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RSNN/FAST Masterclass on NAMs; December 9th, 2025

The NAM Landscape: Who is doing what?

Dr. Martijn Nolte
Senior programme manager
Programme More Knowledge with Fewer Animals (MKMD)
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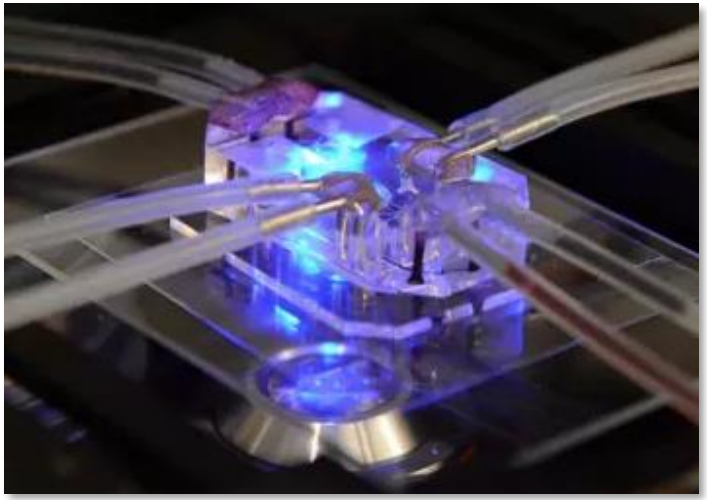
Transition towards animal-free innovations

Golden standard



Many organizations and initiatives play a role
→ who is doing what?

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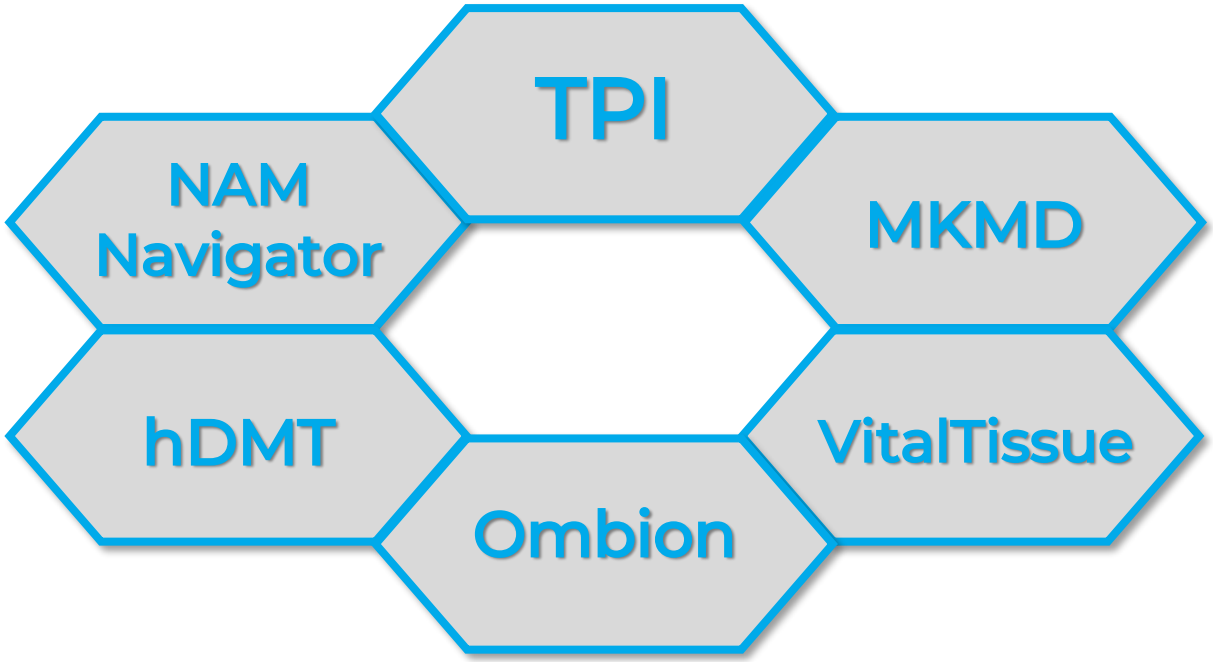
TPI
NAM Navigator
MKMD
hDMT
VitalTissue
Ombion

