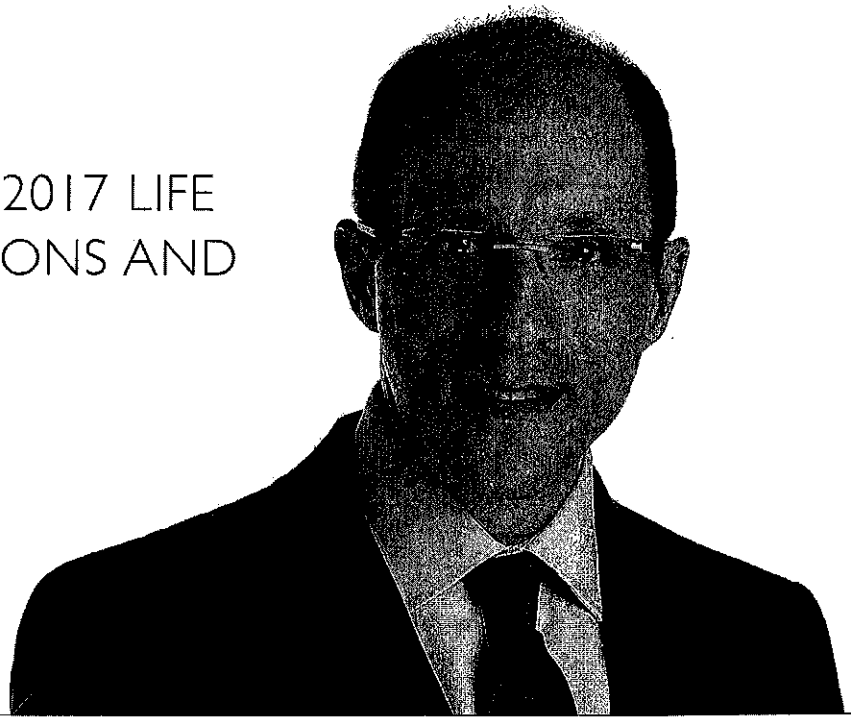

COMMENTS ABOUT 2017 LIFE SCIENCE TRANSACTIONS AND OUTLOOK FOR 2018

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It has been an exciting year in 2017, with many significant factors affecting growth and development, along with several transactions that we have been involved in. I will focus on the five most interesting in our practice.

DATA, DATA, DATA

Big data, analytics and artificial intelligence have presented new opportunities in the life science and medical device sectors. Dozens of new companies have formed, with most focusing on analysis of publicly and privately sourced information and some engaging in "deep learning". Data is driven from an abundance of sources: genetic testing, medical procedures, imaging tests (x-rays, MRIs), and user-generated sources (compliance).

Data is being used or offered for multiple related areas. Developers of technology and caregivers are seeking access to data for analytics for treatment (personalised medicine); for diagnosis; and for the drug development process and patient population identification. Some companies are developing deep-learning capabilities in order to expedite treatment and advice. Medical institutions are involved, to an increasing extent, in the provision of their stored data to companies, for the technology development. Such data allows companies to analyse their technologies and verify the underlying assumptions, but also to analyse the data and create novel means of diagnosis. Organisations are searching for devices and means to connect and optimise caregiving. They are involved in the integration of data driven solutions. Automated review and response of clinical data, including comparison and analysis of existing data, will allow for a more efficient and quicker outcome, for the benefit of patients, institutions and payers. Finally, centralised treatment of data is evolving, as well as development of data platforms, accessible across jurisdictions and platforms, which allow for online information relating to the status of treatment and use by parallel caregivers.

The data that is being licensed or used by technology development companies needs to be anonymised, and requires the approval of Internal Review Boards (formed under the Declaration of Helsinki) and relevant informed consents. In addition, the use and transfer of data raises multiple issues relating to cybersecurity, privacy and regulation.

In Europe, the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) will become enforceable on 25 May 2018. This will strengthen and unify data protection standards across the European Union, and, unlike the Directive of 1995, will be binding within the EU member countries. The GDPR prescribes that consent by the provider of data must be clear, explicit, distinguished from any other matter and provided in an intelligible and easily accessible form. Such consent must also be as easy to withdraw as it is easy to be given. Data subjects will be entitled to receive confirmation from the data controller as to whether or not (and where) personal data concerning them is being processed, and for what purpose. Increased enforcement and penalties, and the strengthening of the conditions for consent of personal data processing are expected to raise new issues in 2018.

Data, its collection, protection and commercialisation, as well as the development of new technologies based on data, will undoubtedly be key in our respective practices in 2018 as well. Or, according to Accenture's 2017 survey, "74% of Life Sciences executives believe A.I. will result in significant change and even completely transform their industry within three years … 74% of life sciences executive agree that their org is entering digital industries that have yet to be defined" (available at hitconsultant.net/2017/10/06/Accenture-life-sciences-industry-tech-visions).

There is still something to be desired in terms of fees and services, but the direction is clear.

COMMODIFICATION OF SERVICES

With the world becoming smaller, companies' managements becoming experienced and buyers being selective, young companies are reaching out to major CROs for a wider array of services, with increasing success. Services, which were provided in the past to large companies only, are now being sought for and provided to smaller companies desiring to conduct the most professional trials from the start. Experienced management focuses on value creation by developing professional building blocks by way of outsourcing, where required, in order to verify success in future scrutiny and diligence reviews in strategic transactions. Technology transfer companies of research institutions are increasingly active in the provision of services to others, thus allowing younger companies to enjoy the breadth of experience and innovation from the earliest stages. These are beneficial outcomes for the companies, and, in turn to the patients. The expedited, more efficient manner in which companies may operate mean less time to market. It allows investors to verify that their funds are well spent, attempting to maximise each payment milestone.