EORTC scientific strategy and activities with patient groups

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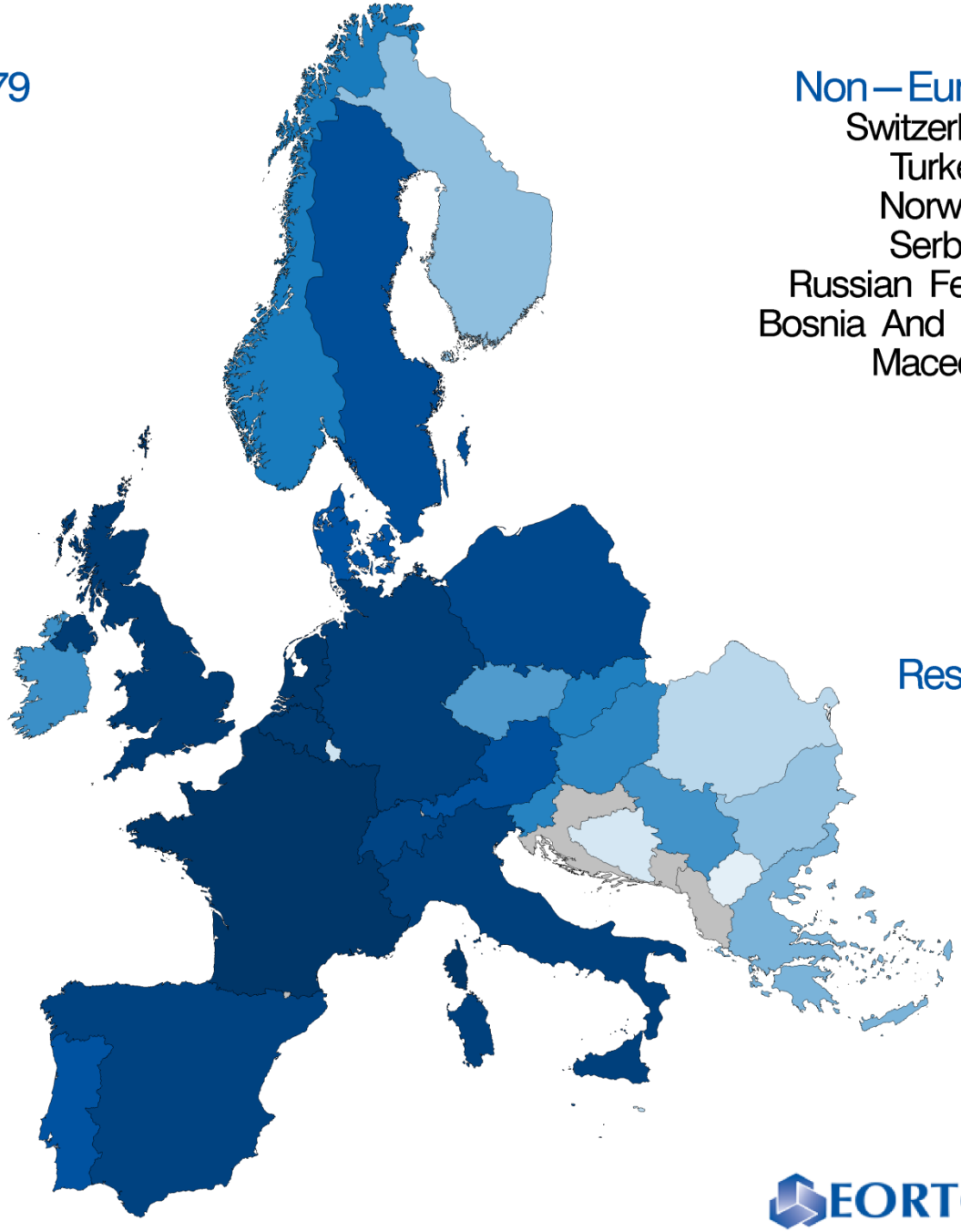
Accrual of screened patients in EORTC clinical studies from 2000 to 2016: 89095 patients

