



**Project No. 101045956**  
**Biomarker and AI-supported FX06 therapy to prevent  
progression from mild and moderate to severe stages of COVID-19**

## **Deliverable 6.6**

# **Web-based implementation of models for decision support**

Work Package 6 – Decision support models

<b>Lead Participant</b>	Johann Wolfgang Goethe Universität Frankfurt am Main
<b>Contributors</b>	Elina Nürenberg-Goloub, Jan Kloka, Benjamin Friedrichson (GUF), Alpo Värri, Antti Kallonen, Francesco DePretis (TAU)
<b>Delivery date</b>	21 July 2025
<b>Dissemination level</b>	Sensitive
<b>Type</b>	Data

**Version 1**



Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

## Revision history

Date	Authors	Revision
21-07-2025	Elina Nürenberg-Goloub (GUF)	Draft version
25-07-2025	Jan Kloka, Benjamin Friedrichson (GUF), Alpo Värri, Antti Kallonen, Francesco DePretis (TAU)	Final version

## Contents

<b>Partner short names</b>	<b>2</b>
<b>Abbreviations</b>	<b>3</b>
<b>EXECUTIVE SUMMARY</b>	<b>4</b>
<b>1 Introduction</b>	<b>5</b>
1.1 Purpose and scope of the deliverable	5
1.2 Context of COVend Deliverables	5
1.3 Outcomes	5
<b>2. Results</b>	<b>7</b>
2.1 Web-based Synthetic Data Generation Pipeline	7
2.2 Educational Module: Baseline and Longitudinal Data Visualisation	9
2.2.1 Baseline Data Visualisation	9
2.2.2 Longitudinal Data Visualisation	10
2.2.3 ARDS Risk Calculator	10
<b>3. Use Cases</b>	<b>11</b>
3.1 ARDS Awareness	11
3.2 Medical Education	11
3.3 Data Science Education	11
3.4 Clinical Trial Planning and Assessment	11
3.5 Other Potential Use Cases	12
<b>4 Modular Design for Open Science</b>	<b>12</b>
<b>5 Platform Availability and Data Protection</b>	<b>13</b>
<b>6 Outlook</b>	<b>13</b>
<b>References</b>	<b>14</b>

## Partner short names

<b>GUF</b>	Johann Wolfgang Goethe Universität Frankfurt am Main
<b>accelCH</b>	accelopment Schweiz AG
<b>ESAIC</b>	European Society of Anaesthesiology and Intensive Care
<b>Fraunhofer</b>	Fraunhofer Institute for Translational Medicine and Pharmacology ITMP
<b>F4</b>	F4 Pharma GmbH
<b>TAU</b>	Tampereen Korkeakoulusäätiö SR
<b>UCD</b>	University College Dublin
<b>UMCG</b>	Universitair Medisch Centrum Groningen
<b>MiDA</b>	Medical Intelligent Data Analytics GmbH
<b>KC</b>	Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos
<b>ICS-HUB</b>	Hospital Universitari de Bellvitge
<b>UMFCD</b>	Universitatea de Medicina si Farmacie Carol Davila din Bucuresti
<b>APHP</b>	Assistance Publique – Hôpitaux de Paris

## Abbreviations

<b>ARDS</b>	Acute Respiratory Distress Syndrome
<b>COVID-19</b>	Coronavirus Disease 2019
<b>D</b>	Deliverable
<b>UI</b>	User Interface
<b>WP</b>	Work Package

## Executive Summary

The COVend project aims to demonstrate the efficacy of FX06 in treating Acute Respiratory Distress Syndrome (ARDS), initially focusing on COVID-19 patients. Due to declining COVID-19 cases, the consortium strategically pivoted the clinical trial IXION from a COVID-19-specific to a mechanism-centered ARDS approach in the IXION2.0 trial in 2023, broadening eligibility to include ARDS of various etiologies. Despite multiple extensions of the recruitment period until December 2024 and expansion across 6 sites in 5 European countries, the trial enrolled only 18 of the targeted 263 patients (6.8%). With unblinding occurring in April 2025 and multiomics data becoming available to WP6 only in July 2025, the consortium faced significant time constraints for comprehensive data analysis within the project timeline.

