Can collaborative molecular screening platforms (CMSPs) support new forms of cancer clinical research?

SPECTA program
(Screening Patients for Efficient Clinical Trial Access)

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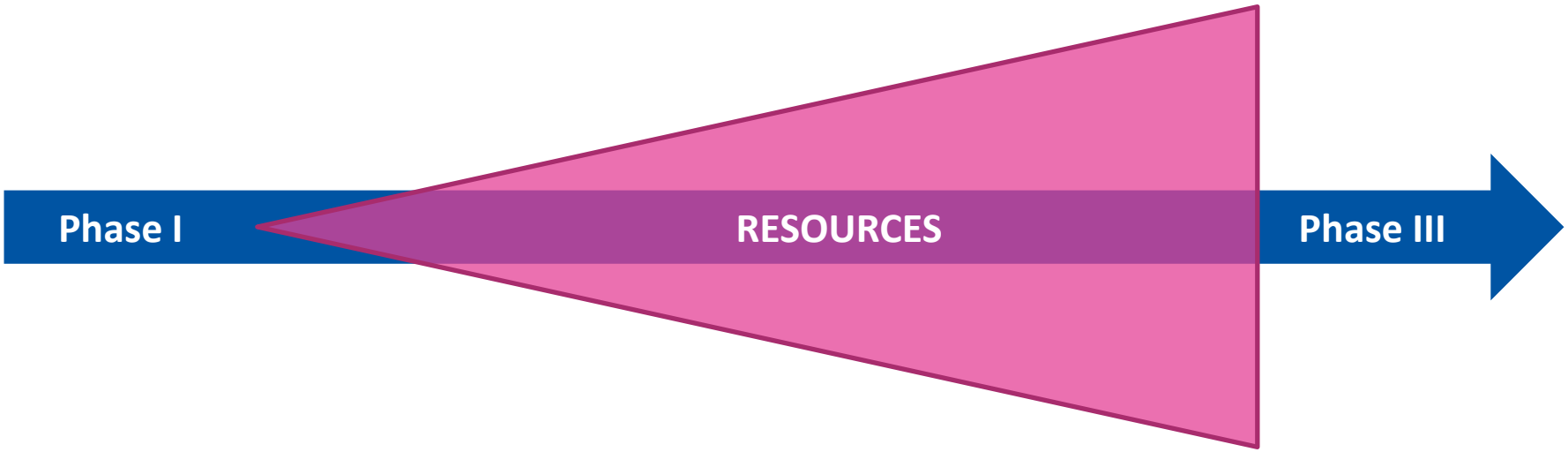
1. Rationale for SPECTA

Changing clinical research pathway (I)

