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Accelerating global research and education through scientific exchange

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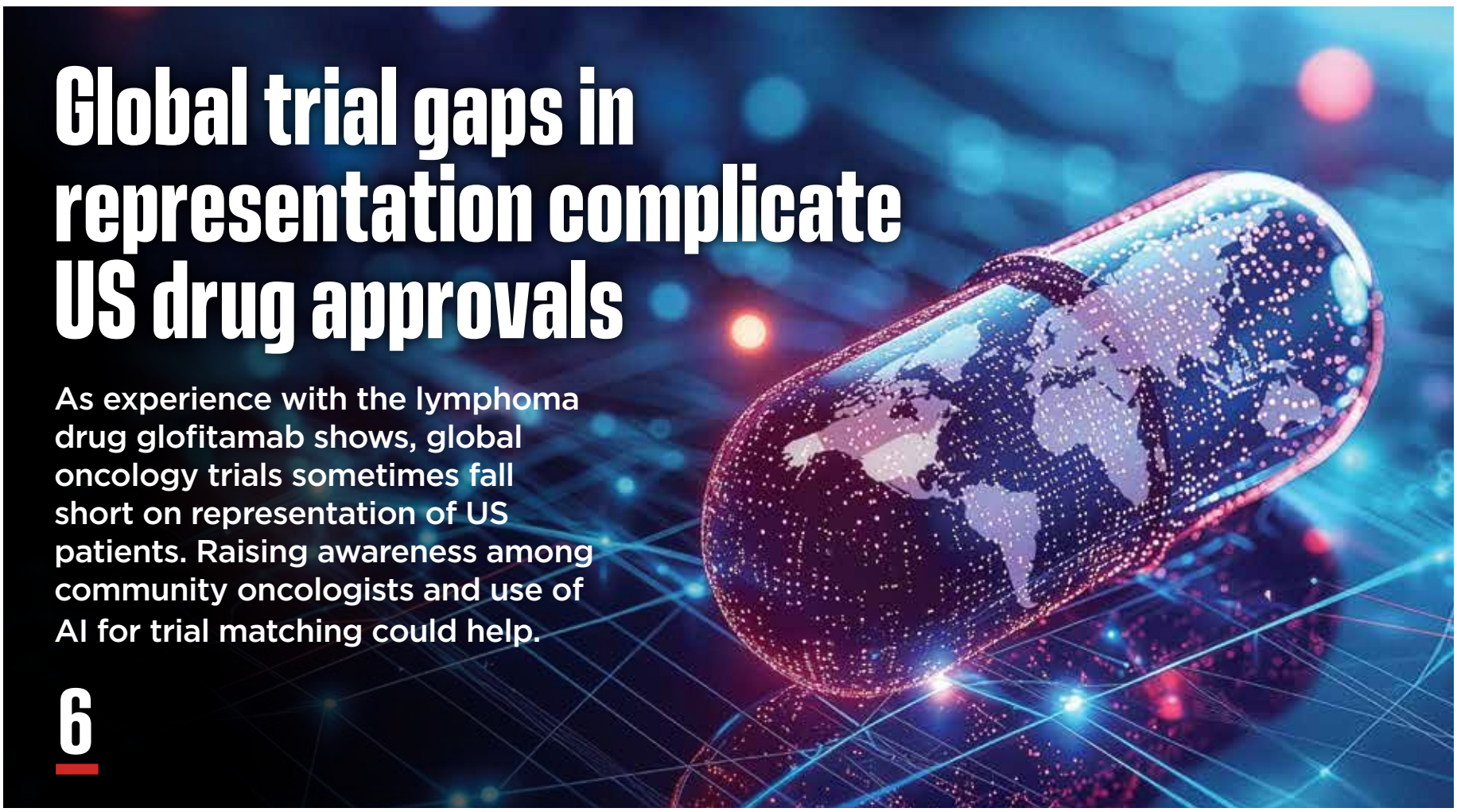

Global trial gaps in representation complicate US drug approvals

As experience with the lymphoma drug glofitamab shows, global oncology trials sometimes fall short on representation of US patients. Raising awareness among community oncologists and use of AI for trial matching could help.

6

3 SOHO strengthens global leadership in blood cancer research

14 NCI director says institute is 'stable' after turbulent year

15 SOHO President Dr. John F. DiPersio honored with top AACR award

Feature

4 Sustaining momentum in R/R CLL/SLL care: a five-month follow-up

Table of Contents

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SOHO strengthens global leadership in blood cancer research

In this letter, SOHO Executive Director Janet M. Cesak, MBA, outlines the latest achievements of the Society of Hematologic Oncology's global Ambassador Program, including two successful inaugural meetings.

Dear colleagues,

As we approach the end of the first quarter of 2026, I am pleased to share a brief update on the exceptional successes of the SOHO Ambassador Program thus far this year.

The Houston-based SOHO team joined the inaugural meetings of both SOHO Asia and SOHO UK, supporting membership efforts on site and engaging directly with attendees. The enthusiasm present at both meetings reflects the growing global engagement across the society and its members.

SOHO Asia was held in Taipei, Taiwan, at the Evergreen International Convention Center January 23–25, 2026. The meeting was organized by SOHO Ambassadors Drs. Bor-Sheng Ko and Hsin-An Hou and drew close to 400 attendees from around the world. The program featured leading hematologists from the University of Texas MD Anderson Cancer Center, Dana-Farber Cancer Institute, National Taiwan University Hospital, and Singapore General Hospital. Read more about SOHO Asia on page 10.

SOHO UK was held at the Royal College of Physicians in London on March 3–4, 2026, bringing together nearly 300 attendees. The program was led and developed by Profs. Charles Craddock and Anthony Goldstone, with input from hematology leaders representing the breadth of the UK hematology community. Read more about SOHO UK on page 12.

Our media platform, SOHO Insider, also debuted its first regional meeting newspaper at SOHO UK, which received strong praise from attendees and helped create a shared sense of community. The newspaper highlighted significant meeting themes, introduced new voices, and showcased the strength and breadth of the program. Readers can view a copy of the digital version online.

As we move further into the year, additional regional SOHO meetings are planned across Israel, Brazil, Central Europe (its inaugural meeting), and France.

The SOHO Ambassador Program appoints experts from around the world to represent the society in their geographic regions. Ambassadors share local developments in hematologic oncology with SOHO and promote its educational resources within their communities.

Sincerely,

Janet Cesak

Visit **soho.click/donate** to support the SOHO Ambassador program.

Sustaining momentum in R/R CLL/SLL care: a five-month follow-up

Karine Cohen-Solal, PhD

Continuous Learning Collaborative (CLC) pilot contributors Meghan C. Thompson, MD, William Wierda, MD, PhD, Catherine C. Coombs, MD.

Two previous articles detailing the Continuous Learning Collaborative (CLC) pilot at SOHO 2025 were published in SOHO Insider in 2025. This initiative was launched to educate clinicians managing relapsed/refractory (R/R) chronic lymphocytic lymphoma (CLL)/small lymphocytic lymphoma (SLL), initially engaging 25 early-career physicians from within and beyond the United States and later expanding to the broader SOHO audience. Phase 1 of the CLC, conducted prior to the meeting, gathered real-world insights through de-identified patient records, interactive case simulations on the Build Your Own Case Study™ (BYOCS)™ platform, and detailed surveys to identify clinical challenges and educational needs. These data informed phase 2, a 90-minute Live Intensive session at SOHO 2025 that used case-based learning, real-time treatment decision exercises, and expert feedback to address adverse event (AE) management, therapy sequencing, and multidisciplinary care considerations. Participants also engaged in small-group discussions with faculty to explore complex clinical scenarios and practical implementation strategies. The multiphase structure of the CLC effectively translated emerging evidence into actionable insights, strengthening clinicians' confidence in evidence-based sequencing, toxicity management, and patient-centered decision-making, with participants explicitly reporting intent to integrate these approaches into routine R/R CLL/SLL practice.

Five months of insights

In the five months since, we have compiled additional insights and clinical implications through phase 3 of the CLC, which includes an enduring component built from the Live Intensive session, as well as 30-minute one-on-one interviews with 18 participants from our cohort and two quarterly meetings with expert faculty. In this article, we highlight the program's impact on clinical practice, underscoring how multiphase learning effectively engages both early-career and experienced clinicians in translating evidence and expert insights into informed care for patients with R/R CLL/SLL.

> Multiphase learning effectively engages both early-career and experienced clinicians in translating evidence and expert insights into informed care for patients with R/R CLL/SLL.