In response to these challenges, WP6, which is fully dependent on clinical trial data, developed an innovative synthetic data approach to ensure valuable scientific outputs. This deliverable describes the web-based implementation of models for decision support in the context of ARDS based on this synthetic data and artificial intelligence-based literature analysis. The document outlines the functionalities of an interactive platform designed to support clinicians, researchers, and educators. The platform is designed to integrate a synthetic data generation pipeline, a risk calculator for individual patient assessment, and a comprehensive data visualisation module. We describe the potential use cases of this tool, including raising ARDS awareness, medical and data science education, and clinical trial planning and assessment. The modular design of the application, which allows for the exchange of code and the visualisation of real trial data, is a key feature which will ensure the sustainability of the tool.

# 1 Introduction

## 1.1 Purpose and scope of the deliverable

ARDS remains a critical challenge in intensive care medicine, characterised by high morbidity and mortality rates. Effective decision-making in ARDS management is paramount, yet it is often complicated by the heterogeneity and dynamic nature of the disease. Advanced computational models and web-based platforms offer opportunities to enhance clinical decision support, facilitate medical education, and streamline research. This deliverable details the development and implementation of a web-based platform designed to serve as a comprehensive tool to support education and research in the context of ARDS. The primary objective is to provide a user-friendly and robust environment that can be utilised by a diverse audience, ranging from medical students and practitioners to data scientists and clinical researchers.

## 1.2 Context of COVend WP6 Deliverables

The COVend project has undertaken several key deliverables related to data and modeling, which belong to the context of this report:

### **D6.2 Research datasets from the models**

This deliverable outlines the strategy for the publication of the IXION2.0 and synthetic data and models.

### **D6.3 Multivariate patient profile models for Decision Support in COVID-19 patients** **D6.4 Time dynamics models for decision support**

These deliverables provide detailed information on the modeling approaches and methodologies for decision-support

### **D6.7 Decision-support models validation report**

This deliverable informs on validation results of the literature-based prior model and the posterior model refined using the IXION2.0 data.

### **D6.6 Web-based implementation of models for decision support**

A web-based tool presented in this deliverable will exploit the datasets and models, enhancing accessibility and utility for researchers and clinicians.

### **D6.5 Model toolbox for the research community** **D6.8 All relevant data and data-analysis results made available to a relevant data portal**

These deliverables provide information on the publicly available models and data.

### 1.3 Outcomes

At the time of this deliverable, the web-based platform is a functional prototype with several key features implemented and operational. The core components of the system are built using Python for the server-side logic and data processing, and the React library<sup>1</sup> for the interactive frontend user interface. The frontend is implemented using React with TypeScript, providing strong type safety and enhanced code maintainability, which is particularly important for handling complex medical data structures. The application utilizes Vite as its build tool, a modern and fast bundler that ensures rapid development cycles and optimized production builds. This architectural choice facilitates a responsive and dynamic user experience while ensuring robust backend capabilities and maintaining code quality standards essential for medical software applications.

Specifically, the following outcomes have been achieved:

- **Web-based Data Generation:** The synthetic data generation pipeline is fully operational, allowing users to generate diverse datasets based on predefined scenarios. This functionality includes the use of cookies to maintain user-specific sessions, ensuring a personalised experience. Data generation runs the sophisticated Python code provided by TAU [1] preserving all technical features and medical scrutiny of this innovative approach (see also D6.4). The code is embedded in the backend library and can be easily exchanged against future versions which could incorporate additional clinical trial data or ARDS knowledge.
- **Data Import Functionality:** The platform supports the import of external data, enhancing its versatility and integration capabilities. Import is possible as an Excel file (Microsoft Corporation, Redmond, USA), which corresponds to the output of the published data generation code [1].
- **Baseline Data Visualisation:** The calculation and visualisation of baseline clinical data are fully functional, providing clear insights into patient characteristics for the different scenarios. Visualisation includes several patient groups.
- **Longitudinal Data Visualisation:** The calculation and visualisation of longitudinal data are operational, enabling the tracking of clinical parameters over time and supporting the analysis of disease progression.

