

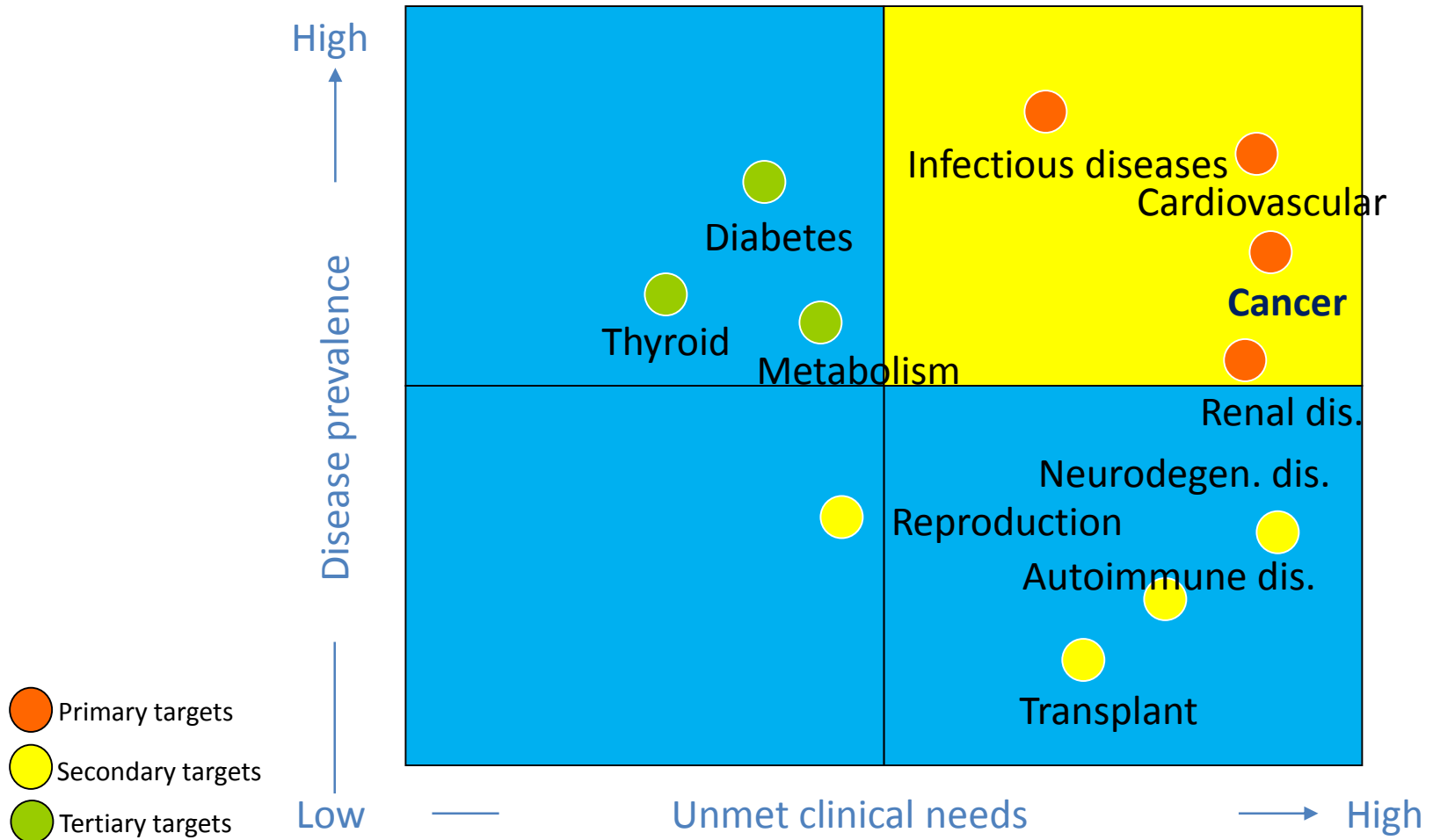
New technologies in diagnostics



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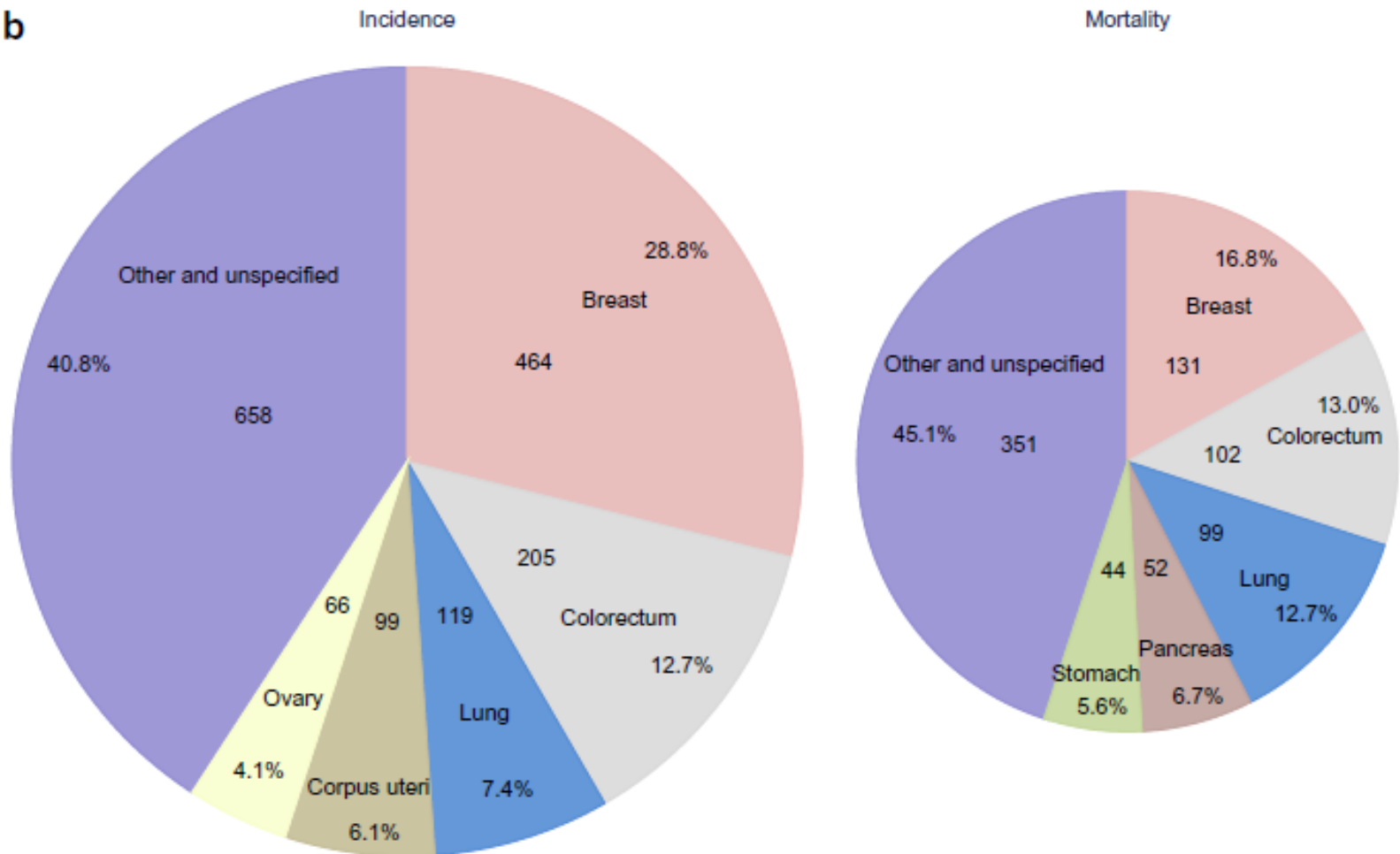
Putting Science Into Standards – Ispra, October 20-21, 2015

