

# STANDARDISING PATIENTS OR FOR PATIENTS

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Precision approaches to the “holistic” patient

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Past secretary Europa Uomo – patient advocate

# Standardising patients or for patients

**New medicines**

**In vitro diagnostics**

# Standardising patients or for patients

**New medicines**

# Standardising patients or for patients

## Drug development

**Candidate new drug**

**Clinical trial**

**EMA – Commission MA**

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graph TD; A[Clinical trial] --> B[EMA – Commission MA]; B --> C[Member State Reimbursement];
```

**Member State Reimbursement**

# Standardising patients or for patients

## Clinical trial



### Inclusion criteria (PC)

- Positive diagnosis
- ECOG status 0-1
- No metastasis
- 9 other in. criteria

### Exclusion criteria (PC)

- Uncontrolled hypertension
- On anticoagulants
- Proteinuria
- 18 other ex. criteria

### Eligibility

Ages:  $\leq 18$  years

Genders: both (?)

Healthy volunteers: NO

# Standardising patients or for patients

## Clinical trial

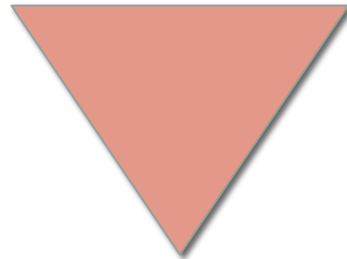


# Standardising patients or for patients

**EMA – Commission MA**



**Member State Reimbursement**



**Approval and reimbursement for specific criteria of disease and disease status**

**No patient selection – **wild** type patients**

# Standardising patients or for patients

**Approval and reimbursement for specific criteria of disease and disease status**

**No patient selection – **wild** type patients**



**Not all  
subpopulations  