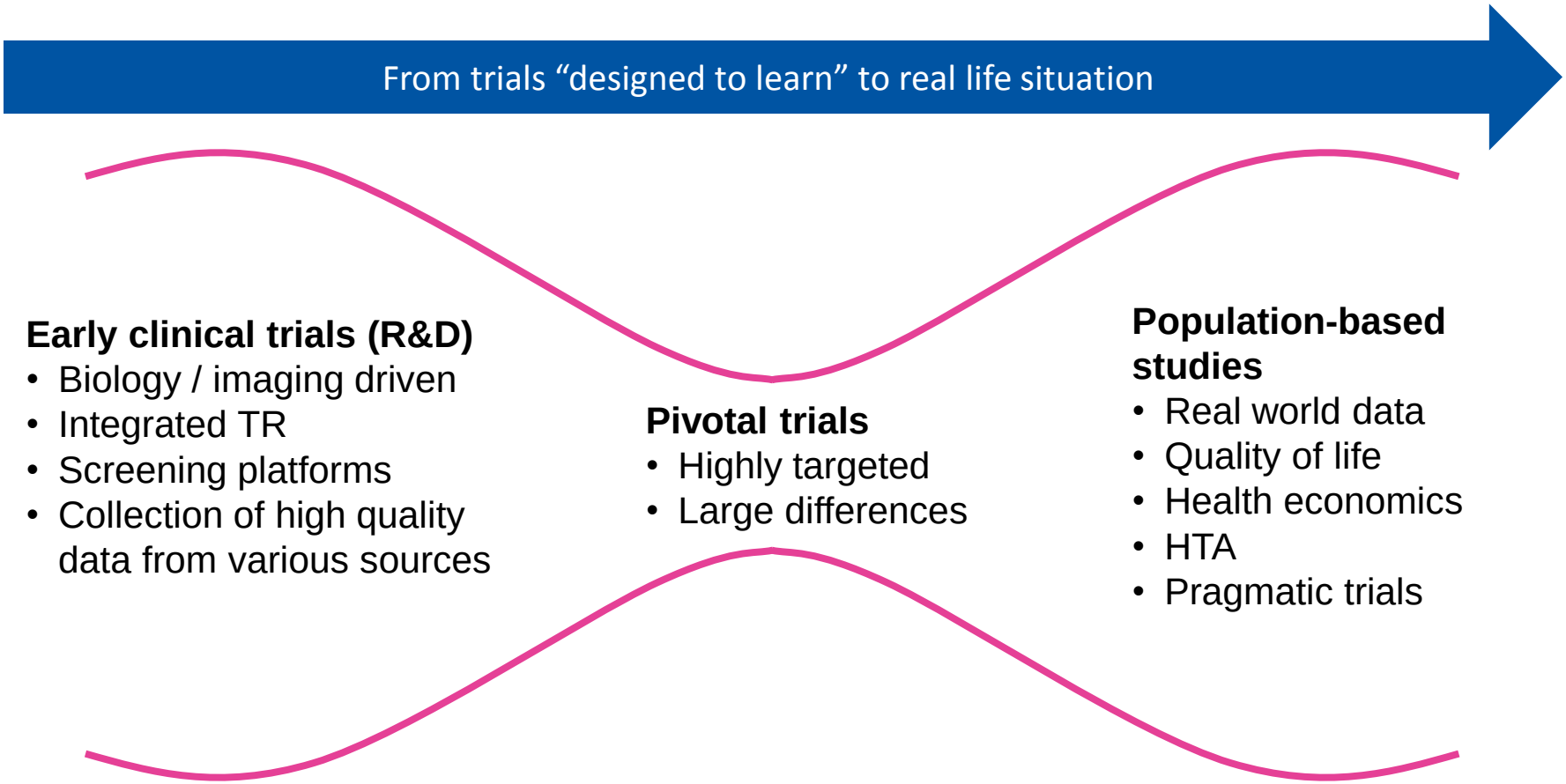
The classical model does not fit disease heterogeneity



