biomedion

# VERSATILE AND DATA DRIVEN PLATFORM

Connect the Dots in Life Science and Improve Excellence in Pharmaceutical Development Processes


**F.A.I.R.**

neuronOS®

Faster Time to Market

Smarter Decisions

Better Quality Culture

The disruptive shift in Biopharmaceutical landscape due to even more decentralization, the trend towards biologicals and the expected shorter development times for medicinal products (after Covid-19) lead to a new demand in the life sciences industry: The need for modular, more versatile and data driven platforms.

Existing and legacy solutions lack connectivity, are partly redundant, and dispersed and handled separately and disjointly by often disconnected staff members. Important decisions are based on what local staff can oversee. Important data is still shared via email and stored redundantly in excel spreadsheets or SharePoint across the corporations or even only in local or regional departments.

This manner of storage often leads to hardships with regards to how the data was managed, updated, and shared; when data needs to be updated, all copies must be updated manually with great care so that out-of-date information is not kept and recirculated through defined processes.

With neuronOS® and the integrated FAIR principles on platform level, customers may overcome problems or findings related to missing consistency and data integrity in a systemic fashion.

The neuronOS® approach is the service-based or service-oriented architecture, at its essence. With this change in paradigm – away from tightly coupled applications that focus on the user interface – neuronOS® as a platform rather exposes the underlying business functions as connected services which can leverage complexity in nearly every process landscape in the life science industry.

Users in their roles can start using the platform after role assignment and limited training-effort. The platform will set some access rules and security roles which users will need to follow.

The platform has several modules, data models and add-ons that are interdependent, thus a careful implementation plan with process review is recommended.

# OUR APPLICATIONS SPAN THE ENTIRE LIFECYCLE!

Through drug discovery, development towards market access and continuously leverage innovation. Create Value along the Life Sciences Processes. With our new Low Code compliance platform for Visualization & collaboration, Trust compliance confidentiality, Customer experience and Operational outcomes.


# IMPROVE EXCELLENCE IN PHARMACEUTICAL DEVELOPMENT PROCESSES AND CONTROL YOUR DATA

The amount of raw data has increased year by year in R&D. New technologies and available storage have created mountains of unstructured data that cannot be assembled by simple human interaction. At the same time, regulatory requirements are forcing companies to keep track of every piece of their data and to control its management and retention.

With neuronOS® the associated metadata and links between raw data sets create value and become assets. Evidence-based medicine requires reliable data at all times and at every stage of a product's life cycle. neuronOS® is equipped to collect data at the point of creation, enrich the data with context and annotations, and make the data streams available for subsequent quality control and evaluation processes and archiving.

Building a successful platform is more about making the right trade-offs than it is about technology. Make the right decisions on what kind of platform you are building with neuronOS® for tomorrow's life science organisations.

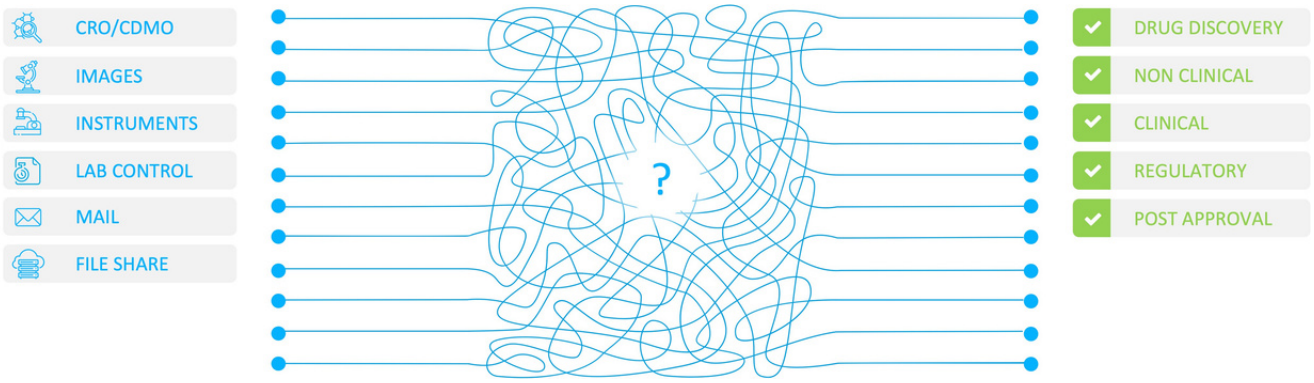
Sustainable success in the modern era lies beyond standalone streamlined processes. Everything is now interlinked.

