RISK HUNT3R Newsletter

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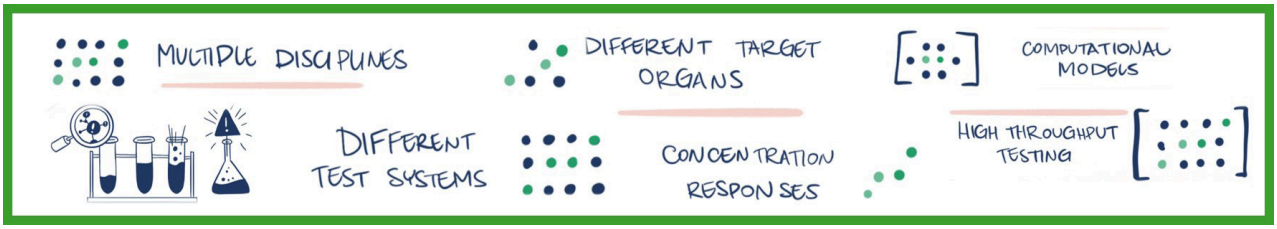

Spotlighting the RISK-HUNT3R Innovation Radar: from research to real impact

Collaborative research projects generate a lot of excellent science. But turning these results into tools and products that regulators and industry can use is still a challenge.
The **RISK-HUNT3R Innovation Radar** aims to help close this gap. It identifies the most promising technologies developed in the project and supports their path from research to commercial implementation.

The initiative currently includes **26 innovations,** ranging from human-relevant *in vitro* models to computational tools. These technologies support next-generation risk assessment (NGRA) by integrating New Approach Methodologies (NAMs) into structured safety assessment approaches. They can help speed up decision-making in chemical safety assessment and regulation, while improving the human relevance of safety evaluations.

Barry Hardy and Paul Jennings, who coordinate the Innovation Radar activities within RISK-HUNT3R, stress the importance of turning research into real impact. According to Barry Hardy, the Innovation Radar is "*an innovation itself*", because it helps to identify technologies that could become long-term sustainable tools or services. For Paul Jennings, the key strength of the initiative is collaboration across disciplines. "*Academics are very good at discovering new things, while businesses focus on turning ideas into products. Bringing these worlds together creates a huge added benefit*".

As the project continues, the Innovation Radar will support innovations at different stages of development, from early research tools to technologies ready for investment and commercialization. The goal is not only to publish scientific results, but also to build a sustainable ecosystem where innovations developed within RISK-HUNT3R can evolve into solutions that benefit regulators, industry, and society.
In this newsletter, we invite you to explore a selection of these innovations.

Paul Jennings (VU Amsterdam) & Barry Hardy (Edelweiss Connect)

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NEFFIT: hiPSC-based kidney models for injury assessment

Renal toxicity remains a major challenge in drug development and safety assessment. Reliable human in vitro models are still limited.

NEFFIT addresses this gap with human iPSC-derived models of proximal tubule-like (PTL) cells and renal podocytes. These are two of the most vulnerable cell types in the nephron.

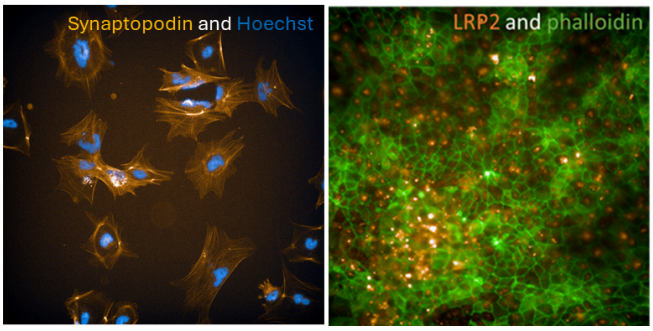
NEFFIT offers specialized screening services. Stakeholders can evaluate **potential nephrotoxic compounds**. It uses cells from multiple donors. This captures inter-individual variability, a key strength of iPSC technology.

The cells also integrate into microfluidic organ-on-chip systems and co-culture settings.

These create more physiologically relevant testing environments.

NEFFIT helps build more predictive approaches for renal toxicity in NGRA.

