

“Big data”: big business?

“Big data” here, “real-world data” there. In the run-up to the 2020s, health data are raising many hopes, but are also whetting financial appetites.

Big data: opportunities. “Big data” in healthcare means digital data produced by healthcare systems, patient management processes and healthcare businesses, by social networks, connected devices and other “healthcare applications” and by search engines. Often promoted as the new “real-world data”, these data have many potential uses. In particular, they can lead to the detection of rare but serious treatment-related adverse effects, for example by assessing the number of deaths caused by the use of *benfluorex* (Mediator[®]) in France (1).

These vast quantities of health data are a useful complement to the knowledge acquired about drugs after marketing authorisation (MA). Nevertheless, their increasing availability must not serve as a pretext for downplaying the value of clinical trials prior to MA, or of rigorous post-MA studies (1). Indeed, the reliability of big data in evaluating the efficacy of a drug is still uncertain, with many interpretation biases which comparative randomised clinical trials are better placed to control, thanks in particular to the use of randomisation and double-blind design (2).

The business of big data: Europe versus the USA and Asia. The exploitation and commercialisation of big data in healthcare are whetting financial appetites in a big way. Some players are hoping to mine data collected, to some extent without the person’s knowledge, via social networks, internet searches, and other healthcare apps, in order to create and exploit databases. This is the case with the US and Asian giants of the internet, social media, smartphones and other connected devices. However, since 2018, the General Data Protection Regulation (GDPR) has forced those operating in Europe to obtain consent from individuals to use their data, and to allow them to control access (3).

Some players have rapidly taken this constraint on board. In early 2019, one of them linked up with France’s Gustave Roussy Cancer Institute to gain access to the healthcare data of patient volunteers, whose consent is recorded in return for remuneration in the form of digital tokens convertible into money (4). Other partners of this consortium are the companies Servier and Pierre Fabre, the latter expressing its enthusiasm at the idea of “*advancing the drug approval process*” (5).

The hunt is on for data on patients’ lives and health.

Prescrire

► Translated from *Rev Prescrire* August 2019
Volume 39 N° 430 • Page 616

Sources 1- Bégau B et al. “Les données de vie réelle, un enjeu majeur pour la qualité des soins et la régulation du système de santé. L'exemple du médicament Rapport final” French Ministry of Health 2017: 105 pages. 2- Gerstein HC et al. “Real-world studies no substitute for RCTs in establishing efficacy” *Lancet* 2019; **393** (10168): 210-211. 3- Chu R “GDPR and blockchain: how the US’ lack of preparation could swing the balance of power to Europe” 24 May 2018. www.ccn.com accessed 10 May 2019: 6 pages. 4- “Gustave Roussy et Embleema nouent un partenariat pour concevoir un modèle européen de valorisation éthique des données de soins” 5 March 2019. www.gustaveroussy.fr accessed 10 May 2019: 2 pages. 5- “Devenez propriétaire de vos données de santé grâce à la blockchain!” www.embleema.com accessed 10 May 2019: 2 pages.