STANDARDISING PATIENTS OR FOR PATIENTS

Precision approaches to the “holistic” patient

Erik Briers PhD
Past secretary Europa Uomo – patient advocate
Standardising patients or for patients

New medicines

In vitro diagnostics
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New medicines
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Drug development

Candidate new drug

Clinical trial

EMA – Commission MA

Member State Reimbursement
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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: ≤18 years
- Genders: both (?)
- Healthy volunteers: NO
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Clinical trial
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EMA – Commission MA

Member State Reimbursement

Approval and reimbursement for specific criteria of disease and disease status

No patient selection – wild type patients
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Approval and reimbursement for specific criteria of disease and disease status

No patient selection – wild type patients

Not all subpopulations respond equally good
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**Benefit** monitoring after [short] phase III
**Monitor** – *wild* type patients
Not only Eudravigilance (side effects)

Not all subpopulations respond equally good
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**Benefit** monitoring after [short] phase III
Monitor – **wild** type patients

Reassessment:
Select “sensitive” sub-populations
Exclude some concomitant diseases
Sub-population based dose adjustments
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In vitro diagnostics
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In vitro diagnostics

Precision medicines

Select patients before treatment procedures or with medicines

Molecular markers, tumour markers
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PSA

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

- All 168 results
- 23 results Av 3.86
- 51 results Av 4.20
- 20 results Av 4.30
- 21 results Av 3.89
- ZNA Av 4.28 SD 0.10
- Sum of 134 results
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QA

BIOSPECIMEN → SAMPLE → RESULT

PROCESSING STORAGE

QC “diagnostic” of collection / processing / storage steps

ANALYSIS

QC “predictive” of analysis feasibility / validity

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EDA
- New biomarker
- New medicine
- De Novo Registration
- Standard material
- QC/QA material
- De Novo MA for IVD setting standards
- Other MA for IVD in agreement with standards

EMA
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Question: tumour poly-clonality

Marker liquid biopsie EGFR

+Cells: 12 / 7,5mL

? What about the 108 negative cells / 7,5mL
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Thank you for your attention

Questions…