The European Institute for Innovation through Health Data

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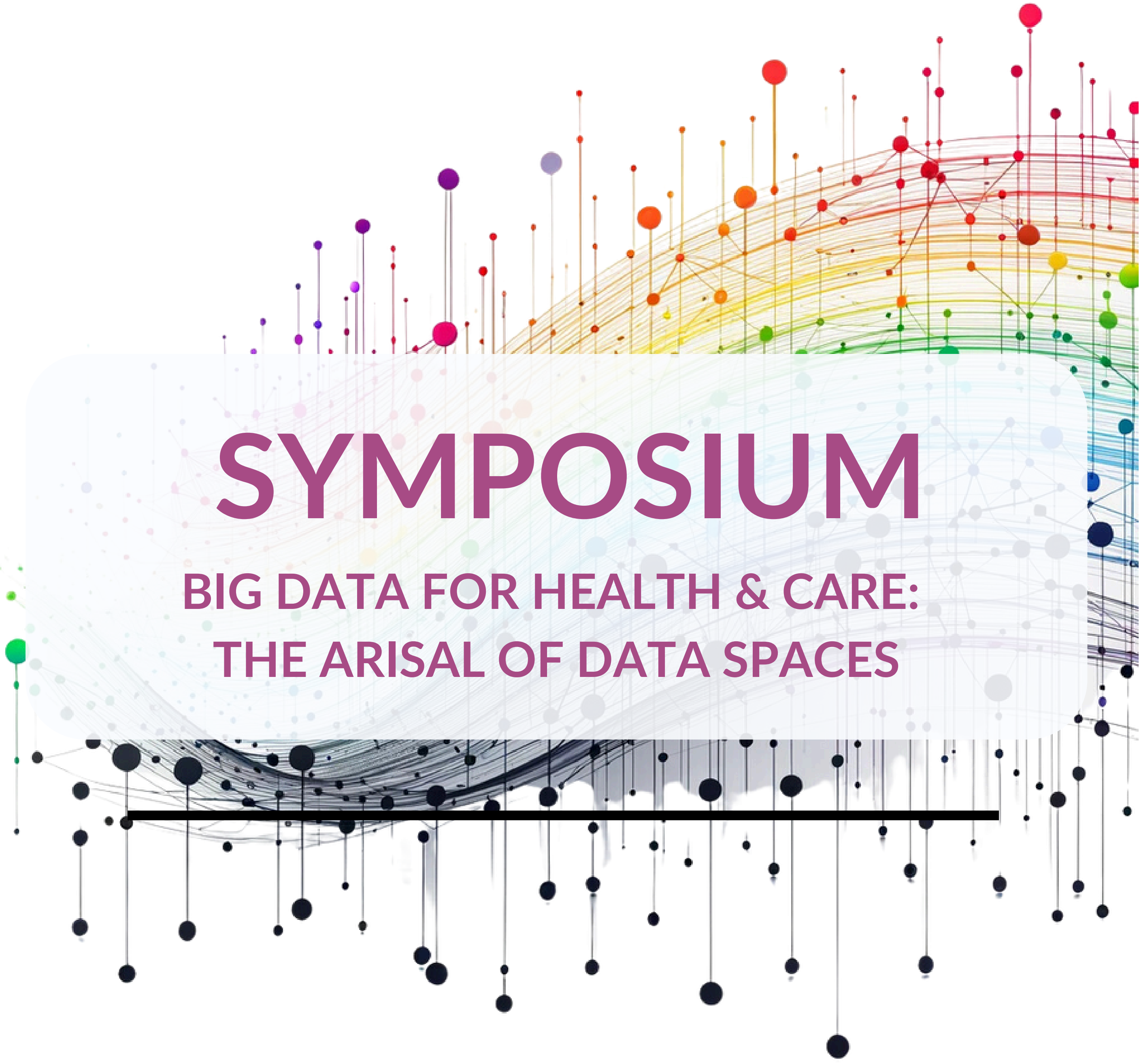

SYMPOSIUM

BIG DATA FOR HEALTH & CARE:
THE ARISAL OF DATA SPACES

Tuesday 23 April 2024 - Corda Conference, Hasselt

Report

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Introduction

The "Big Data in Health & Care: the Arisal of Data Spaces" symposium was held on April 23, 2024, at the Corda Conference in Hasselt. Organized by i~HD and the reseach group of Biomedical Data Sciences from UHasselt, this well-attended event drew over 150 participants from Belgium and neighboring countries. The symposium featured a series of presentations, panel discussions, and interactive debates moderated by Liesbet M. Peeters and Dipak Kalra. The goal was to explore the complex dynamics of health data ecosystems, address socio-technical challenges, and discuss strategic approaches to data sharing and utilization.

The symposium targeted health data enthusiasts from Belgium and its neighboring countries, catering to both novices and experts in the field. It emphasized the importance of making real-world health data accessible for research, innovation, and policy-making.

This report summarizes the proceedings of the symposium, focusing on the evolving landscape of health data ecosystems. The event brought together experts and stakeholders to discuss the integration, challenges, and future of data spaces in healthcare, emphasizing the European Health Data Space initiative. The symposium aimed to provide clarity and strategic insights into effective data utilization and collaboration within the field.

Over 150 health data enthusiasts participated in this symposium - #DataSavesLives

Key messages & takeaways

Scaling real-world data across Europe: the European Health Data Space (EHDS) - The EHDS aims to empower citizens by providing greater control over their health data, enhance healthcare delivery, and foster innovation. The COVID-19 pandemic accelerated the development of the EHDS, highlighting the importance of real-time data. Key challenges include ensuring data interoperability, quality, and public trust, as well as addressing legal and ethical concerns.

Collaboration and innovation in healthcare - Effective collaboration among regional authorities, universities, and industries is crucial for fostering healthcare innovation. Initiatives such as Health Campus Limburg serve as models for creating collaborative ecosystems. Projects focusing on digital health solutions, remote monitoring, and mobile health are essential for advancing precision medicine and improving healthcare delivery.

Real-world data (RWD) utilization - The symposium emphasized the importance of utilizing real-world data for research, policy-making, and improving patient care. Platforms like “Zorgatlas” in Flanders and various initiatives in Belgium demonstrate the potential of RWD in predicting health outcomes and enhancing healthcare management. Overcoming challenges related to data governance, privacy, and interoperability is essential for maximizing the benefits of RWD.

Digital health and data quality - Standardization and rigorous quality assessments are critical for the successful implementation of digital health innovations. Drawing parallels with the aviation industry, the need for unified global standards and robust data interoperability was highlighted. Initiatives like AssessDHT & xShare aim to harmonize digital health assessments and improve cross-border data sharing.

Population health management (PHM) - Shifting from reactive to proactive healthcare is vital for addressing chronic diseases and improving health outcomes. PHM strategies focus on identifying and addressing population needs through targeted interventions. Engaging healthcare workers and integrating automated feedback systems are key to enhancing care quality and efficiency.

Enhancing health data governance - Establishing effective health data governance frameworks is essential for the ethical and secure use of health data. Initiatives such as the Belgian Health Data Agency (HDA) aim to standardize and facilitate the secondary use of health data while ensuring data privacy and public trust. Collaboration with national and European bodies is crucial for aligning strategies and enhancing data governance.

Integrating diverse data domains - The integration of diverse data types, including clinical, -omics, and brain-related data, can significantly enhance healthcare research and policy-making. Ensuring high data quality and leveraging emerging technologies are critical for effective data integration. Collaborative efforts and strategic partnerships are necessary to harness the full potential of diverse health data.

Future directions and strategic oversight - The symposium underscored the importance of strategic oversight to avoid redundant efforts and ensure cohesive progress in health data initiatives. Emphasizing the need for clear governance structures, stakeholder alignment, and regulatory frameworks, the discussions highlighted the path forward for maximizing the utility of health data in Europe.

By addressing these key areas, the symposium concluded with a call-to-action for continued collaboration, innovation, and strategic efforts to create a more integrated and efficient health data landscape, ultimately improving healthcare outcomes across Europe.

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe

Moderator: Liesbet M. Peeters

Keynote by Dipak Kalra (i~HD) – Setting the scene: introducing the European Health Data Space (EHDS) and explaining the overall challenges of scaling-up health data and how they are currently handled at the European level

The link to Dipak Kalra's presentation can be found here.

Dipak Kalra's keynote presentation provided a comprehensive exploration of the European Health Data Space (EHDS), effectively setting the tone for the symposium. Prof. Kalra explained the dual approach within EHDS, focusing on primary use for direct patient care and secondary use for research and policy-making.

Prof. Kalra emphasized that the EHDS is driven by a threefold ambition: to empower citizens with greater control over their health data, to enhance the healthcare sector, and to accelerate business opportunities and innovation. The COVID-19 pandemic highlighted the necessity of real-time data learning, which in turn accelerated the development of EHDS. This initiative is intended to create two major "superhighways": one for standardized access to personal health records across Europe and another to enable the secondary use of data under strict ethical standards.

Primary use of data

Prof. Kalra elaborated that primary use of data within EHDS aims to empower individuals by providing them with greater control over their health information. Key aspects include:

- **Certification of EHR systems**: EHR systems across Europe must undergo self-certification to ensure they can import/export data in the European EHR eXchange Format (EEHRxF) and provide transparent audit logs for data access.
- **Enhanced access**: Citizens will have consolidated access to their health data and the ability to nominate others to access it, such as for seeking second opinions. This initiative also mandates that healthcare professionals across the EU can access patient data through the MyHealth@EU platform.
- **Interoperability and quality investments**: Significant investments are required to improve data quality and interoperability, ensuring that different systems can seamlessly communicate and share information.

