



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2024 #41

December 6, 2024

INSIDE:

REGULATORY NEWS....	2
WORD IN WASHINGTON	2
2025 ADRP Annual Conference Early Bird Registration & Call for Abstracts Are Open	4
Results Available: 2024 Prehospital Blood Utilization Survey.....	4
Call for ADRP Board Nominations Is Open....	5
Recording Available: SMT Journal Club Webinar...	5
Workforce Trends Survey Report Available	5
PEOPLE.....	5
RESEARCH IN BRIEF	6
BRIEFLY NOTED.....	6
GLOBAL NEWS	7
COMPANY NEWS	8
CALENDAR.....	9
POSITIONS.....	10

FDA Communication on Cybersecurity Resiliency for Blood Establishments

On December 5th the U.S. Food and Drug Administration (FDA) [published](#) a communication for blood establishments to serve as, “a resource for strengthening their cybersecurity practices in order to prevent and mitigate cybersecurity incidents that could affect the availability and safety of blood and blood components for transfusion or further manufacture.”

The communication encourages blood establishments and transfusion services, “to identify possible shortcomings of their current disaster plans and implement and strengthen measures for cybersecurity resiliency to protect their data, ensure continuity of operations, and maintain a safe and adequate blood supply for patients.”

Considerations from the agency for the blood community include:

- “blood establishments must establish, maintain, and follow standard operating procedures (SOPs) for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for allogeneic transfusion, autologous transfusion, and further manufacturing purposes;
- blood establishments must report to FDA when there is an interruption in manufacturing likely to result in a significant disruption in supply in accordance with 21 CFR 600.82;
- in the event of a cybersecurity incident, blood establishments must continue to maintain records for the performance of each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components;
- blood establishments that cannot follow their standard operating procedures during a cybersecurity incident should request a meeting with the Office of Blood Research and Review (OBRR) through the Regulatory Project Manager; [and]
- Blood establishments with general questions can contact OBRR at CBERO-BRRBPBInquiries@fda.hhs.gov.”

With the America’s Blood Centers (ABC) Policy Council working to finalize the 2025 ABC Advocacy Agenda, ABC encourages member blood centers to please share feedback, for potential inclusion as an advocacy priority, explaining how the federal government can support blood centers in strengthening information technology (IT) systems to avoid cyberattacks. Please contact [Diane Calmus, JD](#), vice president of Government Affairs at ABC with questions or comments.

(Source: FDA [Communication](#), 12/5/24) ♦



REGULATORY NEWS

The Agency for Healthcare Research and Quality (AHRQ) has [published](#) a notice in the *Federal Register* titled, “Supplemental Evidence and Data Request on Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock.” The notice explains that the agency is, “seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock, which is currently being conducted by the AHRQ’s Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.” The submission deadline is December 26th.

(Source: *Federal Register* [Notice](#), 11/26/24)

The U.S. Food and Drug Administration (FDA) has [published](#) a draft guidance titled, “Frequently Asked Questions — Developing Potential Cellular and Gene Therapy Products.” According to the agency, the draft guidance is, “intended to provide industry with answers to frequently asked questions (FAQs) and commonly faced issues that arise during the development of cellular and gene therapy (CGT) products and is intended to help facilitate the development of safe, effective, and high-quality CGT products. The FAQs represent common questions directed to the Agency and span multiple disciplines, including regulatory review, chemistry, manufacturing, and controls (CMC), pharmacology/toxicology (PT), clinical, and clinical pharmacology.”

(Source: FDA [Draft Guidance](#), 11/21/24) 💧

WORD IN WASHINGTON

President-elect Trump has [announced](#) his intention to nominate [Martin A. Makary, MD, MPH](#) as commissioner of the U.S. Food and Drug Administration (FDA). Dr. Makary is a surgeon and public policy researcher at Johns Hopkins. Other nominees of interest include:

- Dave Weldon, MD (director of the U.S. Centers for Disease Control and Prevention (CDC));
- Janette Nesheiwat, MD (U.S. Surgeon General);
- Jay Bhattacharya, MD, PhD (director of the National Institutes of Health (NIH)); and
- Jim O’Neill (deputy secretary of the U.S. Department of Health and Human Services (HHS)).

