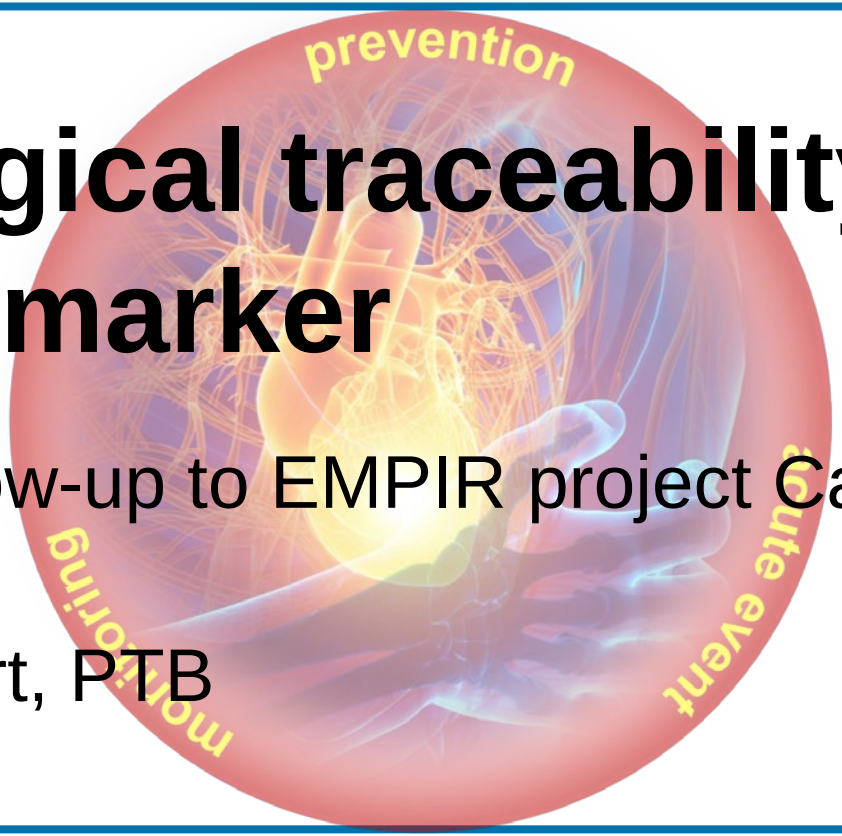
Physikalisch-Technische Bundesanstalt
Braunschweig and Berlin
National Metrology Institute



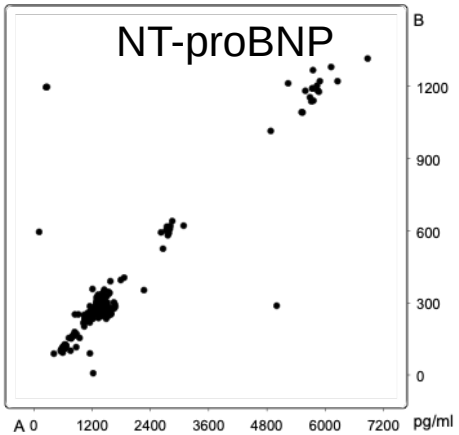
Metrological traceability for cardiac marker

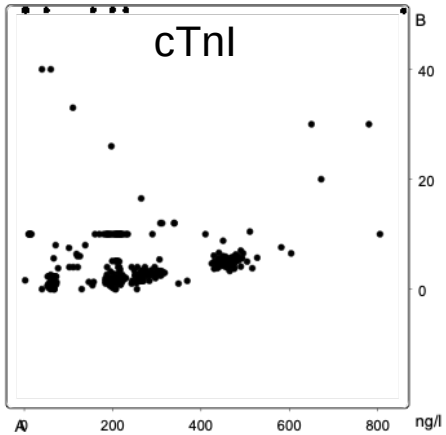
Potential follow-up to EMPIR project CardioMet

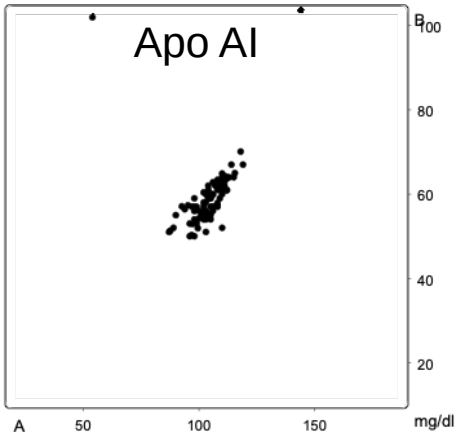
Claudia Swart, PTB

State-of-the-Art

- 1.16 million deaths/year in the EU in 2018 with estimated costs of € 169 billion/year (https://ec.europa.eu/eurostat/)
- Large between-methods variability due to a lack of reference methods / traceability required by Regulation (EU) 2017/746
- Cardiac biomarkers challenging to quantify due to the low concentrations and complex biological matrix
- Important markers to evaluate heart involvement in Covid-19 disease progression





