



## SPECTA

Screening Patients for Efficient Clinical Trial Access

Recent developments of the EORTC collaborative program towards precision medicine

## Why SPECTA?

The understanding of tumor biology has improved, continues to expand at a rapid pace, and is opening new opportunities for cancer clinical trials. The identification of molecular alterations in the cancer, and the possibility to specifically and selectively target them, has dramatically improved treatment efficacy in cancer patients.

SPECTA has embraced this change. Through SPECTA, oncologists can now allocate patients to clinical trials based on both their clinical characteristics as well as the molecular profiles of their tumors, and going a step further, can help identify new sub-groups of tumors. This EORTC research program also provides the opportunity to conduct further research that might lead to the identification of new biomarkers or help in the planning of future clinical trials.

Positioned in Europe as a unique, international, cross tumor, and multidisciplinary clinical research infrastructure, the EORTC stands out with supportive assets that enable it to integrate clinical, biological, and imaging data with high quality, longitudinally annotated human biological material collection in a regulatory compliant environment, all guiding principles and pillars at the basis of the SPECTA Program.

## What is SPECTA?

SPECTA is a pan-European network built by EORTC with key institutions collaborating to provide efficient access for patients to molecularly driven clinical trials.

Disease-specific screening platforms for colorectal, lung, melanoma, brain, and rare cancers optimize drug access, precision medicine, and new healthcare delivery.

To date, the SPECTA platforms for colorectal cancer and thoracic tumors are fully operational, thus proving that a logistically complex infrastructure to run innovative trials in a multinational setting is feasible.

### An EORTC comprehensive program towards precision medicine

#### SPECTAplatforms

SPECTAcolor  
SPECTAlung  
SPECTAmel  
SPECTAbrain  
SPECTApros  
SPECTArare  
(Prospective)

#### SPECTAleads

##### Addresses drug developments

Stakeholders: Academia, Patients, Pharmaceutical & Diagnostic companies, Payers, Governments, Regulators

#### SPECTApath

- Human biological material collection, Storage and processing in clinically annotated biobanks
- Molecular screening (Next Generation Sequencing) and relevant single target tests
- Quality assessment/Control including HTA (Health Technology Assessment)

#### SPECTAreg

##### Addresses regulatory issues

Procedures  
Licensing  
Market access  
Implementation

## A collaborative network for reliable and effective cancer management, innovative drug and companion diagnostic development for healthcare

### SPECTA: The key to precision medicine

- Collaborative longitudinal clinically annotated biobanks and molecular screening platforms, shared risk and benefit model between academia, industry and healthcare providers
- Rapid access to patients' clinico-pathological data and molecular profiles to identify molecular sub-groups of patients based on biomarker identification and validation
- Efficient access to innovative, biomarker driven, statistically sound basket clinical trials within the individual platforms and cross-platform umbrella trials targeting specific molecular alterations for small cohorts of patients
- Integrated biomarker/drug/companion diagnostic development solutions
- Cross-validation and benchmarking of innovative technologies (Health Technology Assessment) alongside strict Quality Assurance/Quality Control criteria
- Large sets of patient-level clinical and biological data for real life benchmarking in support of adaptive licensing for specific drug development challenges such as multiple combinatorial approaches

SPECTA breaks the current silo approach to precision medicine

A European vision of drug development and healthcare delivery through the prospective development of longitudinal clinically annotated biobanks and molecular tumor profiling

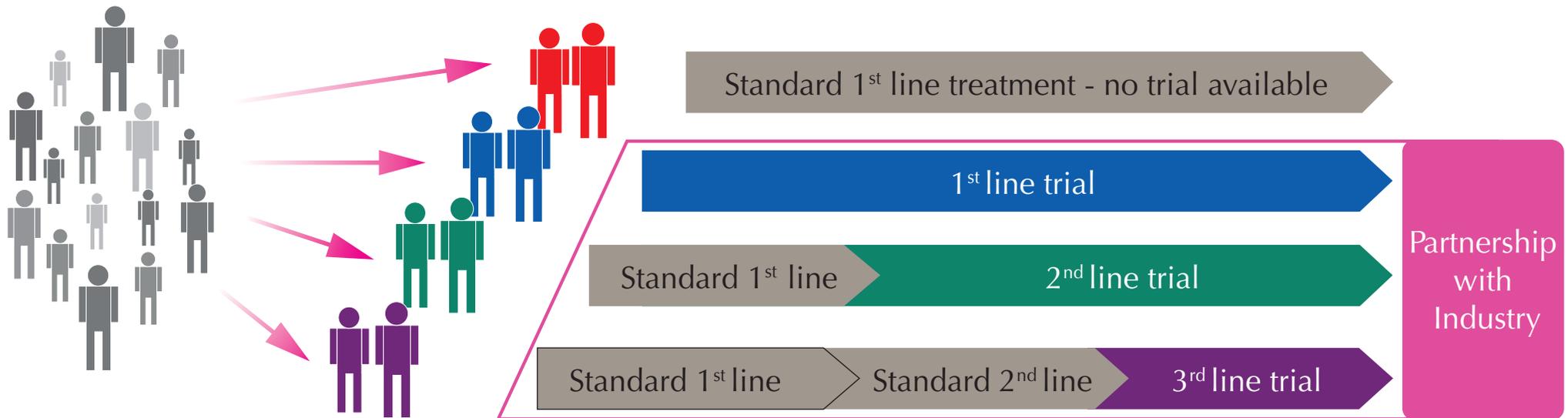
A wide network of specialists for an improved access to the latest treating technologies regardless of geographical differences

