

# Research and care: partners for access to innovation

A view of the EORTC for boosting the social  
impact of innovative cancer research in the  
context of the mission-oriented approach to  
cancer

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# Accrual of screened patients in EORTC clinical studies from 2000 to 2017: 91771 patients

European Union: 82136

France: 18080

Netherlands: 17486

Belgium: 10030

United Kingdom: 8803

Germany: 8437

Italy: 7769

Spain: 4023

Poland: 1368

Sweden: 995

Austria: 977

Portugal: 759

Denmark: 663

Slovakia: 481

Slovenia: 472

Hungary: 393

Croatia: 374

Ireland: 304

Czech Republic: 220

Greece: 114

Cyprus: 101

Estonia: 69

Finland: 67

Bulgaria: 51

Latvia: 35

Malta: 20

Romania: 20

Lithuania: 16

Luxembourg: 9

Non-European Union: 3774

Switzerland: 2124

Turkey: 631

Norway: 497

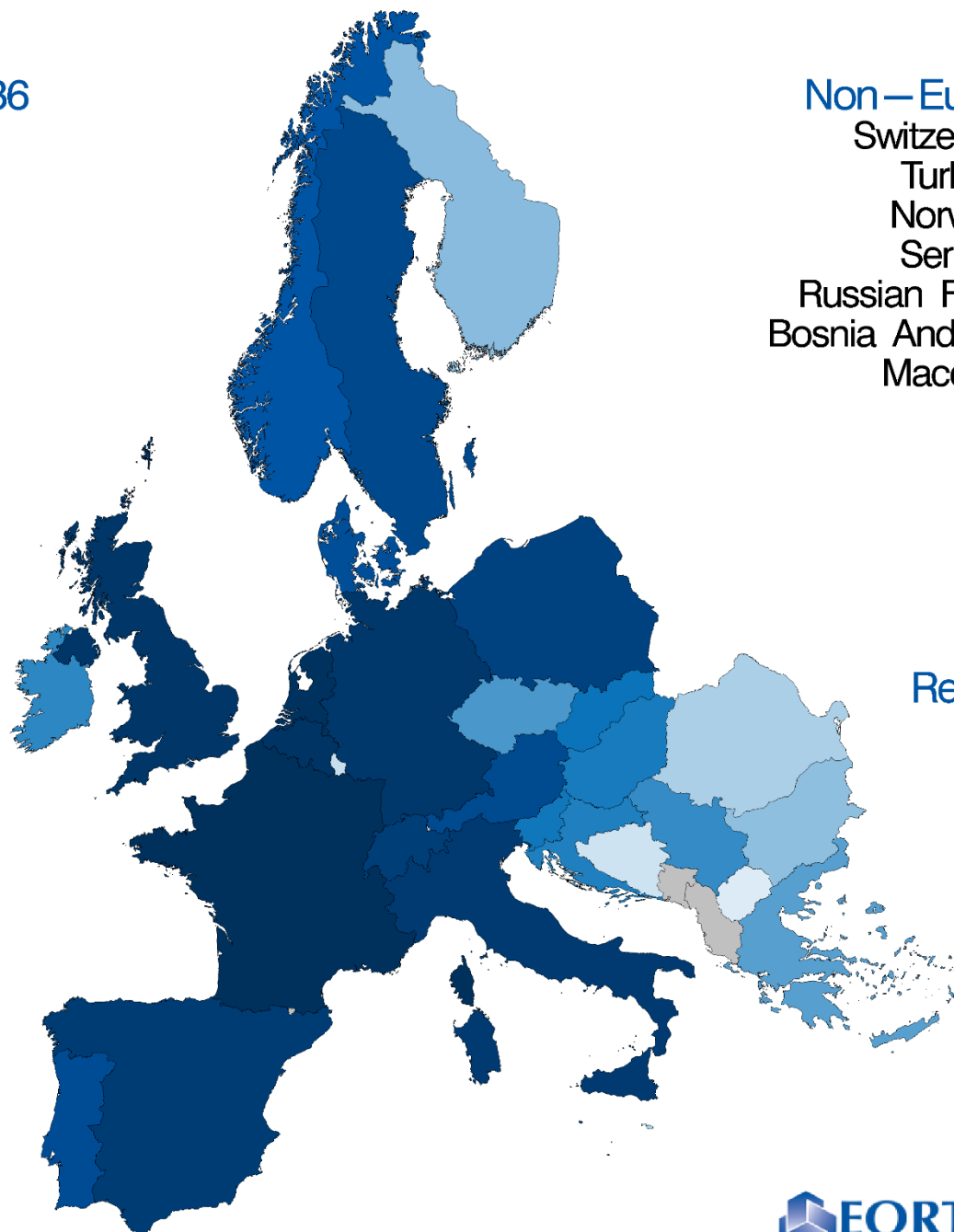
Serbia: 287

Russian Federation: 221

Bosnia And Herzegovina: 8

Macedonia: 6

Rest of the world: 5861



# The changing clinical research pathway

From trials “designed to learn” to real life situation



## Early clinical trials (R&D)

- Biology / imaging driven
- Integrated TR
- Screening platforms
- Collection of high quality data from various sources

