

TraceLabMed

A European Metrology Network

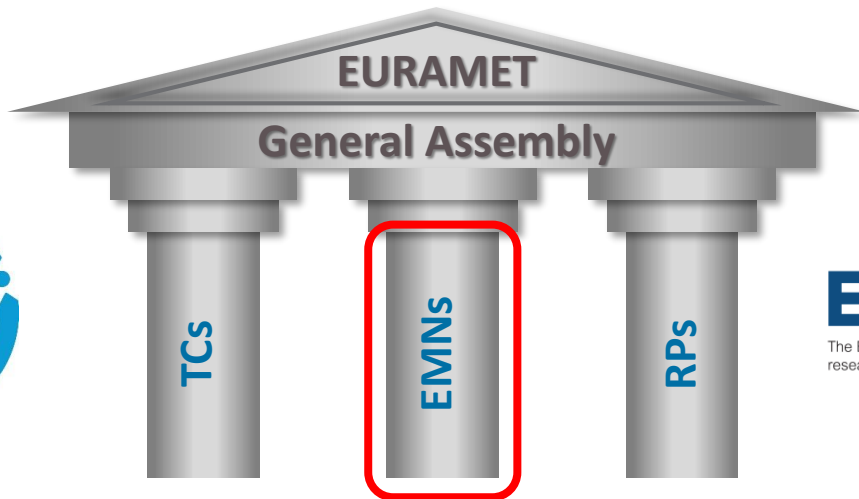
David Auerbach, Rainer Stosch

3 December 2019

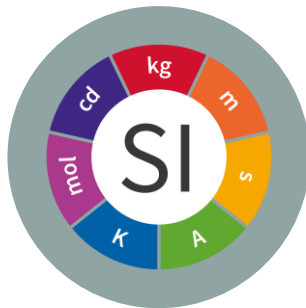
The TraceLabMed logo features a stylized blue icon of a laboratory flask with a caduceus (a staff with two snakes and wings) superimposed on it. Below the icon is a horizontal line, and then the text "TRACE LAB MED" in a bold, blue, sans-serif font.

TRACE LAB MED

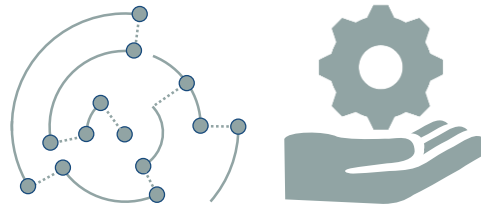
EMNs within EURAMET



Societal Challenges



Scientific Excellence



Infrastructures & Services

EURAMET EMNs

EURAMET'S EUROPEAN METROLOGY NETWORKS

Close collaboration in measurement science with a new sustainable structure

The vision of EURAMET and its members is to ensure Europe has a world-leading metrology capability, based on high-quality scientific research and an effective and inclusive infrastructure, that meets the rapidly advancing needs of end users. EURAMET's European Metrology Networks (EMNs) help realising this aim.

Currently there are six EMNs: [Mathematics and Statistics](#), [Laboratory Medicine](#), [Quantum Technologies](#), [Smart Electricity Grids](#), [Energy Gases](#), and [Climate and Ocean Observation](#).

The EMNs will analyse the European and global metrology needs and address these needs in a coordinated manner. EMN members will then formulate common metrology strategies including aspects such as research, infrastructure, knowledge transfer and services. The members will be committed to contributing to the EMN, helping to establish sustainable structures that are strategically planned from the outset.

By providing a single point of contact for information, underpinning regulation and standardisation, promoting best practice and establishing a comprehensive, longer-term infrastructure, the EMNs aim to create and disseminate knowledge, gain international leadership and recognition, and build collaboration across the measurement science community.

- to address metrology needs in a coordinated manner
- establishing and maintaining sustainable structures
- to act as a single point of contact



EMNS

[Climate and Ocean Observation](#)
[Energy Gases](#)
[Laboratory Medicine](#)
[Mathmet](#)
[Quantum Technologies](#)
[Smart Electricity Grids](#)

Existing EURAMET EMNs



- 2017: initiated by PTB with support from European NMIs/DIs
- 2018: EMN proposal submitted to and approved by EURAMET GA
- 2019: MoU signed and Kick-off

EMN TraceLabMed



12 NMIs/DIs
9 Countries

TRACE LAB MED



EU IVDR (2017/746):
Demand for **metrological Traceability**



International Standards for medical Laboratories:
Demand for **metrological Traceability**



EU citizens: Metrological traceability for
patient safety & public confidence in LM