(Source: *New York Times*, “[Tracking Trump’s Cabinet and Staff Nominations](#),” 12/6/24)

Baxter has provided an [update](#) on intravenous (IV) solution allocations following a disruption at its manufacturing facility in North Carolina in the wake of Hurricane Helene. According to the company, “two IV solutions manufacturing lines that restarted in November produce ~85 percent of the site’s pre-hurricane capacity of 1-liter IV solutions, the most commonly used size by hospitals and clinics. Baxter released the first product – 1-liter IV solutions -- that was manufactured post-hurricane the week of Nov. 18th. Initial batches were manufactured concurrently with ongoing quality activities and are only being released in accordance with applicable regulatory requirements to ensure the quality and safety of the products. All of the above milestones have been ahead of our original expectations and made possible by the dedication and resilience of the North Cove and broader Baxter teams, working in coordination with FDA. While we currently expect that all available lines will be restarted by the end of the year, we do not yet have a specific date for when we expect North Cove production to be fully restored to pre-hurricane levels... Baxter communicated details on allocation increases for several IV product groups to U.S. customers and distributors effective Nov. 26th. Customers are advised that there is a typical 1 to 2-week lag time for product to flow through the full distribution network after allocation changes are implemented. Barring any unanticipated developments, Baxter expects to share details on planned, phased increases in allocations again in

(continued on page 3)



WORD IN WASHINGTON (continued from page 2)

mid-December and at year-end, which includes reaching 100 percent allocation across several IV product codes by the end of 2024. Baxter’s ability to adjust allocation levels is based on the current and projected status of our North Cove remediation efforts, our expectations regarding our ability to reallocate capacity from other Baxter facilities, and 3) temporary importation of certain products. To date, we have evaluated and approved hundreds of allocation exception requests to help support neonatal and pediatric patient needs.”

(Source: Baxter [Update](#), 12/5/24)

HHS has [announced](#) a final rule that will, “expand access to kidney and liver transplants for people with HIV by removing clinical research requirements for these transplants.” According to an agency news release, “[t]he final rule, which further implements the HIV Organ Policy Equity (HOPE) Act, removes the clinical research and institutional review board (IRB) approval requirements for kidney and liver transplants between donors with HIV and recipients with HIV. This change is based on research demonstrating the safety and effectiveness of kidney and liver transplants between donors and recipients with HIV... This final rule builds on the Biden-Harris Administration’s commitment to advancing health equity and reducing barriers to care for people with HIV. By increasing the pool of available organs and streamlining the transplantation process, this policy can save lives, reduce stigma and discrimination associated with HIV, and lower costs and wait times. The final rule applies specifically to kidney and liver transplants, for which the evidence is robust, and shows the power of biomedical evidence to inform policy.” Additionally, NIH has published a [notice](#), “seeking public comment on a proposed revision to its research criteria for HOPE Act transplants of other organs, such as heart, lung, and pancreas. This effort aims to streamline the HOPE Act research requirements and continue to build an evidence base of outcomes data on HOPE Act transplants of organs other than livers and kidneys.”

(Source: HHS [News Release](#), 11/26/24) 💧



The *ABC Newsletter* (ISSN #1092-0412) is published by America’s Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2024 by America’s Blood Centers. Reproduction of the *ABC Newsletter* is forbidden unless permission is granted by the publisher (ABC members need not obtain prior permission if proper credit is given).

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the health care system; promote partnerships, policies, and programs that increase awareness about the need for blood donation; and serve as a thought leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

America’s Blood Centers

Chief Executive Officer: Kate Fry
 Chief Medical Officer: Jed Gorlin
 Editor: Mack Benton
 Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: \$420

Send subscription queries to memberservices@americasblood.org
 America’s Blood Centers
 1717 K St. NW, Suite 900, Washington, DC 20006
 Phone: (202) 393-5725
 Send news tips to newsletter@americasblood.org.



America's Blood Centers®
It's About *Life*.

INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staffs only, unless otherwise specified.