Enduring activity data

- While guideline updates and pirtobrutinib approval for second-line application are quite recent, 87% of learners adopted the change quickly due to the activity (a 40% gain).
- The activity effectively closed knowledge and competence gaps around novel therapies, their associated AEs, treatment algorithms, implementation and relevant post-Bruton tyrosine kinase inhibitor (BTKi) mutations. Learners showed a 52% increase in knowledge of obinutuzumab-related AEs, a 40% improvement in competence in selecting the appropriate treatment setting for chimeric antigen receptor (CAR) T-cell therapy, a 55% gain in knowledge of non-C481 BTK mutations associated with BTKi treatment, a 46% gain in competence in selecting the next treatment line, and a 39% improvement in ability to select BTKi for their patients with R/R CLL/SLL.
- An impressive 93% of learners stated that the program provided strategies to overcome barriers in R/R CLL/SLL care, including lack of knowledge regarding evidence-based strategies, lack of time/resources to consider change, access to a multidisciplinary care team for AE management and care coordination and patient adherence to treatment.
- After participating in the enduring activity, 52%-61% of learners reported the intention to implement changes by using guideline-informed approaches, apply the latest data on novel therapies, integrate updated evidence and sequencing strategies gained from the activity, and re-prioritize shared decision-making (SDM) for next-step treatment planning in patients with R/R CLL/SLL. In addition, 33%-42% answered that their current practice has been reinforced in those areas as a result of learnings from the activity.

These findings suggest that the enduring activity both strengthened clinician confidence in current management strategies and encouraged further alignment with evolving evidence and patient-centered approaches for R/R CLL/SLL care.

Insights and clinical implications derived from participant interviews

Questions in the previously mentioned one-on-one interviews focused on navigating novel therapy integration and sequencing, AE management, and SDM practices. The following key insights were revealed by asking, "What's the one thing from this program so far that has had the biggest impact on your practice?"

- Participants frequently cited reduced clinical isolation as the most transformative impact. Access to experts boosted practice confidence, even without immediate consultation. Education for community oncologists should prioritize peer-to-peer connections beyond mere content delivery. Knowing expert support is available enhanced confidence in decision-making. As expressed by one of the interviewees, "I think the biggest impact is just being part of the community. I felt like I'm joining a group, and that part of collegiality, sharing my own problems with somebody who has also encountered similar problems, and then discussing with expert. That was just mind-blowing. You'll be surprised, because it is when you start to practice and you're in your niche, you sometimes get isolated."
- Expert guidance on managing atrial fibrillation (AFib) and cardiac AEs associated with BTKi treatment directly influenced prescribing behaviors. Clinicians who had previously avoided BTKis in patients with arrhythmias now feel confident prescribing them while co-managing with cardiology. The program helped fill gaps that guidelines alone cannot address. Pragmatic, expert-led algorithms prove more effective at changing behavior than published evidence or guidelines, as confirmed in discussions with **Dr. William Wierda** at the first quarterly meeting (detailed below).

William G. Wierda MD, PhD

- At least one institution updated its CLL/SLL testing panel to include next-generation sequencing directly because of program insights. The CLC initiative drove systemic changes in testing protocols at the institutional level, improving diagnostic and testing accuracy and, subsequently, treatment personalization.
- The program increased clinician confidence in treatment sequencing and discussing therapy options with patients, including decisions about switching or continuing treatments and framing risk-benefit profiles. Building SDM skills is an often-overlooked outcome for continuing education in R/R CLL/SLL. Since effective communication can meaningfully improve patient outcomes and satisfaction through informed, shared decisions, it is just as important as knowledge acquisition.
- For under-resourced community oncologists and international oncologists, subsidized access to the SOHO conference was one of the highest-impact elements. The intimate, disease-focused, interactive format was preferred over larger generalist meetings. Investing in conference subsidies provides exceptional value in professional development and knowledge as well as skills dissemination, with positive ramifications at the institutional level.
- In this regard, one international learner used the program content to deliver lectures on BTKi therapy and its AEs to colleagues, amplifying the skills/strategy spread. Program participants act as regional multipliers, extending educational reach and fostering broader adoption of best practices.

Quarterly meetings with CLL/SLL expert faculty

In December 2025, the first quarterly meeting of phase 3 was conducted with Dr. William Wierda and learners from the cohort of 25 investigators participating in the CLC. Several illuminating questions—some submitted by learners before the meeting and others raised during the session—about real-world challenges or specific case scenarios were discussed. Topics covered included:

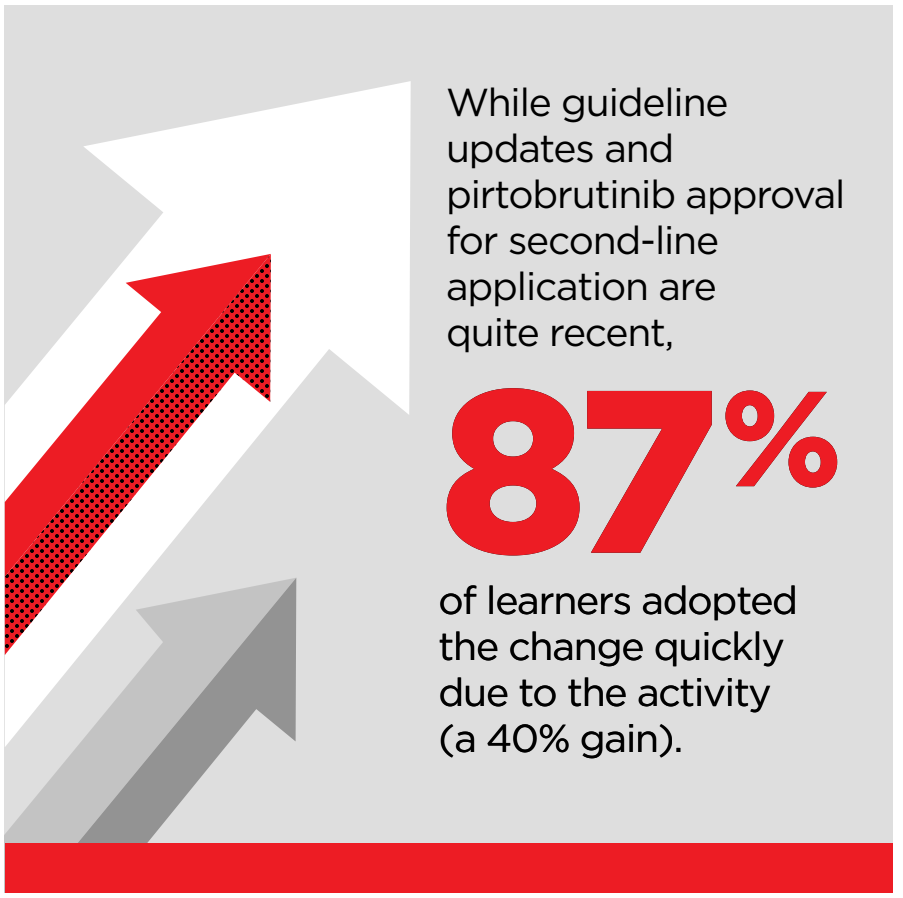
- Richter's transformation in CLL: What is the optimal treatment for a patient with CLL that evolved into Richter's in post-covalent BTKi exposure? Pirtobrutinib or venetoclax plus R-CHOP? How to determine a clonality relationship between CLL and new onset of large-cell lymphoma (Richter's from CLL versus de novo [large B-cell lymphoma])? The 20-minute exchange resulting from this query highlighted a significant unmet clinical need and the uncertainty clinicians face in effectively treating patients who develop Richter's.
- Minimal residual disease (MRD) is a rapidly evolving endpoint in clinical trials and treatment algorithms for hematological malignancies, and its utility in guiding therapy in CLL/SLL was addressed in depth in response to multiple learner questions: Which method to use? ClonoSEQ or flow cytometry? Which threshold: MRD 4, MRD 5 or MRD 6? Do we perform it on bone marrow or peripheral blood? When to check MRD? How long do we need to treat post-MRD undetectable status? How do you currently incorporate MRD assessment into the management of patients with R/R CLL? Could MRD-adapted, limited therapy have any role in the R/R setting?
- Pirtobrutinib: Can pirtobrutinib be used as monotherapy to induce durable remission, other than as a bridge to CAR T-cell therapies? If pirtobrutinib was moved into the frontline setting, what would be the impact on treatment sequencing and resistance patterns after relapse?
- In a patient with a pre-existing history of permanent Afib, how do you follow them when starting a BTKi? Do you involve cardiology from the start?
- How do you manage severe cytopenias during obinutuzumab plus venetoclax early on with bone marrow clean out? How much do you rely on growth factor and transfusion support?

These discussions signal that community HCPs are changing prescribing behavior on BTKi for patients with Afib as a result of the CLC program education. In particular, the shift from falling back on venetoclax-based therapy to utilizing BTKi with cardiology co-management represents a concrete practice evolution.

