HONEUR
Haematology Outcomes Network in EURope

Accelerated real-world data analysis and evidence sharing

Federated network connectivity, data always stay local

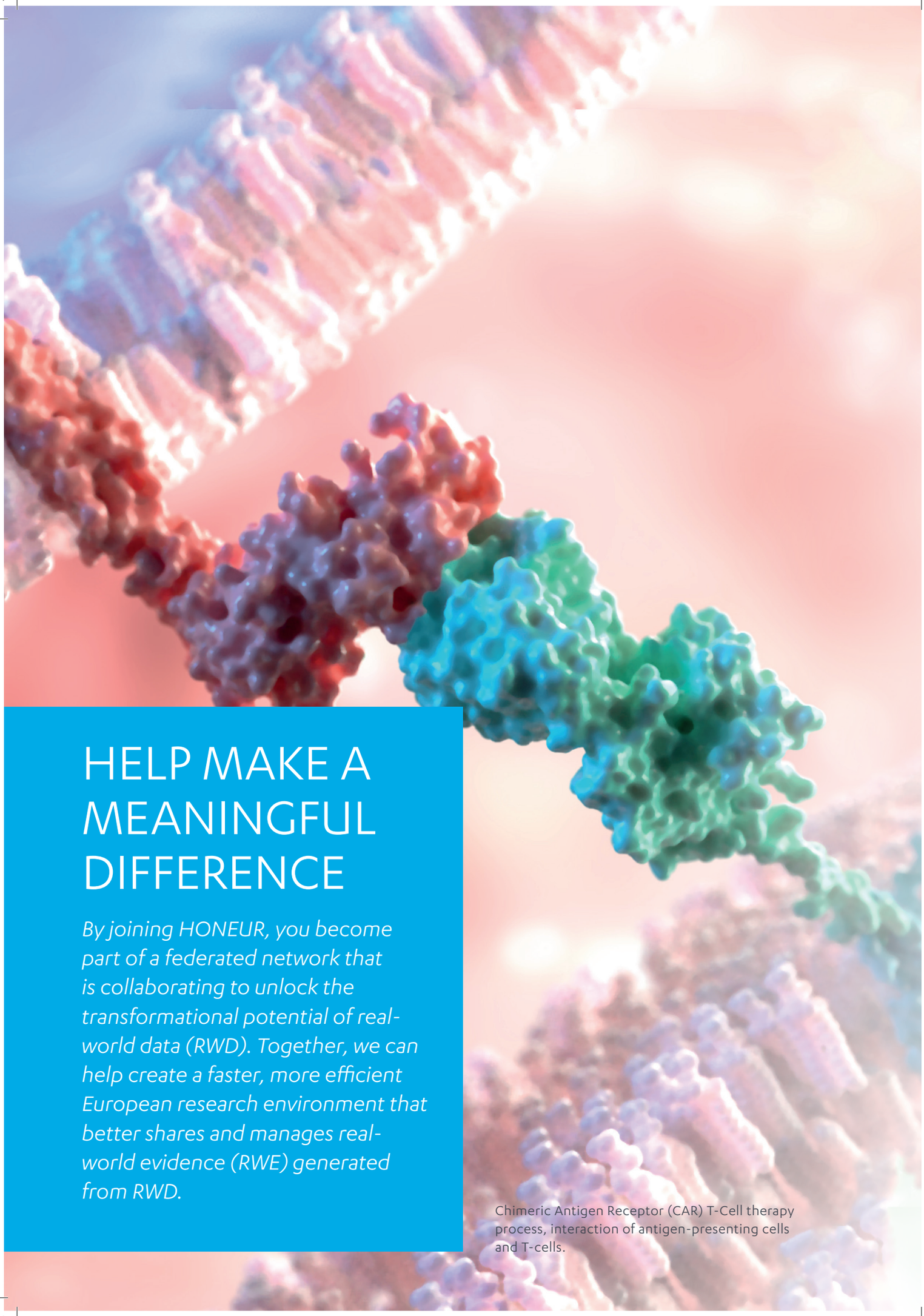
Janssen Pharmaceutica NV

YOUR DATA CAN IMPROVE UNDERSTANDING OF TREATMENT OUTCOMES

By joining HONEUR (Haematology Outcomes Network in Europe), you become part of a secure, federated network, which increases the value of the data you collect by enabling you to address key ***research questions*** *of interest and* ***run larger studies more quickly.***

OUR **VISION**

HONEUR represents Janssen's commitment to increase knowledge and understanding of haematological malignancies, and improve outcomes for patients across Europe.



