

Personalized Entry Programs symposium presentation 2018



Advice, analysis and training to facilitate access to the optimal treatment for the appropriate patients

make practice and policy work

LYSIAC BV

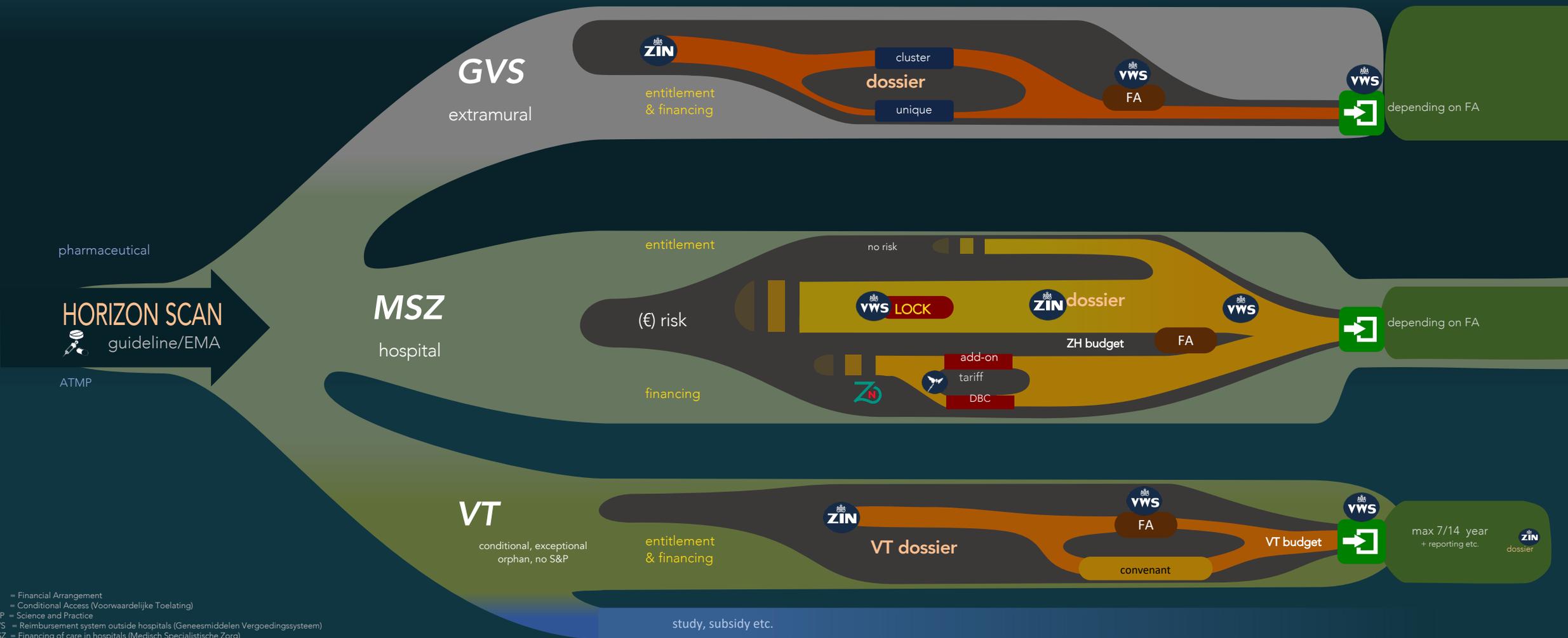
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Drs. Evelien Yap, PharmD, expert reimbursement & access

INFOGRAPHIC ACCESS ROUTES for NEW PHARMACEUTICALS

development clinical research assessment, reimbursement, financing, budgets, tariffs access use