However, certain functionalities are still under active development and are not yet fully integrated into the public-facing prototype:

- **Risk Calculator Integration:** The Bayesian prior-based risk calculator module (see D6.4), while conceptually designed, is still in the process of being fully built into the platform. Its integration will enable real-time risk prediction based on patient data from the synthetic datasets or from manual input.
- **Export Functions:** While data generation and import are functional, the export capabilities for generated or analysed data require further improvement.

---

<sup>1</sup> React is a free and open-source front-end JavaScript library that aims for a seamless building of user interfaces based on components. It is maintained by Meta Inc. (Menlo Park, USA) and a community of individual developers and companies, <https://react.dev/>

- **Data Protection and Privacy Notes:** Comprehensive data protection and privacy notes are currently being developed and will be integrated into the platform. Due to the strict legal requirements, the platform cannot yet be fully disclosed to the public until these measures are robustly in place.
- **Extensive Documentation:** Comprehensive documentation is currently under development, including technical documentation for system administrators and future developers to ensure proper deployment and maintenance of the platform. To support users, a best practices guide for synthetic data usage in research to ensure scientifically sound applications of the generated datasets will be provided and links to the codes for the synthetic data generation pipeline and the ARDS risk calculator, which are published in Zenodo, will be added.

These outcomes demonstrate significant progress in the development of a powerful decision support tool for ARDS, with a clear roadmap for future enhancements.

## 2 Results

### 2.1 Web-based Synthetic Data Generation Pipeline

The platform incorporates a robust synthetic data generation pipeline, a crucial component for various applications, particularly in medical research and education where access to real patient data may be restricted due to privacy concerns or data scarcity. This pipeline is designed to produce high-fidelity synthetic datasets that mimic the statistical properties and complex interdependencies observed in real-world clinical data, without compromising patient confidentiality (see D6.4).

For the user, the process begins with the selection of a specific scenario, such as "Effective", "Ineffective Safe", or "Ineffective Unsafe", which dictates the underlying clinical characteristics and outcomes of the generated patient cohort. Users can initiate data generation by simply clicking the "Generate Data" button on the dashboard. Upon successful initiation, the system provides immediate feedback, indicating that the data generation process has commenced. The status of the ongoing job, along with its timestamp and the selected scenario, is displayed in the "Recent Generation Jobs" section, allowing users to monitor progress. The sessions are user-specific which enhances usability but **requires the use of cookies and the respective privacy statements to be implemented.**

Once the data generation is complete, the status of the job updates to "completed". Concurrently, key metrics such as "Total Patients" and "Clinical Records" are updated on the dashboard, reflecting the newly generated synthetic dataset. This feature enables rapid prototyping, algorithm development, and educational simulations, providing a flexible and ethical alternative to real data. The synthetic data can be subsequently utilised for various analytical tasks within the platform, including populating the risk calculator and visualising baseline and longitudinal trends. The synthetic dataset can also be downloaded as a comma separated values (CSV) file for training purposes (Figure 1 and 2).

