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The Revolution in Clinical Trials in Israel

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Dr. Osnat Luxenburg, a physician and a public health expert and Director of Medical Technologies, Health Information and Research Directorate at the Israel Ministry of Health, describes the initiatives and action taken by the Ministry to improve, facilitate, and support clinical trials in Israel, and explains how as a result Israel had become an attractive location for conducting such trials.

"Until a few years ago, clinical trials in Israel were not handled properly. The regulatory processes that supported the experiments were not optimal, the timetables were long, and the transparency was insufficient. All this has changed dramatically. The Israeli Ministry of Health understood the potential of clinical trials and the need to change regulation to ensure that the potential is realized, especially in light of the advantages of Israel in this field. We can now say with confidence that Israel is in the midst of a clinical trials' revolution." Says Dr. Osnat Luxenburg, Director of Medical Technologies, Health Information and Research Directorate at the Israel Ministry of Health.

"The situation I described spurred the Ministry to make profound changes in the management and approval of clinical trials in Israel," she explains. "Following the Ministry's initiative, we mapped and accelerated the entire clinical trials' process, as we worked to maximize the potential. We addressed the entirety of obstacles we identified in the process of development and production of a drug or a medical device; from the idea, through the lab, to the market. The intent was to speed up the process as much as possible, simplify bureaucracy, support and guide companies, entrepreneurs and researchers while establishing a robust infrastructure for efficient clinical trials in Israel. "

> "Establishing a robust infrastructure for efficient clinical trials in Israel"

According to Dr. Luxenburg, the process generated fast results. 80% of the researches reviewed by the Clinical Trials Department, in the field of medical devices, are First-in-Human and initiated by Israeli companies. Schedules have become competitive and aligned with those accepted in the world, administrative procedures are carried out concurrently, and permits are granted faster. "Many clinical trials that start in Israel go to next phase which makes me very pleased. I believe that the professional actions we initiated and the steps we took will result in more and larger companies conducting their trials in Israel, alongside the small companies and startups."

> "The unique mechanism we put in place and nicknamed 'the Israeli FDA' supports companies"

Another issue the Ministry addressed was the agreements between hospitals and the industry. "We built a framework for the parties and put together a basic agreement that improves transparency, simplifies processes, and shortens timelines without compromising quality. In addition, the next stage in the changes we are making is the establishment of one committee for multi-center experiments so that companies conducting experiments in several institutions can receive one response from the committee. The process has become more attractive for companies conducting clinical trials", adds Dr. Luxenburg, and further explains. "The unique mechanism we put in place and nicknamed 'the Israeli FDA' supports companies in their clinical trials as well as welcomes consultation with ministry officials during the experiments."

Over the years, the Medical Technologies, Health Information and Research Directorate at the Israel Ministry of Health has accumulated valuable knowledge and experience. Including the understanding of medical trends, criteria for approval of drugs in Israel and abroad, funding for new medical technologies and drugs, etc. This extensive knowledge is now available for the industry as well as entrepreneurs. "We have established a consultation and support mechanism in which stakeholders are welcome to consult with us throughout the process, ensure they are on track with their products and improve development processes. In other words, the Medical Technologies, Health Information and Research Directorate at the Israel Ministry of Health ensures that clinical trials in Israel combine technological innovation, therapeutic efficiency, and that future reimbursement is secured. The idea is to help the industry become more efficient."

> "Regulator has to be highly available and respond to any real-time needs that arise from the field, provide vital information, and communicate openly"

"As regulators, we have a three-pronged goal," says Dr. Luxenburg: "to make it easier for the industry to conduct clinical trials, develop new drugs and medical devices, as well as encourage entrepreneurs, researchers, and scientists to remain in Israel. To achieve these goals the regulator has to be highly available and respond to any real-time needs that arise from the field, provide vital information, and communicate openly with its clients while keeping public health's interests and needs.

"This is a win-win situation for all parties," concludes Dr. Luxenburg, "the patients receive innovative treatments using the most advanced technologies while from the industry's point of view, we facilitate the approval of pharmaceuticals and medical devices, as well as improve processes' efficiency."

About The Medical Technologies Health Information and Research Directorate

The Medical Technologies Health Information and Research Directorate (MTIR) is like the Israeli FDA (excluding the food administration). MTIR is responsible for the regulation and licensing of all medical technologies (including – pharmaceuticals, biological products, medical devices, procedures etc.) as well as being in charge of decision-making on reimbursement at a national level of health services according to the National Insurance Law. Other roles of the MTIR include licensing all the hospitals and other medical facilities, the regulation of radiation protection and formulating national health policy. The Directorate is also responsible for the health information in the Ministry including gathering national data as well as national registries. Another major activity is supporting research on a national level and promoting innovation in the bio-tech field in Israel.