

Re: Rép. : Putative misconduct in SG relevance to France clinical trial

Sent: Sunday, February 14, 2021 2:09 PM

From: Helmy, M. helmy.m@protonmail.com

To: lanceur alerte lanceur.alerte@ansm.sante.fr

CC: lanceur alerte lanceur.alerte@ansm.sante.fr, presse@ansm.sante.fr presse@ansm.sante.fr, communication.ANSM@ansm.sante.fr communication.ANSM@ansm.sante.fr, ansm-factures@ansm.sante.fr ansm-factures@ansm.sante.fr, agence.comptable@ansm.sante.fr agence.comptable@ansm.sante.fr, experts.missions@ansm.sante.fr experts.missions@ansm.sante.fr, dsi-contact@ansm.sante.fr dsi-contact@ansm.sante.fr, dajr@ansm.sante.fr dajr@ansm.sante.fr, exportation-medicaments@ansm.sante.fr exportation-medicaments@ansm.sante.fr, importation-medicaments@ansm.sante.fr importation-medicaments@ansm.sante.fr, communications.DM@ansm.sante.fr communications.DM@ansm.sante.fr, affaires.internationales@ansm.sante.fr affaires.internationales@ansm.sante.fr, contactspharmacopeefrancaise@ansm.sante.fr contactspharmacopeefrancaise@ansm.sante.fr, preparations-hospitalieres@ansm.sante.fr preparations-hospitalieres@ansm.sante.fr, atu@ansm.sante.fr atu@ansm.sante.fr, materiovigilance@ansm.sante.fr materiovigilance@ansm.sante.fr, reactovigilance@ansm.sante.fr reactovigilance@ansm.sante.fr, cosmetovigilance@ansm.sante.fr cosmetovigilance@ansm.sante.fr, erreur.medicamenteuse@ansm.sante.fr erreur.medicamenteuse@ansm.sante.fr, visapublicite@ansm.sante.fr visapublicite@ansm.sante.fr, insbio1@ansm.sante.fr insbio1@ansm.sante.fr, biosecurite@ansm.sante.fr biosecurite@ansm.sante.fr, Inspection.PSL@ansm.sante.fr Inspection.PSL@ansm.sante.fr, ipplf@ansm.sante.fr ipplf@ansm.sante.fr, insmp@ansm.sante.fr insmp@ansm.sante.fr, BPC@ansm.sante.fr BPC@ansm.sante.fr, insmar.cos@ansm.sante.fr insmar.cos@ansm.sante.fr, insmar.dm@ansm.sante.fr insmar.dm@ansm.sante.fr, insmar.div@ansm.sante.fr insmar.div@ansm.sante.fr, dvs.defauts-qualite@ansm.sante.fr dvs.defauts-qualite@ansm.sante.fr, rupture-stock@ansm.sante.fr rupture-stock@ansm.sante.fr, rsmcd@ansm.sante.fr rsmcd@ansm.sante.fr, cardio@ansm.sante.fr cardio@ansm.sante.fr, eccardio@ansm.sante.fr eccardio@ansm.sante.fr, infhép@ansm.sante.fr infhép@ansm.sante.fr, gaelle.louin@ansm.sante.fr gaelle.louin@ansm.sante.fr, pascale.lebleis@ansm.sante.fr pascale.lebleis@ansm.sante.fr, an.le@ansm.sante.fr an.le@ansm.sante.fr, helene.bruyere@ansm.sante.fr helene.bruyere@ansm.sante.fr, pascal.di-donato@ansm.sante.fr pascal.di-donato@ansm.sante.fr, nathalie.marliac@ansm.sante.fr nathalie.marliac@ansm.sante.fr, virginie.di-betta@ansm.sante.fr virginie.di-betta@ansm.sante.fr, helene.duvignac@ansm.sante.fr helene.duvignac@ansm.sante.fr, ec.dm-cos@ansm.sante.fr ec.dm-cos@ansm.sante.fr, cnq.labm@ansm.sante.fr cnq.labm@ansm.sante.fr, guichet.associations@ansm.sante.fr guichet.associations@ansm.sante.fr, communications.dm@ansm.sante.fr communications.dm@ansm.sante.fr, communication@ansm.sante.fr communication@ansm.sante.fr, efides@ansm.sante.fr efides@ansm.sante.fr, EC.DM-COS@ansm.sante.fr EC.DM-COS@ansm.sante.fr, etapharm@ansm.sante.fr etapharm@ansm.sante.fr, innovation@ansm.sante.fr innovation@ansm.sante.fr, Contactspharmacopeefrancaise@ansm.sante.fr Contactspharmacopeefrancaise@ansm.sante.fr, pharmacovigilance@ansm.sante.fr pharmacovigilance@ansm.sante.fr, dmcdiv@ansm.sante.fr dmcdiv@ansm.sante.fr, rh@ansm.sante.fr rh@ansm.sante.fr

Dear Sir or Madam,

Suspected fraud in clinical trials taking place on French territory and in the context of the report previously attached (*SG_misconduct_France_clinical_trial.pdf*) include:

1. Donepezil for cognitive impairment sponsored by Eisai Limited

(i) EudraCT Number: 2007-005435-28; Sponsor's Protocol Code Number: E2020-G000-333; Trial Status: Ongoing (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-005435-28/FR>)

(ii) EudraCT Number: 2007-005442-20; Sponsor's Protocol Code Number: E2020-G000-334; Trial Status: Ongoing (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-005442-20/FR>)

