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In This Issue

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WCG Clinical Trial Trends & Insights for 2024: Part One

Despite a number of major hurdles and transitions facing the industry, 2024 is anticipated to be another year of forward motion and exciting progress for clinical research.

In WCG's Clinical Research Trends & Insights 2024 report, eight distinguished experts share their thoughts on where decentralized/hybrid trials, sites and diversity efforts in rare disease trials are headed and discuss emerging opportunities around psychedelics, artificial intelligence (AI) and digital biomarkers. The following is a selection of expert insights from the report.

Diversity, Equity & Inclusion in Rare Disease Clinical Trials

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A rare disease affects, by definition, fewer than 200,000 individuals in the U.S., and an ultra-rare disease affects many fewer. There are more than 10,000 identified rare diseases affecting more than 30 million Americans and their families, with similar numbers in other parts of the world. Individuals with rare diseases and their families face significant challenges due to such factors as uncertainty in/availability of a diagnosis and potential treatment options that ultimately affect their medical, psychological, economic and social health.

Considering rare disease prevalence, a lack of diversity, equity and inclusion (DE&I) considerations in research of these conditions and practices around treating them leads to diminished opportunity for care and poorer outcomes. These include limited access to diagnosis and care, ongoing trials for a person living with a rare disease, their child or their partner, and the availability of support for their concerns and ongoing needs.

When we think about social determinants of health-related access barriers, we must consider factors related to healthcare professional education and knowledge regarding rare diseases. It is the case that many families first rely on available sources of primary care, including family and general practice physicians or nurse practitioners, who may not be as informed about current information regarding rare and ultra-rare diseases. Similarly, primary care practices may not have enough resources or advanced technologies available for faster diagnosis and treatment options.

These challenges can be further complicated for minority and underresourced communities when awareness of specialty care and the availability of practitioners versed in understanding the diverse needs of affected individuals is more limited.

It has been recognized that there is a significant need to provide healthcare professionals and trial investigators with relevant continuing education and training about the importance of DE&I strategies regarding the diagnosis and treatment of individuals with rare diseases. Starting early with medical and healthcare training, the integration of curricula regarding the social and behavioral determinants of health has begun to contribute to better coordination of elements of care, leading to faster diagnosis and, when available, access to developing and approved treatments. Furthermore, improving resources and availability of specialist care and adding greater diverse community representation, such as connecting with patient advocacy groups, have improved outcomes for minority persons with rare diseases and their caregivers.

More specifically, sponsors running trials, including pharmaceutical companies and the individual investigators conducting their studies, have been directed to think more clearly and to state explicitly within their study objectives and design how they will directly address diversity and equity considerations. Unique in 2024 is the extent to which emerging practices regarding equitable trials have

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Taking a Kaleidoscope Approach to Diversity, Equity and Inclusion

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A kaleidoscope can be thought of as an analogy for the diversity of human beings. A kaleidoscope consists of different shapes and colors that merge and form beautiful patterns when reflected through mirrors. With the slight turn of a kaleidoscope, one gets a new perspective and views of fresh imagery. Similarly, human beings consist of different ethnicities, genders, sexual orientations, abilities and other characteristics that, when embraced, form a beautiful and diverse society.

The concepts of genetics, epigenetics and social determinants of health can be likened to the mirrors that reflect the shapes and colors in a kaleidoscope. Genetics represent the basic building blocks of our individual traits, which are passed down through generations. Epigenetics looks at environmental influences, such as stress, diet and lifestyle, that affect the expression of our genes and can determine the inheritance of traits across generations.

Social determinants of health represent the structural inequalities that shape the way people live, work and grow and also impact their health outcomes. These can include such factors as access to healthcare, education, housing, employment opportunities and social support networks.

Bringing together these concepts can create intersectionality, a framework that emphasizes how various forms of social inequality, such as race, gender, sexuality, class and ability, interconnect to produce unique experiences and challenges for individuals. Intersectionality acknowledges that individuals are complex, multifaceted and cannot be understood fully through one dimension.

In this way, the principles of diversity, equity and inclusion (DE&I) in health can be seen as a means of embracing and celebrating the beautiful and nuanced differences and similarities between human beings while also working to address and dismantle the structural inequalities that prevent all individuals from thriving.