Transition Programme for Innovation without the use of animals

Partner program: joined efforts to accelerate the transition to animal-free innovations → coordinated strategies and actions

Ministry of Agriculture, Nature and Food Quality

Government of the Netherlands

Netherlands National Committee for the protection of animals used for scientific purposes

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

Health~Holland

hollandbio

Samenwerkende GezondheidsFondsen SGF

KNAW

DMT
HUMAN ORGAN AND DISEASE MODEL TECHNOLOGIES

Universities *of* The Netherlands

PROEFDIERVRIJ

young tpi
Transition Programme to Animal-Free Innovations

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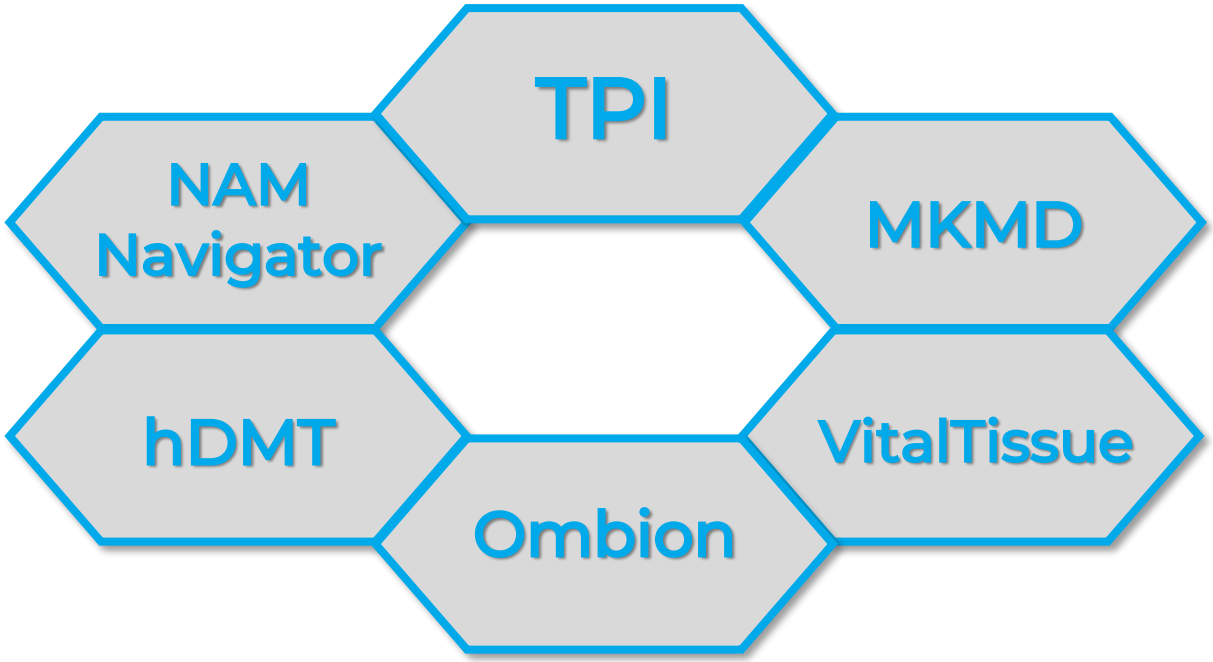
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MKMD

ZonMw progra lge with Fewer An

Stimulate develop ementation of NAMs

ZonMw has bee through:

- Focusing on mo m animal studies
- Funding researc dels
- Encouraging use actice