Diagnostics R&D focuses in critical areas

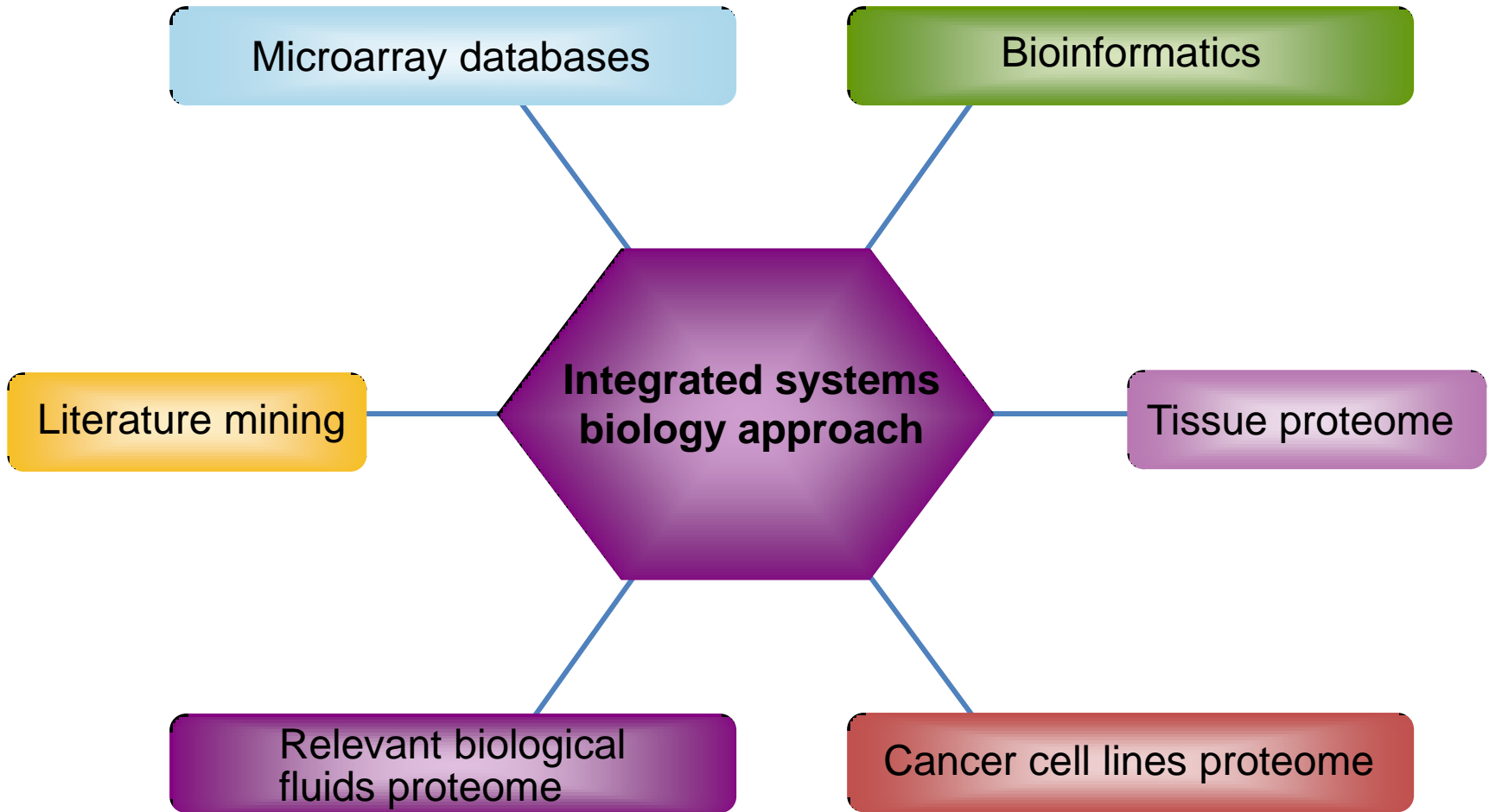


Cancer in Europe: incidence and mortality rates

b

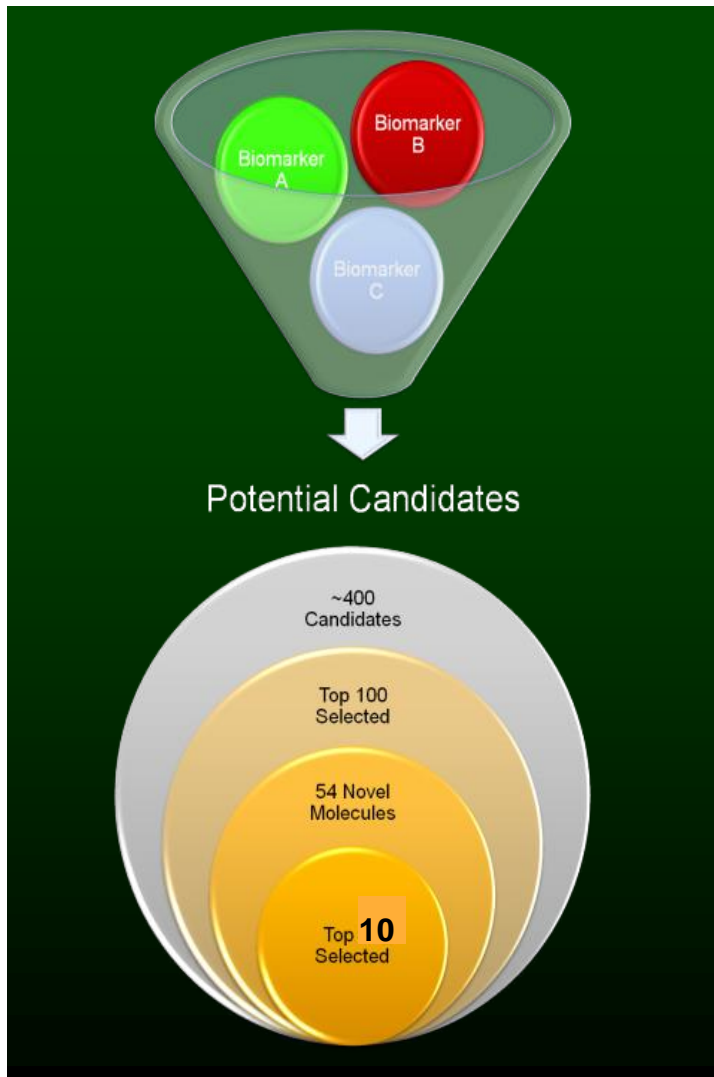


Biomarkers discovery: the approach



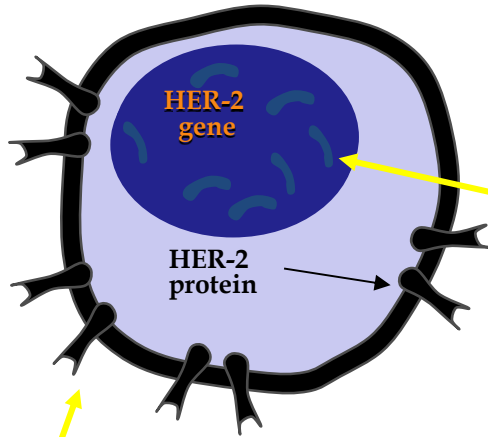
Biomarker discovery process

An example: breast cancer

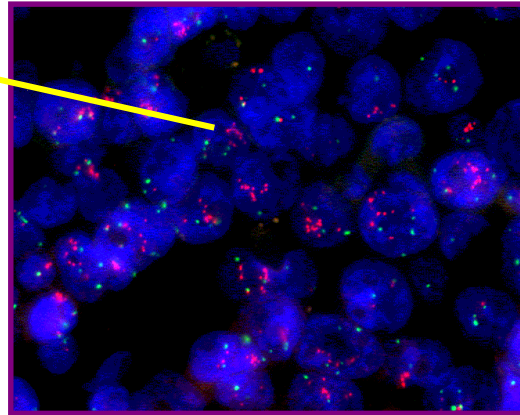


- ~400 proteins (membrane, secretory, unclassified)
- “Top 100” (spectrographic analysis)
- 54 molecules not previously studied in serum of breast cancer patients
- Candidate for further analysis: ~10

