Ukrainian Clinical Trials - Resilience, Efficiency, and Strategic Opportunity

Kyiv, September 12, 2024 - The Ukrainian Association for Clinical Research (UACR) and the State Expert Center (SEC) of the Ministry of Health of Ukraine jointly hosted a webinar showcasing Ukraine's vibrant clinical trials landscape. The event highlighted how Ukraine continues to offer significant benefits for international sponsors, demonstrating resilience and adaptability in the face of ongoing geopolitical challenges.

Key Takeaways for International Sponsors:

1. Thriving Clinical Trial Ecosystem: As of April 2024, 290 clinical trials were active across various therapeutic areas in Ukraine, with oncology, gastroenterology, and rheumatology leading the field. Importantly, 75 new clinical trials were approved by Ukrainian regulatory authorities in 2023-2024 (through September), including studies from top sponsors such as AstraZeneca, MSD, Sanofi, Teva, and Janssen Pharmaceutica NV, as well as other middle and small-sized sponsors.

2. Efficient Regulatory Process: The country offers faster study start-up times compared to many European countries, with regulatory review timelines reduced to 30 days for new trial applications and 25 days for substantial amendments.

3. Strong Recruitment and Top Enroller Status: Ukraine consistently ranks as a top-enrolling country in global trials, often exceeding recruitment targets.

4. Site Readiness and Operational Resilience: Over 95% of surveyed sites report full operational capacity, with adequate investigational medicinal product supply and logistics for biosample shipments. Notably, 78% of sites are actively engaged in new trial feasibilities, showcasing their readiness for upcoming studies.

5. Mitigating Geopolitical Risks: While acknowledging ongoing conflicts, particularly in eastern regions, the webinar emphasized that the majority of Ukraine's research infrastructure in western and central regions remains fully operational. Sponsors are encouraged to focus on these low-risk areas to maximize trial success while mitigating potential challenges.

6. Experienced Workforce and Engaged Patients: Ukraine offers a pool of experienced investigators and research staff familiar with complex global trials. The patient population is technologically savvy and eager to participate in clinical research, contributing to lower-than-average screen failure rates.

7. Flexible Approaches to Ensure Continuity: Regulators and sites have embraced decentralized trial elements, including telemedicine visits, direct-to-patient drug shipments, and remote monitoring where necessary. This adaptability ensures trial continuity and data integrity despite geopolitical challenges.

8. Cost-Effective Operations with High-Quality Data: While maintaining high standards, conducting trials in Ukraine can be more cost-effective compared to Western European countries. Sponsors consistently report high-quality data from Ukrainian sites, offering a compelling value proposition.

The SEC and UACR remain committed to supporting clinical research in Ukraine, continuously working to enhance the regulatory framework and operational environment.

Conclusion: A Strategic Destination for Global Clinical Trials

Ukraine's resilient clinical trial ecosystem, combined with regulatory efficiency, site readiness, and cost-effective operations, presents a compelling opportunity for international sponsors. The approval of 75 new clinical trials in less than two years, including studies from both industry leaders and smaller sponsors, underscores Ukraine's continuing attractiveness as a clinical research destination. By leveraging the country's strengths in patient recruitment, data quality, and flexible trial designs, sponsors can accelerate their drug development timelines while benefiting from the unique advantages Ukraine offers. Despite geopolitical challenges, Ukraine continues to demonstrate its ability to deliver high-quality, efficient clinical trials, making it a strategic choice for sponsors seeking to optimize their global research programs.