The regulatory pathway is evolving towards

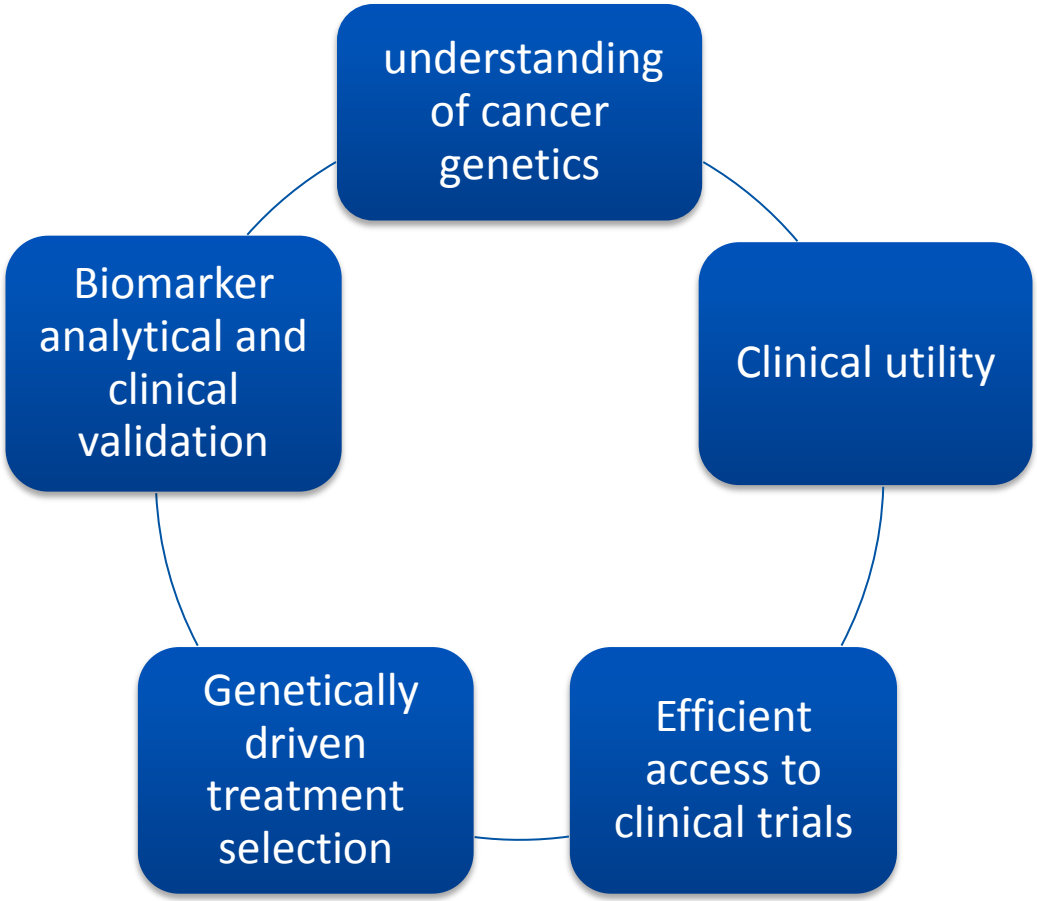
- Either document for sub groups at the end of all comers approach
- Or apply subgroup selection at start of development

The changing clinical research pathway (II)



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

Towards personalized drug development



Ambition: bring to Europe an international collaborative think tank infrastructure to build innovative forms and methods of clinical research

Why our set ups are sub-optimal?

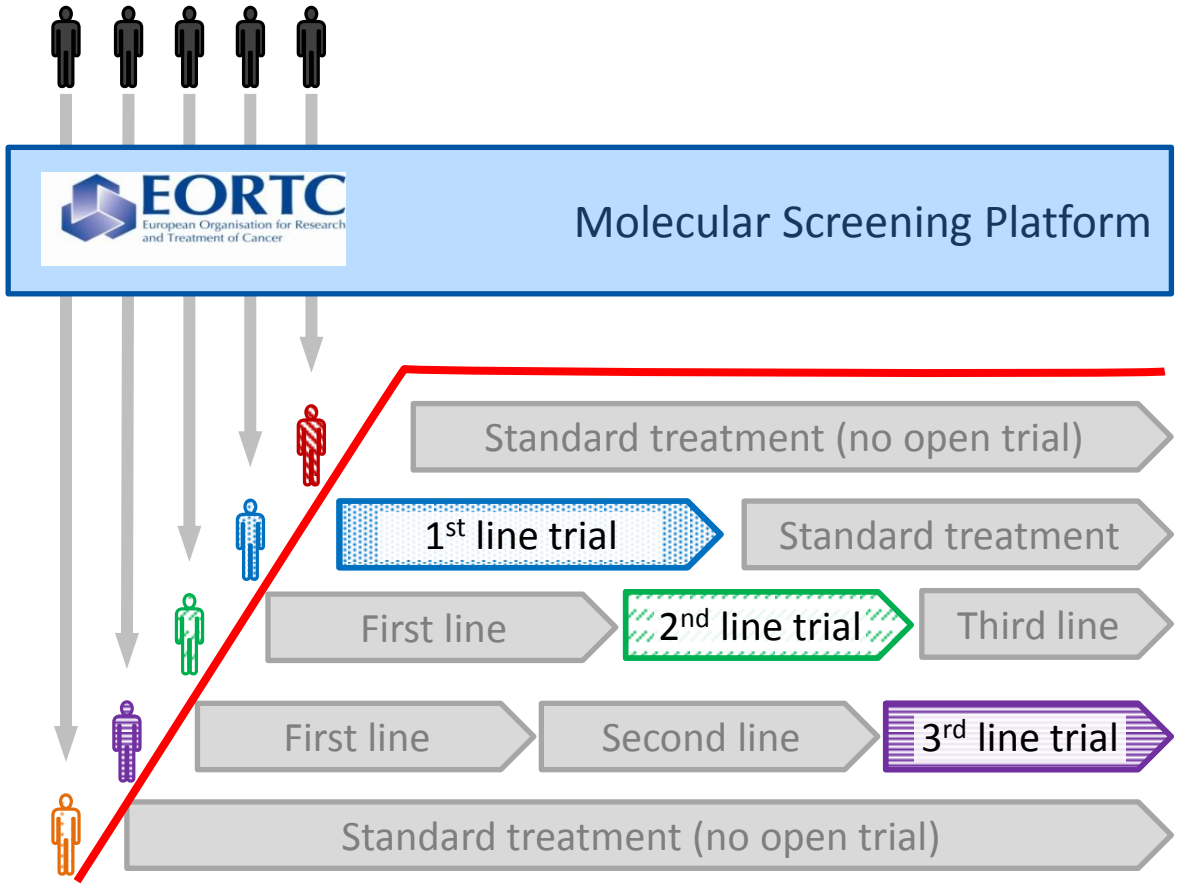
- Blurred lines between the classical phase I, II and III
- Duplicative and costly screening programs to target molecularly defined sub groups of patients
- No possibility to observe consistent groups of patients in a longitudinal manner to understand patterns of resistance and recurrence
- Chaotic benchmarking of emerging technologies
- Variability of QA/QC programs
- Varying bioinformatic approaches for data interpretation

