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İTÜ NOVA TEKNOLOJİ TRANSFER OFİSİ

TTO Boğaziçi Üniversitesi Teknoloji Transfer Ofisi A.Ş.

İSTANBULTTO TEKNOLOJİ TRANSFER OFİSİ

KOÇ ÜNİVERSİTESİ

MİTTO MARMARA ÜNİVERSİTESİ İNOVASYON VE TEKNOLOJİ TRANSFER UYGULAMA VE ARAŞTIRMA MERKEZİ

YTÜ YILDIZ TEKNOPARK

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Horizon Europe Cluster 1:

Health Brokerage Event

Project Idea / Field of Expertise :

Organisation Name:

Addressed Topic(s) & Call(s):

NAM toxicological in-silico expertise to avoid preclinical animal studies

Tox by Design

HORIZON-HLTH-2024-IND-06-09
HORIZON-HLTH-2024-TOOL-05-06-two-stage

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Tox by Design

Keep calm
and ask a toxicologist

QSAR in-silico tox project is the base of our renewal of French tax refund for innovative R&D activities 2022-2024

International **pure player**
Tox experts team
lead by a **European Registered Toxicologist**

EUROTOX REGISTERED TOXICOLOGIST

ToxByDesign methodology

Database and literature search

In silico assessment of the toxicological potential

Tox classification

Risk characterization

Derivation of acceptable intakes TTC, PDE or OEL

Developed NAM processes for drug candidates
before human clinical trials phase I (human safety)
that could be leveraged to minimize preclinical animal trials

Tox data: Literature review

No tox data
use of *in silico* tools

Top 3 EU tox company regarding **in silico toxicity assessments** of **drug candidates** or **impurities** for

- human Clinical Trials
- workers on production line
- patients exposure via cross contamination

ToxByDesign *In silico* tools

Leadscope
Instem
Danish (Q)SAR Database
650,000 Substances
VEGA
ProtoQSAR

Successful
past experience
EU consortium
Horizon Phase I and II
SMEInst-03-2016-2017

REGULAXIS
REGENERATIVE MEDICINE • GROWTH DYSREGULATION • ONCOLOGY

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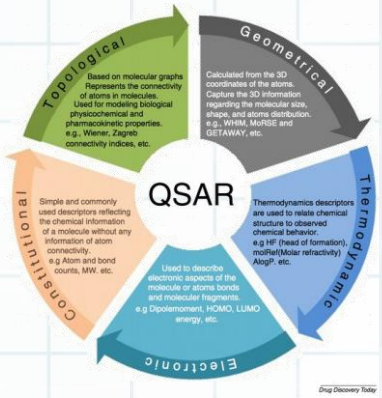
Tox by Design Horizon 2023 project



Given the Tox by Design **extended experience** in
Quantitative structure-activity relationship (“**QSAR**”)

in-silico computational modeling method for revealing relationships between

- *structural properties of chemical compounds and*
- *biological activities*

- **Share our experience** of in-silico tox assessments **processes and methodology** with Biotech and pharmaceutical companies, and democratize Real World cases of preclinical animal trials cancellations

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Discuss with **European Medicine Agency** and **EU Member states Regulatory bodies** how we could **leverage** in-silico QSAR NAM tools to **minimize preclinical animal trials**, while robustly documenting expected toxicology of drug candidates, or even drug manufacturing or degradation impurities

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THANK YOU...