Interview: Ruth Ladenstein – Executive Director, OKIDS, Austria

"We were created because children have become isolated from the field of industry-driven clinical trials."

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Prof. Ruth Ladenstein, executive director of the Medicines for Children Research Organisation (OKIDS) in Austria, explains OKIDS' drive to ensure drugs are paediatric specific by conducting child-specific clinical trials. Furthermore, she highlights the challenges associated with achieving a participating child's consent and defines what must be done to gain governmental and industry support to bolster this sector in the future.

Can you explain the role of OKIDS and the main challenges that you face today?

OKIDS is run as a private-public partnership in Austria, supported by the Ministry of Health and PHARMIG. In addition, we are sponsored by a special grant; the 'Joint Health Objectives of the Pharma Master Agreement,' a cooperative project of the Austrian pharmaceutical industry and social insurance. We applied for this grant to build up a network that develops medicine for children and contributes to providing innovative medicines with optimized safety for children in Austria.

We were created because children have become isolated from the field of industry-driven clinical trials. This has become a real problem as a lot of medicines for children have never been correctly tested. For example, in neonatology and oncology, 80 to 90 percent of the drugs used by children are not tested. This situation has been unchanged for too long, and we need to focus on this issue for the future health of children in Austria and around the globe.

Another glaring problem is approved drugs for adults are being utilized for child usage, despite differing weight, height, organ functions and body type; we should be calculating a product in proportion these factors before administering drugs. The healthcare ecosystem has more than 30 years' experience in this field – although – even with this experience the risks of side effects are still high for children and this is why we are completely devoted to this topic. We need to work together a collective unit with the pharmaceutical companies and the Coordinating Centre for Clinical Trials (CCS) on all the drugs gaining market access.

What initiatives have been put forward to help improve this situation?

There have been a few initiatives on the European level in relation to paediatric regulations to change the process of child drug approvals. Therefore, drug testing for children is being considered and the development for specific child drugs is increasing, but it takes time. On the paediatric oncology side, we are pushing very hard to modify regulations as in this area specifically we need an improvement in drug indications.

OKIDS serves as a competent partner and service provider for universities. We have a close relationship with the medical universities of Vienna, Innsbruck, Salzburg and Graz. These universities provide their know-how by combining competencies and resources. Furthermore, we are always looking for experts to represent all sub-specialities, which ensures prioritization of paediatric therapeutic needs and of the most promising new developments within the sector. It is intensive work where we have 90 percent of effort for 10 percent return on investment.

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What are the pros and cons of conducting paediatric clinical research in Austria?

Austria being a small country does not help because we have fewer patients available to participate in clinical trials. Regardless, the reason why the paediatric network needs support from private and public partnerships in Austria is because the network alone is not self-sufficient. Other countries have solved this problem differently. For example, in the UK, the government is very engaged in paediatrics, contributing one euro per child of the total UK population.

Nevertheless, OKIDS may reach out to efficient and well-trained personnel in science and trial administration support, consisting of activities such as planning, study protocol and advisory services. Without these people, it would not be possible to conduct clinical trials with such great competency, and thus far we have been successfully involved in more than 100 trials involving children and adolescents.

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In summary, OKIDS acts as a connector between the industry and the academics, particularly focusing on giving academia the required support. Another mission of OKIDS is helping families to fully understand the reasons why their child is offered participation and associated opportunities in a clinical trial.

How are you able to convince families to have their children participate in clinical trials?

For our children we only want “the best” and prefer not to take any risks. Entering into a trial is for many parents like requires a lot of explanation to be given to reassure that the environment is quality controlled and often risks are minimal in such settings. Sometimes it is as little as donating some blood or taking a needle. Parents need to understand that if we do not run clinical trials to improve treatments, it is impossible to see true innovation. This in-turn will lead to lower treatment quality due to exposing children to drugs that have never been tested properly; this is riskier than having a child on a trial.

During the trials, children are followed thoroughly. If any medication risk is discovered, the treatment is stopped. OKIDS drives forward positive communication in the public about involvement of children in trials as children deserve the best medication. It is a real partnership effort between academia, the industry and parent patient groups to understand the topics and increase the number of paediatric clinical trials in the future.

Nevertheless, it is always difficult to push your purpose if you are in a sector that is not well funded as we cannot run expensive publicity campaigns. However, we have been able to produce a brochure targeting parents to explain the benefits of clinical trials and to address their many questions.

Where do you see paediatric medicine in the next 20 years?

The vision is that medication needed for children across their disease spectrum has undergone appropriate drug development and approval to insure drug safety and access to drugs for this vulnerable population.

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