Slaying the Cancer Demons:
Optimising Patient Outcome by Leveraging Learnings through Big Data and Clinical Research Platforms in a Dual Longitudinal Continuity Framework

Denis Lacombe, MD, MSc
EORTC, Director General
Brussels, Belgium

EORTC

The future of cancer therapy

EORTC by the numbers

A world-class network	An expert HQ	Unique output
• 4,600 collaborators • 640 institutions • 37 countries • 21 groups & task-forces • 100 collaborative groups	• 191 employees • 190,000 patients in database • 24,000 patients in follow-up	• **18 new studies opened in 2015** • **48 studies open to patient entry** • 25 studies in protocol outline development • 22 studies in protocol development • 14 studies in regulatory activation • 83,551 pts on studies (2000-2015) • **Working on ≈ 190 studies**

SPECTA: precision oncology platform

The basic principles towards transformation

- Precision oncology is here to stay
- Immunotherapy is taking a central role in drug development and in therapeutic strategies
- Increasing role of predictive biomarkers
- New types of end-points and data.
- Rapid changes of the health care systems

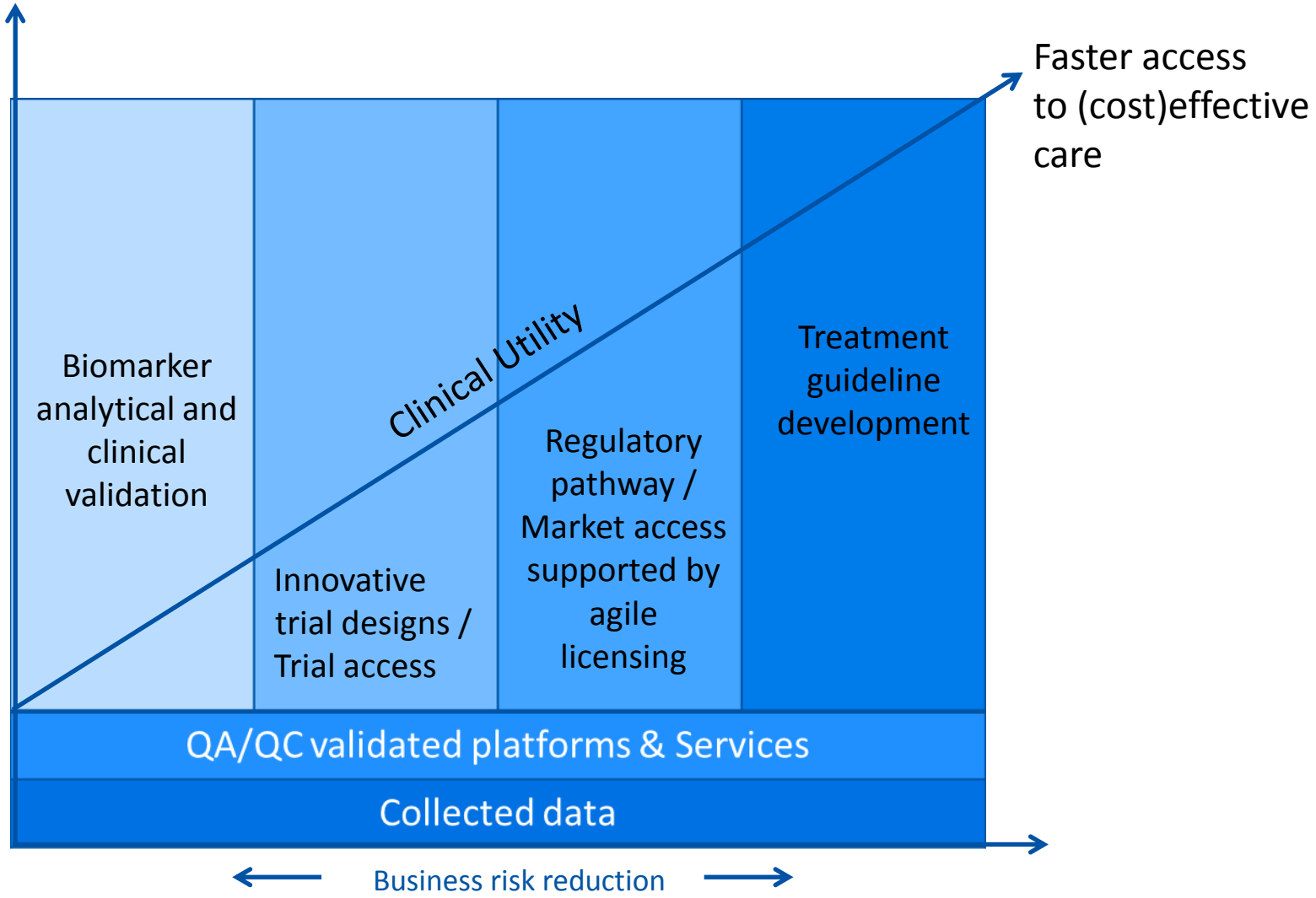
Tumor heterogeneity and escape mechanisms to be the next challenges