2025 ADRP Annual Conference Early Bird Registration & Call for Abstracts Are Open

[Register now](#) for the [2025 ADRP Annual Conference](#) in Oklahoma City, Oklahoma, from May 6th to 8th at the Omni Oklahoma City Hotel. Secure early bird rates by registering before January 17th and remember to [book your hotel room](#) by April 11th for the discounted rate. This conference offers a chance to learn about industry trends, share ideas, and connect with other donor recruitment, donor services, collections, marketing, and communications professionals. Join more than 400 of your peers by participating in pre-conference workshops, attending compelling educational sessions, engaging in roundtable discussions, exploring an expansive exhibit hall filled with innovative solutions. [Seize this extraordinary opportunity](#) to learn, share, and grow within the blood community.

Also, remember to submit an [abstract](#) to present your work through abstract lectures, quick hit topics, or posters. ADRP welcomes submissions on:

- collaboration between blood center departments for best outcomes;
- industry innovations;
- donor journey/donor management;
- marketing/public relations strategies;
- staff retention and satisfaction;
- leadership and staff development;
- social media applications in blood centers/TikTok use/social interaction;
- donor recruitment, engagement, and retention;
- collections technical and operational topics;
- social sciences and donor behaviors;
- artificial intelligence; and
- cellular therapies.

The abstract submission deadline is December 31st. Please [contact us](#) with any questions.

Results Available: 2024 Prehospital Blood Utilization Survey

America's Blood Centers (ABC) has [released](#) the findings from the 2024 ABC Member Prehospital Blood Utilization Survey. A total of 42 members took part in the survey with 81 percent (34/42) of participants supplying blood and/or blood products to a prehospital blood program. Other survey highlights include:

- approximately 32,052 blood products were distributed by surveyed ABC members for use in a pre-hospital program. This figure has more than doubled since 2023 when 14,882 blood products were distributed;
- low titer whole blood units are the most frequently distributed blood product in a prehospital setting; and
- the 2024 survey report features data from 2022–2024 collected via the ABC Member Prehospital Blood Utilization Survey showing growth in members' involvement in the prehospital space.

(continued on page 5)



INSIDE ABC (continued from page 4)

ABC thanks all participating blood centers. In alignment with ABC's Advocacy Agenda, we remain committed to addressing the barriers that limit the widespread availability of prehospital blood transfusions.

Call for ADRP Board Nominations Is Open

ADRP, The Association for Blood Donor Professionals invites interested individuals to consider [applying](#) to serve on the [ADRP Advisory Board](#) for the term beginning in May 2025. This is your chance to amplify your voice and help shape the future of your association! The ADRP Advisory Board is responsible for providing guidance towards, and prioritization of, the [strategic direction](#) of the organization and its mission to educate and empower blood banking professionals worldwide who are committed to donor recruitment, donor experience, and donor management. ADRP is looking for individuals that are team-oriented with leadership skills, and technical knowledge and expertise. The application deadline is December 31st. Please [contact us](#) with questions.

Recording Available: SMT Journal Club Webinar

ABC members can access the December 2nd ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar [on-demand](#). A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars. A link to the articles discussed during the webinar is also [available](#) to ABC members.

Workforce Trends Survey Report Available

ABC has published the 2024 Workforce Trends Survey Report. This resource is available for [purchase](#) by ABC member blood centers and offers deep insights into compensation, benefits, human resources policies, turnover and retention rates, and workforce trends specific to blood centers. Member blood centers who participated in the Workforce Trends Survey can purchase the report at a discounted price (discount code required). This survey combines the previous Compensation & Benefits and Employee Turnover & Retention surveys. Please [contact us](#) with questions. 💧

PEOPLE

New York Blood Center Enterprises President and Chief Executive Officer (CEO) [Christopher D. Hillyer, MD](#) has been [recognized](#) by being [named](#) to the PoliticsNY Power Players in Health Care List for 2023. According to an announcement, “the list honors individuals who have dedicated their careers to ensuring the health and wellness of all New Yorkers while also pioneering positive change and innovation throughout the industry. Their unwavering commitment to excellence is leading New York’s health care industry into a future defined by innovation, compassion, and improved health outcomes for all.”