HELP MAKE A MEANINGFUL DIFFERENCE

By joining HONEUR, you become part of a federated network that is collaborating to unlock the transformational potential of real-world data (RWD). Together, we can help create a faster, more efficient European research environment that better shares and manages real-world evidence (RWE) generated from RWD.

Chimeric Antigen Receptor (CAR) T-Cell therapy process, interaction of antigen-presenting cells and T-cells.

REAL INSIGHTS FROM **REAL-WORLD DATA**

In recent years, significant progress in treating patients with haematological malignancies has led to new treatment options, but extensive scientific research is still needed. Fortunately, there's a huge untapped resource that can help – real-world data.

WHY IS REAL-WORLD DATA (RWD) IMPORTANT?

- Complements the results from randomised clinical trials (RCT) and expands knowledge on treatment outcomes in the real world
- Deepens understanding of disease epidemiology and the impact on patients and public health
- Provides insights for improved patient care and benefits future research

RWD is, however, highly fragmented in Europe due to heterogeneous data collection systems.

OUR MISSION

With HONEUR, we have created a secure, collaborative platform that enables partnering data centres across Europe and Janssen to liberate the transformational potential of RWE.

OUR APPROACH

We use a holistic approach: **combining technology and data science** to be able to analyse data from different hospitals/registries.

Real-world data (RWD)* is an umbrella term for data regarding the effects of health interventions (e.g., benefit, risk, and resource use) that are not collected in the context of conventional RCTs. RWD can be obtained from many sources including patient registries, electronic medical records, and observational studies.

Real-world evidence (RWE)* is the evidence derived from the analysis and/or synthesis of real-world data (RWD).

* IMI (Innovative Medicines Initiative) definitions

CORE PRINCIPLES

HONEUR optimises how real-world data are analysed to speed-up the generation of real-world evidence

HONEUR data partners share real-world insights that can contribute to improved patient outcomes

HONEUR ensures data partners keep full control of their data at all times

HONEUR respects individual rights and follows all local processes and regulations, e.g., FAIR and GDPR

HONEUR increases the value of your data by enabling its re-use across a wide range of research studies and encourages publishing results

BENEFITS FOR DATA PARTNERS

Collaboration with **full data control – data always stays local**

Strengthened ability to perform **high quality research** as part of a federated network

Compensation of efforts based on Fair Market Value

Increased data value via expanded authorship in publications and the possibility of sponsored studies

Access to **17,000 data sets of patients with MM/CLL/AML**

Participation in a network that is **pioneering data management and analysis**

Improved understanding of **how patients are treated in the real world**

* At publication date of September 2020

OUR INVESTMENT IN **REAL-WORLD EVIDENCE**

Our compensation is based on Fair Market Value (FMV) and consists of three pillars:

SET UP REMUNERATION

When you join the network, we compensate your IT-based efforts. Remuneration is dependent on the data model/ organisational complexity and IT efforts needed to implement HONEUR at your site.

FEASIBILITY QUERIES

We grant an annual remuneration to participate in feasibility queries.

TAKING PART IN RESEARCH QUESTIONS

Remuneration is dependent on the data volume, quality and the complexity of the analysis and will be calculated before start of the study.

WHY JOIN HONEUR?

HONEUR Haematology Outcomes Network in EURope

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WHO CAN PARTICIPATE **IN HONEUR?**

HONEUR focuses on the following haematological disease entities: Multiple Myeloma (MM), Chronic Lymphocytic Leukaemia (CLL), Diffuse Large B-Cell Lymphoma (DLBCL), Mantle Cell Lymphoma (MCL), Myelodysplastic Syndrome (MDS), Acute Myeloid Leukaemia (AML), Follicular Lymphoma (FL), Marginal Zone Lymphoma (MZL) and AL-Amyloidosis.

