Italy adopts new rules for the conduct of non-profit clinical trials, allowing the commercial use of the related results

On 8 May 2019, the Italian government approved in a definitive way the legislative decree intended to enhance the social and ethical use of research by supporting non-profit clinical trials.

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On 8 May 2019, the Italian government approved in a definitive way the legislative decree implementing Article 1 of Law no. 3/2018 (so called "*Legge Lorenzin*"), which mandated the government to reform the Italian legislation on clinical trials, with the purpose of paving the way towards the future application of the Clinical Trial Regulation (EU) 536/2014.

Among other things, the approved legislative decree is intended to enhance the social and ethical use of research by supporting non-profit clinical trials. In particular, the new provisions allow a wider use for commercial purposes of the results of observational clinical studies and non-profit clinical trials, provided that the sponsor reimburses direct and indirect costs related to the trial, as well as any lost revenue resulting from the qualification of the study as a non-profit activity, including potential income related to the exploitation of intellectual property rights. This is one of the most significant changes introduced by the legislative decree at issue, since the pre-existing legislation on non-commercial trials (Ministerial Decree 17 December 2004) prevented pharmaceutical companies from acquiring *ex ante* contractual rights to study data, thereby generating uncertainty and hindering effective and socially useful research.

Furthermore, the approved legislative decree provides that, by means of a decree to be issued within 31 October 2019, the Ministry of Health shall:

- adopt measures aimed at facilitating and supporting non-profit clinical trials and observational studies
- identify procedures for the coordination between public and private sponsors in the context of the same clinical trial or clinical study, also in order to acquire information following the placing on the market of medicines
- establish criteria to identify non-profit clinical studies and clinical trials conducted with collaboration between private and public sponsors, and
- set out procedures for the transfer of data relating to the clinical trial to the sponsor and their use for medicines registration purposes.

The new legislative decree will enter into force following its publication on the Italian Official Journal, which is expected to occur soon.

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