Furthermore, the long exchange between the cohort and Dr. Wierda on managing patients who have Richter's transformation highlighted an unmet clinical need in community settings for which more education is needed. Key discussion points on this topic revolved around the role of pirtobrutinib, the venue of transplant, BTKi as post-transplant maintenance, and CAR T-cell therapy for these patients.

Overall, the first quarterly meeting reinforced the current standard

••• See **Momentum** continued on page 9



Global trial gaps in representation complicate US drug approvals

By Emily Hayes

When you prescribe a newly approved hematologic oncology drug, you ought to have confidence that it will be both effective and safe for the types of patients you treat and that it fits with the US standard of care.

"It has long been recognized that clinical trial participants should reflect the population for which the health product is intended," the American Society of Hematology (ASH) explained in its diversity, equity, and inclusion roadmap. "This is important because biological, social, and other variables can affect the way a health product functions in different populations, potentially resulting in different safety and/or efficacy profiles."

But due to real-world pressures on sponsors, physicians, and patients, there are some formidable barriers to ensuring that drug trials supporting approvals include enough patients from the US and reflect the ethnic diversity of the populations likely to be treated.

The US Food and Drug Administration (FDA)'s rejection last year of Roche/Genentech's bispecific antibody glofitamab-gxbm (Columvi) in second-line treatment of diffuse large b-cell lymphoma (DLBCL) is an example of what can go wrong with the regulatory reviews of a promising drug. Glofitamab, a bispecific CD20-directed CD3 T-cell engager, had received accelerated approval as a single agent for relapsed or refractory (R/R) DLBCL or large B-cell lymphoma arising from follicular lymphoma in 2023, based on a single arm trial that showed strong response rates.

The pivotal STARGLO study testing glofitamab with gemcitabine and oxaliplatin (GemOx) in second-line DLBCL patients not eligible for transplant was lined up to support full approval later on.

But there was good news and bad news in the STARGLO results. Overall, there was a 41% reduction in the risk of death. The European Commission approved the combo for its member countries in April 2025, based on STARGLO. To date, the combination has been approved for the second-line DLBCL indication in more than 50 countries, according to Genentech.

The FDA, however, issued a complete response letter in July 2025 for second-line DLBCL.

When US representation falls short

So, what went wrong in the US? It boiled down to regional representation. The study tested Columvi/GemOx against Roche's rituximab (Rituxan) with GemOx in 274 patients. The overall survival hazard ratios for the test combo vs control were .41 for the 161 Asians participating in the study, 1.09 for the 88 Europeans and 2.62 for the 25 North Americans. The study wasn't powered to detect statistical changes in subgroups, but these analyses can be helpful for looking at trends and other measures like progression-free survival and complete response rate also showed better results for Asian participants.

FDA's Oncologic Drug Advisory Committee (ODAC) voted 8-1

against approving the new indication—the one yes vote coming from a patient advocate concerned about preserving access and satisfied with the overall result.

The STARGLO study took place at the time of the pandemic, which made enrollment more challenging in the US, according to the manufacturer, but COVID-19 was a global crisis and other regions were able to recruit more patients. Most of FDA's ODAC members were not able to conclude that the overall result would apply to patients in the US.

That's certainly not the end of the story. Glofitamab/GemOx is still included as a preferred regimen for second-line DLBCL in National Comprehensive Cancer Network guidelines for B-cell lymphomas, paving the way for continued use and reimbursement. Other studies could bolster glofitamab's regulatory outlook, like the phase III SKYGLO study of Columvi with polatuzumab vedotin (Polivy) in first-line large B-cell lymphoma.

"For some programs, including Columvi, we have initiated US-dedicated clinical trials to help ensure we are generating evidence that reflects the needs and characteristics of US patients living with the disease," Genentech said in an emailed statement to SOHO Insider.

Genentech is also testing mosunetuzumab (Lunsumio) in combination with Polivy in the phase III SUNMO study of R/R DLBCL.

"There remains a significant unmet need for people with R/R DLBCL, and Genentech is committed to advancing multiple potential treatment options through an innovative, broad development program," the company added.

Loretta Nastoupil MD

For patients with large B-cell lymphoma, glofitamab can be a very effective, well-tolerated treatment, said **Loretta Nastoupil, MD**, a hematologist and oncologist at Southwest Oncology in Durango, Colorado.

"I would be grossly disappointed to not have access to it for patients," Dr. Nastoupil commented in an interview.

Considering the impressive early-stage results in a hard-to-treat population and the fact that physicians in the community were pretty excited, Dr. Nastoupil said that she would have expected that the study would be easy to enroll in the US.

"I do think something positive can be gained from this—we need to revisit why we're doing a poor job of recruiting American patients on studies," Dr. Nastoupil said.

How high is the US bar?

In recent years, concerns about the lack of US representation in pivotal clinical trials has been a major issue in reviews of several cancer drugs, including Eli Lilly/Innovent Biologics' sintilimab for non-small cell lung cancer and GlaxoSmithKline's multiple myeloma drug belantomab mafodotin (see **TABLE**).

The FDA has indicated in public meetings it would like to see those multiregional clinical trials—defined as studies conducted in more than one region under a single protocol— include at least 20% US participants.

FDA guidance documents related to inclusiveness in clinical trials include the "E17 General Principles for Planning and Design of Multiregional Clinical Trials," for MRCTs used in global regulatory approval submissions. Designed in line with the International Council of Harmonization (ICH), the guidance advises "ensuring sufficient sample size to be able to evaluate the overall treatment effect, assuming that the treatment effect applies to the entire target population, particularly to the regions included in the trial."

The US FDA published a complementary guidance specifically on planning, design and analysis of oncology MRCTs in September 2024, noting that the proportion of US participation in MRCTs has been decreasing, which can make it harder to study the treatment effects in US compared to other participants. It advises trial sponsors to enroll an adequately representative subgroup of US participants in an MRCT and that sponsors should achieve enrollment of a population that adequately represents the US population affected with the cancer indication being studied.

The FDA also published guidance on diversity action plans for phase III trials of drugs and devices to improve enrollment of historically underrepresented populations (race, ethnicity sex, and age) in 2024, meeting the obligations of the Food and Drug Omnibus Reform Act of 2022 (FDORA).

According to an IQVIA analysis of oncology approvals between 2013 and 2017, US enrollment was lower than 20% in one-third of oncology pivotal trials and the average was actually only 8%.

In a blog published in CenterWatch in mid-2025, a WCG Clinical Services executive wrote that her company's benchmarking data for the past three years showed that of 85 oncology MRCTs in the last three years with 10 or more countries involved, only 8% of participants came from the United States.

US leads global R&D, but China's on the rise

Meanwhile, FDA commissioner Martin Makary has been warning that China is gaining ground over the US in early drug development.

While China is growing fast and significantly expanding in drug development, the US still leads global R&D, according to a review article in Nature Signal Transduction and Targeted Therapy. However, the article also noted that there are "constraints in the R&D ecosystem, including the high costs of drug development and the lengthy timelines required for clinical trials."

Ray U. Osarogiagbon MBBS

There's a conundrum in addressing representation, commented **Ray U. Osarogiagbon, MBBS**, lead author of an American Society of Clinical Oncology

••• See **Clinical Trials** continued on page 8

TABLE. **FDA scrutiny of clinical trials with limited US representation (chronological)**

Year	Drug Sponsor	Indication	Core issue	Regulatory outcome
2022	Sintilimab (Eli Lilly/Innovent Biologics)	Non-small cell lung cancer (NSCLC)	Pivotal ORIENT-11 trial conducted entirely in China; concerns about lack of diversity and differences from US standard of care.	ODAC vote 14–1 against approval; application withdrawn and FDA advised new globally representative trial.
2022	Surufatinib (Hutchmed)	Neuroendocrine tumors (NETs)	Two phase 3 trials conducted primarily in China; small US bridging study deemed insufficient.	Complete response letter (CRL); FDA requested broader multi-regional clinical trial data.
2022	Toripalimab (Coherus BioSciences/ Junshi Biosciences)	Nasopharyngeal carcinoma	Submission relied heavily on China-based trials with limited US representation.	CRL issued citing inspection and data concerns; later approved after resubmission.
2023–2024	Sugemalimab (CStone Pharmaceuticals/ EQRx)	NSCLC	Pivotal clinical data largely generated in China, raising questions about applicability to US treatment patterns.	US regulatory strategy delayed/paused amid FDA scrutiny of China-dominant datasets.
2024–2025	Glofitamab (Roche/Genentech)	Relapsed/Refractory DLBCL (2L)	STARGLO trial survival benefit largely driven by Asian subgroup; small U.S. subgroup showed no clear benefit.	Negative ODAC vote (8–1) followed by CRL.
2025	Belantamab mafodotin (GlaxoSmithKline)	Multiple myeloma	Low US trial enrollment.	Heavily scrutinized during advisory review but then approved.
2025–2026 (ongoing)	Serplulimab (Henlius Biotech)	Extensive-stage small cell lung cancer	Trial population largely from China, prompting questions about global generalizability.	Under FDA scrutiny regarding multi-regional clinical trial expectations.

