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The new Health Information Institute in France

In France, the Health Information Institute ('INDS') has begun to accept requests for authorisation to access the new National Health Data System ('SNDS'), as part of measures brought in by Act No. 2016-41 of 26 January 2016 (the 'Reform Law'). Jeanne Bossi Malafosse, Partner at Delsol Avocats, and Carol Umhoefer, Partner at DLA Piper, assess the new authorisation procedure for the provision of health data access in France, and consider the issues that may arise from its implementation.

Background

France's Reform Law provided for the creation of the INDS. One of the INDS's principal purposes is to authorise access to another measure of the Reform Law, the SNDS. Two decrees published in December 2016 specified, respectively, the governance rules of the SNDS and the entities having access to it, as well as the rules for the INDS authorisation procedure. More recently, the INDS's by-laws were officially adopted in June 2017 and the INDS launched its preliminary website in July 2017 (see www.indsante.fr). Requests for authorisation have been accepted from 28 August 2017.

These changes have occurred in the context of another significant development ushered in by the Reform Law, which revised Chapter IX, and rescinded Chapter X, of the French Data Protection Act. Now, the new Chapter IX regroups all health research activities and sets out the various requirements for authorisation of personal health data in the context of those activities, whereas before, Chapter X set out simplified requirements, notably for certain observational research, which were relied upon by industry.

The INDS' role

The INDS is the successor to the Health Data Institute founded in 2007. The INDS has five objectives, namely to:

- oversee the quality of health data and the terms of access to that data, and ensure the security of the data and facilitate its use;
- issue an opinion regarding the public interest of proposed research activities;
- ease access to certain types of data under conditions approved by the French Data Protection Authority ('CNIL');
- contribute to the definition of uses for anonymised data and statistics made available to the public, and;
- operate as a 'one stop shop' for requests to access health data for research purposes, including requests to access the SNDS.

Even in the context of a national health insurance scheme, such as France's, the SNDS compiles a particularly impressive quantity of health-related data from multiple sources, notably data from France's national health insurance database (the 'SNIIRAM') and from the Epidemiology Centre of the world-renowned French National Institute of Health and Medical Research ('INSERM'). The SNDS was officially created on 1 April 2017.

In connection with requests to access the SNDS (and also more generally), the INDS may evaluate the public interest of a research project, either upon request from the CNIL or from the Ministry of Health, or upon the INDS' own initiative. The INDS must issue its opinion within one month. However, the full significance of the INDS' role is not yet known, as the notion of public interest is not clearly defined, and this therefore potentially injects subjectivity into the INDS' process for issuing opinions. Moreover, as the public interest was not previously a criterion for determining whether a research project complied with applicable laws or whether an authorisation should be issued, there is understandably some concern in the sector about this new focus on public interest.

To assist the INDS, an expert committee has been created, which reports to the INDS' President. The Committee's goal is to establish and maintain a policy on how to evaluate the public interest in research

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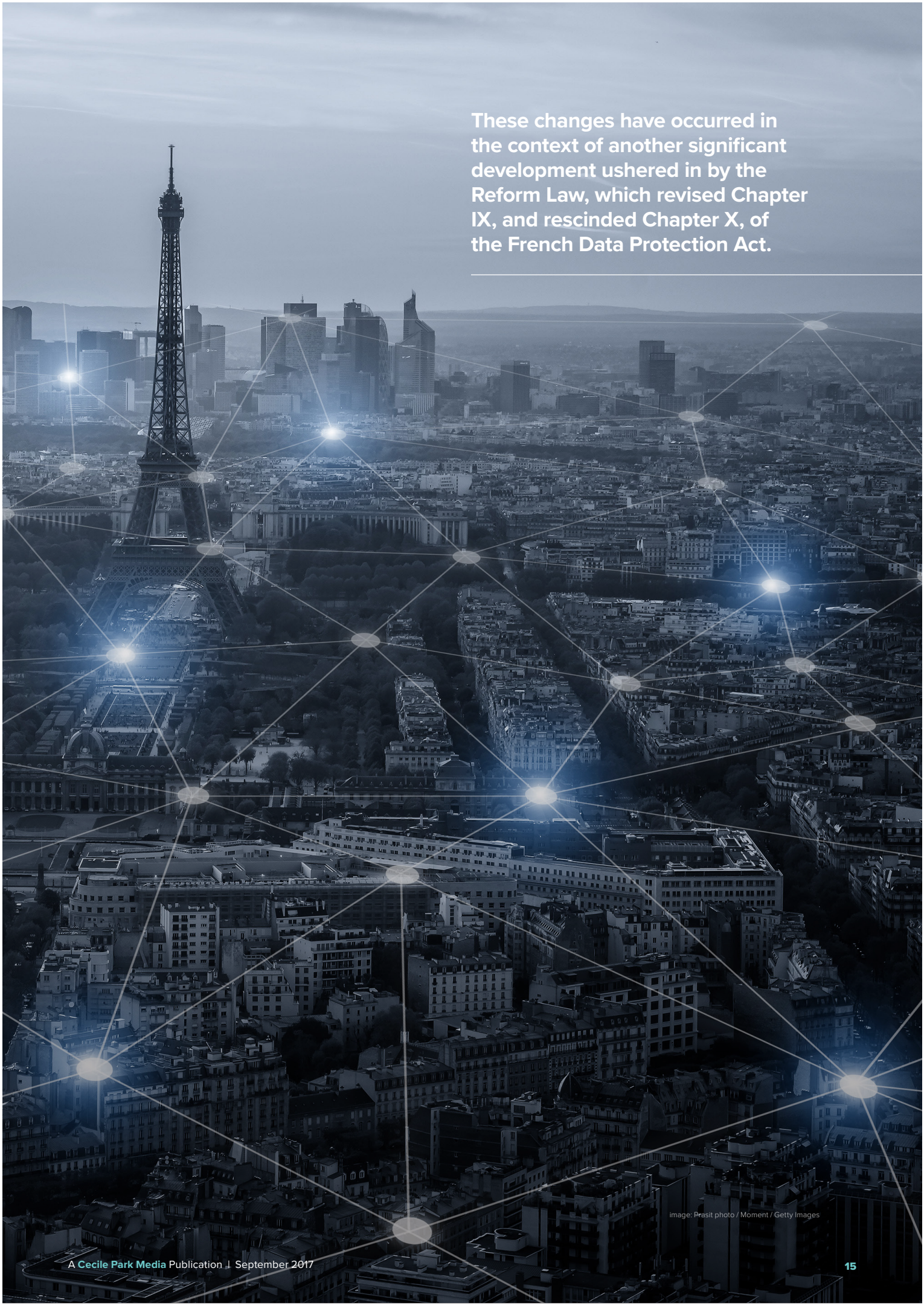