Secondary use of data

The secondary use of data is focused on utilizing health data for research, innovation, policy-making, and other purposes. Key elements include:

- **Legal obligations**: All data holders are legally required to make personal health data available for secondary use. These datasets must be labeled with FAIR metadata (Findable, Accessible, Interoperable, and Reusable) and managed by Health Data Access Bodies, which will oversee data access requests and publish summaries of data usage.
- **Permitted and prohibited uses**: Data can be used for public health, regulatory activities, scientific research, and policy-making, but it must not be used for harmful or unethical purposes.

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe

Opt-out mechanisms

Prof. Kalra highlighted the rights of individuals to opt out of secondary data use. Citizens can opt out completely or selectively for certain types of data or specific secondary uses. However, public authorities can override these opt-outs for public interest purposes, such as addressing public health threats or conducting research on rare diseases.

Challenges and future directions

Prof. Kalra identified six grand challenges that need to be addressed to fully realize the potential of EHDS:

1. **Interoperability standards**: Limited adoption of standards hinders collaborative care.
2. **Data quality**: Ensuring the accuracy, completeness, and consistency of health data remains a significant challenge.
3. **Perception of digital health**: Viewing digital health as a cost rather than an investment.
4. **Data protection**: GDPR and other data protection concerns often obstruct data sharing.
5. **Public trust**: Building trust in the secondary use of health data.
6. **Incentives for data sharing**: Lack of incentives to share data for both care and research purposes.

Prof. Kalra's presentation underscored the importance of collaborative efforts to overcome these challenges.

By improving data quality, ensuring robust data protection measures, and engaging the public effectively, the EHDS can significantly enhance the utility of health data across Europe.

Dipak Kalra (i~HD)

Together we are immense, but fragmented we are not.

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe

Moderator: Liesbet M. Peeters

Presentation by Piet Stinissen (UHasselt) - Health Campus Limburg

The link to Piet Stinissens's presentation can be found here.

Professor Piet Stinissen discussed the Health Campus Limburg as a microcosm of effective health data usage. He detailed the Corda Campus's evolution from a Philips site into a thriving hub for technology innovation, involving over 250 companies and more than 5,000 employees, a true inspiration of what he aspires the Health Campus Limburg in Diepenbeek will become for healthcare innovation.

Building a collaborative ecosystem

Prof. Stinissen emphasized the critical role of collaboration between various stakeholders, including regional authorities (POM Limburg), universities, local government, and investment companies. He highlighted the necessity of investing in infrastructure to support these collaborations, envisioning an environment where innovators and researchers could coalesce to drive advancements in healthcare. This approach is not just about creating physical spaces but also fostering an ecosystem conducive to the cross-pollination of ideas and expertise.

Focus on digital Innovation and healthcare projects

One of the central themes of Prof. Stinissen's presentation was the focus on digital innovation in healthcare. He introduced the concept of the Digihub, a facility dedicated to companies working in health IT and AI, and the REVAL research center, which focuses on visualizing movements for rehabilitation purposes. These centers aim to address specific healthcare challenges, particularly chronic diseases and preventive care. The integration of digital solutions is seen as pivotal in advancing precision medicine and enhancing healthcare delivery.

Specific projects and initiatives

Prof. Stinissen provided detailed examples of ongoing projects that embody the campus's innovative spirit. One such initiative is MS Data Connect, which consolidates scattered clinical data into comprehensive dashboards for clinicians, significantly improving the practical utility of real-world data in clinical settings. Another project, DigiPath, involves creating a digital pathology platform for research, diagnostics, and AI applications, highlighting the intersection of technology and healthcare.

Emphasis on multi-stakeholder collaboration

The triple helix model of collaboration—combining academia, industry, and government—was underscored as a vital component in fostering an environment where health innovations can thrive. Prof. Stinissen described formal relationships developed with regional hospitals - in the context of the Limburg Clinical Research Center (LCRC) - and the University MS Center (UMSC), facilitating projects that elevate the collaboration to a new level. He stressed the importance of engaging primary care providers, despite their less structured nature compared to hospitals, to ensure comprehensive healthcare innovation.

Remote monitoring and mobile health

Another notable project discussed was the Remote Clinical Monitoring Center (RCMC), which aims to adopt and implement hybrid care in the healthcare system. The RCMC functions as a medical service center for telemonitoring and clinical command, supporting disease management and hospital-at-home initiatives. Additionally, the Mobile Health Unit focuses on validating mobile health innovations, ensuring they are fit for clinical application. This initiative includes projects like PREMOM, a prenatal remote monitoring program for mothers at risk, and telemonitoring solutions for chronic conditions like heart failure and hypertension.

Future vision and infrastructure development

Prof. Stinissen concluded by discussing the future trajectory of Health Campus Limburg, emphasizing the ongoing development of infrastructure to support hybrid healthcare pathways. The integration of these pathways into the regional healthcare system is expected to provide structural support and foster a connected ecosystem for data sharing. He highlighted the planned RCMC DemoLab, which will serve as a simulation and education center, further embedding innovative healthcare solutions into practical applications.

In summary, Piet Stinissen's presentation at the symposium was a comprehensive overview of how Health Campus Limburg aims to become a beacon of healthcare innovation, leveraging the successful model of Corda Campus and focusing on collaboration, digital innovation, and practical healthcare solutions.

Piet Stinissen (UHasselt)

Health Campus Limburg is building the future of healthcare by stimulating collaborations, entrepreneurship, innovation and valorization.

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe

Moderator: Liesbet M. Peeters

Presentation by Koenraad Jacob (Department of Care) - Flemish Health Data Space

The link to Koenraad Jacob's presentation can be found here.

Koenraad Jacob presented on the advancements and challenges in scaling real-world data in Flanders. He provided insights into the CareAtlas platform, a project developed rapidly due to the urgent needs presented by the COVID-19 pandemic, which now serves as a predictive model platform for healthcare. Mr. Jacob discussed the disruptive impact of digitalization and AI, framing them as crucial tools for advancing healthcare but also highlighting the governance challenges they present, such as issues of data ownership and privacy concerns.

Disruptive waves in healthcare data

Mr. Jacob highlighted that the healthcare sector faced five disruptive waves that reshaped the landscape:

1. **Adaptation of AI**: The integration of artificial intelligence into healthcare processes has transformed data analysis and patient care.
2. **COVID-19 pandemic**: The pandemic shook up our way of life, tested the resilience of healthcare sectors, and accelerated the shift towards a more data-driven approach in healthcare.

Development of the Zorgatlas platform

The Zorgatlas platform project began in 2018, but the onset of COVID-19 necessitated rapid development, leading to its completion in just three months. This platform provides a centralized repository for healthcare data, facilitating the use of AI to analyze and predict health outcomes.

Challenges in data management

Mr. Jacob discussed several challenges encountered in the context of data management:

- Issues related to interoperability between different data sources and the limited sharing of metadata.
- Concerns about the implications of storing data centrally, including privacy and security challenges.
- Emphasizing the importance of trust in data governance, it was noted that ethical and legal issues must be thoroughly investigated, especially under the European GDPR framework.

European Health Data Space (EHDS)

Mr. Jacob also touched upon the alignment with the European strategy for data and the establishment of the European Health Data Space (EHDS) agency. He noted the common public sentiment of distrust, encapsulated in the fear of "Big Brother" watching, when sharing data with the government. He highlighted the need to address these concerns to foster trust and ensure ethical data usage.

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Achievements and future directions

Main achievements:

- MVP Diabetes dashboard: Development of a diabetes dashboard providing population health managers insights into regional diabetes risk probabilities.
- Connector user interfaces: Creation of interfaces for both data providers and consumers to facilitate dataset management and access.

Future prospects: Mr. Jacob expressed excitement about the future, especially the potential of emerging technologies like quantum computing to significantly accelerate the processing capabilities required for large-scale health data analysis. He also noted the ongoing projects such as Gaia-X and the start of the EHDS, which aim to further enhance data connectivity and usability on a European and international scale.

A key focus has been on developing a proof of concept for the (Flemish) Health Data Space, demonstrating its potential benefits and addressing its challenges to stakeholders, including the government and healthcare providers. The concept includes different building blocks such as IDS connectors and ensuring data is centrally stored but managed by data owners.

Conclusion

Koenraad Jacob concluded by emphasizing the importance of continued innovation and adaptation in the healthcare data space. He is optimistic that with robust governance and advanced technologies, we can harness the power of health data to improve patient outcomes and healthcare efficiency.

Koenraad Jacob
(Flanders Department of Care)

> Synergy and collaboration with the Health Data Agency and the EHDS are essential when shaping the Flemish Health Data Space.

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe

Moderator: Liesbet M. Peeters

Presentation by Sofie De Broe (HDA / Sciensano) - Belgian Health Data Agency

The link to Sofie De Broe's presentation can be found here.

Sofie De Broe explored the creation and role of the Belgian Health Data Agency (HDA) in standardizing and facilitating the secondary use of health data. She described the structure and mission of the agency, which was significantly influenced by lessons learned during the COVID-19 pandemic.

Rationale behind the creation of the HDA

Dr. De Broe elaborated on the rationale behind the creation of the HDA, highlighting the numerous regional initiatives in Belgium and the impetus from European-level directives pushing for a more integrated digital healthcare system. She emphasized that the HDA focuses on the secondary use of health data, creating a bridge between data holders and data users. The HDA's role includes acting as a health data access body, providing access to metadata, and promoting data literacy and education. It also facilitates verification and governance processes, ensuring that data is managed ethically and securely.

Structure and mission of the HDA

The agency's legal framework does not recognize data ownership in a traditional sense but confirms rights and obligations for various parties involved in data handling. The HDA promotes the concept of data as a common good, akin to paying taxes, where collective data usage benefits society at large. This ethical framework supports the creation of representative data samples for research, emphasizing patient involvement.

The HDA metadata catalogue and HDA academy

Dr. De Broe provided a detailed view of how the agency aims to serve as a facilitative body, ensuring that health data is collected, standardized, and used responsibly. She used the example of the metadata catalogue that the agency is developing, which will guide users on where data resides and how it can be accessed and used, thereby enhancing transparency and efficiency in health data usage across Belgium.

