Session 1
Cell / Molecular Diagnosis and Therapeutics

Helen Parkes, LGC
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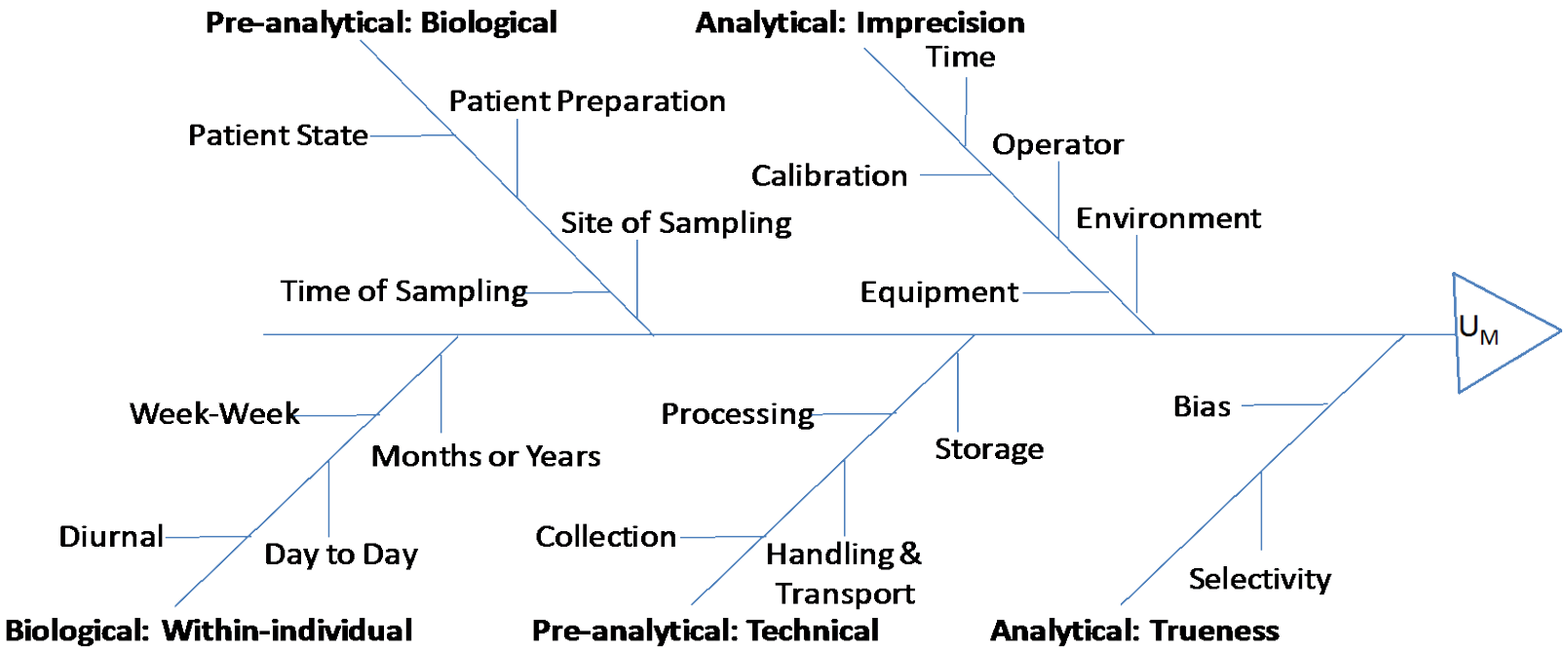
Stakeholder input – Dr Michael Messenger "The Future of Precision Medicine"

"Right decisions, at the right time, tailoring the right intervention, with every person"

- Precision medicine - research infrastructure inc patients cohorts, biobanks, big data, analytical platforms (eg omics..., high performance computing...)
- Role of personalized medicine - prediction & prevention, screening, early diagnosis, molecular phenotyping, prognosis, treatment benefit/ response, monitoring - metrology important contribution
  - Key influence of metadata
  - What is the uncertainty of the measurement being fed into the models?
  - What is the uncertainty in the evidence base?
  - Measurement validity is key focus
  - Knowledge of bias - can give key ramifications for diagnostics
  - Metrology critical in determining value of molecular diagnostics for precision medicine.