The journey through cancer is not simply like the same disease that reccurs

Recurrent pivotal questions

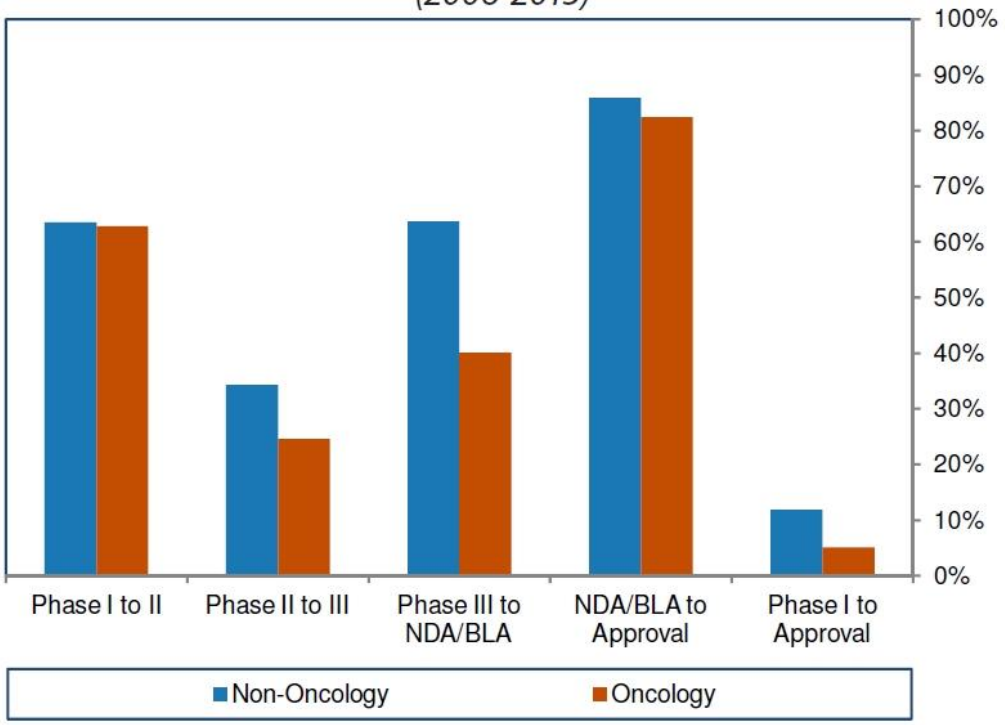
- Is the classical phase I, II, II process still adequate?
- How to access efficiently sub- group of molecularly defined patients?
- What are the pre-analytical requirements for biological samples, handling?
- What are the adequate steps for analytical and clinical validation of a biomarker and related assay?
- How to qualify cut-off values for decision process?
- What is the impact on clinical trial designs and optimal assessment of clinical utility?
- How the process of drug registration and access will evolve?
- How will new treatments be valued at the light on their true benefit in real life?

Towards a data driven Healthcare
From “omics” to economics



Oncology Has The Lowest Success Rate

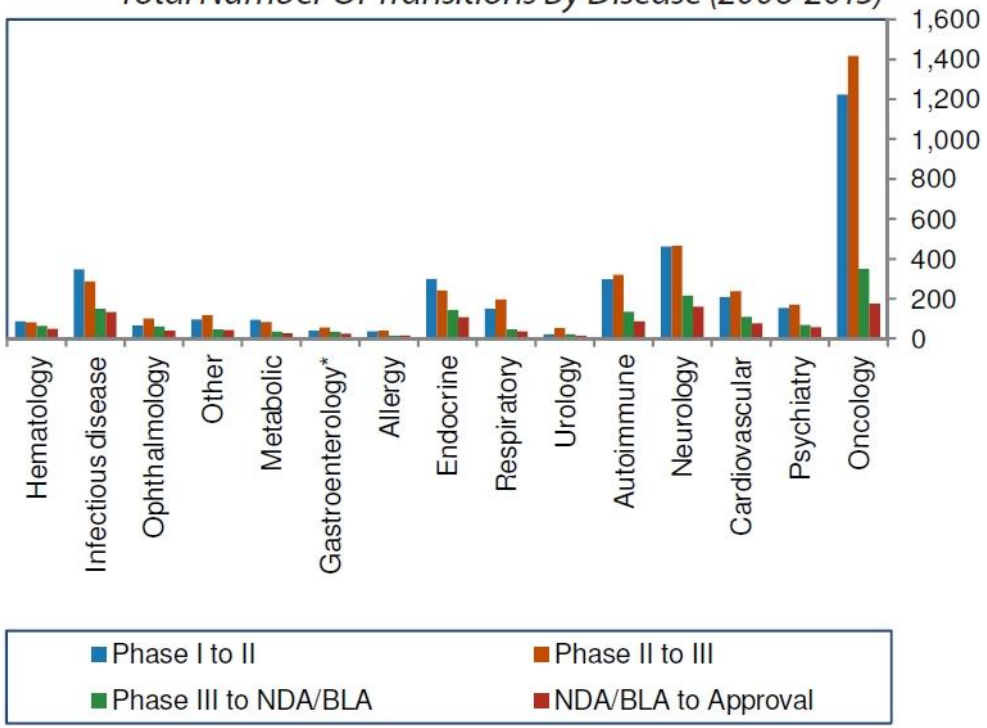
Probability Of Success For Oncology vs Non-Oncology (2006-2015)