She also mentioned the HDA Academy, an initiative aimed at increasing data literacy within the Belgian health data ecosystem. The academy provides resources and training to enhance understanding and responsible usage of health data.

Additionally, the HDA facilitates FAIR principles through guidelines, tools, governance, and coordination, ensuring that health data can be efficiently and effectively reused.

Alignment with Sciensano's data governance strategy

Sciensano's involvement in the HDA is also noteworthy. The agency has developed a comprehensive data strategy, published in 2022, and has since prioritized data governance as a strategic goal for 2023-2029. Sciensano's approach includes strengthening data collection and management, increasing data literacy, and ensuring data quality and validity. The establishment of a new scientific directorate for data governance on April 1, 2024 (led by Sofie De Broe), underlines Sciensano's commitment to managing health data ethically, securely, and transparently.

Conclusion

In summary, Sofie De Broe's presentation illustrated the pivotal role of the HDA in facilitating the secondary use of health data in Belgium, backed by strong legal, ethical, and governance frameworks. The agency's efforts to enhance data literacy and promote the FAIR principles underscore its commitment to improving the quality of healthcare data usage for research, policy-making, and innovation.

Sofie De Broe
(HDA / Sciensano)

> Data solidarity demands shifting our focus from self-interest to a dedication to the common good.

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe

Moderator: Liesbet M. Peeters

Panel debate – Bridging local insights with European ambitions

The panel debate delved into the practical and strategic aspects of scaling health data initiatives from local to European levels. Discussions focused on:

- **Harmonizing data practices**: The panel explored how regional initiatives like Health Campus Limburg can align with broader frameworks like EHDS. The importance of adopting data interoperability standards across borders was emphasized, with concrete examples such as the need for standardized data formats and certification processes for EHR systems across Europe.

- **Ethical and legal challenges**: The debate highlighted the complex ethical landscape of data usage, discussing the need for frameworks that allow patients to control their data while ensuring that such data can be used effectively for health advancements. The panelists debated the potential of an opt-out model for secondary data use, discussing its implications for patient privacy and research quality.

- **Future directions**: The discussion concluded with a forward-looking perspective on the integration of data spaces, with panelists agreeing on the need for a unified approach to data governance that could facilitate better research, policy-making, and patient care across Europe. They expressed optimism about the role of new technologies in overcoming current barriers and enhancing the scalability and utility of health data.

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Moderator: Dipak Kalra

Keynote by Christophe Maes (i~HD) – Enhancing hybrid digital healthcare: Principles of quality assurance in digital innovations

The link to Christophe Maes's presentation can be found here.

Christophe Maes, Business Development Officer at i~HD, delivered an insightful keynote on the principles of quality assurance in digital health innovations, emphasizing the need for rigorous standardization, regulation, and training.

Lessons from the aviation industry

Drawing parallels with the aviation industry, Mr. Maes illustrated how aviation's unified global standards and data interoperability could serve as a model for the fragmented healthcare sector. He highlighted the critical aspects of big data, interoperability, assessment frameworks, and training, which ensure the seamless operation of planes and could similarly transform healthcare.

Current challenges in healthcare

Mr. Maes noted that the healthcare sector is currently encumbered by regulatory and operational barriers, unlike the aviation industry, which adheres to strict, globally standardized procedures and regulations. While aviation's interoperability issues have been largely resolved, resulting in a significant reduction in incidents, healthcare continues to struggle with fragmented regulations and data standards across different countries.

Harmonizing assessment frameworks: AssessDHT

To address these challenges, Mr. Maes introduced two major projects aimed at harmonizing assessment frameworks and enhancing data interoperability in healthcare. The first project, AssessDHT, focuses on harmonizing digital health tools' assessment frameworks across Europe.

- **Project goals**: Map existing frameworks, identify common grounds, and develop a toolkit to ensure that digital health systems comply with minimal requirements to enter the EU market.
- **Key aspects**: Aligning practical aspects, GDPR compliance, and other regulatory perspectives.

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Enhancing data interoperability: xShare

The second project, xShare, addresses cross-border data flows and aims to create a standardized data exchange format that allows seamless data sharing across different systems.

- **Project vision**: Create a future where data can be shared with a single click, enhancing interoperability and providing data-driven insights.
- **Consortium efforts**: Involves a large consortium working on defining the exchange format and ensuring that data sharing is efficient and secure.

Mr. Maes also discussed the "Yellow Button" initiative within this project, which aims to simplify the data sharing process by allowing users to select and share specific data elements in the European Electronic Health Records Exchange Format (EEHRxF) easily. This initiative is part of the broader goal to enhance data interoperability and accessibility in healthcare.

Conclusion

In summary, Christophe Maes emphasized that by adopting principles from the aviation industry, such as standardized procedures and robust data interoperability, the healthcare sector can overcome its current barriers. The projects AssessDHT and xShare represent significant steps towards achieving a more integrated and efficient digital health ecosystem in Europe.

Christophe Maes (i~HD)

> Healthcare is not the only sector dealing with Big Data, interoperability issues and innovation barriers. We could learn from these others sectors, like aviation, and leverage lessons learned where possible.

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Moderator: Dipak Kalra

Presentation by Bert Vaes (KUL / Intego) - Primary Care & PHM

The link to Bert Vaes's presentation can be found here.

Professor Bert Vaes from KU Leuven discussed the transformational impact of big data in first-line care, emphasizing the critical role of the Intego database in collecting primary care morbidity data. His presentation began by highlighting two significant issues in healthcare: the reactive nature of current practices and the challenges posed by the pandemic of chronic diseases and shortages of healthcare workers.

The case for Population Health Management (PHM)

Dr. Vaes illustrated how PHM can address these challenges by shifting from reactive to proactive care. He described the segmentation of patients based on care needs, with about 80% managing their conditions largely independently, 18% requiring disease management, and only 2% needing complex case management. PHM focuses on identifying population needs and implementing targeted interventions to improve health outcomes.

Roadmap for implementing PHM

Despite policy actions in Belgium to shift from supply-based to needs-based healthcare, Dr. Vaes noted that PHM remains in its infancy. He described a roadmap developed to advance PHM, which includes:

- Fostering a sense of urgency to speed up PHM development.
- Building a learning health system supported by a robust data and knowledge infrastructure.
- Reducing investment uncertainties to enable new payment models and pilot projects.
- Starting from a joint population-oriented vision.
- Enforcing collaborative relationships and joint responsibility at regional levels.

Engaging healthcare workers through automated feedback

Dr. Vaes emphasized the importance of engaging healthcare workers in high-quality data registration by showing the benefits through automated feedback systems. These systems are designed to integrate seamlessly into existing workflows, providing immediate benefits without additional tasks. For example, during the COVID-19 pandemic, automated GP barometers were developed, currently monitoring four parameters, including diabetes and antibiotic usage. These barometers are integrated into all seven EHR systems used in Belgian practices, exemplifying the effective use of real-world data to enhance care quality.

The presentation also covered the development of an audit and feedback ecosystem within the Intego network. For instance, eleven specific variables were selected for diabetes care, such as blood sugar, albuminuria, and blood pressure monitoring. This system includes automated data collection, performance benchmarking, and targeted follow-up actions to improve patient outcomes.

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Federated data network and dynamic dashboards

Dr. Vaes introduced the conceptualization of setting-up a federated data network in general practice - an initiative led by the Data4PHM consortium, a multi-stakeholder collaboration including partners such as KU Leuven, IMA, UAntwerpen, Sciensano, Farmaflux, Zorgzaam Leuven and UHasselt - emphasizing the integration of data from multiple sources, including EHR, pharmacists, and national insurance data. This integration supports the development of dynamic PHM dashboards that provide feedback at various levels, from individual patients to federal policy makers. These dashboards facilitate triple accountability, ensuring that healthcare workers, policy makers, and patients share responsibility for health outcomes.

Conclusion: The future of data-driven healthcare

In conclusion, Dr. Vaes highlighted the potential of data-driven policy to enable proactive, multidisciplinary care and task delegation. He reiterated that while PHM in Belgium is still developing, there is a clear roadmap to its implementation, supported by technology like the GP barometers that provide real-time feedback and underline the societal role of healthcare providers and their EHRs in improving population health. The collaborative efforts of the Data4PHM consortium are crucial in realizing these goals through an integrated and dynamic approach.

Bert Vaes (KUL / Intego)

> Population Health Management in Belgium is still in its infancy, but is guided by a clear roadmap.

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Moderator: Dipak Kalra

Presentation by Ingrid Maes (Inovigate) - RWD4BE

The link to Ingrid Maes's presentation can be found here.

Ingrid Maes explored the potential of Belgium's RWD with the RWD4BE initiative, focusing on outcomes-based healthcare and innovation. She emphasized the complexity of addressing challenges due to the fragmented healthcare landscape and the diverse interests of stakeholders including governments, hospitals, and pharmaceutical companies.

The RWD4BE initiative

The RWD4BE initiative aims to position Belgium better on the national scale of real-world data reuse, not only by making data accessible but by creating a value-based healthcare system at the forefront of innovation. The initiative has two primary application elements crucial for enabling RWD reuse: outcome-based healthcare and reimbursement, emphasizing the wise expenditure of the budget. Additionally, it seeks to position Belgium as a prosperous ecosystem where innovation can thrive, focusing specifically on hospital data and its secondary use.

Challenges in addressing these goals are significant, requiring a balance between the interests of various parties including the government, hospitals, companies, and citizens. A transparent multi-stakeholder dialogue and platform are essential for finding alignment and co-creating solutions that are supported by all involved. The RWD framework, published in 2022, provides a structure for better stakeholder discussions and preferred solutions for data collection, assessment, and reporting. This framework includes building blocks that have been co-created to address these needs.

