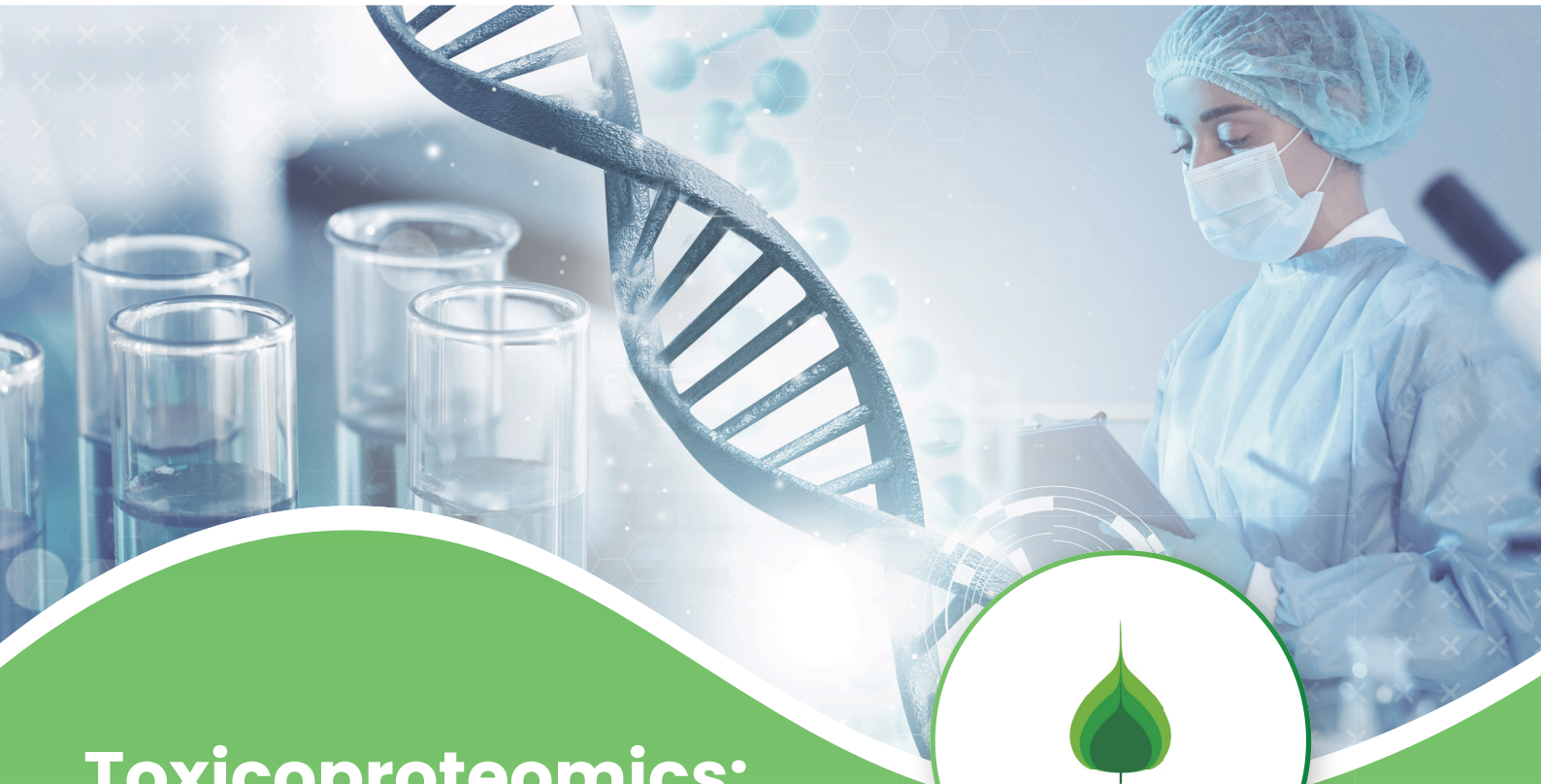


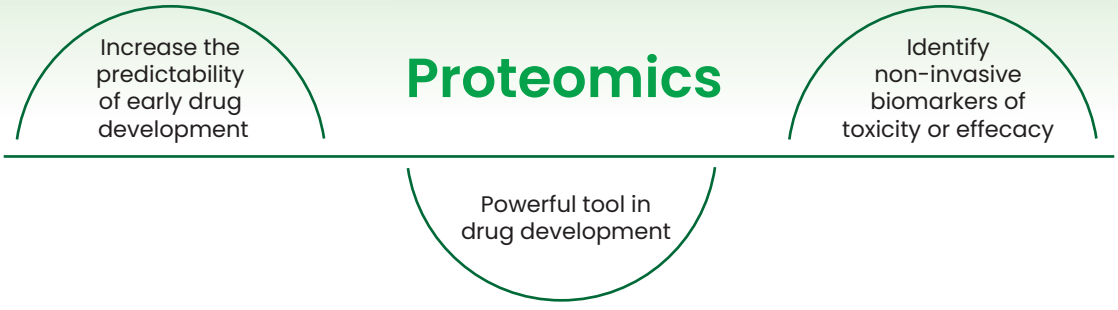
Toxicoproteomics:
An Emerging Technologies in Safety Evaluation

JRF GLOBAL

OMICs approaches have a potential for application in comprehensive toxicological interpretations. They offer a range of tools to characterise and quantify the molecular and biochemical changes in cells, tissues and organisms induced by chemicals and toxic substances.

Proteomics

Proteomics is the study of proteomes. A proteome is a set of proteins. Proteomics is systematic study of proteins to provide a comprehensive view of the structure, function and role in the regulation of a biological system.

