CLINICAL RESEARCH NEWS
Clinical Trials to the Clinic
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Singapore's Largest Respiratory Medicine Research Collaboration, New Brain Health Intervention Research Initiative, More

September 29, 2022 | A first-of-its-kind benchtop platform that enables researchers to assess multiple critical quality attributes of cell samples in a single automated workflow; a prospective pan-tumor therapeutic trial designed to evaluate the efficacy and safety of numerous FDA-approved cancer therapies in new, biomarker-guided patient populations; and more.

Unlearn announced that the **European Medicines Agency** (EMA) released its final favorable qualification opinion providing a regulatory framework for applying the company's TwinRCT solution in Phase 2 and 3 clinical trials. The three-step PROCOVA procedure (patent-pending) describes using patient-specific prognostic scores derived from digital twins to reduce clinical trial sizes by up to 35% while controlling Type-1 error rates. This qualification opinion represents the first time a regulatory body has formally supported a machine learning-based method for reducing sample size in pivotal trials. The EMA's validation of Unlearn's cutting-edge technology signifies broader regulatory acceptance of AI in clinical development. Press release (https://www.businesswire.com/news/home/20220928005391/en/European-Medicines-Agency-Qualifies-Unlearn%E2%80%99s-AI-powered-Method-for-Running-Smaller-Faster-Clinical-Trials).

The National Cancer Institute Community Oncology Research Program (NCORP) designated-**Louisiana State University** (LSU) **Health New Orleans** and **ConcertAI** announced a five-year partnership to improve the diversity of clinical trials and ensure broader clinical trial access throughout the Gulf South region. The collaboration aligns with ConcertAI's Engaging Research to Achieve Cancer Care Equality program, which furthers equitable access, care, and outcomes for all patients using real-world data and advanced technologies. Together with LSU Health's clinical trial sites and real-world data from ConcertAI's nationwide cancer care settings and "system of evidence," the collaboration will assess the impact of the Gulf South Minority Underserved NCORP program on minority enrollment in clinical trials, retention, and health outcomes. Press release (https://www.prnewswire.com/news-releases/nci-ncorp-designated-lsu-health-new-orleans-and-concertai-advance-multi-year-collaboration-addressing-diversity-in-clinical-trials-301633659.html).

Becton, Dickinson and Company (**BD**) launched the BD Research Cloud, a cloud-based software solution designed to streamline the flow cytometry workflow to enable higher quality experiments with faster time to insight for scientists working in immunology, virology, oncology, and infectious disease monitoring. The BD Research Cloud bridges and integrates all of the flow cytometry workflow steps, enabling scientists to more efficiently design reagent panels, connect instruments with data analysis software, store experimental data and procedures, and manage collaboration with colleagues. Future releases will provide panel design education sessions, e-books, and dedicated applications support as a cloud-based open system. Press release (https://www.prnewswire.com/news-releases/bd-launches-state-of-the-art-cloud-software-solution-to-streamline-flow-cytometry-research-301633392.html).

PerkinElmer launched the Cellaca PLX Image Cytometry System. This first-of-its-kind benchtop platform enables researchers to assess multiple quality attributes of cell samples in a single automated workflow, including cell identity, quality, and quantity. The cutting-edge Cellaca PLX system combines best-in-class image cytometer hardware, software, validated consumables, and trackable data reporting. As a result, researchers can now detect multiple markers simultaneously (multiplexing) and perform immunophenotyping and viability assays in seconds. Press release (https://www.businesswire.com/news/home/20220926005402/en/PerkinElmer-Unveils-Industry-first-Cell-Analysis-Solution-to-Streamline-Cell-and-Gene-Therapy-Research-and-Manufacturing).