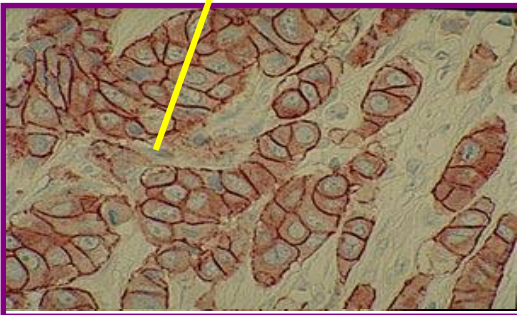
Testing for HER-2/*neu*



Gene amplification



Protein expression

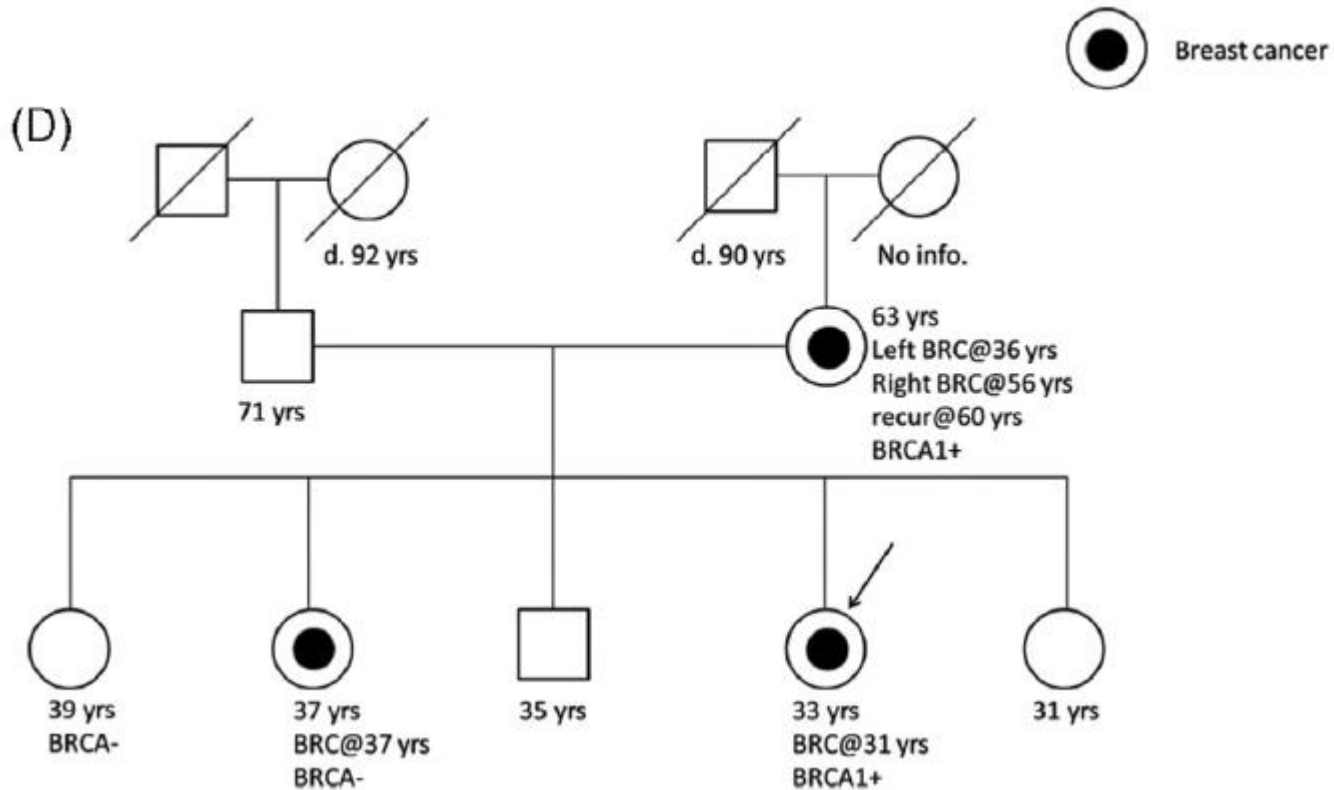


IHC target= HER-2 protein
Subjective score 1+, 2+, 3+

FISH target: = HER-2 gene (DNA)