Factors Contributing Towards Measurement Uncertainty



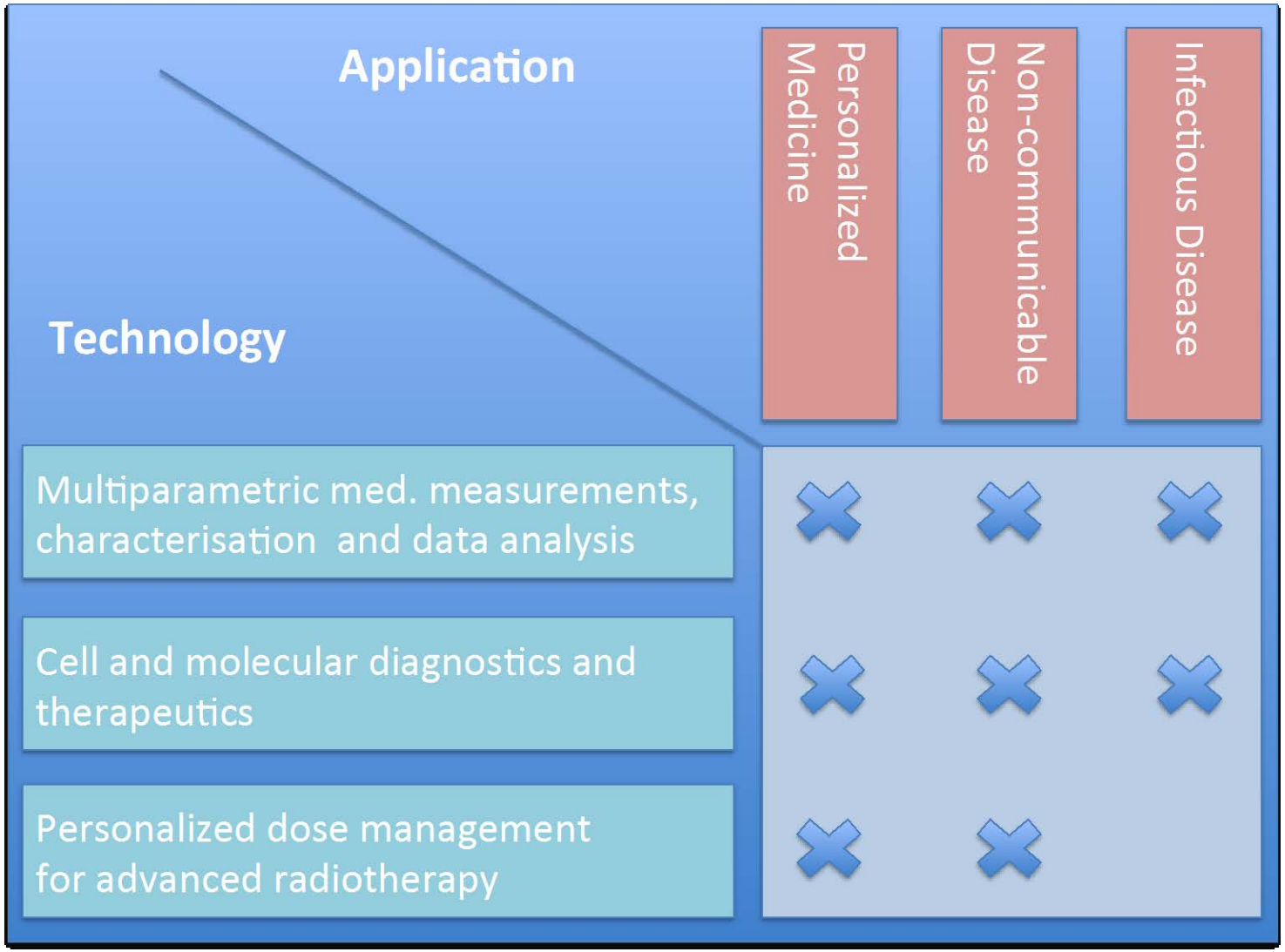
Stakeholder input - Dr. Christa Cobbaert "The quest for standardisation of targeted proteomics tests in precision diagnostics "

