ESC European Society of Cardiology

BREAKOUT SESSION 4
Minimum Dataset for Cardio-Oncology: Towards a Common Language

Chair: Dimitrios Farmakis
Rapporteur: Mirko De Melis (Medtronic)

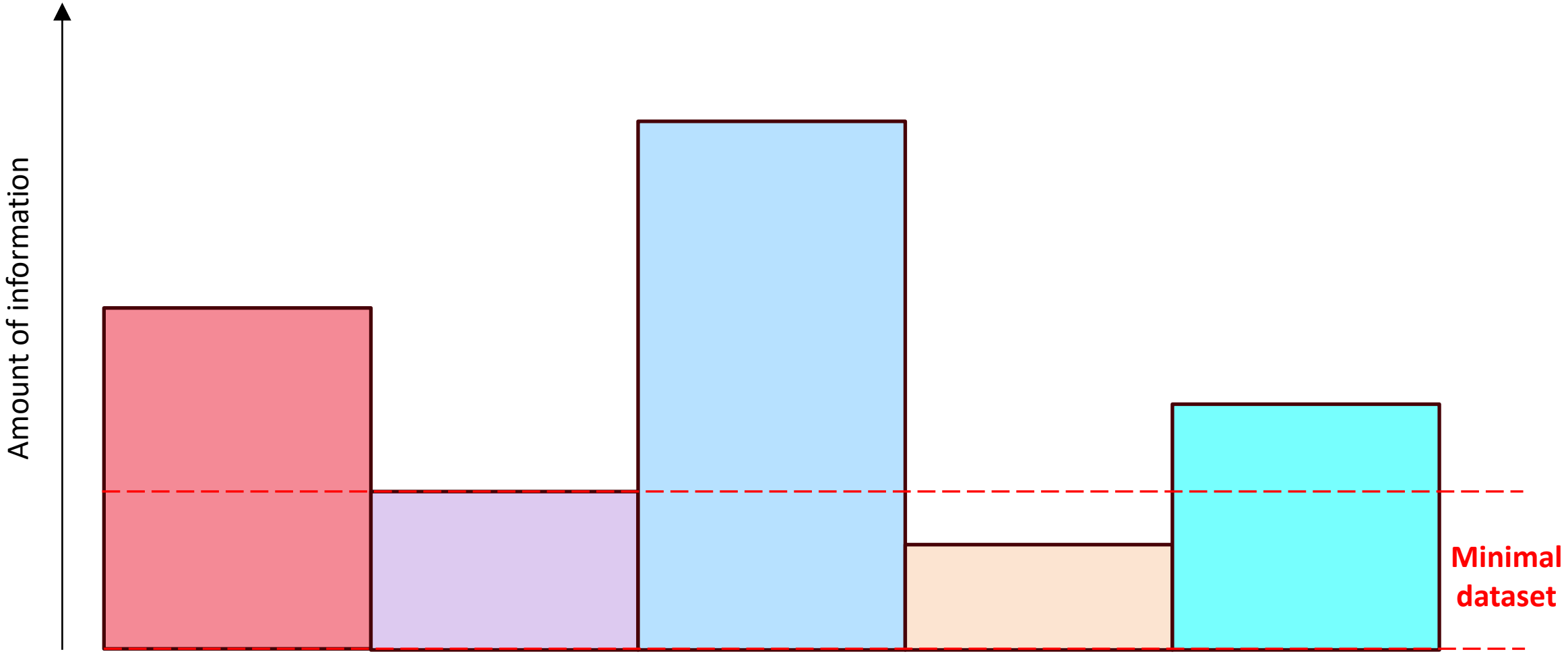
1.Determine the **key data elements required to create a practical and comprehensive minimum dataset in cardio-oncology**

2.Examine **challenges related to feasibility, duplication, and missing variables** to guarantee the dataset is both robust and usable.

3.Develop a **strategy for ESC–EMA–industry collaboration**, including pilot projects and pathways for wide-scale adoption.

ESC European Society of Cardiology

The concept of the minimal dataset



Pietro Ameri

1. Key data elements

Minimal dataset for CV assessment before, during and after therapy:

- Cardiac function (Echo MRI, PROM , EKG parameters (i.e. QT))
- Differences in early vs. late trials: more data early, to be narrowed in later trials
- Focus on Serious Adverse Events at a minimum for the study duration
- Long term follow-up monitoring in registries as in cardiology
- Drop the adjudication but trust clinical assessment or patient reported symptoms/experience
- Balanced conditions are crucial so include caregivers to support QoL and independent measured parameters (activity)
- Patient phenotyping and risk stratification to allow patient specific therapies
- Minimal datasets would not be optimal while developing a new drug

ESC European Society of Cardiology

2. Challenges

1. Lack of joint assessment
2. Different perception between cardiologists and oncologist about the role of certain parameters
3. Missing harmonization across countries
4. Data duplication
5. Coding inconsistencies

ESC European Society of Cardiology

3. Strategies

1. Recommend to include a Cardio-Oncologist in design of an oncology trial
2. Recommend Industry Research to approach EMA while considering oncology studies
3. Define/harmonize a list of exclusion criteria (for example post MI patients) and make an assessment of appropriateness
4. Differentiate between sponsored and ISR