Welcome

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Collaboration between Academia and Pharmaceutical Companies

Well-known pathway

Examples

- Collaborative studies
- Harmony

EMA - Collaboration Framework

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Collaboration with academia to be reinforced

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Press release 03/04/2017

EMA publishes framework and action plan for closer interaction

As a science-driven organisation, the European Medicines Agency (EMA) has developed a framework to formalise, structure and further develop interactions with the academic community in the context of the European medicines regulatory network.

The framework and an action plan for the next three-years were adopted by EMA's Management Board at its March 2017 meeting.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

EMA – Clinical Trials Information System

Update: EMA has revised the Clinical Trials Information System project plan to improve delivery and to ensure that stakeholders can give **feedback more regularly** so that their expectations can be taken into account, whilst enabling the Clinical Trial Regulation to come into application as early as possible, but retaining the possibility to extend functionalities in the future.

It restructred the contract for the system's delivery, so that the code for safety reporting can be merged with EU Clinical Trial Portal and Database system modules and key bug fixing can be carried out. The system can then enter a phase of iterative, **agile development as of June 2019**.

Collaborative Studies

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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Save this study

Daratumumab-bortezomib-dexamethasone (Dara-VCd) vs Bortezomib-Thalidomide-Dexamethasone (VTd), Then Maintenance With Ixazomib (IXA) or IXA-Dara

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03896737

Recruitment Status : Not yet recruiting
First Posted : April 1, 2019
Last Update Posted : April 17, 2019

See Contacts and Locations

Sponsor:
European Myeloma Network

Collaborator:
EMN Research Italy

Information provided by (Responsible Party):
European Myeloma Network

Collaborative Studies

U.S. National Library of Medicine
ClinicalTrials.gov

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Save this study

Comparison of Pomalidomide and Dexamethasone With or Without Daratumumab in Subjects With Relapsed or Refractory Multiple Myeloma Previously Treated With Lenalidomide and a Proteasome InhibitorDaratumumab/Pomalidomide/Dexamethasone vs Pomalidomide/Dexamethasone (EMN14)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03180736

Recruitment Status : Recruiting
First Posted : June 8, 2017
Last Update Posted : April 13, 2018

See Contacts and Locations

Sponsor:
European Myeloma Network

Collaborator:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
European Myeloma Network

Collaborative Studies

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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Save this study

Daratumumab, VELCADE (Bortezomib), Lenalidomide and Dexamethasone Compared to VELCADE, Lenalidomide and Dexamethasone in Subjects With Previously Untreated Multiple Myeloma (Perseus)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03710603

Recruitment Status : Recruiting
First Posted : October 18, 2018
Last Update Posted : January 17, 2019

See Contacts and Locations

Sponsor:
European Myeloma Network

Collaborator:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
European Myeloma Network

HARMONY

Harmony

Healthcare
Alliance for
Resourceful
Medicines
Offensive against
Neoplasms in
hematologY

Innovative Medicines Initiative IMI

HeaDS SATELLITE SYMPOSIUM

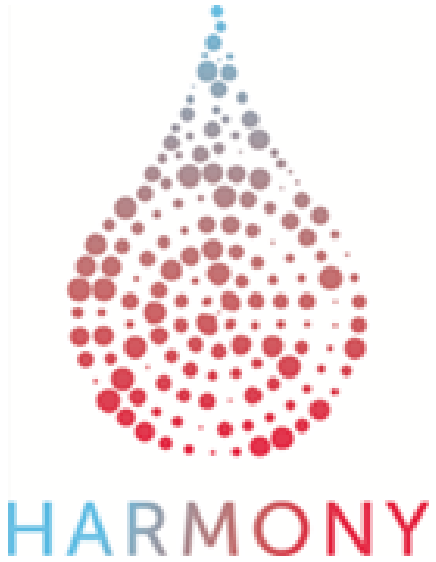
Harmony

- European Network of excellence
- Captures, integrates, analyzes, and harmonizes big data from high quality multidisciplinary sources

With the purpose

- To unlock valuable knowledge on various hematologic malignancies
- To enable of more rapid definition of promising treatment strategies and adverse events likely to be associated with such treatments

Harmony Work Packages



- Multiple Myeloma
- Acute Myeloid Leukemia
- Acute Lymphoblastic Leukemia
- Chronic Lymphocytic Leukemia
- Non-Hodgkin Lymphomas
- Myelodysplastic Syndromes
- Pediatric Hematology

Harmony

- 51 partners: 44 participants & 7 pharmaceutical companies (EFPIA)
- from 10 European countries
- Key stakeholders from the:

➢Clinical
➢Academic
➢Patient
➢HTA
➢Regulatory
➢Economical
➢Ethical
➢Pharmaceutical

fields

HARMONY

Agenda

08:00 - 08:20	**Welcome, Coffee -Breakfast**
08:20 - 08:35	**Insights from Industry** **Tobias Kampfenkel** Janssen Pharmaceuticals
08:35 - 08:50	**The viewpoint of Scientific Groups: Part 1** **Meletios A. Dimopoulos** European Myeloma Network
08:50 - 09:05	**The viewpoint of Scientific Groups: Part 2** **Meral Beksac** Balkan Myeloma Group
09:05 - 09:20	**A CRO's perspective** **Ioannis Orfanidis** Health Data Specialists
09:20 - 09:30	**Discussion-Questions**

Thank You and Welcome!