4 main facts will drive oncology

- Developing new routes for market access, addressing the gap efficacy-effectiveness for new heath care models
- Long term follow up of patients, real life implementation, health technology assessment of therapeutic strategies
- Optimizing clinician access to high quality and reliable “omic” information
- Providing guidance for target assessment and molecular guidelines through tumor boards

2. What is SPECTA?

The SPECTA collaborative platform



Academic capture of biological sub groups coupled with technological expertise

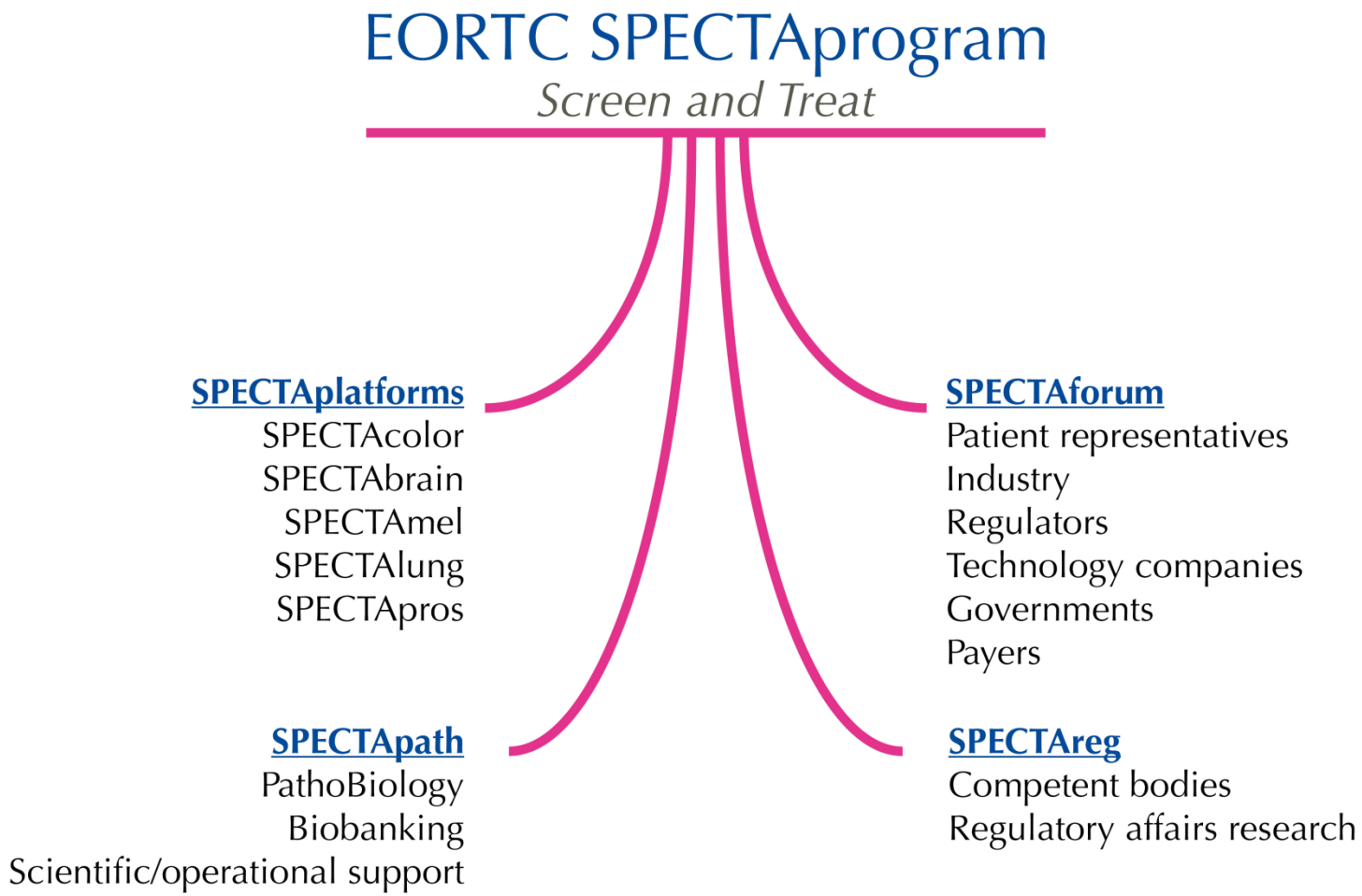
Industry Cooperation for drug development