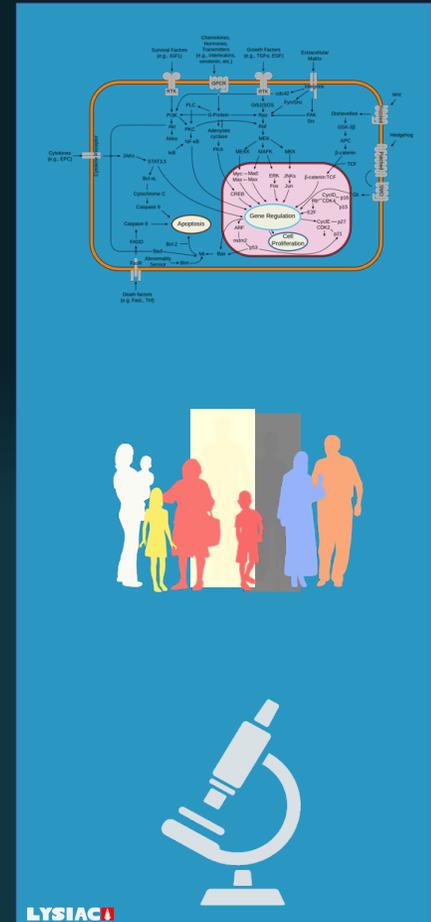
FA = Financial Arrangement
 VT = Conditional Access (Voorwaardelijke Toelating)
 S&P = Science and Practice
 GVS = Reimbursement system outside hospitals (Geneesmiddelen Vergoedingsysteem)
 MSZ = Financing of care in hospitals (Medisch Specialistische Zorg)

Insufficient certainty for 'standard' HTA assessment at group level

- For group: insufficient certainty effect
 - variation response
 - heterogenous group
 - placebo/RCT not feasible or unethical

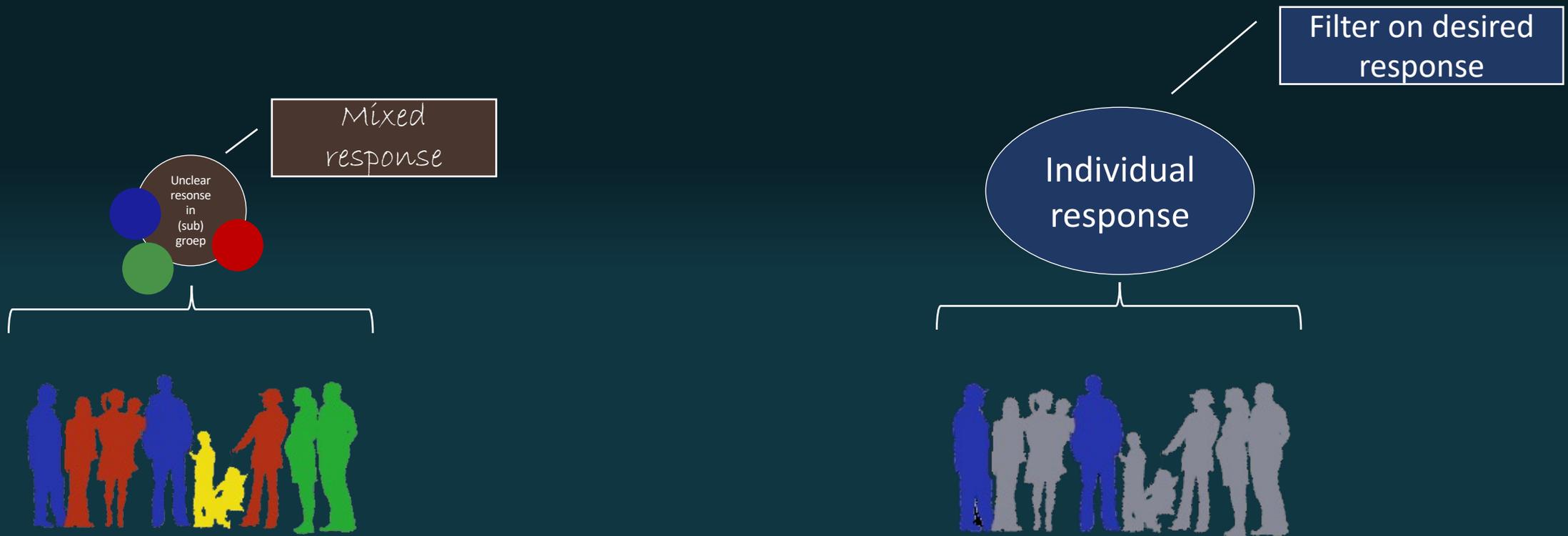
- Promising information on efficacy
 - mechanism of action
 - individual response
 - EMA registration

