Role of Diagnostics in cancer treatment
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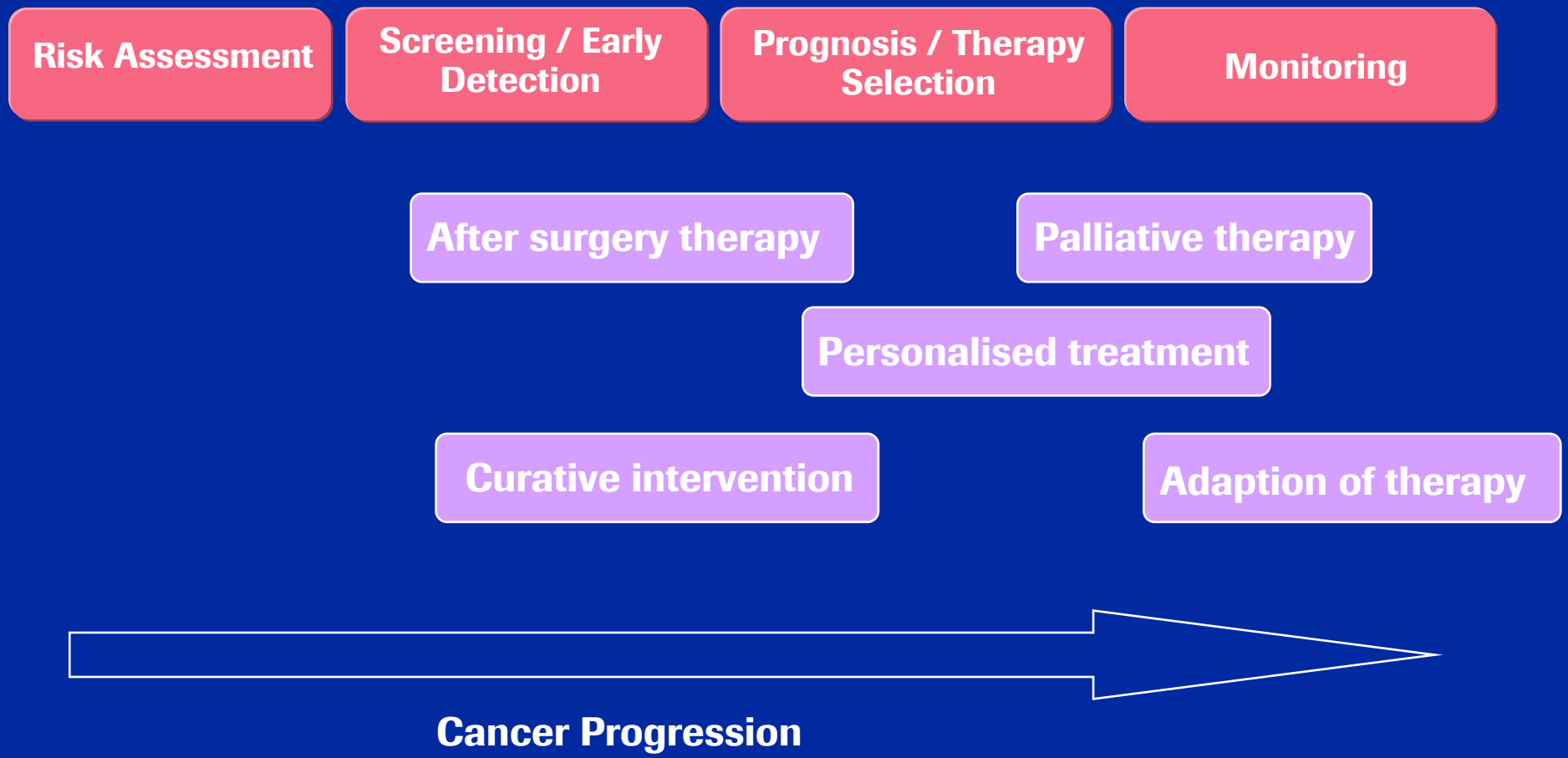
Joachim Eberle, Head of R&D Roche
Centralized Diagnostics

Tests measuring a person's health status

Risk Assessment / Predisposition	Gene setup predisposes for disease
Screening / Early Detection	Discriminate "healthy" from asymptomatic "disease" state
Prognostic	Predict probable course of the disease ("slow" vs. "fast" progression)
Patient Stratification/ Therapy selection	Discriminate "responders" from "non-responders"
Therapy Monitoring	Monitor efficacy of treatment or recurrence of disease

