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

SCIENTIFIC COMMITTEE MEMBERS AND EXPERTS

I, Francesca Rocchi

Organisation/Company: N/A

Country: Italy

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

Name of pharmaceutical company	Subject Matter
Innovative Medicines Initiative 2 (Grant agreement N. 853992)	Pharmaledger _ Blockchain Enabled Healthcare
Innovative Medicines Initiative 2 (Grant agreement N.777389)	conect4children (COllaborative Network for European Clinical Trials For Children) _ c4c _ IMI2_2016_10_04 Creation of a pan_European Paediatric Clinical Trials Network
PENTA Foundation and ViiV Healthcare UK (ViiV)	EPIICAL 2020_2024 (Novel strategy to induce long_term viral remission in Early Treated HIV Infected Children)
Innovative Medicines Initiative (IMI) 2	PROMISE (Preparing for RSV Immunisation and Surveillance in Europe): prosecution of the RESCEU _ REspiratory Syncytial virus Consortium in EUrope.
HORIZON_HLTH_2022_DISEASE_06_two_stage	In the framework of HORIZON_HLTH_2022_DISEASE_06_two_stage call (ID:

call (ID: 101080247)	101080247), the Applicant Bambino Gesù Children Hospital (OPBG), on the behalf of the Consortium ERK_TREAT, submitted to EMA a request for a Scientific Advice procedure, as a mandatory requirement requested by the call itself. The Scientific Advice procedures have to be submitted by the Applicants via the EMA IRIS platform. The undersigned, Francesca Rocchi, registered on the IRIS platform on behalf of her institution (OPBG) with the role of Industry Manager. The procedure was successfully submitted (EMA/SA/0000102580) and is under evaluation by CHMP. This Horizon Europe call is focused on the development of preclinical and clinical studies for rare diseases and conditions. ERK_TREAT Consortium has proposed, in addition to an extend program of preclinical studies, to perform some pilot studies, each involving exploratory proof_of_concept clinical tests of molecules licensed for different indications in six very_rare or ultra_rare renal diseases. The Scientific Advice EMA/SA/0000102580 was sought for the treatment with alpelisib of five patients harboring invalidating mutations of the OCRL gene that cause Dent 2 disease, in the framework of a proof of concept study.

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

I declare to be part of the PENTA ID Network _ https://penta_id.org/

On 31st of January 2024, I have been elected President of the INCIPIT Consortium (Italian Network for Paediatric Clinical Trials). The role is completely free of charge and does not involve any change in my position within the Bambino Gesù Hospital, the institution where I am employed.
INCIPIT is a recognised legal entity in the legal form of a not-for-profit consortium composed by the main Italian Paediatric Hospitals. INCIPIT represents the Italian network in the c4c project (see section 2.1.7 above) and acts as the Italian National Hub.
As a legal entity, INCIPIT is involved in several activities:
- feasibility and site selection for clinical trials sponsored by pharmaceutical companies (within the IMI2 c4c project)
- Regulatory advice to Angelini Pharma for a drug development through clinical experts identified within the INCIPIT Members.
- Sponsor of two multi-centre, non-profit, observational, prospective and retrospective (non-pharmacological) clinical studies.

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:	Francesca Rocchi
Date:	2024-02-06

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