You can benefit from network participation, if you fulfill the following prerequisites:

Patient-level data
comprehensive, individual patient history

Disease characteristics
confirmed diagnosis and date of diagnosis

Patient baseline characteristics
year of birth and gender

Medications
lines of treatment with start-stop dates

Outcomes
time to next treatment, last follow-up, death

WHAT ARE THE STEPS TO BECOME **A MEMBER OF HONEUR?**

1. Contact HONEUR Leads on back page or via www.honeur.org
2. Meeting (phone or in person) for Q&A and to provide more information
3. Data profiling to determine structure (no access to patient data)
4. Signing of Access Agreement
5. Data transfor-mation*, use of HONEUR technical functionalities
6. Access to HONEUR portal; ready to participate/ initiate research questions

TIMELINES

The onboarding process can vary, but from initial data profiling (a process that evaluates your data structure, not patient-level data) to signing the Access Agreement can take between 3-6 months. Subsequently, data transformation may take 3-4 months, after which you have access to the HONEUR portal and can initiate/participate in research questions.

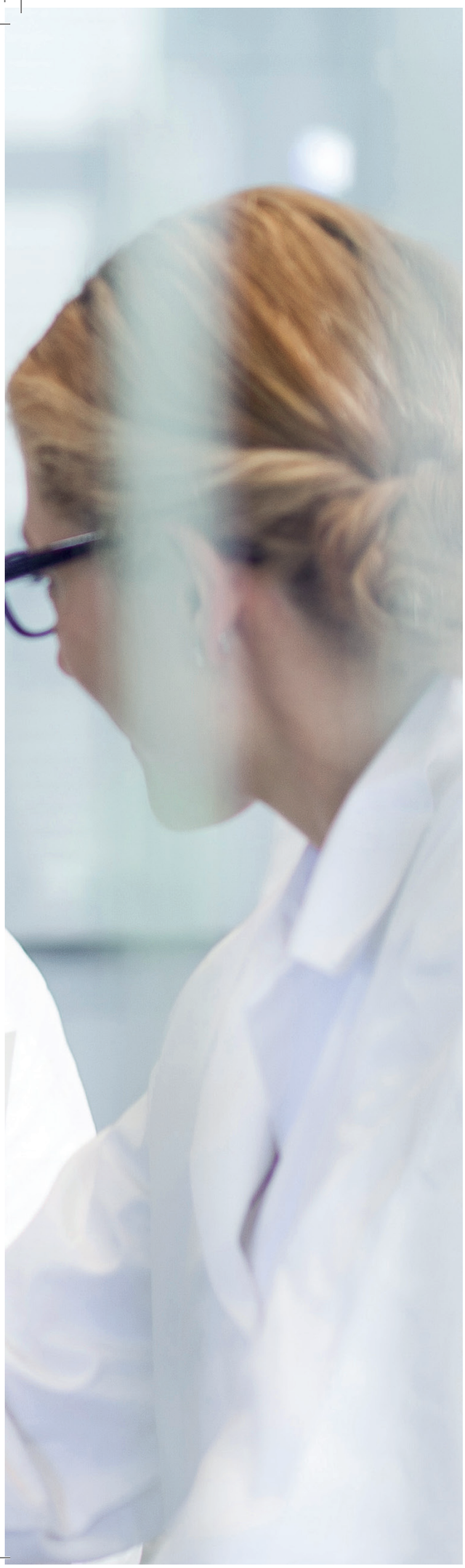
* In a joint effort between the data partner and Janssen, data is transformed to the OMOP common data model, which was developed by the scientific community of OHDSI (www.ohdsi.org).

WHAT DATA **PARTNERS ARE SAYING:**

HONEUR DATA PARTNERS*:

- *Oncotyrol – Centre for personalised medicine, Austria*
- *The Czech CLL Study Group, Czech Republic*
- *The Registry of Monoclonal Gammopathies, Czech Republic*
- *iOMEDICO, Germany*
- *O.I.s, Germany*
- *IRST of Meldola, Italy*
- *The University of Perugia's Department of Medicine, Italy*
- *The Kazakh Institute of Oncology and Radiology, Kazakhstan*
- *Aragon Region Hospital Group, Spain*
- *The Research Institute Hospital 12 de Octubre, Spain*
- *Leicester Royal Infirmary, UK*

* At publication date of September 2020



"Building on our tradition of high quality standards and excellence in research, 12 de Octubre University Hospital is committed to collaborating in initiatives that offer the best chances for success. We're very confident that becoming a member of the HONEUR network will enable us to maximise the value of our Multiple Myeloma data so that we may ultimately improve healthcare for our patients."