Potential use of biomarkers in oncology



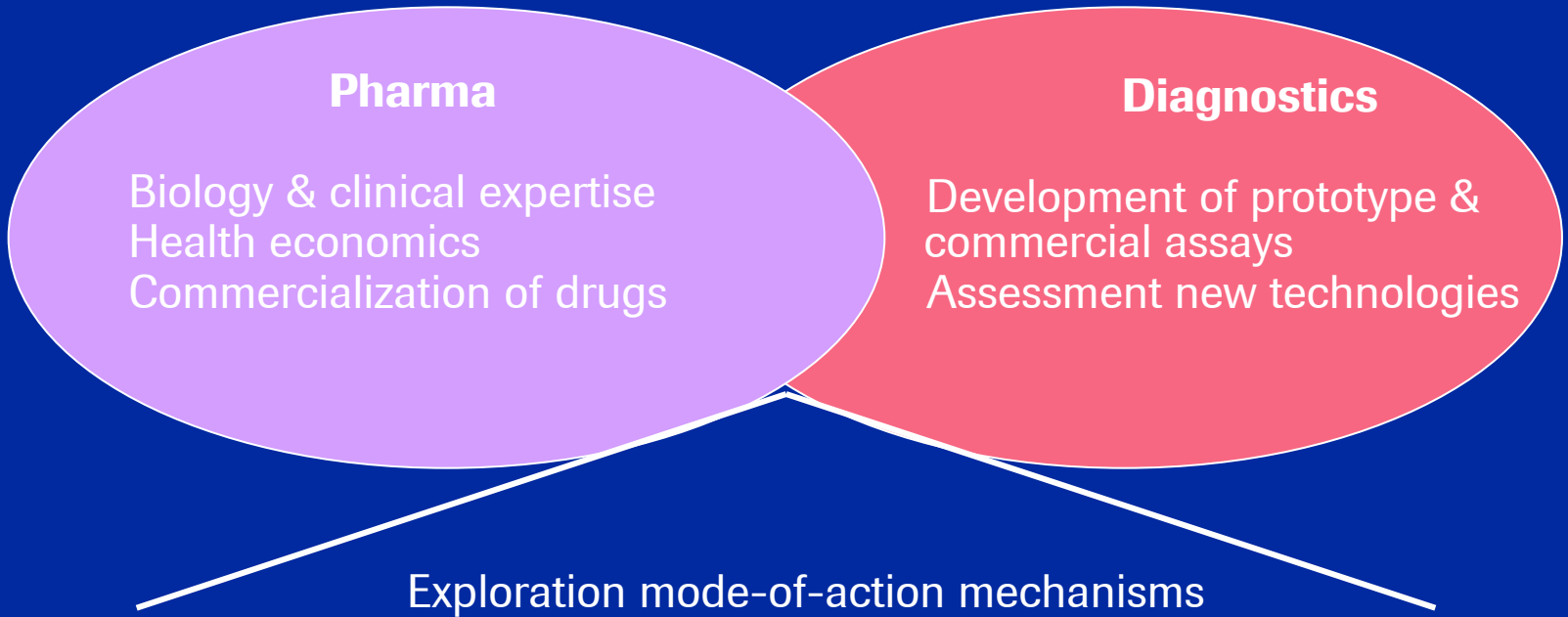
Why do biomarkers make a difference?

- **Patients & Clinicians**
  - early detection can increase chance of cure
  - patients can be selected to maximize benefit and minimize toxicity in therapy
- **Payers**
  - optimized therapy allows more efficient use of limited healthcare budgets
  - increased cost benefit per patient to reach “threshold”
- **Regulatory**
  - Targeted treatment may be essential to gain regulatory approval
- **Pipeline & Positioning**
  - biomarker allow to make better development and portfolio decisions