Objective interpretation: Yes/No

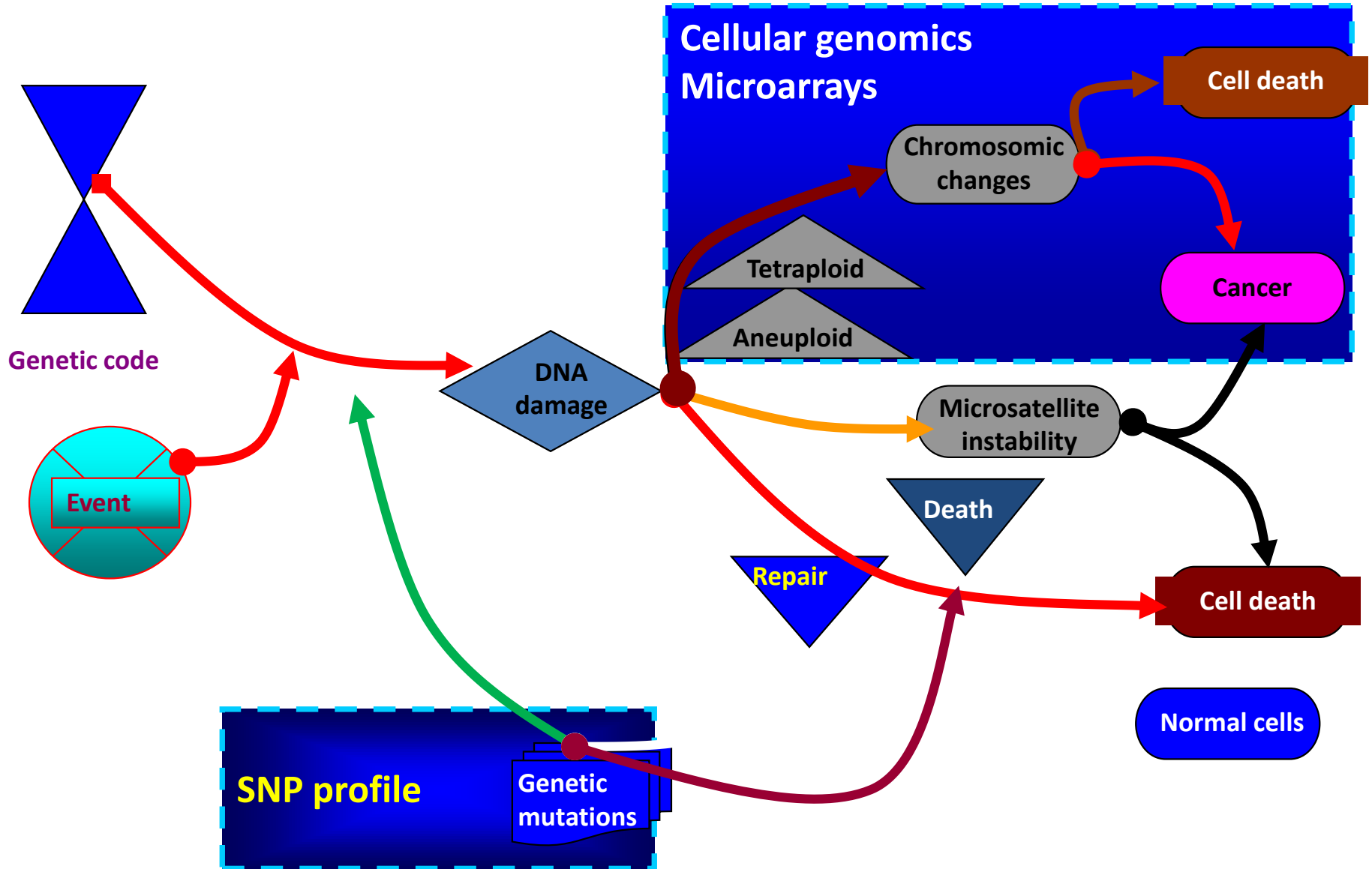
HER2 overexpression	'HER2-positive (non-luminal)' HER2-positive ER and PgR absent
'Basal-like'	'Triple-negative (ductal)' ER and PgR absent HER2-negative