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

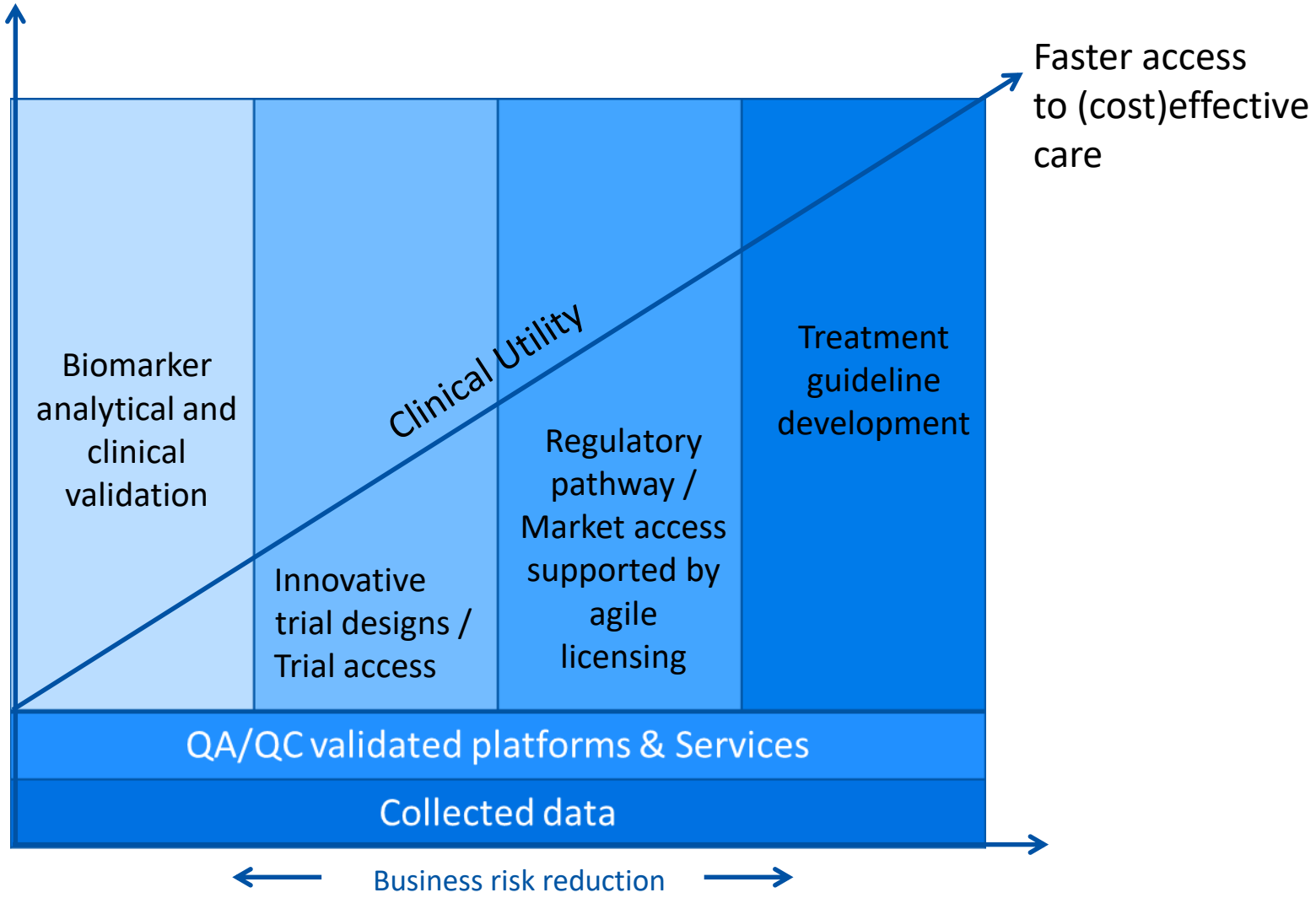
EORTC The future of cancer therapy

EORTC by the numbers (2016)