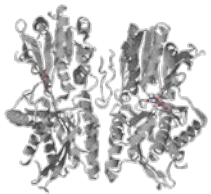


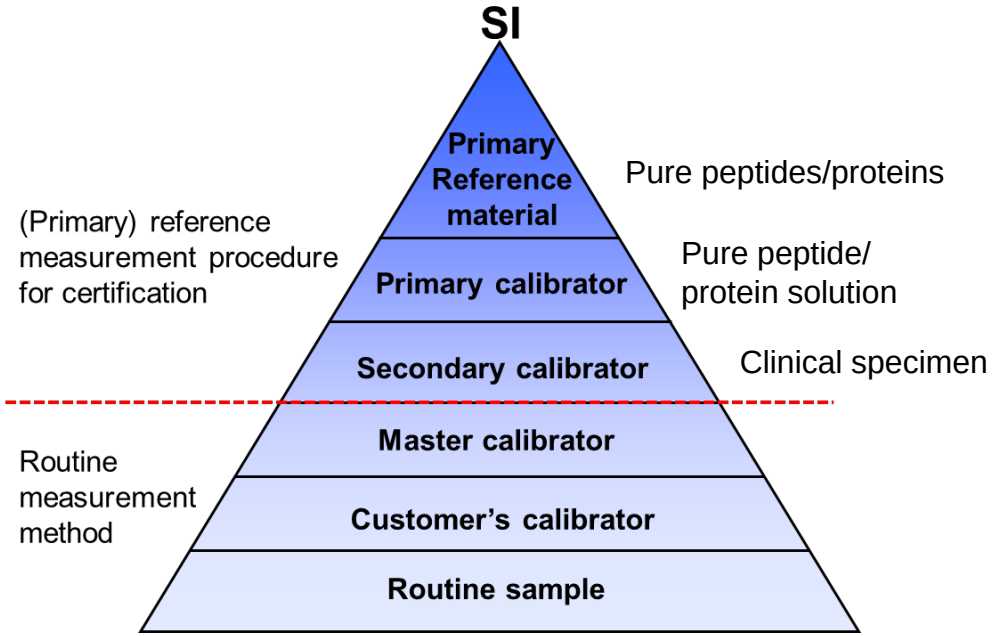
https://www.rfb.bio/cgi/results?rv_type=all&rvTypeForDetails=CM&year=2021&rv_num=4&analyte=BNP&searchType=analyte CM4/21

18HLT10: CardioMet

Reference measurement procedures including characterisation of calibration material for:

- apolipoproteins
- NT-proBNP
- 1-32 and total BNP
- cTn





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Proposal for CardioMet2

- In-depth research of biological modifications of clinical cardiac markers and their clear definition
  → requires investigation in post-translational modifications and their changes in diseased state (personalised medicine)
- Definition of actual measurand of the various methods and correct coding to support post-market surveillance
- Developing a transition plan to guide IVD-manufacturers to (re)calibrate routine assays (apoAI, B, (a)) to the new reference measurement system (RMS) in cooperation with the IFCC WG APOMS
- Evaluating the value of a standardised serum apolipoprotein panel compared to the current serum lipid screening/monitoring panel for dyslipidemia, which has a high residual risk, and define standardised reference ranges

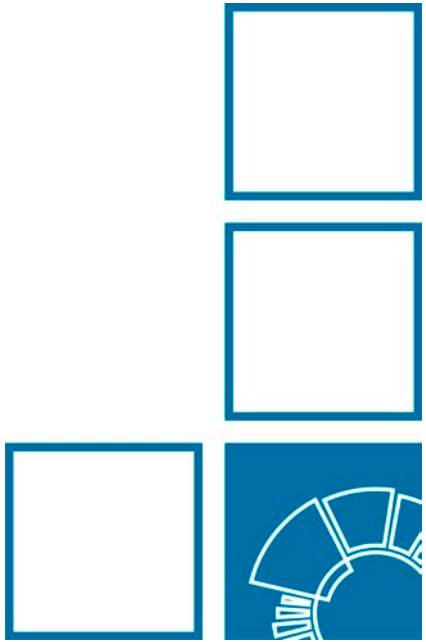
Proposal for CardioMet2

- Evaluating suitable reference materials for cardiac markers including commutability
- Suggestion of a procedure to accelerate the implementation of new RMS (time from bench to bedside)
- Focusing on improving patient outcome when defining and choosing clinical cardiac markers
- Possibly including person centred outcome by standardising evaluation of lifestyle related risk factors
- Improving the biosensor for cTn developed within CardioMet and make it fit for the use in emergency settings
- All activities require handling of large datasets $\Rightarrow$ use of AI-based approaches

Potential stakeholder

- Joint Committee for Traceability in Laboratory Medicine (JCTLM)
- International Federation of Clinical Chemistry and Laboratory Medicine (IFCC):
  WG on Apolipoproteins by Mass Spectrometry, WG on Commutability,
  WG on Standardisation of Troponin I, proposed WG on Standardisation of Natriuretic Peptides
- European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)
- EQALM and national EQA providers
- French Society of Clinical Biology (FSCB)
- Accreditation bodies such as COFRAC
- Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM): Protein Analysis WG
- Cardiologists
- Manufacturers of analysis kits
- Clinical research in cardiology

Thanks to….



PTB

LGC

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS LNE

BAM Bundesanstalt für Materialforschung und -prüfung

TÜBİTAK UME

RfB Referenzinstitut für Bioanalytik

UPPSALA UNIVERSITET

UK NEQAS International Quality Expertise

GOETHE UNIVERSITÄT FRANKFURT AM MAIN

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

LUMC Leiden University Medical Center