



the Belgian pharmaceutical conference

ECONOMIC FOOTPRINT OF CTs IN BELGIUM

STRATEGIC PLAN TO PROMOTE CTs

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PwC

Thank you!

THE INITIATIVE

TO PROMOTE CLINICAL TRIALS IN BELGIUM

www.theinitiative.be



1. Actual situation on clinical trials in Belgium
2. Future evolutions in clinical research
3. Conclusions and recommendations

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Actual CT situation in Belgium

Past trends:

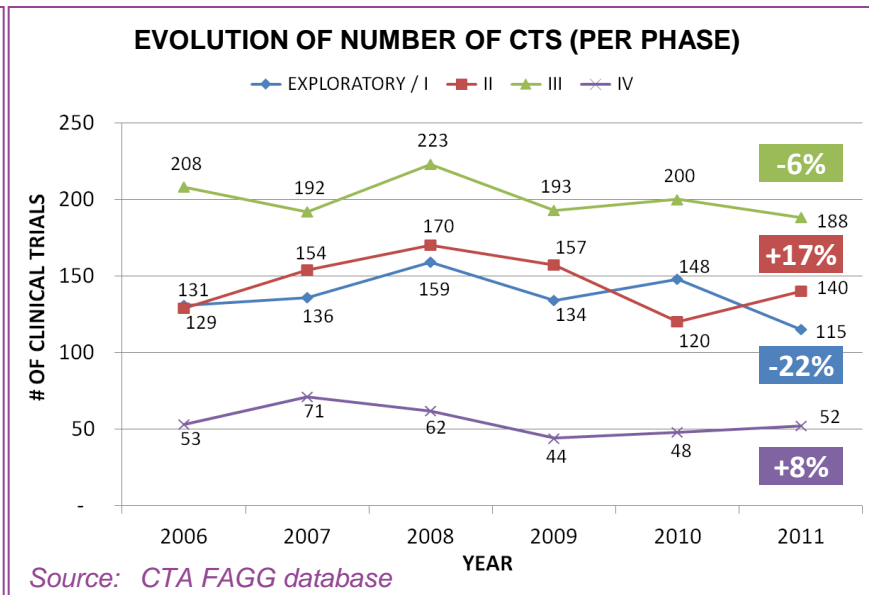
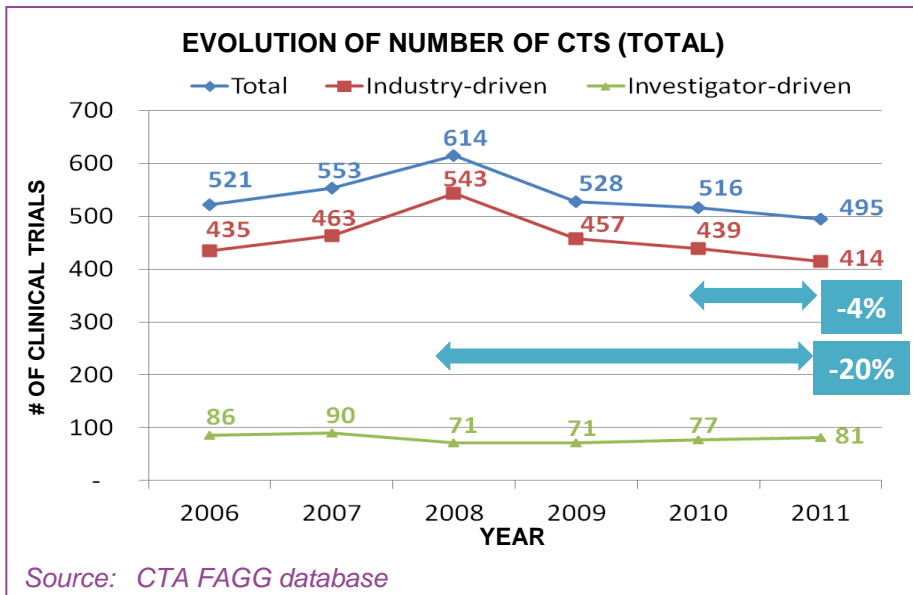


Our research is based on:

- **Investigation of trends** based on the **FAGG database on CTs**
- **Survey** held in Jan-Feb 2012 with **53 representatives of various stakeholders**
- **Comparison study of other countries** (benchmarking)

Group	Nr. of respondents
Health Authority	2
Research based pharma	17
CROs	8
Hospital Direction	9
Ethical Committees	9
HC practitioners/ Investigators	5
Patient Organisations	3

2006-2012 number of CTs



Since 2008 continuous decline in industry-driven CTs. Exploratory studies (I+II) stable.

