Opportunities for Clinical Research Transformation EORTC's lessons learned for precision medicine in Europe

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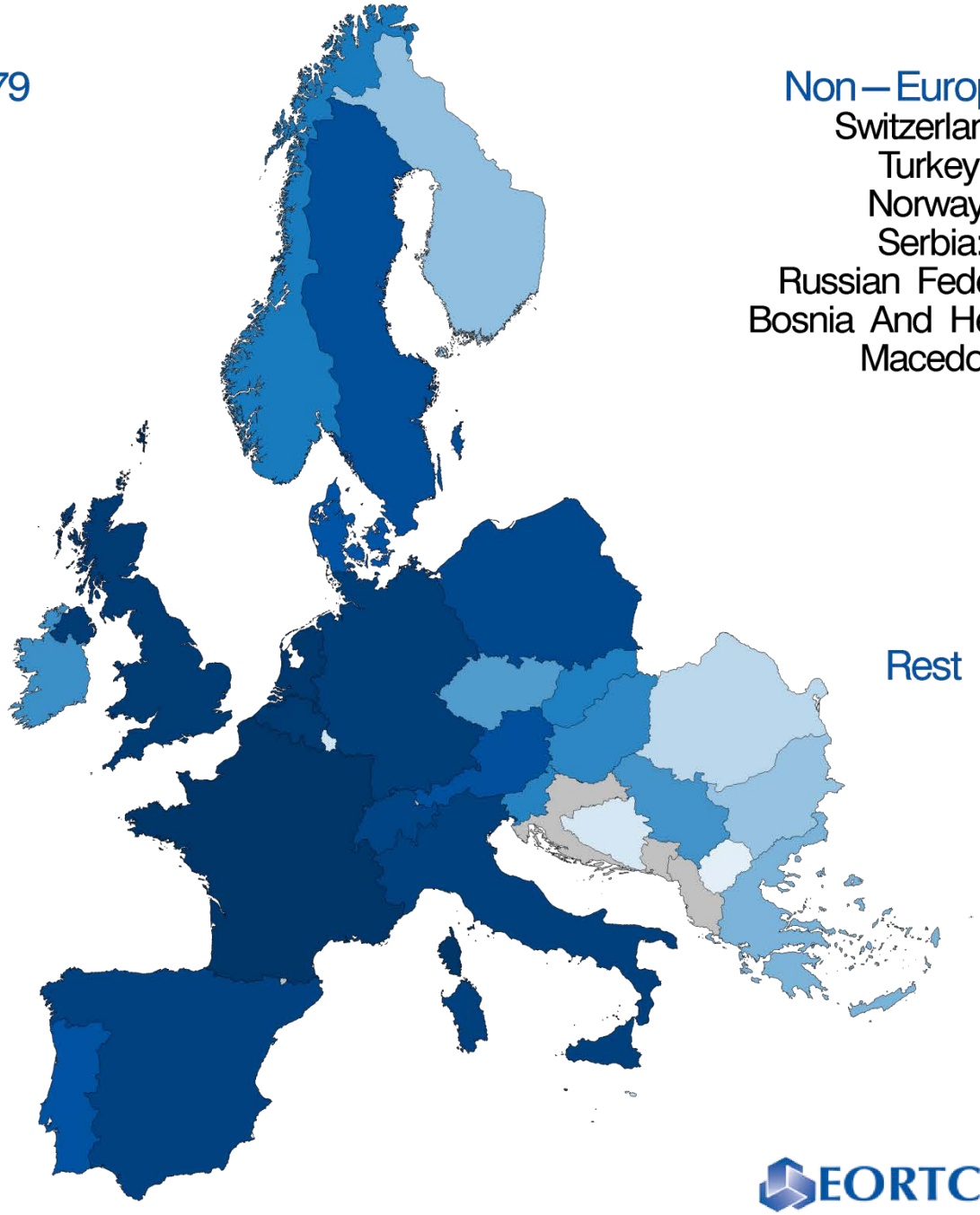
Accrual of screened patients in EORTC clinical studies from 2000 to 2016: 89095 patients

European Union: 79479

France: 17779
Netherlands: 17350
Belgium: 9472
United Kingdom: 8604
Germany: 8174
Italy: 7479
Spain: 3823
Poland: 1296
Sweden: 977
Austria: 960
Portugal: 725
Denmark: 642
Slovakia: 480
Slovenia: 414
Hungary: 364
Ireland: 286
Czech Republic: 209
Cyprus: 101
Greece: 96
Finland: 64
Bulgaria: 51
Estonia: 39
Latvia: 34
Malta: 20
Romania: 20
Lithuania: 11
Luxembourg: 9