Source: BIO
The Biotechnology Innovation Organization, Emerging Therapeutic Company Investment and Deal Trends, June 2016

Strong Pipeline In Oncology Highlights Increasing Competition In The Future

Total Number Of Transitions By Disease (2006-2015)



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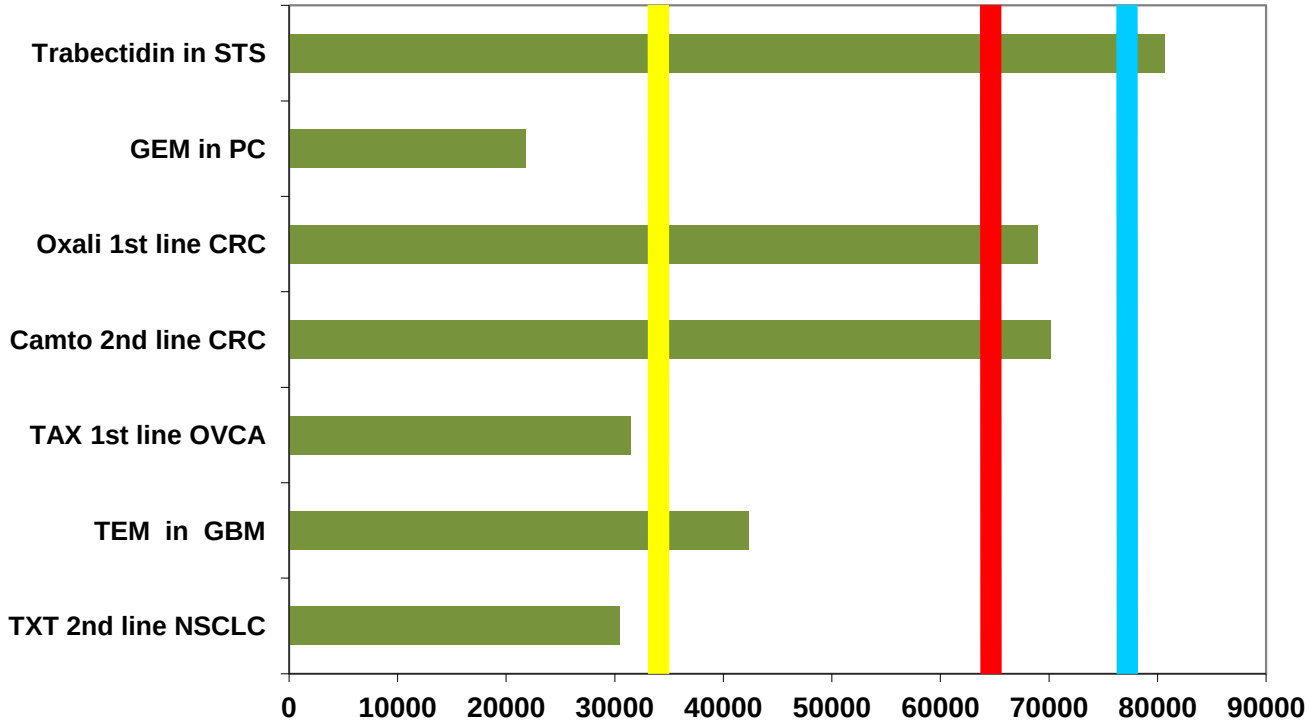
Quality Adjusted Life Years

Costs (€) per QALY
Cytotoxic drugs

Erasmus MC



Courtesy of J Verweij

- *Upper limit NICE*
- *Upper limit US Government*
- *Upper limit Dutch Government*
- *Median limit US Medical Oncologists*