(Source: New York Blood Center Enterprises [Announcement](#), 12/2/24) 💧





RESEARCH IN BRIEF

Effects of Donors on Red Blood Cell β S-Nitrosylation. A [study](#) published in *Vox Sanguinis* was conducted using the hypothesis, “after long periods of storage (≥ 35 days), blood from older donors (≥ 45 years [of age]) would have higher nitric oxide (NO) levels, and the levels of S-nitrosylated h[e]moglobin (SNO-Hb) in red blood cells (RBCs) from older donors (≥ 45 years [of age]) would be reduced.” The authors explained that, “S-nitrosylation (S-NO) of h[e]moglobin β chain in RBC plays essential roles in [vasodilation and tissue oxygenation.] The balance between NO and SNO-Hb is vital for maintaining blood flow and tissue oxygenation.” They noted that, “[t]his study involved 42 healthy donors, with 26 younger (≤ 30 years old) and 16 older donors (≥ 45 years old). Males and females were equally distributed.” For this study, “blood samples within 8-day storage were fresh blood, and blood samples with a storage time beyond 35 days were stored blood. Total NO and nitrate/nitrite assay was employed to quantitatively evaluate levels of NO.” The authors stated that a, “mass spectrometry-based targeted relative quantitation of S-nitrosylation levels of Hb β Cys94” was used. They explained that, “[t]here was no significant difference between Days 4 and 8, while Days 20 and 35 had significantly higher levels of total NO compared with Day 8 which indicates that short periods of storage did not cause remarkable total NO level changes.” The paper described that, “[i]n fresh blood, males and females had similar levels of total NO, while older donors showed higher levels of total NO than younger donors. [Both] older males and older females had higher levels of total NO relative to younger males and younger females, respectively.” Additionally, the authors noted that, “after 35-day storage, total NO levels in blood storage solution increase regardless of donor age and gender. [though the study] did not observe a significant difference in S-nitrosylation level in fresh RBCs between younger and older donors or between male and female donors... Compared with fresh RBCs, overall, S-NO levels significantly decreased in stored RBCs. Additionally, RBCs from older donors significantly lost their S-nitrosylation in stored RBCs when compared with fresh RBCs. S-nitrosylation levels from females significantly decreased in stored RBCs, whereas no significant changes in males were observed between fresh RBCs and stored RBCs. Finally, when grouping the donors based on age and gender, only S-nitrosylation levels from older females were significantly lower in stored RBCs than in fresh RBCs.” The study concluded that, “age, gender and storage duration affect NO levels in RBCs... S-NO levels in RBCs significantly decrease, and NO metabolites levels in storage solution significantly increase with donor age, female gender, and storage duration.”

Citation: Zhang, C., Huang, P., Singh, R.J., and Zubair, A.C. “[Effects of blood donor characteristics and storage on red blood cell haemoglobin \$\beta\$ S-nitrosylation.](#)” *Vox Sanguinis*. 2024.

Contributed by Richard Gammon, MD, Chief Medical Officer at Carter BloodCare 

BRIEFLY NOTED

The Coalition for Effective Diagnostics is [urging](#) Congress to, “enact a comprehensive diagnostic testing reform package to tailor the U.S. Food and Drug Administration (FDA) regulatory oversight of laboratory-developed tests (LDTs).” The group includes, “pathologists, academic medical centers, diagnostic manufacturers, laboratories, and patient groups [seeking] to build consensus legislation to establish a fit-for-purpose regulatory paradigm for diagnostic tests that preserves innovation and ensures continued access to accurate and reliable tests.” Specifically, the coalition [letter](#) explained that, “Congress has an opportunity to pass legislation with regulatory approval pathways designed to match the unique characteristics and risk profiles of diagnostic tests.”