Non–European Union: 3649

Switzerland: 2011
Turkey: 631
Norway: 489
Serbia: 283
Russian Federation: 221
Bosnia And Herzegovina: 8
Macedonia: 6

Rest of the world: 5967

EORTC *The future of cancer therapy*

EORTC by the numbers (2016)

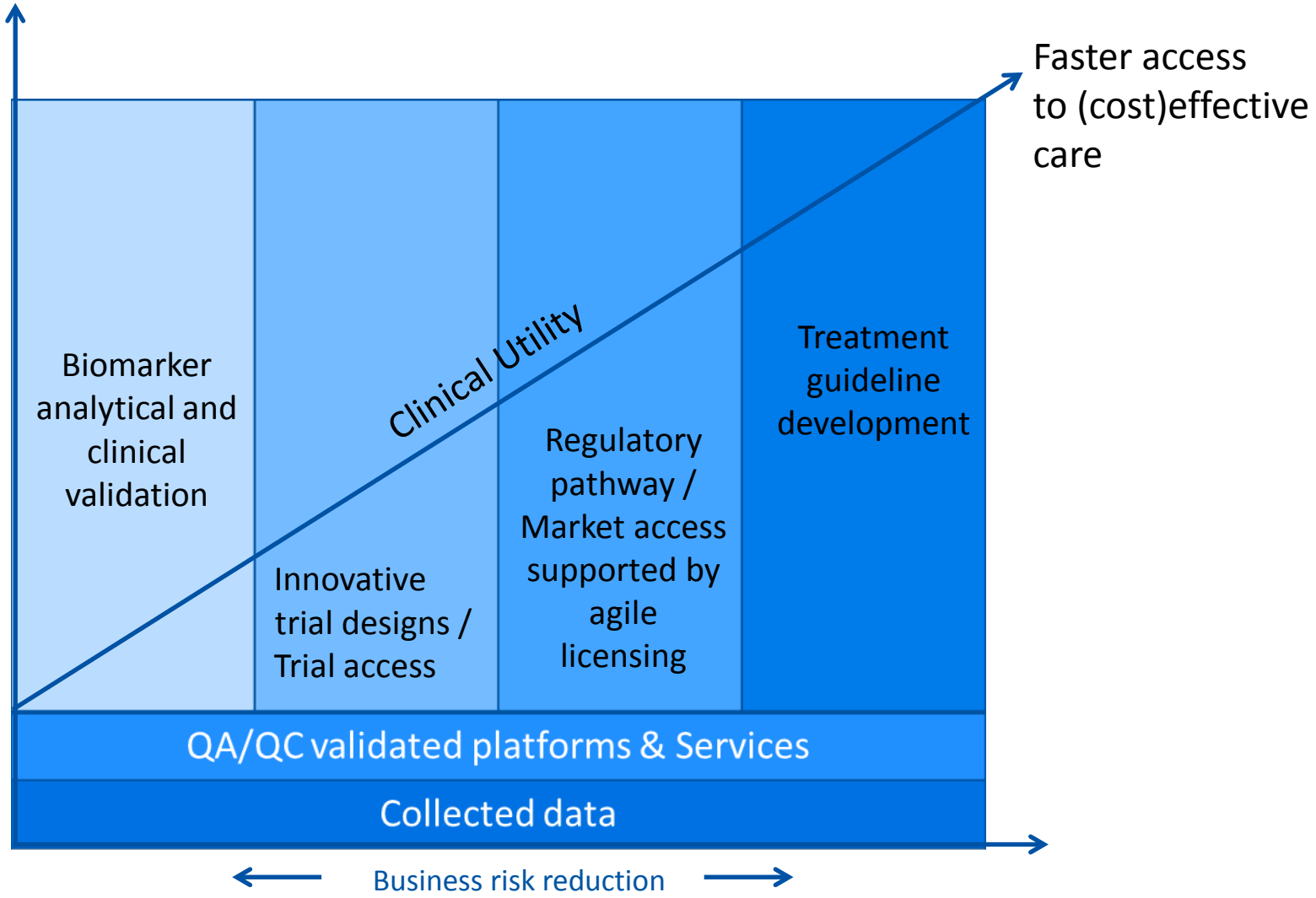
A world-class network	An expert HQ	Unique output
• ± 5,000 collaborators • 870 institutions • 35 countries • 21 groups & task-forces • 111 collaborative groups	• 202 employees • > 195,000 patients in database • 24,000 patients in follow-up	• **12 new studies open to patient entry in 2016** • **54 ongoing studies** • 19 studies in protocol outline development • 15 studies in protocol development • 15 studies in regulatory activation • **Working on ≈ 193 studies**