### COVend Synthetic Data Dashboard

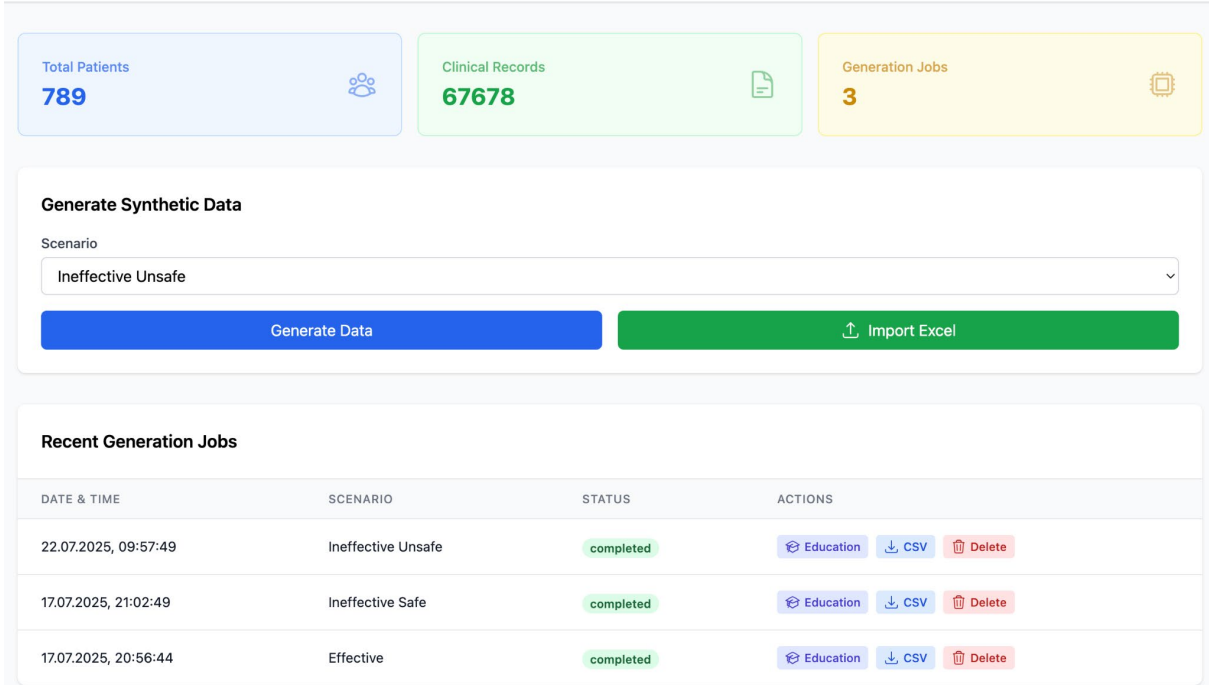


Figure 1: User interface (UI) of the COVend synthetic data generation pipeline includes a user-specific, job-based functionality that requires the use of cookies. Scenario-specific data can be generated with one click and appear ready for download or further analysis in the education module. The statistics are likewise user-specific.