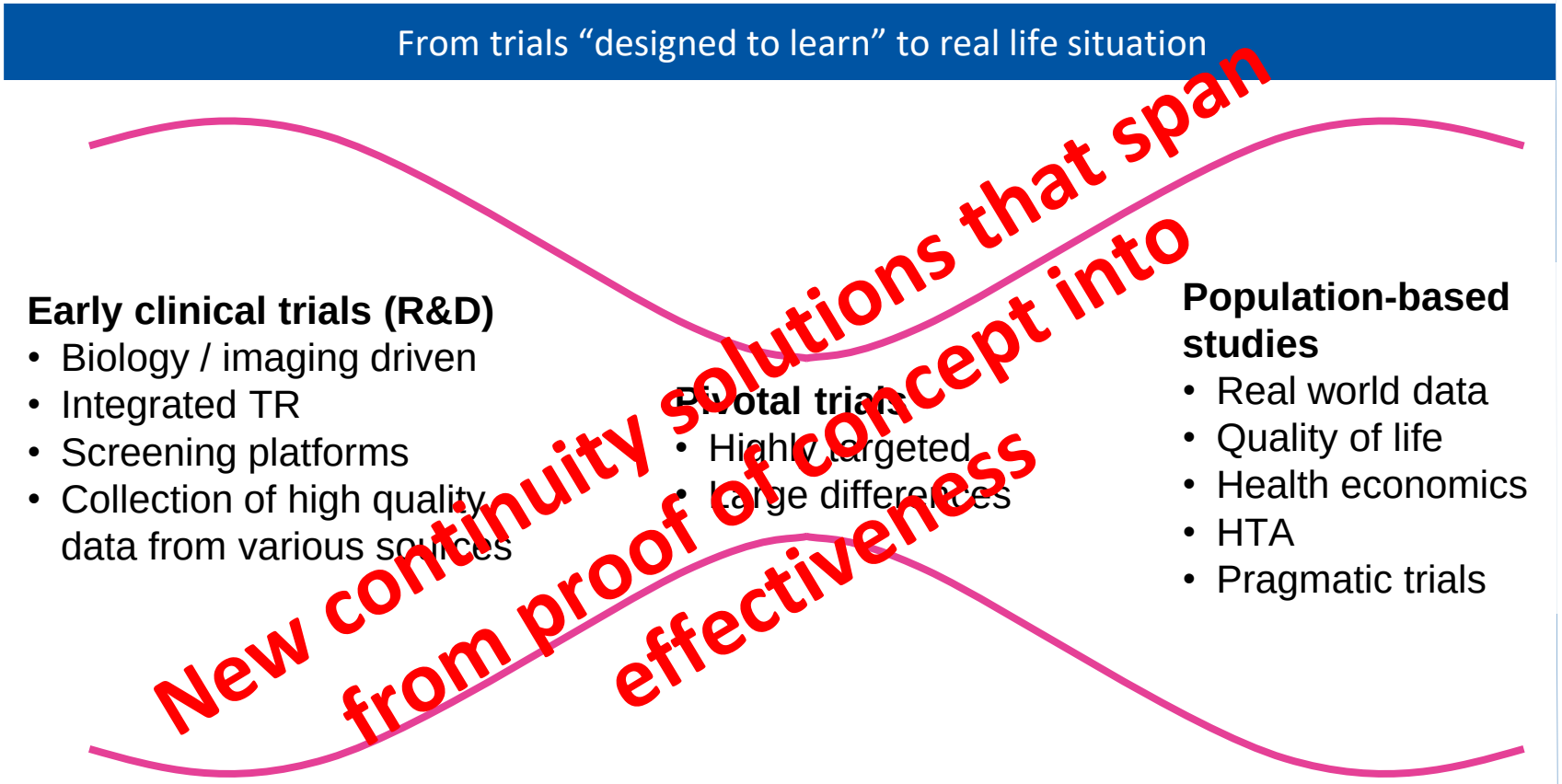
A world-class network	An expert HQ	Unique output
• ± 5,000 collaborators • 870 institutions • 35 countries • 21 groups & task-forces • 111 collaborative groups	• 202 employees • > 195,000 patients in database • 24,000 patients in follow-up	• **12 new studies open to patient entry in 2016** • **54 ongoing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

SPECTA: precision oncology infrastructure

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 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?