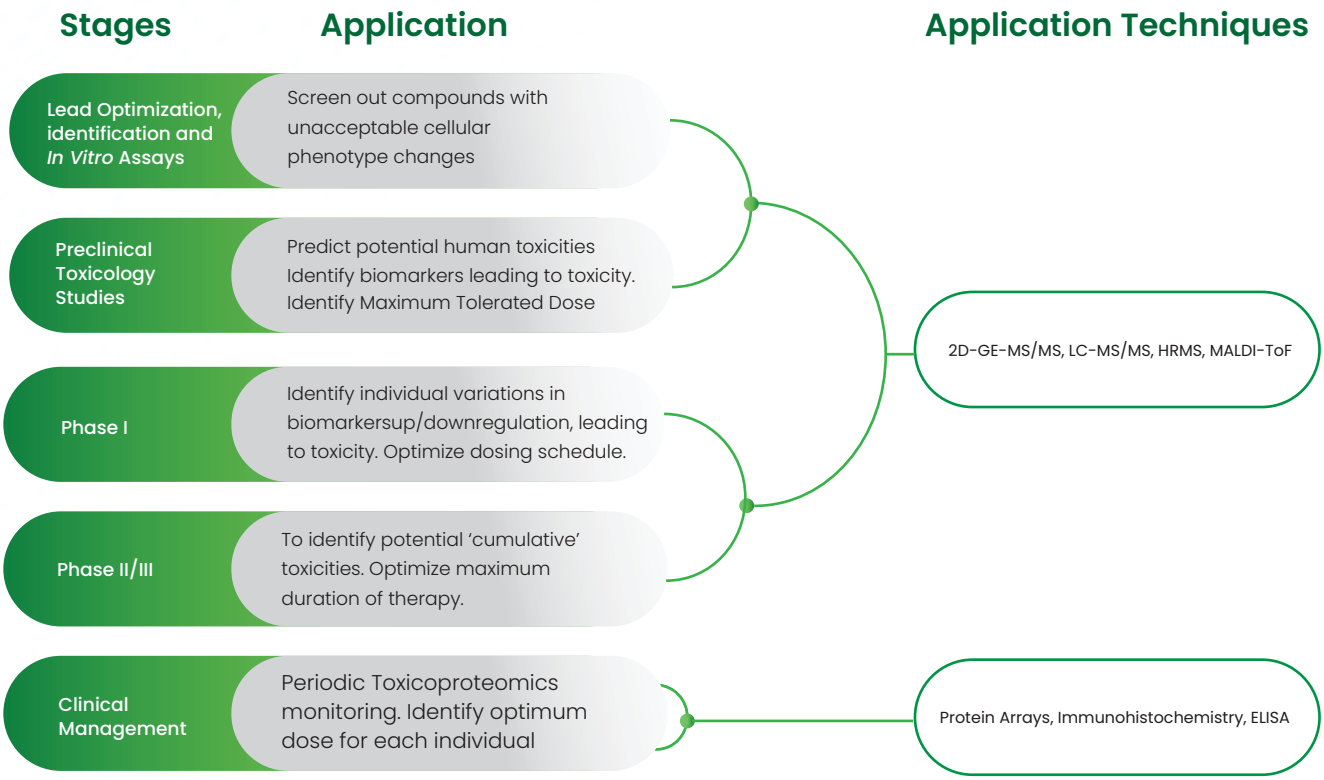


Toxicoproteomics

Historically, toxicologists have primarily relied on histopathological findings supported by biochemical markers, to detect toxicity of any chemical as outlined in different global regulatory guidelines i.e., OECD, EPA, ICH, etc. A recent dynamic development in protein or human genome studies has unveiled new opportunities to detect certain sensitive biomarkers. These recent advancements towards the study of protein changes or proteomics led intense interest of regulators and toxicologists to explore them for prediction of tissue toxicities in animals.

Toxicoproteomics involves studying how certain chemical exposure affects the cells and tissues by identifying and quantitatively assessing changes in the proteome profile. The emerging field of toxicoproteomics is well-positioned to enhance our understanding of protein expression in the context of toxicity and environmental diseases, ultimately benefiting public health advancement.

Toxicoproteomics: An Emerging Technologies in Safety Evaluation



Current Update on Implementation of Omics Technologies in Risk Assessment

Over the past few decades, the evolution of proteomics technologies reached a new milestone of systems biology. Scientists across the spectrum of industry, academia, research institutes, and regulatory bodies are growing in this direction. They are collaborating to generate data and relevant guidance in this area as mentioned below.

OECD has started acknowledging the role of omics technologies in providing more mechanistic insights into toxicity. They have recognized the need for harmonization in the application of such technologies, which could include proteomic approaches for assessing chemical hazards and evaluating toxicity. For this purpose, OECD Omics Reporting Framework (OORF) was developed and guidance document published on November 23, 2023.

EPA scientists also acknowledged the significance of OMICs in toxicology. Recently EPA has release one draft guidance document i.e., Standard Methods for Development of EPA Transcriptomic Assessment Products in May 2023.

The document provides clear guidelines and reporting format for collection of toxicotranscriptomic information for substances which have poor toxicity formation with no existing or publicly accessible repeated dose toxicity studies or suitable human evidence.