Implementation at the hospital level

The RWD4BE initiative aims to establish a connected health data reuse environment in Belgium, fostering transparent and patient-centric RWD projects. This vision includes increasing transmural quality of care, promoting value-based healthcare, optimizing cost efficiency, and reinforcing Belgium's position as a research and innovation hub. The mission involves enabling and implementing the connected RWD reuse framework through education, integrating medical and patient perspectives, and providing essential tools and well-informed policy recommendations.

Action groups within RWD4BE are responsible for implementing the framework at the hospital level (bottom-up approach), promoting and enabling multi-stakeholder collaboration and co-creation. These groups work on deliverables like data quality frameworks, data integration, standardization, and structuring. They also conduct hospital exchange meetings and pilot cases to address practical challenges in RWD reuse.

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Policy recommendations

Policy recommendations from RWD4BE propose a unified governance model for RWD applications, pooled funding to support substantial projects, and the establishment of a data quality labeling and certification framework. They emphasize the need for interoperability standards, a multi-stakeholder collaboration platform, and education efforts for healthcare professionals (HCPs) and the general public.

Future challenges

Future challenges include the need for more top-down guidance from the EU, expanding the RWD framework to include non-hospital data (such as GP, pharmacy, and environmental data), and broadening education efforts to encompass not only patients but also healthy individuals. This comprehensive approach is essential for overcoming the hurdles and fostering a sustainable and innovative healthcare system in Belgium.

Ingrid Maes (Inovigate)

> Belgium has one of the best healthcare systems in Europe and is the home to one of the strongest health and life science research clusters.

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Moderator: Dipak Kalra

Presentation by Hans Danneels (Byteflies) - Remote monitoring (mHealth)

The link to Hans Danneels's presentation can be found here.

Hans Danneels from Byteflies discussed the transformational potential of wearable technology in healthcare. During his presentation, he shared personal anecdotes to illustrate the practical benefits and challenges of remote monitoring technologies, particularly in managing acute health episodes from home.

Dr. Danneels highlighted the need for a healthcare paradigm shift where remote monitoring enables a transition from hospital-based acute care to home-based continuous care. He reflected on the barriers to reimbursement and the slow pace of regulatory change that impedes broader adoption of these technologies.

Personal story: The catalyst for change

Dr. Danneels began with a personal story, detailing a stressful experience when his twins, at around two months old, had an acute breathing problem. This incident required an immediate trip to the hospital, where they encountered bulky monitors with lots of wires, creating a high-overhead environment. The first day was critical, with constant monitoring by hospital staff. Despite the acute phase being over after the first day, the family stayed for another nine days for continuous monitoring. Dr. Danneels questioned the necessity of such prolonged hospital stays when the same monitoring could potentially be done at home, reducing the overhead and hospital pressure.

Dr. Danneels indeed emphasized the immense pressure on healthcare systems due to staff shortages, an aging population, and the closing of hospital beds. He pointed out that healthcare is evolving, with the "hotel function" of hospitals moving to homes. Remote monitoring at home, versus specialized services in clinics, is becoming the future of healthcare. Everyone is convinced that this transition will happen, driven by incremental changes. Telemonitoring, though not entirely new, is becoming more refined and efficient.

Incremental improvements and existing technologies

Existing technologies like the holter monitor, used for remote monitoring of heart conditions, are bulky and uncomfortable, requiring significant overhead for staff. However, Byteflies and similar companies are working on making these devices more comfortable and efficient (i.e. 24h Flow). By optimizing existing monitoring technologies, longer and more effective monitoring can prevent conditions like strokes and heart rhythm disorders. Despite these advancements, the reimbursement system remains a significant hurdle.

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Challenges in reimbursement and regulatory framework

Dr. Danneels discussed the ongoing struggle with the reimbursement system, noting that while studies show the effectiveness of remote monitoring, reimbursement is still not widely available. Incremental progress is being made, but radical change is needed, especially for conditions like epilepsy. Current methods involve costly hospital stays with intermittent monitoring, which can be inefficient and ineffective. Byteflies offers a solution with continuous home monitoring, allowing for dynamic treatment adjustments. However, the lack of reimbursement limits the scale of its application.

The importance of collaboration and innovation

Dr. Danneels stressed the importance of collaboration among top talents, health professionals, companies, and universities. He emphasized the need to break down data silos to enable comprehensive remote monitoring. From a reimbursement perspective, a leaner and more responsive approach is necessary. Temporary reimbursement models should be adopted to allow companies to demonstrate the value of their technologies. If Europe does not lead in this field, it risks falling behind countries like China.

Conclusion: Technology as an investment

Dr. Danneels concluded by reiterating that technology should not be viewed as a cost but as an investment that can significantly impact patients and the healthcare system. The goal is to enable patients to be monitored in their normal environments, ensuring better quality of life and more efficient healthcare delivery. Through continuous monitoring, healthcare providers can make informed decisions about treatment efficacy, as exemplified by cases where patients remained seizure-free due to optimized medication adjustments based on remote monitoring data.

Hans Danneels
(Byteflies)

> Everyone sees the value of remote monitoring. But implementation at scale remains challenging.

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Moderator: Dipak Kalra

Panel debate – Bridging local innovations and system-wide changes

At the end of session 2, the panelists engaged in a vibrant discussion about how localized innovations could influence broader healthcare systems. They explored several themes:

- **Standardization and regulation**: The discussion underscored the importance of establishing global standards within digital healthcare, similar to those in aviation, to ensure safety, interoperability, and efficiency.

- **Adoption of proactive health management**: The conversation highlighted the shift from reactive to proactive health management systems, emphasizing the role of data in enabling healthcare providers to anticipate patient needs rather than merely reacting to them.

- **Aligning stakeholders**: The necessity of aligning diverse stakeholders around shared goals to implement RWD effectively was emphasized. This involves transparent collaboration and the co-creation of policies and frameworks that address the needs of all parties involved.

- **Technological integration**: The incremental approach needed for the integration of wearable technologies into healthcare was discussed. This includes advocating for temporary reimbursement models to demonstrate value and effectiveness in real-world settings, thereby accelerating regulatory approval and adoption.

Session 3 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Moderator: Liesbet M. Peeters

Keynote by Jens Declerck (i~HD) – Assuring research excellence: strategies for assessing data quality in European projects

The link to Jens Declerck's presentation can be found here.

Jens Declerck, a PhD student and Data Quality Manager at i~HD, delivered a comprehensive keynote that addressed the crucial role of data quality in healthcare research. His presentation emphasized the importance of rigorous data quality assessments as foundational to impactful research and policy-making, detailing the challenges and methodologies surrounding the evaluation of data quality within the context of the EHDS.

EHDS data quality requirements

The EHDS outlines specific requirements for data quality in healthcare research. These requirements are detailed in two key chapters:

- **Chapter III**: Article 23 specifies that Electronic Health Records (EHRs) must include requirements related to data quality, specifically focusing on completeness and accuracy.
- **Chapter IV**: Article 56 elaborates on the composition of a data quality and utility label, outlining obligatory compliance with specific requirements for data holders sharing their data.

The **data quality and utility label** within the EHDS framework covers several aspects:

- Metadata documentation regarding data models, dictionaries, and standards used.
- Technical quality, including dimensions such as completeness, uniqueness, accuracy, validity, timeliness, and consistency.
- The maturity level of data quality management processes, including review and audit processes.
- Coverage of the provided data, such as representativity of the population sampled and the average timeframe in which individuals appear in the dataset.
- Information on data access and provision, including the time between data collection and addition to the dataset, and the time required to provide electronic health data following access approval.
- Details on data enrichments, such as merging and adding data to existing datasets and links with other datasets.

QUANTUM
THE HEALTH DATA QUALITY LABEL

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

Defining data quality

Several definitions of data quality have been proposed over the years:

- Juran (1988): Emphasized "fitness for use" as the primary criterion, focusing on data accuracy, relevance, and timeliness to meet healthcare needs.
- **ISO 9000 (2015)**: Defined quality as the degree to which inherent characteristics fulfill requirements.
- **DAMA International (2017)**: Described data quality as the degree to which data dimensions meet requirements.
- **i~HD (2022)**: Introduced the concept of "dynamic complexity," highlighting the ever-changing nature of data quality requirements across different projects and timeframes.

However, a significant gap exists between the EHDS requirements and the academic literature on data quality. Various studies have attempted to define the complex, multidimensional aspects of data quality, resulting in numerous frameworks and definitions:

- **22 reviews included**: These reviews compared 22 frameworks, identifying 23 different terms for dimensions and 62 definitions.
- **Primary vs. secondary sources**: The definition of data quality dimensions varies between primary sources (patient-level data) and secondary sources (population-level data).

Nine **data quality dimensions** commonly appear in the literature, forming the basis of the i~HD Data Quality Framework. These dimensions are critical regardless of whether the data is for primary or secondary use.

The QUANTUM project

The QUANTUM project, running from 2024 to 2026, aims to develop and implement a health data quality label for the secondary use of health data in the EU. Its objectives include:

- Conceptualizing and developing a data quality and utility label within a data holder maturity model.
- Designing, developing, and testing the labeling of datasets' quality and utility, and data holders' maturity.
- Analyzing implementation challenges to ensure the labeling process is transferable and sustainable as part of HealthData@EU.
- Developing a capacity-building program to engage the data quality professional community, patients, and citizens.

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

Capacity-building program

The capacity-building program aims to enhance understanding of data quality from primary to secondary use. A data quality syllabus will be developed to educate various stakeholders, ensuring they comprehend the dimensions of data quality and their implications.

Jens Declerck emphasized that a quality label alone will not improve data quality. Education is crucial to understanding and implementing data quality dimensions effectively. A study facilitated by RWD4BE in seven Belgian hospitals highlighted the challenges of data completeness and the need for better data collection and transformation processes to improve secondary use.

Conclusion

Jens Declerck's keynote underscored the importance of data quality in healthcare research and the necessity of rigorous assessment methodologies. The EHDS framework and the QUANTUM project represent significant steps toward standardizing data quality assessments and improving the overall quality of healthcare data in Europe. Through comprehensive education and robust data quality frameworks, substantial healthcare improvements can be achieved across Europe.

