Clinical Research Transformation Towards Patient Centered Approaches An opinion of the EORTC

Denis Lacombe, MD, MSc

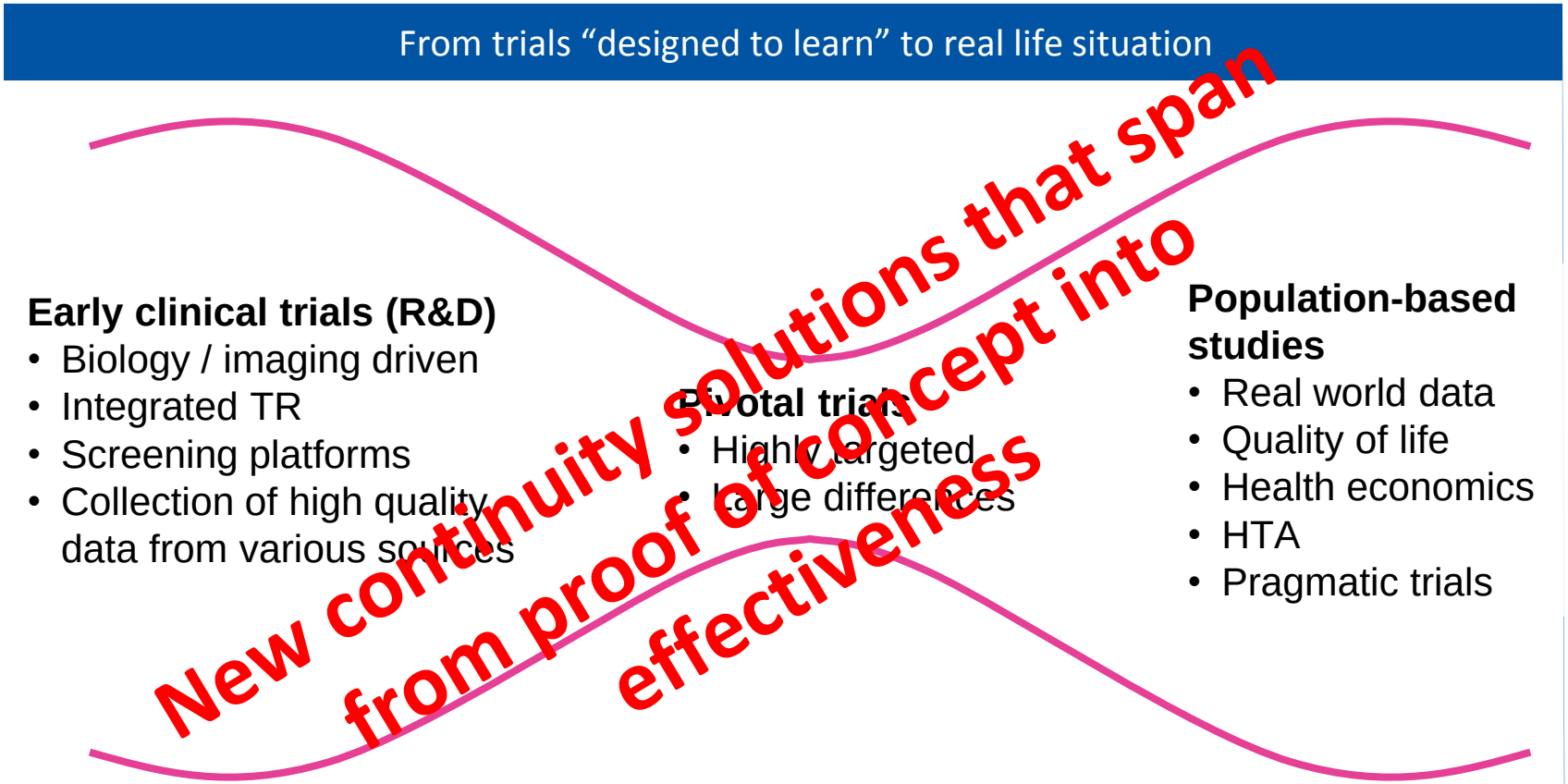
EORTC, Director General

Brussels, Belgium

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**

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 cancer clinical research

- 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 …

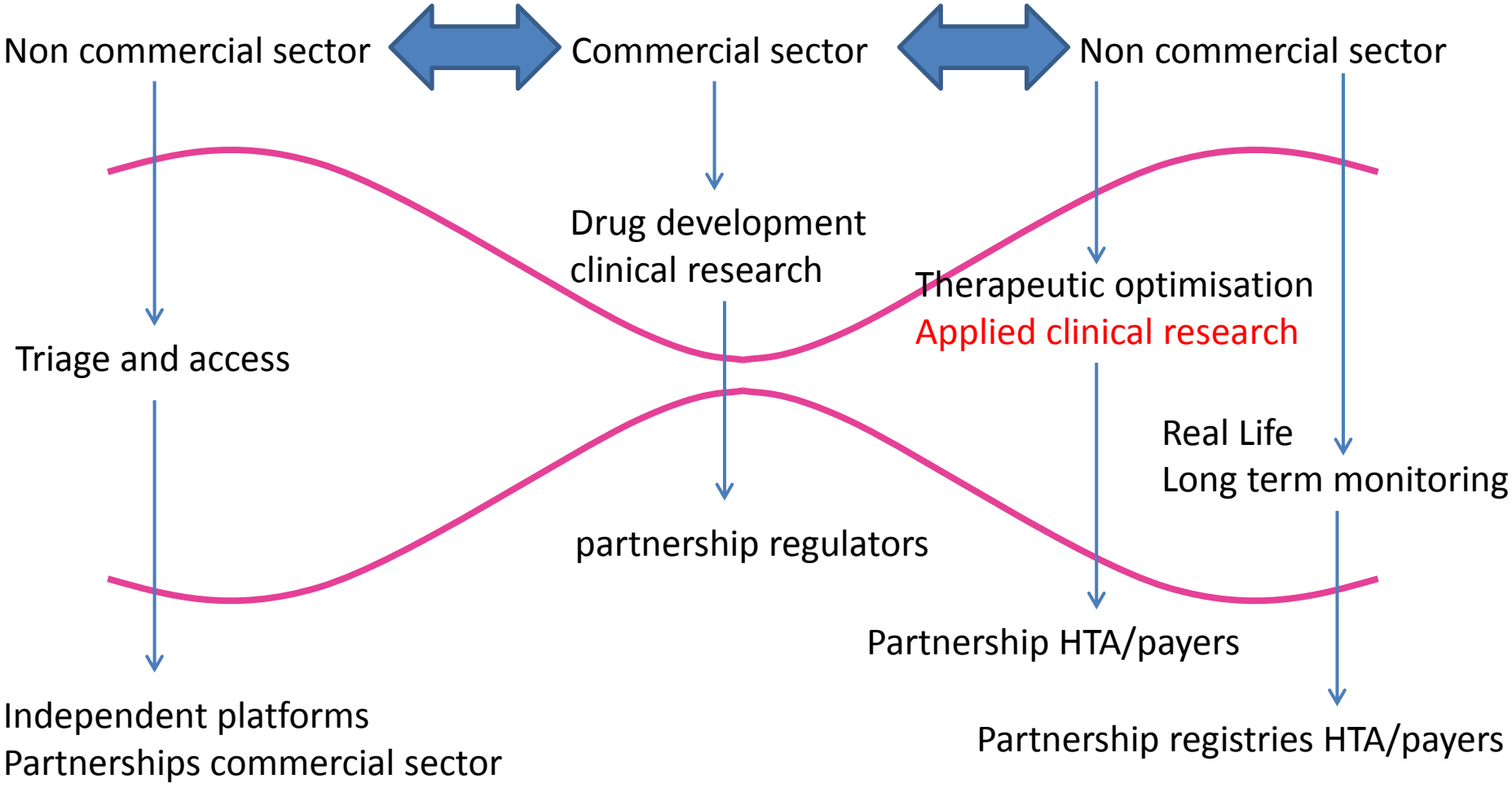
  The need: build on applied (often independent) clinical research

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?

Comments on the changing landscape

- Regulatory trials are not representative of real life
  - Surrogate end-points may not mirror hard clinically relevant outcomes
- MAPPs/ conditional approvals generate earlier data sets
  - Though potential benefits tend to be diluted over the development process
- Drugs will be more active as biological pathways get uncovered
  - Multiplication of expensive drugs for niches is not sustainable
  - The drug based model approach is no longer suitable
- Let's talk about immunotherapy….

A different perspective



Key observations and conclusions

- Health care is long overdue for transformation
  - Not adapted to precision medicine / technology based treatments
- Pharma sector dominates while the drug development system is not patient centered
  - tell the patient the truth, and rebuild
- Value, in a reformatted environment, applied clinical research
  - Implementation of practice known to be effective, with methodological rigor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