## Pivotal trials

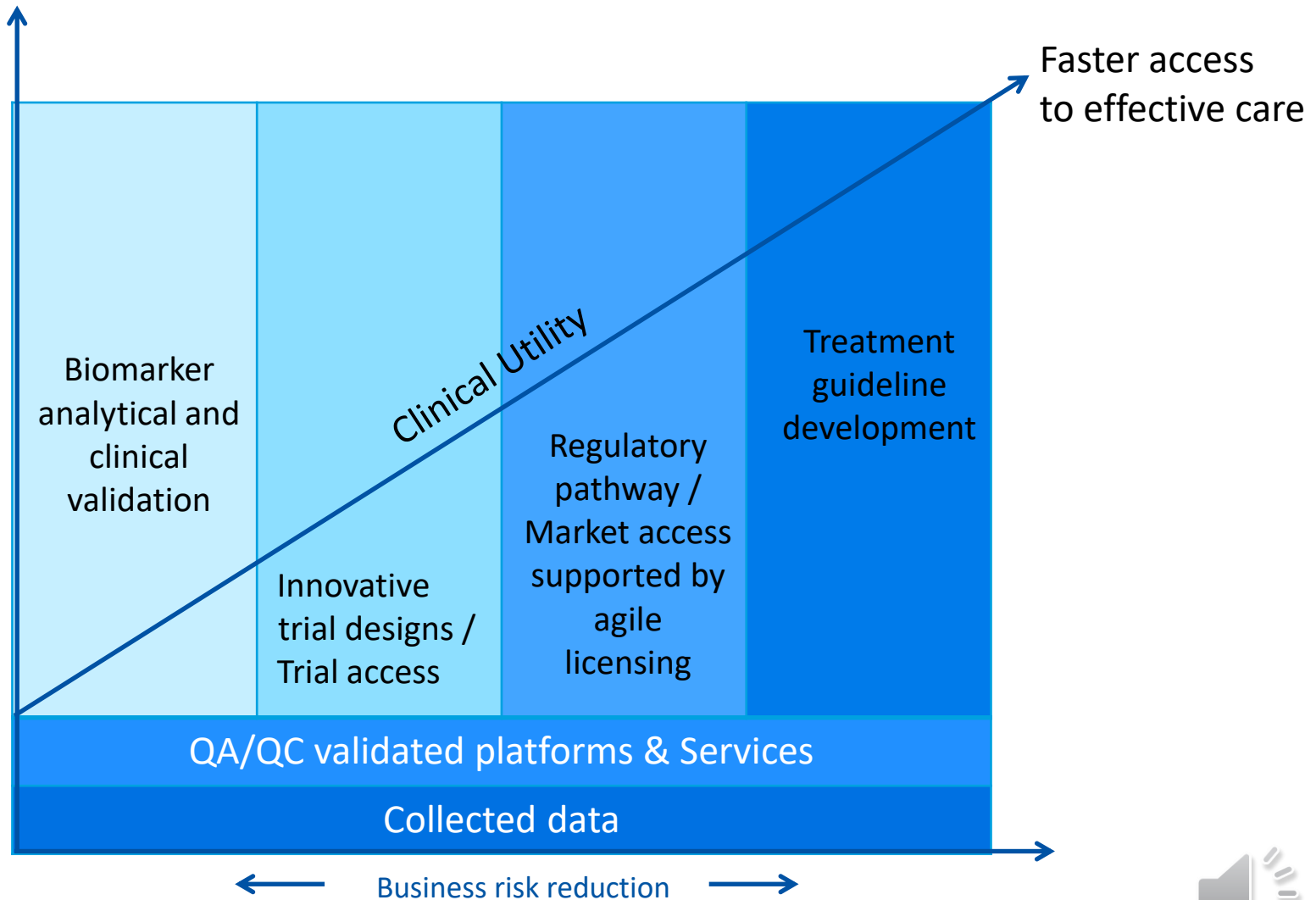
- Highly targeted
- Large differences

## Population-based studies

- Real world data
- Quality of life
- Health economics
- HTA
- Pragmatic trials

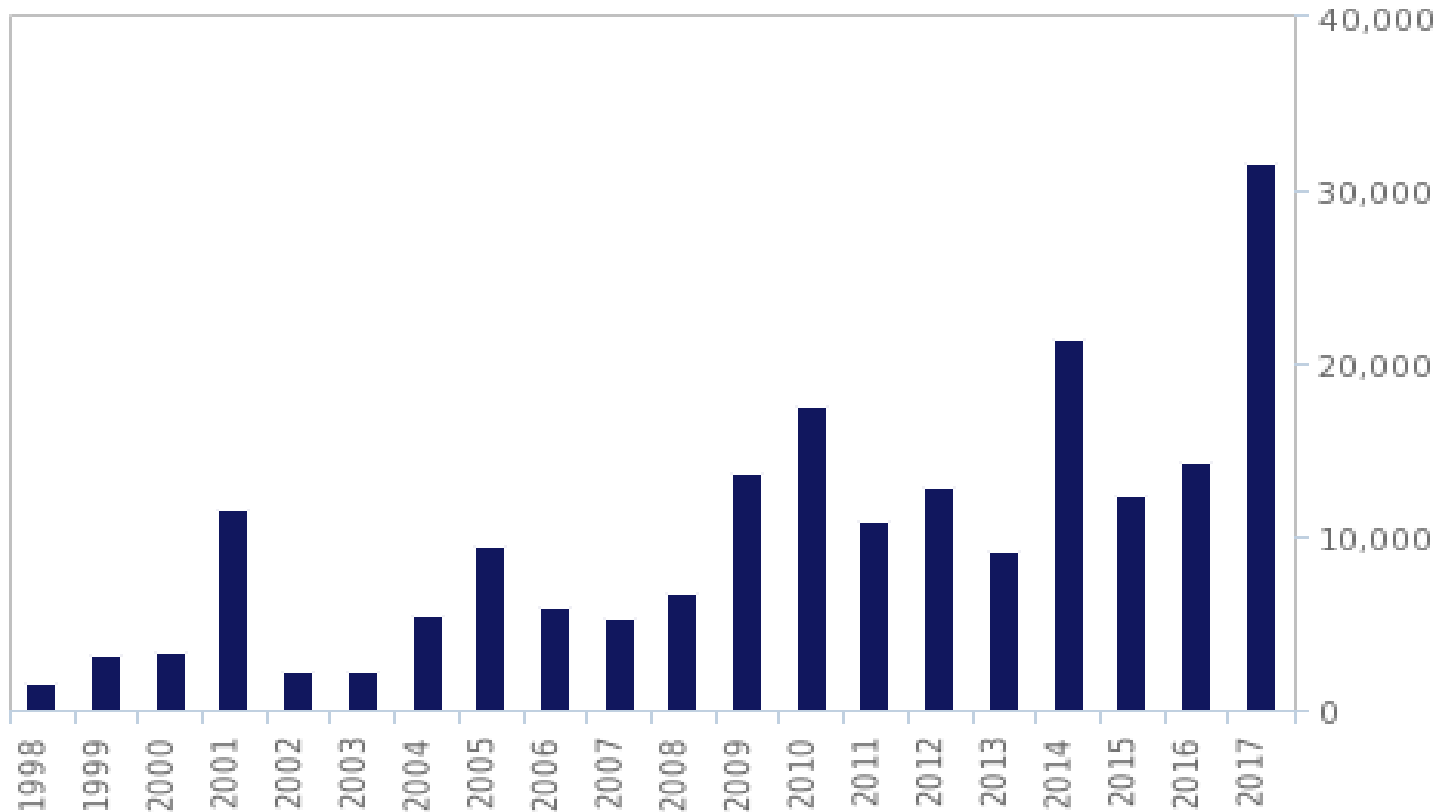


# Towards a data driven Healthcare



# Cancer Prices Rising Significantly

## Average Cancer Drug Costs per Month (USD) in June 2018



Source: *Memorial Sloan Kettering Cancer Center, BMI  
Cancer Drug News of June 6, 2018*

# Selected challenges

- Regulatory trials aim at documenting new drugs but....
  - Primary end-point(s) frequently purely drug centered
  - Heavily selected populations
  - Control arm, possibly debatable
  - Poor external validity
- Clinically needed questions are not addressed i.e.
  - Optimal patient population/ cut-off values of biomarkers
  - Combination and sequence
  - Duration of treatment
  - Rarer tumor are not addressed
- Nevertheless, treatment access of expensive new drugs is made on such datasets