respond equally good**





# Standardising patients or for patients

**Benefit** monitoring after [short] phase III

Monitor – **wild** type patients

Not only Eudravigilance (side effects)



Not all  
subpopulations  
respond equally good



# Standardising patients or for patients

**Benefit** monitoring after [short] phase III  
Monitor – **wild** type patients

Reassessment:

Select “sensitive” sub-populations

Exclude some concomitant diseases

Sub-population based dose adjustments



# Standardising patients or for patients

**In vitro diagnostics**

# Standardising patients or for patients

**In vitro diagnostics**



## Precision medicines

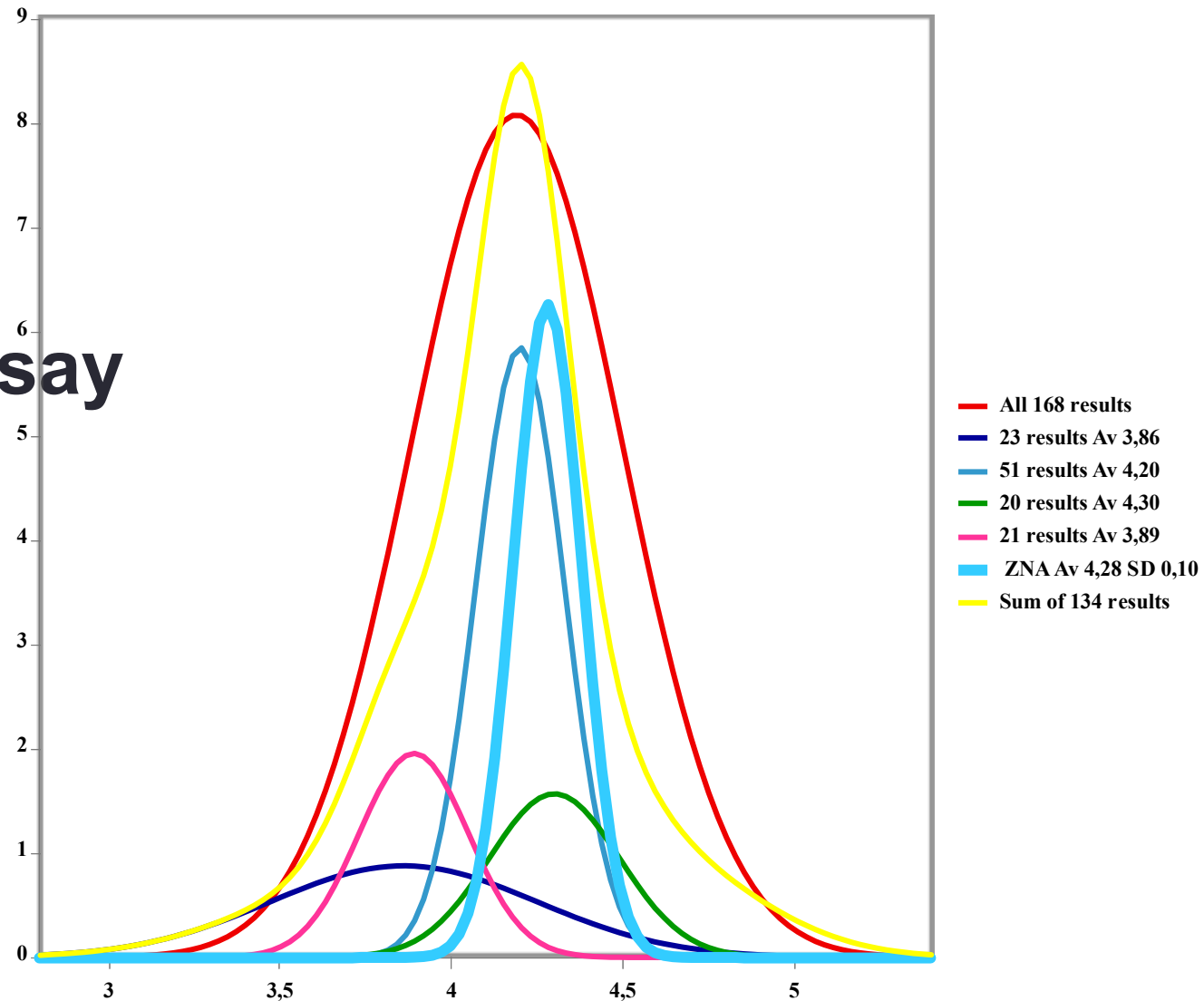
**Select patients before treatment procedures or with medicines**

**Molecular markers, tumour markers**

# Standardising patients or for patients

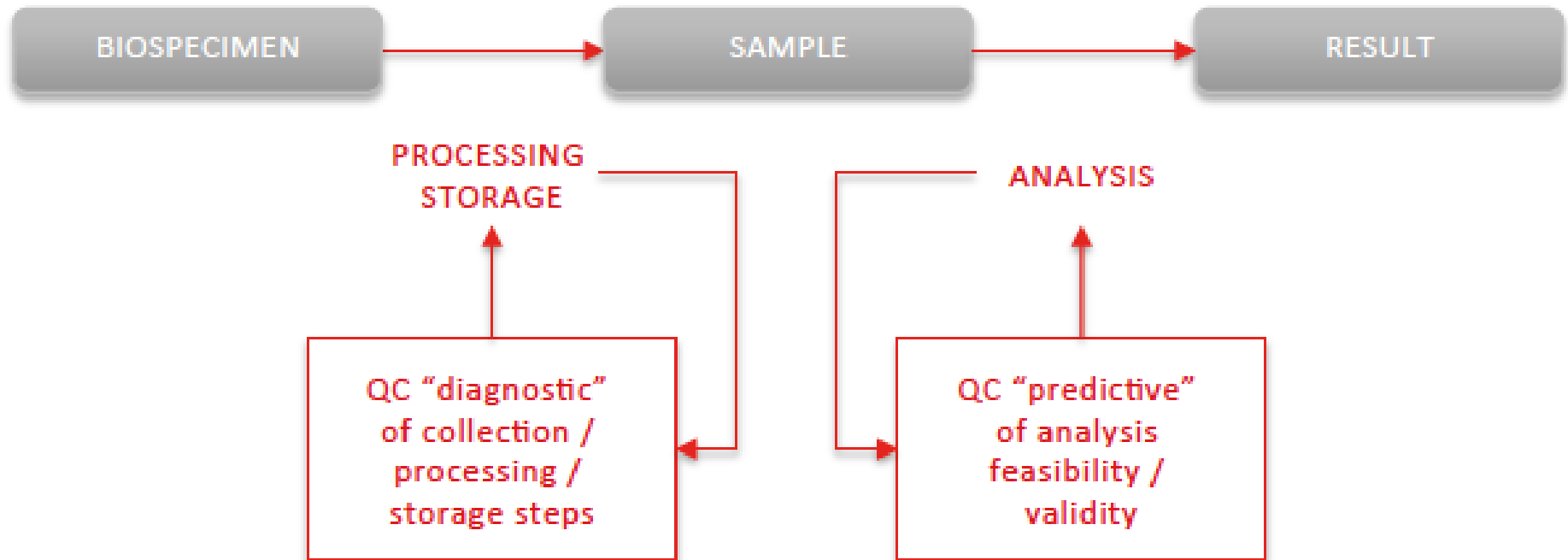
**PSA**

**“Simple” assay**  
**External QC**  
**Belgium**  
**One sample**  
**134 results!**  
**+ one lab**



# Standardising patients or for patients

**QA**



# Standardising patients or for patients

**EDA**

**New biomarker**

**New medicine**

**De Novo Registration**

**EMA**

**Standard material**

**QC/QA material**

**De Novo MA for IVD setting standards**

**Other MA for IVD in agreement with standards**

# Standardising patients or for patients



**Question : tumour poly-clonality**

**Marker liquid biopsy EGFR**

**+Cells: 12 / 7,5mL**

**? What about the 108 negative cells / 7,5mL**



# Standardising patients or for patients

**Thank you for your attention**

**Questions...**