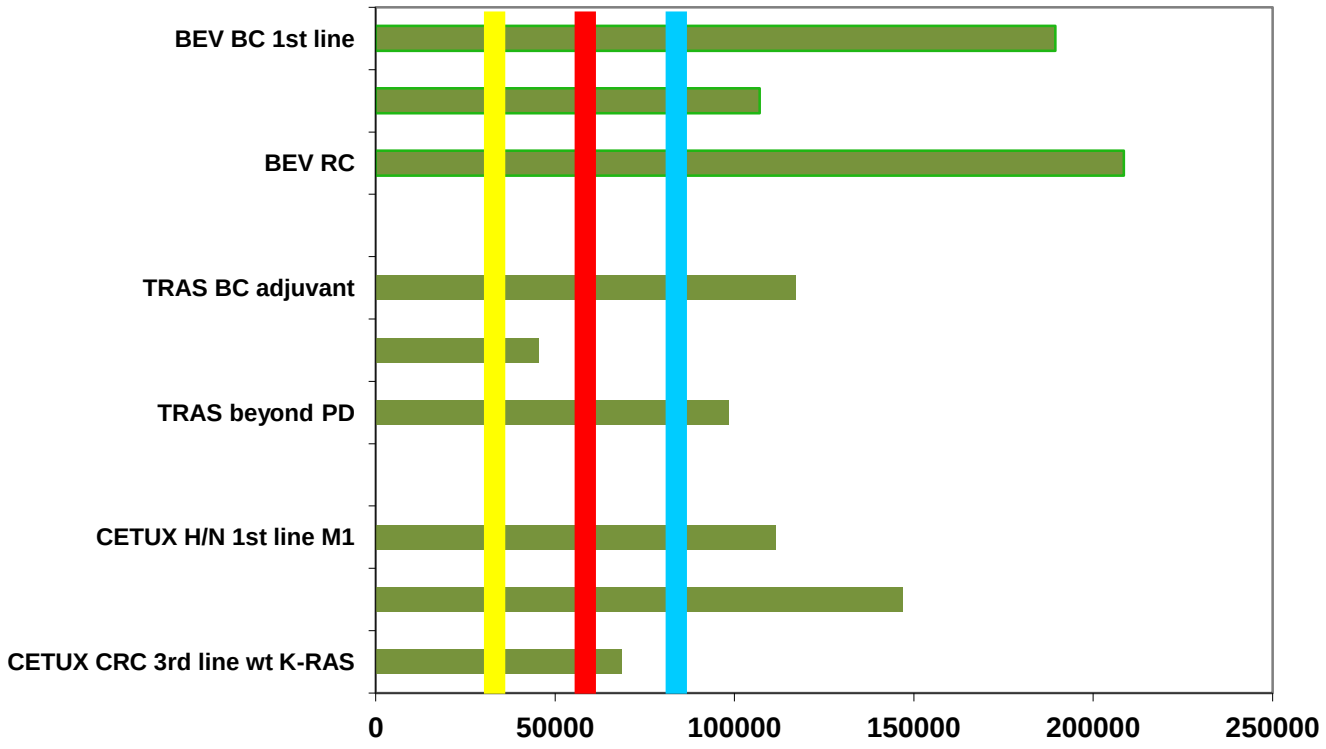
50 JAAR
AMBITIES VERBINDEN BOUWEN AAN EXCELLENTIE
GEZONDHEID, ONDERZOEK EN ONDERWIJS

Barret A et al, BMJ 2006; 333:1118-1120

Quality Adjusted Life Years

Costs (€) per QALY
Monoclonal antibodies

Erasmus MC



Courtesy of J Verweij

Dedes KJ et al; EJC 2009; 45: 1397-1406
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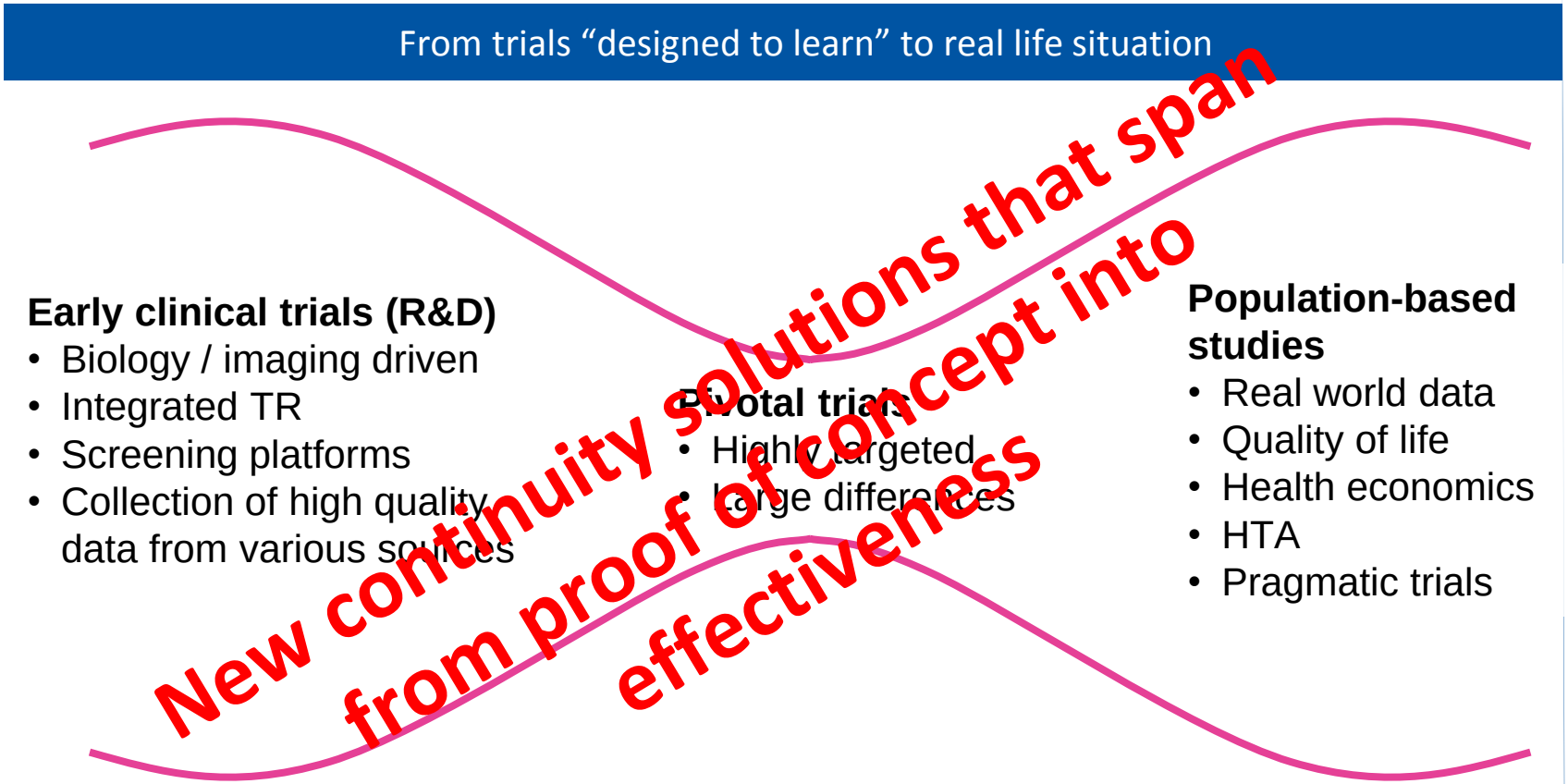
The changing clinical research pathway