# Critical observations

- The forms and the methods for clinical research and treatment access should be revisited through the continuum of development
- Drug development and patient centeredness may be a continuation of the process across stakeholders based on role and missions
- Independent pragmatic studies/data sets should inform the ultimate users of treatments for optimal use. It is being referred as applied clinical research
- Clinical research and health care systems are long due for complementary transformation.



# Possible solutions

- Applied clinical research should be central for robust informative datasets made available to patients, doctors and society for rationale decisions
- Re-align the sequence and roles of stakeholders in the process of research, embedding applied clinical research
- Evolve towards patient centeredness addressing knowledge development and changing practice in an informative manner for society
- Always, strive to produce robust evidence based on solid prospective research
- Establish systems reaching all patients which are anticipative and agile as technology evolves
- Implement pragmatic solutions associating and educating all health care providers for delivering constantly evolving standards of care according to latest science.





# Suggested readings

- Availability of evidence of benefits on OS and QoL of cancer drugs approved by EMA: retrospective cohort study of drug approvals 2009-2013. Davis C, et al. *BMJ* 2017;359:j4530/ doi:10.1136/bmj.j4530
- Research: increasing value reducing waste. *Lancet Series* vol 383, 2014
- Applied Research and Development in Health Care-Time for a Frameshift. Lieu T, Platt R. *N Engl J Med* DOI:10.1056/NEJMp1611611
- Why most clinical research is not useful? Ioannidis J. *PLoS Med*, DOI:10.1371/journal.pmed.1002049
- Real-World Evidence- What is it and what can it tell us? Sherman R. et al. *N Engl J Med*. DOI:10.1056/NEJMs1609216





# EORTC

European Organisation for Research  
and Treatment of Cancer

*The future of cancer therapy*

