ADVANTAGES AND LIMITATIONS OF PRECISION ONCOLOGY IN CLINICAL PRACTICE

- Tissue journey from patient to genetic test and adequate treatment in precision oncology
- Molecular profiling of tumors to identify targetable genetic alterations (DNA vs RNA)
- Quality of genetic and molecular testing:
  - Choice of assay
  - Tissue quality
  - Bioinformatics analysis (NGS)
  - Clinical interpretation (MTB)
  - Experience, development and certification
  - Biobanking (biological material, nucleic acid, sequence)

THE BEST IMPLEMENTATION OF PRECISION ONCOLOGY IN CLINICAL PRACTICES (ÅSLAUG HELLAND, OSLO)

- Case story about a young man having a painful right shoulder showing a lung cancer after PET-Scan and biopsy
  - Treatment included: surgery and postop radiotherapy to arm, chemotherapy and several ALK-inhibitor
- Overview of the national infrastructure for precision diagnostics, InPreD Norway
- Presentation of the IMPRESS-Norway trial for patients with rares diseases:
  - All Norwegian hospitals with an oncology department
  - Study-design = combined umbrella-basket, Simon two-stage model
- Key learnings:
  - Need National engagement
  - Structure the field of precision cancer medicine
  - Public private partnerships
  - Health economy and reimbursement
  - Policy and politics at multiples levels
  - Patient’s expectations
  - International position

“Tissue is still the issue for precision oncology”

ECONOMY: COST-EFFECTIVENESS AND THE VALUE OF PRECISION MEDICINE IN ONCOLOGY (EBBA HALLERSJO, SWEDEN)

- Implementation and scale up help to determine whether an innovation as affordable and equitable
- PM is about finding the equilibrium between demand and supply leading to the equilibrium on price and quantity.
- How to prioritize? Need to allocate resources in a fashion that maximize output (cost-effectiveness)
  - Economic evaluation and principles of health care delivery
  - Cost-utility
  - Defining the comparator
- Overview of clinical trials in economic evaluation
  - General and limitations
  - Challenges with evaluating precision health/medicine in oncology
- Case: design of a national precision medicine treatment study in Sweden (Megalit)

“A principal barrier to this advancement is in meeting requirements of the payers or reimbursement agency for health care”

EU INITIATIVES FORWARD IMPLEMENTATION OF RESEARCH AND CARE FOR PRECISION ONCOLOGY (HANS GELDERBLOM, NETHERLANDS)

- Premises of precision medicine in oncology and flow of the studies
  - Basket Trials
  - Umbrella Trials
  - Platform Trials
- In the Netherlands: two initiatives that paved the way to next generation PCM trials
  - Center for Personalized Cancer Treatment (CPCCT)
  - Hartwig Medical Foundation (HMF)
- In 2016: the DRUP (“Drug Rediscovery Protocol”) was founded by pharmaceutical companies, Dutch Cancer Society and Fundraising activities
  - DRUP Trial Design presentation: 1 tumor type + 1 molecular profile + 1 study drug or tumor-agnostic with same biomarkers
- Keys to success adequate diagnostics and knowledge
  - Availability of drugs
  - First successful second stage agnostic cohort
  - Pay for performance model in 3rd stage meeting the criteria led to reimbursement since 1st July 2022
  - Some cohorts closed due to lack of clinical activity
- Overview of the future DRUP in Netherlands and abroad:
  - DRUP-ATTAC: combination targeted treatment
  - DAP: Drug Access Protocols Early-Access
  - National multi-stakeholder collaboration: ZINL (HTA), Payers
  - TAPUR and CAPTUR collaboration
  - European collaboration: PCM4EU and PRIME ROSE EU projects

EU PROJECT FUNDING

- PCM4EU (2023-2025):
  - Implementing molecular diagnostics and provide guidelines, documents and educational contents
  - Sharing protocols and all necessary resources about precision medicine
- PRIME ROSE (2023-2028):
  - Helping countries to set up Drug Like Clinical Trial and precision medicine
  - Sharing data, results and practices

HOW TO GET INVOLVED?

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FOR MORE DETAILS ON OUR TRAINING SESSIONS AND TEACHING MATERIALS