SPECTA: precision oncology platform

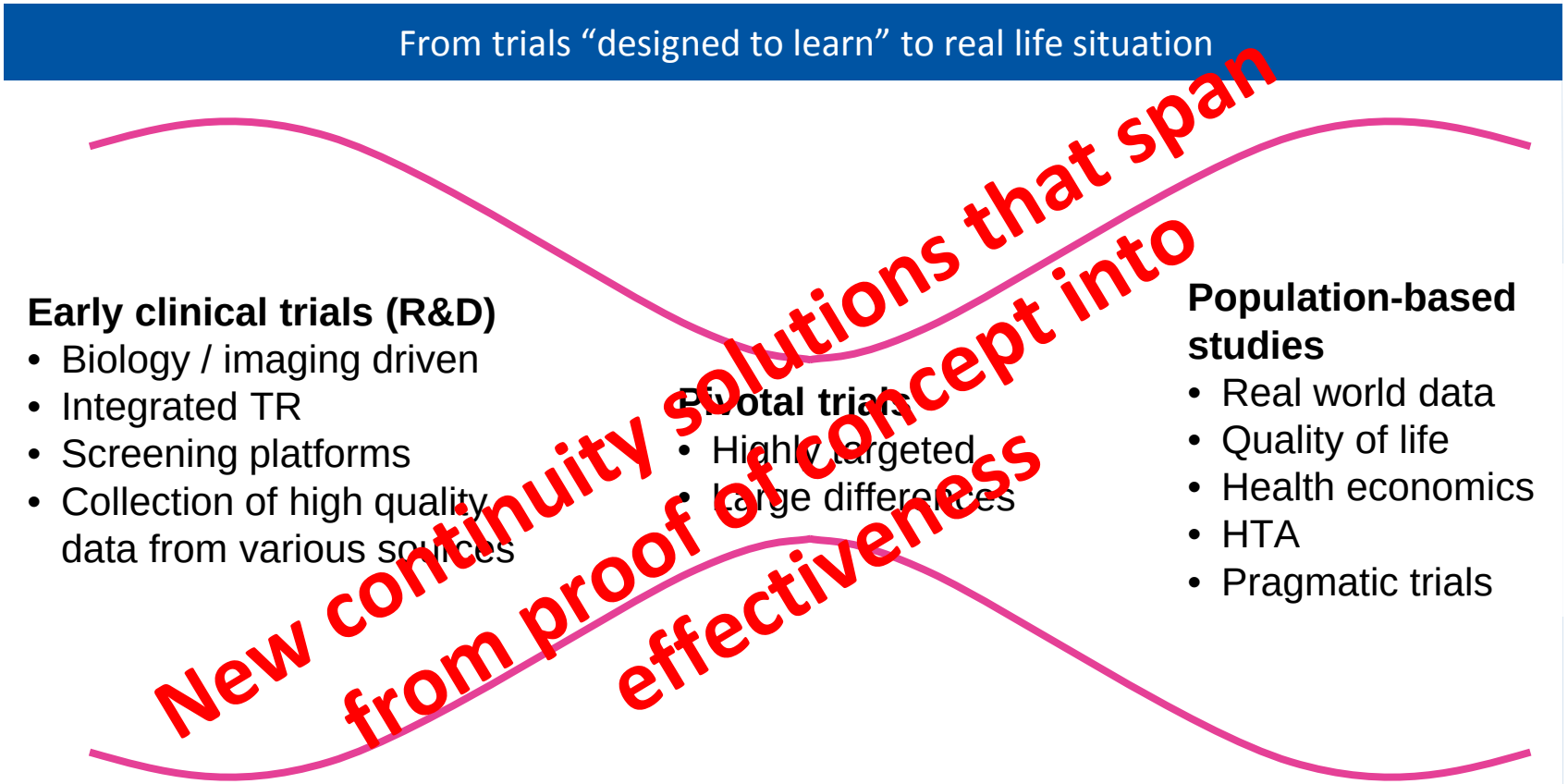
Recurrent pivotal questions

- 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



The changing clinical research pathway



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

The 2 major challenges for precision medicine

- Drug development clinical research is currently not patient centered