BRCA as a predictor for breast cancer

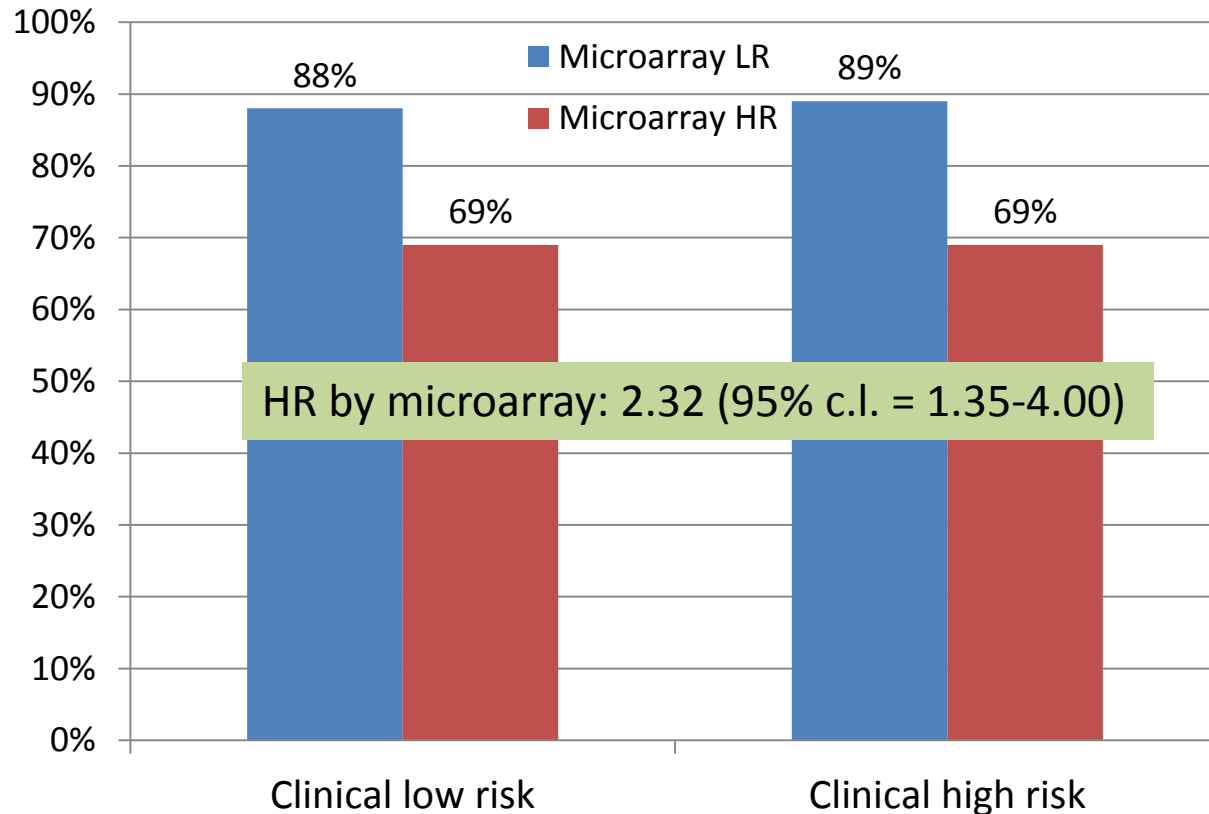


Integration of classical sequencing and LGRs to avoid false negatives

