CONCEPT NOTE

GENESIS

EXPLAINABLE NEW-METHOD ENGINE FOR SAFE IN SILICO SIMULATIONS

HORIZON-HLTH-2026-01-TOOL-03

idener SCIENTIFIC COMPUTING

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A Bit of Context About IDENER.AI

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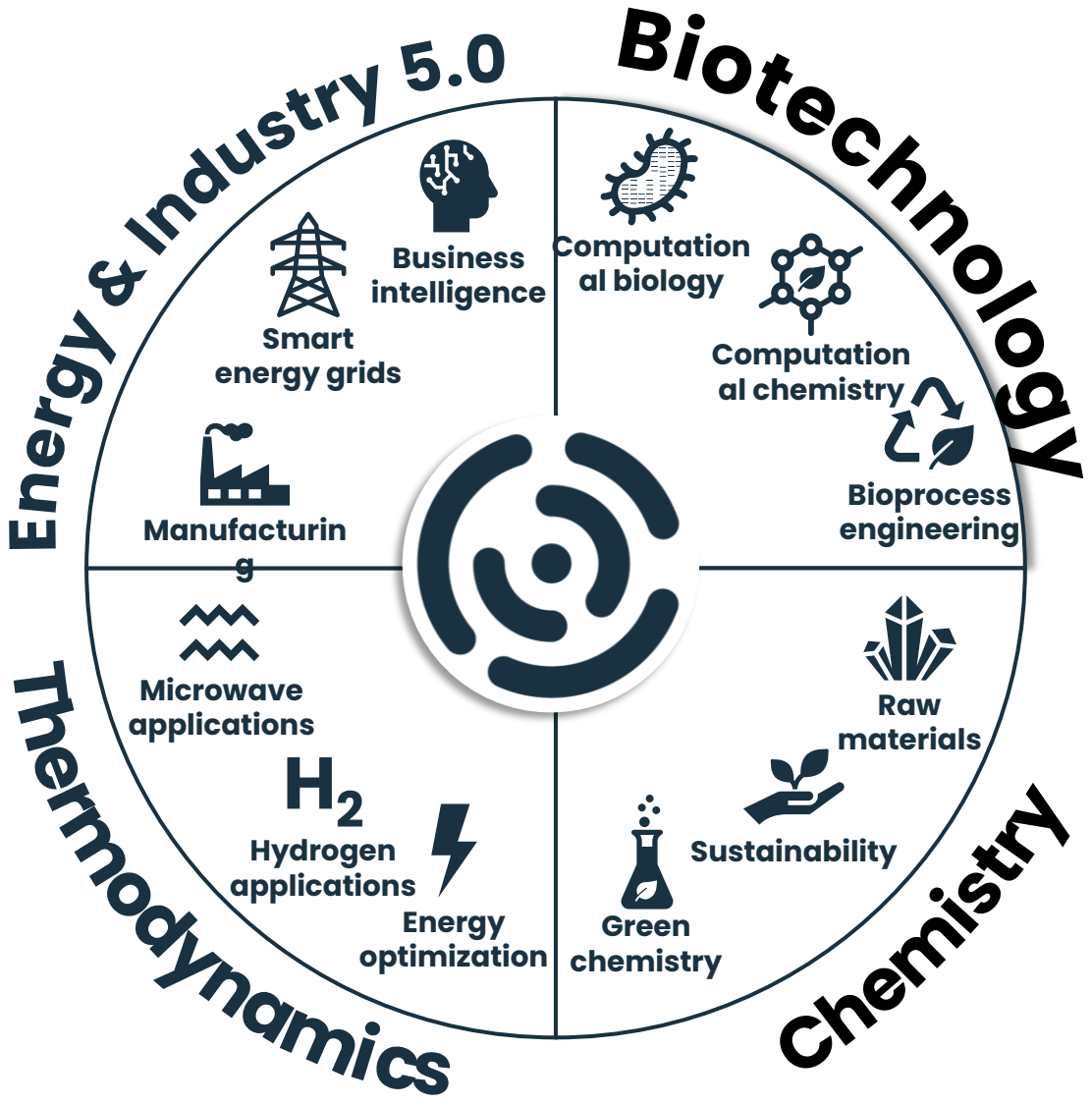
Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing

HORIZON-HLTH-2026-01-TOOL-03

PROFESSIONAL CAPACITY

- A private research SME, spin-off of University of Seville funded in 2010
- Headquarts in Seville in Aeropolis (Aerospace technology park)
- 100+ engineers, mathematicians and physicist (around 60% are PhDs)
- 65+ European and national projects (with 25 coordinated and 60 ongoing within the H2020/HEU framework)
- 45+ international journal articles 25+ in book format
- 3 patents in Microwave heating



SUCCESSFUL PROJECTS

Energy and Environment	Logistics	Chemical Apps	Industry & Manufacturing	Biotechnology
DENiM		ZEOCAT-3D	FUDIPO	Liberate
islander	LAW-TRAIN	ION4RAW	cocop	BIOGREEN
PHOTORAMA		CROCODILE	morse	AFTERLIFE
SUNSON		METGrow		BioRECOVER
		REBIEW		CityLoops

