

French Consultative Ethics Committee for health and life sciences creates a Pilot Ethics Committee for digital technology

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In France, the National Consultative Ethics Committee for health and life sciences (the CCNE - *Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé*) was created in 1983. Its mission is "to give opinions on ethical problems and societal issues raised by progress in the fields of biology, medicine and health" (Article L. 1412-1 of the French Public Health Code).

In a [press release dated 2 December 2019](#), the CCNE announced that it set up a Pilot Ethics Committee for digital technology (*Comité pilote d'éthique du numérique*) on instructions from the French Prime Minister. This pilot committee is composed of 27 members who are digital specialists, academics, doctors, lawyers, and representatives of public institutions and authorities (such as the CNIL - the French data protection authority). Various working groups will be set up. The mission of the pilot committee is to issue some guidance and opinions on ethical issues raised by digital technology and artificial intelligence (AI). It will work closely with some public authorities and institutions, such as the CNIL, the French National Institute for computer science and applied mathematics (Inria), the National Centre for Scientific Research (CNRS), and the French digital council (CNNum).

The first opinions of the pilot committee will be related to:

- Conversational agents (*chatbots*) on mobile phones and smart home devices for instance. The ethical issues concern notably transparency and information in the processing of collected data.
- Autonomous cars. The committee will analyse in particular shared responsibility for the producer, the insurer and the user.
- Medical diagnosis and AI. The committee will discuss the risks when predictive analytics are not followed, as well as the need for health professionals and users to understand these analytics and algorithms.

The first meeting of the pilot committee took place on 4 December 2019. Its first activity report

will be submitted to the CCNE in early 2021.

The set-up of this committee is a further step in the shift of focus in France on ethical concerns surrounding digital transformation and AI, which may lead to further regulation of technologies using AI.

For instance:

- upcoming [regulations on bioethics](#) (planned to be adopted in H1 2020) will impact the use of AI tools by healthcare professionals, with particular requirements in terms of information of patients, involvement of HCPs in the configuration of the tools, and a new concept of "traceability by design" for AI tools;
- the French authority in charge of health technology assessments (the HAS - *Haute Autorité de Santé*), is also developing an [evaluation matrix](#) for medical devices with decision-making systems incorporating AI. This matrix would support evaluating control over decision-making process of medical devices such as the characteristics of training, test and validation data as well as the applicable AI model and algorithm. The draft matrix is subject to a public consultation procedure which will close on 15 January 2020.

Industry players should pay close attention to these regulatory developments, in particular medical device companies devising their market access pathway in France for AI-enabled technology, and any other companies venturing with medical devices companies to develop such products.

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