Jens Declerck (i~HD)

"Completeness" differs for primary and secondary users: for individual patients versus population level. This distinction is crucial for **improving data quality** and ensuring data serves its intended purpose effectively.

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

Moderator: Liesbet M. Peeters

Presentation by Annelies Verbiest (UZA) - OHDSI Belgium

The link to Annelies Verbiest's presentation can be found here.

Dr. Annelies Verbiest's presentation provided a comprehensive overview of the establishment and role of OHDSI Belgium. As a distinguished medical oncologist at UZA and co-chair of OHDSI Belgium, she emphasized the collaborative efforts aimed at enhancing health data usability and research reproducibility through standardized, harmonized data frameworks.

Addressing data challenges

Dr. Verbiest began by discussing the challenges faced in traditional observational research. These challenges include non-interoperable and siloed datasets, which lead to differing analytics and significant delays from question to answer. As a researcher, Dr. Verbiest expressed frustration with being confined to small, isolated datasets, which hampers the ability to produce meaningful and timely results. She stressed the need for a more integrated approach to data analysis, where decisions are informed by comprehensive knowledge from diverse data sources.

Solutions through OHDSI

Dr. Verbiest highlighted the solutions provided by the OHDSI community (Observational Health Data Sciences and Informatics) to overcome these challenges. Central to this is the OMOP Common Data Model (CDM), which standardizes various vocabularies and allows for analyses across different disease areas and perspectives. The adoption of the OMOP model enables researchers to conduct large-scale, multicenter studies with standardized data, significantly reducing the time and effort required for data processing.

A key component of this approach is the Extract, Transform, Load (ETL) process, which transforms source data into "OMOPped" data, making it ready for reliable and reproducible analyses. This method ensures that data is prepared efficiently, allowing researchers to clear most studies within weeks rather than years. Dr. Verbiest emphasized the safety and efficiency of this process, which is essential for scaling up multicenter studies and improving clinical research.

OHDSI's mission and vision

Dr. Verbiest outlined the mission and vision of OHDSI, which aims to improve health by empowering a community to collaboratively generate evidence that promotes better health decisions and care. The vision of OHDSI is to achieve a comprehensive understanding of health and disease through observational research, fostering a global community where researchers can share and build on each other's work.

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

OHDSI Belgium - officially launched in June 2023 - has seen significant growth, with over 60 organizations and 138 individuals involved as of April 2024. This community includes a diverse range of partners from academic institutions, hospitals, and industry players, all committed to data harmonization and research collaboration. Dr. Verbiest highlighted the enthusiasm and collaborative spirit within the OHDSI Belgium community, which is driving forward data-driven healthcare innovation.

Dr. Verbiest also discussed the integration of the OMOP model within European standards and adherence to FAIR data principles. This alignment ensures that health data is used effectively and ethically, supporting the evolution of data-driven healthcare.

Future prospects and challenges

In her concluding remarks, Dr. Verbiest emphasized the potential of leveraging health data to provide the best care for all patients. She acknowledged the ongoing challenges, including the need for enthusiastic collaboration among stakeholders and overcoming administrative hurdles. Despite these challenges, she remained optimistic about the future of data-driven healthcare, driven by the collective efforts of the OHDSI community.

Annelies Verbiest (UZA)

> As a researcher, I'm often stuck with my own little dataset, leading to huge delays from question to answer, but with the OHDSI community and the OMOP model, we can now run **multicenter studies** efficiently, transforming observational research into impactful, evidence-based decisions.

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

Moderator: Liesbet M. Peeters

Presentation by Wim Vanduffel (KU Leuven) - EBRAINS Belgium

The link to Wim Vanduffel's presentation can be found here.

Professor Wim Vanduffel of KU Leuven (Leuven Brain Institute), representing EBRAINS Belgium, shared the recent advancements in brain research facilitated by the EBRAINS infrastructure. His presentation, titled "Advancing Neuroscience: Integrative Approaches in Brain Research," focused on the integration of various research methods and technologies to understand complex brain functions and disorders.

The complexity of brain research

Prof. Vanduffel emphasized the brain's complexity, describing it as the most intricate organ in the body. Disruptions at any level—from molecules to cells to larger structures—can lead to pathology, affecting approximately one billion people globally. Current research limitations and the inability to fully fix brain disorders highlight the necessity of sophisticated neurotechnologies and multimodal approaches.

EBRAINS: A catalyst for neuroscience

EBRAINS, established five years ago from the EU-funded Human Brain Project, aims to catalyze neuroscience research and improve brain health. This initiative leverages the collective expertise of multidisciplinary researchers across Europe, integrating data from different modalities to provide a comprehensive understanding of the brain. Collaborative efforts are essential for developing new therapeutic strategies and advancing medical research.

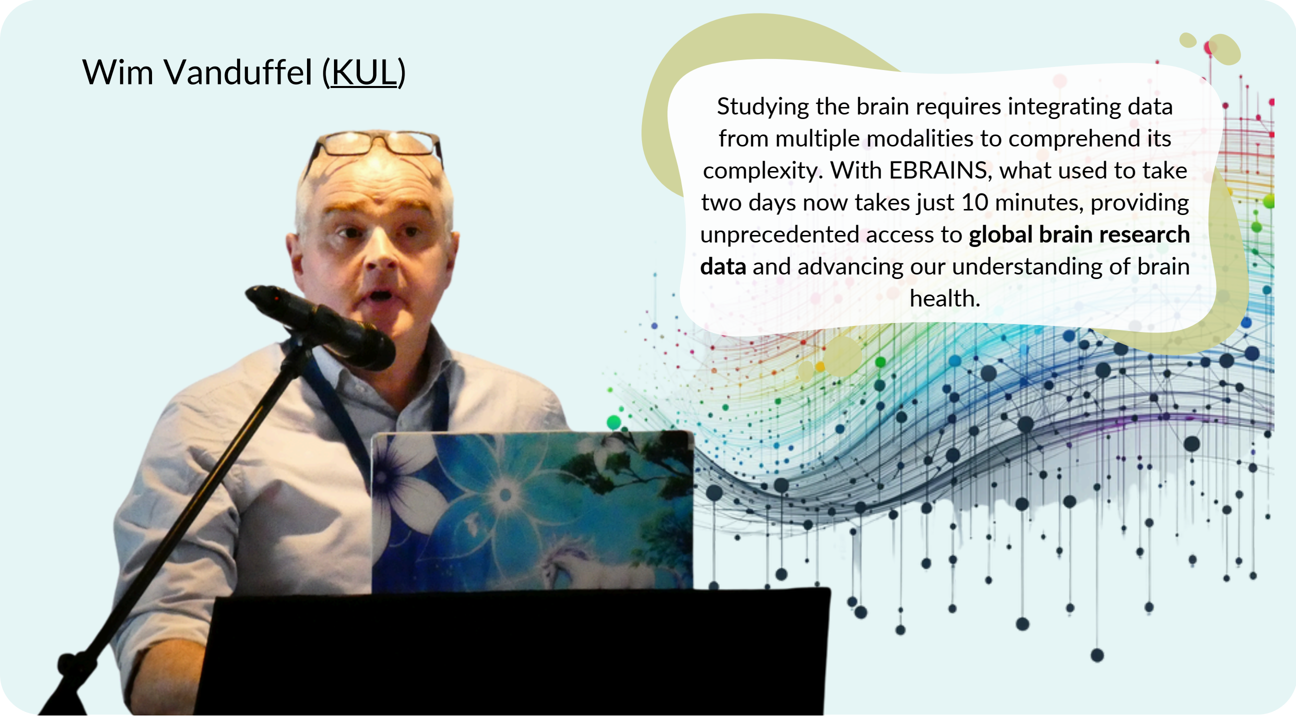
Infrastructure and support

Prof. Vanduffel highlighted the importance of data interoperability and accessibility, facilitated by EBRAINS' high-level support and curation teams. The infrastructure promotes extensive collaboration, significantly improving research efficiency; for example, tasks that previously took days can now be completed in minutes. With over 10,000 account holders and ongoing development projects, EBRAINS is rapidly growing and enhancing its impact on neuroscience research.

Future prospects and conclusion

Prof. Vanduffel underscored the critical role of initiatives like EBRAINS in pushing the boundaries of neuroscience. By fostering collaborative European research, EBRAINS is pivotal in advancing our understanding of the brain and developing novel therapeutic strategies to address neurological and mental health challenges.

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios



Wim Vanduffel (KUL)

Studying the brain requires integrating data from multiple modalities to comprehend its complexity. With EBRAINS, what used to take two days now takes just 10 minutes, providing unprecedented access to **global brain research data** and advancing our understanding of brain health.

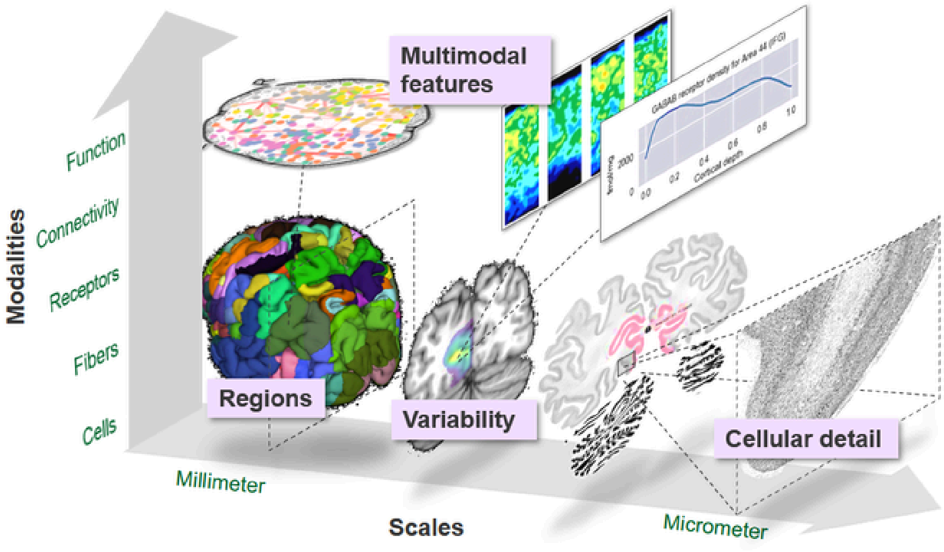


Illustration EBRAINS: A multilevel brain atlas connecting scales and modalities

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

Moderator: Liesbet M. Peeters

Presentation by Frederik Coppens (VIB Data Core) - ELIXIR Belgium

The link to Frederik Coppens's presentation can be found here.