In clinical trials, the intentional focus on DE&I is paramount to ensuring a health solution is developed and verified safe and efficacious for individuals impacted by a particular disease or ailment. When we focus on the intersectionality or similar patterns reflected in the kaleidoscope of our expressions of humanity, we can align health with wellness and micro with macro to make larger impacts on the health and wellbeing of populations. Planning your DE&I efforts in clinical trials starts with understanding of populations and your health solution targets, followed by detailing actions to bridge any inequities to drive equal representation in the trial and assurance that the target performs positively in those earlier identified intersections of genetics, epigenetics and social determinants of health.

A kaleidoscope is a beautiful mosaic of color and light and, really, that's what individuals are: complex humans that are connected by similar bases. Yet when living in an imperfect world, they express differently to develop a perfect image of uniqueness worthy of all that life has to offer, endless possibilities and yet so many shared desires. Everyone deserves access to the same tools to make the life they desire; health, opportunity, education, and kindness can drive overall wellness. A small impact when made continuously or by many can lead to mountainous outcomes. Do what you can from where you are to ensure individual kaleidoscopes have the opportunity shine bright!

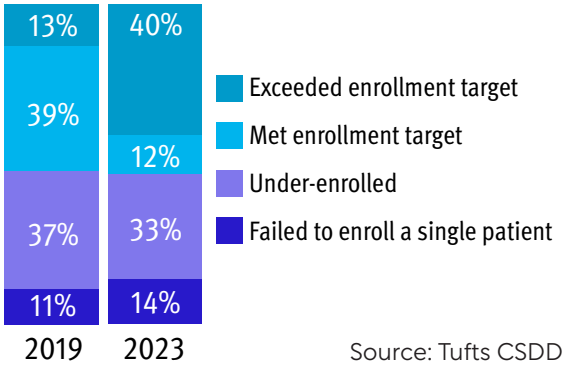
Data Point

Many Sites Surpassed Enrollment Targets in 2023

A significantly higher rate of sites went above and beyond hitting their enrollment targets last year compared to sites in 2019, new data from the Tufts Center for the Study of Drug Development (CSDD)'s latest Impact Report show.

At the same time, nearly half (47 percent) of sites either under-enrolled or failed to enroll any patients, a rate that's barely changed since 2019.

In conducting its assessment, Tufts CSDD collected activation and enrollment achievement metrics on 11,000 global sites in addition to data on recruitment and retention strategies. Access the latest Impact Report here.



Source: Tufts CSDD

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begun to standardize as drug developers and other stakeholders become familiar with the methods of diversification required of them, which will ultimately lead to a required increase in the numbers of diverse participants who are represented in and serve as beneficiaries of treatment research.

During protocol development, sponsors and investigators are also encouraged to carefully assess research methodologies and approaches, research outreach and recruitment methods, and improve the availability of adequate resources to accommodate minority populations for ease of recruitment. Community-based participatory research methods can support this effort, ensuring that individuals from minority communities with rare diseases are included in the design and implementation of the research from the start, and by identifying and resolving potential clinical biases. Community-based participatory research uses collaborations between research organizations, investigators and community members throughout all aspects of a research project. This approach is important given its commitment to engaging and representing intersectionally diverse populations affected by rare and more common diseases and fostering greater engagement across minority communities.

Trial diversity and rare disease drug development together will benefit from the growing collaboration by the FDA regarding the necessity for diverse and equitable representation in clinical trials and biotech companies' increasing familiarity with the resulting best practices in development. Tools to reduce the diagnostic odyssey will continue to reduce the cost and burden of rare diseases, while advocates' work with policymakers will better open access to these tools and strategies.

The DEPICT Act passed by the U.S. Congress requires the FDA to require sponsors to submit diversity action plans with their phase 3 or other pivotal trials (CenterWatch Weekly, Jan. 2, 2023). The FDA has urged both large pharmaceutical companies and the growing number of smaller biotech drug developers involved in rare disease research to reach out and work with the agency early in the investigatory process to develop protocols and find solutions to the challenges this new requirement presents. 2024 is a specific year to watch this translate directly into best practices.

> Unique in 2024 is the extent to which emerging practices regarding equitable trials have begun to standardize as drug developers and other stakeholders become familiar with the methods of diversification required of them, which will ultimately lead to a required increase in the numbers of diverse participants.

