

# Israel's Big Data Health Project of "historical significance"

Israel's Prime Minister Benjamin Netanyahu announced on 25 March 2018 the investment of NIS 1 billion in digital health and the launch of a new Big Data Health Project that aims to provide researchers, developers and global companies with the ability to access the health data of almost nine million Israeli citizens currently held by Israel's four Healthcare Maintenance Organizations ('HMOs') in order to aid the development of preventative and personalised medicine. Netanyahu's speech, made during his weekly Cabinet meeting, stressed the importance of each Israeli citizen's consent to sharing their personal health data as an absolute right, whilst commenting on the immense value of such a healthcare database at global level and that he has already met with many global companies that are interested in coming to Israel to be involved in the Project.

"Israel is making a move of historical significance," said Dr Yossi Bahagon, Founder and CEO of Luminos, and Member of the *Digital Health Legal* Editorial Board. "Israel is positioning itself as an industry leader in healthcare innovation in the years to come. This goes way beyond becoming the first country in the world to build a comprehensive and longitudinal clinical data asset at a national level. The multifaceted data repository, which will span clinical, physiological, genetic, imaging and pathology datasets, will be the substrate for advanced Big Data and artificial intelligence technologies that will create a new era of healthcare - one that will be outcome-based, proactive and personalised."

Despite Israel being one of the first countries in the world to develop a fully digitalised healthcare system, privacy and confidentiality concerns have been raised in relation to the amount of sensitive personal data that will be accessible by pharmaceutical and other private companies through the Project. The current legal framework in Israel provides for general protection of health data as private, sensitive and confidential. "The Government appears to be aware of such concerns and has declared that it plans to address them, *inter alia*, by implementing 'de-identification' measures to reduce the risk that medical data can be connected to an identifiable person, by creating consent mechanisms and by imposing restrictions on the access and use of data by companies," explains Assaf Harel, Partner at Gornitzky & Co. "In implementing the Project, the Government will need to carefully define what constitutes informed consent of an individual for the use of his/her personal data and make sure that consent mechanisms are unambiguous. Obtaining such consent could create an administrative challenge, especially with respect to medical data that was collected prior to the implementation of the Project."

According to Netanyahu the field of digital health has the potential to be the next growth industry for the Israeli economy, with greater potential than intelligent transport and cyber security. Netanyahu explained that the development of Israel's strong markets in intelligent transport and cyber security has not always been a result of Government decisions. "The vehicle industry developed on its own, we just did not bother it. We did not bother it with over-regulation or high taxes and it developed on its own with the advantage of Big Data, connectivity and artificial intelligence. It happened on its own. Cyber did not happen on its own. It required feeding, our unceasing investments in our computer and intelligence units; therefore, it depends on government investment. Health will not happen on its own; it requires our investment, to set this vision and guide it in a healthy way - and we are doing so," commented Netanyahu.

Efrat Shapira-Orren, Head of the Healthcare practice group at Tadmor-Levy and General Counsel of Assuta Medical Centers Ltd, explains that Israel's new Big Data Health Project attempts to utilise the special characteristics of the Israeli health market, which is centralised into four HMOs that provide medical services and possess the electronic medical records of the entire population, in order to promote and develop personalised and preventative medicine. "It still remains to be seen what actual outcomes may result from such a broad national initiative, which involves several ministries and requires coordination, standardisation and connectivity between all medical records of all four HMOs," explains Shapira-Orren. "It also questionable to what extent HMOs will be interested in cooperating with such an initiative, as opposed to utilising their own data for research and commercial collaborations with artificial intelligence companies. Local collaborations may yield greater benefits to specific HMOs, which may be reluctant to share with the State or other HMOs."

The Israeli Ministry of Health is currently in the process of developing a detailed regulatory framework, following the OECD Recommendation on Health Data Governance made in January 2017 that called for the creation of a governance framework for the use of health data to encourage greater availability and processing of health data within countries and across borders for health-related public policy objectives, while ensuring privacy and security risks are minimised and appropriately managed. "According to circulars, which have already been published by the Ministry, it appears that such regulatory framework will include, in addition to data security, confidentiality and de-identification requirements, detailed reporting to the Ministry of Health regarding collaborations between health organisations and third parties pertaining to the use of health data," adds Shapira-Orren. "So, the big question is whether the regulatory framework will be sensitive and wise enough to provide for the essential protection for privacy, data security and proper use of data, while, at the same time, fostering and incentivising creativity and allowing health organisations to move quickly, at the pace required by startup companies, without imposing cumbersome bureaucratic requirements."

There is no specific timeline for implementation of the Big Data Health Project however, explains Daniel Lorber, Associate at Barnea Jaffa Lande & Co Law Offices. "Based on public statements, the high level of commitment of the Israeli Government to implement the Project and the significant resources being invested in this field - NIS 922 million in the next five years - we believe we will begin seeing developments in this field in the very near future," comments Lorber.