IDENER R&D as a top-tier private research center

Top 20 Spanish entities (public and private) by research grant value in Horizon Europe (2021-2023)

Most outstanding entities (public and private)	Activities Total	Activities Coordinated
Agencia Estatal Consejo Superior de Investigaciones Científicas	465	153
Fundación Tecnalia Research & Innovation	152	24
Universidad Politécnica de Cataluña	129	27
Universidad Autónoma de Barcelona	105	46
Universidad Politécnica de Madrid	118	27
Barcelona Supercomputing Center - Centro Nacional de Supercomputación	108	21
Universidad Pompeu Fabra	78	44
Universidad de Barcelona	105	40
Universidad Politécnica de Valencia	114	20
Indra Sistemas, S.A.	31	5
Fundación CIRCE - Centro de Investigación de Recursos y Consumos Energéticos	56	15
Universidad de Valencia	67	27
Fundación CARTIF	56	9
Fundació Privada Clínic per a la Recerca Biomèdica	42	11
Asociación de Investigación Metalúrgica del Noroeste	50	8
Idener Research & Development, A.I.E.	37	16
Institut de Ciències Fotòniques	45	23
Fundació Eurecat	54	6
Universidad del País Vasco	79	32
Fundación Privada Instituto de Salud Global de Barcelona	30	11

First Spanish private research center by research grant number in Horizon Europe (2021-2023)

Second Spanish private research center by research grant value in Horizon Europe (2021-2023)

Most outstanding entities (private)	Activities Total	Activities Coordinated
Indra Sistemas, S.A.	31	5
Idener Research & Development Agrupación de Interés Económico	37	16
Telefónica Investigación y Desarrollo, S.A.	48	3
Airbus Defence and Space,SAU	13	1
Acciona Construcción, S.A.	16	2
Etra Investigación y Desarrollo, S.A.	18	7
Arquimea Research Center, S.L.	2	1
EIT Manufacturing West, S.L.	2	1
Atos It Solutions and Services Iberia, S.L.	44	7
Iris Technology Solutions, S.L.	30	0
Airbus Operations, S.L.	13	0
Zabala Innovation Consulting, S.A.	24	2
Natac Biotech, S.L.	2	1
Idiada Automotive Technology, S.A.	25	3
Centro de Referencia Investigación Desarrollo e Innovación ATM, A.I.E.	21	1
Royal Melbourne Institute of Technology Spain, S.L.	5	1
GMV Aerospace and Defense, S.A.	10	5
Repsol Química, S.A.	1	0
Iquadrat Informática, S.L.	13	1
Pal Robotics, S.L.	13	0

PROPOSAL DETAILS

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Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing

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Topic Description

Topic	Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing
Type	Research and Innovation Action (RIA)
Budget	**5-8 M€ per project (50.00 M€ in total) – lump sum**
Winners	~7 winner proposals
Deadline	16th April 2026

EXPECTED OUTCOMES

Researchers

- Access to improved, human-relevant NAMs
- Genetic, phenotypic, immune, microbiome, and environmental variability
- Equitable and personalised healthcare

Industry

- Platforms that accelerate innovation
- Faster and more cost-effective development of therapies and safety assessment of chemicals and medical products

Patients

- Better prediction, prevention and treatment of diseases
- Enhanced understanding of biological mechanisms and pathways

General population

- Improved protection through detection and mitigation of risks from chemicals and potentially harmful substances

Regulatory bodies

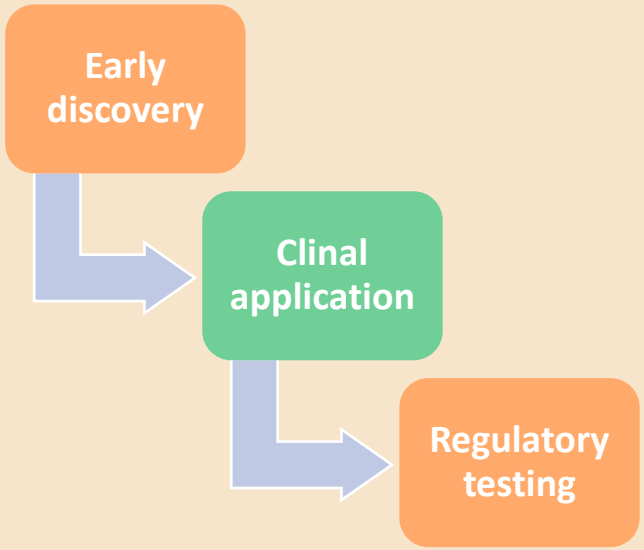
- Increased confidence in NAMs
- Facilitates integration into product development, risk assessment, and approval processes

Animal Welfare

- Significant reduction in the use of animals for biomedical research and regulatory testing

SCOPE

Support the paradigm shift in biomedical research and regulatory safety assessment by **fully integrating NAMs** across the entire spectrum



