PATROLS
Advanced Tools for NanoSafety Testing

PATROLS: Physiologically Anchored Tools for Realistic nanOmateriaL hazard aSsessment

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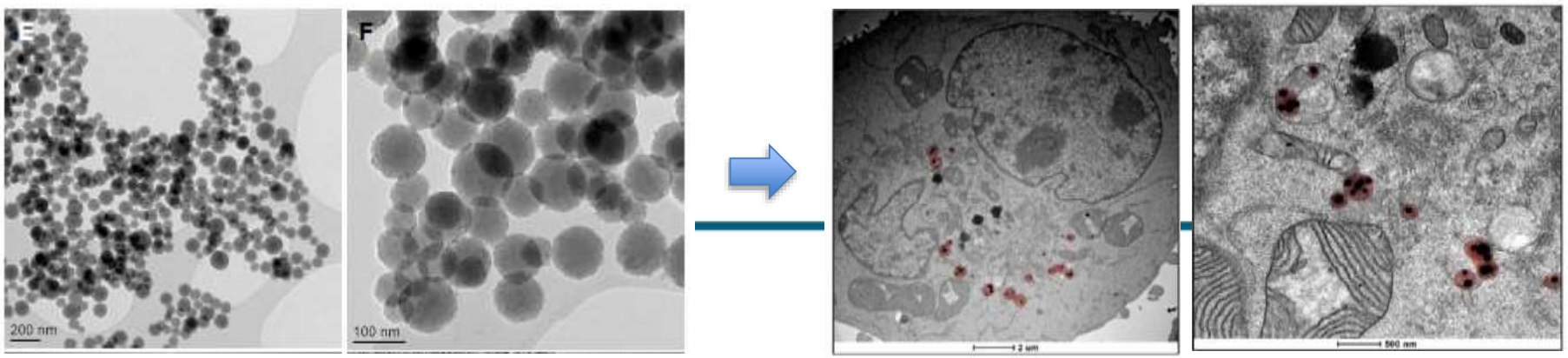
Agenda and format

- Introduction to drivers behind PATROLS
- PATROLS scientific objectives
- PATROLS impact
- Questions – chat function and audio
- Get involved

The Nanotechnology Industry

- Nanotechnology is a Key Enabling Technology (KET) - considered the next global frontier of science
- Global nanotechnology market is projected to grow to $173.95 billion by 2025
- Expected to provide major economic & social benefits.
- Barrier: uncertainty regarding ENM potential health & environmental risks & lack of appropriate tools for ENM safety assessment



Hazard identification

- Mammalian toxicity testing:
  - Skin corrosion / irritation: *in vitro* and/or confirmatory *in vivo*
  - Eye irritation: *in vitro* and/or confirmatory *in vivo*
  - Skin sensitisation: *in vitro* and/or confirmatory *in vivo*
  - Genotoxicity: *in vitro,* if positive, confirmatory *in vivo*
  - Acute Toxicity: *in vivo* (oral, dermal, inhalation)
  - Subacute, sub-chronic, repeated dose toxicity: *in vivo*
  - Carcinogenicity: *in vivo*
  - Developmental & reproductive toxicity: *in vivo*