Clinical Trials continued from page 7

(ASCO) 2025 special report about access to clinical trials in the United States.

"You don't want to extrapolate and assume that because something worked in a certain homogeneous population elsewhere, that those results will be directly translated into our population," said Osarogiagbon, who is director of the multidisciplinary thoracic oncology program and the Thoracic Oncology Research (ThOR) Group at the Baptist Cancer Center, in Memphis, Tennessee.

So caution is important, but on the other hand, there are practical access and drug development issues. Cancer treatment is increasingly personalized with biomarker-directed treatment, so the pool of patients for these highly selective agents is getting smaller. Industry wants to get answers about whether a compound will work quickly but they need to work within the US clinical trials infrastructure that is slow and bureaucratic, Osarogiagbon said in an interview.

"Our clinical trials enterprise is relatively inefficient, and especially in recent times with all the constraints of funding, it has become even more so," Osarogiagbon said.

Robert Califf, MD

Robert Califf, MD, FDA Commissioner from 2015-2017 and 2022-2025, has been addressing the inefficiencies of the US clinical research infrastructure in multiple posts on his Substack account. In one, he noted that the US comprises only 4% of the world's population, but the majority of profit in the medical products industry is made in the United States.

"While I believe there are reasonable questions about the preferred distribution of clinical trial enrollment across continents and countries for the global medical products industry, the distinct impression I get is that the difficulty and cost of conducting biomedical research in the U.S. is pushing the industry away," Dr. Califf wrote.

Improving access to patients in communities

Currently, few adults with cancer take part in US trials and they tend to be "younger, healthier and less racially/ethnically and geographically diverse than people seen in clinics," according to a joint statement from ASCO and the Association of Community Cancer Centers (ACCC).

In an interview, Dr. Califf said that there tends to be a view that patients in the United States don't want to participate in clinical trials, but surveys suggest they would if they were asked to.

Dr. Califf sees the problem with US enrollment as more of a systems issue—most oncologists work for either a university system or a big practice and are under tremendous financial pressure to provide paid services and to not get distracted by research.

"They're not masters of their own fate like they used to be," Dr. Califf said. "And so they're operating in systems that disincentivize research for the most part, and they need to reorganize and stress professionalism more, which would include research as part of clinical care."

Experts interviewed for this article also cited challenges for patients getting to academic trial sites where the trials are conducted versus the need for more outreach to patients where the patients are located— in the community.

Hans Lee, MD

"Many patients don't necessarily live in large urban centers, near large major medical centers to enroll in clinical trials. So how can we improve access to clinical trials where the patients are at in the community setting?" commented **Hans Lee, MD**, director of myeloma research at the Sarah Cannon Research Institute (SCRI).

This is the mission of SCRI, to really provide access to cutting-edge trials to patients where they are and thinking about operational barriers to enrollment and breaking them down, Dr. Lee said. Early in clinical development, sponsors need to be thinking about whether a trial could be accrued not only at major academic centers but also in the community where most people are being treated.

Dr. Lee will be addressing enrollment in clinical trials in a free webinar on September 2, as part of a community oncology brown bag educational series sponsored by SOHO Insider and managed by Southwest Oncology's Dr. Nastoupil.

Information needs to get to the treating physicians in time for them to make fair and balanced recommendations about cutting-edge treatments, Dr. Nastoupil commented.

Could AI boost access—and efficiency?

In general, research options are not as visible in the community setting and clinical trials become a last resort for very hard to treat patients, said **Arturo Loaiza-Bonilla, MD**, network chief of hematology and oncology at St. Luke's University Health Network in Pennsylvania.

Arturo Loaiza-Bonilla, MD

In 2015, Dr. Bonilla cofounded a company Massive Bio, which developed algorithms that match patients to oncology and hematology clinical trials worldwide. Among the disease types covered are lymphoma, multiple myeloma, and chronic myeloid leukemia. The goal is to get patients on trials faster and to accelerate drug development overall.

The introduction of generative AI in 2023 supercharged the company's capabilities.

Physicians or patients can access the service for free, searching over 19,000 oncology clinical trials. Just like food orders can be tracked in an app, patients can be followed in their cancer journey and notified when a trial opens that fits their criteria. Patients need to be matched fast enough for them to get in while they are still eligible and to be offered options in real time, Dr. Loaiza-Bonilla explained in an interview.

Among other partnerships, Massive Bio is working with the American Cancer Society on its trial matching program ACS Acts.

"Millions of patients get diagnosed every year with cancer and we don't have that many slots available in clinical trials, but many of [those slots] go unfilled," Dr. Loaiza-Bonillla said.

"We're able to solve protein folding. Why can't we solve clinical trial enrollment?" Dr. Loaiza-Bonilla asked.

Massive Bio is aiming to solve the enrollment problem with a patient-centric solution, leveraging AI, he explained. The company offers two platforms, one for clinicians (DrArturo AI) and another for patients (AskFiona AI), both designed to analyze patient data and match it to clinical trial eligibility.

Ideally, decentralized trial designs will make it possible for trial participants to get lab work and imaging studies close to home. Dr. Loaiza-Bonilla sees positive signs in efforts by the current US administration to support improving healthcare delivery in rural areas. In late 2025, the US Centers for Medicare and Medicaid Services announced plans to award $50 billion to improve rural healthcare delivery in 50 states. This along with other initiatives is a big opportunity to bring trials closer to communities and minimize the financial toxicity of healthcare, he said.

AI promises to help improve inclusiveness of trials, while cutting time and money from drug development, though challenges remain, such as ensuring data privacy, eliminating algorithmic bias risk, evaluating the true fitness of patients, and incorporating a wide range of biomarkers.

"This is a transformational moment when we can use technology to bring trials to community centers in a much more proactive and deeply enabled way," Dr. Loaiza-Bonilla said. "So that's my dream, but it's not futuristic, it's real [now]. We just need to make it happen at scale."

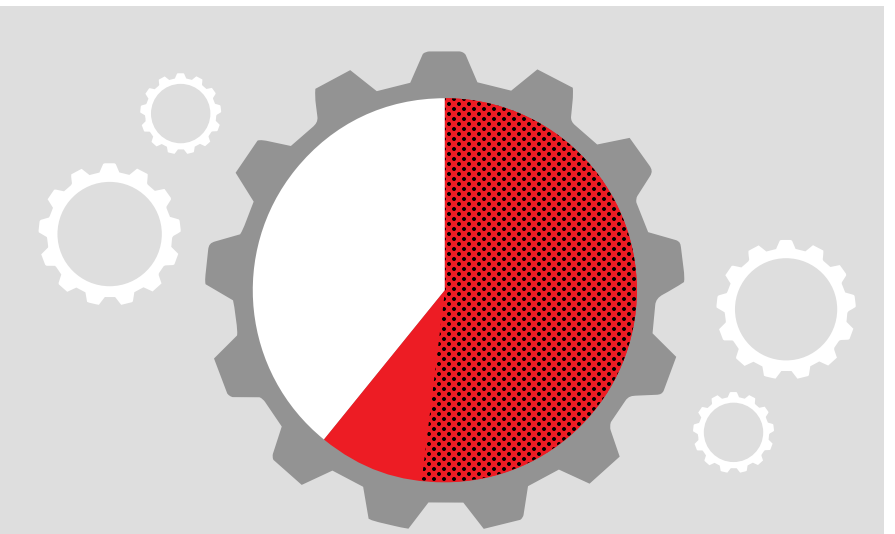
Momentum continued from page 5

of care and increased physician confidence in applying evidence, noticeably influenced clinical practice and introduced the cohort to emerging directions in R/R CLL/SLL, fostering substantial, reflective dialogue with faculty.

