Artificial **I**ntelligence in **ME**dicine **D**evelopment

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Who we are

Pioneering GenAI-Driven Solutions For Clinical Research

AIMED Trial provides cutting-edge GenAI-powered tools

and Computational technologies to optimize clinical trials

by enhancing design, feasibility, costs, and outcomes

Leaders in GenAI Technology

We empower industry sponsors, non-profit organizations, and CROs to streamline clinical trials **using GenAI, Machine Learning, and Computational-powered solutions.**

A.I.M.E.D

Committed to Clinical Trial Success

Our mission is **to set a new benchmark for innovation in clinical research**, transforming how trials are conducted **and advancing the future of medicine** by making cutting-edge research more efficient, faster, cheaper and reliable.

AIMED SUITE© of solutions

- **GenAI-OSCAR ML© / SCA:** *GenAI-Driven Synthetic Control Arm*
- **GenAI-OSCAR ML© / RWE:** *GenAI-Driven RWD Acquisition and Analysis*
- **GenAI-OSCAR ML© / TTE:** *Target Trial Emulation for Drug Repurposing*
- **AIMED GENERATOR©:** *Precision Synthetic Data for Enhanced Clinical Trials*
- **AIMED SIMULATOR©:** *Clinical Trial Simulation in Silico*
- **AIMED SPIDER© / PDD:** *Patient's Data De-Identifier*
- **AIMED ENROLL© :** *GenAI-Driven Remote Verbal Consent*

Gen.AI-OSCAR ML©

1 platform and 3 modules to harness the power and value of RWD

- **Synthetic Control Arm (SCA)**
- **Real World Evidence (RWE)**
- **Target Trial Emulation (TTE)**

GenAI Components

Technical and Operational Features

- **Natural Language Queries**: Enables users to create specific queries in natural language to obtain desired RWD insights effortlessly.

- **Comprehensive Visualization**: Transforms ML outputs into intuitive graphs, images, tables, and detailed textual commentary for better understanding.

GenAI Components

Technical and Operational Features

- **5 different GenAI Agents (retrivier, planner, executor, generator, indexer)** each of which automatically performs one part of the process to lead to the required result, such as the creation of a synthetic control group or an advanced, predictive analysis of RWD.

- **Simplified Data Interpretation**: Converts complex data and findings into easily digestible formats, making insights more accessible.

ML Component

Technical and Operational Features

- **Generation of Synthetic Data**: Enhances dataset richness and robustness by replacing missing data with synthetic data.
- **Advanced Analytics**: Identifies trends and correlations across subgroups, performs comprehensive analyses, and predicts outcomes for proactive decision-making.
- **Automated Processing**: Streamlines data cleaning, normalization, and processing, reducing manual effort and errors.
- **Scalability**: Efficiently handles large and diverse datasets, enabling quick, in-depth analysis.

Summary Technical and Operational Features

- Stand-alone and cloud-based application
- Automated patient data anonymization
- Controlled access and audit trails
- Selection of data eligible transparent and traceable with audit trials available to Authority's inspections
- Universal connector to any kind of external source databases
- Compliant with the latest Regulatory Authorities guidance on RWD/RWE submission
- Applicable to any kind of trial protocol
- Validated according to 21 CFR part 11 and other industry standards
- GDPR compliant

Gen.AI-OSCAR ML© / SCA

GenAI-Driven Synthetic Control Arm

GenAI-Driven Synthetic Control Arm (SCA)

- **Randomized controlled trials (RCTs) are the gold standard** to investigate efficacy and safety of new treatments
- **In certain settings, however, randomizing patients to control may be difficult for ethical or feasibility reasons**
- If researchers are investigating a **potentially life-saving treatment** they believe will be particularly effective, **it can be unethical to randomize the trial participants to a placebo arm**

GenAI-Driven Synthetic Control Arm (SCA)

- **Using** relevant individual patient data as control from **external trials or RWD sources may then allow to reduce, or even eliminate, the concurrent control group**
- **With Synthetic Control Arm (SCA) , the problem of a placebo or no or standard treatment arm is not an issue**, because the comparison group is outside of the study, there are no patients in the study who miss out on active treatment.

GenAI-Driven Synthetic Control Arm (SCA)

- Because **some disease types have very small patient populations, it can be impractical or prohibitively difficult to find enough patients to enroll in an RCT**, which can lead to sample sizes that are too small to obtain meaningful results
- **SACs** can be particularly useful **in life-threatening or rare diseases, rare oncology spaces and even to increase an underrepresented subgroup of patients** with a specific genetic or biomarker profile.