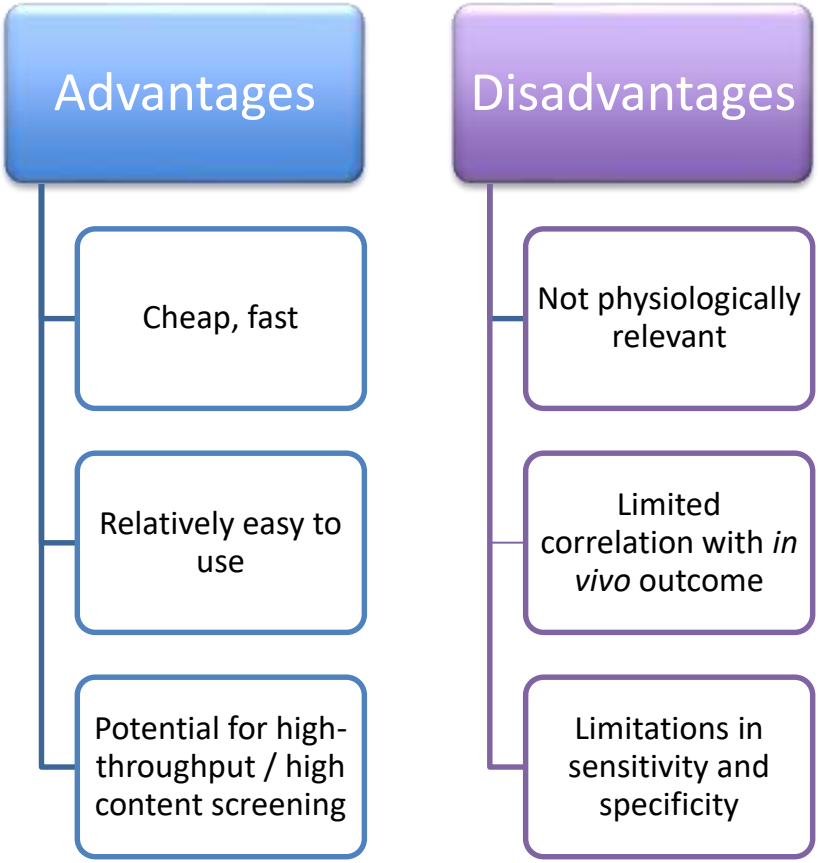
Current position

- Great strides made in understanding nanosafety.

- BUT standard *in vitro* hazard evaluation strategies not sufficiently reliable.
  - Test methods not always relevant for ENM - interaction with a range of *in vitro* assays; standardised test methods missing.

- Room for *in vitro* test improvements for chemicals assessment too.
  - General appreciation that we need more physiologically relevant and reproducible *in vitro* test systems with improved reliability and predictivity.

New generation *in vitro* tests required



1. *In vivo* tests are expensive & time consuming
2. EU Cosmetics Directive prohibits animal use for genotoxicity testing since March 2009
3. Shared 3Rs vision

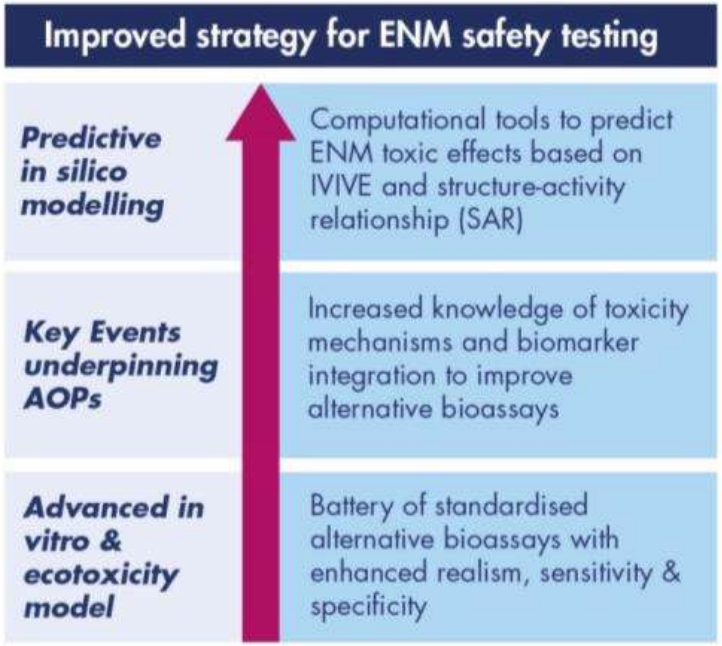
Key Gaps in NanoSafety Testing

- Current knowledge gaps:
  - Inadequacy of current existing *in vitro* and *in silico* hazard detection systems.
  - Long term effects of realistic ENM exposures for both human health & the environment.