(Source: College of American Pathologists [News Release](#), 11/12/24)

(continued on page 7)

BRIEFLY NOTED (continued from page 6)

A clinical trial is now [enrolling](#) patients for an investigational gene-editing treatment for sickle cell disease patients. According to a news release from the University of California San Francisco (UCSF), “the trial is the first in the U.S. to apply non-viral CRISPR-Cas9 gene-editing technology in humans to directly correct the genetic mutation that causes the disease...UCSF’s research involves taking the patient’s blood stem cells to correct the mutation and returning those edited cells to the patient through a bone marrow transplant. It’s hoped the corrected blood stem cells will then multiply and create a new blood system, one free of sickle cell.” The clinical trial includes, “[t]he project team from UCSF, the Innovative Genomics Institute (IGI) and UCLA have developed CRISPR_SCD001, a patient-specific blood stem cell therapy product derived from the patient that has been modified by a CRISPR-Cas9 nuclease to stimulate repair of the sickle mutation. In the current trial, the patient’s blood stem cells will be extracted and sent to UCLA’s Human Gene and Cell Therapy Facility to be processed using electrical pulses that create temporary pores in their membranes. These pores allow the CRISPR-Cas9 platform to enter the cells and travel to the nucleus without the use of a viral vector. Once in the nucleus, it corrects the sickle cell mutation before the cells are returned to the patient in a bone marrow transplant procedure.”

(Source: UCSF [News Release](#), 11/22/24) 💧

GLOBAL NEWS

Social media influencers in France raising [awareness](#) for blood donation and encouraging eligible individuals to donate. [Arkunir](#) and streamer [Farès Bichard](#) asked their followers to, “set a new European record of blood donation.” According to a report from *Yahoo! News*, “posts from both in mid-November boosted registrations for a blood donation event being held in Paris [last week.] Of [the] 4,100 appointments originally available there were just 350 left the day before the drive began, with 30 percent of those who had signed up younger than 30 years old. The duo of influencers, who will host a Twitch special [on Saturday], spontaneously contacted the French national blood bank” resulting in a “20 percent jump in donors in September and October across France.”

(Source: *Yahoo! News*, “[French influencers call on followers to break blood donation record](#),” 11/30/24)

The United Kingdom Health Security Agency (UKHSA) [published](#) a communication, “reminding those heading abroad to take precautions against mosquito-borne infections. The latest UKHSA data show a rise in travel-related mosquito-borne infections such as dengue and malaria, which can cause serious illness.” The advisory also explained that, “[the] annual malaria report for 2023 shows that there were 2,106 cases of imported malaria reported in the UK. This is 26 percent higher than the cases reported in 2022 (1,555 cases) and is the highest total number of cases seen in the UK since 2001. The rise in cases is linked to the resurgence of malaria in many countries and an increase in overseas travel following the removal of pandemic restrictions. [Additionally, in] a separate report, looking at other mosquito-borne infections between January and June 2024, there were 473 dengue cases reported in returning travelers across England, Wales, and Northern Ireland, a significant increase from the 157 cases reported during the same period in 2023. This is the highest number of cases reported in the first six months of any year since dengue surveillance began in 2009 and reflects the substantial rise in cases reported globally in 2024. The Joint Committee on Vaccination and Immunization (JCVI) has recently recommended a dengue vaccine for some travelers.

(Source: UKHSA [Communication](#), 12/3/24)

(continued on page 8)



GLOBAL NEWS (continued from page 7)

The World Health Organization’s (WHO) International Health Regulations (2005) (IHR) Emergency Committee met on November 22nd, “regarding the [upsurge](#) of mpox 2024.” The committee recommended to the WHO Director-General that, “the event continues to meet the criteria of a public health emergency of international concern (PHEIC).” Temporary recommendations for areas experiencing transmission of mpox include:

- emergency coordination;
- safe and scalable clinical care;
- vaccination;
- community protection;
- financing preventative measures; and
- addressing research gaps.

“The WHO Director-General concur[red] with the advice of the Committee that the event continues to constitute a PHEIC.”

