Forum for the development of clinical diagnostic assays

Registration is now closed!

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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 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, and Cytognos

16.00 – 16.30: wrap-up & future directions

Program:

10.00 – 11.00: Regulatory perspectives

Chairs Paolo Ghia (IT) and Andy Rawstron (UK)

Andy Rawstron **MRD as an intermediate licensing endpoint: lessons from CLL & Myeloma**

James Witty (Associate Director, Regulatory Affairs Celgene), Andy and Paolo
MRD as a licensing endpoint – panel discussion

11.00 – 11.30: Refreshment break

11.30 – 12.30: Academic laboratory perspectives: strategies for developing and applying clinically relevant assays

Chairs Jan Gratama (NL) and Andy Rawstron (UK)

Vincent Van Der Velden **Euroflow/EuroMRD in acute leukemia: flow, PCR or both?**
Gerrit Schuurhuis **AML MRD – total disease burden or leukemic stem cells?**
Ruth de Tute **Myeloma MRD: ICCS/ESCCA consensus**
Andy Rawstron **Translational assays including pathway inhibitors – panel discussion**

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

Chairs Paolo Ghia (IT) and Andy Rawstron (UK)

Paul Sherrington **Senior Director, Medical Affairs, Celgene**
Sharon McBain **Senior Director, Global Regulatory Affairs, Oncology, Janssen**
Kirsten Mundt **Oncology Biomarker Development, 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

Chairs Jan Gratama (NL) and Andy Rawstron (UK)

Michael Kapinsky **Beckman Coulter: Purpose-built RE (Rare Event) Duraclone Panels**
Gert Boschman **BD Biosciences: from Euroflow to OneFlow**
Marta Martín-Ayuso **Cytognos: NGF Data Analysis: from Research to Clinical Diagnosis**
Jesper Kuhnau **Agilent: Improving disease detection during/after antibody therapy**

16.00 – 16.30: wrap-up & future directions