Meghan C. Thompson, MD

The second quarterly meeting with **Dr. Meghan Thompson** and the learners from the 25-cohort occurred in March 2026. Ahead of the meeting, we collated challenging real-world cases from learners to guide the discussion, which also followed paths emerging from questions that arose during the session. Major discussions included:

- One international learner presented a highly complex case that illustrated the gap faced by patients around the globe in accessing novel therapeutic agents, wherein a patient with high-risk disease (TP53 mutation, unmutated IGHV) received suboptimal chemoimmunotherapy not by clinical choice, but by resource constraint. The patient is a 36-year-old woman with SLL, concurrent autoimmune hemolytic anemia, myelofibrosis, and disease progression in a setting with no access to BTKi, venetoclax, positron emission tomography scanning, or combination fludarabine, cyclophosphamide, and rituximab.
- Another learner described a patient, a man who lives in a remote location and has CLL with triple-positive antiphospholipid antibody syndrome, prior endocarditis with valve replacement, impaired ejection fraction, and a history of ventricular tachycardia. Discussion around this case, representative of patients with compounding BTKi contraindications, emphasizes the importance of peer-to-peer exchanges—a key component of the current educational design—in complementing guideline-informed care.
- In an exemplification of program-driven practice change, a cohort-member described how they applied the BTKi/venetoclax overlap strategy learned at the SOHO intensive to their patient, keeping the covalent BTKi during the venetoclax ramp-up. The physician explicitly attributed this strategy to content delivered at the SOHO intensive. The patient who received the BTKi/venetoclax overlap strategy responded well, and our learner is now considering employing this when faced with a fit patient who had controlled disease, as novel agents like pirtobrutinib may draw responses that are often not durable when Richter's transformation has developed.
- A participant discussed the case of their 40-year-old patient who had CLL and developed Richter's transformation with splenomegaly and severe cytopenias after multiple prior therapies, including venetoclax/obinutuzumab and covalent BTKi. Treatment with pirtobrutinib produced a nodal response and was being used as a bridge to allogeneic stem cell transplant (allo-SCT). During the exchange with Dr. Thompson, this learner was reassured that selecting allo-SCT was a reasonable, potentially curative strategy



The peer-to-peer exchanges that occurred in this meeting produced significant practice impacts that extend beyond what can be achieved by purely data-driven or didactic presentations.

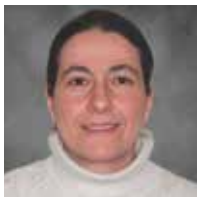
As the examples above illustrate, the case-based discussion between the physician cohort and expert faculty was highly beneficial for learners. The group explored complex patient cases, including those in which management of R/R CLL/SLL was compounded by comorbidities, complications, the onset of concurrent myeloid neoplasms, and lingering toxicities. The peer-to-peer exchanges that occurred in this meeting produced significant practice impacts that extend beyond what can be achieved by purely data-driven or didactic presentations. Learners from both the United States and international settings reported strikingly positive experiences.

The insights and data gleaned from this program demonstrate that the CLC method of incorporating multiple approaches, including structured interviews and regular quarterly meetings (the next meeting in June 2026, will be led by **Dr. Catherine Coombs**),

Catherine C. Coombs, MD

reinforced participants' learning and progressively deepened their knowledge and confidence. The interactions served as touchpoints for reflection, feedback, and peer-to-peer exchange, helping to solidify acquired knowledge and strengthen participants' ability and willingness to apply newly acquired knowledge, competencies and skills in clinical practice.

ABOUT THE AUTHOR



Karine Cohen-Solal, PhD, is an experienced scientific and medical writer with extensive expertise in oncology, dedicated to advancing cancer care through clear, evidence-based communication and continuing medical education. Drawing on over 20 years of experience in oncology research, she combines deep scientific insight with exceptional writing skills to translate complex discoveries into meaningful narratives that inform clinical practice changes and ultimately elevate patient outcomes.

SOHO Asia debuts in Taipei with 400 attendees from across Asia-Pacific region

SOHO Asia convened for the first time earlier this year, a step toward strengthening hematology education and collaboration across the Asia-Pacific region, meeting organizers said.

"The Asia-Pacific area has a growing economy and a large population, but there are many differences in socioeconomic status and healthcare systems," said **Bor-Sheng Ko, MD**, director of the Department of Hematological Oncology at the National Taiwan University Cancer Center in Taipei. "Some countries have full national health insurance coverage, such as Taiwan, Japan, Korea, and Australia, while other countries face limitations in access to high-cost medicines."

The meeting, which was organized by Dr. Ko in less than six months, drew nearly 400 attendees and featured some of the leading hematologists in the world, including those from the University of Texas MD Anderson, Dana-Farber Cancer Institute, National Taiwan University Hospital, and Singapore General Hospital.

The sessions were designed to address unique challenges in the region, including a large and diverse patient population and wide disparities in healthcare access.

IN ASSOCIATION WITH:

"Those differences create a need for region-specific education on how to use novel therapies in daily clinical practice," Dr. Ko said. "We need to understand how to utilize these novel medications in real-world care."

In addition, SOHO Asia allows for younger physicians in the region to attend a meeting with leading international clinicians as most major hematology meetings are often inaccessible due to cost and limited institutional support.

"For young staff, it is very hard to get support to attend meetings," Dr. Ko said. "We felt this meeting could be more educational and more practical for physicians in this region."

Looking ahead, Dr. Ko identified access to novel therapies and region-specific biology as areas of focus. Despite therapies having promising results, healthcare systems can delay the introduction of novel drugs into daily clinical practice.

"We need more collaboration between Asia-Pacific experts and Western experts to facilitate research and improve care for these diseases," Dr. Ko said.

Given the vast differences, regional collaboration is essential to improving patient care, according to **Hsin-An Hou, MD**, a SOHO Asia co-organizer and professor and attending physician in the Division of Hematology in the Department of Internal Medicine at National Taiwan University Hospital in Taipei.

"In many areas, there are still limitations in testing, diagnosis, and treatment, so it is important that we work together to improve patient care," Dr. Hou said.

Taiwan has strong capabilities in the treatment of hematologic malignancies, but limitations remain and broader collaboration is needed, according to Dr. Hou.

"There are still limitations in Taiwan," he said, adding that the group hopes to collaborate with SOHO and partners across the Asia-Pacific region to improve patient care.

During the meeting's closing remarks, SOHO President **John DiPersio, MD, PhD**, said the meeting successfully brought together global scientific communities and created a foundation for future collaboration.

"This is a combination of Eastern societies that really meld together well," Dr. DiPersio said. "I think this is the ingredient for a successful future meeting, and I'm hoping that we continue this meeting in perpetuity."

1st SOHO UK meeting draws nearly 300 attendees for 2-day meeting

soho UK
society of hematologic oncology

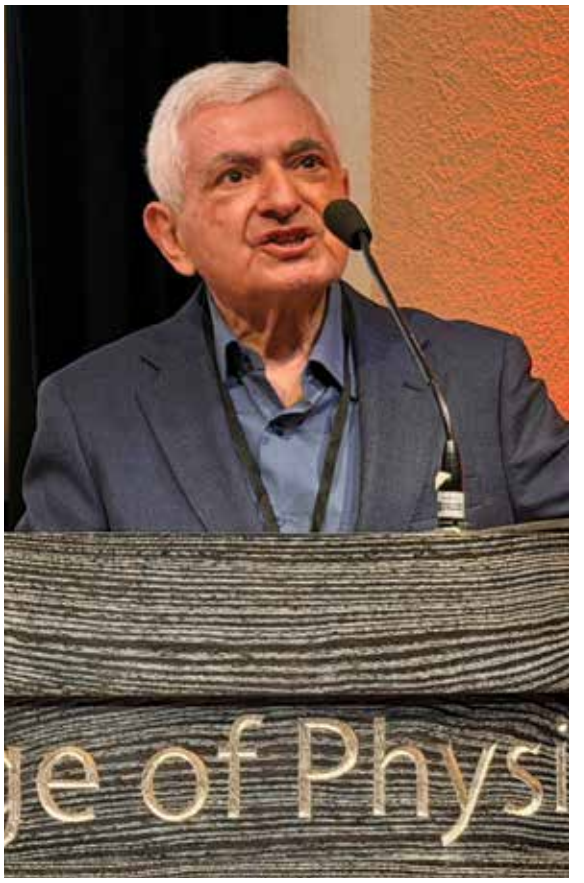
The first SOHO UK was held March 3–4 at the Royal College of Physicians in London and drew close to 300 participants, including both trainees and leading hematologists. The meeting was co-chaired by Prof. **Charles Craddock, CBE**, and **Prof. Anthony Goldstone, CBE**, with individual specialties chaired by leading UK clinicians, including **Prof. Claire Harrison** (MPN), **Dr. Priyanka Mehta** (AML) and **Dr. Rakesh Popat** (myeloma).

Both Prof. Goldstone and Prof. Craddock said SOHO UK was comparable in format and scientific scope to the SOHO Annual Meeting in Houston, while reflecting the unique aspects of the UK medical system and incorporating elements that highlight UK training structures and service pressures.

"We want SOHO UK to stand alongside the Houston meeting, but also to offer something different that speaks to the next generation," Prof. Goldstone said.

Prof. Craddock described the meeting as a response to the pace of change in the field and the widening gap between discovery and delivery.

He pointed to the SOHO conference model as one that has gained broad support by focusing on education across the field's specialties.