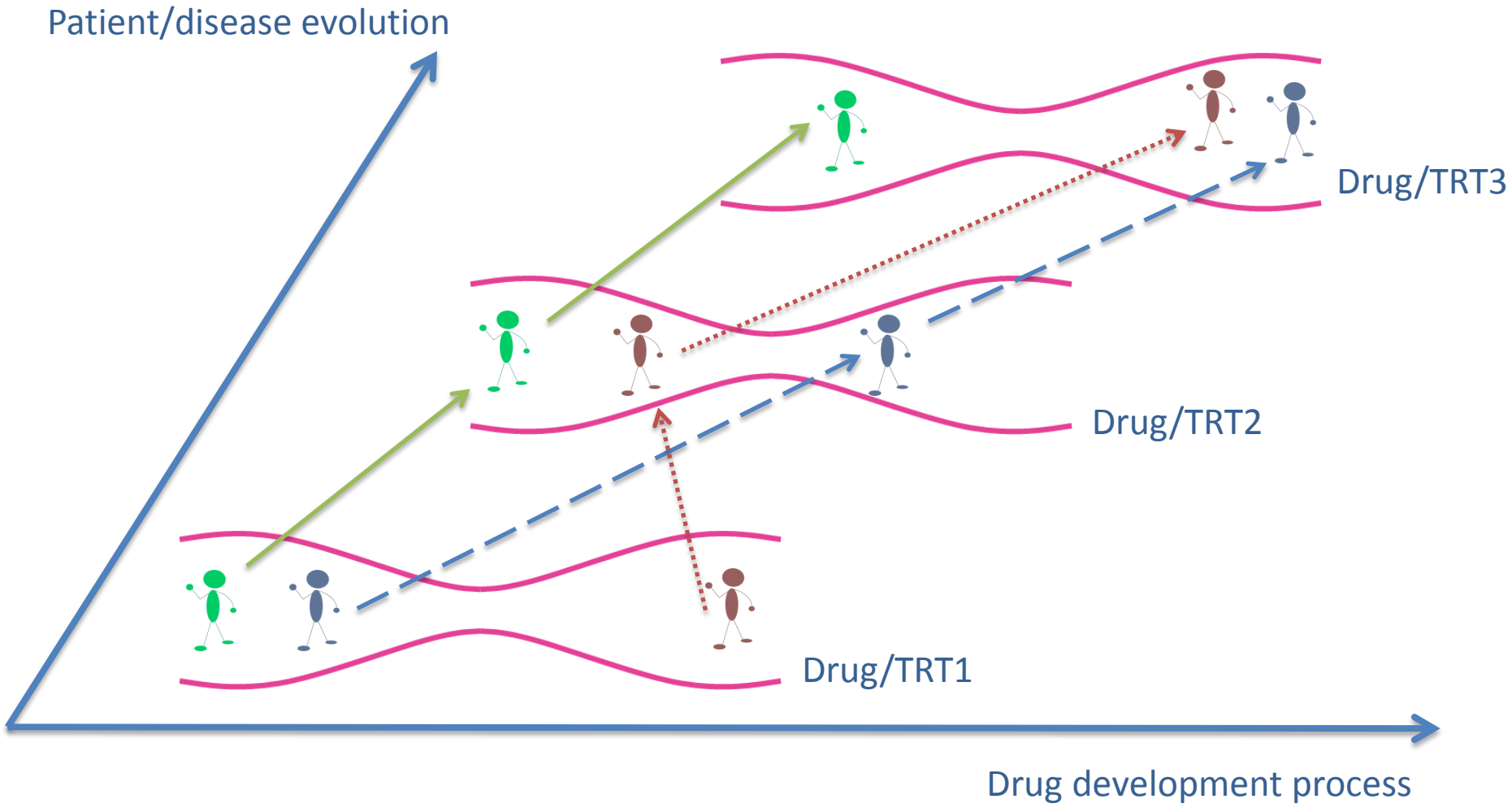
Burock et al. Eur.J.Cancer (2013), http://dx.doi.org/10.1016/j.ejca,2013.05.016