The oncogenic process

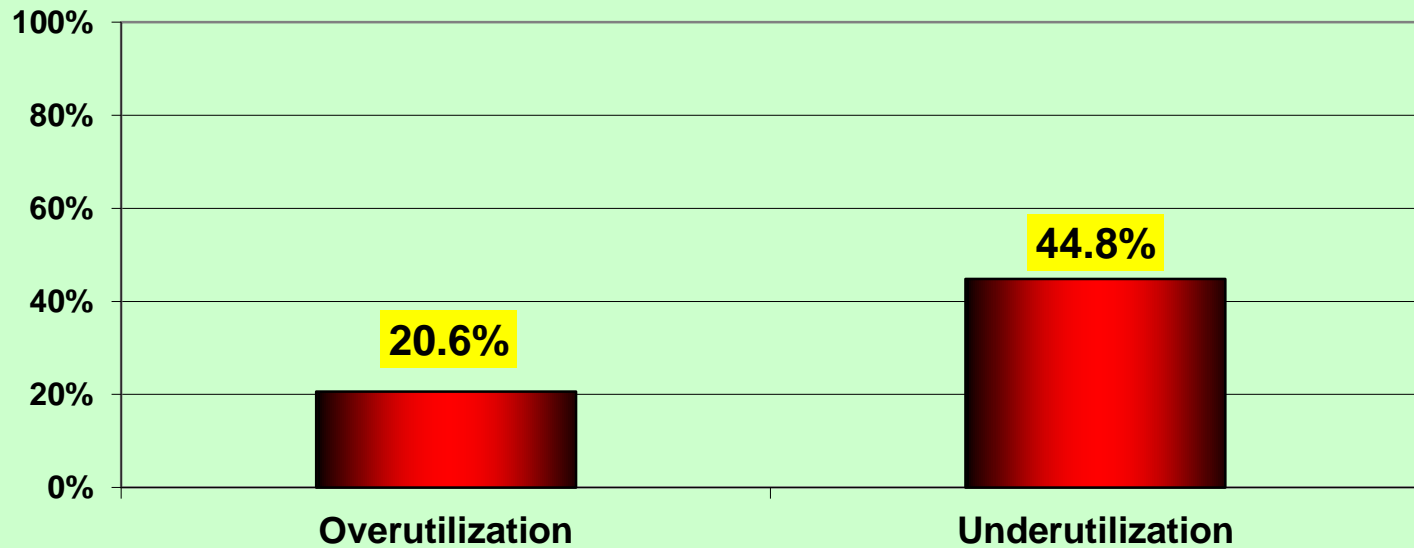


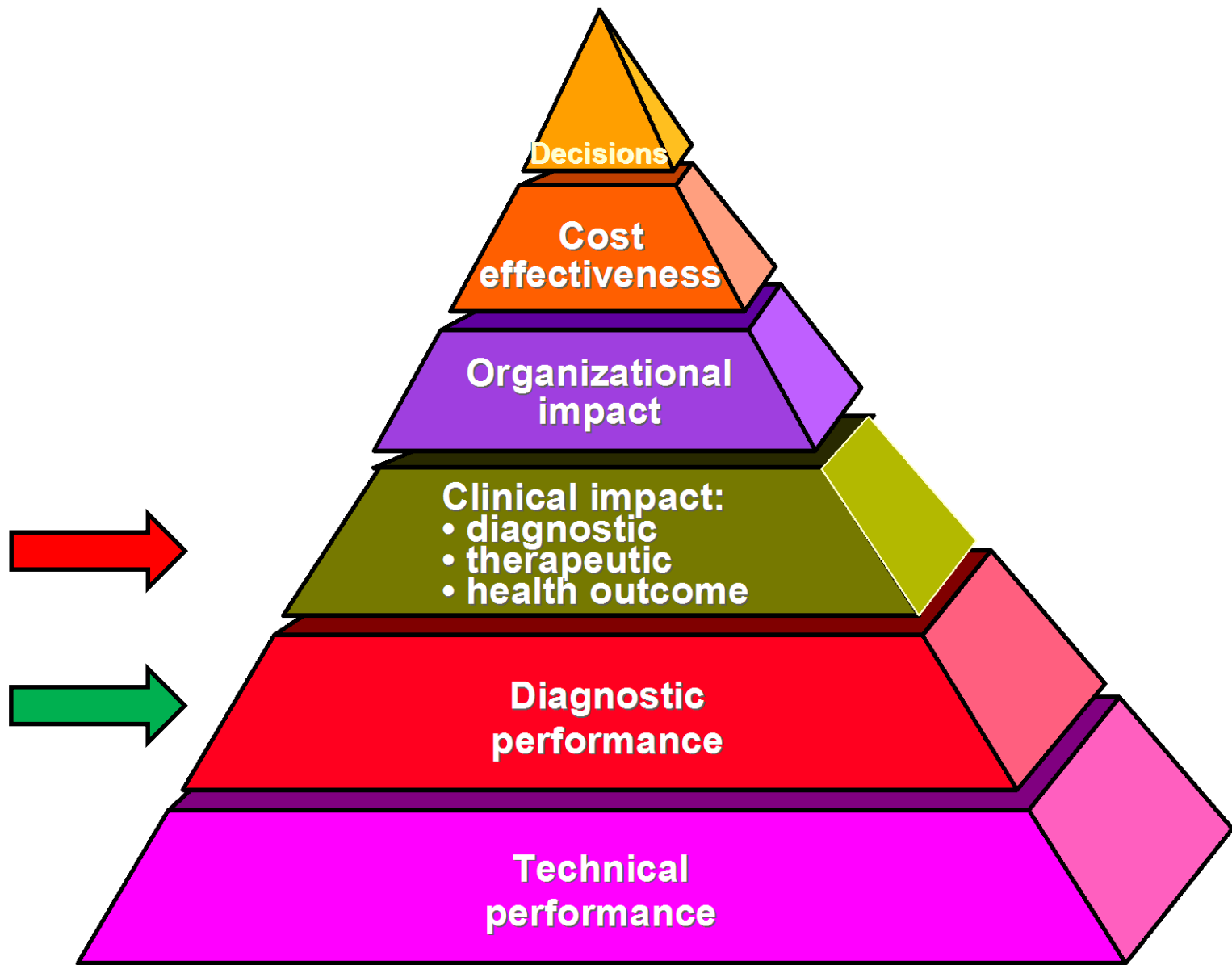
Microarrays: the future?



