CLINICAL EVALUATION OF BIOMARKERS

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Clinical Evaluation of a Biomarker

- Pathology and identification of marker
- Measurement of marker

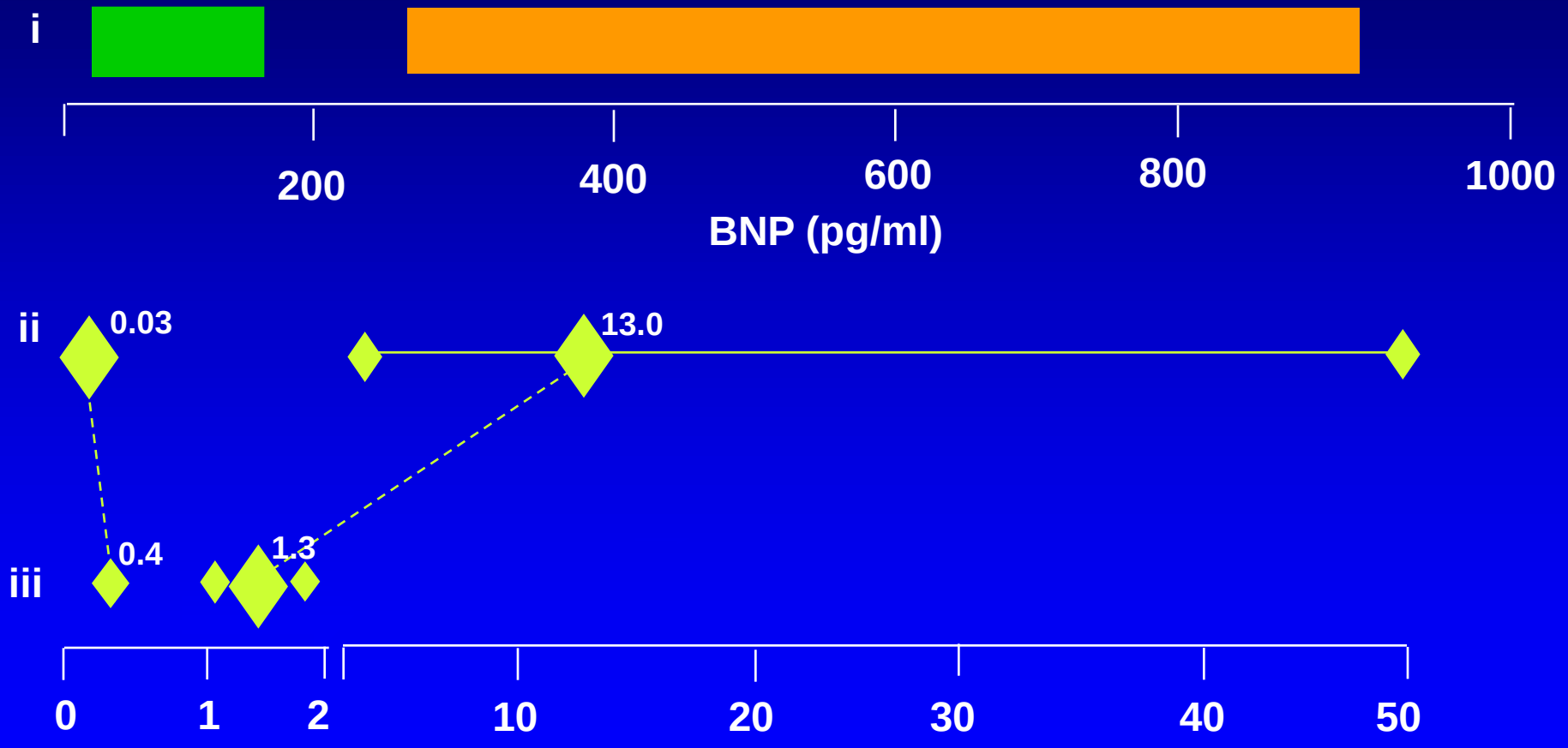
  :analytical variation

  :biological variation
- Results; affected differ from normals: relation to disease severity
- Patients with certain results more likely to have the condition
- Results differentiate those with disease from those without disease
- **Patients having the test have better outcomes**

