Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA)

SCIENTIFIC COMMITTEE MEMBERS AND EXPERTS

I, Nathalie Gault

Organisation/Company: National Agency For The Safety Of Medicine And Health Products

Country: France

Declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical companies and in medical device companies are those listed below:

Pharmaceutical company interests

1.1 Employment

No interest declared

1.2 Consultancy

No interest declared

1.3 Strategic advisory role

No interest declared

1.4 Financial interests

No interest declared

1.5 Principal investigator

No interest declared

1.6 Investigator

No interest declared

1.7 Grant / Funding to organisation /institution

No interest declared

1.8 Close family member interest

No interest declared

1.9 Repurposing of a medicinal product

No interest declared

1.10 Any other interests or facts

_ Member of the scientific board of the French National society of Gastroenterology (January 2016_September 2021): evaluation and expertise of 50 study protocols/year; 20 granted/year
_ Member of the scientific committee of the Parisian regional clinical research group (January 2018_August 2021): evaluation and expertise of 200 study protocols/years; 40 granted/year
_ Member of the Data Safety Monitoring Board of PRETIPUV trial (prospective clinical trial of early oxybutinin treatment for boys with posterior urethral valves) (December 2019_September 2021). Academic sponsored and publicly funded.
_ Member of the steering committee and methodologist of the QUID NASH consortium (Identification of Validation of non_invasive biomarkers of the diagnosis and severity of NASH in type 2 diabetics) (January 2017 _ September 2021). Academic sponsored and publicly funded. Servier in the consortium.
_ methodologist of RIPORT study (Xarelto versus no treatment for the prevention of recurrent thrombosis in patients with portal vein thrombosis (January 2014 _ December 2022). Academic sponsored, publicly funded. Inclusions closed, manuscript published.
_ methodologist of VALDICAUSE study (efficacy of eculizumab on mortality in patients with vascular liver diseases and paroxystic noctural hemoglobinuria) (September 2017 _ September 2021). Academic sponsored, publicly funded. Inclusions closed, to be published.
_ methodologist of a database study on the use of proton pump inhibitors and the risk of pneumopathy in children (December 2020 _ September 2021) Academic sponsored, publicly funded.
_ methodologist of ICP_trastu01 (efficacy of intraventricular perfusion of trastuzumab in the treatment of leptomeningeal metastases of HER2+ breast cancer. Phase IIa clinical trial) (January 2019 _ December 2019). Not funded, not started, academic sponsored.
_ methodologist of PYELOCOURT (3_days IV antibiotic therapy versus 3_days IV followed by 7_days oral antibiotic therapy for acute pyelonephritis in children 1 month to 3 years old: a non inferiority open trial) (January 2021_September 2021).Academic sponsored, publicly funded.
_ methodologist of LOSTINDIAB (efficacy of low dose versus standard dose of insulin therapy in reducing the risk of complication in diabetic acidocetosis of adults in intensive care unit) (January 2019 _ December 2019) Academic sponsored, publicly funded.
_ methodologist of COTRIVAP (cotrimoxazole versus standard of care in the treatment of ventilation_acquired pneumopathy in intensive care unit). (January 2019 _ September 2021) Academic sponsored, not funded.
_ methodologist of a database study on the risk of cardiac events associated with checkpoint inhibitors. (January 2019 _ December 2020) Academic sponsored, not funded.
_ methodologist of LICHEN_IL17 (efficacy and safety of Ixekizumab in the treatment of lichen planopilaris and frontal and fibrosant alopecia resistant to corticosteroids) (January 2017 _ December 2021). Academic sponsored, not funded.
_ methodologist of a study of the evolution of muscular mass and performance before and after initiation of insulin therapy in diabetic elderly patients. (January 2021 _ December 2021). Academic sponsored, not funded.

1.11 Committee for Advanced Therapies (CAT) member or alternate

Not a CAT member or alternate

Medical device company interests

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

No interest declared

2.6 Investigator

No interest declared

2.7 Grant / Funding to organisation /institution

No interest declared

2.8 Close family member interest

No interest declared

2.9 Any other interests or facts

No interest declared

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality as long as the information or document has not been made public/is not in the public domain.
- Not to disclose (or authorise any other person to disclose) in any way to any third party [1] any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.
- When expressing views to indicate clearly that the views are my own if acting in my own capacity or those of the EMA, Management Board, Committee, Working Party, Expert Group or other group if acting on behalf of that group.
- Not to disclose any commercially confidential information.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate and complete to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

1. Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

Full Name:	Nathalie Gault
Date:	2024-03-20

For definitions of activities etc, refer to the policy on handling of competing interests.