MKMD programme 2024-2028

MKMD

Knowledge Infrastructure

Transition-thinking

Validation via public-private partnerships

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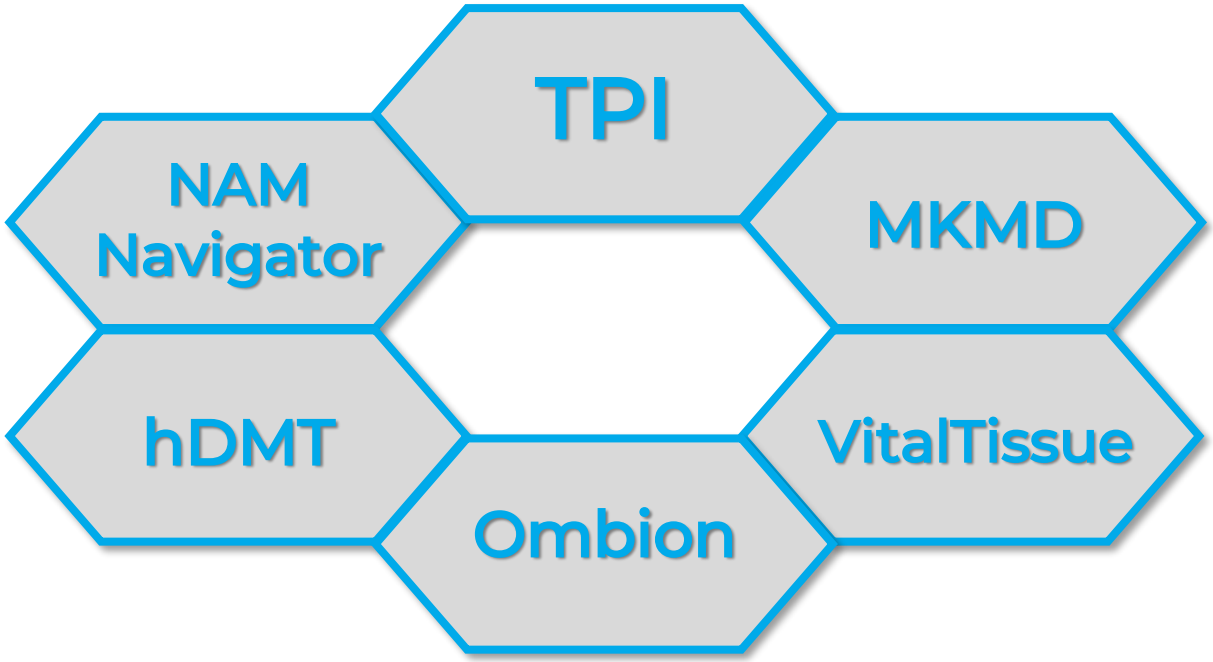
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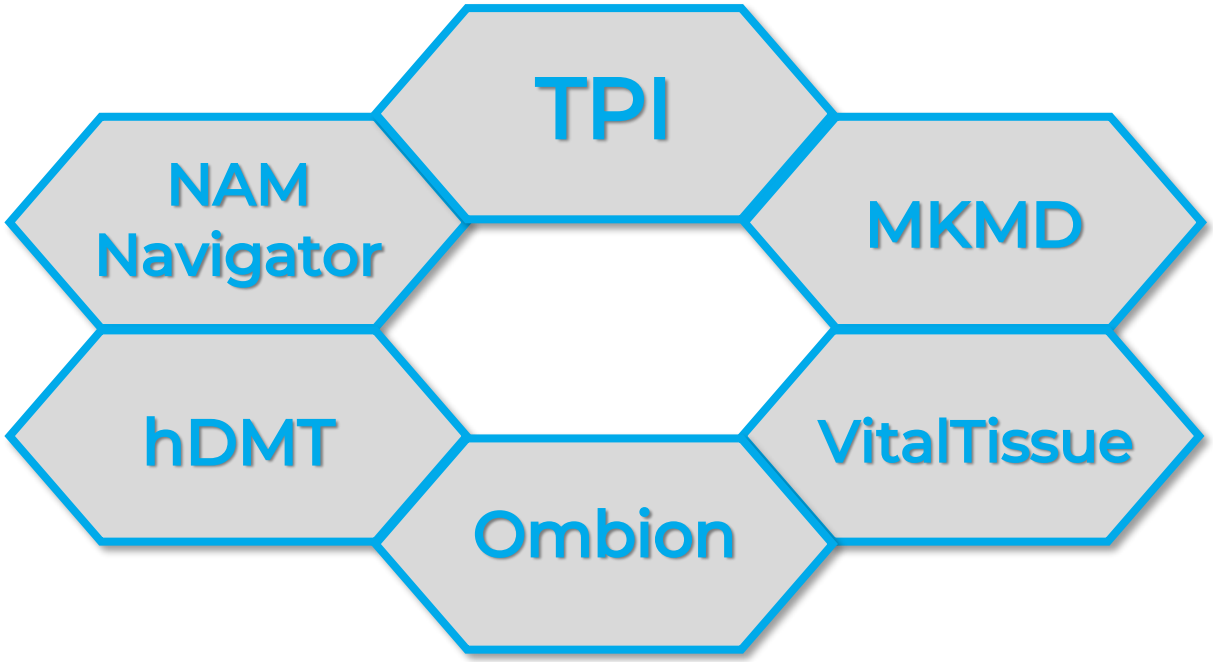
VitalTissue: reliable and affordable supply of vital human residual tissues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Ombion: Centre for Animal-free Biomedical Translation