Additionally, better tools in genomic screening are available now, which help reduce the diagnostic odyssey and connect rare disease patients with new treatment options and early interventions that can save their lives and prevent unnecessary damage from the disease. Policies to open access to these fresh solutions more broadly across diverse affected communities will remain an active focus for rare disease advocates and collaborating policymakers in 2024.

A growing body of evidence shared recently has shown how policies that help families of rare diseases also benefit society. Two studies commissioned by the EveryLife Foundation for Rare Diseases will be used in dialogue with policymakers. One quantifies the cost burdens on families and society of rare diseases, and the other quantifies the avoidable costs of the diagnostic odyssey. Legislation is in the works to provide access to treatments and diagnostic tools to people regardless of zip code and income level. Watch for legislative efforts to open access to newborn screening, including rapid genome sequencing, genetic counseling and early intervention services. Small patient populations have always hampered rare disease research. As we expand our definition of who participates in the research and its benefits, the population sizes grow.

Lastly, the FDA has already issued draft guidance on enhancing the diversity of trial populations (CenterWatch Weekly, April 18, 2022). This is being further supported by IRBs reviewing current research proposals with an eye toward DE&I and representative justice. IRBs play a key role in determining the availability of trials for minority populations in rare diseases. One of the criteria for approval is consideration of the equitable selection of research subjects.

As per the Belmont Report, no individual group should be absolutely included or excluded from clinical study without justifiable scientific or ethical reasoning. IRBs can review the submitted justification and study design for scientific and ethical validity, and ensure adequate safeguards and protections are in place for the study population more broadly. This will lead to both

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greater recruitment of diverse participants and clearer knowledge regarding potential outcomes.

Supporting Research Sites and the Road Ahead

Sandy Smith
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The tumultuousness of the "pandemic years" has lessened, giving rise in 2024 to an intense focus on people, timelines and quality in conducting clinical research. Near the end of 2023, research sites reported more stabilization in the research workforce, consistent with the U.S. Bureau of Labor Statistics report of declining resignations in healthcare. Since 2020, the most critical concern at sites has been workforce retention and recruitment. The availability of qualified research professionals will remain a top concern in 2024. Innovations in workforce development will continue to expand through sites, professional organizations and partnerships as the industry highlights the role of the clinical research professional as an intentional career choice.

Aside from workforce issues, sites continue to face numerous headwinds ranging from capacity limitations to increasingly complex protocol designs and the inability to meet trial enrollment targets and timelines. These factors contribute to the increasing trend in trial completion taking an average of 10 months longer to complete in 2023 versus 2020.

While the impact of the "Great Resignation" has lessened, sites and pharmaceutical company partners are mutually invested in accelerating trial activation. Focusing on oncology, a therapeutic area representing more than 40 percent of the sponsored trials opened in 2023, guidance from the National Cancer Institute suggests a target activation timeline of 90 days. Some sites report meeting or exceeding this target, but far more are establishing action plans to reduce their activation times currently surpassing 100, 200 or even 300 days.

Across all therapeutic areas, there is disparity in median time for trial activation, defined as time from site selection to completion of contract. For the past three years for phase 1-3 trials, the median timeframe for academic medical centers and hospitals is 8.12 months vs. independent sites/physician practices with a median of 4.37 months. With many steps and variables in the start-up process, one task consuming weeks to months is the negotiation process for both budgets and contracts. Budget negotiation timelines trended an average of eight days longer in 2023, likely impacted by higher site costs due to inflation. Concentrated efforts on improving activation timelines through workflow optimization will include use of centralized ethical and biosafety review, deployment and linking enabling technologies, evaluating options for outsourcing administrative services, and enhanced communication in negotiations.

The availability of qualified research professionals will remain a top concern in 2024. Innovations in workforce development will continue to expand through sites, professional organizations and partnerships as the industry highlights the role of the clinical research professional as an intentional career choice.

Recapturing the Progress Made with CTA Negotiations During the Pandemic

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The time it takes to finalize clinical trial agreements (CTA) is among the most pressing challenges in trials, but our industry proved during the COVID-19 pandemic that rapid improvement is possible. CTAs that previously took months to negotiate before the onset of the pandemic were suddenly finalized in a matter of days. However, CTA negotiations have largely reverted to pre-pandemic practices just as research on treatments and vaccines have allowed society to return to some form of normalcy. With trial volume normalizing after a postpandemic boom and pharmaceutical sponsors and healthcare providers reconsidering their trial portfolios and resources, those involved in trial contracting have an opportunity to refine their processes and standards in a way that would bring us closer to those rapid turnarounds we saw during the pandemic.