neuronOS® is based on a keen awareness of the drivers in pharmaceutical development; prudently disrupting or blending in. It is built specifically to support Advanced Analytics on Big Data and enable Artificial Intelligence on multiple levels to increase speed and enable the right data-driven decisions. Instead of being slammed by frequent regulatory waves, neuronOS® enables a smart digitization from early stages onwards.

Understanding success factors in Clinical Trials and Regulatory Submissions increase the probabilities and enable early attrition by predictive analysis. Turning massive data into valuable information which can lead into earlier decision readiness. Understanding fundamental functional patterns manifest in digital forms and workflows which are core principles of the biomedion approach - quick and data-driven.

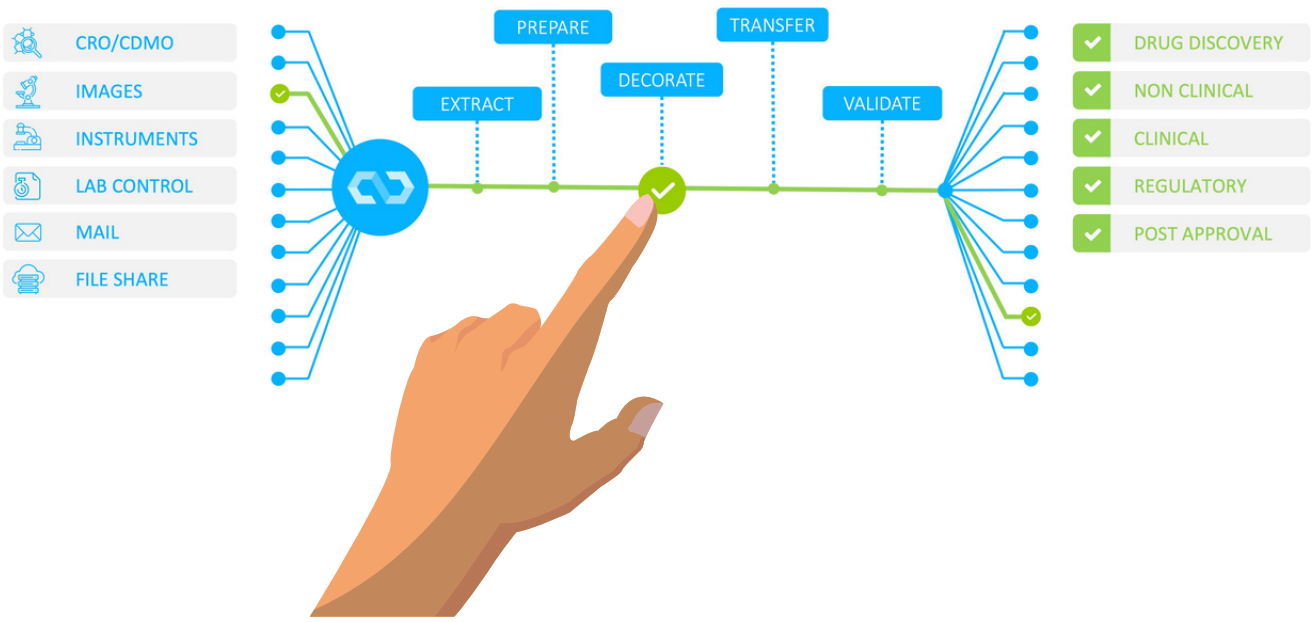
# STRUCTURE YOUR DATA AND DO NOT LOOSE THE THREAD

The amount of raw-data has increased year by year in drug research and development. New technologies and simply the available storage have created mountains of unstructured data that cannot be assembled by a simple human interaction. At the same time, regulatory requirements are forcing companies to keep track of the created data, ensure data integrity and to control the retention. The value lies in the data, so you should be able to find your data, be able to access, to inter-operate and to finally re-use data at any time in your product life cycle.