GenAI-OSCAR ML©/SCA: features

- **AI-Powered RWD Integration**: aggregates and analyzes vast RWD, including patient registries, medical records, and historical trials, to construct SCAs that accurately reflect real-world patient populations.
- **Advanced Data Modeling**: the platform uses advanced machine learning algorithms to model disease progression and treatment outcomes, ensuring that the synthetic control arm is a precise match for the trial's target population.
- **Handling Missing Data**: can generate synthetic data to replace missing or incomplete real-world data, providing a comprehensive dataset for robust analysis.

GenAI-OSCAR ML©/SCA: features

- **Regulatory Compliance**: generated SCAs developed are designed to align with regulatory standards, facilitating acceptance by authorities such as the FDA and EMA.
- **Accelerated Trial Timelines**: by reducing recruitment challenges and expediting data analysis.
- **Cost-Effectiveness**: lowers trial costs by reducing the need for large control groups and streamlining data processing.
- **Enhanced Insights**: provides robust and accurate comparative data, leading to more reliable study outcomes.

GenAI-OSCAR ML© / RWE

GenAI-Driven RWD Acquisition and Analysis for innovative retrospective non-interventional studies

The «Traditional» Retrospective Observational Study

- In a **traditional retrospective observational study**, data acquisition is typically done through an eCRF, where **researchers manually collect patient data** from medical records, healthcare databases, or registries.

- This **data are aggregated in the study database** and then standardized, cleaned and extracted for standard statistical analysis to assess outcomes and treatment effects.

The «Traditional» Retrospective Observational Study

- **The process is time-consuming**, involving manual data entry, cleaning, error correction and extraction.

- Additionally, **this approach is hampered by the generally poor quality RWD**, including missing and unstructured data, which makes it challenging with traditional analyses to generate reliable results despite significant costs and extended timelines.

GenAI-OSCAR ML©/RWE
the «Innovative» Retrospective Observational Study

- **With GenAI-OSCAR ML© /RWE**, the process is significantly streamlined.

- **Anonymized RWD is imported automatically via a FHIR (Fast Healthcare Interoperability Resources) connector**, which directly pulls structured and unstructured data from various sources like EHRs and clinical databases.

- **The platform cleans, harmonizes, and analyzes the data using GenAI and ML,** generate synthetic data replacing the missing ones, providing real-time insights without the need for manual data entry, ensuring faster, and more accurate results.

GenAI-OSCAR ML©/RWE : key benefits

- **Superior Quality**: Unlock deeper insights and more accurate results through advanced analytical techniques.
- **Unmatched Speed**: Achieve rapid data processing and analysis for timely results.
- **Cost Efficiency**: Reduce resource requirements and cut costs through automated processes.
- **Scalability**: Seamlessly handle vast and diverse datasets, scaling operations as needed.
- **Real-Time Insights**: Make informed decisions quickly with real-time data analysis capabilities.

GenAI-OSCAR ML© / TTE

Target Trial Emulation from RWD for Drug Repurposing

Target Trial Emulation from RWD

- **Target Trial Emulation (TTE) using Real-World Data (RWD) can be a highly effective tool for drug repurposing**, which involves identifying new therapeutic uses for existing drugs.
- By applying the principles of randomized controlled trials (RCTs) to observational data, **TTE helps answer causal questions about the efficacy and safety of drugs in different clinical contexts.**
- This approach **can provide valuable insights** into the potential repurposing of drugs, especially **when RCTs are not feasible due to ethical, time, or cost constraints.**

Target Trial Emulation from RWD: applications

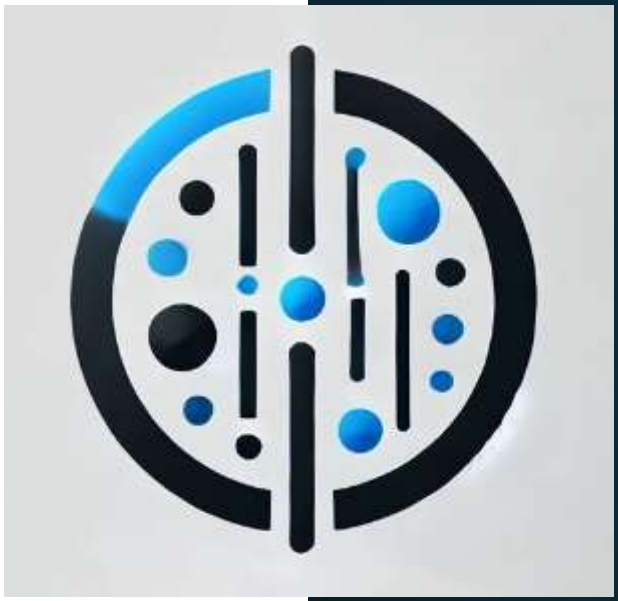
- Identifying New Indications
- Retrospective Analysis of Real-World Use
- Overcoming the Limitations of Traditional RCTs
- Reducing Bias in Observational Studies
- Evaluating Safety and Efficacy Across Diverse Populations
- Supporting Regulatory Submissions
- Causal Inference for New Treatment Strategies