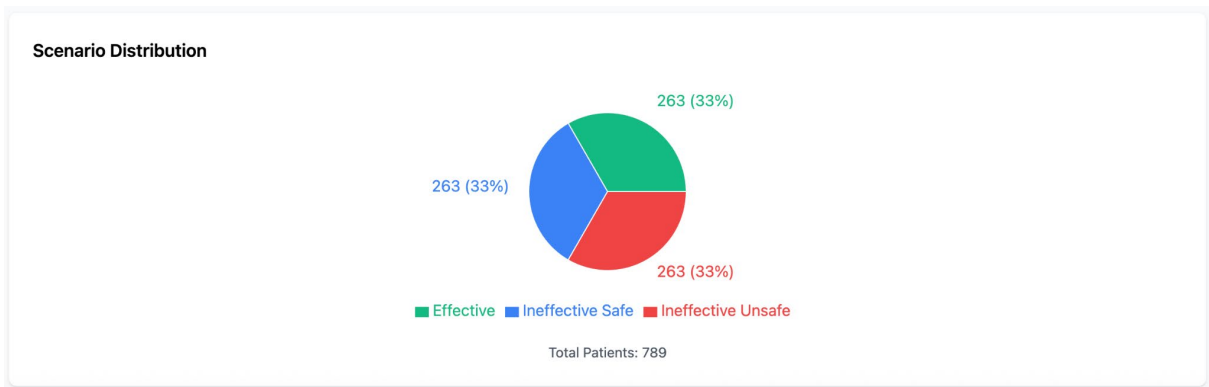


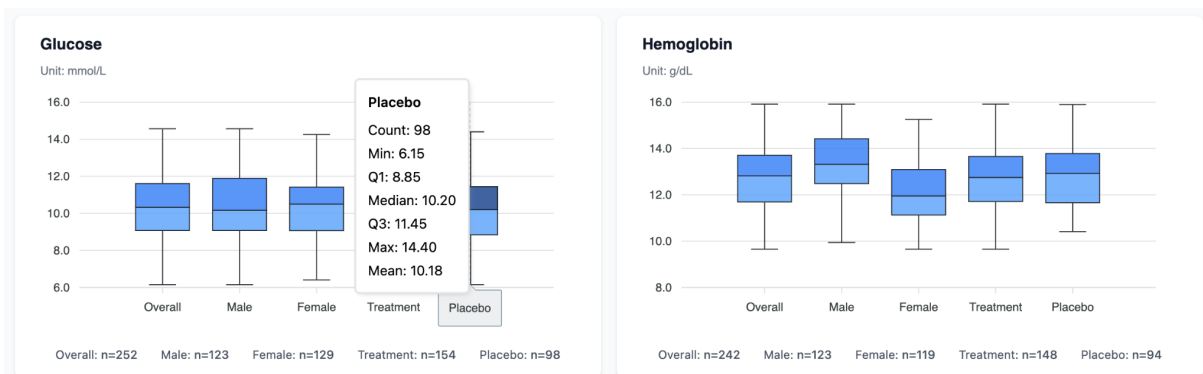
Figure 2: User-specific statistics for the generated scenarios and patients. The synthetic data generation pipeline has the intrinsic feature of generating 263 patient records - the planned enrolment number for the IXION2.0 trial.

## 2.2 Educational Module: Baseline and Longitudinal Data Visualisation

The platform features a dedicated educational module, designed to provide comprehensive insights into patient data through interactive visualisations. This module is accessible via distinct tabs, currently encompassing "Baseline (Day 0)" and "Longitudinal Analysis", organised in tabs within the UI of the application. These visualisations serve multiple purposes aligned with the platform's core use cases. For ARDS awareness, they help illustrate the complexity and progression of the condition through clear visual representations of clinical parameters. In medical education, students and practitioners can explore synthetic patient data to understand disease patterns and treatment responses in a risk-free environment. The module supports data science education by providing real-world examples of clinical data structures and analysis techniques. For clinical trial planning and assessment, researchers can visualise trial data patterns, assess protocol feasibility, and monitor outcomes across different patient cohorts. The interactive nature of these visualisations makes complex medical data accessible to diverse audiences, from healthcare professionals to researchers and educators.

