CDDF MULTI-STAKEHOLDER WORKSHOP

Minimal Residual Disease

London, United Kingdom
18–19 October 2017

PROGRAMME

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Day 1 Wednesday 18th October 2017

13:30 **Start of the meeting**
Introduction

SESSION 1 : SURROGATE ENDPOINTS AND MRD

Chairs: *Beatriz Flores & Mohamed Zaki*

13:40 **Overview of requirements for surrogate endpoint adoption by CHMP/EMA**

- **Regulatory perspective**
  Beatriz Flores (Medicines and Healthcare Products Regulatory Agency - MHRA, UK)
- **ASO-PCR based MRD quantification in newly diagnosed multiple myelona patients: academic perspective**
  Hartmut Goldschmidt (Heidelberg University Hospital, Germany)

14:10 **Overview of validated methods and thresholds used to assess MRD in MM**
Andy Rawstron (Leeds Teaching Hospitals NHS Trust, UK)
Bruno Paiva (University of Navarra, Spain)
Herve Avet-Loiseau (CancerResearch Center of Toulouse, France)

14:55 **Roundtable discussion**

15:25 Coffee break

SESSION 2 : CURRENTLY AVAILABLE DATA: HOW TO DEFINE THE OPTIMAL DATA SET FOR VALIDATION?

Chairs: *Mélanie Frigault & John Smyth*

15:55 **Overview of two published meta-analyses**
Walter Gregory (University of Leeds, UK)

16:15 **In-depth look at specific data-sets; which ones meet requirements?**
Individual data 'owners'/cooperative groups

- **Spain:** Bruno Paiva (University of Navarra, Spain)
- **UK:** Roger Owen (St James's Institute of Oncology Leeds, UK)
- **France:** Herve Avet-Loiseau (Cancer Research Center of Toulouse, France)
- **Italy:** Stefania Oliva (University of Turin, Italy)
- **Germany:** Hartmut Goldschmidt (Heidelberg University Hospital, Germany)

17:05 **Roundtable discussion**
Aim to agree on optimal data-sets to be used by CHMP/EMA

17:35 End of the day

19:30 Networking dinner: Hilton Hotel London - Docklands Riverside

Day 2 Thursday 19th October

SESSION 3 : THE REGULATORS' VIEW

Chairs: *Davy Chiodin & Kyriaki Tzogani*

09:00 **The FDA view**
Nicole Gormley (Food and Drug Administration, USA)

09:30 **Clinical Development Strategy for validation of MRD as a surrogate endpoint**
Walter Gregory (University of Leeds, UK)

10:00 **Roundtable discussion**

10:30 Coffee break

SESSION 4 : MRD AS A SURROGATE ENDPOINT: WHAT IS BEYOND MM?

Chairs: *Davy Chiodin & Kyriaki Tzogani*

10:50 What hurdle for concordance with endpoints does MRD negativity need to achieve to shift practice in other indications?

To be announced

SESSION 5 : WRAP UP SESSION

11:20 Summary and discussion on next steps - CDDF
Facilitator - John Smyth

- Agreements, gaps
- How to bridge gaps
- Applicability to other indications

12:20 End of the workshop

Event Outline

The The CDDF Minimal Residual Disease Working Group will bring together academia, regulators, payers and industry for an opportunity to engage on the concerted development of Minimum Residual Disease (MRD) as a validated tool for drug development and treatment decision.

The recently published 'Concept paper on the need to revise Condition – Specific guidance, Appendix 4 to the guideline on the evaluation of anticancer medicinal products in man' addresses the use of minimal residual disease (MRD) as a clinical endpoint in multiple myeloma (MM) clinical studies. Advances in MM therapy have significantly improved PFS and OS times meaning that clinical trials with survival endpoints take many years to complete. Despite these advances, MM is still incurable and the majority of patients relapse. A surrogate endpoint for survival could radically reduce the read-out times for MM trials and facilitate earlier patient access to novel therapies. Therefore the objectives of the meeting are to establish how MRD negativity might be adopted as a surrogate or intermediate endpoint for PFS (+/-OS) in clinical trials.

The long term goal of the CDDF Minimum Residual Disease Working Group would aim for MRD to become a tool/study endpoint that is recognized by regulators, as exemplified by MRD based labels. By working together, the Working Group will create the right platforms and develop the tool for MRD data to be considered an important consideration in treatment decisions given MRD data in the context of advancing of the standard of care. The overarching objective is to aid timely access to drugs for the patient against high standards set by the community.

Meeting Co-chairs

- John Smyth (CDDF)
- Paul Sherrington (Celgene)
- Davy Chiodin (Acerta/AstraZeneca)

Target audience

Oncologists, scientists, government officials (EMA, FDA, HTA representatives), pharmaceutical industry, assay developers, patient representatives, policymakers

Meeting Venue

DoubleTree by Hilton Hotel London - Docklands Riverside

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Meeting Secretariat

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