EVOLVING TO NEW MODELS OF PARTNERSHIP

SPECTA is a value proposition taking into account the interests and needs of all staekholders

- ✓ Breaks the silo approach of drug development
- ✓ Provides clinically annotated biological material across tumor types
- ✓ Streamlines duplicative and costly screening programs
- ✓ Rapid identification of patients with specific genotypes
- ✓ Possibility to call back patients
- ✓ Integrated Drug/Biomarker/Drug Development solutions
- ✓ Cross validation and benchmarking of technologies alongside strict Quality Assurance/Quality Control criteria
- ✓ Chain of custody for biological material documented through e-infrastructure
- ✓ Central biobank audit compliant with regulatory standards
- ✓ Provides systematic NGS for all patients

SPECTA program: a forum for dialog and collaboration



3. How does SPECTA function?

SPECTA Platforms

The status on the SPECTA platforms

SPECTAplatforms:	
• **Colorectal cancer**	Accruing
• **Melanoma**	Protocol being finalized First investigator meeting done
• **Brain tumors**	Protocol being finalized
• **Lung cancer**	EORTC ETOP partnership Protocol being finalized
• **Prostate cancer**	Concept launched

SPECTAcolor actual status by numbers
(as of Sept. 17, 2014)

✓	10	countries
✓	30	sites
✓	22	sites have signed the consortium agreement
✓	26	sites with full EC and regulatory approvals
✓	19	sites authorized to enroll patients
✓	14	sites are actively enrolling
✓	412	patients enrolled
✓	3	intergroup set up