- ✓ **Scalable and reproducible NAMs platforms** for biomedical and regulatory use
- ✓ **Biological diversity** (genetics, phenotype, age, immune status, microbiome)
- ✓ **Embedded sensors** for real-time physiological monitoring
- ✓ **AI-predictive modelling and virtual twins** for enhanced disease prediction and clinical trial optimisation
- ✓ **FAIR data principles** for interoperability and reuse
- ✓ Collaborate across **academia, SMEs, industry, regulators**, and involve **JRC/EURL ECVAM** for regulatory uptake
- ✓ Demonstrate **validation and regulatory relevance** for chemicals, medicinal products, and medical devices

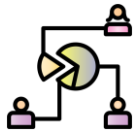
Our Approach

New Approach Methodologies (NAMs)

NAMs refer to novel methods that are compliant with the so-called "**3Rs principles**" for the ethical use of animals in medicine testing across EU.

In silico

Artificial Intelligence and Machine Learning



Quantitative Structured-Activity Relationships (QSAR)

Physiological kinetics

In chemico

- No living organisms
- Evaluation of substances than can be potentially harmful to determined tissues

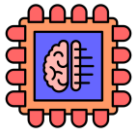
In vitro

Isolated specified cell cultures

Induced pluripotent stem cells (iPSCs)

Ex vivo

Isolated organs and organoids



Organ-on-Chips (OoCs)

Limitations and risks

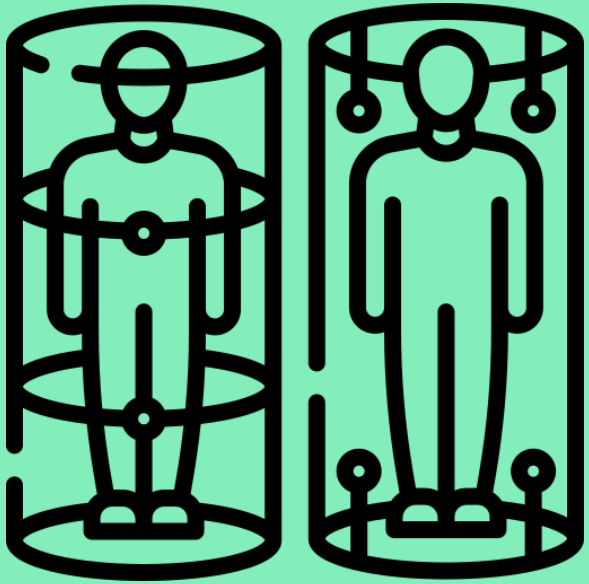
Rigorous data standards and comply with the context for which specific NAM assays have been validated.
NAMs can be used to **generate hypotheses**, but they must be rigorously tested before being incorporated into regulatory decisions

OUR PROPOSAL

Response to pharmacological interventions

Disease onset and progression

VIRTUAL HUMAN TWIN



Capture differences between healthy and pathological states

Enable regulatory acceptance of advanced NAMs

PLATFORM BASELINE AND INFORMATION GATHERING

Available data

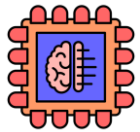
Regulatory datasets

Scientific literature

Available clinical data

NAMs experimental data generation

Induced pluripotent stem cells (iPSC)

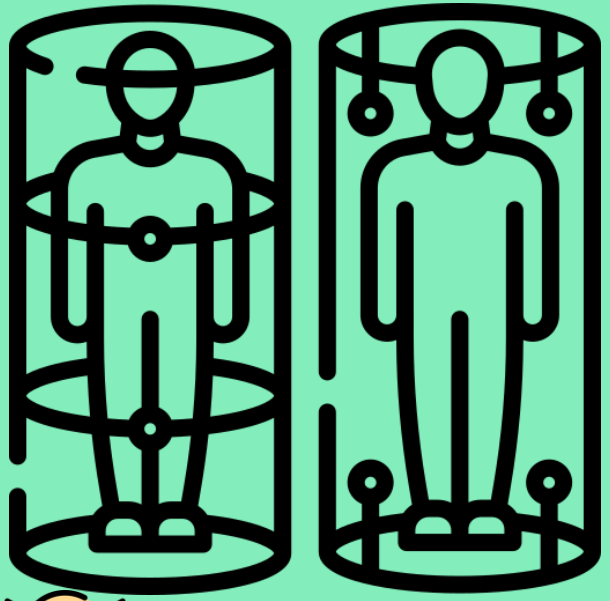


Organ-on-Chip (OoC)

1st step

2nd step

VIRTUAL HUMAN TWIN



Explainable AI
Interpretable and reliable from conception

Deep reinforcement learning
Exploration and optimisation (dose-response, intervention times)

- Advanced regulatory readiness
- Reduced reliance on animal experimentation
- Fast and cost-effective development of new therapies
- Improved protection and societal confidence

CONCEPT NOTE

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GENERATIVE EXPLAINABLE NEW-METHOD ENGINE FOR SAFE IN SILICO SIMULATIONS

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