News from the 2026 American Association for Cancer Research (AACR) annual meeting

Anthony Letai, MD, PhD

NCI director says institute is 'stable' after turbulent year

By Leah Sherwood

During a session at AACR 2026, National Cancer Institute (NCI) Director **Anthony Letai, MD, PhD**, said that despite a turbulent past year, the institute is stable and its mission unchanged.

"This past year... [has] been very turbulent," Dr. Letai said. "But let me reiterate to you: The NCI is stable. Our mission remains unchanged and funding is strong."

The sources of that turbulence were not directly addressed, even as recent reporting has pointed to funding instability, workforce disruption, and early signs of a potential brain drain in US science. Reported funding cuts to National Institutes of Health (NIH) grants linked to the Department of Government Efficiency (DOGE), a cost-cutting unit associated with Elon Musk, have been tied to disruptions across the research ecosystem, including reported clinical trial disruptions and workforce instability.

"I really do see stability going forward," Dr. Letai said. "I've had the opportunity to talk fairly regularly with the president and the secretary and to legislators on both sides of the aisle in both houses of Congress, and they just want us to cure cancer," he said. "People want to support cancer research because it's politically the right thing to do. It's so overwhelmingly popular. And I hear the same thing from the executive branch."

For fiscal year 2026, the NCI saw a $128 million increase after Congress rejected deeper proposed cuts. The NCI is funded at approximately $7.3 billion in 2026.

Given that, Dr. Letai cautioned against "doom and gloom" and urged researchers to rely on "sources that reflect the truth."

"I want to remind you, the only budget that really counts is the budget that is approved by Congress and signed by the president," he said.

However, he did note Congress has not shown strong enthusiasm for expanding multiyear funding, a development that has raised concerns in terms of its impact on the number of research awards allocated to investigators.

"I do not see enthusiasm in Congress for continuing increasing multiyear funding," he said, adding that underlying funding constraints mean that "that baseline might not be what you wish it was" and "we can't fund all the grants."

One area of focus for the NCI will be to ensure continued US competitiveness in biomedical research, said Dr. Letai.

He described global competition as a "wake-up call," noting that "the United States is no longer the world's only engine of biomedical innovation." He pointed to faster trial activation overseas and acknowledged that "it takes too long in this country to move from a promising idea to testing in patients," adding that some processes "could be done in parallel... and maybe move much faster."

He pointed to Australia as a good model for the United States to follow for clinical trial administration and noted that the FDA is starting to roll out initiatives to help with efficiency.

"While we can't duplicate the Australian approach ... [we can] imitate some of things they have done to have made them faster," he said.

Another area of focus is the NCI's functional precision medicine initiative. The approach is part of a larger NIH initiative to move away from animal models in cases where human tissue testing is considered an optimal alternative.

"If you want to know whether a drug will work on a patient's tumor, take that living tumor tissue, expose it to the drug, and observe what happens," rather than "inferring whether a treatment will work based on... model systems," he said.

He also said that in July 2025 the NCI will be announcing a workshop to support these efforts.

"All of us here share a common goal: to reduce suffering from cancer," he said. "We have made enormous progress to the goal in the last 35 years."

Clinical care still needs human intelligence in the AI era

By Leah Sherwood

Human intelligence will be more important than ever as artificial intelligence continues to proliferate throughout clinical care, according **Yu Shyr, PhD, FAACR**, chair of the Department of Biostatistics at Vanderbilt University Medical Center in Tennessee. Dr. Shyr was the keynote speaker at the AACR Oncology Industry Partnering Event, which was held April 16–17 in San Diego.

The growing use of AI in clinical care comes as more than 1,000 FDA-authorized tools have entered use, largely without evidence from randomized trials, Dr. Shyr explained to an audience of industry experts, investors, and healthcare professionals.

He stressed that AI should change how clinical trials are designed and interpreted, but must ultimately demonstrate real clinical value. Dr. Shyr pointed to a gap between the strength of evidence generated in controlled settings and how treatments perform in practice, where patient populations and care delivery are far less uniform.

"We ask the question, does it work in real-world practice," Dr. Shyr said, pointing to pragmatic clinical trial designs that are embedded in routine care and reflect how patients are actually treated.

That distinction between controlled and real-world settings also shapes how trial results are interpreted, Dr. Shyr noted, since even so-called negative trial results may still contain meaningful signals at the individual level.

In one example he provided, an ICU oxygen study published in the New England Journal of Medicine showed no overall difference between treatment strategies, but patients appeared to respond differently. A subsequent machine learning analysis identified distinct groups who benefited from different approaches.

"ML-derived individualized treatment effects from RCTs can change practice," Dr. Shyr said, noting that one such model has been incorporated into the EHR system Epic to support ICU decision-making.

He also said the focus of those learning new AI

tools should shift from coding to understanding. "We need to spend more time [focused] on knowledge and learning," Shyr said, noting that students "need to understand [what] is the right method… and when [AI] is incorrect."

Former FDA-OCE Director Richard Pazdur: 'there is a palpable sense of anxiety at FDA'

By Leah Sherwood

Gloomy was the mood as the former director of the FDA's Oncology Center of Excellence (OCE), **Richard Pazdur MD**, fielded questions about the state of the FDA during an AACR-Oncology Partnering event in San Diego. Padzur offered a candid look at an agency he helped shape for more than two decades.

Richard Pazdur, MD

He described a workforce under strain, pointing to what he called a "palpable sense of anxiety" following staffing cuts, leadership uncertainty, and shifting priorities. "It has not been a pleasant situation working in the agency over the past year," he said at one point.

Pazdur, who was at the agency for 26 years, resigned in December 2025 just weeks after being appointed to the lead the FDA's Center for Drug Evaluation and Research (CDER) division.

Pazdur expressed concern about the "disheartening" decline in the number of Oncology Drugs Advisory Committee meetings, noting that it obscures the thinking behind the FDA's approval decisions, which he said is "probably more important than the actual discussion of a specific drug."

"I've been disheartened about, over the past year or so, a decrease in the number of advisory committees, and there have been public statements by this administration that they don't believe in advisory committees," he said. "I totally disagree with that. It's not only the importance of the drug under consideration, but also the thinking of what the FDA is formulating decisions on."

He outlined several ways the process could improve. Advisory meetings should be more issue focused rather than repeating large volumes of data. He also called for broader and more transparent selection of committee members, with positions advertised and applicants reviewed by a diverse group that includes regulators, industry, and patient representatives to guard against any bias. That, he said, would strengthen rigor and trust.

Acknowledging the current reality of political bias sneaking into the advisory process, he said ODAC needs qualified people on the committees.

"My biggest fear is we do not want committees chosen where behind the scenes people are selected based on already known ideologies," he said.

In the past, he said, there was a clear firewall between political appointees and career staff, which protected scientific decision making. Now, he suggested, that boundary has eroded. He pointed to the so-called "fork in the road" letter sent to federal employees early in the administration, which encouraged staff to consider leaving service and signaled that conditions could worsen if they stayed. That message, followed by staffing cuts and unclear leadership structure, contributed to what he described as "low morale" and a "palpable sense of anxiety" across the agency.

"How would any of you feel if you got that letter?" Padzur asked. "It certainly does not endear any confidence … regarding your job."

He lamented that many of the senior and midcareer staff who left the agency, who had career options outside the agency because of their credentials, had expertise the FDA relied on.

He also cautioned against looking at hiring numbers, drawing attention to a deeper loss within the agency. "I'd like to remind people that it's not about the numbers of people that are hired," he said. "It's really about the quality of people that have left."

That loss comes at a time of major transition as AI is incorporated into more and more regulatory processes.

"AI is going to have a profound effect on the agency and how we review things," he said, explaining that routine data analysis that once took reviewers hours or weeks can now be done in seconds.

As a result, the FDA will need a different kind of workforce. "They're not just going to be number crunchers," he said.

Instead, Pazdur said, the agency will depend more on experienced clinicians and scientists with deep knowledge of disease and the flexibility to adapt as drug development evolves. "We're going to need a workforce that is much different," he said, adding that reviewing the growing number of therapies will be "a heavy lift" that requires both expertise and regulatory flexibility.

On drug development, Pazdur warned against chasing early response rates at the expense of long term outcomes. High doses that produce strong early signals may not be sustainable, limiting real benefit on endpoints like overall survival.

John F. DiPersio, MD, PhD

SOHO President Dr. John F. DiPersio honored with top AACR award

By Leah Sherwood

SOHO President **John F. DiPersio, MD, PhD**, received the 2026 AACR Award for Outstanding Achievement in Blood Cancer Research at its annual meeting this year in San Diego on April 21. The award recognizes an individual's achievements and contributions in any aspect of blood cancer research.