Selected but non exhaustive challenges…

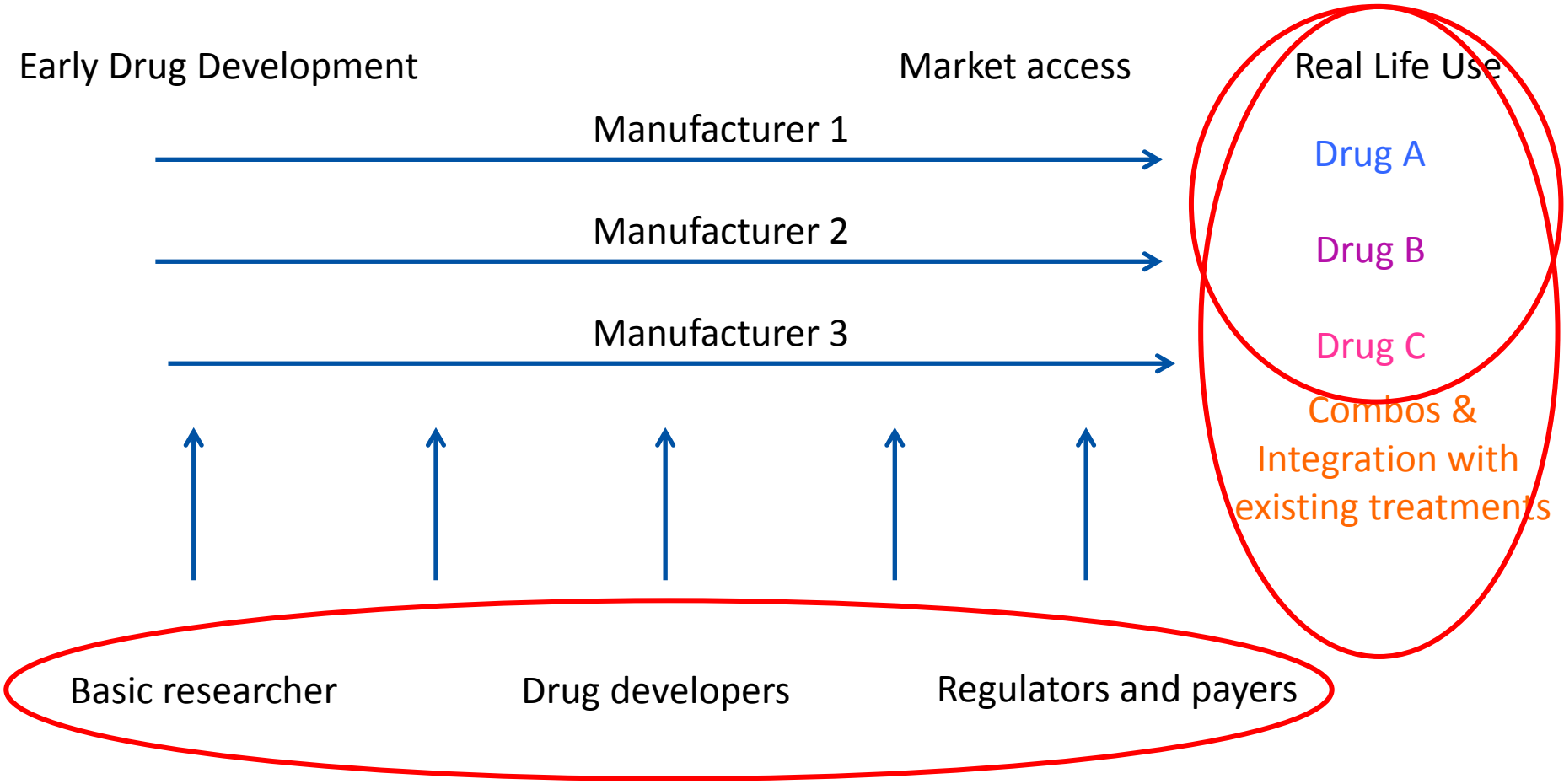
- Drug development is currently not patient centered
  - Protocols seeking patients ⟶ patient seeking protocols
  - One protocol/one drug/one population/one technology is non efficient
  - Sub-optimal anticipation of real life questions i.e. combinations…
  - Number of combinations novel-novel remain very small
  - Inappropriate set ups for long term outcome research
  - Patients do need continued solutions along the evolution of their disease (patterns of progression and resistance)

How to reconcile the continuum of care and the continuity of solutions for drug development?

