Optimapharm Connect

Clinical trials rely heavily on data, making it essential for Optimapharm to embrace a data-driven approach as a growing organization. Data is critical throughout the study design and planning lifecycle, from protocol development where historical data supports protocol rational and sample size calculation.

Effective recruitment strategies depend on data to develop predictive models, allowing for the identification and targeting of potential patient populations more accurately. Ensuring patient safety and maintaining data integrity are paramount in clinical trials, and real-time data monitoring enables prompt identification and resolution of issues.

Optimapharm's operational plans must also be data-driven. For example, resource allocation requires data to determine staffing needs, preventing bottlenecks and delays. Project timelines are crucial for planning clinical trials, and data from sites, countries, and functional areas ensure trials are conducted on schedule.

I encourage each of you to share other areas within clinical trials where a data-driven approach is essential. Please feel free to contact me with your insights.

Looking ahead, we must consider emerging trends in data-driven clinical trials, including artificial intelligence and machine learning. Rapid evolution in these areas will require all stakeholders to embrace these changes.

For more details, my colleagues Raivo Verk and Manigandan Murugaperumal will provide additional insights in this edition of our newsletter, Optimapharm Connect. Enjoy reading!

Miguel Salcedo,

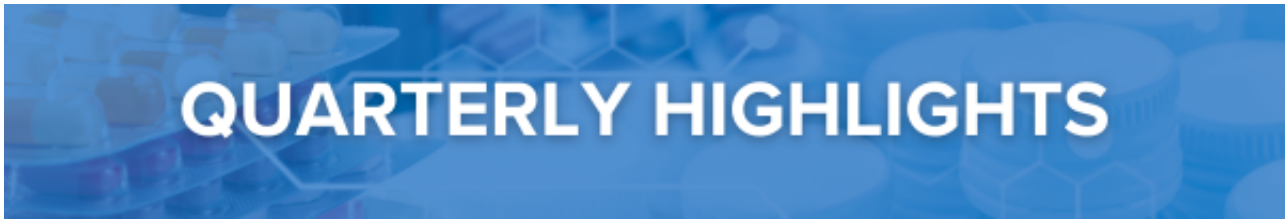
Chief Operating Officer

Data Driven Clinical Research Organization - an Interview with Raivo Verk

In the dynamic and highly regulated world of clinical research, data management stands as a cornerstone for ensuring the integrity, accuracy, and reliability of clinical trial data. As clinical trials become increasingly complex, with vast amounts of **data being collected from diverse sources**, the role of data management has never been more critical. Effective data management not only facilitates compliance with stringent regulatory standards but also enhances the **efficiency and success of clinical trials**, ultimately bringing new therapies to patients faster and more safely.

We spoke with **Raivo Verk**, Director of Data Management at Optimapharm, to better understand the strategies, processes, and challenges of data management in clinical trials.

Read the Interview



666

Phase IV, NIS study in Atrial Fibrillation successfully closed on time with 666 patients enrolled

1st

1st site initiated and 1st patient enrolled in Phase II, Multiple Myeloma study

1

Soft database lock completed in Medical Device in Aortic Valve Replacement study with 443 subjects randomized

154

Last Patient In (LPI) in Phase II, Alcohol Use Disorder (AUD), 154 patients randomized across Europe and North America

1

First subject enrolled (FPI) to Phase I, First in Human (FIH) trial in Head and Neck Squamous Cell Carcinoma study