We envision stakeholders seeking more opportunities to use a template or another source of agreed-upon language, including previous CTAs between parties and industry-recognized tem-

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plates, such as those from Accelerated Clinical Trial Agreement (ACTA) and MAGI. While some sponsors may, for example, deem ACTA's approach to the General Data Protection Regulation or intellectual property ownership insufficient to protect their interests, these types of issues do not preclude the use of templates. It just means some terms, but not all, may require adjustments before final agreement is reached. At the very least, these resources can provide a great starting point, allowing the parties to focus on key issues, as was the case when the industry turned to those resources for rapid startup on COVID-19 trials.

Contract teams also will look for ways to become more efficient in 2024 when templates are not used, and two ways to improve efficiency are through reprioritization of workload and revising internal standards, such as the CTA playbook. By prioritizing CTAs that are nearly complete ahead of new CTAs, you can shorten negotiation timelines and prevent overaccumulation of contracts on your to-do list. In other words, do not automatically relegate incoming tasks to the bottom of the priority list; focus on reducing the size of your to-do list by resolving those CTAs that can be finalized quickly. Just as we prioritized our vaccine and treatment trials during the pandemic, prioritizing those CTAs that are closest to finalization can have a tremendous effect on turnaround.

Drafting an adaptable CTA playbook that works within a wide variety of CTA templates will help set your contracts team up for efficient CTA negotiations in 2024 and beyond. Focus on key words, phrases and concepts, with examples of agreeable text to help guide the CTA reviewer. Avoid mandating long blocks of text that are required verbatim. Allowing your contracts team to work key ideas and terms into the existing template language leads to more productive conversations with the opposing side. The first step to accomplishing that goal is strategically drafting or revising your CTA playbook.

> With trial volume normalizing after a postpandemic boom and pharmaceutical sponsors and healthcare providers reconsidering their trial portfolios and resources, those involved in trial contracting have an opportunity to refine their processes and standards in a way that would bring us closer to those rapid turnarounds we saw during the pandemic.

Lastly, with efficiency as a priority, teams should be willing to pick up the phone earlier and more frequently. Too often "negotiations" happen in the comment bubbles, especially when the reviewer is short on time. This method, while convenient, is inefficient. It leads to prolonged discussions and more rounds of ineffective back and forth. Simply removing and replacing language with comments such as "not approved" is not negotiation and it certainly does not constitute collaboration. A phone call allows both parties to clarify points in real time, which leans more toward collaborative problem-solving than combative dispute.

The decrease in CTA negotiation time that was experienced during the pandemic was more easily obtainable as all parties had the same shared goal of supporting COVID-19 clinical trials. We cannot forget that patients who suffer from any disease or disorder also experience a disruption to their daily lives. While one specific health issue may not have as widespread of an impact as a pandemic, all parties should be able to continue to share this same goal. Focusing on common goals can change negotiations from an adversarial relationship to a team approach. It is important to move away from the "us vs. them" mentality. The clinical research ecosystem requires all parties of a CTA to work together to be successful.

Site Readiness in Vaccine Trials: Lessons Learned from the COVID-19 Pandemic

Tyler Bye
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Vaccine research will forever be linked to the COVID-19 pandemic. For all the heartache and troubles the pandemic brought us, it showed the collective power our industry holds when unified for a singular focus. While the pandemic brought new awareness to vaccine research, it also elevated the expectations of sites without accounting for their own aspects of pandemic challenges.

At the height of COVID-19 vaccine research, everyone was on board: site staff, sponsors, CROs, vendors, and most of all, patients, unified for a singular focus. Our industry and the world saw incredible speed and results. Now that the world has progressed and individual

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factors are no longer aligned, the goal of vaccine research stays the same. Because of this, the next year will see the continued trend of high expectations, with traditional resource constraints in place, bringing the need to focus on enhancing efficiency at sites.

One practice that enabled the speed of pandemic vaccine research was the clear delegation of duties at sites. Recruitment and retention needs are not mutually exclusive, but sites should clearly assign the tasks associated across the patient journey to team members. These specific tasks require not just delegation, but dedication from team members. When the team knows who carries each responsibility, members can focus on their specific tasks and work efficiently. The concept sounds simple but putting it into a repeatable practice takes effort and specialization.

