Important updates regarding clinical trial contracts in Italy

As of January 31, 2022, there is full implementation of the Regulation (EU) No. 536/2014 (the "Regulation"). From such date, a one-year transition period began, during which applications for clinical trial authorizations under the former Regulation can still be submitted (on a voluntary basis). After this transition period, this option will not be applicable, nor will be the governing national regulations. In fact, within the next three years all ongoing trials will switch to the new requirements under the EU Clinical Trials Regulation (CTR).

In order to increase the transparency of clinical trial information, a portal dedicated to the management of all clinical trials in Europe (Clinical Trials Information System, CTIS) has been developed, and it will be key to enhancing transparency and strengthening collaboration, information exchange and decision-making processes between and within member states.

The National Coordination Center for Ethics Committees by circular dated May 30, 2022, adopted new contract schemes for clinical trials on medicines and clinical investigations on medical devices, which can be downloaded from https://www.aifa.gov.it/en/centro-coordinamento-comitati-etici

The Coordination Center adopted the following contract outlines:

(a) Contract for conducting clinical trial on medicines;
(b) Contract for conducting independent clinical trial on medicines;
(c) Contract for conducting clinical investigation on medical device not CE marked or CE marked but used outside the scope of its intended use.

The "Contract for Conducting Clinical Investigation on Medicinal Products" (letter a) has been updated with reference to the normative of the Regulation.
The "Contract for Conducting Independent Clinical Trial on Medicines" (letter b) was adopted for the first time following the publication of the Decree of the Minister of Health in November 30, 2021.
The "Contract for conducting clinical investigation on medical device not CE marked or CE marked but used outside the scope of its intended use" (letter c) has been entirely revised from the version adopted on September 25, 2020, in particular considering the application of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017, on medical devices.

These updates, which are part of a broader process of standardization of Member States' regulations, could be a driving force for investment by overseas sponsors, who until now -and before the recent regulatory changes- were deterred by bureaucracy and non-homogeneity of procedures.