(Source: WHO [Announcement](#), 11/28/24) 💧

COMPANY NEWS

Haemonetics Corporation has [agreed](#) “to sell its whole blood assets to GVS, S.p.A. According to a December 3rd announcement, “GVS will acquire Haemonetics’ complete portfolio of proprietary whole blood collection, processing, and filtration solutions, along with Haemonetics’ manufacturing facility in Covina, Calif. where certain of these products are produced, and related equipment and assets located at Haemonetics’ manufacturing facility in Tijuana, Mexico. This transaction is expected to close in the first quarter of calendar [year] 2025, subject to the satisfaction of customary closing conditions. Haemonetics’ Blood Center business will continue to manufacture and provide customers with its full line of apheresis solutions for automated blood collection. These include devices and disposable kits that support a variety of apheresis collections, including platelets, plasma, and red cells, and ensure efficient blood center operations.” This agreement comes in the wake of Haemonetics previously announcing a transaction, “in 2020 to sell its Fajardo, Puerto Rico manufacturing operations to GVS and enter a long-term supply and development agreement granting GVS exclusive rights to manufacture and supply the proprietary blood filters produced at the Fajardo facility for Haemonetics.”

(Source: Haemonetics Corporation [News Release](#), 12/3/24)

Terumo Blood and Cell Technologies (Terumo BCT) is providing [funding](#) support for a clinical trial that, “aims to confirm that the benefits from early treatment of severe acute chest syndrome (ACS) [in sickle cell disease (SCD) patients] using automated red blood cell exchange versus manual exchange will translate to a faster resolution of ACS and reduced adverse events during hospitalization for these extremely vulnerable patients.” A company news release explained that trial will be led by, “experts at France’s Henri Mondor University Hospital and sponsored by Assistance Publique-Hôpitaux de Paris. ACS occurs when vaso-occlusion occurs within the pulmonary vasculature. It can progress quickly and requires prompt treatment. Management of ACS mostly involves a symptomatic approach using hydration, analgesics, supplemental oxygen and red blood cell exchange, [which] replaces damaged cells with healthy ones, helps improve oxygenation and can be done using manual or automated exchange. Manual exchange requires time-consuming sequential steps, while automated red blood cell exchange meets hematological targets more quickly and consistently.”

(Source: Terumo BCT [News Release](#), 12/3/24)

(continued on page 9)



COMPANY NEWS (continued from page 8)

Fresenius Kabi has announced a 510(k) notification [submission](#) to the U.S. Food and Drug Administration (FDA), “seeking clearance of the Aurora Xi Plasmapheresis System software version 2.0.” According to the news release, “[t]he Aurora Xi is [the only] Plasmapheresis currently cleared in the U.S. for source plasma collection using two existing nomogram algorithms (Standard and Optimized), which determine the amount of plasma to be collected from donors. Aurora Xi Software Version 2.0 includes a new, linear nomogram that uses each donor’s unique characteristics to target a collection volume. [Additionally, the] 510(k) submission was supported by a multicenter, prospective randomized controlled clinical trial, conducted to evaluate the new nomogram in Aurora Xi Software Version 2.0 compared to the existing nomogram in the predicate device. In the trial, more than 52,400 procedures were completed at three of Takeda’s BioLife Plasma donation centers.”

(Source: Fresenius Kabi [News Release](#), 11/21/24)

A report from **Valneva SE** [indicates](#), “positive antibody persistence data three years after vaccination with a single dose of its chikungunya vaccine Ixchiq®.” The company stated in the announcement that, “[t]he results are in line with Valneva’s expectations for this vaccine, confirming a strong and long-lasting antibody persistence across all age groups investigated. The three-year persistence data are also in line with positive twelve-month and two-year persistence data the Company reported in [December 2022](#) and [December 2023](#) respectively. Among the 278 healthy adults still enrolled in the trial, 96 percent maintained neutralizing antibody titers well above the seroresponse threshold three years after the single-dose vaccination. Persistence of antibodies in older adults (age 65+) in terms of geometric mean titers (GMTs) and seroresponse rates (SRRs) was comparable to younger adults (18-64 years of age). Hence, the primary endpoint was met.” Valneva noted that the, “latest analysis does not include a further safety evaluation since safety data collection was concluded at two years after vaccination according to the Clinical Trial Protocol. No safety concerns were reported or identified during the two-year follow-up and no adverse event of special interest were ongoing at the time of participant enrollment in the trial...The vaccine was launched in the U.S. at the beginning of March 2024, following adoption of the U.S. Advisory Committee on Immunization Practices’ (ACIP) recommendations by the U.S. Centers for Disease Control and Prevention (CDC) and launches in France and Canada are currently underway.”