  Drug centered based on non representative/highly selected patient population

  The need: Protocols seeking patients ⟶ patient seeking protocols

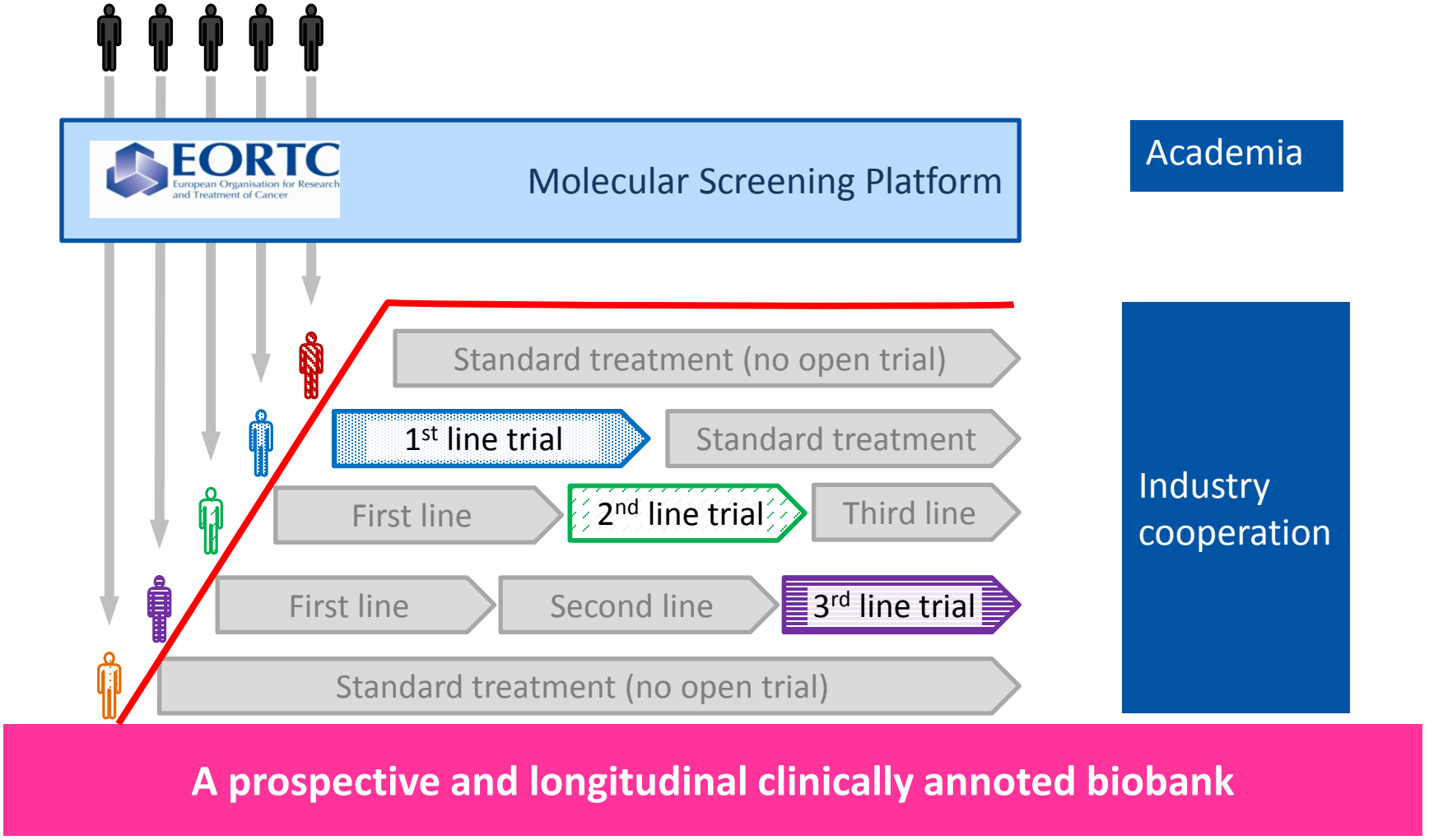
- Sub-optimal anticipation of real life questions:
  - combinations, sequence, duration, QoL, long term outcome and toxicity …

