Allbright, VP Global Services

Vendor Address:

12810 W Alameda Pkwy, Lakewood, CO 80228

Email:

S.Allbright@futuristictech.com

Categories:

Lab Supplies & Equiptment, Labeling (Blood), Quality Assurance, Other

Regions:

Europe, North America, South America

Description

The mission of Futuristic Technological Solutions is to improve the quality of labs across the world through peer-developed standards, education, and accredidation for the benefit of patients. Our staff is made up of experts in various fields who hold themselves accountable to the highest possible standard. Originally known as Wild Bill's Infirmary Supplies, Futuristic Technological Solutions was founded in 1721. Though the times have changed, our goal of improving patient safety never has.

2022 Balance Sheet

ASSETS

Current assets		
Cash	\$	749,860
Investments		3,243,619
Total current assets		3,993,479
Equiptment		
Office furniture and equiptment		72,827
Computer hardware and software		37,513
Less accumulated depriciation		110,340 (90,144)
Less accumulated deprication		(30,177)
Net equipment		20,196
Deposits		6,254
Total assets	\$ _	4,019,929
LIABILITIES AND NET ASSETS		
Current liabilities	\$	7,097
	\$	7,097 29,632
Current liabilities Credit card liability Accrued retirement plan contributions	\$	29,632
Current liabilities Credit card liability	\$ _	
Current liabilities Credit card liability Accrued retirement plan contributions Total liabilities Net assets Without donor restrictions	\$ _	29,632
Current liabilities Credit card liability Accrued retirement plan contributions Total liabilities Net assets Without donor restrictions Undesignated	\$ -	29,632 36,729 2,219,365
Current liabilities Credit card liability Accrued retirement plan contributions Total liabilities Net assets Without donor restrictions	\$	29,632 36,729
Current liabilities Credit card liability Accrued retirement plan contributions Total liabilities Net assets Without donor restrictions Undesignated Designated	\$ _	29,632 36,729 2,219,365 1,763,835
Current liabilities Credit card liability Accrued retirement plan contributions Total liabilities Net assets Without donor restrictions Undesignated	\$	29,632 36,729 2,219,365

Total liabilities and net assets

\$ 4,019,929

2022 Income Statement

(US Dollars)

\$ 2,033,359
1 170 040
1,178,043 585,792
303,732
1,763,835
269,524
(473,822)
(204,298)
4,187,498
1/10//150
\$ 3,983,200

TOTAL EXPENSES

Staff Costs	\$1,311,733
Scientific Congresses and Exhibitions	\$73,516
Office Rental	\$90,467
Professional Services	\$88,977
Insurance	\$22,649
Bank and Credit Card Fees	\$42,693
Donations	\$20,000
Depreciation	\$11,815
Staff Business Travel	\$25,756
Office Expenses	\$46,580
Communication Services	\$14,530
Recruitment and Miscellaneous	\$15,119
Total	\$1,763,835

For additional information, please visit https://www.isbt128.org/annual-reports.

Goals and Strategic Plans

ICCBBA is working on four main strategic lines:

ENHANCE USER ENGAGEMENT AND UNDERSTANDING

Empower User Voices: Implement surveys, create more opportunities for user-team interactions, and foster networking to strengthen the user community's influence.

User-Centric Education: Develop innovative educational resources in user-friendly formats, enabling non-experts to grasp the essence of ISBT 128 and harness its full potential.

Data-Driven Insights: Collect and analyze data to gain insights into user engagement levels and activity within various MPHO fields, driving informed decision-making.



ELEVATE COMMUNICATION EFFECTIVENESS

Dynamic Newsletters: Revamp newsletters and announcements, infusing them with dynamism and relevance to engage and inform stakeholders effectively.

Social Media Amplification: Boost ICCBBA's online presence across social media platforms, using them as a dynamic communication channel to reach a broader audience.



ENHANCE ISBT 128 INTEROPERABILITY

Cross-Sector Collaboration: Actively collaborate with other Standards Development Organizations within the healthcare data sector. Aim to minimize data exchange barriers, fostering seamless interoperability of ISBT 128.



OPTIMIZE OPERATIONAL EFFICIENCY

Digital Transformation: Harness the power of existing and emerging digital tools to enhance the user experience. Streamline processes to make ICCBBA's services more accessible, efficient, and user-friendly.



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