Key observations

- Health care is long overdue for transformation
  - Not adapted to precision medicine / technology based treatments
- Pharma sector dominates while the big pharma model is reductive, duplicative, and generates public waste
  - 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

Conclusions

A major re-engineering 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

Patient centred, optimizing therapeutic strategies should be promoted to guarantee robust data to health care providers and patients in real life

SAVE THE DATE

Innovation and Biomarkers in Cancer Drug Development

A Joint Meeting by EORTC, NCI, EMA and AACR

29 - 30 November 2018
Brussels, Belgium

EORTC
The future of cancer therapy

NATIONAL CANCER INSTITUTE

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

AACR
American Association for Cancer Research

EORTC and ECPC partnership

- Long standing history of informal contacts
- Memorandum of Understanding: Improve collaboration around topics of common interest
  - Seminars, meetings and round tables
  - Joint projects
  - Training activities
  - Communication and publications

Patient course

EORTC ECPC

Background and History

- EORTC Clinical Trials: One Day Introduction for Patients
  - 13 September 2012
  - 15 attendees
  - 5 faculty members
- EORTC course: Understanding Clinical Research
  - 28 February - 1 March 2014
  - 54 participants
  - 25 faculty members
- EORTC Cancer Clinical Research Methodology Course for Patient Advocates
  - 4 - 5 March 2016
  - 45 attendees
  - 13 faculty members

Patient course 2018

- March 2-3, 2018
- Principles of the agenda:
  - Cancer biology and development
  - Legal and ethical environment of clinical research
  - Clinical trial methodology
  - Protocol develop
  - Dabates over specific questions: placebo, randomisation
- Registration opening Nov 6, 2017
- Registration form will include a survey for expectations