Clinical trial access made possible for smaller cohorts of patients with specific molecular profiles



## SPECTA: An EORTC precision medicine program tailored for stakeholders

### ACADEMIC INVESTMENT

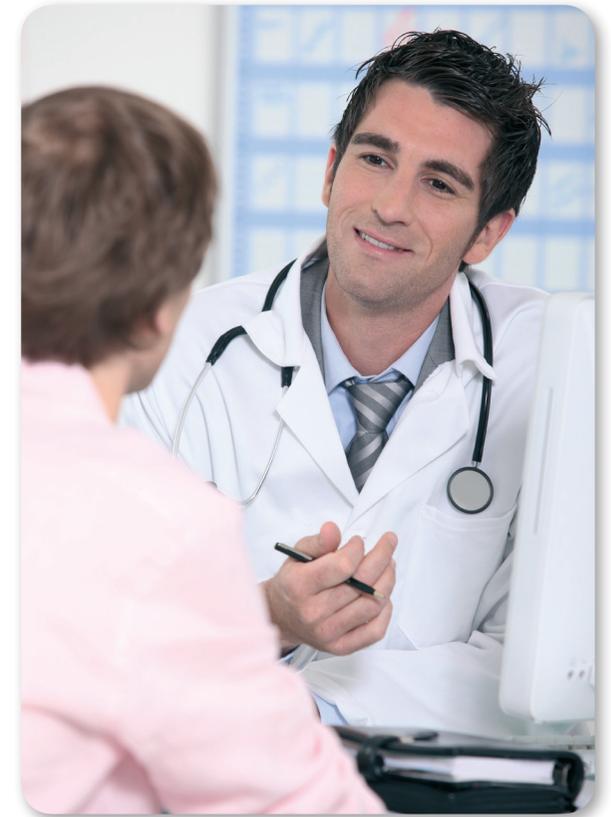


### Streamlined cross border operational access for patients and their treating physicians to precision medicine clinical trials

- Single informed consent patient signature and procedures for potential access to multiple trials
- Centralized Quality Assurance/Quality Control performed by certified pathologists (tissue and liquid samples plus derivatives such as DNA/RNA)
- Rapid and thorough personalized molecular tumor profiling including targeted next generation sequencing for all known recurrent cancer genes
- New improved access to the latest treating technologies regardless of geographical differences towards a better clinical outcome for patients
- Access to clinically targeted clinical trials offered to all patients whenever possible
- A wide and robust network of cancer specialists with extensive expertise to ensure best clinical practice and avoid duplication of effort
- Availability of EORTC driven educational initiatives to raise patients' awareness on the importance and potential benefits of clinical trials