Objective: treating patients that will benefit, not treating those that will not

Roche Oncology Biomarker Programme

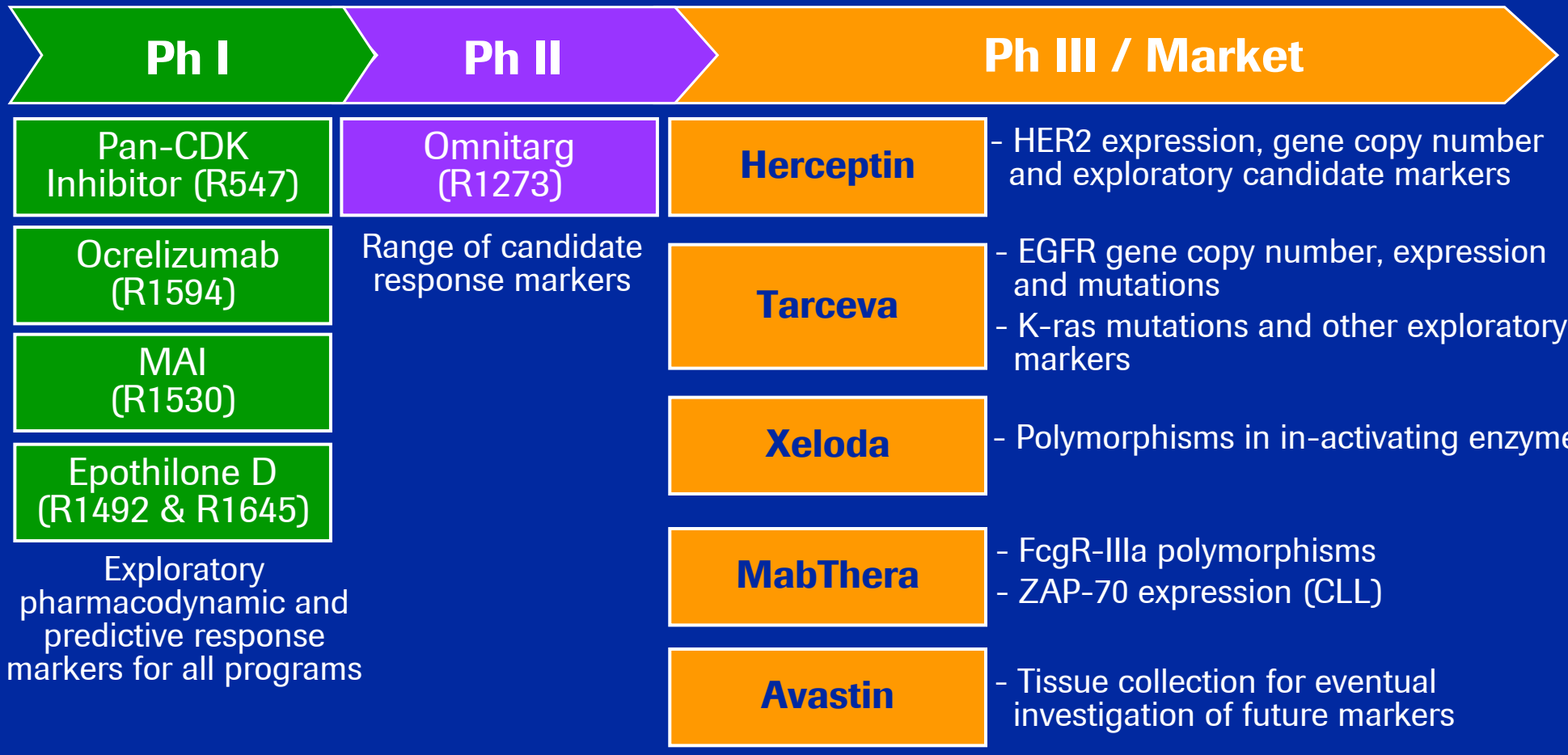
For all clinical candidates, throughout their lifecycle



Exploration mode-of-action mechanisms
Biomarker-guided development of new medicines
Predictive Biomarkers for drug selection/ differentiation
Sample sharing