### 2.2.1 Baseline Data Visualisation

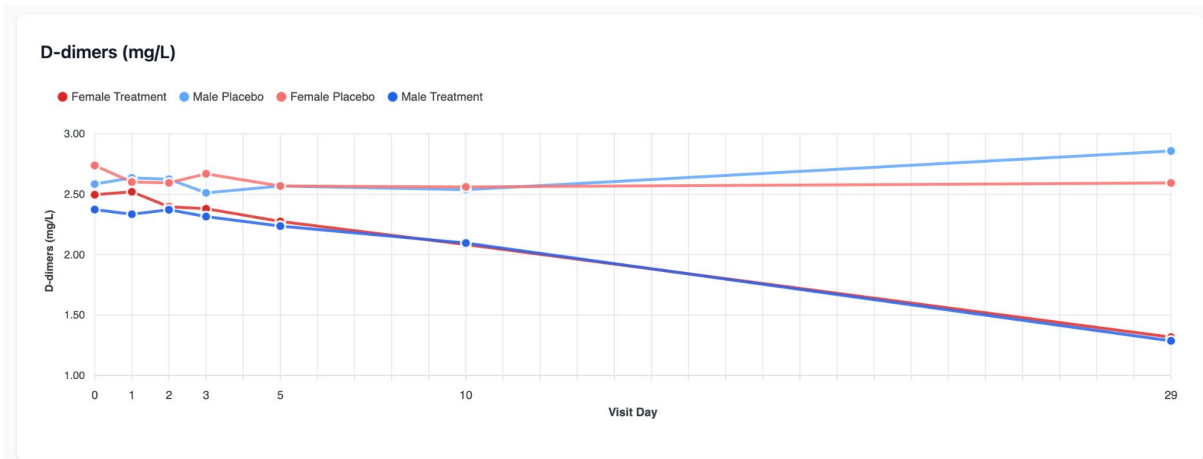
The "Baseline" section offers a detailed overview of clinical parameters at the initial assessment point (Day 0 in the IXION2.0 trial). This section presents boxplot visualisations of various clinical parameters, segmented by the key demographic and treatment characteristics gender and treatment arm. These visualisations are interactive and provide major statistical features (total patient count per group, total range, interquartile range, median and mean) during tipover. They are scientifically robust and widely used in medical and epidemiological studies to allow readers to quickly grasp the distribution and central tendencies of critical biomarkers and physiological measurements at the commencement of the observation period in a clinical trial. This is particularly useful for understanding the initial state of patient cohorts and identifying potential differences or imbalances across groups (Figure 3). Note that the synthetic data generation code features missing data to mimic the real-life situation in many clinical studies (see D6.4) which results in different patient counts for some laboratory parameters.



**Figure 3: Exemplary boxplots with key statistical parameters per group in a tipover box. Hemoglobin is a gender-sensitive parameter and this dataset presents the clinically sound finding of women having lower values than men.**

## 2.2.2 Longitudinal Data Visualisation

The Longitudinal Analysis section provides dynamic visualisations of Parameter Development Over Time. This critical component displays the progression of all clinical parameters across various visit days, illustrating mean values along with their 95% confidence intervals. These line graphs enable users to observe trends, identify patterns of improvement or deterioration, and assess the impact of interventions over the course of a patient's stay or study period. The ability to track parameters over time is important for understanding disease trajectories and treatment responses (Figure 4).



**Figure 4: Exemplary D-Dimer longitudinal visualisation for an “Effective” drug scenario. Notably, D-Dimers are important coagulation factors and markers of endothelial function. D-Dimer decrease in the treatment groups is characteristic for a successful treatment of endothelial dysfunction as suggested by FX06.**

## 2.2.3 ARDS Risk Calculator

The platform will include a sophisticated risk calculator developed by TAU [2], accessible via a dedicated tab in the education module which is not yet implemented. This module is designed to provide clinicians and researchers with an intuitive tool for assessing the risk of ARDS in individual patients.

One of the key functionalities of the risk calculator will be its ability to fetch patient data directly from the generated synthetic datasets. This allows for rapid analysis of hypothetical patient cohorts or for validating the predictive models against diverse synthetic populations. In addition to utilising pre-existing data, the risk calculator also offers the flexibility of manual data entry. This feature is particularly valuable for clinicians who wish to assess the risk for a specific patient in real-time, using their current clinical parameters. Users can input individual patient data points, such as vital signs, laboratory results, and demographic information, to obtain an immediate risk assessment (see D6.4). This dual input capability ensures the utility in both research and practical clinical settings.

## 3 Use Cases

The web-based platform, with its integrated synthetic data generation, risk calculation, and data visualisation capabilities, serves a multitude of critical functions across various domains. Its versatility makes it an innovative tool for raising awareness, facilitating education, and supporting advanced research and clinical planning.