EORTC studies: PIS/IC review by patients

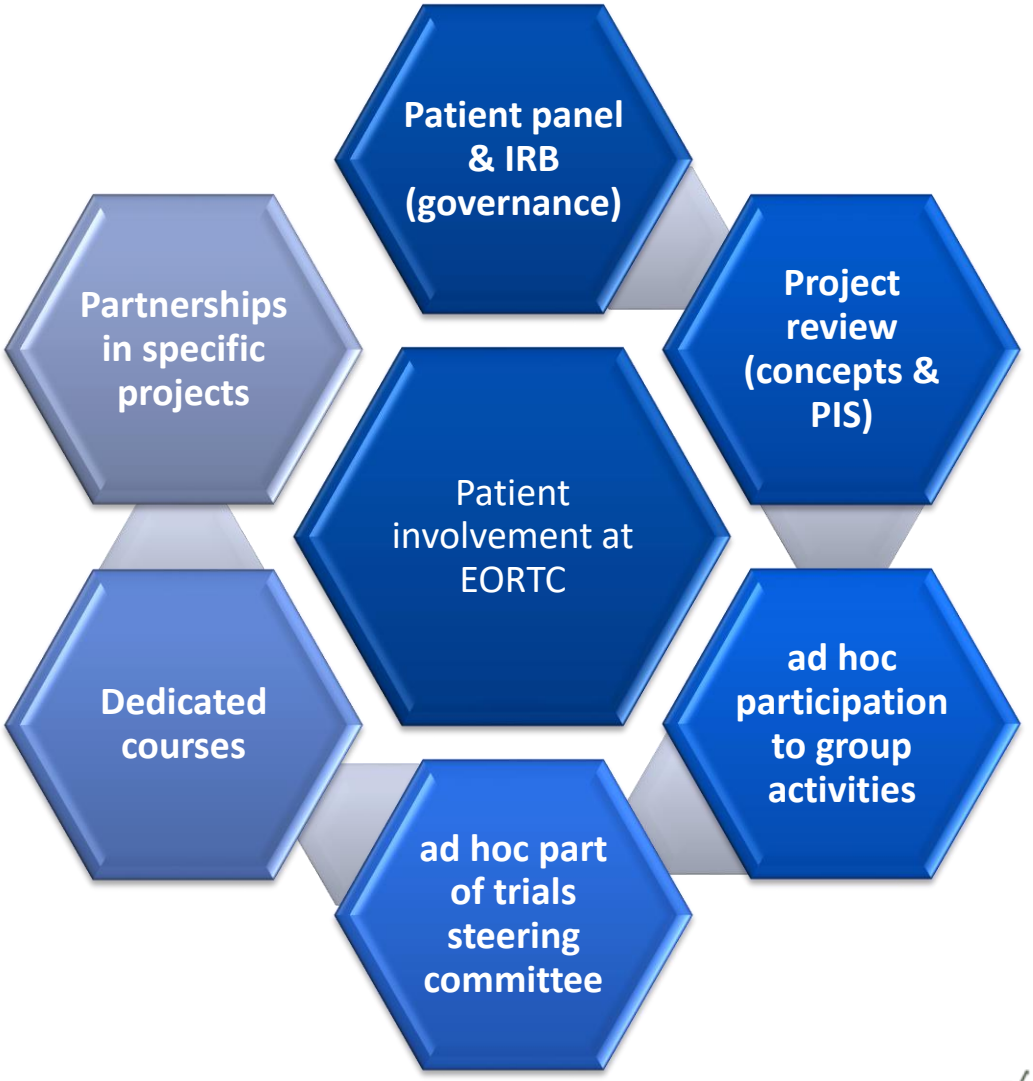
	Patient advocates contacted	Number reviewers responded	
Leukemia	9	4	2014
Soft tissue & Bone	9	6	2014
Lung	8	5	2014
Esophageal/Gastric	8	1	2014
Colorectal	8	1	2014
Prostate	6	1	2014
Lung	6	2	2014
Brain	5	1	2014
Mesothelioma	5	1	2014
Lung	6	2	2014
Prostate	4	1	2016
Esophageal/Gastric	3	1	2016
Brain	2	1	2014
Breast	2	2	2015
Colorectal/Liver	4	1	2015
Rare Tumors	5	1	2016
Lung	4	1	2016
Mesothelioma	4	2	2016
Head & Neck	6	1	2016
Colorectal	10	2	2017
Thymoma	4	0	2017
	118	**37**	

EORTC study outline reviews

year	No of studies	Patient advocates contacted	No of reviews done that year
2016	9	32	12
2017	10	59	24

- More challenging to find patients able to review sciences and methodology
- Higher rejection rate
- Increase number of patient requiring compensation

Conclusion:
Full spectrum of patient involvement at EORTC



Key challenges
for international & multi-cancer research

- Patient organizations
- Representativeness
- Expertise
- Availability, reliability and timelines
- Communication
- Reward / retribution
- Expectations &estimation of added value

Reward/retribution

- Refund of travel and expenses (if F2F)
- EORTC believes honorarium is not appropriate as it may create conflicts of interests or other types of bias…
- Other types of reward:
  - Acknowledgement? Some would prefer not to be named…
  - Recommendations in the scope of patient advocacy work?
  - Privileged access to courses and events?
  - Regular feed-back?
- How to keep reviewers motivated?

Some suggestions for the future

- Having patients at the table is not conducting patient centred clinical research
- Patients to be more demanding on the real issues which matter and act on those
- Improve interactions for operational aspects (PIS/IC), practical aspects/ acceptability of protocols
- Continue both ways education: researchers-patients but with a focus on where expertise is!
- Optimize efforts on common issues: do not be exclusively tumor centered: PROs, end-points, placebo, HTA, access etc… (possibly a central activity for ECPC and EORTC)