Our competitive edge: sharing core expertise & development of targeted medicines

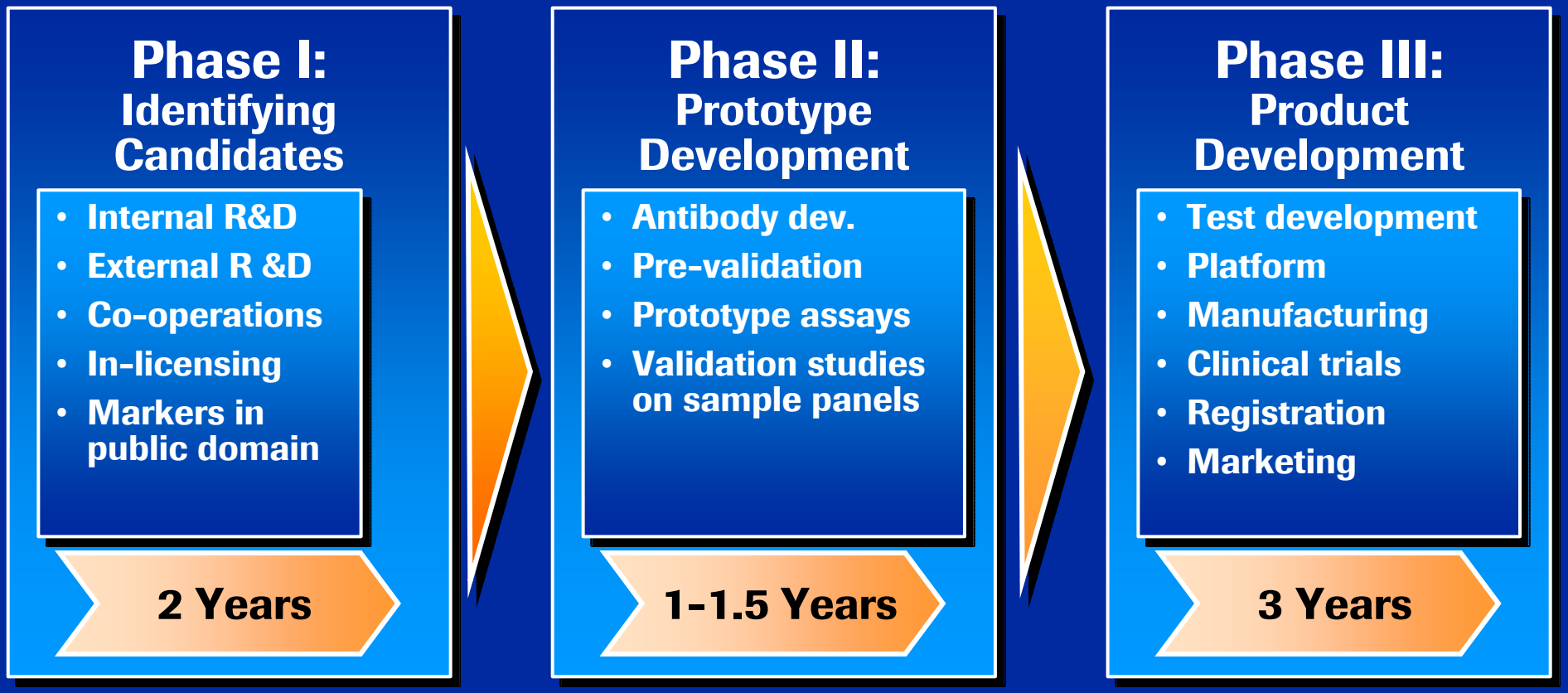
Biomarker projects in support of Oncology projects



Research assay **Validated assay** ***In-vitro* Diagnostic assay** (if applicable)

From marker candidate to a product

Three development phases (Ex. Colorectal cancer)



Marker Candidate
100 candidates → **Validated Candidate**
20 candidates → **Commercial Product**
~5 potential markers

High medical need in colorectal cancer (CRC)