  The need: build on applied (often independent) clinical research

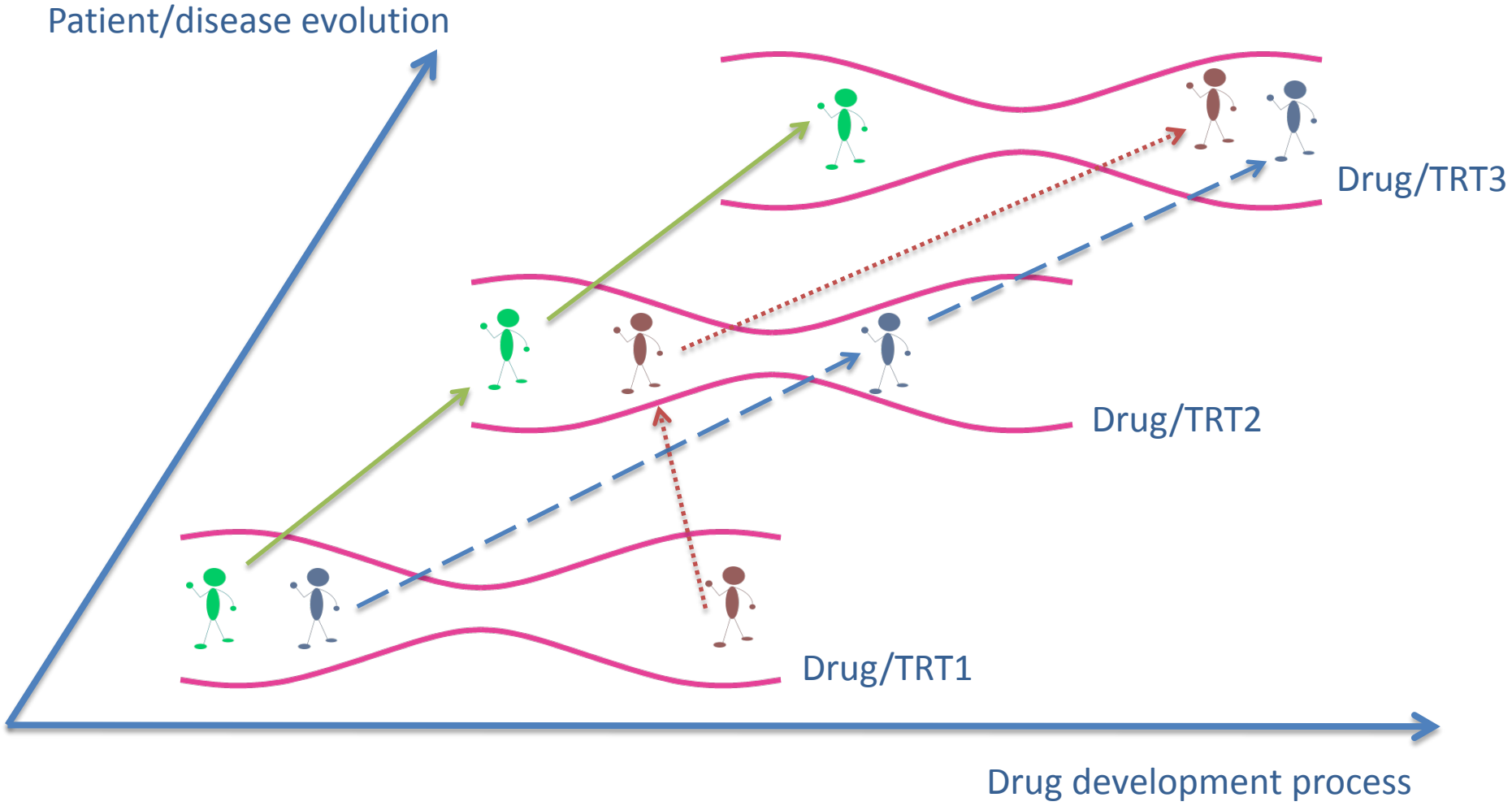
How to reconcile the continuum of care and the continuity of solutions for drug development?

Do our systems function correctly: Why do HTA bodies and payers would take decision based on drug development research when it should happen based on applied clinical research?

