# Accessible Innovative Methods for the Safety & Sustainability Assessment of Chemicals & Materials

## CHIASMA's Vision

The CHIASMA Project will devise and demonstrate a comprehensive set of New Approach Methodologies (NAMs) and integrate them in a user friendly, reliable and robust framework to perform human and environmental safety evaluation in a regulatory context.

## CHIASMA's R&I Approach

The CHIASMA R&I approach to testing and assessment aims to provide regulators with an integrated framework (the CHIASMA SSbD Assessment), allowing human and environmental safety and environmental impact assessment using an iterative multi-step approach based on next generation safety assessment (NGSA) approaches.

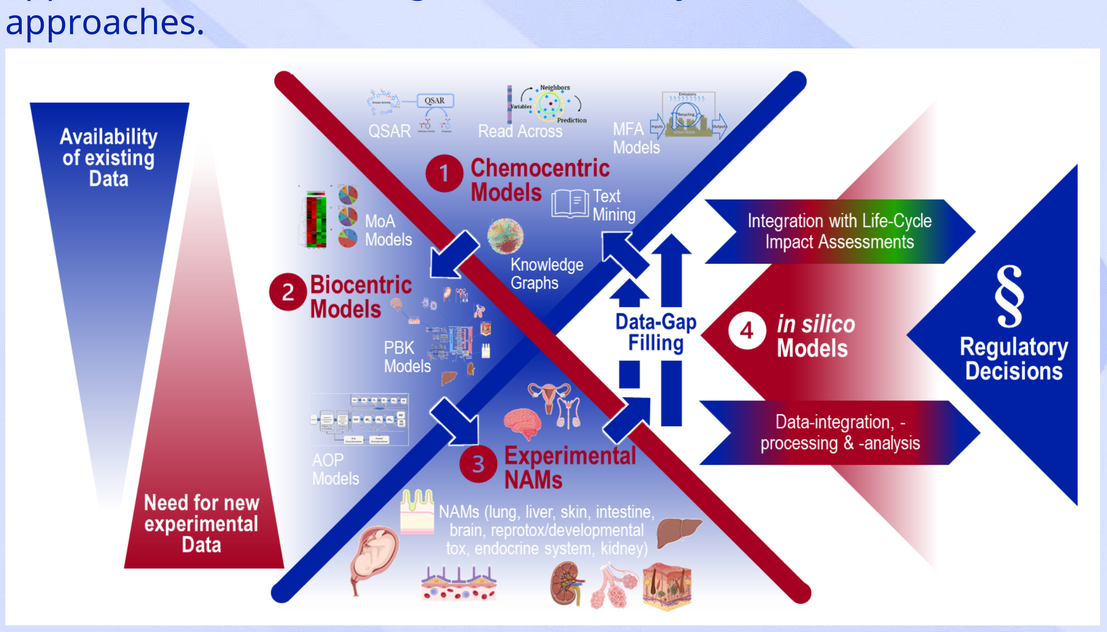



Illustration of the CHIASMA R&I approach to testing and assessment of materials using an iterative approach based on the integration of (1) chemocentric, (2) biocentric and (3) new experimental models into a conceptual framework for data-integration and -processing.

## CHIASMA's SSbD Assessment

The integrated CHIASMA SSbD Assessment framework heavily relies on reuse and integration of existing toxicity and environmental impact data. To fully benefit from these, all chemicals/materials to be assessed will be subjected to chemocentric analysis, based on text-mining tools and knowledge graph approaches, to allow the gathering and structuring of large amount of existing data that will be further processed by other in *silico tools* (e.g. read across and QSAR models), with the aim to infer new knowledge and establish new interactions.

All data will be critically evaluated in light of regulatory requirements: if the amount and quality of the data is sufficient, the CHIASMA SSbD Assessment will lead to a regulatory decision; if data gaps are identified, the Framework will run biocentric models (e.g. PBK, AOP and MoA models) and integrate the knowledge of chemocentric analysis (in this case, data will be critically evaluated with the aim of reaching regulatory decisions to identify data gaps); if - after this iteration - further data gaps are identified, the CHIASMA NAMs will be deployed to generate new experimental results and fill gaps, simultaneously integrating optimised NAMs with existing environmental impact (and sustainability) assessments.

