



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

Deliverable 6.5

Model toolbox for the research community

WP 6 – Decision support models

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Contents

PARTNER SHORT NAMES	4
ABBREVIATIONS	4
EXECUTIVE SUMMARY	5
1 INTRODUCTION	6
1.1 Purpose and scope of the deliverable	6
1.2 Context of COVend WP6 Deliverables.....	6
1.3 Outcomes	6
2 ZENODO REPOSITORY	7
2.1 Repository contents and file descriptions.....	7
3 OUTLOOK	7

Partner short names

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

Abbreviations

ARDS	Acute Respiratory Distress Syndrome
COVID-19	Coronavirus Disease 2019
D	Deliverable
WP	Work Package

Executive Summary

The COVend project aims to demonstrate the efficacy of FX06 in treating Acute Respiratory Distress Syndrome (ARDS), initially targeting COVID-19 patients. However, as COVID-19 cases declined, the consortium made a strategic decision in 2023 to pivot the clinical trial from the COVID-19-specific IXION study to a mechanism-centred ARDS approach in IXION2.0. This pivot broadened patient eligibility to encompass ARDS of various aetiologies. Despite extending the recruitment period multiple times until December 2024 and conducting the trial across six sites in five European countries, enrolment remained critically low, with only 18 of the targeted 263 patients recruited (6.8%). The timeline constraints became particularly acute given that unblinding occurred in April 2025, with multiomics data only becoming available to WP6 in June 2025, leaving insufficient time for comprehensive data analysis within the project runtime. To address these challenges, TAU developed an innovative synthetic data approach, ensuring the project could still deliver valuable scientific outputs despite the limited real patient data.

This document describes the contents of a publicly accessible Model Toolbox developed under the COVend project to support predictive modelling for ARDS risk in hospitalized patients. The toolbox contains temporal and multivariate modelling frameworks, openly accessible via the Zenodo repository. These resources facilitate reproducibility and promote further research into predictive decision-support models for ARDS.

1 Introduction

1.1 Purpose and scope of the deliverable

Deliverable D6.5 provides an open-access Model Toolbox to the research community for predicting ARDS risk using patient-specific temporal and multivariate data. This toolbox supports the broader COVend project aim to enhance clinical decision-making and prevent progression to severe ARDS.

1.2 Context of COVend WP6 Deliverables

The COVend project has undertaken several key deliverables related to data and modelling, 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 modelling 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

The primary outcome is the public release of the Model Toolbox on Zenodo, ensuring reproducibility and facilitating broader research.

2 Zenodo Repository

The Model Toolbox is publicly accessible via Zenodo at the following permanent link:

<https://zenodo.org/records/15809173>

2.1 Repository contents and file descriptions

- **bayesian_logreg_multivar_model.py**: Script that trains a Bayesian logistic regression on multivariate patient profiles. The script reads prior coefficient estimates, performs data cleaning, runs Markov-Chain-Monte-Carlo (MCMC) sampling with PyMC, and stores posterior draws together with training diagnostics.
- **bayesian_logreg_multivar_eval.py**: Lightweight inference module. Loads the pickled posterior (`logistic_model.pkl`), standardises incoming patient data according to the original training statistics, and returns risk probabilities with configurable credible intervals. Intended for clinical integration and rapid benchmarking.
- **time-model-analysis.py**: Analysis pipeline illustrating the temporal modelling workflow introduced in **D6.4 Time dynamics models for decision support**. Demonstrates preprocessing of longitudinal vital-sign trajectories, feature engineering of temporal trends, model fitting, receiver operating characteristic (ROC) analysis, and visual diagnostics.
- **logistic_model.pkl**: Pickled Python dictionary containing posterior samples of intercept and coefficients and a JSON-serialised block of training statistics. Provides an immediate starting point for evaluation without re-training.

3 Outlook

The Model Toolbox represents a significant contribution to the open science ecosystem for ARDS research, providing the global research community with immediate access to validated predictive modelling frameworks through the permanent Zenodo repository. The publicly accessible Python scripts and pre-trained Bayesian models enable researchers worldwide to build upon the COVend methodological innovations without requiring extensive computational resources or starting from scratch. The lightweight inference module facilitates rapid integration into existing research workflows, whilst the comprehensive temporal modelling pipeline provides a robust foundation for longitudinal ARDS studies.

The modular design encourages collaborative development, allowing researchers to adapt and extend the frameworks for their specific datasets and research questions. The inclusion of both multivariate patient profile models and temporal dynamics approaches provides flexibility for different analytical needs, from snapshot risk assessment to trajectory-based predictions. The pre-trained models and standardised preprocessing pipelines will enhance reproducibility across studies, addressing a critical challenge in medical artificial intelligence research.

Beyond immediate research applications, the toolbox serves as an educational resource for training of clinical data scientists and biostatisticians. The documented code and accompanying analysis pipelines offer practical examples of implementing Bayesian methods in clinical contexts, whilst the synthetic data approach demonstrated in the broader COVend project provides a template for addressing data

scarcity in rare conditions. As the research community adopts and refines these tools, the initial framework will likely evolve into a more comprehensive suite of ARDS prediction models, establishing a foundation for sustained methodological advancement in critical care research and ultimately contributing to improved patient outcomes through more precise risk stratification and clinical decision support.