# FIND, ACCESS & REUSE YOUR DATA TO PULL THE RIGHT STRINGS

If you pull one string in your data universe, you should stay on top on how strings are pulled together, keeping valuable data available on your fingertips even years or decades after creation. Connecting the dots has never been easier! Collecting data at the point of creation, enrichment with context and annotations, even supported by machine learning and artificial intelligence all in fully controlled process flows, subsequent quality-checks, evaluation, validation and later archiving. Untangle your Data and follow the data in your decentralized universe.
**Pull the right strings! Be ready for any inspection! Access data easily!**



# CREATING VALUE ALONG THE LIFE SCIENCES PROCESSES

# WITH BEST PRACTICE READY-TO-GO SOLUTIONS

**iARQ** intelligent and quality conscious archiving solution

**iRSC** intelligent regulatory content services

**iTMF** intelligent trial master file

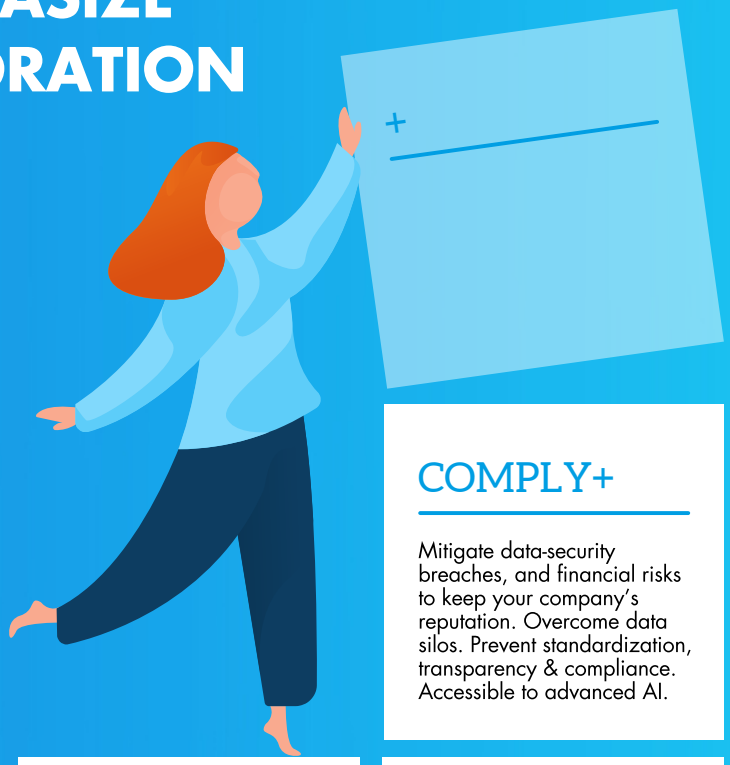
**iRAW** intelligent raw data archiving watcher

**iPQM** intelligent pharma quality management

best practice

# FULLY FLEXIBILITY TO BRIDGE THE ENTIRE PROCESS END-TO-END

# WITH MULTIPLE ADD-ONS TO EMPHASIZE COLLABORATION



## MIGRATE+

Integrate eTMF and Clinical data from various sources to accelerate research with decentralized trials. Access raw & processed data, analyze multiple eTMF sources, integrate CRO data.

## COMPLY+

Mitigate data-security breaches, and financial risks to keep your company's reputation. Overcome data silos. Prevent standardization, transparency & compliance. Accessible to advanced AI.