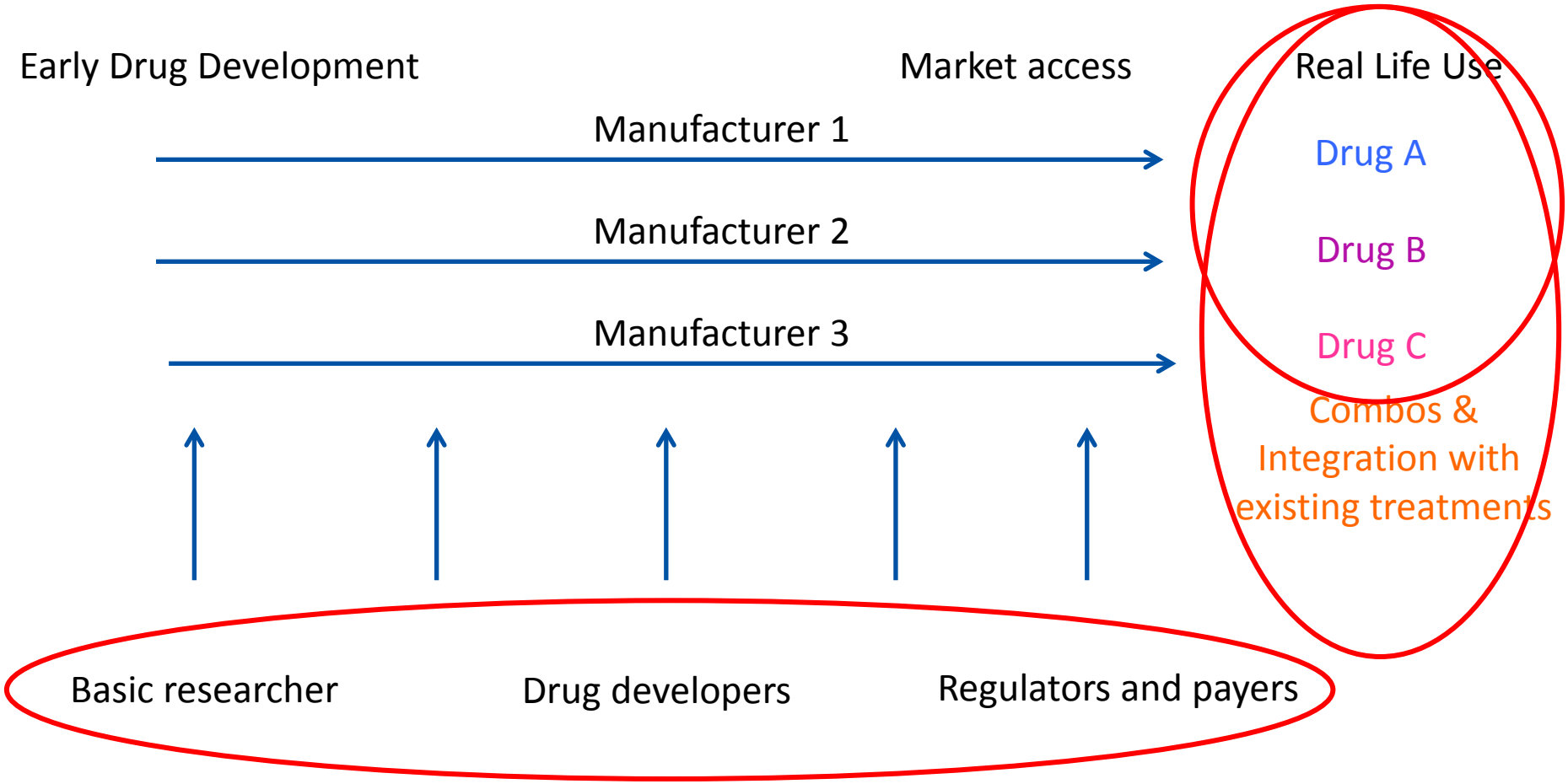
Solution to challenge 1: collaborative platform



Solution to challenge 1:
The principle of dual longitudinal continuity



Solution to challenge 2: from R&D to real life



Conclusions

A major transformation of clinical research building on the strengths and complementarity of stakeholders working alongside new business models must be tackled to make the above possible.

The proposed continued solutions should happen through new collaborative, complementary and interactive sequences taking into account the interests and needs of all stakeholders

How could it happen?