The NEFFIT platform is currently under development.



iPSC-derived podocytes *iPSC-derived renal proximal tubular cells*

Anja Wilmes & Paul Jennings (VU Amsterdam)

TXG-MAPr toolbox

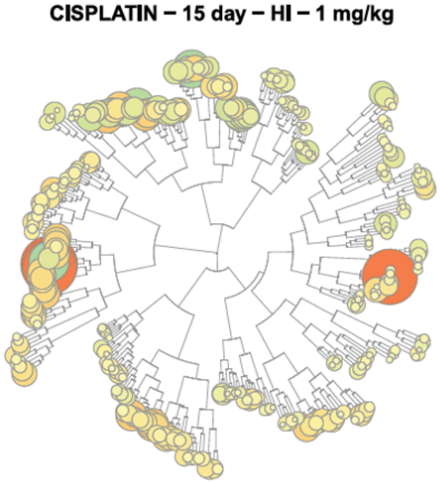
qualitative and quantitative omics-based hazard assessment

TXG-MAPr tools are a network-driven platform for quantitative and qualitative analysis of toxicogenomics data. Unlike traditional enrichment-based omics tools, TXG-MAPr uses **gene co-expression networks to cluster thousands of genes into co-regulated modules**. This reduces data complexity by over 95% while preserving biological information, enabling clear visualization and quantification of gene responses.

TXG-MAPr is tissue- and cell-type specific. Each cell type responds differently to chemicals, so specific tools are essential. Users can evaluate preservation across systems to identify modules most likely associated with human adversity. The initial liver and kidney models are expanded to lung and neuronal models.

TXG-MAPr is available online and via software licensing with training. Next steps include a Leiden University spin-off (IT4TOX), and collaboration with *InSphero* for liver microtissue analysis.

Rat kidney TXG-MAPr



Steven Kunnen & Bob van de Water (Leiden University)

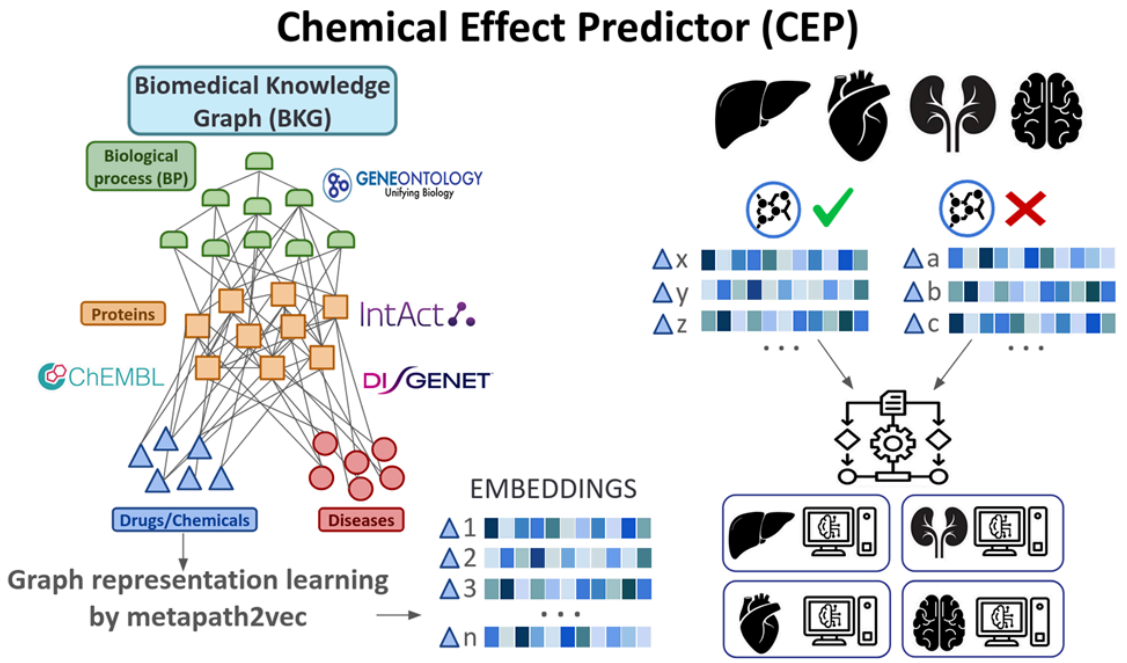
Chemical Effect Predictor (CEP): a biomedical knowledge graph driven by *in silico* NAM for chemical safety assessment

The Chemical Effect Predictor (CEP) predicts organ-specific toxicity before chemicals reach people. It combines machine learning with a large biological knowledge base that links drugs, proteins, pathways and diseases.