Frederik Coppens, head of VIB Data Core and representative of ELIXIR Belgium, discussed the critical role of data management in life sciences in his talk, "Enhancing Research Outcomes Through Standardized Data Practices." He emphasized the need for rigorous data standardization and management across the entire data lifecycle to ensure reproducibility and validity in scientific research. Detailing ELIXIR's efforts in supporting scientists with advanced data services, Dr. Coppens highlighted the collaborative work on a European scale to facilitate efficient, transparent, and FAIR-compliant research practices.

Harmonizing research infrastructure in Europe

ELIXIR Belgium plays an important role in ELIXIR Europe, an ESFRI acknowledged research infrastructure. Dr. Coppens emphasized how the collaboration among research institutes across the continent aims to harmonize and standardize systems, making them user-friendly for researchers. He noted the involvement of ELIXIR Belgium in several key projects today, underscoring the consortium of Flemish universities and institutions like Scienscano, which focus on data management and the development of platforms to gather, analyze, and make data available in a FAIR manner.

The Research Data Management (RDM) toolkit

Dr. Coppens introduced the Research Data Management (RDM) toolkit, a comprehensive resource that consolidates the knowledge of data management experts. While the toolkit provides guidelines and tools used successfully by ELIXIR, he encouraged researchers to adapt these resources to their specific needs. He also discussed the concept of data brokering, which not only explains data management practices but also facilitates their implementation. For instance, ELIXIR Belgium assisted ITG (Institute of Tropical Medicine) by simplifying complex documentation and retrieving metadata efficiently.

Collaborative projects and initiatives

Highlighting the BY-COVID initiative, Dr. Coppens described how ELIXIR Belgium collaborates with various institutes to mobilize and connect data for enhanced analysis and response. He elaborated on the creation of a robust ecosystem around data management and analysis, which includes a flexible software structure applicable to a wide range of scientific inquiries.

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

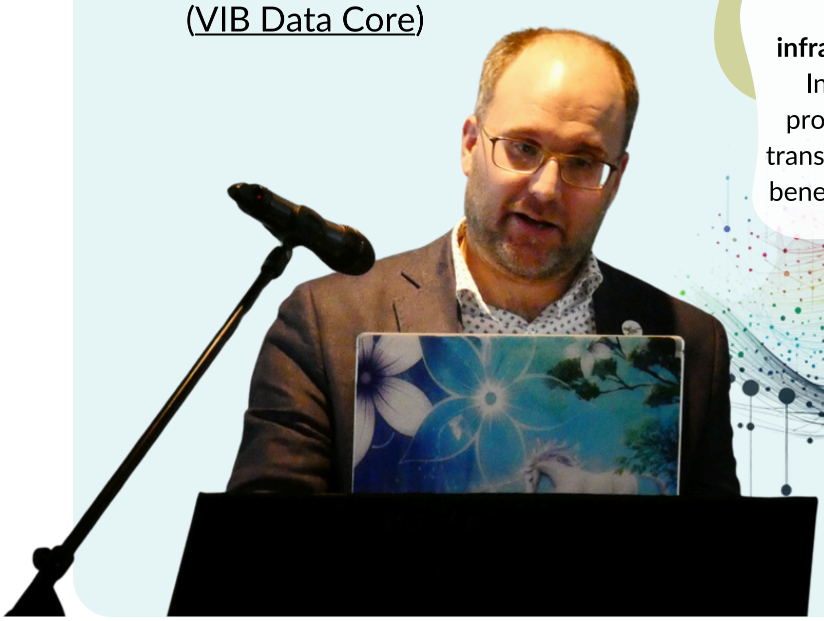
One of the significant projects Dr. Coppens detailed was the European Genomic Data Infrastructure, which aims to achieve the objectives of the 1 Million Genomes initiative. This project seeks to sequence the genomes of one million individuals across Europe to advance personalized medicine. Dr. Coppens emphasized the importance of integrating genomic data with healthcare applications to realize tangible benefits. He mentioned the existing European Genome-phenome Archive (EGA) and the necessity of having the right metadata and interoperability agreements to facilitate data sharing and access.

In Belgium, efforts are underway to build a genomic library, starting with a Belgian reference genome. This initiative, although driven by research objectives, is intended to contribute to healthcare advancements and could *e.g.* also be reused for cancer imaging. Dr. Coppens stressed the need for similar infrastructures to support various aspects of healthcare data, aligning with the EHDS requirements.

Conclusion

Dr. Coppens concluded by acknowledging the funding support from the European Union's Digital Europe Programme for projects like GDI and BY-COVID, and reiterated the commitment of ELIXIR Belgium to fostering a cohesive and efficient data management environment for life sciences research across Europe.

Frederik Coppens
(VIB Data Core)



Creating a **standardized research infrastructure across Europe** is essential. Initiatives like the 1 million genomes project aim to make data accessible and transform research into tangible healthcare benefits, advancing personalized medicine.

Session 3 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Moderator: Liesbet M. Peeters

Panel debate – Bridging diverse data domains for enhanced healthcare solutions

The panel debate, involving all the session speakers, thoroughly explored the integration and management of diverse data types within healthcare research. The debate was structured around several key themes:

- **Maintaining high data quality standards** - The critical importance of high data quality across different research domains was emphasized. Challenges and strategies for ensuring data integrity in healthcare research and policy-making were highlighted, underscoring the need for robust frameworks.

- **Best practices for data integration** - The debate highlighted various approaches to integrating clinical, -omics, and brain-related data. Insights on the complexities of combining neuroscientific data with clinical outcomes were shared, stressing the need for advanced data infrastructures.

- **Leveraging emerging technologies** - The role of emerging technologies and infrastructures in enhancing data scalability and utility was explored. Innovations in data management and standardization were discussed, highlighting their potential to facilitate more effective and comprehensive health research.

- **Implications for healthcare and policy** - The debate focused on how diverse data integration can impact health outcomes and inform policy decisions. The potential of harmonized and high-quality data to revolutionize patient care and health systems was underscored.

- **Collaborative strategies and future directions** - The necessity for ongoing collaboration across disciplines and borders to harness the full potential of diverse health data was emphasized. Continued innovation in data management practices and a unified approach to address the challenges of data diversity in healthcare research were called for.

The session concluded with a consensus on the need for strategic partnerships, standardization, and innovation in data management to achieve the overarching goal of improving healthcare through enhanced data utilization.

Session 4 – Synergizing tomorrow: Unveiling strategies to maximize collaboration and progress

Moderators: Liesbet M. Peeters & Dipak Kalra

Keynote by Liesbet M. Peeters (UHasselt) – Arisal of data spaces: Why I am excited and worried?

The link to Liesbet M. Peeters's presentation can be found here.

Liesbet M. Peeters opened the final session with an engaging and thought-provoking presentation titled "Arisal of Data Spaces: Why I am Excited and Worried?" She began by discussing the emergence of data spaces, expressing both her excitement for the potential advancements they could bring and her concerns about the accompanying challenges.

Current landscape of health data

Prof. Peeters elaborated on the current landscape of health data, noting how individual health data is often stored in disparate silos, preventing comprehensive analysis and utilization. This fragmentation is not only an issue for individuals but is a widespread problem affecting everyone.

Throughout a person's lifetime, data is collected in various silos—ranging from medical scans and blood samples to personal health records—yet these datasets remain disconnected. She posed a compelling vision: imagine if all this data were available for research purposes. The possibilities for answering significant health-related questions and advancing medical knowledge could be tremendous.

Challenges to realizing the vision

However, Prof. Peeters underscored the many socio-technical barriers obstructing the scaling of health data reuse:

- **Limited awareness and engagement**: There is a general lack of awareness about the potential for reusing health data on a large scale. This leads to limited engagement from key stakeholders such as clinicians, government bodies, and researchers.
- **Governance, ethical, and legal issues**: Integrating and securing vast amounts of data, as well as addressing governance issues related to data privacy and ownership, pose significant obstacles and impacts the execution of large-scale initiatives.
- **Divergent stakeholder expectations**: Different stakeholders, such as industry players and citizens, have varying expectations and needs regarding health data, complicating large-scale collaborative efforts.

Session 4 – Synergizing tomorrow: Unveiling strategies to maximize collaboration and progress

Personal reflection

In her personal reflection, Prof. Peeters shared her journey and worries about the data landscape. She emphasized the need for strategic efforts to ensure that the emergence of parallel data spaces serves the best interests of all stakeholders. Reflecting on her experiences since the symposium “Big data for Health & Care” she organized two years ago, she noted her ongoing concerns about the fragmented state of health data.

To address these challenges, Prof. Peeters called for a comprehensive catalogue of health data initiatives to help achieve strategic oversight and connect the dots in this fragmented landscape. She shared her own efforts in publishing an open-source Excel file listing various initiatives, aiming to help stakeholders navigate the complex landscape of health data reuse.

Call-to-action

In closing, Prof. Peeters reiterated the need for a collective approach to ensure that the development of parallel data spaces benefits all citizens and stakeholders. She urged the audience to reflect on what they could contribute to this effort, invoking a sense of duty and collaboration. Her final question, "How can we safeguard that the arisal of these parallel data spaces remains in the best interest of all citizens and stakeholders?" served as a call-to-action for everyone involved in the health data ecosystem.