- Individual outcomes can give sufficient substantiation
 - treatment criteria
 - response during treatment



PEP-route: access for responders

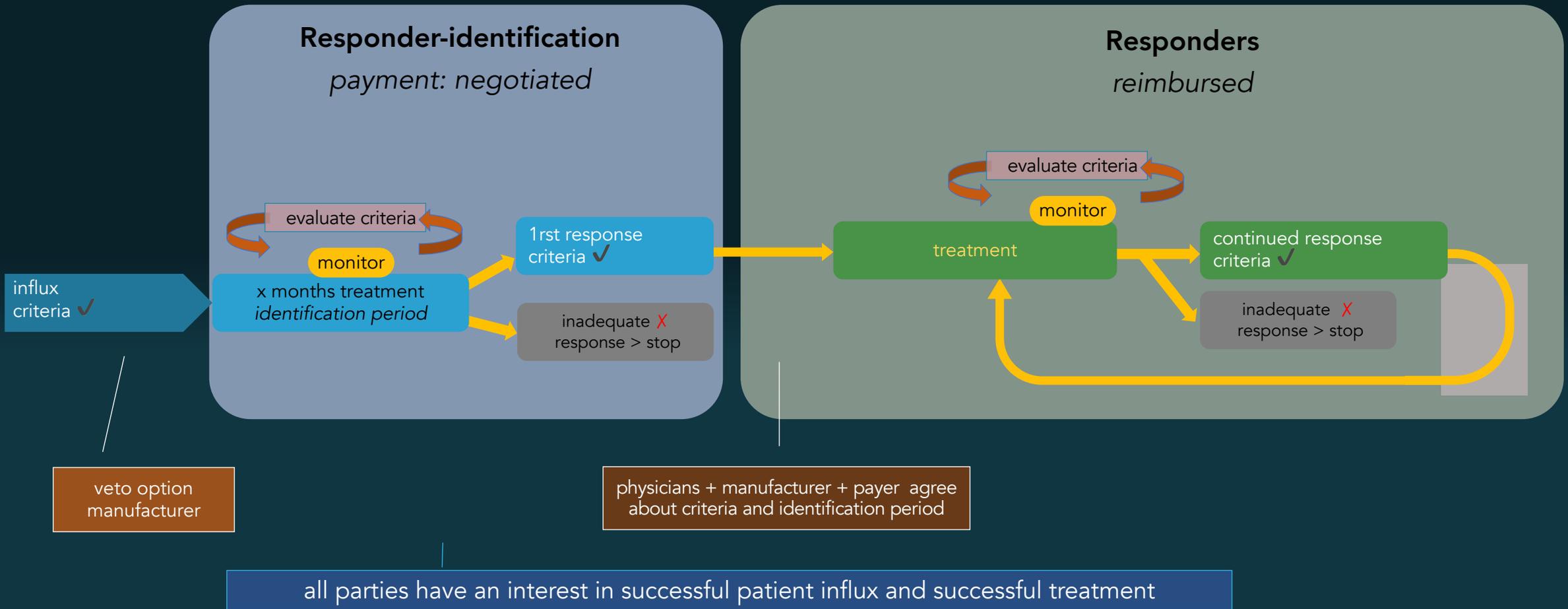
Not based on subgroup <> but on effect per person



subgroup = mixed > uncertain > no access

Individual = clear effect > certain > access

Personalized Entry: package decision based on individual response



Personalized Entry Program (PEP)

Goals PEP:

- Solution for access in case of:
 - Insufficient evidence for (sub)group
 - Clear individual response

Specifics:

- Access per individual during research phase
- Clear identification of responders is possible
- Criteria may change based on evaluation
- Stakeholders have a common interest: finding the right patients
- Insurer manufacturer and HCPs are partners in this procedure
- Works for hospital and home treatments

Agree on:

- *Identification period*
- *Response criteria*
- *Price and cost sharing*