EMPIR



The EMPIR initiative is co-funded by the European Union's Horizon 2020 research and innovation programme and the EMPIR Participating States



EMN TraceLabMed - Aims



Support for EU reference laboratories



Metrological traceability for *in vitro* diagnostics



Service-oriented European metrology infrastructure



Coordinated top-down research

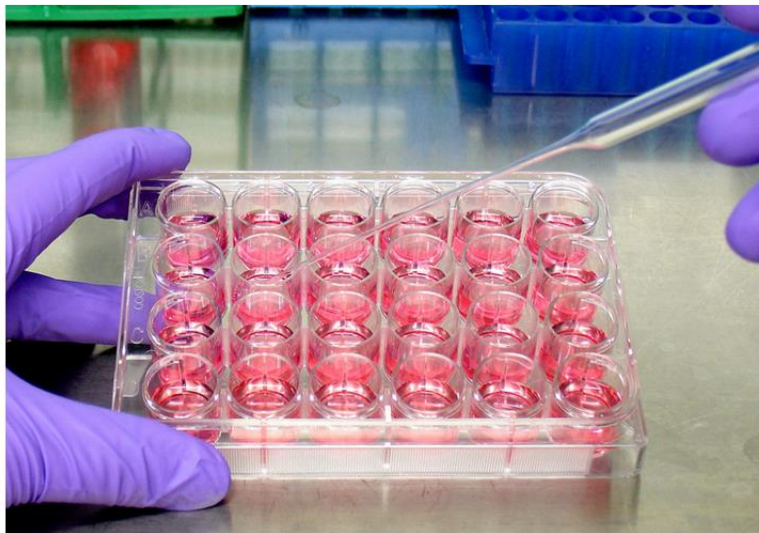


Capacity building & knowledge transfer

EMPIR JNP 18NET02

Support for a European Metrology Network on traceability in laboratory medicine

Short Name: TraceLabMed, Project Number: 18NET02



PARTICIPATING EURAMET NMIS AND DIS

BAM (Germany)

INRIM (Italy)

LGC (United Kingdom)

LNE (France)

METAS (Switzerland)

NIBSC (United Kingdom)

NPL (United Kingdom)

PTB (Germany)

UME (Turkey)

OTHER PARTICIPANTS

Universiteit Gent (Belgium)

INFORMATION

TYPE
EMPIR

FIELD
Support for Networks

PROJECT TYPE
Joint Network Project (JNP)

STATUS
in progress

CALL
2018

DURATION
2019-2024



Coordination and support actions
Funding of networking activities only

JNP 18NET02: A workplan for the EMN

- **WP1:** Setting up a sustainable European metrology infrastructure for traceability in laboratory medicine
self governance, Web portal, legal framework, stakeholder communication
- **WP2:** Strategy for a joint European response to the IVDR
How to address the need for traceability, activities of NMIs, EQA provider, routine labs, IVD manufacturer, “demonstrator comparisons”
- **WP3:** Joint strategy for the prioritisation of clinical measurands and R&D needs
list of current priority clinical measurands, gap analysis, identification of R&D needs,
- **WP4:** Creating Impact

EMN TraceLabMed - Activities



TRACE LAB MED

2020

- Self-governance
- Stakeholder involvement
- Web portal beta version

2021

- Workshops
- Surveys
- Consultations

2022

- First demonstrator comparison
- Web portal final version

2023

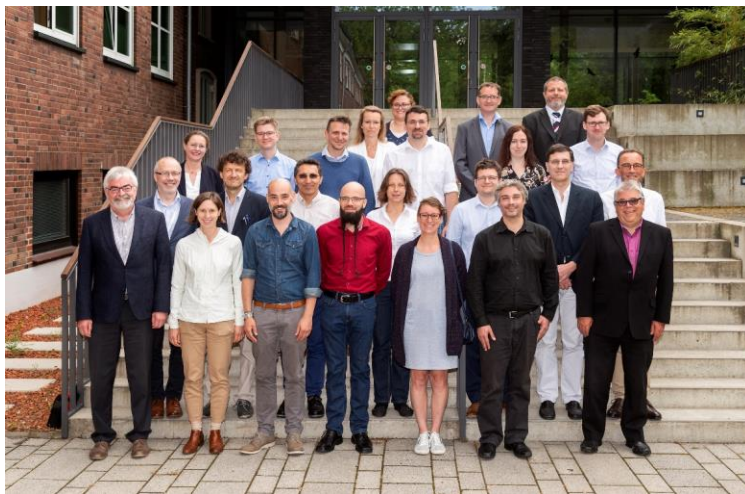
- Strategy plan: prioritisation
- Roadmap for R&D activities
- Second demonstrator comparison