Ombion

➔ **Public Private Partnership** with over 60 national and international organizations (academia, industry, regulatory bodies, patient organizations)

Mission: To accelerate the transition of new biomedical knowledge and innovations to patients and users, making the process animal-free, faster, and more effective.

Key activities and contributions:

- Transition Science, Ethics, and Sustainability
- Regulatory Innovation
- Educational Program Development
- Data Science, Supporting Tools, and Models

Focus on 4 diseases:

- ALS
- Asthma / COPD
- Cystic Fibrosis
- Osteoarthritis / Rheumatic Diseases

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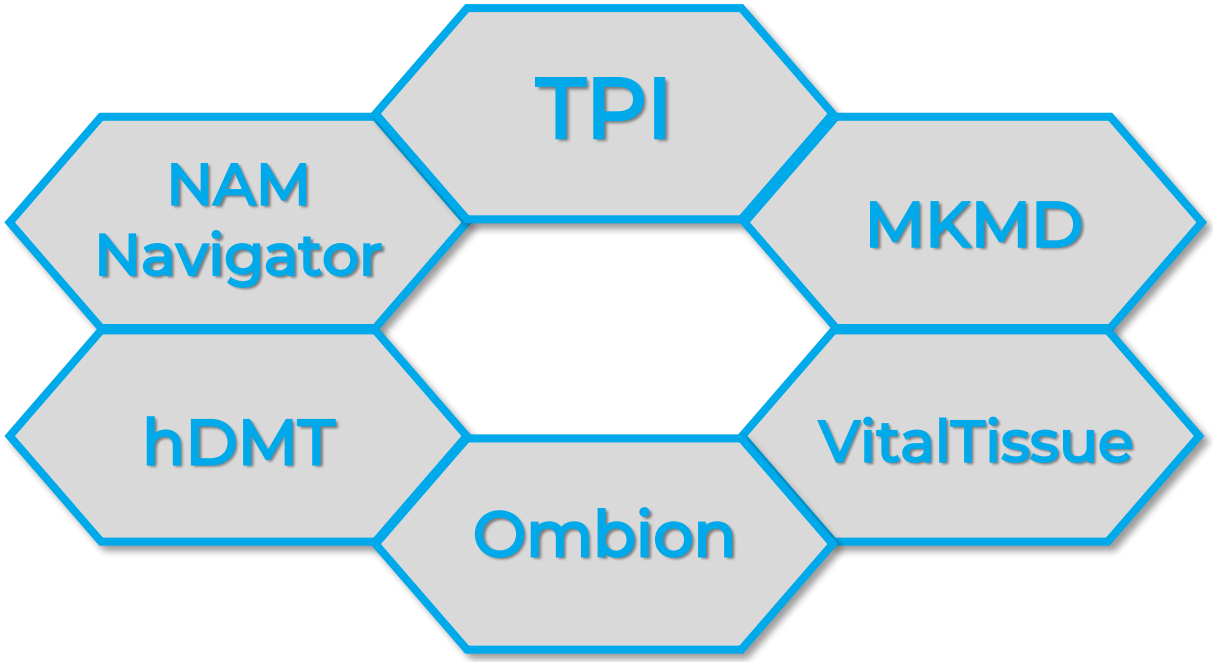
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hDMT: Institute for human Organ and Disease Model Technologies.