## New research opportunities for scientists (Medical Doctors, Pathologists, Molecular Biologists)

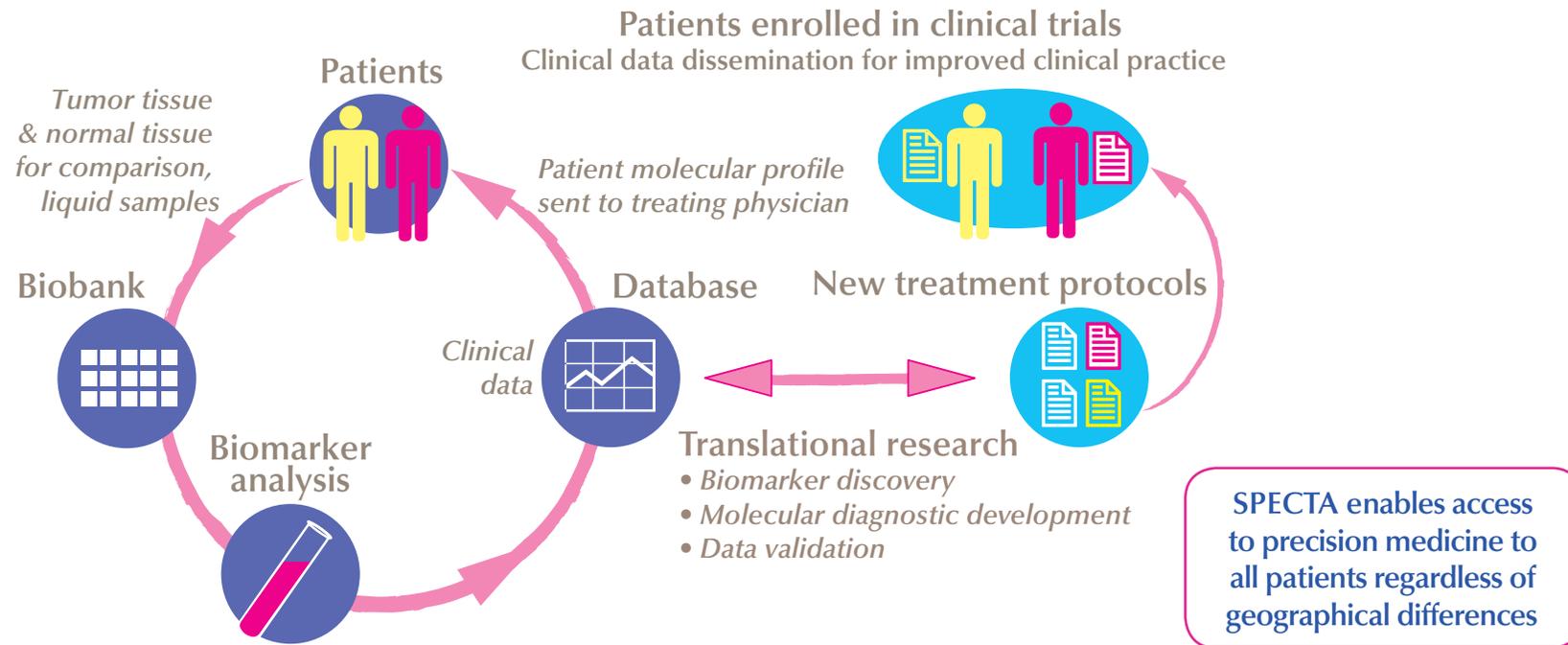
- Integrated clinical and translational research infrastructure in international settings
- Facilitated operations through single entry point to multiple possible studies
- Access to high quality clinically annotated biological material for research purposes
- Genetic data biomarker discovery through validation research studies
- Longitudinal patient follow-up improves understanding of disease evolution/progression patterns and therapeutic response
- Standardized process ensures comparability of outcomes
- **New!** Clinical trial access now possible for smaller cohorts of patients with 'rare' combination of mutations
- Human biological materials made available upon request for additional profile analyses for trial entry



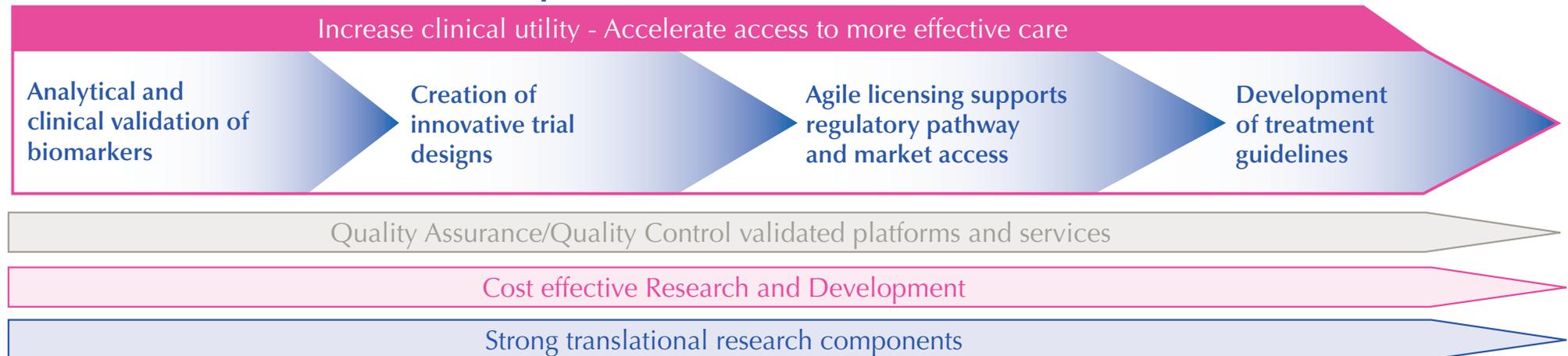
## Provision of agile partnership models for drug developers/pharmaceutical industry in compliance with European regulatory bodies