2024

- Metrology needs for future novel IVDs
- Final reporting

... EMN established to continue its efforts and services

EMN TraceLabMed – Kick off



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11:30 - 12:30 Registration
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Kick-Off Meeting EMN Traceability in Laboratory Medicine & Joint Network Project 18NET02

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Braunschweig, Germany

www.euramet.org/laboratory-medicine

www.euramet.org/?event=67-726

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TraceLabMed@euramet.org

Stakeholder engagement

- Knowledge and capacity to conduct large-scale demonstrator comparisons
- Studies on economic benefits are missing
 - Strategic research agenda
- Missing data on national priority lists
 - Collection via the network
- IFCC: intensify communication with NMIs
 - EMN for efficient communication
 - Establish EMN representative at IFCC C-TLM
- Promoting metrological traceability to regulators, patient organisations
- Plan to include the EMN on a webpage common to IFCC, JCTLM, BIPM, ...



Stakeholder engagement

Association of the German Diagnostics Industry
Expert committee meeting at 26/11/2019



What are the benefits of metrology for IVD producers?

- Metrology does not have the highest priority
- Efforts towards standardization often appear unjustified
“patient samples are too individual”
- If at all, advantages are seen in risk management and performance evaluation, comparisons could be helpful
- Recommendation to contact a medical society working in the field of a widespread disease: How do they rate the importance of standardisation for diagnosis and treatment.



Stakeholder engagement



“We will not make progress with a performance based approach – the clinical relevance is what is most important”

As the German Diagnostics Industry
Expert committee meeting at 26/11/2019

“IFFC is focused on the analytical aspects of laboratory medicine, they do not represent clinicians/physicians.”

What are the benefits of metrology



“There are two types of clinicians: those that have great faith in numbers and those that treat laboratory results as one of many factors. The first group benefits from standardisation the second group doesn't.”

- priority
- appear unjustified

“All organisations that were present at your kick-off stand for analytics – they have objectives that are partly incompatible with those of manufacturers.”

- patient samples are too individual
- If at all, advantages are seen in risk management and performance evaluation, comparison
- Recommendation to contact a medical expert of a widespread disease: How do they rate the importance of trueness and standardisation for diagnosis and treatment.





euramet.org/laboratory-medicine



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"We will not make progress with a performance based approach – the clinical relevance is what is most important"

"There are two types of clinicians: those that have great faith in numbers and those that treat laboratory results as one of many factors. The first group benefits from standardisation the second group doesn't."

"Nowadays, you can determine reference intervals, also by using existing data and you will get fantastic results - but clinicians do not judge on the basis of these values. At the end of the day, you are measuring an individual sample whose influence on the outcome can not be determined. The result is one indicator among many others. It is not justified to spend large sums for standardisation "

"All organisations that were present at your kick-off stand for analytics – they have objectives that are partly incompatible with those of manufacturers."

"Physicians judge based on an empirical threshold derived from the current clinical/medical experience – it is often not important if a biomarker is elevated 2-, 3- or 5- fold."

"Physicians/Clinicians require training to understand the concept of traceability."

"IFFC is focused on the analytical aspects of laboratory medicine, they do not represent clinicians/physicians."

"IFFC looks mainly after European belongings, US and other international interests are not covered very well."

Stakeholder Interaction



- Large scale demonstrator comparison
- Collaboration:
 - Other EQA providers
 - Members of the EMN



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Kick-Off Meeting EMN Traceability in Laboratory Medicine & Joint Network Project 18NET02

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Stakeholder Interaction



Verband der Diagnostica-Industrie

- Manufacturers have other priorities
- Meeting with industry representatives:
26/11/2019



European
Metrology
Network



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Stakeholder Interaction



Accurate results
for patient care

- Studies on economic benefits are missing
 - Strategic research agenda
- Missing data
 - Collection via the network
- Participation at the JCTLM stakeholder workshop 2&3 December 2019



European
Metrology
Network



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Stakeholder - IFCC



- Standardization groups for several measurands
- IFCC wants to intensify interactions with NMIs
 - EMN for efficient communication
 - Idea / Plans to establish an EMN representative at IFCC C-TLM
- Participation of the EMN at the IFCC WorldLab Seoul 2020 meeting



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Stakeholder - BIPM



- Organization through which Member States act together on matters related to Metrology
- Improved communication is required (regular meetings attached to CCQM)
- Promoting metrological traceability to regulators, patient organisations
- Plan to include the EMN on a webpage common to IFCC, JCTLM, ICHLR, ILAC



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