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activities, and to advise the INDS in connection with its opinions regarding the public interest. The Committee will be composed of nine to 17 experts with requisite experience, nominated by the INDS' President and selected by its board of directors. The policy positions of the Committee are eagerly awaited by the sector, as the Committee could be key in establishing *de facto* the contours of the public interest criterion.

The INDS and the new authorisation procedure

The authorisation procedure - from which notably clinical trials and observational studies involving health products are expressly excluded - commences with the filing of a request with the INDS. The INDS directs the request either to the Committee for the Protection of Persons ('CPP') or the newly formed Committee for Research, Studies and Assessments in the field of Health ('CEREES'), which replaces the Advisory Committee on the Treatment of Research Information in the Field of Health ('CCTIRS'). The CEREES will issue an opinion on whether use of personal data is necessary, on the relevancy of that data in view of the purposes of the research activities and, as applicable, on the scientific value of the proposed research.

After issuance of an opinion by the CEREES or the CPP, the CNIL is then consulted and will issue its authorisation 'in accordance with the principles set forth in the [data protection law] and in light of the public interest of the research, study or evaluation.' If the research project requires access to the SNDS, the procedure will vary depending on whether the petitioner is in the private sector (such as manufacturers of health products or insurance companies) or the public sector.

Private sector actors must provide the INDS with an authorisation from the CNIL and a declaration of interest in respect of the purpose of the project and the protocol, specifying the methodology for verifying the validity and the results of the research project. The INDS then publishes the CNIL authorisation, the declaration of interest, and subsequently the results and methodology.

Open questions about the new authorisation procedure

A first line of questions about the new authorisation procedure relates to its apparent complexity, and whether it can be simplified.

A second line of questions, as mentioned above, concerns the notion of public interest, which is not defined and appears to be the principal criterion for the INDS's evaluation of whether to authorise a particular project.

Third, if the petitioner cannot demonstrate that the conditions of processing make it impossible to use SNDS data for any prohibited purpose, the petitioner must engage a research lab or a technical organisation to conduct the processing. To this end, in July 2017 a decree was published setting forth standards of confidentiality, expertise and independence for these labs and technical organisations that process health data for, *inter alia*, pharmaceutical companies and other actors that manufacture or sell health products.

Fourth, there remain fundamental questions about the authorisation procedure applicable to certain observational studies, which may or may not still benefit from a simplified procedure (the so-called MR-003) adopted by the CNIL (see below).

Faced with the multitude of requirements and uncertainties, several industry federations announced earlier this year that they would not participate in the creation of the INDS, claiming that the authorisation procedure is contrary to the stated purpose of making health data more widely available, restricting access to some while the 2016 Reform Law provides permanent access (either to the totality of the SNDS data, or to portions of it) for others. Add to this the delay in setting up the INDS and the CEREES (while the latter's predecessor, the CCTIRS, stopped accepting petitions nearly a year ago, in November 2016), and the current dismay of the industry is evident. One bright light however is the power granted to CNIL to simplify the authorisation procedure. Several recent CNIL decisions demonstrate its willingness to reduce the complexity of these procedures, consistent with the spirit of the EU General Data Protection Regulation, which will apply from 25 May, 2018.

The CNIL is authorised to adopt simplified standards (méthodologies de référence, or 'MR') for the most common cases of health data processing. The abovementioned MR-003 for observational studies - the application of which is now unclear - is just one example of this. Clinical trials (excluded from the INDS authorisation procedure) have long been eligible for a simplified standard, the MR-001, where the trial sponsor ensures that clinical trial data is processed consistent with the standards set out in MR-001 (co-author of this article, Jeanne Bossi Malafosse, led the development of the MR-001 standard for clinical trials while she was at the CNIL).

The CNIL is also authorised to adopt so-'single authorisations' (autorisations uniques, or 'AU'), such as for pharmacovigilance schemes. Like an MR, entities that qualify under a 'single authorisation' adhere to its terms and once certified as compliant are eligible to obtain an authorisation automatically. As a consequence, the sector is waiting on new initiatives from the CNIL to reduce the complexity of the authorisation procedure inaugurated by the Reform Law, which would go far in reassuring sector actors that the promise of access to important health data resources is not illusory.