- Economically attractive cost and benefit sharing models
- Closing the gap between efficacy and effectiveness enabling faster market access
- Efficient benchmarking of emerging biomarkers
- Timely activation of specific downstream studies via pre-agreed regulatory models
- Matched opportunities for tumor-drug, drug-biomarker, drug-diagnostic biomarker technology, drug developer/academic researchers
- Database compliant with CDISC/CFR 11
- Development of standardized Quality Assurance/Quality Control procedures in consultation with regulators
- Launch of innovative trials to improve clinical practice to benefit patients and real life benchmarking (including combinatorial approaches in rare sub-groups)

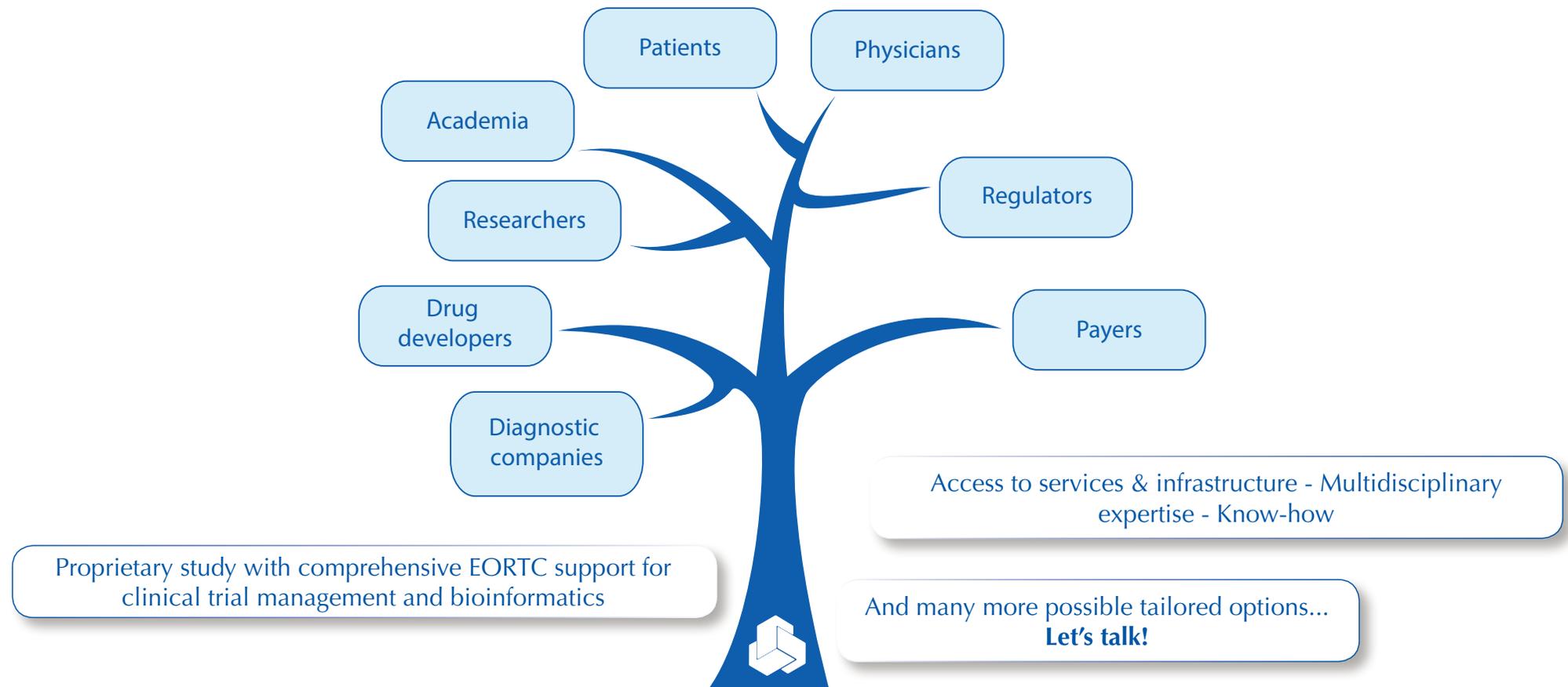
## How does SPECTA work in practice?



## Towards data driven healthcare and an improved return on investment



## Models of collaboration



Cancer genetics has led to increasingly fragmented populations eligible for specific treatments. Precision medicine targets specific sets of molecular alterations, only useful for the relevant subsets of patients. The complexity of the underlying cancer biology and the high economic costs (R&D, regulatory requirements for clinical trials, market authorization) associated with the drug development of these products expose companies to high economic risks.

The SPECTA investigators, all recognized worldwide for their expertise in their fields, fulfill and commit to a set of basic criteria: quality of care, numbers of patients, laboratory infrastructure, availability of dedicated oncology facilities, and high recruitment of patients in clinical trials.

**Interested in knowing more? The EORTC has it all.**

SPECTA is an initiative of the EORTC  
For any further information, please visit [www.eortc.org](http://www.eortc.org)

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