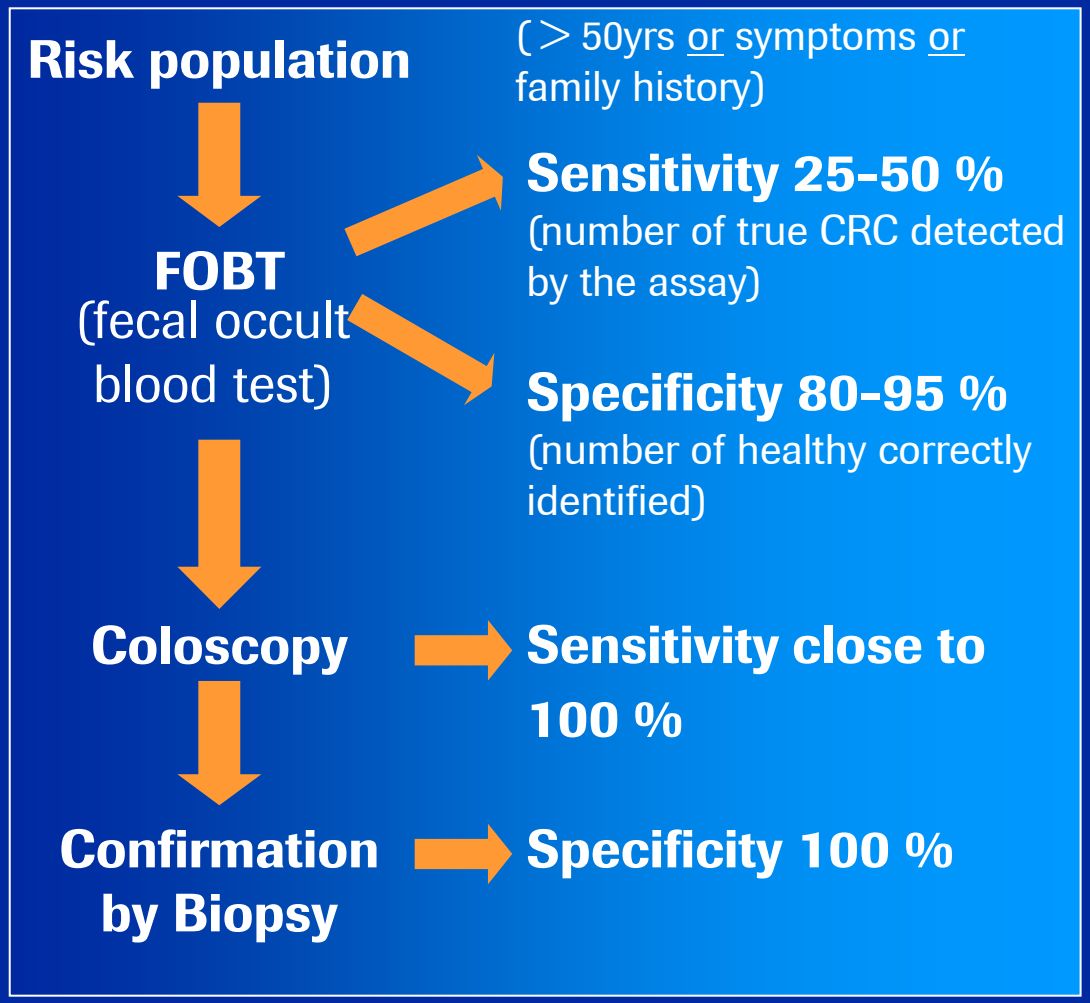
Early detection saves lives

Location	Stage I + II Local	Stage III Regional (Lymphnodes)	Stage IV Distant (Metastasis)
Stage at first diagnosis:	40 %	40 %	20 %
5-year survival:	90 %	65 %	9 %

CRC is No.1 of cancer related death among non-smokers

Issues with current screening methods in CRC

No reliable single assay available



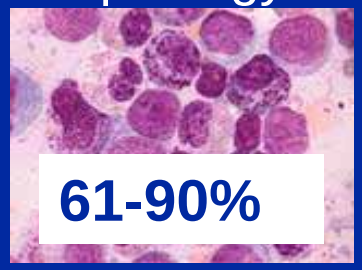
unsatisfactory as first-line screening assay

- highly invasive
- poor acceptance
- not useful as general screening method

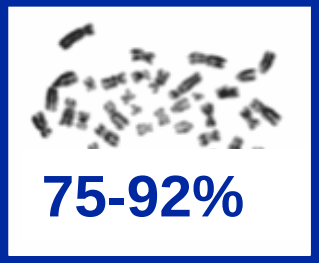
Current standards in diagnosis of leukemia

Varying reproducibility rates of gold standards

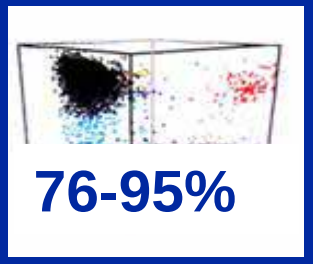
Morphology



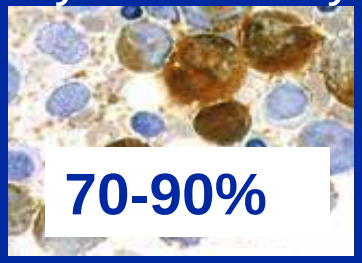
Cytogenetics



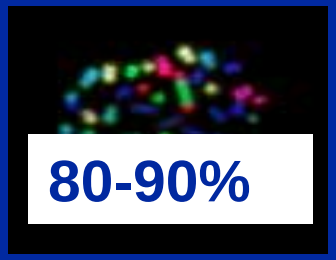
Immunophenotyping



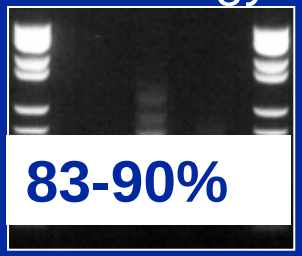
Cytochemistry



FISH



Molecular Biology



- **No single test currently sufficient to establish diagnosis**
- **Current tests subjective, with up to 7 days turnaround**
- **Lack standardization & automation – need highly skilled staff**

