

Forum for the development of clinical diagnostic assays

During the past few years, minimal residual disease analysis has moved from single-centre small-scale trials through to becoming an intermediate endpoint for licensure in CLL and potentially other diseases. However, the development process is not straightforward and this may in part be due to a lack of interaction between different sectors at the earlier stages of development.

ESCCA will host a one day meeting on the 29th January 2018 at the Villa Malpensa hotel (5mins from Malpensa airport). The meeting will provide an informal platform for interaction between academic scientists/clinicians, biotechnology and pharmaceutical companies and regulatory bodies. The aim of the meeting is to facilitate future assay development by:

- providing an opportunity to understand the challenges in developing clinically relevant assays from the different viewpoints of laboratory, industry and regulator.
- identifying areas of development that would benefit from closer collaboration between different sectors

Target audience: scientists and clinicians involved in the development of clinical assays, pharmaceutical companies interested in developing intermediate/surrogate licensing endpoints and biotechnology companies focussed on providing relevant diagnostic kits

Program outline:

10.00 – 11.00: Regulatory perspectives: focus on the impact of new EU IVD Regulations on health institutions and MRD as an intermediate licensing endpoint

11.00 – 11.30: Refreshment break

11.30 – 12.30: Academic laboratory perspectives: strategies for developing and applying clinically relevant assays with approaches from Euroflow/EuroMRD and ICCS/ESCCA

12.30 – 13.30: Lunch break

13.30 – 14.30: pharmaceutical company perspectives - focus on the needs of the pharmaceutical industry that can be provided by academic laboratories and biotech companies, including presentations from Abbvie, Celgene, Janssen & Roche.

14.30 – 15.00: Refreshment break

15.00 – 16.00: biotech company perspectives - focus on the challenges of turning a laboratory assay into a diagnostic kit, including presentations from Agilent, BD Biosciences & Beckman Coulter,

16.00 – 16.30: wrap-up & future directions