The Comptroller General of the United States, Gene L. Dodaro, who serves as the head of the **U.S. Government Accountability Office**, announced the appointment of six new members of the **Patient-Centered Outcomes Research Institute**'s Board of Governors. The newly appointed Board members are as follows: Chris Boone, Ph.D., Vice President, Global Head of Health Economics and Outcomes Research, AbbVie; Ryan Bradley, N.D., M.P.H., Director of Research and Senior Investigator, National University of Natural Medicine; Zoher Ghogawala, M.D., FACS, Professor, Department of Neurosurgery, Tufts University School of Medicine and Chairman, Department of Neurosurgery at Lahey Hospital & Medical Center; Debbie Peikes, Ph.D., M.P.A., Vice President, Humana Healthcare Research; Kimberly Richardson, Founder, Black Cancer Collaborative and Christopher L. White, Esq., General Counsel and Chief Policy Officer, Advanced Medical Technology Association (AdvaMed). Press release (https://www.pcori.org/news-release/gao-announces-six-new-appointments-pcori-board-governors).

Akadeum Life Sciences announced a new early access program launch of an industry-first: the Microbubble Leukopak Human T Cell Isolation Kit. This new research use-only kit was developed to give scientists an essential solution to biological and workflow challenges in the lab. The product combines unique advantages of microbubbles with a Buoyancy Activated Cell Sorting (BACS) Separation Tube that is poised to transform large volume cell separation workflows. Akadeum's BACS Separation Tubes create timesaving and performance benefits with the easy separation of target cells from the remainder of the sample and increased throughput. Press release (https://www.biospace.com/article/releases/akadeum-life-sciences-announces-new-early-access-launch-of-first-of-its-kind-microbubble-powered-large-scale-cell-isolation-kit-for-leukopaks/).

Propath UK and **Nucleai** announced their collaboration to develop and validate a 30-plex immunofluorescence panel focused on protein targets relevant to immuno-oncology. Nucleai's proprietary AI-powered, pathology-based biomarker discovery platform combined with Propath's multi-omic spatial biology and high-plex immunofluorescence will accelerate the pharmaceutical industry's drug development and research programs. In addition, the combined expertise will allow computational analysis of the tumor microenvironment, feature selections to predict disease prognosis and drug response, and support early detection and prognosis. Press release (https://apnews.com/article/technology-science-health-biology-middle-east-059e6937fc2c4373a5925b2e9d77c20a).

Researchers from the **Lewis Katz School of Medicine at Temple University** announced that a device known as the BASHIR Endovascular Catheter (THROMBOLEX) significantly reduces the size of blood clots lodged in the pulmonary arteries, leading to improvement in heart function in patients with pulmonary embolism (DOI: 10.1016/j.jcin.2022.09.011 (https://www.sciencedirect.com/science/article/pii/S1936879822017526?via%3Dihub)). The BASHIR catheter is made of an expandable basket with mini-infusion catheters. Once placed inside a clot, the infusion basket expands, creating new channels in the clot and increasing the surface area exposed to clot-dissolving drugs delivered through the catheters. THROMBOLEX now has FDA clearance on seven devices in the BASHIR family of catheters, all of which are currently in commercialization. Press release (https://medicine.temple.edu/news/endovascular-catheter-developed-lewis-katz-school-medicine-temple-university-shows).

A research network formed by **Nanyang Technological University Lee Kong Chian School of Medicine** and other prominent hospitals in the region has set up the Singapore Severe Asthma Registry (SSAR), the first of its kind in the country. This national registry joins the International Severe Asthma Registry as the largest international research collaboration in Singapore's respiratory medicine history. The SSAR aims to improve understanding of severe asthma, collect evidence of treatment effectiveness and safety, and identify predictors of treatment success. Press release (https://www.eurekalert.org/news-releases/965104).

The **Center for BrainHealth** is excited to announce three rapid-launch research initiatives to develop improved brain systems in response to interventions. The first project will use neuroimaging data from The BrainHealth Project to glean insight into how the brain's blood flow and connectivity change as an individual engages in brain health training. The second project uses a different machine learning approach to determine differences in the brain's connectivity as brain health gets better. Finally, the third project seeks to create a structure and system to securely share data from The BrainHealth Project platform with other researchers. Press release (https://www.news-medical.net/news/20220914/Three-rapid-launch-research-initiatives-seek-to-advance-the-development-of-brain-health-metrics.aspx).