Target Trial Emulation from RWD: benefits

- Makes this process even more accessible by **automating and enhancing the emulation of trials using GenAI and machine learning,** enabling the identification and validation of new therapeutic uses for existing drugs.
- Supports drug repurposing by **generating reliable, bias-adjusted evidence** that meets regulatory standards for efficacy and safety assessment.
- Allows **for efficient, cost-effective, and scientifically rigorous exploration of drug repurposing** opportunities, making it a valuable tool in modern clinical research and development.

AIMED GENERATOR©

Precise Synthetic Data
for Enhanced Clinical Trials



Synthetic Data in Clinical Trials

- Synthetic data in clinical trials **refers to artificially generated data that mimics real patient data but doesn't involve actual patients.**

- **It's created using algorithms, computational and GenAI models based on patterns observed in real-world data**

Synthetic Data in Clinical Trials

- **Synthetic data protect privacy by replacing real patients' data**.
- Unlike real data, synthetic records are not linked to real individuals and **don't undergo the application of GDPR regulations.**
- The **AI Act mentions synthetic data as a preferred data source in AI development**, along with other forms of non-personal data (art. 59.1.b).

Synthetic Data in Clinical Trials: advantages

Clinical Data Augmentation and Enhancement

- **Synthetic data can be used to supplement small datasets**, especially in rare diseases or specialized studies where patient recruitment is challenging.
- By generating realistic synthetic patient profiles, researchers can **increase the dataset size, making statistical analyses more robust and reliable.**
- Synthetic data can help **create balanced datasets**, which is especially important in scenarios **where some subgroups are underrepresented**.

Synthetic Data in Clinical Trials: advantages

Accelerating Feasibility Studies and Trial Design

- Synthetic data allows researchers to **simulate different scenarios and predict outcomes before conducting actual trials, optimizing trial design and protocol.**

- Researchers **can test different variables, such as dosages or patient demographics**, in synthetic datasets to identify the most promising approaches, which **improves efficiency and reduces trial-and-error in actual clinical trials.**

Synthetic Data in Clinical Trials: advantages

Avoiding Privacy and Compliance Restrictions

- Using **synthetic data in place of real patient data helps protect patient privacy**, as synthetic data does not contain personally identifiable information.

- Synthetic data **can be shared across institutions, partners, or countries without risking privacy breaches,** as the data is inherently anonymized and doesn't correspond to actual individuals.

AIMED GENERATOR©

- The **RWD data is imported and automatically structured through AIMED GENERATOR©** Synthetic Data GenAI technology.
- **All involved attributes are recognized automatically and represented in tables.**
- Subsequently, a **synthetic database is created to mimic these tables, without sensitive information about real patients.**