### 3.1 ARDS Awareness

The platform can significantly contribute to raising awareness about ARDS among healthcare professionals and the general public. By providing interactive visualisations of patient data, disease progression, and risk factors, it can demystify the complexities of ARDS. Educational modules within the platform can highlight the prevalence, severity, and diagnostic criteria of ARDS, thereby fostering a deeper understanding of this critical condition. The ability to simulate different scenarios and observe their impact on patient outcomes can serve as a powerful educational tool, making the abstract concepts of ARDS more tangible and relatable.

### 3.2 Medical Education

For medical students and junior doctors, the platform offers a safe and interactive environment to learn about ARDS pathophysiology, diagnosis, and management. The synthetic data generation feature allows educators to create diverse patient cohorts, exposing students to a wide range of clinical presentations without the ethical constraints associated with real patient data. Students can utilise the risk calculator to practice patient assessment and decision-making, receiving immediate feedback on their choices. The longitudinal analysis visualisations can help them understand disease trajectories and the impact of interventions over time. This hands-on approach to learning can significantly enhance clinical reasoning and preparedness.

### 3.3 Data Science Education

The platform provides an excellent resource for data science students and practitioners interested in healthcare applications. The availability of synthetic clinical datasets, coupled with the integrated analytical tools, offers a practical sandbox for learning and applying data science methodologies. Students can explore data cleaning, feature engineering, model development, and validation techniques using realistic data.

### 3.4 Clinical Trial Planning and Assessment

The platform can be instrumental in the planning and assessment of clinical trials for ARDS. Researchers can use the synthetic data generation pipeline to simulate trial populations, allowing for the optimisation of study designs, sample size calculations, and power analyses. The risk calculator can be employed to identify suitable patient cohorts for trial enrolment or to stratify patients based on their predicted risk. Furthermore, the capability to visualise real trial data in safe, user-specific sessions with the option to delete files tracelessly directly after use, enables real-time monitoring of trial progress, identification of trends, and rapid assessment of intervention efficacy. This can lead to more efficient and impactful clinical research.

### 3.5 Other Potential Use Cases

Beyond the primary applications, the platform holds potential for:

- **Continuing Medical Education (CME):** Providing interactive modules for ongoing professional development for experienced clinicians.
- **Clinical Decision Support Systems (CDSS) Prototyping:** Serving as a testbed for developing and evaluating new decision support algorithms before their integration into electronic health records.
- **Public Health Initiatives:** Supporting epidemiological studies and public health campaigns by visualising population-level trends and the impact of various health interventions.
- **Personalised Medicine Research:** Exploring how individual patient characteristics influence disease progression and treatment response using synthetic data.

## 4 Modular Design for Open Science

The web-based platform has been architected with modularity at its core, embodying Open Science principles that promote transparency, reproducibility, and collaborative innovation. This design philosophy ensures that the platform can evolve with advancing medical knowledge while remaining accessible to the global research community.

**Key Design Principles:** The modular architecture of the platform separates core functionalities into independent, interchangeable components. The synthetic data generation engine operates as a standalone module, allowing researchers to update or replace the underlying algorithms without affecting the visualization or risk calculation components. Similarly, the risk calculator functions independently, enabling the integration of new predictive models as they emerge from ongoing ARDS research.

**Open Science Implementation:** In alignment with Open Science practices, all computational modules are designed for transparency and reusability. The synthetic data generation code from TAU is published on Zenodo with proper documentation, allowing external validation and improvement by the research community. This approach ensures that the scientific methods underlying the platform are open to scrutiny and enhancement.

**Collaborative Development Framework:** The modular design facilitates collaborative contributions from diverse research groups. New visualization types can be added to address specific research questions, alternative risk models can be integrated for comparative studies, and additional data import/export formats can be incorporated based on community needs. Each module maintains clear interfaces and documentation, enabling researchers with varying technical expertise to contribute improvements.