Strata Oncology announced the expansion of its clinical collaboration with **Pfizer** in the Strata Precision Indications for Approved THerapies (Strata PATH) trial. Strata PATH is a prospective pan-tumor therapeutic trial designed to evaluate the efficacy and safety of multiple FDA-approved cancer therapies in new, biomarker-guided patient populations. Pfizer will provide Braftovi (encorafenib), Mektovi (binimetinib), and Lorbrena (lorlatinib) for up to six new cohorts of patients with early-stage lung, melanoma, colorectal, and other cancers. An advanced molecular therapy selection profile is created simultaneously for every patient assessed with the MRD test. The profile enables rapid identification of clinical trial opportunities, including Strata PATH, for patients who are positive for ctDNA. Press release (https://www.prnewswire.com/news-releases/strata-oncology-announces-expansion-of-clinical-collaboration-with-pfizer-for-strata-path-trial-into-early-stage-cancer-301622256.html).

The **National Institute of Allergy and Infectious Diseases**, part of the **National Institutes of Health**, is sponsoring a clinical trial evaluating alternative strategies for administering the JYNNEOS monkeypox vaccine to increase the number of available doses. The trial is currently enrolling volunteers and hopes to secure more than 200 adults across eight U.S. research sites. Investigators will assess whether the peak immune responses induced in recipients receiving the vaccine intradermally are at least as good as those generated by the licensed subcutaneous regimen and will compare the relative safety and tolerability of the

different regimens. Investigators anticipate the trial will take 15 months to complete; however, initial results could be available in early 2023. Press release (https://www.nih.gov/news-events/news-releases/clinical-trial-evaluating-monkeypox-vaccine-begins).

The **University of Texas MD Anderson Cancer Center** and **Virogin Biotech** announced a strategic collaboration to accelerate the development of investigational treatments—including oncolytic viruses and immunotherapies—for patients with advanced cancers. The five-year partnership will support the clinical development of Virogin's therapies with multiple clinical trials in various cancer types to evaluate the safety and clinical benefit of these therapies and to identify prognostic biomarkers of response. Virogin's viral therapies are engineered to eliminate tumor cells and stimulate innate and adaptive anti-tumor immune responses. Press release (https://www.mdanderson.org/newsroom/md-anderson-and-virogin-biotech-announce-strategic-collaboration.h00-159542901.html).

AiCure announced the launch of its clinical site services offering. The new program provides sites with end-to-end, customized support and monitoring of metrics related to adherence, compliance, data management, and technology use among study participants. With this offering, AiCure equips study coordinators with proactive insights into their patient populations to minimize risk across studies and optimize workflows. AiCure positions itself as a zero-friction product for sites by reducing their data burden, refining their focus, and simplifying their view of their patient population. Press release (https://www.prnewswire.com/news-releases/aicure-launches-site-services-to-reduce-burden-and-optimize-research-operations-for-clinical-sites-301619081.html?tc=eml_cleartime).

Medable announced that it had entered a four-year enterprise contract with **GSK** to enable decentralized clinical trials (DCTs) across its portfolio using the company's industry-leading DCT platform to accelerate the delivery of new medicines and enable their clinical trials to be more inclusive and representative of all patient populations. Medable's technology was chosen after a rigorous evaluation of the leading clinical trial platforms, as it best aligns with GSK's goals of increasing access to research, improving diversity, and creating more patient-centric trial designs. Press release (https://www.businesswire.com/news/home/20220907005594/en/Medable-Selected-by-GSK-to-Power-Decentralized-and-Hybrid-Clinical-Trials-Across-Global-Product-Portfolio).

