



HARMONY 4th General Assembly 2019

Towards the second wave of HARMONY Research Projects

Palazzo Ximènes Panciatichi

Thursday, 26th September 2019

09:30 – 10:00	Registration
10:00 – 10:15	Opening Ceremony and Welcome by Dr Andrea Pellacani, General Manager, Menarini Ricerche
10:15 – 10:30	HARMONY achievements - Jesús M. Hernández / Frederico Calado
10:30 – 12:00	Round Table around the value of data sharing, big data approaches, artificial intelligence and advances in data analysis, and HARMONY's unique position and added value for precision medicine. Moderator: Bob Löwenberg Participants: Kimmo Porkka (University of Helsinki, Member of EHA Executive Board); Miklós Szócska (Semmelweis University); Christian Reich (IQVia); Nathan Intrator (Tel Aviv University).
12:00 – 12:30	Update of HARMONY Results <ul style="list-style-type: none">— AML: "A proof-of-concept study in AML: Big Data for Better AML Outcomes (impact of genomics and value of intensive treatment approaches in MDS/AML)" - Lars Bullinger— MM: "Revised International Staging System for Multiple Myeloma: extended follow-up in the European clinical trial population and evaluation of the efficacy of different novel agents and treatment approaches in subsets of patients with standard- and high-risk features" – Mario Boccadoro
12:30 – 12:50	Pitching Research section <ul style="list-style-type: none">— APL: Open issues in the management of Acute Promyelocytic Leukemia (APL) – Maria Teresa Voso— MDS: Prognostic factors of treatment with hypomethylating agents in higher risk MDS and advanced Chronic myelomonocytic leukaemia (CMML) – Valeria Santini— NHL: Big Data for Better Outcomes of T-Cell Lymphomas – Bridging the Gap between Molecular Understanding and Treatment Reality (Impact of Genomics on Prognostification and Treatment of T-Cell Lymphomas) – Thomas Weber— CLL: Large-scale mutation analysis - Novel prognostic/predictive scheme for improved risk stratification aimed at personalized medicine – Paolo Ghia
12:50 – 13:00	Mid-Term Review procedure - Karroum Oussama
13:00 – 14:00	LUNCH



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Afternoon - Thursday, 26th September 2019

14:00 – 19:00 **Research-a-thons per HM** *All afternoon workshops (with a coffee break in the middle). Join this working session to look into AML relevant issues, and help us shaping the second wave of HARMONY Research Projects*

AML RESEARCH-A-THON | MAIN ROOM

- *The cooperating mutational pattern of cases showing mutations in classical splicing factors such as SRSF2, SF3B1 etc., and investigate in further depths the cohesion factor mutations which are also involved in transcriptional regulation and splicing;*
- *Differences in mutational patterns with regard to gender differences and performing gender-dependent outcome analyses in defined AML subgroups;*
- *Mutational profiles of sAML and tAML cases as well as into de novo AML that was primary refractory or showed early relapse.*

CLL RESEARCH-A-THON | ROOM C

- *Secondary neoplasia in the history of CLL (with or without therapies; CIT or novel therapies);*
- *Correlation between MRD and outcomes in CLL; validation of establishing UMRD as a relevant primary endpoint in CLL.*

ALL AND PEDIATRICS RESEARCH-A-THON | ROOM I

- *KMT2A (MM) re-arrangements in ALL patients;*
- *Adult B cell precursors in ALL.*

MDS RESEARCH-A-THON | ROOM B&D

- *Event free survival (EFS) as surrogate endpoint for OS to be used in clinical trials. Implement recently modified IWG criteria for response;*
 - *Are patients with isolated monosomy 7 more sensitive to HMAs? (and the effect of cytogenetic alterations on response).*
 - *Specific outcome of patients with TP 53 mutation after HMAs. And other mutations and commutations?*
 - *Outcome of CMML dysplastic (azacitidine) and proliferative (decitabine in clinical trials).*
 - *Incidence and prognostic value of febrile neutropenia and relative treatment/prophylaxis.*
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- *Characterize features of specific subgroups of patients: long responders, elderly, hypocellular marrow etc*
 - *Evaluation of clonal evolution during/after HMA therapy (for cases with sequential samples).*
 - *HMA as bridge to transplant : how many cycles? Which kind of response?*

MM RESEARCH-A-THON | ROOM E

- *Predictors of initial response duration in patients newly diagnosed with MM.*
- *Are there specific predictors of patients who relapse early after initial treatment?*

NHL RESEARCH-A-THON | ROOM G

DLBCL:

- *Newly approved novel targeted agents bring both value and complication to treatment selection and sequencing in DLBCL.*
- *Is there space to improve R-CHOP strategy by adding new drugs, drug combinations or sequences? Some recent attempts have failed, why? Will large scale genetic datasets help to refine first-line treatment strategies?*
- *Novel therapeutics in R/R DLBCL are needed, we still deal with poor survival outcomes despite salvage chemotherapy with or without SCT in a relevant number of patients.*
- *High-grade B-cell lymphoma /Double-hit lymphoma (DHL) need new therapeutic approaches: anti BCL₂, MYC, or other associated pathways.*
- *There is limited data on differential therapy by DLBCL subtype.*
- *DLBCL remains a heterogeneous disease. We need refinements in the understanding of the complex pathogenesis and to improve strategies for treatment choice.*

PTCL:

- *Is it pcALCL or psALCL? ALCL with uncertain classification regarding primary systemic vs. primary cutaneous ALCL origin. Genetic and biological characterization and impact of treatment approach on outcome.*
- *What patients benefits from upfront SCT; clinical, biological and genetic stratification.*

19:00 Departure for Paszkowski caffè, accompanied by hostess

19:30 **Networking cocktail + dinner in Paszkowski caffè**

Piazza della Repubblica 6
50123 Firenze FI, Italia



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Friday, 27th September 2019

08:30 – 09:30

Research-a-thon (2)

Review of work done the previous day and FINALIZATION of a research proposal per pillar.

09:30 – 10:30

Research-a-thon – cross-pillar Research questions.

Evaluation of surrogate outcomes and related regulatory strategies. From a regulatory point of view, the operating characteristics of the regulatory rules that are based on surrogate endpoints are of high importance to understand the consequences of regulatory decisions based on surrogates and to potentially adjust regulatory rules. Join this working session to help us shaping the next HARMONY research project on regulatory strategies based on surrogate endpoints on AML.

10:30 – 10:45

Coffee break

10:45 – 12:00

Presentation of Research Questions

12:00 – 12:30

Roundtable format – Providing data to the HARMONY Data Platform. Q&A session for Public and Private Data Providers.

Focus on anonymization, security, what's my data is going to be used for, data transfer process, legal requirements...

Participants: [Gabriele Nagel](#) / [Jesús M. Hernández](#) / [Rubén Villoria](#) / [Frederico Calado](#).

12:30 – 13:00

Associated Members update session – for Associated Members | ROOM C **Making HARMONY "EMA compatible": Qualification of novel methodologies (Task 6.4): [Pall Jonsson](#) / [Katy Harrison](#) – for Partners | MAIN ROOM**

13:00 – 13:15

Scientific and non-scientific dissemination: Current status and how to improve the project impact - [Ellen de Waal](#)

13:15 – 13:30

WRAP-UP and Closing of Working sessions – [Pam Bacon](#) / [Guillermo Sanz](#)

13:30 – 15:00

NETWORKING LUNCH - End of the 4th General Assembly

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