Potential consequences of declining number of CTs in Belgium

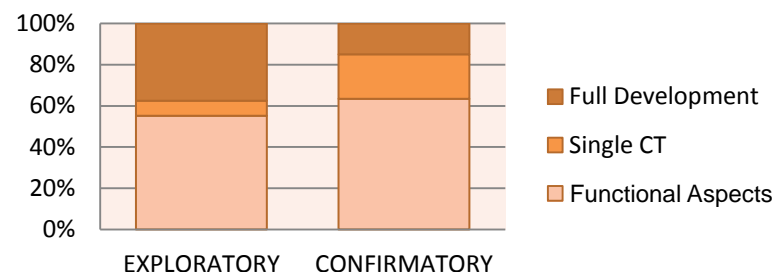
“In your opinion, what would be the impact of a decline in CTs in Belgium?”



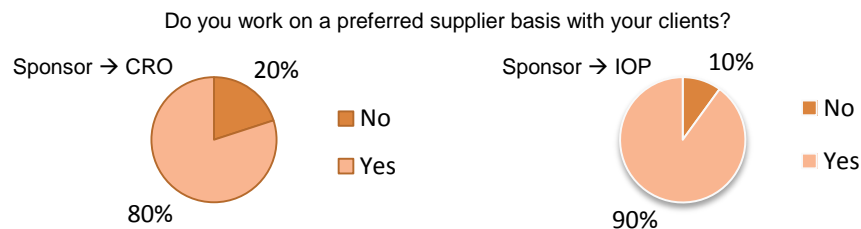
- Job losses
 - Loss of expertise in R&D
 - Loss of qualified staff
- Loss of innovation
- Closing down of CT and research units
- Less access to innovative drugs

- CTs are **increasingly in- and outsourced** for full development or part thereof (functional aspects)
- **Key drivers for this trend:**
 - **Efficiencies**, mainly in terms of *resource and portfolio management, flexibility and cost savings*
 - More **standardised study approach**
 - **Specialty expertise** of the provider and the resulting faster *speed of enrolment*
 - **Easy access** to in/outsourcing providers
- For **complex or innovative CTs** however (e.g. FIH, phase II) more **local expertise & resources** are needed.

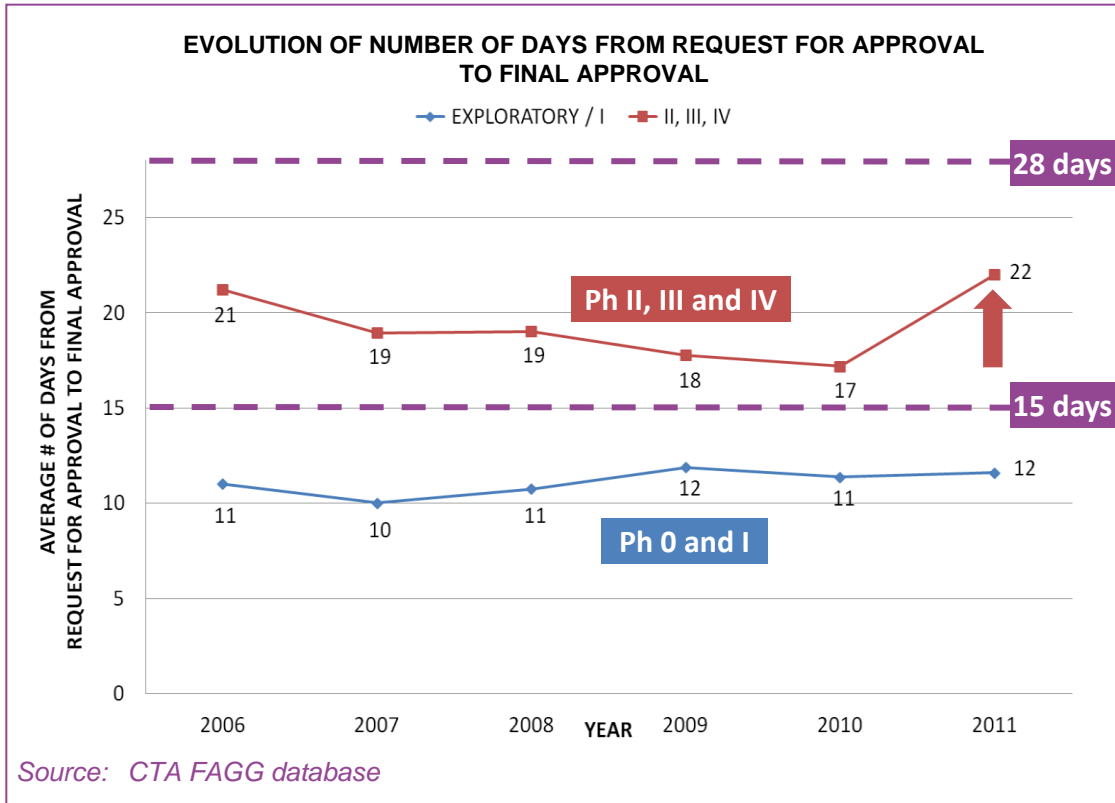
Sponsors mostly **outsource specific functional aspects** of their CTs