Liesbet M. Peeters
(UHasselt)

Solving wicked problems requires a deep understanding of the stakeholders involved and requires a strong network of thinkers to come up with innovative and creative approaches to solving them.

The power of data lies in all of us - **#DataSavesLives**

Session 4 – Synergizing tomorrow: Unveiling strategies to maximize collaboration and progress

Moderators: Liesbet M. Peeters & Dipak Kalra

Closing panel debate – Insights and reflections

The panel debate, moderated by Liesbet M. Peeters and Dipak Kalra, brought together th following experts from previous sessions: Sofie De Broe from the Health Data Agency, Bert Vaes from Intego, Hans Danneels from Byteflies, Annelies Verbiest from OHDSI Belgium, and Frederik Coppens from ELIXIR Belgium. The discussion revolved around maximizing synergy, strategic oversight, and future aspirations for health data integration.

Discussion on specific initiatives and strategic oversight

The discussion began with a query about the necessity of mentioning additional initiatives beyond those covered during the symposium. Participants concurred on the significance of strategic oversight to prevent redundant efforts, emphasizing the need to integrate existing initiatives rather than launching new ones. It was noted that while many initiatives are currently in progress, they often lack a clear governance structure and strategic direction. The focus was placed on foundational elements, such as data harmonization and concrete use cases, to demonstrate the value of integrated health data.

Challenges of data integration and governance

The conversation then turned to the challenges of data integration and governance. Participants highlighted the difficulties in matching sample information with clinical data, calling for clear processes and standards. It was observed that healthcare providers often face overwhelming administrative requirements without immediate benefits. Advocacy was made for creating use cases that provide direct feedback and rewards to healthcare providers, thereby enhancing data quality and care outcomes.

Experiences with developing quality indicators for using Electronic Health Records (EHR) systems were shared, emphasizing the need for feedback loops to improve these systems and support clinicians in their work. The concept of data solidarity was introduced, suggesting a shift in focus from individual benefits to community benefits in data sharing, similar to the model used in official statistics where data is collected for the common good.

Economic and regulatory considerations

Insights were provided on the economic incentives necessary for successful health data projects, stressing the importance of having a high-level vision and sufficient budget to support these initiatives. The significant impact of regulations like the GDPR on research was discussed, advocating for a balanced approach that minimizes burdens while ensuring compliance.

The discussion expanded to the Data Governance Act and the GDPR's influence, highlighting the need for rule changes to facilitate research while ensuring data privacy and security. It was acknowledged that while GDPR provides essential protections, its stringent requirements often pose challenges for large-scale health data projects.

Session 4 – Synergizing tomorrow: Unveiling strategies to maximize collaboration and progress

Role of technology and future perspectives

The role of technology in assisting clinicians and improving data entry processes was explored. The potential for automated systems to enhance efficiency and care quality was highlighted, emphasizing the need for clear incentives and perspectives for all stakeholders to encourage participation and data sharing. It was stressed that technology should support clinicians rather than replace them.

The necessity of a holistic view integrating different data sources and validating the information was discussed, acknowledging that while technology can significantly enhance data management, human oversight remains crucial to ensure data quality and relevance.

Government and policy implications

The role of government in mandating data sharing for the common good was discussed, suggesting that the state should play a more active role in collecting and using health data to benefit society. The idea was proposed to extend the principles used in official statistics to health data, where the state requires certain data to run the country effectively.

The importance of creating a supportive policy environment that encourages data sharing and integration was emphasized, with discussions on the need for clear incentives and perspectives for all stakeholders, including healthcare providers, researchers, and policymakers.

Session 4 – Synergizing tomorrow: Unveiling strategies to maximize collaboration and progress

Moderators: Liesbet M. Peeters & Dipak Kalra

Closing remarks

In their closing remarks, Dipak Kalra and Liesbet M. Peeters reflected on the rich and sophisticated discussions of the session. Prof. Kalra praised the energy and passion of the participants, emphasizing the importance of collective effort and strategic collaboration to prepare for the European Health Data Space. He urged the audience not to wait for EHDS to happen but to start joining the dots and solving problems pragmatically. He highlighted that while EHDS is an exciting opportunity, it will come empty, and it is up to the stakeholders to fill it with quality data.

Prof. Peeters acknowledged Dipak Kalra's inspiring contributions and the valuable insights shared by the panelists. She urged continued collaboration and innovation to overcome socio-technical barriers in health data utilization. The session concluded with a strong sense of optimism and a call-to-action to harness the collective energy and intelligence to create a more integrated and efficient health data landscape.

Annex 1 - About the organizers

About i~HD

The European Institute for Innovation through Health Data (i~HD) is a neutral, multi-stakeholder, non-for-profit organization dedicated to maximizing the value of health data. It promotes, develops, and shares best practices, tools, and quality assessments to drive innovations in health, care, and research. i~HD aims to catalyze smarter healthcare and efficient research by creating and combining high-quality health data and advocating for its trustworthy use.

i~HD's vision is to foster a world where stakeholders collaborate in the trustworthy use of high-quality health data to continuously improve care and accelerate research. To realize this vision, i~HD leverages multi-stakeholder cooperation, operating as a membership-based organization uniting diverse health data stakeholders, including patient organizations, health policy makers, academia, and the health ICT industry.

The institute's mission involves promoting collaboration through education and events, participating in national and international R&D projects, developing practical methods and solutions, and creating international quality certificates, seals, and labels. i~HD boasts over 30 years of experience in European projects, contributing to more than 100 R&D initiatives and maintaining a network of 150 experts.

Quality is a cornerstone of i~HD's operations. The organization has implemented a Quality Policy Statement compliant with ISO 9001:2015, ensuring continuous improvement and high standards in service delivery. This system includes regular audits, client feedback analysis, and a robust framework for quality improvement and compliance.

i~HD distinguishes itself through its neutrality, focus on practical solutions, and commitment to trustworthy health data use. It connects a network of world-leading experts and brings decades of expertise to its quality certifications. By convincing stakeholders of the benefits of high-quality health data, uniting them in a neutral forum, creating innovative solutions, certifying data practices, and catalyzing change, i~HD plays a pivotal role in the health data ecosystem.

More information can be found on the i~HD website.

About the research group of Biomedical Data Sciences (UHasselt)

The Biomedical Data Sciences Research Group at the University of Hasselt (UHasselt) is dedicated to enhancing healthcare through innovative data science methods. Affiliated with the Biomedical Research Institute (BIOMED), the Data Science Institute (DSI), and the University MS Center (UMSC), the group aims to provide timely and personalized treatments by leveraging Big Data in health and care.

Mission, vision and approach

The group's mission is rooted in the belief that data saves lives. They focus on real-world health data and work in a multi-stakeholder environment to derive actionable insights. Their research spans various high-innovative use cases, from federated artificial intelligence for multiple sclerosis (MS) patient trajectories to harmonization strategies for MS data sources.

Annex 1 - About the organizers

The group envisions a world where healthcare is personalized and timely, with data playing a crucial role in improving patient outcomes. Through their civic and educational activities, they aim to foster a community that values and utilizes data to save lives and enhance healthcare.

Research - PhD Projects

The group has currently 7 PhD-students, working on different projects, including:

1. Federated AI for MS patient trajectories.
2. Harmonization of real-world MS data.
3. Introduction of radiomics and -epomics to improve MS care.
4. Accelerating open data integration.
5. Enhancing data quality in complex health data spaces.
6. Developing prognostication tools for MS.
7. Population health management in Limburg.

Collaboration and civic engagement

The group collaborates with other Flemish universities such as KU Leuven, UGent, and UAntwerp, as well as international partners in e.g. initiatives like the MS Data Alliance. They focus on creating a multi-stakeholder ecosystem and developing tools to manage and utilize real-world data effectively.

Educational Role

UHasselt's Biomedical Data Sciences Research Group also plays a significant educational role, offering courses and supervising students in Biomedical Sciences, Bioinformatics, and Data Science in Health and Care. They aim to prepare future professionals for the digital transformation in medicine and life sciences.

Notable Initiatives

- Flanders AI Research (FAIR) Program: Leading the use case for real-world evidence.
- BELTRIMS: Collaborating on the Belgian MS Registry to improve data interoperability.
- EHDEN: Contributing to the European Health Data and Evidence Network by mapping datasets to the OMOP common data model.
- ELIXIR Belgium: Engaging in research data management and reproducible data analysis via toolbox development, within a European infrastructure.
- MS Data Alliance: UHasselt is a core partner, with the group building bridges between stakeholders and developing tools for better MS data management and utilization.
- EBRAINS Belgium: UHasselt leads the national node, focusing on creating a federated infrastructure for brain-related research and leveraging big data and AI technologies.
- OHDSI Belgium: UHasselt co-founded this node, promoting harmonization of health data to set-up large-scale collaborative efforts to improve citizen health, aligning with European initiatives and legislation.

More information can be found on the research group’s website.

Annex 2 - About the speakers

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe

Dipak Kalra (i~HD)

Dipak Kalra is the President of The European Institute for Innovation through Health Data (i~HD) and a distinguished expert in health informatics. As a keynote speaker and co-moderator at the "Big Data for Health & Care: The Arisal of Data Spaces" symposium, prof. Kalra provided valuable insights into the development of health data spaces in Europe. His keynote focussed on the European Health Data Space (EHDS) and the challenges of scaling up health data management at the European level.

Prof. Kalra's career is dedicated to advancing Electronic Health Records (EHR), including the development of ISO standards for EHR interoperability. He has led numerous Horizon 2020 and IMI projects, significantly impacting the field of health informatics. Additionally, he serves as a Professor of Health Informatics at University College London and is a visionary in eHealth privacy, contributing to the governance, quality, and interoperability of health data.