➔ **Dutch network** with 16 partner organizations (universities, UMCs etc)

Mission: To accelerate the development and implementation of human-based cell models for biomedical research and drug development.

Goals:

- Provide researchers and companies with high-quality, standardized tools and expertise → focus on **Organs-on-Chips, hiPSC & adult stem cells**.
- Enable the future of **personalized medicine** by allowing more accurate testing of potential therapies using human-specific models.
- Advance **ethical and legal frameworks** necessary for the effective use of human-based models.

Coordinator of infrastructure project **hDMT INFRA**

R&D community facilitated by dedicated Service Centers of Expertise (SCE)

Researcher
How can I develop my model towards implementation?

End-user
Can you develop a specific human model?

Biotech
Can you qualify my products?

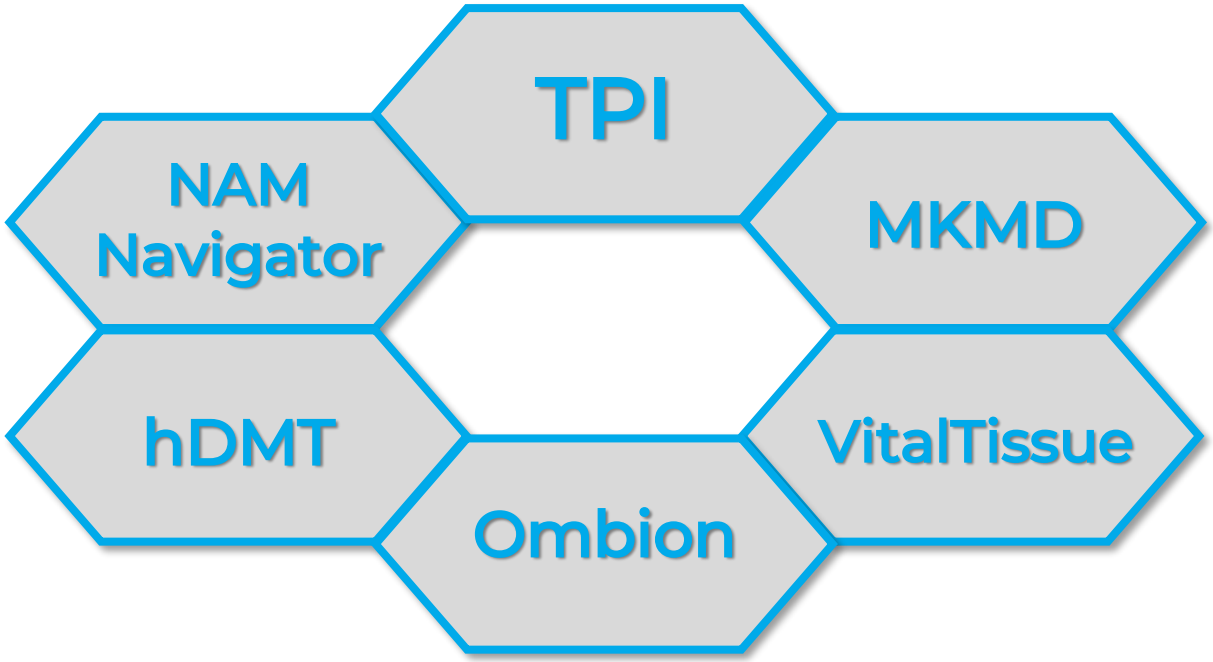
Regulator
How can I be educated about human models?

DMTInfra
Dutch R&D Infrastructure

- Advisory
- ASC/Organoids
- Biopsy processing
- Cell production
- Culture of primary cells
- Embryonic stem cells
- Ethical approval
- Facility Access
- hiPSCs
- Provision of cell lines
- Research and development
- Training

Service Center of Expertise

- **Share and connect local facilities & expertise**
- **Strong interaction of private & public sector**
- **A strong NL for Life Science & Health**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What is needed for NAM application?

