

To whom it may concern,

Regarding the document for public consultation : "Implementation of the Advanced Therapies Regulation: public consultation on the Revised Clinical Trial Application Form as regards advanced therapy investigational medicinal products"

**COMMENTS FROM The EU FP6 integrated project "RISET" : Reprogramming the immune system for the establishment of tolerance, Contract N° 512090 IP, web site : [www.risetfp6.org](http://www.risetfp6.org) . Coordinator: Pr. Michel Goldman.**

Person submitting the comments on behalf of the Riset consortium : Anne Cambon-Thomsen, [cambon@cict.fr](mailto:cambon@cict.fr)

Document prepared with the help of Aurélie Mahalatchimy (PhD in Law).

The document was highlighted by Kathryn Wood to the RISET consortium involved in clinical trials using cell therapy and in regulatory and ethical issues, upon suggestion by Anne Cambon-Thomsen. It was circulated in September 2008 to all the partners.

RISET is a research integrated project under FP6 dealing with biotherapies and especially cell therapy to the immune manipulation in the context of transplantation. Although several aspects of the project deal with diagnostic tests and assessment of markers for tolerance, one WP in RISET (WP3), under the leadership of Lucienne Chatenoud (Paris) is dedicated to clinical trials related to 1) tolerance induction. 2) Minimisation of immunosuppression. 3) Refining the use of tolerogenic drugs. More than 10 clinical pilot studies are being performed, in the context of transplantation.

People involved in this WP were especially asked to comment on the public consultation paper, but this possibility was also given to all partners. At this stage of development of such therapeutical products of human origin the Regulation (EC) No 1394/2007 does not apply.

No member of the consortium communicated substantial comments on this Form. However the members of the Riset Consortium continue paying attention to the implementation of the Regulation, in the eventuality of a future marketing application.

In case some late comments would be communicated we would send them to you for information.

On behalf of the Riset Consortium

Anne Cambon-Thomsen and Aurélie Mahalatchimy

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