- High priority to develop and adopt realistic and advanced *in vitro* tests with potential to substantially improve the relevance of *in vitro* approaches

PATROLS aim & vision

Establish and standardise a battery of innovative, next generation hazard assessment tools that more accurately predict adverse effects caused by long-term (chronic), low dose ENM exposure in human and environmental systems to support regulatory risk decision making.



1st Jan 2018 – 30th June 2021 (42months)

12.7million Euros

PATROLS Impact & Goals

We aim to deliver:

1. Realistic & predictive human lung, gastrointestinal tract & liver 3D tissue models for ENM safety assessment, reducing the need for animal testing.
2. Innovative methods for safety assessment in ecologically relevant test systems & organisms, selected according to their position in the food chain.
3. Creating robust computational methods for ENM exposure and dose modelling, as well as hazard prediction.
4. Characterising ENM under relevant experimental conditions dictated by the advanced human and environmental model development.

PATROLS Concept

Project Partners

UK	• Swansea University • Exeter University • IOM • Heriot-Watt University • NC3Rs
USA	• Harvard Global Research and Support Services, Inc • University of South Carolina
Switzerland	• University of Fribourg • InSphero
South Korea	• Korea Research Institute of Standards and Science
Poland	• QSAR Lab Ltd
Netherlands	• RIVM • University of Leiden
Japan	• Japan Bioassay Research Center
Italy	• University of Pisa • Consiglio Nazionale delle Ricerche (ISTEC)
Germany	• BASF • Leibniz Research Institute for Environmental Medicine • European Research Services
Finland	• Misvik Biology Oy
Denmark	• Danmarks Tekniske Universitet • NRCWE
Canada	• Health Canada
Belgium	• Louvain Centre for Toxicology and Applied Pharmacology (LTAP) • University of Namur • Nanotechnology Industries Association

End-User Benefits

- Industrial impact
- Regulatory / legislative impact
- Scientific community
- General public

End-User Benefits

- **Industrial impact**
- Regulatory/legislative impact
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Enhanced & robust *in vitro* test systems & computational models for hazard prediction to:

- Enable choices early in the innovation and development pathway
- Reduce number of animals used
- Longer term product life
- Accessed in house or through specialist service providers

End-User Benefits

- Industrial impact
- **Regulatory/legislative impact**
- Scientific research community
- General public

Test method guidance on *in vitro* test systems & computational models for hazard prediction to:

- Support risk assessment frameworks
- Improve confidence & reduce uncertainty in human health and environmental risk evaluation methods
- Support product-safety legislation (EU Directives) and regulatory processes, e.g.:
  - REACH (EC) 1907/2006
  - EC Cosmetics Regulation (EC) 1223/2009
  - Food Additives Regulation (EC) 1333/2008

End-User Benefits

- Industrial impact
- Regulatory/legislative impact
- **Scientific research community**
- General public

Innovative & physiologically relevant *in vitro* models of the human lung, liver and GI tract:

- *In vitro* and *in silico* models for safety assessment across a broad range of chemical compounds.
- Applications in the drug discovery and development pipeline for efficacy and safety of novel drugs at an early stage.
- Reduced animal testing requirements.

End-User Benefits

- Industrial impact
- Regulatory/legislative impact
- Scientific research community
- **General public**

Increased confidence in the sector while minimising animal testing:

- Improved public perception of ENM – safety perspective
- Reduced animal testing
- Greater consumer choice from nano-enabled products

Get involved

Stakeholder involvement throughout project important to its success:

- Tissue models and modelling tools fit for purpose
- Integration into regulatory and standards frameworks

PATROLS activities:

- Visit www.patrols-h2020.eu
- Newsletter: Sign up to follow updates – via website
- LinkedIn Group: www.linkedin.com/company/patrols
- Conference activities 2018: EuroTox, nanoTox, 20th International Congress in *in vitro* toxicology (ESTIV), Industrial Technologies, NanoSafe

Thank you!

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Newsletter: Sign up!

Twitter: @PATROLS_H2020

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