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Votre lettre du	Vos références	Nos références	Annexe(s)	Date
12/06/2016		911635	/	

Concerne : Request for Statement by the Agency confirming KCE Trials as non-commercial trials

Monsieur Hulstaert,

Vous trouverez ci-dessous le *statement* de l'AFMPS demandé par le KCE afin de rassurer les hôpitaux universitaires que les droits non exclusif d'utilisation des données reconnus par eux au KCE n'auront pas d'impact négatif sur la reconnaissance des expérimentations comme non commerciales, à partir du moment où l'article 2, 15°, a) et b) de la loi du 7 mai 2004 sont également respectés.

FAHMP understood that the question of the candidate-sponsors is whether the rights which are requested to be granted to KCE under the template agreement, more particularly the non-exclusive right to use the results (including anonymized and/or coded study data), correspond with the requirement of article 2, 15°, c) of the Law of 7 May 2004.

The sponsor will be selected by KCE to initiate, perform and manage the study within the KCE Trials Program, which objectives are to achieve better care for the patients, increase efficiency in health care and to design and evaluate health care related policies and decisions. KCE will fund the study. In this set-up it is justified that KCE (or other governmental agencies or bodies) receives the right to use the results for such non-commercial purposes.

To the extent that the sponsor exercises the intellectual property rights on the concept and performance of the study and on the scientific data arising therefrom and that the rights granted to KCE under the agreement are non-exclusive and for the aforementioned specific non-commercial purposes only, said rights granted to KCE under the agreement (including the right to use anonymized and/or coded study data) are not in contradiction with the requirement set forth in article 2, 15°, c) of the Law of 7 May 2004.

Of course, the experiment will also have to meet the criteria under a) and b) of Article 2, 15°, of this Law, to be qualified as « non-commercial ».

It is advisable that the sponsor, in its request for permission of the study, refers explicitly to the above confirmation.

Je vous prie d'agréer, Monsieur Hulstaert, l'assurance de ma considération la plus distinguée.



Xavier De Cuyper
Administrateur général