EFSA also initiated a program for development of a roadmap to identify the main actions needed for a wider use of Omics in future risk assessments. This roadmap will provide suggestions on how to the use of omics technologies and associated approaches in regulatory science.

Recently European Chemicals Agency (ECHA) has contracted a consortium led by the Fraunhofer Institute for Toxicology and Experimental Medicine Item, coordinated together with Michabo Health Science and BASF Metabolome Solutions. By this contract ECHA is planning to get additional NAMs accepted by regulatory authorities, focusing on OMICS technologies.

Future Prospects of Toxicoproteomics

Advanced Mechanistic Understanding of Toxicitys

- Post -translational Modification
- Protein-Protein Interaction
- Cellular Pathways and networks

Biomarker Discovery for Toxicity

- Early detection of chemical exposure
- Disease states induced by toxicants
- Organ-specific damage

AlternativeTesting for Toxicology

- High-throughput screening
- Quantitative Toxicology

Personalized Toxicology and Risk Assessment

- Individualized risk assessment
- Quantitative Toxicology
- Personalized medicine

Regulatory Applications and Drug Development

- Preclinical safety profiling
- Regulatory compliance

Technological Advancements and Data Integration

- AI and machine learning applications
- Regulatory compliance

Our team at JRF Global is excited about the upcoming improvements through the "Omics" route. We are convinced that these technologies will generate a stronger and reliable predictions by employing Omics based tools in the conventional in vitro as well as in vivo toxicology studies. On June 25, 2025, OECD has updated repeated dose toxicity guideline with the provision for storage of tissue for further possible OMICS evaluation. We have kicked-on a project based on the US EPA guidance released in October 2024. In this study we shall interpret transcriptomics-based endpoints as our initial effort.

We hope to release our next newsletter based on the outcome of such a study by end of year 2025.

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Ms. Pragati Kumari is the Research Officer at the toxicology department of JRF. She is involved in conducting short term and long term studies like subacute, subchronic, neurotoxicity, toxicokinetic and safety pharmacology studies and participate in validation of new studies. She has professional experience of more than 6 years in CRO industries.

Ms. Pragati Kumari
Research Officer