The next year of vaccine development will continue to focus on respiratory diseases, including new variants of influenza and COVID-19. It will also see a growing focus on new and emerging diseases, such as dengue fever and Zika, and advances in bacterial and viral indications, including meningococcal disease, hepatitis and chicken pox. Each specific indication will require sites to focus on healthy but at-risk populations. Sites must continue engaging with the target population to bring awareness of these vaccine areas and ensure the efficacy endpoints can be achieved.

Sites can expect sponsors to work on bringing efficiencies through new and consolidated technology. From a site's perspective, some will work, some will not, and the ongoing trend of technical issues will persist. Still, sites should work openly through the challenges and approach changing technologies with the basics of the scientific method. There is a hypothesis that changing technology will benefit research. To continue to advance as an industry, we all need to go through the methodology to determine if the results support the hypothesis.

Vaccine research in 2024 will continue to press forward, and sites will continue to find ways to be more efficient in their processes. The pandemic proved what is achievable and efficiencies were born from the process. With the mindset of continuous process improvement, patients will be the beneficiaries of the work to come.

Patient Recruitment Barriers in Oncology

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As the industry continues to recognize advancements in oncology, it also continues to recognize the challenges in patient recruitment, a vital component in bringing these advancements to market. Patient recruitment comprises two distinct components — identification and enrollment — with each component bringing forth its own set of challenges.

While often overlooked, understanding how patients will enter the study is the first step in developing a successful recruitment strategy to identify potentially eligible patients. The referral pathway can be internal to the site through electronic medical records (EMR), through physicians within the same organization, or through physicians outside the organization.

Internal referral pathways using EMR are the easiest means to identify potential patients, but it takes time and experience. Building a comprehensive query within the EMR can be challenging due to limitations of the platform and experience of the research staff. Entering complex eligibility criteria commonly found in oncology studies often requires medical record "superusers" to build algorithms for capturing the appropriate patient population. It takes ample resources with the required expertise to properly query the site's EMR to obtain a list of highly eligible patients.

A properly managed referral pathway continues to the enrollment stage of recruitment. Once highly eligible patients are identified, ensuring they are informed and engaged is critical to successful enrollment and retention. Building a rapport and solid foundation for communication requires patience, understanding and time. There is a heavy focus on the administrative components of clinical research and the increase in those requirements. The administrative tasks completed in the background are essential to maintaining regulatory compliance but may cause study teams to sacrifice the time needed to build relationships with enrolling patients. Assigning a designated team to address administrative and compliance requirements is impractical for most sites. Collaborating with a vendor can ensure potential research participants are well-informed and engaged while also supporting administrative and regulatory compliance.

As complex eligibility requirements continue to be a component of clinical oncology research protocols, developing a strong and comprehensive patient recruitment plan is the first step to mitigating patient identification and enrollment barriers. Utilizing internal resources in combination with the right external partners can help research sites continue the drive forward in conducting clinical research and propel oncology treatments to the next level.

The March issue of The CenterWatch Monthly will present Part Two of this article series featuring even more insights from WCG experts.

Access the full report here.

Study Lead Opportunities

CenterWatch analyzes data in its drug intelligence database to provide advance notice of clinical trials expected to enter the next phase of clinical development soon. Contact information is provided for follow-up. **Sponsors/CROs:** to list an upcoming trial here, contact Leslie Ramsey, 703.538.7661, lramsey@wcgclinical.com.

Company name	Drug name	Indication
phase 1		
Biora Therapeutics	BT-600	Moderate-to-severe ulcerative colitis
Eli Lilly	SIT-011	Chronic autoimmune and inflammatory diseases
Fate Therapeutics Ono Pharmaceutical	FT825/ONO-8250	HER2-expressing advanced solid tumors
Indapta Therapeutics	IDP-023 cell therapy	Multiple myeloma and non-Hodgkin's lymphoma
Kairos Pharma	ENV105 plus osimertinib	EGFR-driven non-small cell lung cancer
Kynexis	KYN-5356	Cognitive impairment associated with schizophrenia
ReCode Therapeutics	RCT1100	Primary ciliary dyskinesia caused by DNAI1 genetic mutations
Ventus Therapeutics	VENT-03	Inflammatory and cardiometabolic diseases
phase 1b		
Genascence	GNSC-001	Knee osteoarthritis
Verge Genomics	VRG50635	Sporadic and familial amyotrophic lateral sclerosis
phase 1/2a		
INmune Bio	INKmune	Metastatic castration-resistant prostate cancer
Tango Therapeutics	TNG348	BRCA1/2-mutant or other HRD+ cancers
Vor Bio	VBP301	Relapsed/refractory acute myeloid leukemia
phase 2		
AM-Pharma	Ilofotase alfa	Cardiac surgery-associated renal damage
Anavex Life Sciences	ANAVEX 3-71	Schizophrenia
Aviceda Therapeutics	AVD-104	Diabetic macular edema
Constant Therapeutics	TXA127	Ischemic stroke recovery
Elicio Therapeutics	ELI-002 7P cancer vaccine	KRAS-mutated pancreatic ductal adenocarcinoma
EyePoint Pharmaceuticals	EYP-1901	Diabetic macular edema

