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TOPIC BRIEFS AND PERSPECTIVES

The Untapped Potential of Clinical Data Management in Ukraine: A Novel Training Program Case Study

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As a populous Eastern European country with a strong medical education system, Ukraine has the potential to become a key player in the field of clinical data management, targeting international clinical research organizations and life science companies worldwide. At present, the country has been slow to develop independent clinical research and biotech sectors, and as a result there is a shortage of clinical data management specialists in the country. This article reviews the current state of clinical research in Ukraine and discusses a novel industry-led training program to increase the pipeline of clinical data managers by retraining healthcare professionals. This is an opportunity for the private sector to attract the brightest professionals and transition them into new careers, such as clinical data management. Further expansion of these training programs to more comprehensive education settings in partnership with local universities will enable growth in Ukraine's academic, biomedical, and clinical research sectors.

Keywords: clinical research; professional development; medical education; Ukraine; data management

Introduction

Many specialized positions in the pharmaceutical industry, even those at entry-level, require training above and beyond standard university degree programs. A shortage of specialized clinical data management (CDMs) professionals in Ukraine means private sector companies are developing internal resource training programs to deepen their pool of available candidates. Given the country's strong medical education system and established IT outsourcing industry, we believe developing a pool of talented clinical data managers within Ukraine serving international clinical research organizations (CROs) and life science companies worldwide is a feasible goal.

Background

Ukraine is the second-largest country in Europe and the 46th largest country in the world. The country has a population of about 43.5 million, making it the 35th most populous country in the world. Ukraine is also the eighth largest European country in terms of population, and about 70% of the population lives in urban centers, five of which have more than one million inhabitants.[1]

The IT outsourcing industry is the second largest export service industry in Ukraine, as well as one of the country's main economic sectors. More than 50% of Ukraine's IT services revenue in 2019 came from the United States, with the rest mostly coming from the European Union.[2] In the IT hotspots of Kyiv and Kharkiv, Ukraine has built a workforce adapted to IT outsourcing,[3] but the lack of local professionals in the fields of CDM and clinical data science hinders similar growth in the clinical research sector.

Ukraine has a well-established medical education system that trains a large number of healthcare professionals in accordance with EU regulations. In 2016 and 2017, medicine was the fourth most popular master's degree subject when measured by number of program applicants.[4] Hospitals are predominantly state owned, and the private medical sector is relatively small.

Despite this, Ukraine spends less of its gross domestic product (GDP) on healthcare than other comparably sized and developed countries.[5] Its academic and non-profit clinical research sectors are small in comparison to Western European countries, and opportunities for careers within those sectors are limited. The lack of opportunities leads to a "brain drain" of medical professionals from Ukraine to other countries in search of higher wages and professional advancement.

Ukraine's public and private biomedical research sectors are also limited. There are few international biotech or pharma companies with sites in the region, and domestic companies largely focus on the development of generic drugs.[6] The field of biomedical research in Ukraine is still in its early stages of growth and cannot be considered a mature field. Preclinical and basic research is mainly carried out within the framework of scientific research in medical universities, while clinical research in these universities is very limited.

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Clinical Research and Data Management in Ukraine

Fortunately, in recent years Ukraine has emerged as an attractive location for clinical studies, and interest in running clinical trials in the country is growing.[7] Clinical trial recruitment and participation rates are high because they give patients access to innovative therapies they can't access otherwise.[8] For these reasons, clinical research is currently one of the largest sources of investment in the field of medical science and practice.[9] According to data prepared by the European Business Association for the International Day of Clinical Research, over the past five years the number of clinical research sites in Ukraine increased by 20% (from 1,878 to 2,250), and the number of researchers rose by 44% (from 815 to 1,174).[10] There are approximately 30 clinical research sites in Ukraine handling studies from preclinical through Phase IV classifications. In September 2021, 599 active or recruiting clinical trials taking place in Ukraine were listed on ClinicalTrials.gov.

Regulatory hurdles and approval timelines have greatly improved in recent years.[11] In Ukraine, clinical trials are regulated by the Ministry of Health and the State Expert Center. Clinical trials legislation focuses on adhering to the principles of the Declaration of Helsinki and is aligned with International Conference for Harmonisation and EU legislation. Ukraine's plans for EU integration also envisage conducting clinical trials in accordance with the rules and recommendations of the European Medicines Agency. Clinical trials in Ukraine are conducted in compliance with the modern legal framework, which meets world standards and norms in the field of healthcare. At the same time, Ukraine's strategy for integration into the European scientific community requires further measures to harmonize the system in accordance with EU standards and directives.[12]

Given the slow expansion of its clinical research sector, Ukraine has not yet established a pipeline of clinical research specialists and CDMs. As the Ukrainian economy has diversified over the last five years, CROs have expanded their service offerings to foreign clients, providing full-service clinical trial support, including in-house CDM and statistical programming. Demand for CDMs within academia and private and non-profit biomedical companies remains almost nonexistent.

Looking at CDM in Ukraine in more detail, we can identify several key areas of its practice. For example, only a few global CROs that provide a full range of CDM processes outside the territory of Ukraine are represented within the country. CDM practice in these CROs complies with international standards and includes the whole range of services: from the development of the case reports forms (CRF) and all related documentation to a full review of data and preparation of results for further statistical analysis. Other CROs, including local ones represented in Ukraine, provide limited CDM services—most often data cleaning and external data reconciliation. CDM services in such CROs can also be provided by other suppliers or representative offices of these companies located outside of Ukraine.

