ansm
Agence nationale de sécurité du médicament et des produits de santé

CLINICAL TRIAL AUTHORIZATION OF DRUG FOR HUMAN USE

Date : 04 JUIN 2018

Identifier of the clinical trial			
Title	PRODIG : Prevention of new onset diabetes after transplantation by a short term treatment of Vildagliptin in the early post-transplant period		
Promotor	CHU Besançon		
Ref. to remember	MEDAECNAT-2018-03-00009	N° EudraCT	**2016-002023-28**

Sender	**Recipient (applicant: name / company / phone)**
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Given the public health code and in particular Article L. 1123-8, and the regulatory provisions adopted for its application, and having regard to the clinical trial authorization application file sent to the National Agency for the Safety of Medicines and health products (ANSM);

Considering the supplements filed by the promoter on May 28th, 2018 and in particular the protocol of the test cited in modified object (version 6 dated May 22, 2018) following the request of the ANSM;

The authorization mentioned in article L. 1123-8 of the Public Health Code is granted for the clinical trial mentioned above.

I ask you to send any request for modifications concerning this file by email addressed to the box: **ams-essaiscliniques@ansm.sante.fr.** When sending these files, I ask you to ensure that the subject of the message is marked: **MSA / EUDRACT No.** for SM submitted for authorization or for mixed dossiers (with modifications submitted for authorization and others for information).

Direction des médicaments en cardiologie, rhumatologie, stomatologie, endocrinologie, gynécologie, urologie, pneumologie, ORL, allergologie
Pôle « endocrinologie, gynécologie, urologie, pneumologie, ORL, allergologie »
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