Dr. Agustín Gómez de la Cámara, Head of Clinical and Epidemiological Research, Health Research Institute of 12 de Octubre University Hospital, Madrid, Spain

"My colleagues and I at the Leicester Royal Infirmary are passionate about the development and use of database records in haematological disorders, as they provide a source of invaluable information for benchmarking, education and research purposes. Joining HONEUR brings us a big step closer to generating Real-World Data that ultimately has a meaningful impact on patients."

Dr. Mamta Garg, Consultant Haematologist, MD, FRCP, FRCPath, Leicester Royal Infirmary, United Kingdom.

"Our registry currently includes different haematological malignancies and we are very much looking forward to collaborating with Janssen and other HONEUR members, so that we can make significant inroads in improving treatments for patients with these rare blood diseases."

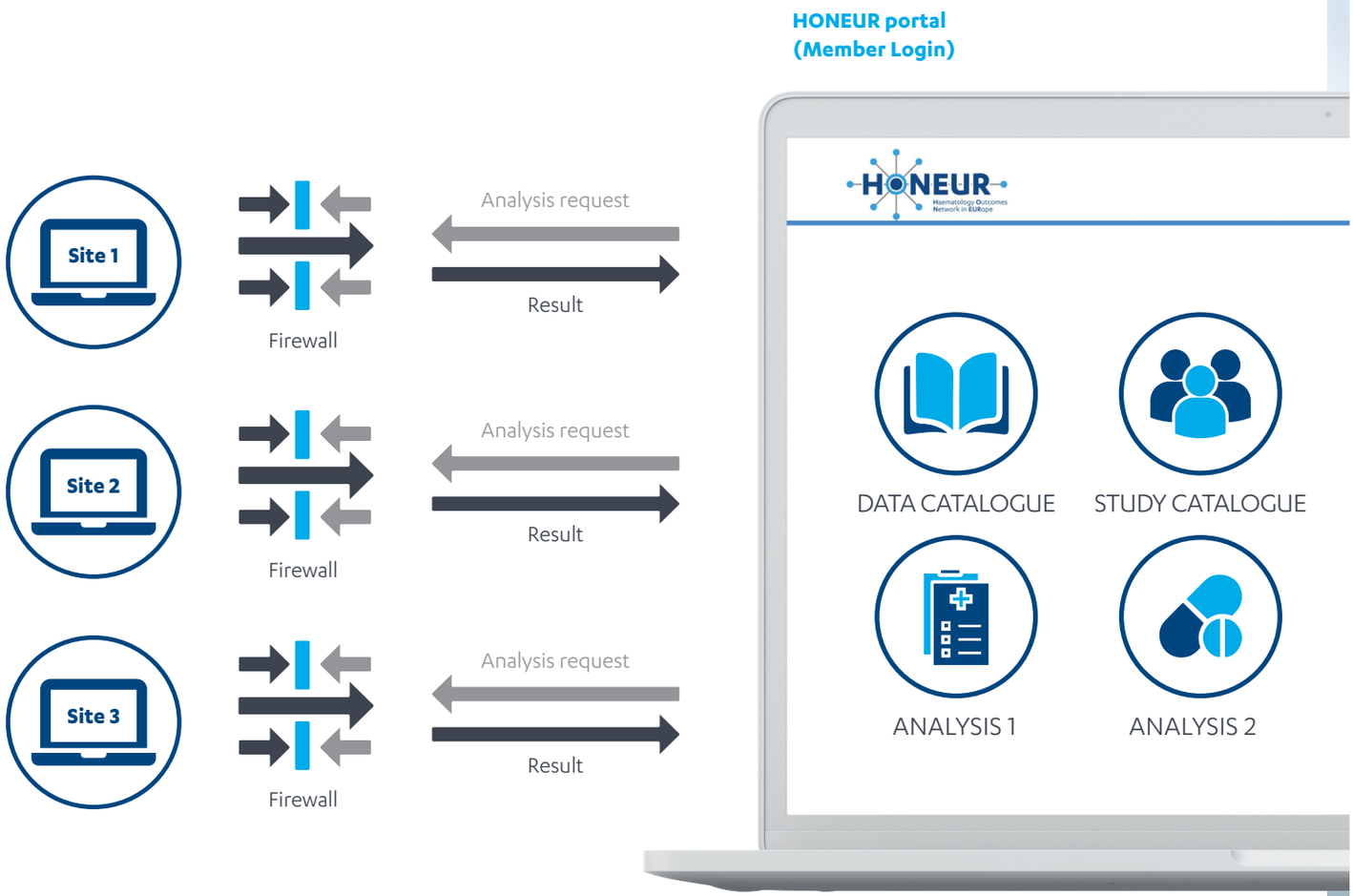
Prof. MUDr. Roman Hájek, CSc. (Haematology), The Registry of Monoclonal Gammopathies (RMG), Czech Republic.