Laboratory Medicine

architecture of diagnostic research

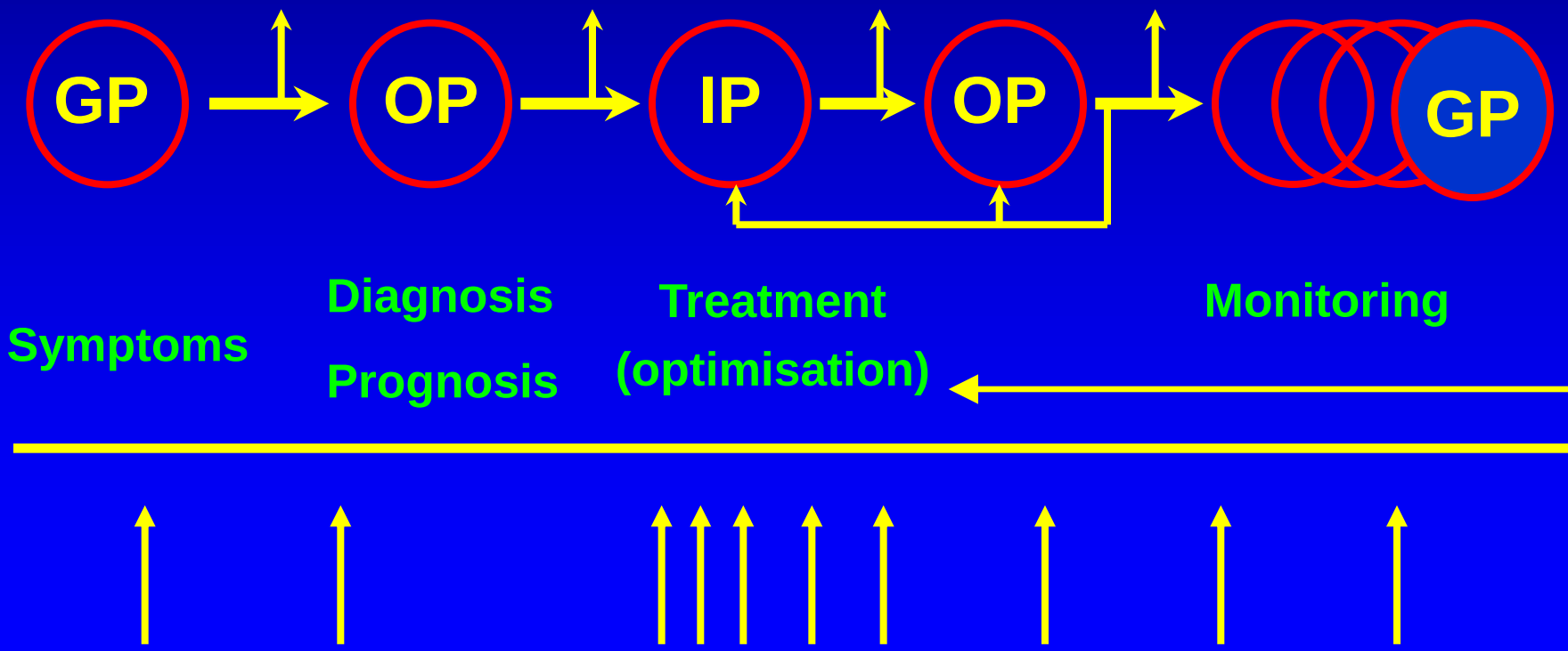
BNP in heart failure



Sackett and Haynes 2002

Biomarkers and the Patient Journey

applications and outcomes



Health Outcomes

care of individual patients

maximisation of benefit

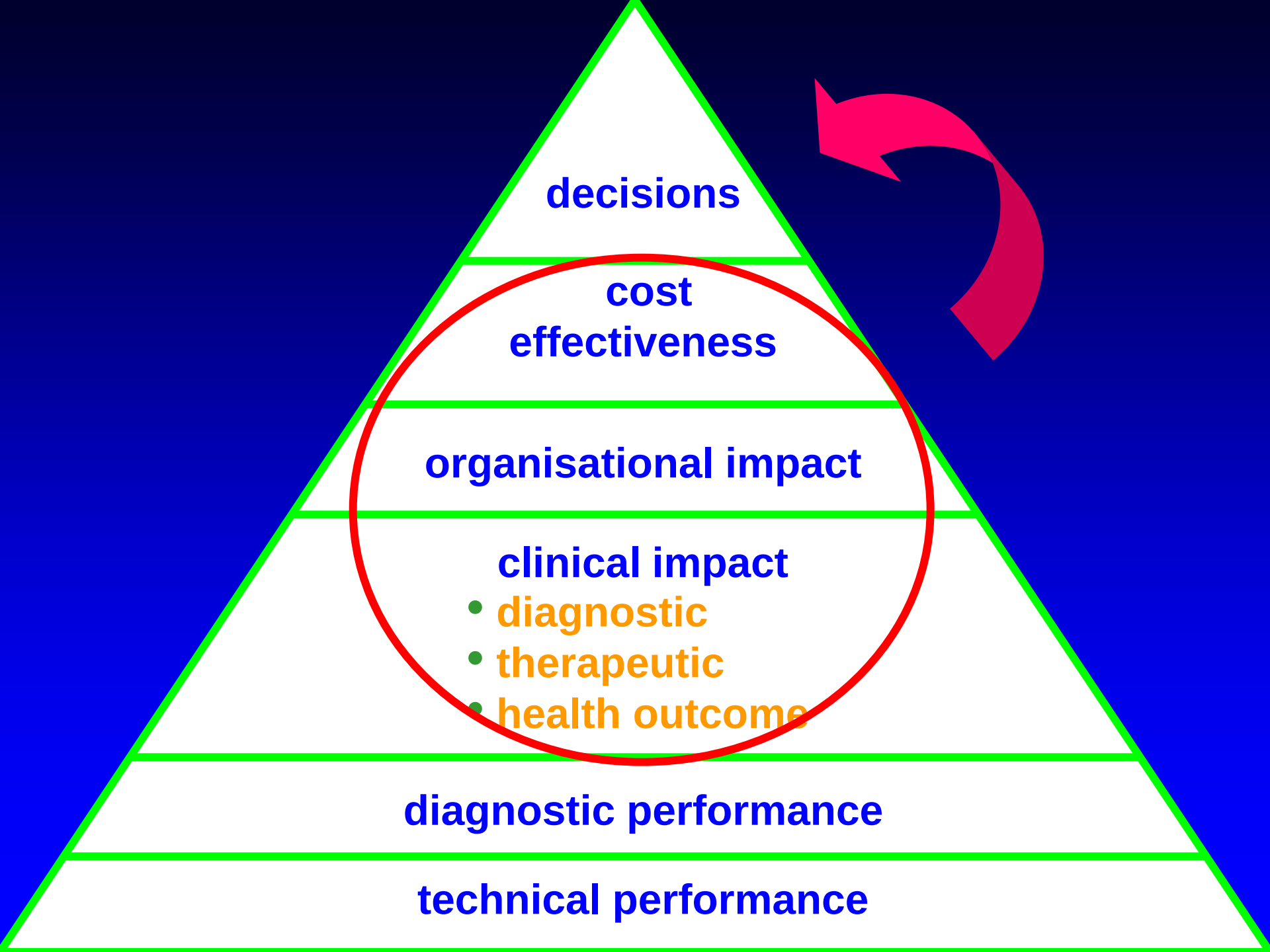
minimisation of risk

reasonable cost

Clinical

Operational

Economic


decisions
cost
effectiveness
organisational impact
clinical impact
• diagnostic
• therapeutic
• health outcome
diagnostic performance
technical performance

Biomarker Utilisation
what are the consequences?

PATIENT

question → **test** → **decision** → **action**

OUTCOME

Biomarker Utilisation
what are the key issues?

- evidence of effectiveness
- reimbursement
- resource reallocation
- change in practice
- adoption