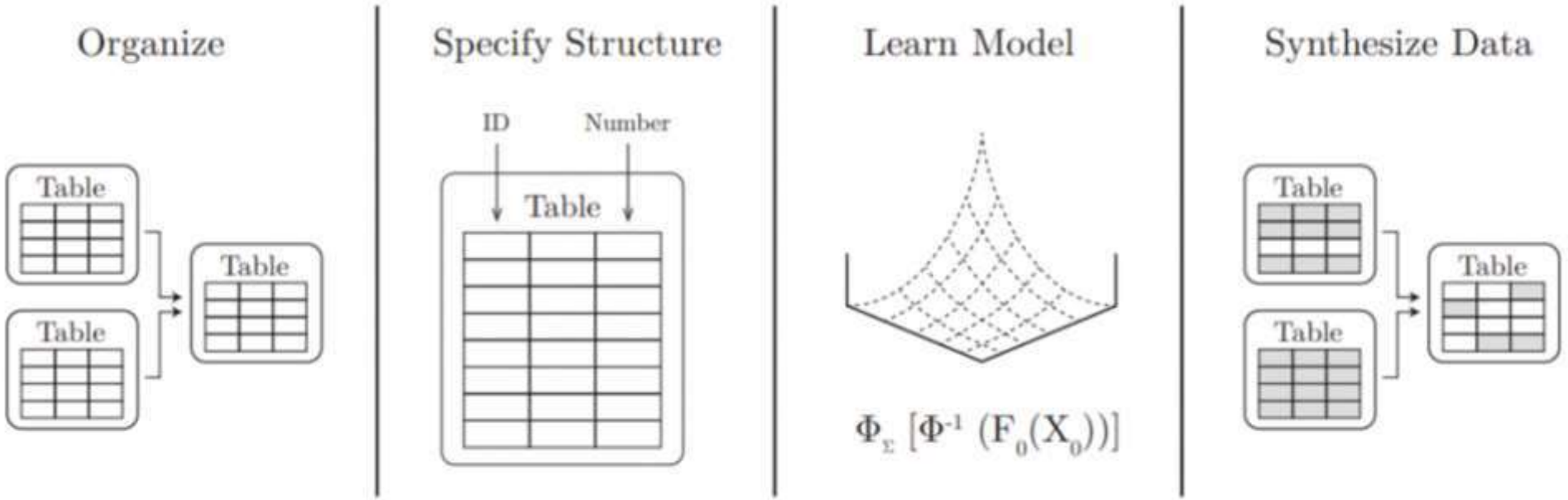
AIMED GENERATOR©: how it works

- **Synthetic data is created using the Python SDV (Synthetic Data Vault) library,** which permits both single table and multi table generation of data from a source maintaining the original distribution.
- **As generative models, 2 options will be used according to the data structure:**
  - CTGAN: as in Conditional Tabular Generative Adversarial Network, for single table data
  - HMA1: as in Hierarchical Modelling Algorithm 1, for multi-table data
- Once the appropriate data sources are identified, **a careful assessment will be made about the potential biases** which are inherent in real world data or present in historical trial data as these data were not collected for the purposes of the comparison with a new single arm trial.

AIMED GENERATOR©: how it works

- **Conditional Tabular Generative Adversarial Networks (CTGANs)**: GANs consist of two neural networks—**the generator and the discriminator**—that are trained simultaneously.
- The **generator creates synthetic data**, while **the discriminator evaluates its authenticity** compared to real data.
- Through this adversarial process, **the generator learns to produce increasingly realistic synthetic data.**

AIMED GENERATOR©: how it works



AIMED GENERATOR©: competitive benefits

- **Cost Reduction**

  By using synthetic control arms or simulating trial scenarios, synthetic data reduces the number of actual patients needed, lowering recruitment and operational costs.

- **Faster Results**

  With synthetic data, researchers can iterate more quickly and design better-informed trials, accelerating timelines for drug and treatment approvals.

- **Increased Flexibility**

  Synthetic data allows researchers to explore “what-if” scenarios, adapt protocols, and refine models without interrupting ongoing trials.

- **Improved Ethics**

  Reduces the need for placebo or control arms in situations where it may not be ethical to withhold treatment from patients.

AIMED SIMULATOR©

Clinical Trial Simulation in Silico

Clinical Trial Simulation

- **AIMED Trial** proudly offers a cutting-edge **clinical trial simulation service powered by the Universal Immune System Simulator (UISS).**

- **AIMED SIMULATOR©** leverages the power of **in silico clinical trials to drastically reduce the time, costs, and risks associated with traditional clinical trials,** while delivering unprecedented accuracy in predicting human immune responses to various medical interventions

Clinical Trial Simulation

- **AIMED SIMULATOR© allows the conduction of clinical trials in silico**, meaning experiments are performed **using virtual patients** instead of real human subjects.

- **These virtual patients are built using a comprehensive array of data, including genetic, physiological, and lifestyle information,** which creates highly accurate and individualized models.

Clinical Trial Simulation by UISS

- **The simulation begins by defining a conceptual map of the disease or immune response** of interest, which is then translated into mathematical models.
- **The UISS platform executes the simulation**, allowing researchers to observe and predict the immune system's behaviour over time.
- This approach **accelerates the development and testing of new treatments** while enhancing precision.

Clinical Trial Simulation by UISS: applications

- **The Universal Immune System Simulator (UISS) is an advanced computational framework designed to model the human immune system.**
- **UISS has been successfully applied to the design and verification of novel treatments for many diseases** including pathologies such as:
  - Cancer (e.g., breast cancer, melanoma, thyroid carcinoma).
  - Autoimmune disorders (e.g., multiple sclerosis, allergic contact dermatitis).
  - Infectious diseases (e.g., tuberculosis, COVID-19, influenza H5N1, parasite).

Additional disease models can be developed upon client request.

