Inserm / Université Paul Sabatier, Toulouse 3
UMR 1027
Epidémiologie et analyses en santé publique : risques, maladies chroniques et handicap

Equipe 4 : Génomique, biothérapies et santé publique : approche interdisciplinaire»
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Instituts thématiques

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MeDALL Mechanisms of the Development of ALLergy

Commission européenne/
Unit SANCO/C/8,
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Toulouse, le 13 mai 2011

Objet : Answer to REVISION OF THE CLINICAL TRIALS DIRECTIVE 2001/20/EC, CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION" by the **MeDALL** Consortium

Please find attached the answer to the "REVISION OF THE CLINICAL TRIALS DIRECTIVE 2001/20/EC, CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION" by the MeDALL Consortium. MeDALL-Mechanisms of the Development of ALLergy is a collaborative project supported by the European Union under the Health Cooperation Work Programme of the 7th Framework programme (grant agreement number 261357) [http://medall-fp7.eu/]. The MeDALL consortium encompasses 23 public and private institutions, including 3 European SMEs. It is coordinated by Institut National de la Santé et de la Recherche Médicale (France). Pr Jean Bousquet (CESP U1018 INSERM, Villejuif, France) is the project coordinator and Dr. Josep M. Anto, (Centre de Recerca en Epidemiologia Ambiental (CREAL), Barcelona, Spain) is in charge of the scientific coordination. MeDALL aims to generate novel knowledge on the mechanisms of initiation of allergy from early childhood to young adulthood, in order to propose early diagnosis, prevention and targets for therapy. A novel definition of phenotypes of allergic diseases and an integrative translational approach are needed to understand how a network of molecular and environmental factors can lead to complex allergic phenotypes. We include also the presentation of the consortium and project and this answer can be made public.
Several Work packages deal with clinical research and are thus interested by the public consultation on the CONCEPT PAPER REVISION OF THE CLINICAL TRIALS DIRECTIVE 2001/20/EC. One work package led by Dr Anne Cambon-Thomsen, Inserm U 1027, Toulouse, France is dealing with bioethical aspects and more generally the ethical, legal and social aspects of the project. As part of this work a regular survey of public consultations of relevance for the project is performed. The present Consultation has been signalled, explained and circulated to all members of the project and contributions solicited. The draft answer has been prepared by Velizara Anastasova, jurist in Inserm U 1027, in collaboration with other members of the team, especially Aurelie Mahalatchimy and Emmanuelle Rial-Sebbag, jurists, under the supervision of Dr Anne Cambon-Thomsen, MD, research director. A discussion between persons interested was then organised and the attached answer circulated to all participants before submission.

The MeDALL consortium is grateful to the Commission to have been given the opportunity to contribute to this consultation.
VELIZARA ANASTASOVA and ANNE CAMBON-THOMSEN, on behalf of the MeDALL consortium.

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