(Source: Valneva SE [News Release](#), 12/3/24) 💧

CALENDAR

***Note to subscribers:** Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)*

2024

Dec. 7-10. **66th American Society of Hematology (ASH) Annual Meeting and Expo (Hybrid)**. San Diego, Calif. [Registration](#) is open. More information available [here](#).

Dec. 12. **FDA Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Town Hall: Best Practices for Regulatory Interactions with OTP (Virtual)**. [Registration](#) is open. More information available [here](#).

Dec. 18. **Association for the Advancement of Blood & Biotherapies eCast: Vaccination and Blood Donation Policies Protect Blood (Virtual)**. [Registration](#) is open. More information available [here](#).

(continued on page 10)

CALENDAR (continued from page 9)

2025

Feb. 4-6. **Department of Defense (DoD) Combat Casualty Care Research Program, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA) Radiation/Nuclear Medical Countermeasures Program, and the Medical Technology Enterprise Consortium (MTEC) Platelet and Platelet-like Products State of Technology Meeting.** Bethesda, Md. [Registration](#) is open. More information available [here](#).

Mar. 10-12. **ABC Annual Meeting.** Arlington, Va. More information available [here](#).

May 6-8. **2025 ADRP Annual Conference.** Oklahoma City, Okla. More information available [here](#).

May 14-15. **International Plasma and Fractionation Association (IPFA)/Paul-Ehrlich Institut[e] (PEI) 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens.** Heidelberg, Germany. [Registration](#) is open. More information available [here](#).

May 20-21. **International Plasma Protein Congress.** Warsaw, Poland. More information is coming soon.

June 1-4. **International Society of Blood Transfusion (ISBT) 35th Regional Congress.** Milan, Italy. More information coming soon.

June 25-26. **HHS OIDP TBDAIC Community Engagement Meeting (Hybrid).** Portland, Maine. More information coming soon.

June 30-July 1. **HHS Administration for Strategic Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2025 (Hybrid).** Washington, D.C. More information available [here](#).

Oct. 12-15. **American Association of Tissue Banks (AATB) Annual Meeting.** Atlanta, Ga. More information is coming soon.

Oct. 25-28. **AABB Annual Meeting.** San Diego, Calif. More information is coming soon.

Nov. 17-20. **American Society for Clinical Pathology (ASCP) Annual Meeting.** Atlanta, Ga. More information coming soon. ◆

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Donor Recruitment Field Training Specialist (Oklahoma, Texas, or Arkansas). Our Blood Institute is looking for a **FIELD TRAINING SPECIALIST** who will be a key member of our Donor Recruitment team, helping to identify skill gaps and develop training paths to fill those gaps. The trainer must be both data and metrics driven, as well as hands-on with excellent communication and donor development skills. Working with our Donor Recruitment Management Team, the Field Training Specialist will oversee sales calls, including prospects and existing donor groups, and work with individual Recruitment team members to develop their

skills to achieve their goals and targets. The role will also act as an advocate to promote the voice of Drive Champions (DC) and ensure DC effectiveness by coaching account consultants on DC engagement strategies. A successful candidate must have 3 years' experience in sales and/or training. This position requires 60 percent travel across Oklahoma, Texas, and Arkansas. Must be 21 years of age or older with clean MVR. Salary Range: Competitive salary with excellent benefits package including

(continued on page 11)

POSITIONS (continued from page 10)

health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. **How to apply:** <https://obi.org/about/careers/>.

