



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

**Public Declaration of Interests and Confidentiality Undertaking of
European Medicines Agency (EMA),
Scientific Committee members and experts**

Public declaration of interests

I, **Ana Clara**

Organisation/Company: Instituto Português de Oncologia de Lisboa FG; Infarmed

Country: Portugal

do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

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

Period	Company	Products	Therapeutic Indication
10/2014-04/2019	CELLTRION	CT-P6 (herceptin biosimilar)	neoadjuvant and adjuvant

			treatment in patients with Her positive early breast cancer
03/2016-(current)	Merck Sharp & dohme corp	pembrolizumab	Advanced/Metastatic Adenocarcinoma and Squamous Cell Carcinoma of the Esophagus that have Progressed after First-Line Standard Therapy
09/2010-04/2013	BOEHRINGER	BIBW 2992 - afatinib	PATIENTS WITH METASTATIC HER2-OVEREXPRESSING BREAST CANCER FAILING ONE PRIOR TRASTUZUMAB TREATMENT
03/2015-(current)	ASTRAZENECA/GRUPO SOLTI	OLAPARIB	adjuvant treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy

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

- In my institution, there are some colleagues that provide consultancy advice and participate in clinical trials as investigators.

- In 2019, I have participated of a formation for Astrazeneca about hereditary breast and ovarian cancer. My participation included a presentation concerning referencing criteria towards consultation hereditary breast and ovarian cancer risk.

- In 2016, I have participated in elaboration of a book chapter about ovarian cancer (epidemiology, cinical features, treatment). This activity was promoted by Astrazeneca.

- I am integrated in a clinical work, promoted by ASPIC (Portuguese Association for Cancer Research) involving several portuguese institutions that treat patients with hereditary breast cancer. The aim of this study is to study prognosis of breast cancer associated with portuguese BRCA2 founder mutation c.156_157insAlu.

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.
- Not to disclose (or authorise any other person to disclose) in any way to any third party 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.

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 to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Full Name:	Ana Isabel Lopes Soares da Clara
Date:	2020-05-10

For Definitions of activities etc, refer to Policy on Handling of Conflicts of Interest / Electronic DOI template