The principle of dual longitudinal continuity



From R&D to real life…



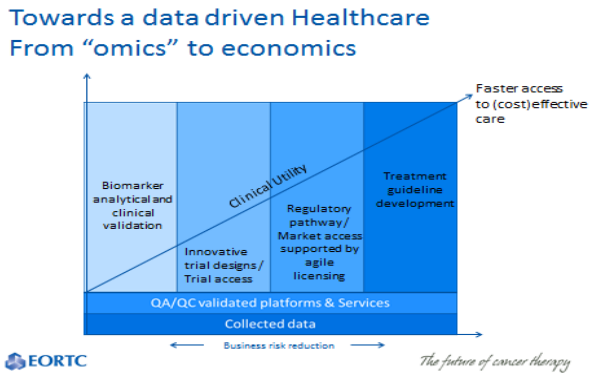
Transformation proposal

Longitudinal large scale data capture platform constantly curated and annotated

- Clinical
- Biological
- imaging

- Treatment details
- Outcomes

- Quality assurance parameters



TRANSFORMATION NEEDS 2 SPECIFIC ASSETS TO BE DEVELOPPED

New clinical research architecture

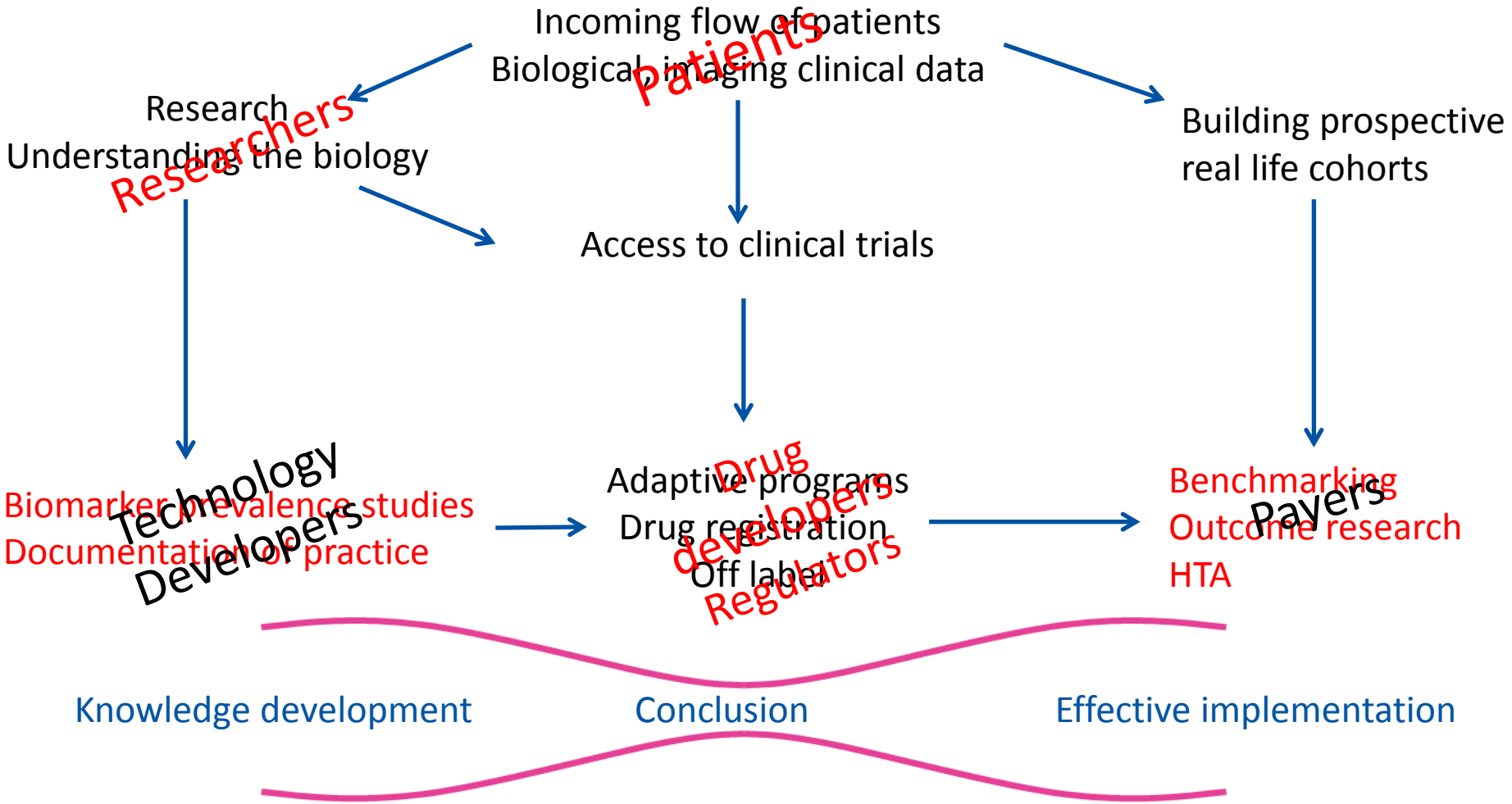
Patient centric
From real life into real life

Operational and regulatory innovation

Collaboration between and across stakeholders

- Multiple new drug development based on biology
- Application at any time of the drug development and beyond
- Standardisation of methodologies: designs, endpoints, technologies, populations etc…
- Shared control population/contemporary benchmarking solutions
- Permanent capacity for enrollment in clinical trials
- Complex clinical trials made easier: basket concept, adaptive designs, MAMS etc…
- Efficient data exchange compatibility
- Shared operational infrastructure