Genomics programme: Leukemia microarray

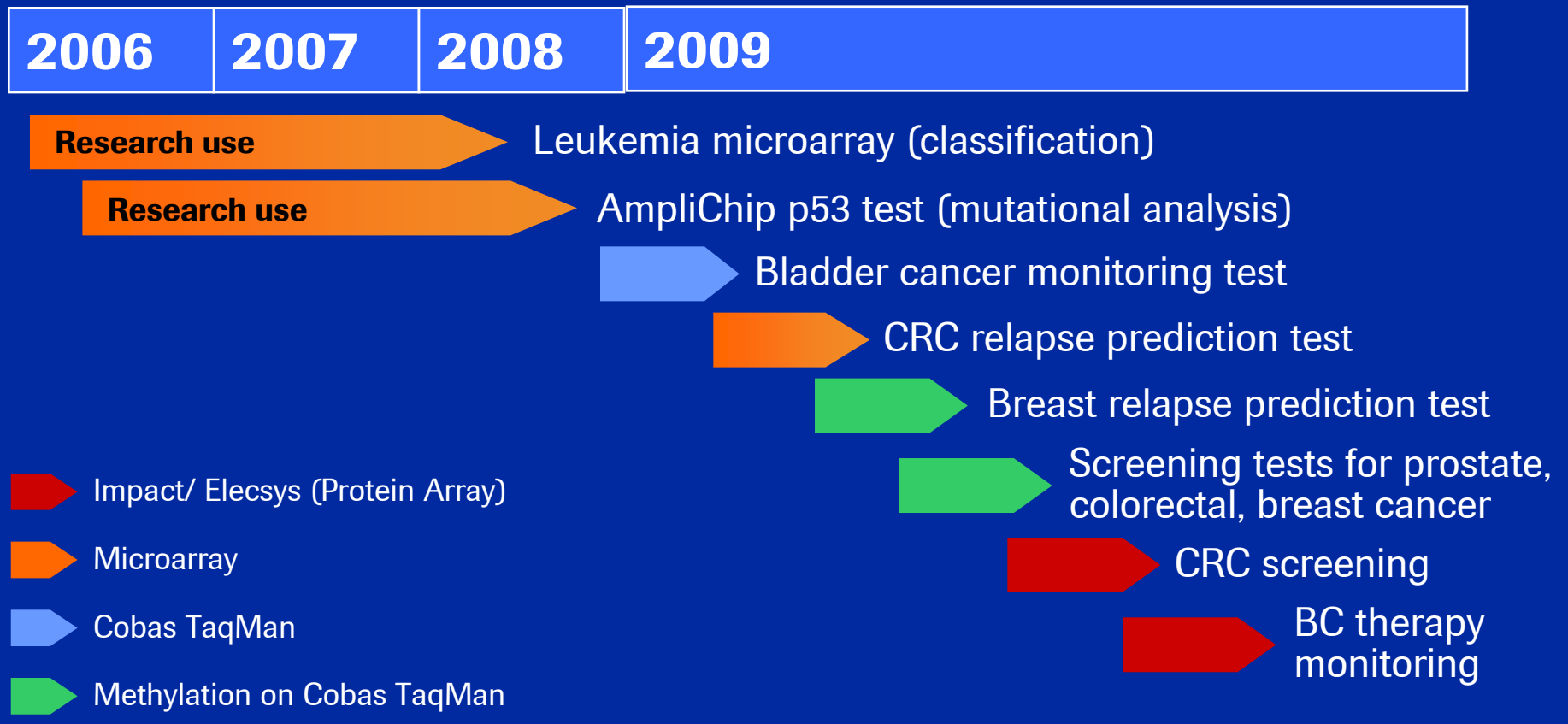
Improved diagnosis enables better treatment

- Heterogeneous disease caused by genetic abnormalities
- Distinction between chronic, acute and sub-classifications essential for successful treatment (~20 subgroups)

AmpliChip Leukemia

- sub-classification of major leukaemia classes
- potential to replace other methods/ technologies
- research programme ’05/ ’06

Anticipated new cancer marker launches



Launch dates are estimates only; US launches may be later than indicated