Clinical Trial Simulation by UISS: benefits

- **Rapid Simulation**: UISS enables millions of immune system interactions to be simulated in a short time, allowing researchers to explore complex immune responses quickly.
- **Patient-Specific Models**: Virtual patients created with detailed data layers provide high accuracy in predicting individual responses to drugs or treatments.
- **Cost-Effective**: In silico trials reduce the financial burden associated with traditional clinical trials, as fewer physical experiments are needed.
- **Improved Patient Safety**: Potential risks or adverse effects are identified in the simulation phase, reducing the likelihood of harm to real patients during actual trials

AIMED SPIDER© /PDD

Patient's Data De-identifier

Patient’s Data De-identifier

- At AIMED Trial, **we prioritize the privacy and security of patient data in clinical trials** and we are committed to upholding the highest standards of data protection.

- The primary objective **of AIMED SPIDER© /PDD is to facilitate the secure and compliant exportation/importation and management of anonymized patient data** from various sources.

Patient’s Data De-identifier

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Patient’s Data De-identifier

- **To qualify a data processing operation as anonymization** and thus exempted from the strict regulations of the GDPR, **the data will be processed in such a way that it is no longer possible to isolate or identify a single individual within the dataset**.

- This means **it should be impossible to trace the identity of a specific person**, even using advanced correlation techniques or additional information.

AIMED SPIDER©/PDD: Key features

- **Unique Identifier Creation**
- **Security and Privacy**
- **Tokenization**
- **Hashing**
- **Non-Reversibility**
- **Additional Security**

AIMED SPIDER©/PDD: Key benefits

- **Enhanced Privacy and Security**
  - Patients' personal data is protected through the use of non-reversible pseudo-identifiers.
  - Strong cryptographic methods and secure salt management ensure data remains confidential.
- **Improved Data Management**
  - Consistent identifiers across sites facilitate the accurate and efficient combination of single patient data.
  - Eliminates data silos and enhances collaboration among different healthcare providers involved in the trial.
- **Regulatory Compliance**
  - Adheres to data protection regulations such as GDPR and HIPAA.
  - Regular updates and security audits ensure ongoing compliance with evolving standards.

AIMED SPIDER©/PDD: Key benefits

Operational Efficiency

- Streamlines the process of managing patient identifiers across different systems.
- Reduces administrative burden and complexity, saving time and resources.

Scalability

- Easily accommodates the addition of new sites and an increasing number of patients without significant changes.
- Handles large volumes of patient data efficiently, supporting extensive clinical trials.

Patient Trust

- Builds confidence among patients by demonstrating robust data privacy and security practices.
- Assures patients that their personal information is managed securely and responsibly.

AIMED ENROLL©

GenAI- Driven Remote Verbal Consent

Definition of Remote Verbal Consent

- Verbal consent means that **the content of the consent form** (i.e. an information sheet), **is made available to subjects in both written and verbal version** and subjects give their verbal consent in place of written consent to participate.
- **Subjects should be given the opportunity to ask questions on the proposed study** and provided with a copy of the information sheet.
- **The EC should be provided with the consent script** to evaluate the remote verbal consent process.

Remote Verbal Consent: applicability

In studies **where a physical or electronic signature cannot be feasibly obtained** such as:

- **retrospective and prospective non-interventional studies**
- **pre-study screening** through analyses **of biospecimens taken previously** and stored at sites
- **the study that could not practicably be carried out** without such approach
- **low intervention and minimal risk studies** enrolling subjects who for many reasons (age, culture standards, education....) are not familiar with the electronic or digital signature
- **emergency medicine studies** where the voice interaction and verbal approval allows for a faster consent procedure
- **Reconsenting** in case of minimal risk protocol amendment

AIMED ENROLL©

- The " **first reliable & compliant and GenAI driven" Remote Verbal Consent** in clinical trial.

- **It enables the investigator to share the informed consent form with patient via smartphone** and to collect the "verbal consent" if patient agrees to participate to the trial.

AIMED ENROLL© : summary features

- **Flexible, fast and easy to use** by users of any age, cultural standards and education
- **Customized verbal communication and workflows**
- **Independent investigator and patient consent procedure** but with the possibility of direct verbal interaction between parties
- **Any language supported**
- **Very fast implementation**
- **GenAI-Driven Chatbot that answers in real-time any patient questions** related to the study's procedures and objectives
- **Entire remote audio consent procedure recorded and** after electronic signature by investigator **transcribed on a final PDF document,** PW protected and delivered to both patient and investigator
- **Encryption and Audit trail** of all audio interactions and transactions
- **GCPs & GDPR Compliant and 21 CFR part 11 validated**

The GenAI Revolution in Medicine Development

A.I.ME.D

Thanks for watching

aimedtrial.com