4. Ambitions and goals of SPECTA
New partnerships

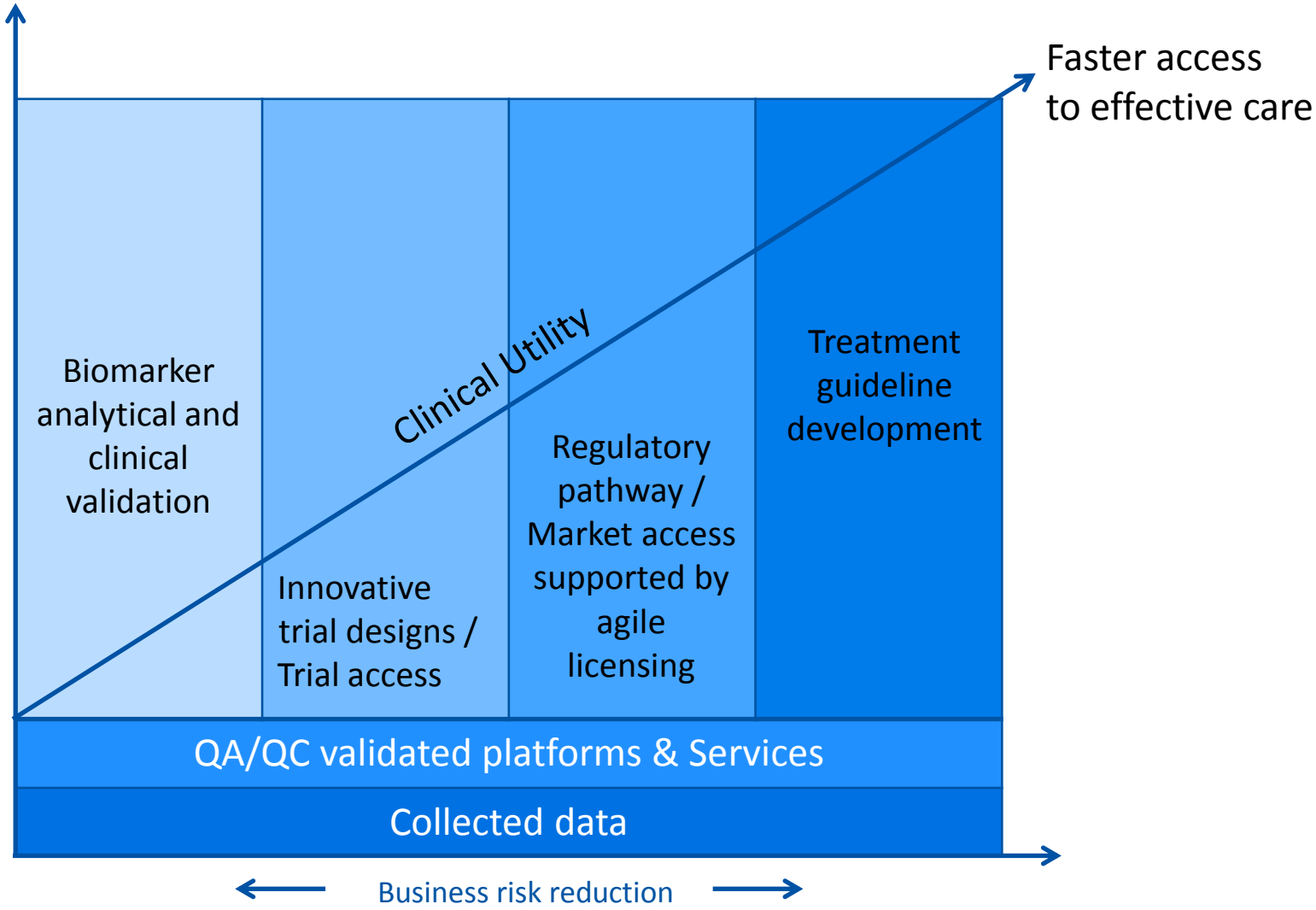
Agile approach to drug development

- Increase the efficiency for clinical trial access
  - Matched opportunities
    - Tumor-drug
    - Drug-biomarker
    - Biomarker-technology
    - Drug developers - Academic researchers
  - Increasing access for patients to trials
  - Scale economy / cost sharing models / PPPs
- Optimise the validation of emerging technologies for the service of drug development based on high QA/QC
- Regulatory acceptability of targets
- Develop a European vision for drug development and health care delivery (data & services)

Challenges

- To develop the adequate QA/QC environment for multigene/NGS panel -use in clinical decision making in the EU.
  - To address technical and (pre/post) analytical issues for assay development.
  - To develop guidelines for appropriate levels of Quality Assurance for biomarker assays and reporting
- To ensure uniform interpretability of genes and clinical correlations across platforms by performing permanent NGS ring studies..
- To establish the infrastructure and logistics for inter-European and transcontinental interlaboratory comparison studies for new emerging technologies such as NGS.