In the field of scientific research, uptake of CDM is very limited in Ukraine. The volume of data processed in the course of basic scientific work does not require extensive CDM expertise, so the work is usually carried out by university employees.

Despite CDM being at an early stage of development in Ukraine, statistical analysis and programming of clinical data is a widely emerging sector, with multiple local and international players. The IT outsourcing and software development market in Ukraine is also very well established and contributes to the development of CDM. Thus, some companies develop electronic data capture (EDC) systems that are widely used worldwide.

Recruitment and Training of CDMs

Currently, when CROs wish to hire data managers to assist with local clinical trials in Ukraine, they have to hire non-specialists who must teach themselves on the job using internal resources. This is an inefficient process that, in focusing only on skills pertinent to their current roles, may not lead to the development of transferable CDM skills. Despite the significant number of universities in the country and the popularity of advanced medical degrees, very few master's programs offered by Ukrainian universities focus on training specialists in the field of clinical research, especially specialists in CDM. Although a small number of university courses aimed at training clinical research specialists have been launched in recent years, at present there are no university courses or formal training programs within the country exclusively for CDMs.[13]

Because universities typically only offer training programs tailored to market requirements for certain specialists, training programs in the field of clinical research have only recently begun to appear in Ukraine. Today, there is rather rapid growth in the number of CROs that provide a full range of services within the country and abroad; therefore, the demand for certain specialists, including in the field of CDM, is increasing. In addition, if Ukraine was previously an attractive location for conducting research within medical centers, there are now companies that can provide a full range of services in the field of clinical trials. As companies in that field grow, the demand for specialists will increase, and most likely, this will lead to changes in Ukrainian education.

Following the success of the Clinical Statistical Programming training program developed by our team at Intego Group and offered since 2013 in partnership with V. N. Karazin Kharkiv National University,[14] we recently launched an in-house CDM training program. Upon program completion, students have the opportunity to transition into full-time employment at Intego Group. Our pilot program is the first centralized training program for clinical data managers in the country.

The program is designed for specialists in the field of medicine and pharmacy with strong basic knowledge of the fields, which will expand the market availability of specialists in the field of CDM in a short time to meet growing demand. In order to achieve the goal of the program—producing graduates capable of joining a clinical project team and immediately contributing at entry level—proper training and education was critical.

Trained MDs, PharmDs, and research associates seeking opportunities and advancements not offered in state

hospitals were recruited into the CDM program. All courses, reading materials, and assessments were conducted in English. The curriculum totaled approximately 400 academic hours over six months of training and project work.

Recruitment of potential candidates was targeted at three groups of healthcare professionals who may be considering a career change into CDM:

- Physicians with MDs, whose opportunities for career advancement are often limited in the state-owned healthcare setting
- Pharmacists with a master's degree
- Clinical research associates, who are seeking a clinical research-based career that does not require frequent travel to clinic sites.

In contrast to other education programs offered through a university setting, this training program was for professionals who have completed their education and accumulated several years of work experience. Recruitment was targeted in two cities where Intego Group has offices, Kyiv and Kharkiv, considered the education centers of Ukraine.

The overall program acceptance rate was under 20%. Potential candidates were scored on education background and technical qualifications, prior work experience, leadership and communication skills, and proficiency in English. The goal of the selective admissions process was to ensure almost every candidate in the program could receive an offer of full-time employment following successful completion of the training and probationary employment period.

Student progress was assessed through Intego's Competency Matrix for Clinical Data Managers. Each student's mentor reviewed this matrix on a bi-weekly basis to ensure expected outcomes were achieved. After three months of coursework, students were transitioned to a research project derived from training datasets. By the end of the training program, students were expected to participate in ongoing projects with minimal supervision and correction, with full independence expected after six months of training and employment.

Next Steps and Outlook

Ukraine has the potential to expand the CDM role within the country as well as internationally. Based on early indicators of the CDM training program, plans are underway to expand the program to larger cohorts and developers are entering into discussions with Ukrainian universities to launch similar academic programs in CDM on a larger scale.

Although the biomedical and clinical research sectors in Ukraine are at early stages of development, the future of CDM remains bright because the main components of the sectors' growth and development are firmly in place. Like many emerging markets, Ukraine concentrates its growth and development on increasing the export share of the GDP, especially that which is integrated into service-oriented industries. Despite an overall decline of Ukraine's GDP by 4.4% due to COVID-19 in 2020, Ukraine's IT export volume rose by more than 20% to more than US$ 5 billion.[15] Based on 2021 numbers, the IT industry's share of all Ukrainian exports is estimated at 8.3%, making the IT and IT-enabled sector one of the key drivers of the Ukrainian economy, placing it closer in importance to traditional economic heavyweights such as agriculture and metallurgy. These are all positive signs of CDM's long-term potential to become an important part of the service-oriented export industry in Ukraine.

Conclusion

CDM may become the next big thing in Ukraine, targeting international CROs and life science companies worldwide. Due to lower cost of living compared with other countries in the Eastern European region, a favorable taxation system for service and export-oriented companies,[16] and a strong education system in the areas of life science and medicine, Ukraine has the potential to earn a significant share of the global market of clinical data science. Considering the state-owned healthcare system requires years of reforms, this is an opportunity for the private sector to attract the brightest professionals with many more competitive offerings and transition them into new careers such as CDM. The only piece of this formula that is missing is training programs like the one discussed in this article, coupled with transitioning this form of training to more comprehensive education settings in partnership with local universities.

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Competing Interests

The authors have no competing interests to declare.

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