New access platforms / shared knowledge



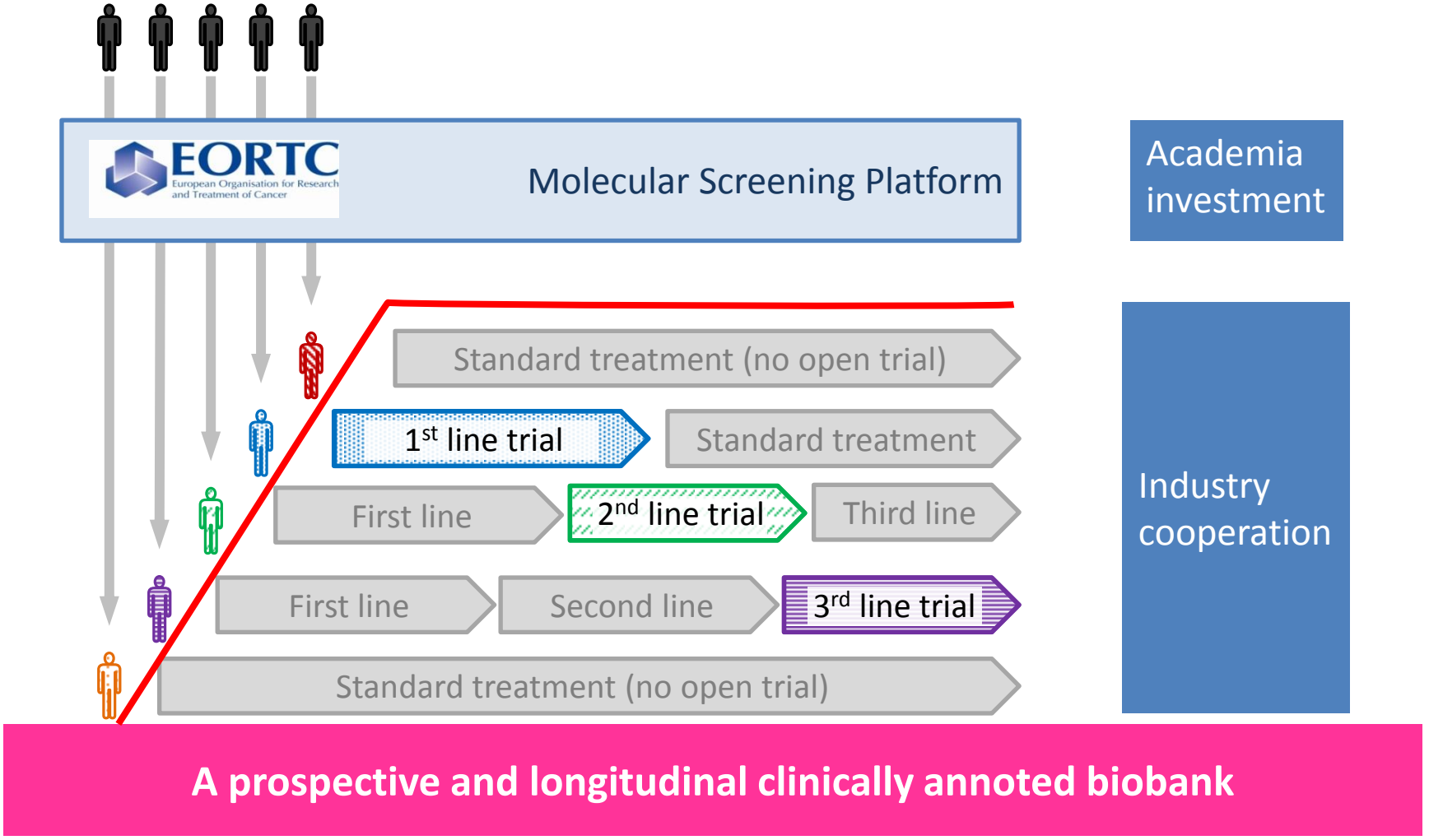
Expected deliveries

- Alignment of competencies of stakeholders
- Rapid identification of patient sub groups in a pre-competitive manner and expedite the start of clinical trials
- Connect more efficiently knowledge development to real life issues
- Benchmarking technologies/benchmarking populations/standardization of methodologies
- Long term outcome research across data sets i.e. immunotherapy

The ultimate need…

Independent data capture for all types of clinical, biological, imaging data and records alongside biomarker test results and all therapies received, in databases which are constantly curated and annotated

The SPECTA collaborative platform: Knowlegde development



28TH EORTC-NCI-AACR SYMPOSIUM

SAVE THE DATE

EORTC NCI AACR 2016

'MOLECULAR TARGETS AND CANCER THERAPEUTICS'

29 NOVEMBER 2016

2 DECEMBER 2016

MUNICH, GERMANY

Organised by ECCO

EORTC The future of cancer therapy

NATIONAL CANCER INSTITUTE

AACR American Association for Cancer Research