"iOMEDICO has been a pioneer in the field of Real-World Data and our vision is to improve oncology by refining RWD methodology and analysis standards. HONEUR offers the unique chance to collaborate with other European researchers while maintaining integrity, security and independence of the databases."

Dr. Norbert Marschner, Medical Oncologist, CEO of iOMEDICO

HOW THE **COLLABORATION WORKS**

As shown below, each of the data partners in this example has the applications in place to interrogate their own data or to execute an analysis script that is developed centrally by other HONEUR data partners. Individual sites are not physically connected to a central platform or to each other, but aggregated results can be shared securely through the HONEUR portal.



RESEARCH **QUESTIONS**

Data partners can choose to initiate their own questions and participate (or not) in those posed by other data partners. Examples:

"What is the overall survival of patients with relapsed and/or refractory multiple myeloma who received at least three prior lines of therapy including proteasome inhibitors, immunomodulatory IMiD drugs, and CD38 monoclonal antibody treatment?"

"What is the time to next treatment, disease progression and long-term overall survival over a 5-year period in the real world vs. predicted overall survival data from clinical trials?"

"What are the treatment sequences in different countries and associated outcomes, e.g. overall survival?"

QUESTIONS & **ANSWERS**

WHAT MAKES HONEUR UNIQUE?

HONEUR is all about **collaboration**. Rather than creating a central data repository, the HONEUR federated data network enables partners to keep full control over their own data and the analysis.

WHAT TYPE OF RESEARCH QUESTIONS CAN BE ANSWERED WITH HONEUR?

The power of HONEUR lies in enabling data analysis on multiple data sets with methodological and statistical possibilities. By analysing data from multiple partners, common research questions on overall survival, time to next treatment, or treatment sequencing can be answered. These are only a few examples - as HONEUR evolves, answers to other questions will follow.

WHAT INFORMATION IS STORED ON THE HONEUR PORTAL?

The HONEUR portal is the core of the network. It's a secured environment that is only accessible to HONEUR data partners. It offers different functionalities to the partners. A data catalogue contains a description of various data sets of data partners and how to engage with them. The study catalogue is the central place where a study request gets initiated, and where the analysis script and eventually aggregated results will be stored (visible to study participants only). **No patient-level data are stored on the HONEUR portal** – only aggregated results of a research question.

HOW IS DATA SECURED AND PATIENT PRIVACY PROTECTED?

The HONEUR network is based on the principle that data partners have local governance and keep control of their own data at all times. The original source data is transformed at the data partner's site to a common data model structure, which always stays at the site.

Data partners don't need a physical connection to the central platform: If a data partner agrees to participate in an analysis, this would be carried out locally and the results would be posted on the central HONEUR portal. In the base case, all results are being aggregated. In the seldom-seen case that a research question can only be answered with patient-level data (and upon explicit agreement), pseudonymised data can be shared. All data are always protected by encryption.

WHAT REMUNERATION WILL BE COVERED BY JANSSEN?

Janssen remunerates for efforts arising from the implementation of HONEUR during the set-up phase as well as for research questions being carried out. Additionally, Janssen pays a yearly fee for performed feasibility queries.

A CROSS-FUNCTIONAL PROJECT SET-UP **WITH EXPERTISE**

EXECUTIVE SPONSOR

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Economics, Outcomes Research
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THE FUTURE OF HEALTHCARE IS NOW. **BE PART OF IT.**

Become a member of HONEUR and unlock the transformational potential of real-world data.

YOU BENEFIT FROM:

- ✓ Collaboration with **full data control – data always stays local**
- ✓ **Compensation of efforts** based on Fair Market Value
- ✓ Access to **17,000 data sets of patients with MM/CLL/AML**
- ✓ Improved understanding of **how patients are treated in the real world**
- ✓ Strengthened ability to perform **high quality research** as part of a federated network
- ✓ **Increased data value** via expanded authorship in publications and the possibility of sponsored studies
- ✓ Participation in a network that is **pioneering data management and analysis**

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For more information about HONEUR or how you can participate please visit **www.honeur.org**

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