"This award truly belongs to my students, trainees, colleagues, and mentors," Dr. DiPersio said in an email to SOHO Insider. "I have been so lucky to be surrounded by such great people."

Dr. DiPersio is a co-chair of the 14th SOHO Annual Meeting in Houston, Texas, which will be held September 9–12. Attendees can register at **soho.click/register**.

SCAN TO REGISTER

In the award announcement, the AACR listed Dr. DiPersio's contributions to the field, including the development of the hematopoietic stem cell-mobilizing agents plerixafor and motixafortide. He also identified AKT1/2 signaling in graft-versus-host disease, which led to the identification and approval of JAK inhibitors, including ruxolitinib (Jakafi).

"His discoveries defining clonal evolution in acute myeloid leukemia have transformed the understanding of cancer relapse and have advanced novel CAR T and CAR-iNKT (invariant natural killer T) therapies for acute lymphoblastic leukemia and multiple myeloma, expanding available treatment options and improving patient outcomes," the AACR press release said.

Meet Naval Daver, MD, a professor and director of the Leukemia Molecular Laboratory in the Department of Leukemia at the University of Texas MD Anderson Cancer Center

Naval Daver, MD, PhD

> Even if we cannot guarantee a cure, patients appreciate that we are trying our best and see MD Anderson and our team as a place of hope. That's the number one thing we can offer.

When did you become interested in pursuing medicine as a career path?

Both my parents are well-known physicians in India. My dad is a cardiothoracic surgeon, and my mom is an OB-GYN. They were both deans of large medical schools, so I was always exposed to medicine, and from a young age it created an interest for me.

My dad trained in the United States with Michael DeBakey in 1986 for three years, so we all lived in the United States at that time. He had very fond memories and still had friends in Houston when I was applying for residency. He was very eager for me to get exposure to the US medical system, which is very advanced in terms of technology, clinical trials, and access to medications. That led me to Baylor College of Medicine for my internal medicine residency. I stayed on at Baylor for my hematology-oncology fellowship and eventually joined MD Anderson as an assistant professor in 2011.

Why did you choose AML as a specialty?

When I was a fellow at Baylor, I was interested in both hematologic malignancies and infectious disease. Those were the two broad areas, more from a clinical and treating physician perspective. During my fellowship, I rounded at MD Anderson and learned more about clinical research and the global impact that clinical trials and drug approvals can have beyond what you can do seeing 20–35 patients a day.

You can impact hundreds or thousands of patients on a weekly basis, many of whom you will not see but who will still have access to and benefit from these treatments.

Around 2011, when I was doing my fellowship and rounding at MD Anderson, we started to see the emergence of new targeted therapies and the potential for immunotherapies. I felt this would be an area where we could make a lot of progress over the next two to three decades. There was a lot to be done. AML was a disease with a huge unmet need for almost 40 years, which is why I became more interested in AML and in clinical trials.

Is AML moving toward mostly targeted therapies, or is there still a meaningful role for traditional treatment?

In AML, we're probably 10 to 15 years behind ALL and maybe myeloma. I often use myeloma as an example because the trajectory of drug development we're seeing in AML is very similar. We now have targeted therapies that have clearly made inroads. FLT3 inhibitors, IDH1, IDH2, and now menin inhibitors can target about 50% to 55% of patients with one or more of these aberrations. Most of the survival improvements we've seen in the past 10 to 15 years have come from these targeted therapies, not as single agents, but when moved into the frontline setting in combination with traditional intensive chemotherapy or lower-intensity therapies.

What we are still missing in AML is a very effective immunotherapy. In ALL, bispecific antibodies, antibody-drug conjugates, and CAR T-cells have really accelerated progress and improved cure rates. There is a lot of effort underway in AML, and I think in the next four to five years we'll see the emergence of new antibody-drug conjugates and potentially cellular therapies, whether natural killer cells or CAR T-cells. That will lead to further progress.

Similar to myeloma, we are already using less frontline intensive chemotherapy and lower-intensity approaches, such as venetoclax with a hypomethylating agent, and then adding targeted therapies when available.

Over the next five to 10 years, I think intensive chemotherapy will be limited to a small subset of patients, maybe 25%, who are truly chemosensitive. For the rest, treatment will shift toward lower-intensity approaches, which would be a major change in how we treat AML.

What have you learned from your patients?

I love interacting with patients; it's what drew me to clinical practice rather than laboratory-based research. For us, the clinic is our laboratory. It's where we learn, then

apply that knowledge to our trials to improve outcomes for our patients.

I think the main thing we've learned is that we're making progress—there's no doubt. In newly diagnosed AML patients who are young and fit, cure rates are now close to 65%–70%, and even in older patients, we're getting better.

There's still a lot of unmet need, especially because the patients who come to MD Anderson tend to have difficult-to-treat disease such as TP53-mutated AML and complex cytogenetics. That keeps us working to develop new treatments, because many patients still need better options.

Even if we cannot guarantee a cure, patients appreciate that we are trying our best and see MD Anderson and our team as a place of hope. That's the number one thing we can offer.

Drs. Daver and Andrew Wei at SOHO Asia in Taipei

What is your advice for early-career investigators?

You have to have a mindset that failure is part of the pathway. It's not realistic to expect the first few things you do will all be successful.

One area I'm focusing on is TP53. It's a difficult condition, and improving outcomes will take effort and many failures, but it only takes one success to improve outcomes for thousands of patients. We've run many trials: CD47 antibodies, APR, and now immune approaches like NK cells, CAR T-cells, and TP53-targeting inhibitors.

Even when a trial doesn't meet a clear statistical endpoint, we learn about the immunobiology, the tumor microenvironment, and co-occurring features. When you design a trial, it's important to build in strong correlatives and molecular and immune analyses. That knowledge will eventually lead to better treatments.

How is MRD used to guide care in AML, and where is it headed?

MRD is probably going to become central in AML treatment as it already is in ALL and CML, for example.

In AML, there has been a lot of challenges in implementing MRD over the last 10 years, mainly because of the type of MRD used, called multiparametric flow cytometry, which has a sensitivity of about 0.01%. This method has to be done in real time, usually within 24 hours to be accurate, and it's very dependent on the expertise of the operator reading it. Also, in general, it cannot reliably go below one in 100,000, and sometimes the sample quality isn't high enough to support that level of sensitivity.

Now, we're moving toward DNA-based molecular MRD assays, similar to what our colleagues in ALL have been doing with ClonoSEQ. We now have NGS-based MRD assays for FLT3 and NPM1, and hopefully soon an RNA-based MRD assay for KMT2A. This will cover about 50% of AML patients, and I do think we're going to have very good NGS-based MRD assays. They can be done on stored DNA samples, are less dependent on operator expertise, and can usually be done centrally across clinical trials.

I think the FDA is open to these approaches, especially DNA-based MRD, for the future. In the coming years, we're going to see more AML trials, using this as the primary endpoint, which could save five to eight years of survival follow-up and help get these therapies approved and out to patients faster.

This is an extensive area of research that we're working on with many colleagues in the United States and internationally, and it will accelerate clinical trial development and approvals in AML.

What hobbies do you enjoy?

I love the outdoors, and when I travel with my family we'll go to places where we can either hike or ski. These are my favorite outdoor activities where I can shut my brain off for a few hours and focus more on physical activity and nature.

What is one thing people would be surprised to know about you?

I did martial arts for many years, and I'm a black belt in karate.

What is one thing that makes the clinical day better?

For me, the most important thing is having good colleagues and friends. We spend a lot of time in the hospital, and at MD Anderson I'm lucky to work closely with great colleagues. If you're only coming to work, spending 10 hours, and leaving, it's difficult. But having friends, joking, and talking about your weekend makes it a much more fun place to be.

This interview has been edited for length and clarity.

Dr. Naval Daver is a professor and director of the Leukemia Research Alliance Program in the Department of Leukemia at MD Anderson Cancer Center in Houston. He is a clinical investigator with a focus on molecular and immune therapies in AML and myeloid disease and is principal investigator on more than 25 ongoing institutional, national, and international clinical trials in these diseases, including multiple registration and label-enabling trials.

Tracking regulatory news worldwide

OPN-6602 in MM granted FDA Fast Track Designation

The US Food and Drug Administration (FDA) has granted Fast Track Designation to OPN-6602, an oral small-molecule EP300/CBP inhibitor, for patients with relapsed or refractory multiple myeloma (MM) who have received at least four prior lines of therapy.

OPN-6602 is an oral, small molecule inhibitor that targets EP300 and CBP proteins, which are involved in the proliferation and survival of MM cells, according to Opna Bio, the manufacturer of the drug. The drug is currently in a phase 1 clinical trial evaluating safety, tolerability, pharmacokinetics and preliminary clinical activity in patients with relapsed or refractory MM.