- IVD regulations significant driver for measurement traceability
- Urgent need better tests for patient stratification, based upon genomics, proteomics (& proteoform) metabolomics & bioinformatics
- Difficult and important to understand & define measurand
- IFCC want to understand a general calibration/ standardisation strategy for mass spec based tests, including analytical precision, robustness
- Important to include all aspects of pre analytical / analytical workflow
- "Need clinical collaboration from the start"

Stakeholder input – Prof.Dr Klaus Pantel. “Liquid biopsy – a new tool for cancer stratification”

- Liquid biopsy "family" - include CTC, cf / ct DNA, exosomes
- Diff approaches for CTC detection... immuno, molecular, functional assay
- Challenges:
  - Very low level mutation detection in high background
  - Need low level detection methods eg ddPCR, Modified NGS, BEAMing, biPAP PCR - how robust / reliable / MU
  - Loss of marker expression with plasticity increase - understand measurand
- CTC driven therapy choice based on CTC count - confidence in count important (MU)
- Pre analytical & analytical variability need measuring

Health call scope



Topics covered by submitted abstracts

- Precision medicine
  Liquid biopsies
  "liquid biopsies" for cancer diagnosis, patient stratification and therapeutic monitoring, Foy, LGC;
  ctDNA and CTCs fragments for early cancer detection in surgical and liquid biopsies, Divieto, INRIM;
  CTCs, ctDNA, micro RNA for personalised medicine of cancer patients, flow cytometry and fluorescence spectrometry of liquid biopsies samples, Hussels, PTB;
  challenging biomarkers such as peptides and proteins, by high-resolution mass spectrometry, Giangrande, LNE.
  (follow-up elements of BioSITrace)

  possible link:
  extracellular vehicles (EV) in liquid biopsies , development of reference material to standardize size, van der Pol, VSL
  (follow-up MetVES)

Topics covered by submitted abstracts

- non-communicable diseases

  Oncology

  biomarker-based molecular profiling of lung cancer, development of reference materials for typical patient profiles, Kardag (Genom, Transcriptom), Nalbantoglu (Proteom) and Sanli (Microbiom), TUBITAK (follow-up LUNGMARK), COPD and lung cancer detection by breath analysis, Meuzelaar, VSL

  Cardiovascular diseases (CVD)

  biomarkers for acute coronary syndromes and heart diseases, Swart, PTB, Artheroscleoris, Aydin, TUBITAK, Blood solid particles clogging, Schakel

  possible link:

  metrology of magnetic separation techniques for molecular diagnostics and blood purification; Wiekhorst, PTB

Topics covered by submitted abstracts

- Non-communicable diseases
  Neurodegenerative diseases:
  neurodegenerative diseases, Quaglia , LGC; MR Spectroscopy and MR-Imaging, Fillmer, PTB; challenging biomarkers such as peptides and proteins, by high-resolution mass spectrometry, Giangrande, LNE (follow up NeuroMET)

  Imaging for chronic diseases:
  quantitative imaging of biomarkers for chronic diseases, applying area resolved spectroscopy, microscopy and mass spectrometry, Douglas, LGC (also in S2).

Topics covered by submitted abstracts

- non-specific application
  application of reference free X-Ray fluorescence analysis; general, Seim, PTB, characterisation of functionalised nanomaterials / surfaces for life science applications, Pollakowski, PTB; antibodies, antimicrobial peptides, fingerprint of Leishmania, Hornemann, PTB

  application of scanning transmission X-ray microscopy, C to Mo with size resolution below 100 nm, Lühl, TU Berlin

  carbohydrate (glycan) metrology, application of ion mobility mass spectrometry and gas phase infrared spectrosopy, Pagel, FU Berlin.

Thank you for your attention-
DISCUSSION…..

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