



# OPEN WORKSHOP ON MEASUREMENT CHALLENGES IN LABORATORY MEDICINE

Metrology Support for the  
Standardization of Clinically  
Relevant Biomarkers  
& further project ideas

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## *Main goals*

- Help the IVD industry and lab professionals to **meet requirements of the IVDR** 2017/746 regarding metrological traceability of results, e.g. feed the JTCLM database
- Support new and existing international projects aiming at **evaluating and improving the accuracy and harmonization of medical test results** (e.g. IFCC, ICHCLR)
- Promote the **actual implementation of RMS** through stakeholders engagement

## *(Technical) objectives*

- Help **identifying biomarkers for which results harmonization / accuracy must be improved** : big data & machine learning for aggregation of EQA data (collab with ICHCLR / EQALM)
- Support the clinical and industry communities to **better define & realize the measurand** : development of hyphenated analytical methods allowing to unravel the structural heterogeneity of complex biomolecules at the molecular level : focus on PTMs & isoforms
- **Development of Reference Measurement Systems** with appropriate APS : purity assessment of primary calibrators, development of RMPs and commutable CRMs
- Build an infrastructure to support **continuous post-market vigilance** through accuracy-based programs : commutability assessment and value assignment of EQA materials

Candidate targets include : PTH, p-Tau, PCT, steroid hormones, apolipoproteins, natriuretic peptides, HbA2, alpha synuclein, biomarkers of auto-immune disorders,...

### 1. Metrology response to future pandemics

- LNE's interest in standardization of serology tests + vaccines characterization
- External partners potentially interested joining / supporting the project : AP-HP, ESPCI, LSMBO

### 2. Metrology for Diagnostic of Heart Diseases

- LNE's interest in apolipoproteins standardization, new diagnostic tools to unravel the undiagnosed CVD risk (biomarkers, imaging)
- External partners potentially interested joining / supporting the project : Leiden University Medical Center, Paris Institute of Cardiometabolism, Uppsala Univ.

### 3. Population aging / Neuro Degenerative Disorders

- LNE's interest in biomarkers for improved patients diagnosis & follow-up, e.g. pTau
- External partners potentially interested joining / supporting the project : Montpellier University Hospital, Gothenburg University, ESPCI, LSMBO, IJM

### 4. Multiparametric measurements for precision medicine

- LNE's interest in multiplexed protein measurements, metabonomics
- External partners potentially interested joining / supporting the project : French National Genotyping Center, CEA LEEM

5. Exposomics
6. Rare disease / auto-immune diseases
7. POCT
8. Food (focus on allergens)
9. Doping
10. Neonatal screening
11. Microbiota

# ***THANKS FOR YOUR ATTENTION!***



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