The therapy was previously granted Orphan Drug Designation in early 2025 by the FDA.

"Opna Bio has been a pioneer in the EP300/CBP inhibitor space and OPN-6602 was selected for its potency, selectivity, and optimized pharmacokinetic properties. We are encouraged by the progress of the study to date and look forward to reporting emerging clinical data at an upcoming scientific congress," said Reinaldo Diaz, Opna Bio CEO, in a press release from the company.

Assay targeting KMT2A rearrangements in AML now available

A new digital PCR–based assay for detecting and monitoring KMT2A rearrangements in AML is now available for research use in clinical trials and as a stand-alone kit for global customers. The assay, LeukoStrat® KMT2A + MRD Assay, will soon be offered as a service through regional LabPMM® laboratories.

The assay, according to its manufacturer Invivoscribe®, gives translational researchers and biopharmaceutical partners a critical tool to assess MRD and to evaluate therapeutic responses.

The company reported that the assay is sensitive and precise, resulting in rapid turnaround times. The LeukoStrat assay and software are integrated to provide both initial screening and long-term tracking in one place. This precision makes the assay a critical tool for researchers and biopharmaceutical partners, particularly those developing new treatments like menin-inhibitors, according to a press release by Invivoscribe. While the assay currently focuses on AML, Invivoscribe plans to expand its utility to include acute lymphocytic leukemia later this year by adding four additional KMT2A rearrangements frequently found in the disease, the company reported.

EC approves nivolumab and BV for relapsed or refractory cHL

The European Commission (EC) has approved nivolumab (Opdivo®) in combination with brentuximab vedotin for the treatment of adult and pediatric patients with relapsed or refractory classical Hodgkin lymphoma (cHL). This indication applies to children ages 5 years and older, adolescents, and adults up to 30 years of age who have received one prior line of therapy.

In its press release, BMS reported that the decision was based on results from the phase 2 CheckMate -744 study, which evaluated the risk-based, response-adapted regimen in younger patients. Data from the trial demonstrated that the combination achieved high complete metabolic response rates, allowing many patients to proceed to consolidation therapy while maintaining a manageable safety profile.

The FDA also approved nivolumab in combination with doxorubicin, vinblastine, and dacarbazine (AVD) for adult and pediatric patients who are 12 years and older and have previously untreated stage III or IV cHL, at the same time of the EU approval.

FDA issues draft guidance on MRD, CR endpoints in MM clinical trials

The FDA released a draft guidance in January 2026 intended to give recommendations to investigators leading MM trials on using MRD and CR as primary endpoints in clinical trials. The agency said the guidance is intended to help drug sponsors in securing accelerated approval for new myeloma therapies.

According to the document, investigators should measure MRD negativity in the bone marrow of patients who have already achieved a CR. The FDA recommends using either flow cytometry or sequencing-based methods for these assessments to ensure the data is robust enough to support an early approval for new treatments.

In 2025, an article published in The Lancet Haematology, unrelated to the current regulatory guidance, called for further research into the use of MRD in hematologic malignancies to guide treatment decisions, and warned that hematologists should remain wary of the often-unquestioned assumptions that accompany MRD.

Brazil regulatory agency approves tafasitamab combo in R/R follicular lymphoma

The Brazilian Health Regulatory Agency (ANVISA) approved tafasitamab (MINJUVI) in combination with rituximab and lenalidomide. This chemotherapy-free triplet regimen is indicated for adult patients with relapsed or refractory follicular lymphoma (FL) grade 1 to 3a after at least one prior systemic therapy.

The review was conducted under Project Orbis, an international partnership allowing for concurrent submission and review of oncology products. Knight Therapeutics distributes the therapy in Latin America under an exclusive 2021 agreement with Incyte, the manufacturer of the therapy.

Beyond this new indication, the drug is already approved in Brazil and the European Union for relapsed or refractory diffuse large B-cell lymphoma, according to a press release by Knight Therapeutics.

This decision follows similar approvals by the FDA and the European Commission.

FDA accepts NDA for iberdomide in relapsed/refractory myeloma

The FDA has accepted a new drug application (NDA) for iberdomide in combination with daratumumab (Darzalex) and dexamethasone for adult patients with relapsed or refractory MM.

Iberdomide is the first in a new class of medicines called CELLMoD agents, which use targeted protein degradation to reach proteins previously considered undruggable. The FDA granted Breakthrough Therapy Designation and Priority Review for the application, which has a target action date of August 17, 2026.

The filing was based on MRD negativity rates from the phase 3 EXCALIBER-RRMM study, where patients continue to be evaluated for progression-free survival. The review is being conducted under Project Orbis for concurrent international assessment, according to the press release by BMS, the manufacturer of the therapy.

FDA approves teclistamab combo in relapsed myeloma

The FDA approved teclistamab-cqyv (TECVAYLI®) plus daratumumab and hyaluronidase-fihj (DARZALEX FASPRO®) for

the treatment of adults with relapsed or refractory MM who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.

The approval is based on data from the phase 3 MajesTEC-3 study, which demonstrated that the combination had significant improvements in progression-free survival and overall survival compared with the standard of care. The study found the treatment reduced the risk of disease progression or death by 83.3% relative to the control arm, according to the manufacturer's press announcement.

This approval is the third approval granted through the Commissioner's National Priority Voucher pilot program. The FDA issued the decision within two months of filing to prioritize innovative therapies that address large unmet medical needs and increase affordability.

FDA grants priority review to rusfertide in polycythemia vera

The FDA accepted an NDA for rusfertide for the treatment of adults with polycythemia vera. In addition to priority review, the FDA granted Breakthrough Therapy Designation, Orphan Drug Designation, and Fast Track Designation for the medication.

Results from the phase 3 VERIFY study supported the filing, showing that the drug improved hematocrit levels and lowered the frequency of required blood removals. The filing also included four-year safety and efficacy data from the phase 2 REVIVE and THRIVE studies, which evaluated long-term durability of response and maintenance of hematocrit control in patients who received the once-weekly subcutaneous injection for more than 12 months according to the press release by Takeda and Protagonist Therapeutics, Inc, the manufacturers.

A decision date was set for the third quarter of 2026 under the Prescription Drug User Fee Act.

FDA clears IND application for TBS-2025 in AML

The FDA has cleared the investigational new drug application for TBS-2025, a novel VISTA-inhibiting antibody, for the treatment of relapsed or refractory acute myeloid leukemia (AML). The therapy will be studied in combination with a menin inhibitor for patients harboring the NPM1 mutation.

The manufacturer of the therapy, TuHURA Biosciences, is planning on initiating a phase 2 study and reported in a press release that it plans to use a Simon 2-stage design and focus on patients who have not previously received a menin inhibitor. Pending final review, the trial is targeted to begin in early Q2 2026, with preliminary results expected in the third quarter of 2026. If the combination proves successful, the company intends to seek guidance on an accelerated approval pathway, according to a press release by TuHURA Biosciences.

"Given the strong scientific rationale, we believe adding TBS-2025 to a menin inhibitor may markedly increase both the remission rate and its duration," said Dr. James Bianco, president and CEO of TuHURA Biosciences.

FDA removes axi-cel limitations of use for primary CNS lymphoma

The FDA approved an update to the prescribing information for axicabtagene ciloleucel (axi-cel; Yescarta), removing the previous Limitations of Use for patients with relapsed or refractory PCNSL.

The decision is based on positive safety data from a phase 1 investigator-sponsored study at Dana-Farber Cancer Institute. This decision makes axi-cel the only CD19-directed genetically modified autologous T-cell immunotherapy approved for relapsed or refractory large B-cell lymphoma to have this specific restriction removed, according to a press release by Kite, a Gilead Company.

"We are pleased that our study, which highlighted the safety of axi-cel in central nervous system lymphoma, supported the FDA's decision," said Lakshmi Nayak, MD, director of the Center for CNS Lymphoma at Dana-Farber Cancer Institute and associate professor of neurology at Harvard Medical School.

FDA accepts NDA for tirabrutinib in relapsed or refractory PCNSL

The FDA accepted an NDA for tirabrutinib (Velexbru) for the treatment of patients with relapsed or refractory PCNSL. The FDA set a target action date of December 18, 2026, under the Prescription Drug User Fee Act, and the agency is reviewing the application under the accelerated approval pathway.

The filing was supported by results from the phase 2 PROSPECT study, which demonstrated an overall response rate (CR) of 67% and a complete response rate of 44%. A global phase 3 trial is currently recruiting patients to serve as a confirmatory study for the indication, according to the press release by the manufacturer of the therapy. If approved, the therapy will be the first Bruton's tyrosine kinase inhibitor available in the United States for this population, following previous approvals for the same indication in Japan, South Korea, and Taiwan, according to the therapy's manufacturer.

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