## REPORT+

Integrated reporting with dashboards and live filtering. Designed with the information demands of authorities and the public in mind, more practical and reliable

## SIGN+

Create a digitally signed validated archive, which can be viewed instantly for inspections and demonstrates data integrity and accessibility via the neuronOS cloud service.

## WATCH+

Decentralized intelligent agents execute defined missions that correspond to actual stages of defined cloud-based business workflows, carrying capabilities to ensure end-to-end compliance.

## BYOD+

Add value and simplify data acquisition through smartphone apps, which can check-in pictures, text, audio and data sets into any GxP compliant process, living on the neuronOS platform.

## ARC+

In addition to storing and managing documentation online, neuronOS with ARC+ allows for digital assets to be migrated, federated, archived and staying GxP compliant at any time.

## BRAIN+

Adds AI powered indexing and archiving to innovative digital asset management for higher quality output and better decision making, enabled by machine learning & data automation.

## IMAGE+

Embed interactive image spheres of high resolution and complex 3D and 2D images or simply present static images with textual, visual and audio annotations.

## TRAIN+

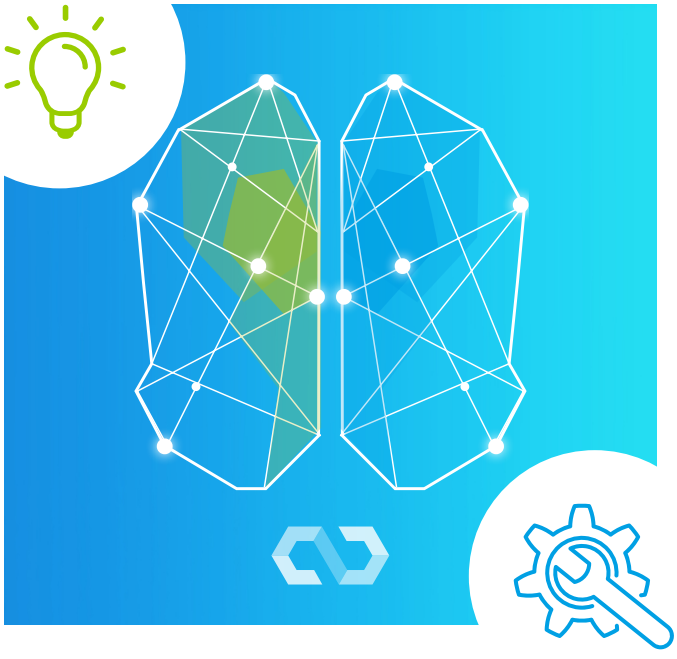
Deploy effective and timely SOP training records and analyze the training status in your organization prior to inspection findings. Keep training records consistent for long-term archiving.

# STRUCTURE YOUR DATA AND DO NOT LOOSE THE THREAD

**CAPTURE**
Acquire your raw data through machines, interfacing APIs and manual form-based entries.

**REVIEW**
Throughout the lifecycle of assets and data documents, value is increased by aggregating and reviewing information.

**MANAGE**
Manage your data with neuronOS®. Each data element in the lifecycle has an expected and controlled lifetime. Regulations and processes determine storage and access at any time, from creation through numerous stages to long-term archiving and finally deletion.



**DESIGN**
Design is not only the most effective differentiator but also has a huge impact on usability of a product. Bringing all aspects of a users experience down to a consistent and frictionless system of colors, forms and shapes with optical and ergonomic advantages demands for a holistic view on human interaction with machines.

**BUILD**
Building requires a vast amount of abstraction not only in a mechanical world also in virtual systems which should be able to interact between humans and machines in order to reach intended goals and create systemswhich are resource concious

**SELL**
The perfectly engeneered product with even a wonderful design cannot be successful in the market, without someone, who finds the market and points out the advantages for a prospective customer. Selling products that solve complex problems is an art in itself and involves a good understanding of technology, user and psychology.

biomedion GmbH | Am Borsigturm 100 | 13507 Berlin | Germany | Phone: +49 30 7701811-0 | eMail: info@biomedion.com