397

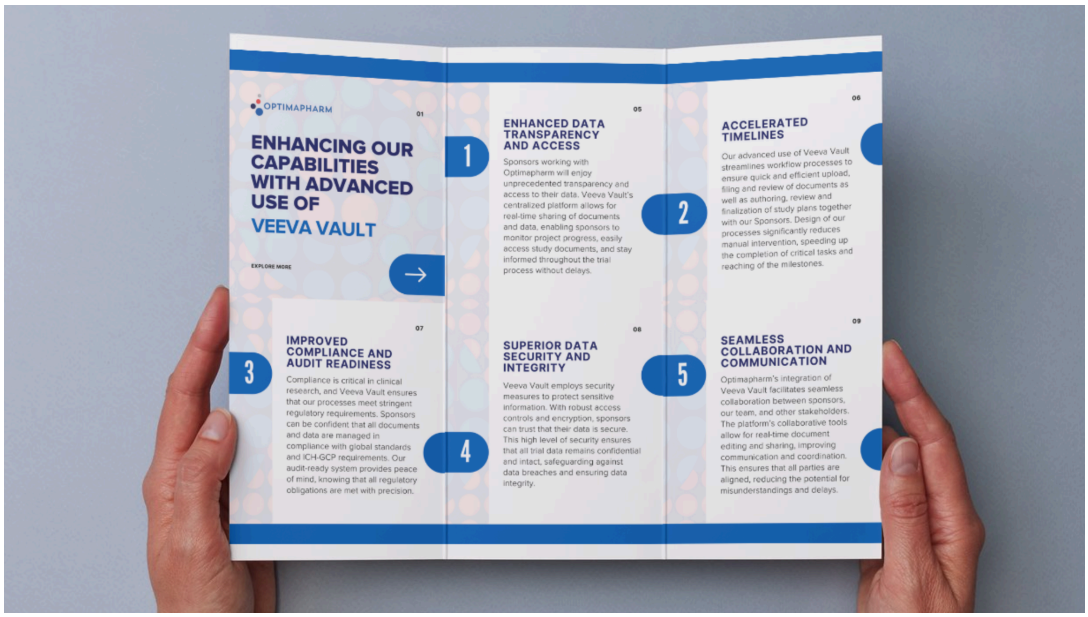
Last Patient In (LPI) in Phase II, Celiac Disease study. We randomized 397 subjects in total

Experience 24/7 project visibility with Optimapharm's advanced reporting tools

Gain unprecedented visibility into the **progress of your clinical trials** with Optimapharm's real-time project reporting capabilities. Our comprehensive suite of reports, available online around the clock, ensures you have the insights needed to make informed decisions, challenge the status quo, and anticipate risks.

Within Project Dashboards, access Site ID and Site Selection report, Monitoring Oversight report or Recruitment Compliance report (actual vs. planned), some of our unified standard reports integrating key data sources for **accurate and timely information**. Empower your team, enhance operational efficiency, and improve decision-making. Watch our video to explore how our advanced reporting tools can transform your clinical research.

Enhancing our capabilities with advanced use of Veeva Vault eTMF



As a leading mid-sized, full-service CRO, we are committed to leveraging the best technology to streamline our processes, ensure compliance, and deliver **exceptional results to our clients**. To ensure exceptional delivery Optimapharm is using Veeva Vault eTMF as leading cloud-based content management platform specifically designed for the Life Science industry.

By integrating Veeva Vault, we are not only modernizing our operations but also enhancing our ability to **manage data and documents** with efficiency and compliance.

Discover the 6 key benefits of Veeva Vault and see how they can elevate your next project!

Explore all the benefits

Ensuring safety and quality: technologies we rely on

Safety

Quality

eTMF audit ready

Both **Oracle Argus Safety** and **Flex Global Pharmacovigilance** are our Tools of Choice when it comes to the management of the pharmacovigilance and/or medical device vigilance, helping ensure the safety and efficacy of pharmaceutical products and medical devices through **efficient adverse event management** and **regulatory compliance**.

By implementing **ZenQMS**, leading validated platform automating and enforcing quality workflows matching our actual processes. This Quality Management System allows us to control quality and ensure compliance from anywhere. Sponsors can be sure that their projects are conducted in a **compliant and transparent** manner.

Thanks to **Veeva Vault eTMF** solution and strong process developed in-house to ensure real-time inspection readiness, full visibility into TMF status and **optimised collaboration** with our sponsors.

Optimapharm's foremost priority is enhancing our clients' clinical research experience.

By leveraging innovative leadership and cutting-edge technology, we expertly navigate challenges in the dynamic world of clinical trials.

This year, we are delving into AI's vast potential, ensuring our approach is thorough and aligned with regulatory standards. Our AI Research Group is at the forefront of our significant strides in artificial intelligence.

Our advanced data analytics capabilities, powered by Azure, enable us to make informed, data-driven decisions that consistently deliver significant value to our clients.

Our vision is to enhance efficiencies and create exceptional value for our clients. With over 20 cutting-edge technology systems from leading providers, we are shaping a future where innovation is at the heart of everything we do. This isn't just a vision for the future; it's our reality, unfolding right now.

Join us on this journey. We are Optimapharm, committed to redefining clinical research for our clients.

Manigandan Murugaperumal,

Senior IT Director

Want to find out more about the technologies we use to make your study more successful?

Contact our team to schedule a meeting!

Contact us

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