Towards data driven healthcare delivery

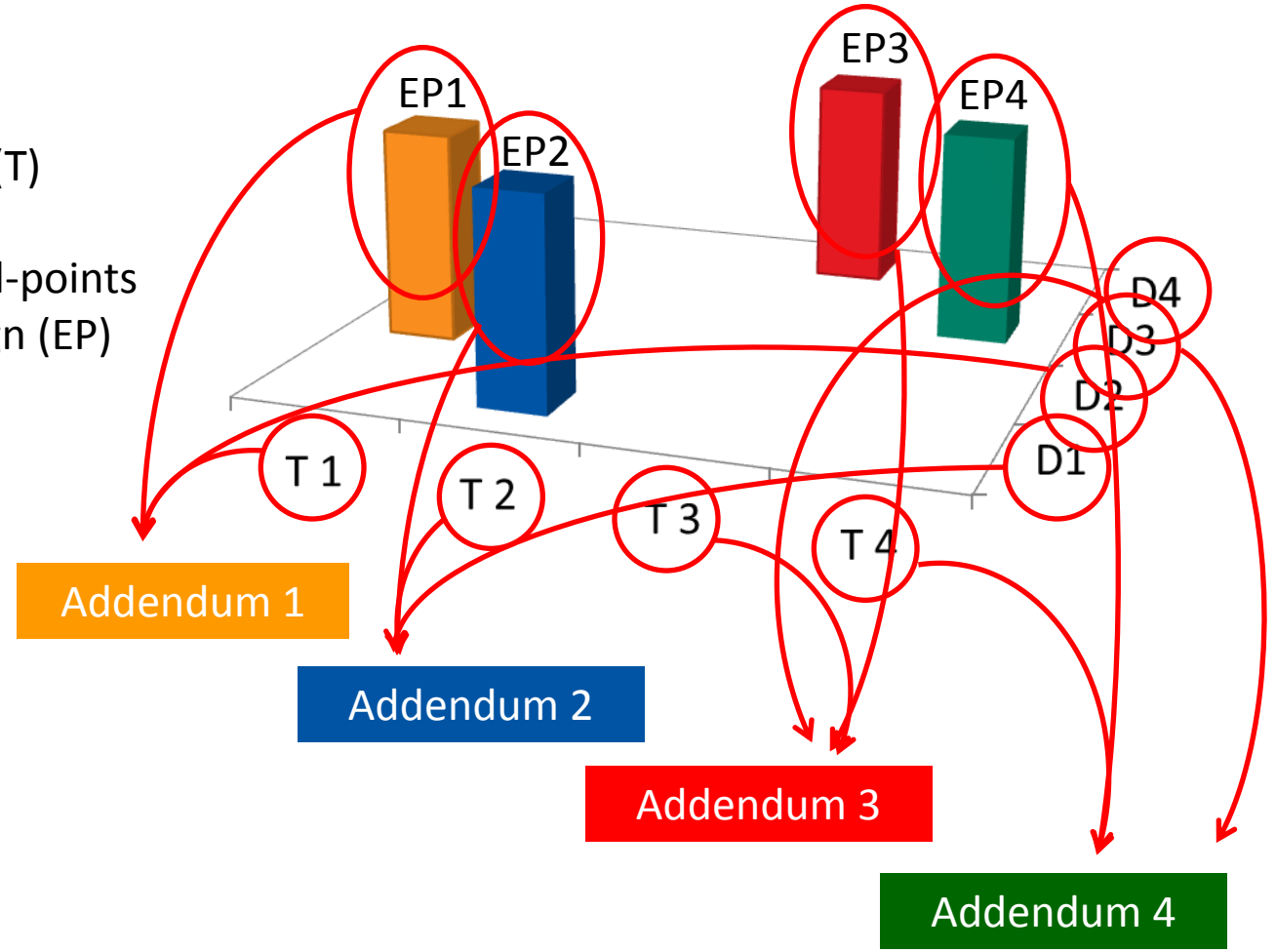


5. Agile access to downstream projects

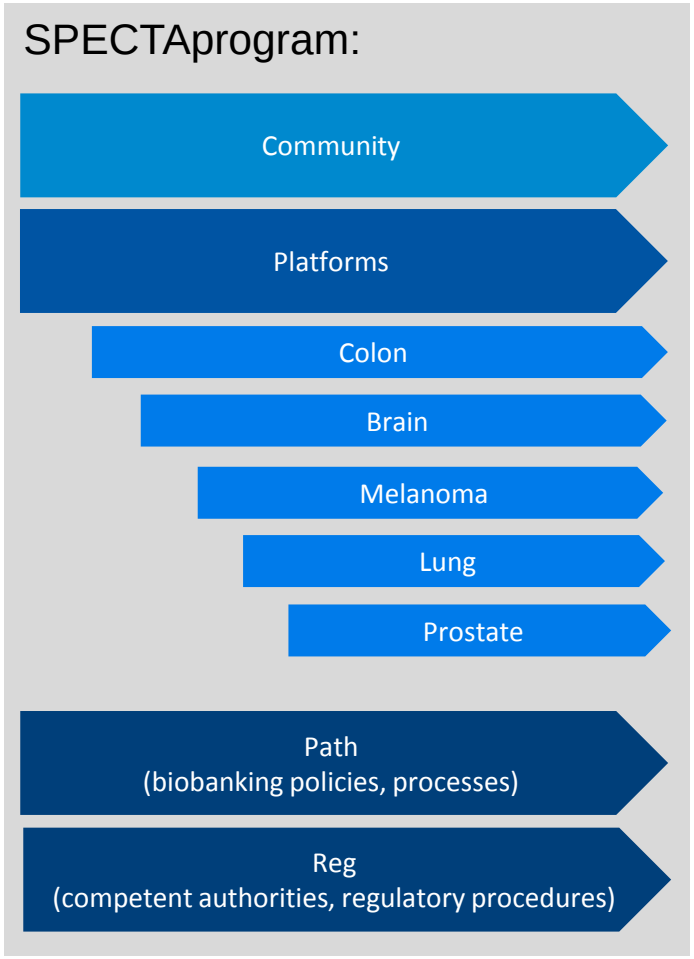
Regulatory flexibility in process

Master protocol

- Tumor eligibility (T)
- Tested drugs (D)
- Pre-specified end-points and related design (EP)



The EORTC SPECTAprogram value proposition



SPECTA, a place to meet…

- Efficient patient selection and access
- Quality assurance and safety
- Partnership & mutualisation of efforts
- Access to new technologies
- Biomarker qualification and validation
- Cost efficiency / cost sharing
- Business risk reduction
- Addresses the efficacy & effectiveness gap
- Access to knowledge

The way to….

- Specific treatment guidelines
- Reducing the costs of diagnostics and treatments

Could be achieved by clinical use of sequencing data

But it will require changing approaches to clinical research so that genetic information can be

- Stored
- Analyzed
- Disseminated in a timely and affordable manner

Changing healthcare models and systems

A major academic commitment…

- EORTC Board
  - R. Stupp
  - S. Tejpar
  - F. Cardoso
  - F. Meunier…
- The EORTC groups
  - Colo-rectal: A. Roth, G. Folprecht
  - Melanoma: L. Eggermont, C. Robert
  - Brain: M Weller, M. van den Bent
  - Lung: B. Besse
  - Prostate: B. Tombal, M Spahn
  - PBG: R. Salgado, D. Aust
- ETOP (SPECTAlung)
  - R. Stahel
  - S. Peters
- EORTC HQ
  - V. Golfinopoulos
  - CRP: C. Messina, R.Karra, S Marreaud, J. Menis
  - TR: E. Varin, E. Szepessy
  - Legal: A. Negrouk
  - And all the operational staff…
- EMA: M. Papaluca, F. Pignatti
- ESP: H. van Krieken, F. Bosman
- Patient advocates