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Company name	Drug name	Indication
phase 2 (continued)		
Faron Pharmaceuticals	Bexmarilimab	Relapsed/refractory myelodysplastic syndrome
PepGen	PGN-EDO51	Duchenne muscular dystrophy amenable to exon 51 skipping
Upstream Bio	Verekitug	Chronic rhinosinusitis with nasal polyps
phase 2a		
Bayer	Elinzanetant	Sleep disturbances associated with menopause
Tryp Therapeutics	TRP-8802	Fibromyalgia
phase 3		
Merck	Bomedemstat	Essential thrombocythemia
Merck	Nemtabrutinib	Chronic lymphocytic leukemia and small lymphocytic lymphoma
Merck	MK-2870	Non-small cell lung cancer and previously treated endometrial carcinoma
Merck Orion	MK-5684/ODM-208	Advanced metastatic castration-resistant prostate cancer
Merck Orion	MK-5684/ODM-208	Front-line metastatic castration-resistant prostate cancer
Spero Therapeutics	Tebipenem HBr	Complicated urinary tract infections including acute pyelonephritis
Stuart Therapeutics	ST-100	Dry eye disease

FDA Actions

The following is a sampling of FDA regulatory actions taken during the previous month, compiled from CenterWatch and third-party sources, including the FDA and company press releases. For more information on FDA approvals, visit centerwatch.com/fda-approved-drugs.

Company name	Drug name	Indication	FDA action
Amplia Therapeutics	Narmafotinib plus folfirinox	Pancreatic cancer	IND approved
Atom Bioscience	ABP-745	Acute gout	IND approved
Caliway Biopharmaceuticals	CBL-514	Dercum's disease	IND approved
Enyo Pharma	Vonafexor	Alport syndrome	IND approved
Focal Medical	ACT-IOP-003	Locally advanced nonresectable pancreatic tumors	IND approved
InnoCare Pharma	ICP-248	Hematologic malignancies	IND approved
OBI Pharma	OBI-992	Advanced solid tumors	IND approved
OnKure	OKI-219	PI3K H1047R mutated advanced solid tumors	IND approved
OnQuality Pharmaceuticals	OQL025	EGFR inhibitor-induced acneiform rash	IND approved
Pasithea Therapeutics	PAS-004	MAPK pathway-driven advanced solid tumors with documented RAS, RAF or NF1 mutations	IND approved
Quanta Therapeutics	QTX3034	KRASG12D-mutated advanced solid tumors	IND approved
Sana Biotechnology	SC262	Relapsed or refractory B-cell malignancies	IND approved
Shuttle Pharmaceuticals	Ropidoxuridine	Glioblastoma	IND approved
Skye Bioscience	Nimacimab	Obesity and chronic kidney disease	IND approved
CRISPR Therapeutics	Casgevy (exagamglogene autotemcel) cell therapy	Transfusion-dependent beta thalassemia in patients 12 and up	Approved
Ligand Pharmaceuticals	Zelsuvmi (berdazimer topical gel, 10.3%)	Molluscum contagiosum	Approved
Merck	Keytruda (pembrolizumab)	FIGO 2014 Stage III-IVA cervical cancer	Approved for additional indication
Takeda	Hyqvia [Immune Globulin Infusion 10% (Human)]	Chronic inflammatory demyelinating polyneuropathy	Approved for new indication
Medtronic	Percept RC Deep Brain Stimulation system	Movement disorders	Approved
Occlutech	Occlutech ASD Occluder and Occlutech Pistol Pusher	Atrial septal defects	Approved

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