## CHIASMA's High-Level Objectives

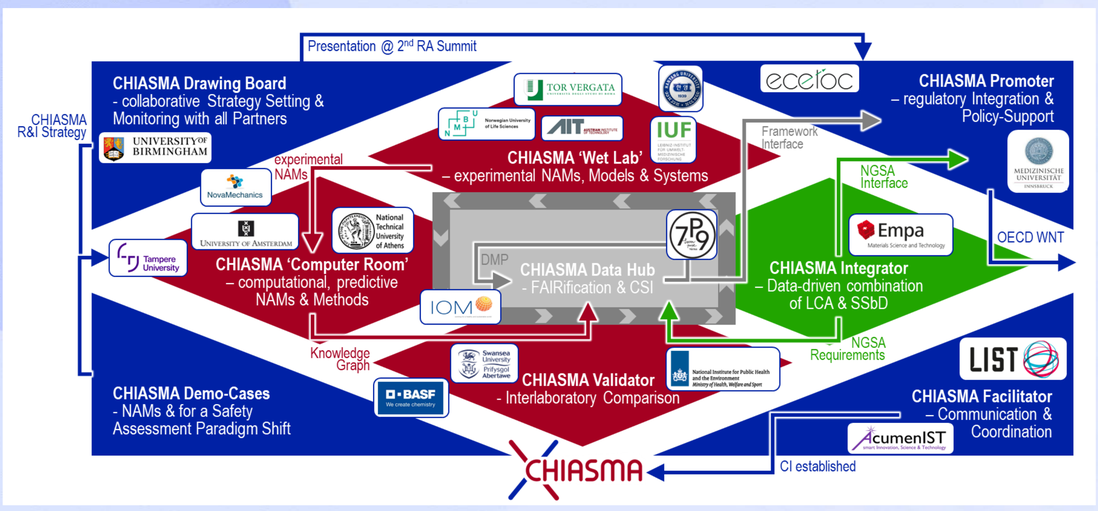
1. Interface Communities and ensure regulatory relevance of NAMs to assess the safety of chemicals/materials.
2. Demonstrate the usefulness of NAMs for the implementation of REACH and CLP regulations.
3. Develop NAMs and validate them for the regulatory assessment of long-term safety.
4. Develop and user-stress-test software interface and insurance of proper handling by authorities, regulators and end users.
5. Demonstrate the transferability of the CHIASMA's NAMs.
6. Demonstrate the trans-domains applicability of the CHIASMA's safety and environmental framework.
7. Improve the Life Cycle Impact Assessment model for human toxicity and ecotoxicity.
8. FAIR-ification and GLP-ification of protocols and methods.

## CHIASMA's Policy Alignment

The CHIASMA Project is fully aligned with the EU strategies for the development of the **Safe and Sustainable by Design** (SSbD) framework to ensure safety and sustainability of enabling and emerging technologies — including those based on chemicals and materials, as addressed in the **EU's Chemical Strategy for Sustainability** (2020), in the **European Green Deal** (2021) and in the Advanced Materials 2030 Initiative (AMI2030). CHIASMA will focus on developing **New Approach Methodologies** (NAMs) and improved **Life Cycle Impact Assessment** (LCIA) approaches and strategies, to ultimately integrate these into the CHIASMA Framework for the combined assessment of SSbD to support REACH , CLP, and other relevant regulations, such as the (proposed) Ecodesign for Sustainable Products Regulation and the EU Ecolabel regulation.

In CHIASMA the term 'material' means 'Advanced Materials' (AdMas), since it includes and surpasses that of 'nanomaterials' (EU, 'Definition of a Nanomaterial'); in this, the Project is aligned with the future-oriented innovation, safety and sustainability considerations of the OECD, the EU, and its Member States.

## CHIASMA's Workflow




Annotated schematic overview of the CHIASMA Project's workflow and the main Partner Roles.

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