Many existing prediction models act like black boxes and are hard to interpret. Their results are often not clearly connected to clinical outcomes used by regulators. This makes it difficult to apply them in real decision-making.

CEP is designed to close this gap. It uses AI models that can handle complex data and a structured knowledge base that **connects early molecular changes to disease endpoints**. Human clinical and safety data are built in so that predictions stay aligned with real-world observations.
The tool reconstructs possible chains of events, from the first molecular interaction to pathway changes and finally organ-level toxicity. This follows the idea of adverse outcome pathways (AOPs), so **each prediction comes with a mechanistic explanation**.

CEP currently covers four major organs: liver, heart, kidney and nervous system.
By connecting molecular mechanisms to translational safety readouts, CEP builds confidence in computational toxicology. It bridges computational models and human outcomes regulators care about.



CEP serves as a decision-support tool for NGRA. It helps advance safer, more human-relevant chemical safety evaluation.

Jaione Telleria & Laura Furlong (MBIS)

Toxys' NAM portfolio: Mechanistic insights with regulatory impact

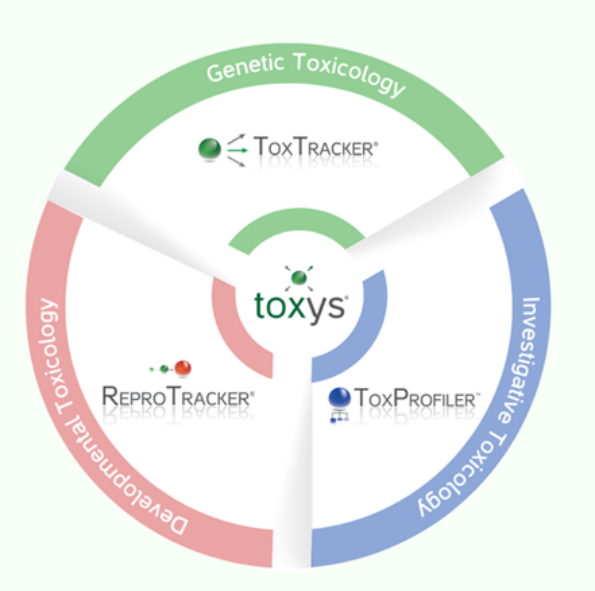
Toxys has developed a focused portfolio of *in vitro* assays. These are robust NAMs that support mechanistic testing strategies aligned with NGRA principles.

What makes ToxTracker® more than a genotoxicity test?

ToxTracker goes beyond traditional genotoxicity tests. This mouse stem cell-based reporter assay identifies genotoxic compounds with high accuracy. Using GFP-tagged biomarkers, it distinguishes DNA damage, oxidative stress, protein damage and p53-mediated responses.

This mechanistic detail helps toxicologists separate direct DNA-reactive compounds from those causing secondary effects. ToxTracker has an important advantage over binary assays.

It is now being evaluated for inclusion in the OECD test guideline framework. This reflects its scientific maturity. It also supports international harmonization for industry and regulators.



Toxys is a Dutch biotech company that provides new in approach methodologies to rapidly identify hazardous and potential carcinogenic properties of novel substances in the field of genetic, developmental and investigative toxicology.

How does ReproTracker® support early identification of developmental toxicants?

ReproTracker supports early identification of developmental toxicants. This human iPSC-based assay investigates developmental toxicology. It combines functional and morphological readouts with tissue-specific biomarkers. The assay detects disruption of embryonic stem cell differentiation into cardiomyocytes, hepatocytes and neurons.

ReproTracker can quantitatively predict a compound's teratogenic potential. It helps extrapolate animal results to humans. Like ToxTracker, it is being evaluated for OECD inclusion based on intra- and inter-laboratory transferability and reproducibility.

ToxProfiler®: A NAM for potency ranking, mode-of-action assessment and chemical read-across.

ToxProfiler is a human cell-based high-content imaging platform. It profiles compounds using seven fluorescent reporter genes. This maps major cellular stress pathways and delivers compound-specific toxicity profiles. ToxProfiler supports mode-of-action identification, potency ranking and read-across.

Tamara Meijer & Noelia Muñoz-Martin (Toxys)

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