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Dev … eptance

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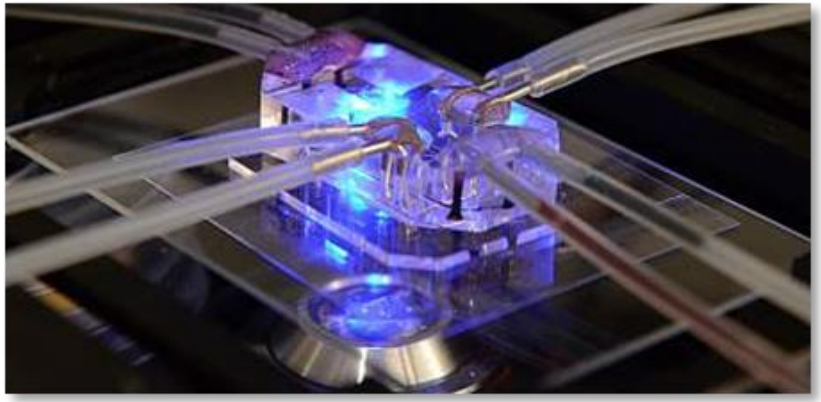


Approaches?

Criteria?

Procedures?

Organizations?

?

News Events NAM Network References About us Contact

NAM Navigator

R&D Standardization Validation Acceptance In Practice Funding

Helping Researchers and Developers Gain Regulatory Approval for New Approach Methodologies.

What are you looking for?

For example: Development

https://namnavigator.eu/

1. Research & Development

About preparation, documentation and more

See Overview

Universities
Research & Tech offices
Datasteward

Knowledge Institutes
RIVM, WFSR, TNO, et cetera

2. Standardization

About standardization in the development, implementation, and validation of NAMs.

About Standardization

NEN

CEN

CELENEC

3. Validation

What data should you have to make validation of your NAM go quicker?

See Overview

Agencies for Safety Assessment of Pharmaceutical Products

EURL ECVAM

EMA-SAWP

Agencies for Safety Assessment of Chemical Substances

EURL ECVAM

PARERE

EU-NETVAL (WFSR, TNO, Triskelion, Charles River)

ESAC

OECD

4. Acceptance

Last step after the validation study and peer-review is regulatory acceptance.

About Acceptance

Agencies for Safety Assessment of Pharmaceutical Products

EMA-CHMP

ICH Assembly

Agencies for Safety Assessment of Chemical Substances

OECD-WNT

ECHA

SCCS

ESAC

EFSA

About Validation

Validation is a continuous process that ensures NAMs are scientifically sound and inte
accepted. It bridges test development and regulatory approval, maintaining credibility
integrity. While validation bodies typically lead this process, developers can contribut
providing key data early, accelerating acceptance...

Pre-validation / Validation study

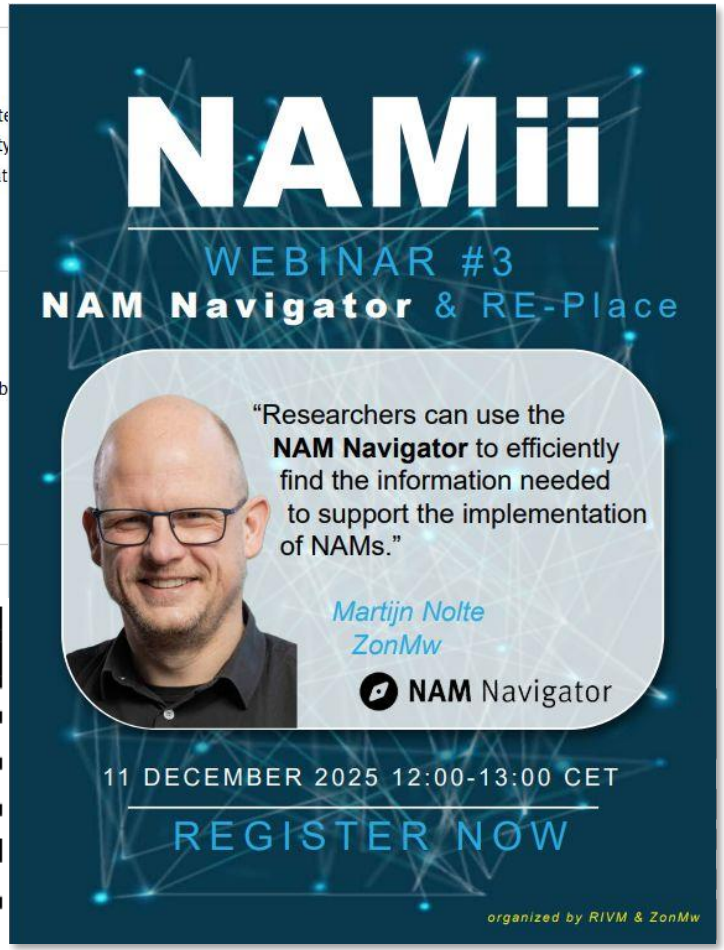
Validation is largely determined by the purpose of the test method, making it adaptab
as a cornerstone for gaining international acceptance of a testing method...