**Sustainability and Future-Proofing:** By separating the presentation layer (React frontend) from the computational core (Python backend), the platform can adapt to future technological changes. As new ARDS biomarkers are discovered or treatment protocols evolve, the relevant modules can be updated

independently. This design ensures the platform remains a valuable resource beyond the COVend project timeline, supporting ongoing ARDS research and education initiatives.

## 5 Platform Availability and Data Protection

**Important Notice - Cookie Usage and Consent:** This platform uses cookies to maintain user-specific sessions and enable personalized data generation workflows. These technical cookies are essential for the platform's functionality, particularly for tracking data generation jobs and maintaining user-specific statistics.

**By accessing and using this platform, you explicitly consent to the use of these cookies.** If you do not agree to the use of cookies, please do not access the platform.

**Data Protection Information:** In accordance with the General Data Protection Regulation (GDPR), we inform you that:

- The platform uses only essential technical cookies required for functionality
- No personal health data is collected or stored - only synthetic data is generated
- Session data is temporary and linked to browser sessions only
- Users can delete their browser cookies at any time to remove session data
- No user registration or personal identification is required
- All generated synthetic data is anonymous and cannot be linked to real patients

**Current Availability:** The platform is currently deployed on a development server for internal testing and evaluation purposes. Access is available at:

<https://ards-data.logikwerk.com/>

**Future Deployment:** The platform architecture supports easy transfer to production environments. Upon completion of data protection impact assessments and comprehensive privacy documentation, the platform can be migrated to institutional servers or cloud infrastructure as required by the hosting organization.

**Disclaimer:** This is a research prototype under active development. Features may change, and data generated should be used only for educational and research purposes as outlined in this deliverable. The platform should not be used for clinical decision-making with real patients.

## 6 Outlook

The web-based platform represents a significant step forward in making ARDS research and education more accessible through synthetic data and interactive visualizations. As the platform evolves from its current prototype status, several key developments are anticipated.

**Platform Enhancement and Feature Completion:** The immediate focus will be on integrating the remaining components, particularly the Bayesian risk calculator module, which will provide real-time

risk assessment capabilities. Export functionalities will be enhanced and the educational module will be expanded.

**Community Engagement and Open Science:** Following the Open Science principles outlined in this deliverable, the platform will be prepared for community adoption. The modular architecture will facilitate the integration of new ARDS research findings, alternative risk models, and additional visualization techniques as they emerge from the scientific community.

**Scientific Validation and Dissemination:** A comprehensive validation study is planned to assess the effectiveness of the platform across its intended use cases. Metrics for measuring educational impact, user engagement, and clinical utility will be developed and evaluated through structured user studies. The methodology and results of these validation efforts, along with detailed user feedback mechanisms, will be presented in a peer-reviewed manuscript. This publication will provide the scientific community with empirical evidence of the platform's value and establish best practices for synthetic data use in medical education and research.

**Long-term Sustainability:** Beyond the COVend project timeline, the platform is designed to serve as a lasting resource for the ARDS research community. Discussions are underway with academic institutions to ensure continued hosting and maintenance. The open-source nature of the core modules will enable the platform to evolve independently of any single institution, fostering a sustainable ecosystem for ARDS education and research tools.

**Broader Applications:** While initially focused on ARDS, the platform's architecture and synthetic data generation approach could be adapted for other critical care conditions. This extensibility opens possibilities for creating a comprehensive suite of educational and research tools for intensive care medicine and research of complex critical care pathologies.

## References

[1] Kallonen, A., & De Pretis, F. (2025). CovEnd Deliverable D6.8 Research data sets from the models [Data set]. Zenodo. <https://doi.org/10.5281/zenodo.15809173>

[2] Kallonen, A., & De Pretis, F. (2025). CovEnd Deliverable D6.5 Model toolbox for the research community. Zenodo. <https://doi.org/10.5281/zenodo.15809150>