

BREAKOUT SESSION 2

Personalised Risk Scores in Clinical Trials: Opportunities and Challenges

Chair: Patrick Vrijlandt (EMA)

Rapporteur: Geeta Gulati

1. Evaluate the **strengths and weaknesses of current cardiovascular toxicity risk models** in the context of modern cancer treatments and diverse patient groups
2. Identify **practical and methodological obstacles hindering the incorporation of personalised cardiovascular risk assessment in oncology trials and routine care.**
3. Suggest **practical measures** to enhance the development, validation, and adoption of personalised cardiovascular risk assessment tools in upcoming research.



"The police called, we're taking you out of the clinical trial and putting you in a criminal trial."

Personalised Risk Scores in Clinical Trials: Opportunities and Challenges

Introduction

- GE- healthcare: No experience. Key input to make tool set
- Patient view: No experience. Look at the pt
- El-physiology: No experience.
- Preventive cardiology: Exercise. Do an evaluation without risk scores.
- Cardiovascular imaging: No experience
- EMA: No experience. Benefit risk assessment. New scores are coming.
- Cardiologist: Used for surveillance. Used in clinical setting. Not much experience in clinical trials.
- Haematologist: Many risk scores. More of a guidelines.
- Philips: What is personalised risk scores, more of risk stratification. Interventionalist have them for TAVR vs Surgery etc.
- Editor EHJ: Not personalized, its stratified. Good for trials, because trials are not personalized.
- Basic scientist UK: No experience.

Opportunities

- Scores with continuable variables
- Input of different data and AI generated prediction
- Genomic tools
- Online calculators
- To be used to develop new therapies/strategies
- Simplifying
- What to do with those who are not included
- Clinical implication of scores

Challenges

- Details EF 48% do you round up or down?
- What imaging modality to use?
- Load dependency
- Is it clinically relevant – look at the patients
- Only perfect patient is included
- Categorization is a problem (cells)
- Validations?
- Collaboration between different fields to get all the data
- Validation
- What is the implication for the patient with the risk score. Do you lower risk scores or the risk

Risk scores at baseline for clinical trials

- Personalized risk assessment for off tumour off target effect

Identify practical and methodological obstacles hindering the incorporation of personalised cardiovascular risk assessment in oncology trials and routine care.

- Clinical
- Scientifical
- Workload (we don't know what's normal, biomarkers)
- Cost



- Risk scores are not personalized
- Risk stratification vs personalized risk scores