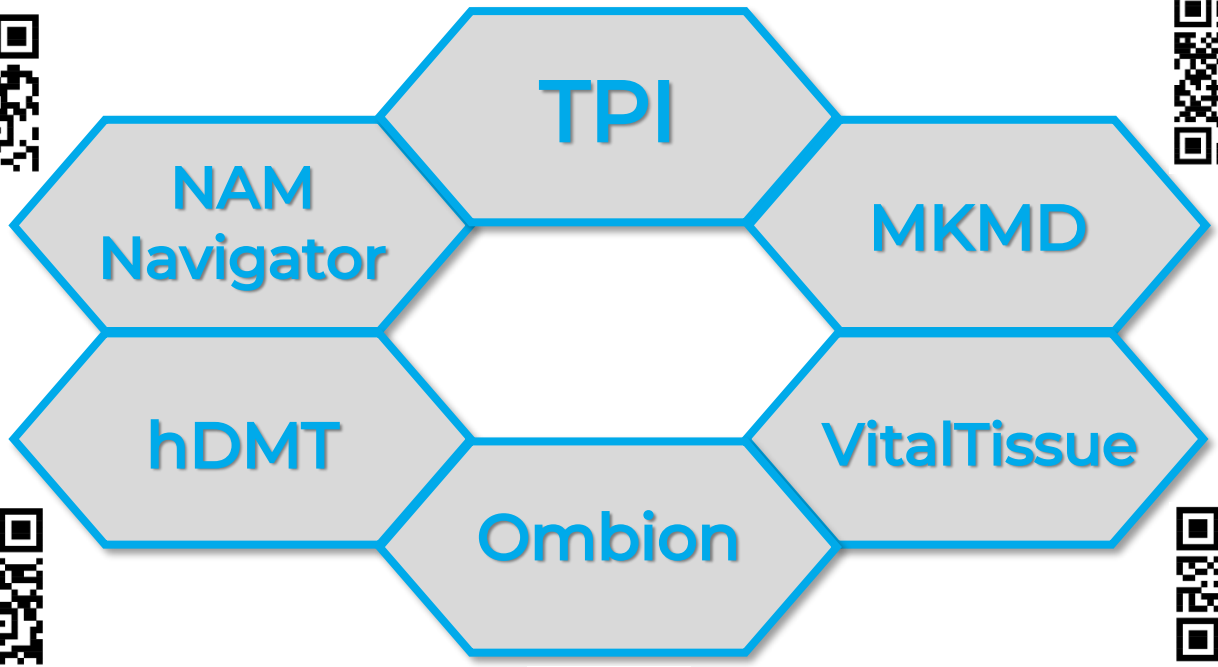
According to Agencies

Validation requirements, guidelines, and
methods meet scientific and regulatory s

Extra Information

Additional resources, guidelines, and refe





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Thank you for your attention!

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https://www.zonmw.nl/en/program/more-knowledge-fewer-animals

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