

New Regulation Supports Clinical Trials in Israel

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Lior Shahory

CEO Incentive Incubator, General Partner at Peregrine Ventures

According to Lior Shahory, CEO of Incentive, Peregrine's incubator, over the past decade there has been a dramatic change in Israel's Ministry of Health regulatory environment; change that supports clinical trials in Israel. In an interview, Shahory explains what has changed and why startups should conduct their clinical trials in Israel, or at least start them here and in one or two other locations simultaneously.

According to Lior Shahory, CEO of Incentive, an award-winning Israeli technological incubator, owned by Peregrine Ventures, the reason that many multinational companies developing medical devices have opened R&D centers in Israel is the comprehensive technological ecosystem Israel has established. This ecosystem features Israeli startup culture, government support through the Israel Innovation Authority (IIA), and the military's technological developments with their spillover effects.

One of the most promising channels, according to Shahory, is the incubators' program, through which the state supports the development of medical devices. Shahory says that due to lack of capital during the initial stages of development (seed), the state's support in the early stages is crucial. "The state's support in the incubators produces fantastic results," he says. "Take Valtech for instance, an Israeli company that grew in our incubator, and was later bought by Edwards Lifesciences, a medical device giant (traded at \$18 billion). Valtech specializes in innovative transcatheter heart valve technologies for patients with valvular insufficiency. Without the government's initial investment, it would not have happened."

Dramatic improvement in clinical trials regulation

The government's involvement brought about welcomed changes in clinical trials. All around the world, the regulator plays an important role in this field, and Israel that is becoming an R&D hub for corporate giants should be no exception. "Medical devices' and digital health startups work under challenging conditions. Resources are scarce, and timetables are tight," explains Shahory, and adds "startups are required to demonstrate their POC (proof of concept), prove their equipment works, and conduct their trials in compliance with stringent quality standards, all the while keeping in mind that the feasibility study could affect raising additional capital."

According to Shahory, in addition to the relatively low costs of conducting clinical trials in Israel compared to elsewhere in the world, Israel also offers excellent networking among physicians, researchers, and entrepreneurs.

"The ability to maintain and sustain close working relationships with the medical community is a win-win situation for all parties.

Entrepreneurs easily access specialists in their respective medical fields while physicians are introduced to innovative technologies and new therapeutic methods that add to their expertise and skills. Working together creates continuity in animal testing and first-in-human studies that eventually translate into better medical care for patients."

Shahory praises the improvements the Israel Ministry of Health made in clinical trials. "Over the past decade, we have seen continuous and consistent improvements in all regulatory aspects. Today, the process is professional, more efficient, and more service-oriented. The regulator strives to align Israeli standards and conform to the international ones, while officials welcome the industry to ask questions and receive feedback before submitting the forms. These changes bring more startups to conduct their clinical trials in Israel or at least submit in Israel as well.

"From an investor's standpoint, says Shahory, "whether Israeli or foreign, when investing in drug development or medical devices, clinical trials are only one factor in a long process of decision-making. Therefore, discussions between the entrepreneurs and the regulator need to be ongoing and unmediated."

More improvements are required

According to Shahory, the Ministry needs to address also the following:

1. Although a company can submit simultaneously in more than one location, currently the Ministry of Health and the Helsinki processes are dependent on each other and not fully synchronized. These dependencies and asynchrony create bottlenecks that could and should be removed.
2. 'Targets,' the software the PI (principal investigator) works with to submit a new clinical trial, is archaic and difficult to work with. Since developing a new, simple online system will take time, Shahory suggests that to simplify the process like in Europe files will be submitted by email.
3. The Ministry should use the same set of rules internally as well as externally. Meaning, the Ministry will apply to the industry the same standards and service level agreement it had implemented internally (60 days response).

Digital health; a tremendous potential

Over the years the hospitals have accumulated immense amounts of information and medical data about appropriate treatment protocols, deterioration patterns, intervention points, and so forth. And, recently, the Israeli Government approved a national digital health program for which it had allocated 922 million Shekels (about \$250 million) over five years. Furthermore, since Israel is known for its exceptional human talent; creative data scientists and artificial intelligence (AI) engineers that have the capacity and the know-how to analyze this valuable information; "Collaborating," says Shahory, "can create significant value and serve as a competitive advantage on the international level for both the Israeli health system and for the industry. This segment", he adds, "has the potential to exceed even the local cyber industry."

However, to realize the potential, there are two barriers to overcome privacy protection, and commercial negotiations between the research institutes/hospitals and the industry. According to Shahory, the government can resolve them by:

- Setting standards for data anonymization.
- Determining criteria as well as clear, transparent, and reasonable compensation mechanisms that will allow and encourage the hospitals to share their information with the industry.

About Lior Shahory

Lior serves as the CEO of Incentive Incubator since 2005 and as General Partner at Peregrine Ventures. Incentive has managed to reach 7 exits (Valtech, Neovasc, Bballoon, NLT spine, Eurekify, Marketyze, Rocketick) and has received 7 excellence awards by the state of Israel for its performance. With extensive experience in early stage investments due diligence, strategic planning, project management and business development Lior is working closely with entrepreneurs to establish successful companies. Prior to joining Incentive Lior served as the Deputy Program Director of the Incubators Program. Lior serves on the Boards of Memic, Eximo, Restore, Cordio, Magneto, Outsense, Sinusafe and Artask.

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Digital health has tremendous potential at a national level but requires the government's help to realize it.

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