Most sponsors prefer to work on a **preferred provider basis** in order to **build a relationship of trust and expertise** and to ensure **efficiency**



Actual status of CT processes: Time to CA approval



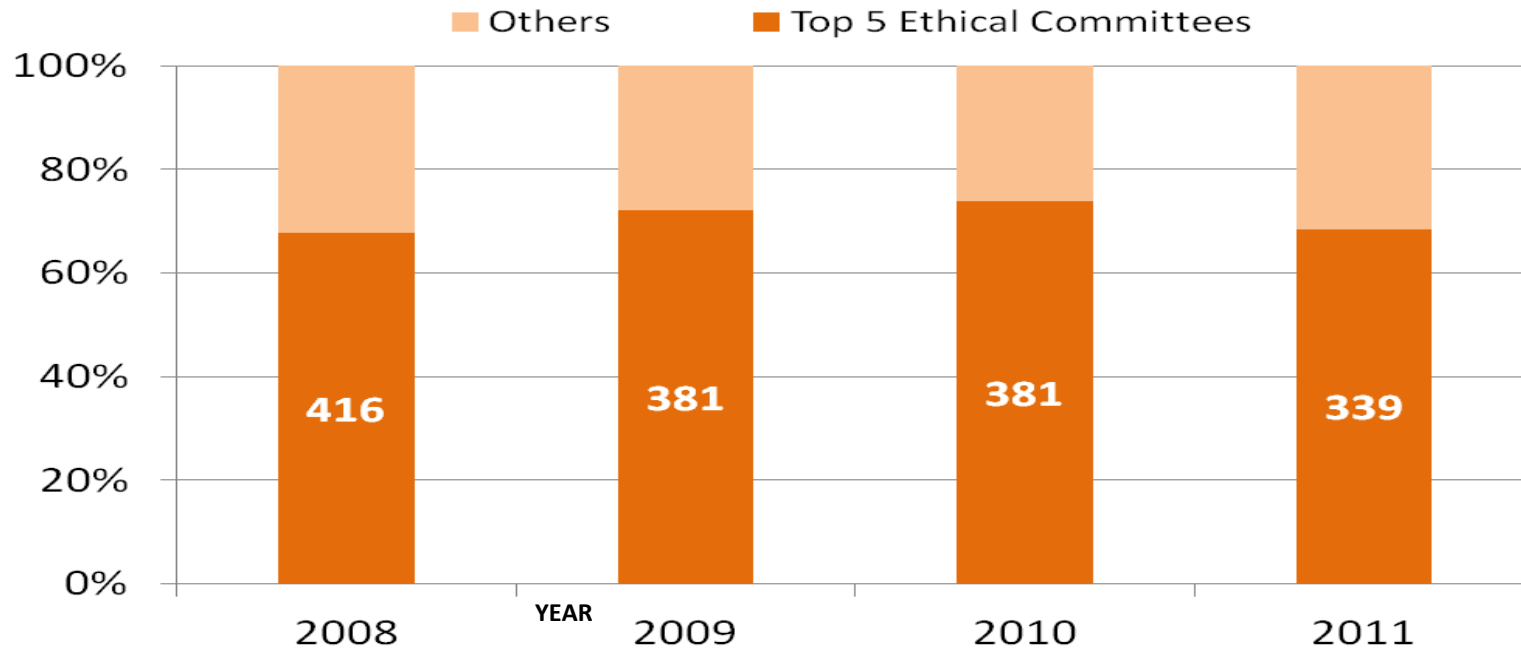
***"clock-stop period" was excluded from this calculation.*

These averages remain **well below the legal delays** of 15 days for exploratory and 28 days for confirmatory studies.

The ambitious Belgian timelines are therefore well respected.