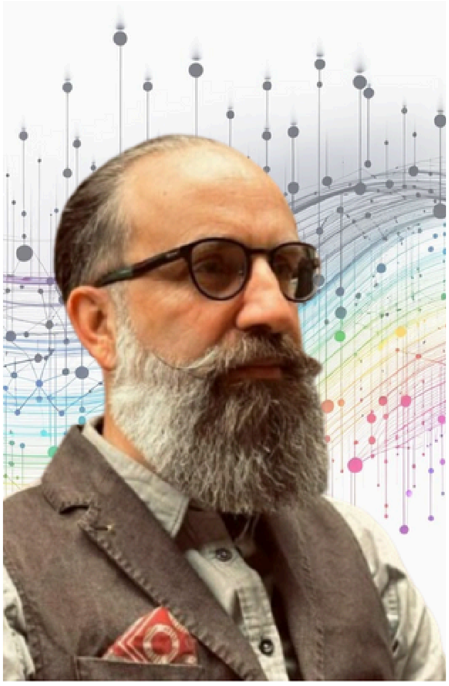
Piet Stinissen (UHasselt) - Health Campus Limburg

Prof. Piet Stinissen is a distinguished professor of immunology and the prodean at the Faculty of Medicine and Life Sciences at Hasselt University. With a rich history in leadership, he served as the dean of the Faculty of Medicine and Life Sciences from 2009 to 2022 and directed the Biomedical Research Institute (BIOMED) at Hasselt University prior to that. His scientific work focuses on autoimmunity, multiple sclerosis, and healthcare innovation.

Currently, Prof. Stinissen leads the Limburg Clinical Research Center (LCRC), promoting collaboration between UHasselt and the ZOL and Jessa hospitals. He is also the co-chair of the University MS Center UHasselt-Pelt and chairs the task force for Health Campus Limburg. At the symposium, he discussed the impact of local health data spaces, with a particular emphasis on Health Campus Limburg, which integrates business, government, education, health institutions, and citizens to advance healthcare innovation.

Annex 2 - About the speakers

Session 1 – Borderless insights: Unveiling opportunities & challenges in scaling RWD across Limburg, Flanders, Belgium, and Europe



Koenraad Jacob (Flanders Department of Care)

Koenraad Jacob is a leading data scientist at the Flanders Department of Care, renowned for his expertise in statistical analysis and machine learning. His ability to transform complex data into actionable insights makes him a pivotal figure in the field of Real-World Data (RWD). With a career focused on bridging the gap between technical data science and business strategy, Mr. Jacob exemplifies innovation and practical application.

As an experienced AI translator and tutor, he has extensive knowledge in deploying data for segmentation, forecasting, recommendation engines, and more. At the symposium, Mr. Jacob shared his insights on scaling RWD across Flanders, delving into pioneering strategies and practicalities. His session provided attendees with a roadmap to unlocking the full potential of data to drive forward health and care innovation in the region.

Sofie De Broe (Belgian Health Data Agency / Sciensano)

Sofie De Broe is a seasoned statistical analyst and methodologist with extensive experience from Sciensano. Currently at the forefront of Belgium's health data evolution, she has played a pivotal role in enhancing health data access and availability, particularly in the wake of the COVID-19 pandemic.

In March 2023, Belgium established the Health Data Agency (HDA), a significant milestone in the country's efforts to collect, standardize, and responsibly use health data. Dr. De Broe, who served as the interim head of the HDA, is now the Scientific Director of Data Governance at Sciensano. Her expertise in overcoming the challenges posed by Belgium's federal structure and her vision for a unified health data ecosystem are crucial for understanding and navigating the complexities of scaling Real-World Data (RWD) in Belgium.

Annex 2 - About the speakers

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Christophe Maes (i~HD)

Christophe Maes is a distinguished expert in healthcare data quality and process management. He serves as the Business Development Officer at i~HD, focusing on enhancing healthcare data quality. Additionally, he is a Project Manager at the European Commission and a Healthcare Management Consultant for Inaequo bvba. Mr. Maes's expertise lies in integrating digital innovations with traditional healthcare practices, providing invaluable insights into the future of healthcare.

His extensive experience in navigating the complexities of real-world data (RWD) and applying quality assurance principles to digital healthcare innovations makes him a leading figure in the field.

Bert Vaes (KUL / Intego)

Bert Vaes is an esteemed MD, general practitioner, and Professor at KU Leuven. He is a leading expert in first-line care and the use of big data to revolutionize this essential healthcare sector. Dr. Vaes is at the forefront of the INTEGO database, a pioneering project initiated in 1990 at KU Leuven's Academic Center of General Medicine. INTEGO is Belgium's first automated general practitioner registration network, providing comprehensive data on primary care morbidity. This database offers valuable insights into disease incidence, prevalence, diagnostic tests, and treatments in Flanders, serving as a foundation for innovative research and healthcare improvement.

Dr. Vaes's work also focuses on Population Health Management (PHM), a proactive approach leveraging data and risk stratification to enhance health outcomes, facilitate cross-sector collaboration, and address health inequalities.

Annex 2 - About the speakers

Session 2 – Breaking barriers: Navigating RWD challenges from first-line to hybrid digital care in transmural integrated settings

Ingrid Maes (Inovigate)

Ingrid Maes is a luminary in the pharmaceuticals and life sciences industry with over 30 years of experience. She is the founder and managing director of Inovigate in Antwerp, Belgium. Ms. Maes has held leadership roles at Siemens and PwC for 15 years, showcasing her expertise in R&D, manufacturing, and regulatory compliance. She excels in integrating science and technology with strategy and finance, focusing on industry insights, market analysis, and strategy formulation, particularly in growth, innovation, and multi-stakeholder collaboration.

Ms. Maes is a key force behind the RWD reuse framework and its implementation via the RWD4BE initiative, demonstrating her commitment to advancing healthcare through data. At the symposium Ms. Maes delivered a session titled "Unlocking Belgium's Health Data Reuse Potential: The RWD4BE Initiative," providing deep insights into the transformative potential of real-world data in healthcare.

Hans Danneels (Byteflies)

Hans Danneels is the co-founder and co-CEO of Byteflies, an Antwerp-based medtech company established in 2015. Byteflies develops sensor technology for remote patient monitoring, reducing hospital pressure and enhancing patient comfort. The company gained momentum during the COVID-19 crisis, raising 4.5 million euros to scale its operations. Their technology is used in 30% of Belgian hospitals and is expanding to Germany, the Netherlands, and the US.

Dr. Danneels advocates for digital solutions in healthcare, emphasizing collaboration with stakeholders to enrich the current system. At the symposium, he discussed how Byteflies' wearable technology captures data and transforms it into actionable insights, streamlining care and facilitating value-based healthcare.

Annex 2 - About the speakers

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

Jens Declerck (i~HD)

Jens Declerck is a PhD student and Data Quality Manager at The European Institute For Innovation Through Health Data (i~HD). He plays a key role in the QUANTUM project, which aims to develop and implement a health data quality label for the EU. This project seeks to create a common label system to ensure data quality and utility for scientific and health innovation purposes.

Mr. Declerck delivered a keynote entitled "Assuring Research Excellence: Strategies for Assessing Data Quality in European Projects," where he guided us through vital data quality aspects and strategies aligned with European project standards.

Annelies Verbiest (UZA / OHDSI Belgium)

Dr. Annelies Verbiest is a distinguished medical oncologist at UZA and the co-chair of OHDSI Belgium. She plays a key role in enhancing health data harmonization to improve data-driven insights in healthcare.

Dr. Verbiest is committed to aligning with European standards and embracing FAIR data principles to advance health data science and contribute to global and European health data integration.

Annex 2 - About the speakers

Session 3 – Data diversity unveiled: Exploring -omics, clinical, and brain-related data in real-world scenarios

Wim Vanduffel (KU Leuven / EBRAINS Belgium)

Prof. Vanduffel is a Full Professor at KU Leuven (as part of the Leuven Brain Institute) and an Assistant Professor at Harvard Medical School, renowned for his expertise in neuroimaging and brain research. He has led significant advancements in primate and human brain imaging, contributing to the understanding of brain function and structure through innovative techniques and collaborative research.

Prof. Vanduffel is a key figure in EBRAINS Belgium, a component of the pan-European research infrastructure from the Human Brain Project, enhancing brain research through advanced imaging, data analyses, and a commitment to interoperability.

Frederik Coppens (VIB Data Core / ELIXIR Belgium)

Frederik Coppens is the Head of VIB Data Core and ELIXIR Belgium. He leads the VIB Data Core, an initiative supporting scientists with advanced data services focused on quality, standardization, and efficiency in data handling, adhering to FAIR principles. His efforts span the entire data life cycle, enhancing research outcomes across the VIB Research Centers.

Dr. Coppens is also involved with ELIXIR, Europe's leading life-science research infrastructure, pioneering research data management and analysis. His work emphasizes reproducible science and impacts a broad spectrum of research fields.

Annex 2 - About the speakers

Session 4 – Synergizing tomorrow: Unveiling strategies to maximize collaboration and progress

Liesbet M. Peeters (UHasselt)

Liesbet M. Peeters is a pioneering researcher in the field of healthcare and big data, affiliated with UHasselt. Her academic career is centered on the transformative potential of RWD in healthcare, particularly through the innovative use of artificial intelligence and machine learning, with use cases in a variety of disease areas, such as multiple sclerosis. Prof. Peeters's vision that #DataSavesLives drives her dedication to improving patient outcomes and revolutionizing healthcare through intelligent data use.

Prof. Peeters's ability to bridge the gap between biomedical research and data science not only accelerates progress in these fields but also fosters collaboration across disciplines. Her contributions to the intersection of healthcare and big data exemplify the spirit of innovation and highlight the potential of data in enhancing healthcare delivery and patient care.

At the symposium "Big Data for Health & Care: The Arisal of Data Spaces," prof. Peeters delivered a keynote and co-moderated the panel debates, bringing her unique perspective and expertise to the forefront of the discussions.

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