A microarray chip that assesses the mRNA expression of the 70 genes in triplicate. Manufactured by Agilent Technologies using the Agilent oligonucleotide microarray platform.

Diagnostic tests utilization



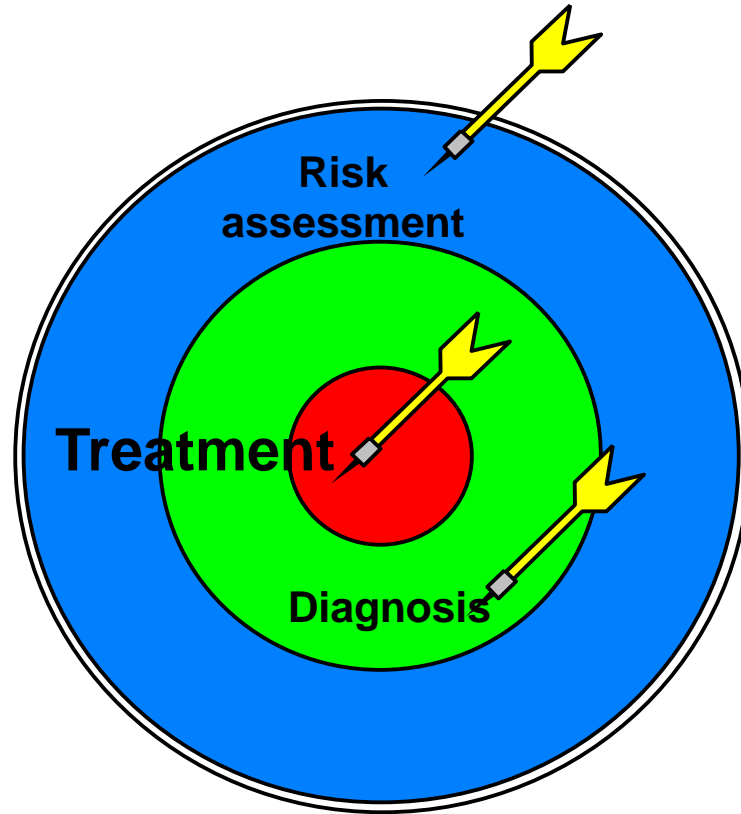


EDMA proposals with regards to clinical evidence

- **Study type:** Better separation between the requirements for general studies (applicable to more than 95% of the IVDs) and those which involve a risk to patients (less than 5% of the IVDs) (Annexes XII & XIII)
- **Concept of clinical benefit:** Criteria for assessment of clinical evidence based on the output of the diagnostic technologies, not on subsequent healthcare pathways or patient outcomes
- **Post-market assessment:** The Council text on continuous assessment must be clarified to enable a feasible and appropriate post-market surveillance system for IVDs.
- **Pre-market evidence gathering:** Information and data driven clinical evidence requirements, rather than process driven requirements

The “four P” Medicine

- **P**redictive
- **P**reventive
- **P**ersonalized
- **P**articipated



A bronze sculpture of a muscular man in a dynamic pose, with arms raised and one leg bent, set against a wall with a relief of several figures. A blue text box is overlaid on the image.

Thank you for your attention