Actual status of CT processes: EC Approval process

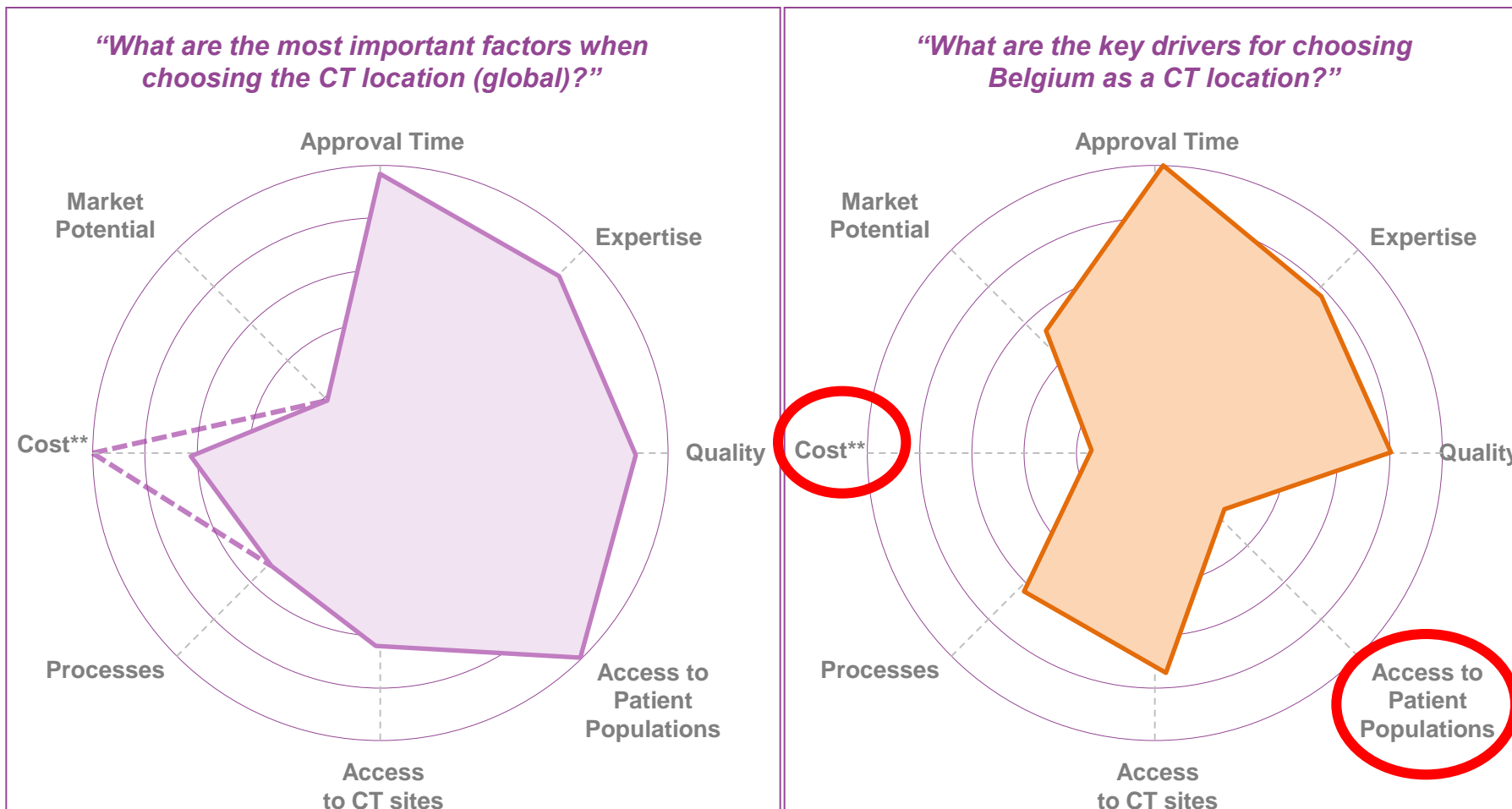
% SINGLE OPINIONS OF TOP 5 ETHIC COMMITTEES ON TOTAL SINGLE OPINIONS



