

# GROUP 1

# WARPEN MEETING ROOM



Cardiovascular Round Table

## GROUP 1 : Defining Cardiovascular Safety Endpoints: Regulatory and Clinical Alignment

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## **BREAKOUT SESSION 1**

### **Defining Cardiovascular Safety Endpoints: Aligning Regulatory and Clinical Perspectives**

**Chair:** Carlo Gabriele Tocchetti

**Rapporteur:** Alar Irs (EMA)

**1. Identify gaps and inconsistencies between oncology and cardiovascular trials regarding the definition of cardiovascular safety endpoints and real-world clinical requirements**

**2. Present practical recommendations for a harmonised framework that enhances the comparability, clarity, and long-term significance of cardiovascular safety data.**

# **Gaps and inconsistencies between oncology and cardiovascular trials regarding the definition of cardiovascular safety endpoints and real-world clinical requirements**

- Clinical development in oncology is not going to change massively, power and duration of studies driven by oncology
- Nevertheless we need to aim for the best possible to detect and manage the cardiovascular adverse effects
- Identify patients at risk, describe the effects to patients and clinicians and be able to manage the effects
- What endpoints are important to the patient (QoL)
- IC-OS consensus is helpful – make sure AF means AF, HT is HT etc
- Preplan according to potential risk and predefine, baseline dataset etc
- We define endpoints differently in cardio and oncology trials, for reasons good and bad
- e.g. in HF cardiologist is less interested in intermediate endpoints, biomarkers (risk indicators), even EF
- Oncology sponsors hesitant to support development of advanced methods to describe injury
- Permissive cardiotoxicity depending on onco setting, precision/sensitivity in safety assessment corresponding to this
- Adjudication – investigator vs adjudication committee
- Non-commercial sponsored studies

## **Recommendations for a harmonised framework that enhances the comparability, clarity, and long-term significance of cardiovascular safety data**

- Co-operation between cardio and oncology in all settings
- What matters to patients should drive
- Standard definitions and possibly standard protocols, follow up algorithms etc
- Cross-training