ProofPilot and **Citeline Connect** announced a strategic partnership to make clinical trials more accessible for all patient populations and clinical trial workflows less cumbersome for research site staff. This collaboration combines ProofPilot's Patient and Site Co-Pilot offerings with Citeline Connect's technology and network of recruitment partners to effectively deliver research solutions that promote enrollment, randomization, protocol adherence, and patient retention. In addition, ProofPilot's digital automation platform orchestrates key stakeholder tasks, optimizing clinical workflows, reducing the burden on staff, and automating tasks to increase patient engagement rates. Press release (https://www.prnewswire.com/news-releases/citeline-connect-and-proofpilot-announce-strategic-partnership-301618669.html).

BGI's Thalassemia Gene Detection Kit has recently obtained CE-IVDD approval. The kit is developed based on the combinatorial probe-anchor synthesis sequencing method, a next-generation sequencing technology, to detect α-thalassemia and β-thalassemia mutations qualitatively. Peripheral blood samples will be used for genetic screening of the general population and diagnosis of abnormal hemoglobinopathy. It was estimated that 5-7% of the world's population carries a mutated gene affecting the production or function of the hemoglobin molecule. Over 330,000 affected infants are born annually (83% sickle cell disorders, 17% thalassaemias). Press release (https://www.bgi.com/global/news/bgi%E2%80%99s-thalassemia-gene-detection-kit-receives-ce-ivdd-certification).

The National Institutes of Health launched a $3 million Connecting the Community for Maternal Health Challenge competition to encourage US community-based and advocacy organizations to conduct maternal health research. The challenge is part of the **White House** Blueprint for Addressing the Maternal Health Crisis. The three-phase challenge is open to non-academic, 501(c)(3) organizations based in the United States, including advocacy, community, and faith-based organizations. Research ideas must align with the

goals of the IMPROVE initiative, which aims to reduce preventable causes of maternal death and improve maternal health before, during, and after delivery. Press release (https://www.nichd.nih.gov/newsroom/news/090122-maternal-health-research).

Stand Up To Cancer (SU2C) announced three new teams investigating treatments for non-small cell lung cancer and Ewing sarcoma. The teams include a Lung Cancer Health Equity SU2C Catalyst Research Team with support from **Bristol Myers Squibb** and two SU2C Catalyst Research Teams with support from **Jazz Pharmaceuticals**. The teams will build on important work done under unique SU2C research programs focused on improving cancer health equity and finding new uses for existing compounds to bring innovative therapies to patients faster. To learn more about the SU2C Catalyst program, visit SU2C Catalyst (https://progress.standuptocancer.org/catalyst). Press release (https://standuptocancer.org/press/stand-up-to-cancer-announces-three-new-teams-focused-on-treatments-for-lung-cancer-and-ewing-sarcoma/).

Mayo Clinic, **Hibiscus BioVentures**, and **Innoforce** launched Mayflower BioVentures. This academic and industry relationship will establish independent cell and gene therapy companies to advance the development of Mayo Clinic technologies through preclinical and early feasibility studies. With a shared interest in identifying treatments and preventing disease, Mayflower aims to develop new cures for severe and complex conditions through cell and gene therapies. The Mayflower management team brings together clinical leaders from Mayo Clinic with operational and investment experience from Hibiscus to move scientific discoveries from the lab bench to patients' bedsides. Press release (https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-hibiscus-bioventures-and-innoforce-announce-mayflower-cell-and-gene-therapy-accelerator/).

OCT Clinical announced the extension of its services via its OCT Oncology solution to address clinical research needs with a particular focus on emerging biotechs. As a CRO, the company delivers a proven process optimization approach with a highly skilled and dedicated clinical team and a network of 300 leading oncology clinics across Central and Eastern Europe. In addition, OCT Clinical provides comprehensive feasibility services, exclusive partnerships, up to 4x faster recruitment, access to suitable patients, and expertise in more than 45 oncological indications. Press release (https://oct-clinicaltrials.com/resources/news/oct-clinical-has-unveiled-its-oct-oncology%E2%84%A2-solution-package-aimed-at-helping-emerging-biotechs).