(iii) EudraCT Number: 2006-004888-54; Sponsor's Protocol Code Number: E2020-G000-326; Trial Status: Ongoing (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2006-004888-54/FR>)

For the same condition and sponsor, see also:

(iv) Unfavorable outcome and risk:benefit with elenbecestat, EudraCT Number: 2016-004128-42; Sponsor's Protocol Code Number: E2609-G000-302; Trial Status: Completed (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-004128-42/FR>)

2. Masitinib for various conditions sponsored by AB Science

(i) EudraCT Number: 2013-000491-14; Sponsor's Protocol Code Number: AB12008; Trial Status: Ongoing (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2013-000491-14/FR>)

(ii) EudraCT Number: 2011-001790-41; Sponsor's Protocol Code Number: AB11002; Trial Status: Ongoing (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2011-001790-41/FR>)

For the same drug and sponsor, see also:

(iii) EudraCT Number: 2010-020803-63; Sponsor's Protocol Code Number: AB07015; Trial Status: Prohibited by CA (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-020803-63/FR>)

(iv) EudraCT Number: 2010-021218-50; Sponsor's Protocol Code Number: AB09004; Trial Status: Prohibited by CA (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-021218-50/FR>)

It would be nice if you signed your message with your own name. It is not like I may hold you responsible for anything, the French People may do that.

Kind regards,
Mohamed Helmy
MD, PhD

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Singapore 648131

----- Original Message -----

On Friday, February 12, 2021 12:42 AM, lanceur alerte lanceur.alerte@ansm.sante.fr wrote:

Dear Sir,
You informed ANSM of suspected frauds that would be committed in Singapore.
However, I inform you that ANSM is only competent for clinical trials taking place on French territory.
Yours faithfully,
La direction des affaires juridiques et réglementaires
Agence nationale de sécurité du médicament
et des produits de santé (ANSM)
143/147 bld Anatole France
F-93285 Saint-Denis cedex
www.ansm.sante.fr
Confidentialité
Cette transmission est à l'attention exclusive du(des) destinataires ci-dessus mentionné(s) et peut contenir des informations privilégiées et/ou confidentielles. Si vous n'êtes pas le destinataire voulu ou une personne mandatée pour recevoir cet e-mail, vous l'avez reçu par erreur et toute utilisation, révélation, copie ou communication de son contenu est interdite. Si vous avez reçu ce mail par erreur, veuillez nous en informer par téléphone immédiatement et nous retourner le message original par courrier. Merci.
Avant d'imprimer, pensez à l'environnement.

"Helmy, M." helmy.m@protonmail.com 27/01/2021 18:38 >>>

Putative systemic misconduct in Singapore institutes of research and higher education and relevance to France clinical trials
Please find attached SG_misconduct_France_clinical_trial.pdf, a report on putative systemic research and academic misconduct in Singapore institutes of research and higher education. At least one France-Singapore clinical trial venture is implicated.
In Part I of this document evidence is presented of gross misconduct perpetrated by a core of 16 Principal Investigators in Singapore. The so-called 'Dementia Consortium' took S\$19.4 million in a grant probably called AcRF Tier 3 Defining the brain circuitry defects that cause dementia; due to systemic obfuscation practiced by the perpetrators this information cannot be verified from what the perpetrators chose to disclose. The grant was announced in 2018 and again in 2020. This grant was not used for the intended purpose. Arguably, nothing demonstrable and of note was done with the money. Ancillary findings in Part I include that individuals who are meant to safeguard due process and the integrity of human and animal research activity in Singapore are the same individuals who are breaching it, such as obscene violations of publisher guidelines in the editorial practice of the Head of the 'Dementia Consortium' who is a professor at Lee Kong Chian School of Medicine, Nanyang Technological University-Imperial College London, a celebrated neurologist affiliated in one way or another with almost all institutes of research and higher education in Singapore as well as the Singapore Ministry of Health, National University Health System, so on, and who absurdly discloses

financial and conflict of interest declarations in publications and in relation to major pharmaceutical corporations; a faculty member who is also on the animal ethics board and so his role in potentially approving his own meagre and substandard work and that of others in the 'Dementia Consortium' is unknown; a faculty member who appears to have two personas at nothing less than the National University of Singapore - assuming that is not the case we should not be in a situation where this is even contemptable; and a long-standing head of department also at nothing less than the National University of Singapore who appears to be running a thesis mill. These are just few examples.

In Part II evidence is presented of gross misconduct in the research and education activities of two faculty members of Nanyang Technological University and over a period of about a decade. These individuals have been receiving grants, producing extremely substandard work rife with indisputable scientific evidence of misconduct, duplicating this substandard work in articles published in indexed and non-indexed scientific journals and doctoral theses, obfuscating this substandard work in scientific terminology and incommensurate statistics, misreporting or forging administrative details such as official experimental protocol, grant details, and metadata in the Nanyang Technological University repository (DR-NTU), and demoralizing bachelor degree students. The co-authors of these two individuals received monies and credit for questionable work produced at Nanyang Technological University, and it is unclear if these co-authors were even in Singapore at the purported time of production of said substandard and duplicated work. Some bachelor degree students showed admirable resistance to dishonest work in their final year projects.

Part III is conflict of interest disclosure by the author.

Unfortunately any number of authorities in Singapore including executive and judicial bodies are not interested in pursuing corrective action which has obvious implications for France-Singapore clinical trial collaborations.

The quantity of resources which must have been thrown to silence, harass, and evict me is flattering.

Kind regards,
Mohamed Helmy
MD, PhD

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