Associate Medical Director (Oklahoma City, OK). Our Blood Institute (OBI) seeks an **Associate Medical Director** for its Oklahoma City headquarters location. The Associate Medical Director is a licensed physician with shared responsibility for the medical, technical, and clinical leadership and direction of OBI's operations. This position will help direct and supervise key staff and processes to ensure the safety and well-being of all blood donors, the quality of all blood products manufactured, and the provision of premier laboratory and patient services. Ample complex medical care and professional growth opportunities arise from our Therapeutic Apheresis, AABB accredited IRL, and FACT accredited cell therapy operations. Numerous clinical research, public health, and product development initiatives can inspire projects ranging from community health surveillance to entrepreneurial start-ups. Empowering resources including clean rooms, a high-volume donor testing laboratory, and sizable software engineering skunkworks. OBI has a variety of outstanding opportunities to propel your career in a nimble, supportive, and friendly environment. Management experience and business skill acquisition is guaranteed in a complex, 1100-employee non-profit organization. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. **How to apply:** <https://obi.org/about/careers/>

Vice President, Quality & Regulatory Affairs (VPQRA). The Vice President, Quality & Regulatory Affairs (VPQRA) leads the Organization's adherence to regulations and standards established by governing agencies (AABB, FDA, CLIA, State, OSHA, NRC, EU, etc.). Kentucky Blood Center is seeking qualified candidates to fill this key executive leadership role which is responsible for our Quality Assurance (QA) program and regulatory compliance activities. The position has oversight of the QA department and team, and reports to the CEO. Qualifications include MLS/CLS (ASCP) with preference given to candidates with a graduate degree, and blood banking experience. Relocation to the Lexington, Kentucky area required (assistance provided). For more information or to apply, visit <https://www.kyblood-center.org/about-us/careers>.

Associate Medical Director/Medical Director (Versiti Blood Center of Ohio). Serve as the physician face of Versiti and Versiti Ohio, translating complex medical issues to educate other physicians, support staff and the public. Opportunities in educational initiatives and clinical/applied research are available within Versiti and with our affiliated health systems. As part of the Versiti physician team you will have the opportunity to participate

in clinical research projects with investigators at our world-renowned diagnostic laboratory and blood research institute. Joining our Medical Science Institute transfusion medicine physician team will provide you with a uniquely diverse and collaborative experience. Requirements: MD or DO Degree. Board certified/eligible in Blood Banking/Transfusion Medicine. At least three years of experience in blood center/transfusion medicine practice preferred. Licensed or eligible for an Ohio and Indiana; other state licenses may be required. Driver's License in good standing. Please click [here](#) to read the full job description and apply.

Mobile Operations Manager (Suncoast Blood Centers: Lakewood Ranch, Florida). Suncoast Blood Centers is seeking a dedicated Mobile Operations Manager to join our team. The Mobile Operations Manager is responsible for overseeing all mobile donor collection activities to ensure safe, efficient, and compliant blood collection operations. Key duties include supervising donor collection staff, coordinating schedules across mobile and fixed sites, and ensuring adherence to regulatory standards. This role involves staff training, quality assurance, and handling donor suitability issues. The Mobile Operations Manager also addresses customer service concerns, promotes positive donor experiences, and supports SunCoast Blood Centers' mission through effective leadership and operational excellence. Please visit [Careers — SunCoast Blood Centers](#) to view the full job description and apply.

Clinical Research Nurse (Suncoast Blood Centers: Lakewood Ranch, Florida). SunCoast Blood Centers is seeking a dedicated Clinical Services and Research Apheresis Nurse (LPN) to perform critical apheresis procedures for patient care in hospitals and research projects. Ideal candidates will have completed a relevant nursing program, hold a current Florida LPN license with central line certification, and possess at least two years of patient care experience, including phlebotomy. Key responsibilities include providing high-standard patient and research subject care, operating and maintaining apheresis equipment, following Good Clinical Practices (GCP) protocols, and assisting in the recruitment of research subjects. Please visit [Careers — SunCoast Blood Centers](#) to view the full job description and apply.

Immunohematology Reference Lab Medical Technologist (2nd Shift/Evenings). LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Atlanta, GA. The position is responsible for following established policies and procedures,

(continued on page 12)



POSITIONS (continued from page 11)

identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply [here!](#)

Immunohematology Reference Lab Medical Technologist (2nd Shift). LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Jacksonville, FL. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. This individual will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure blood is there when you or your family is in need. Visit our careers page to learn more about this position, and [apply here!](#) 💧