Source: CTA FAGG database

70% of CTs are evaluated by 5 leading ECs

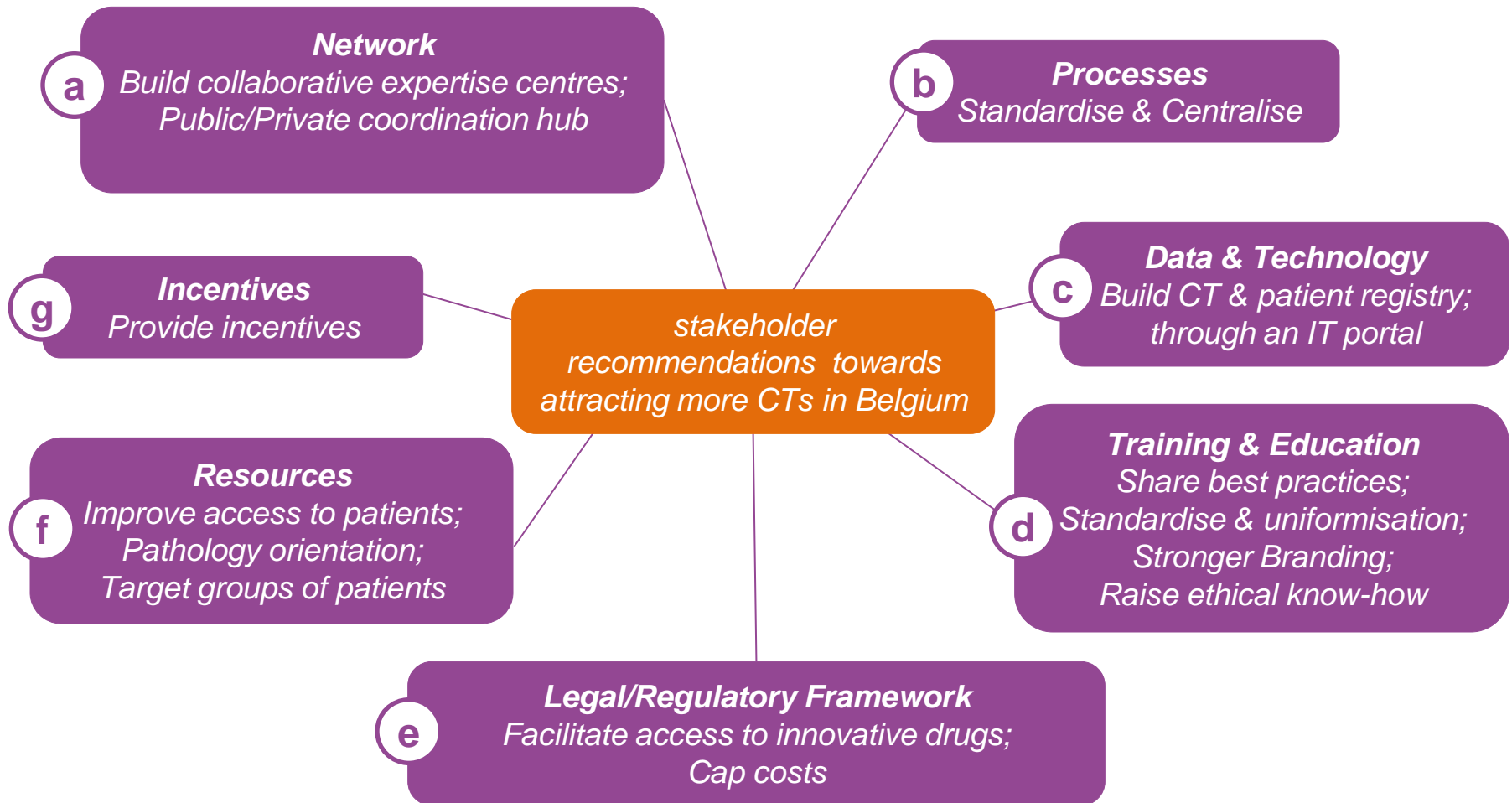
General drivers for location choice vs. drivers for choosing Belgium*



* Chart depicts relative values, not absolutes

** PwC global study shows cost to be a highly critical factor

Stakeholders recommendations



Demand a CT environment that better facilitates the execution of CTs

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Opportunities based on future environment to boost clinical research activities in Belgium

Future Trends

- Evidence Based Medicine evolves to a continuous process of data gathering in clinical practice



Opportunity

- Increased demand for post approval continuous data gathering, reimbursement renewals (live-licensing)

- More collaborative models



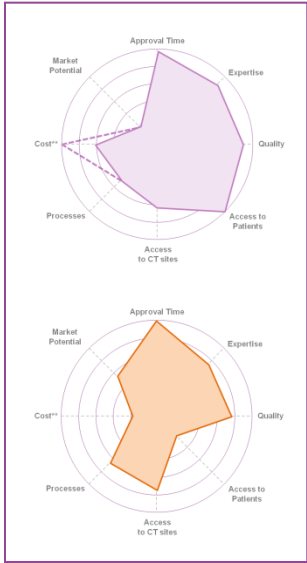
- Create a network of expertise centres

- More evidence required for and from early development
- New EU regulatory environment



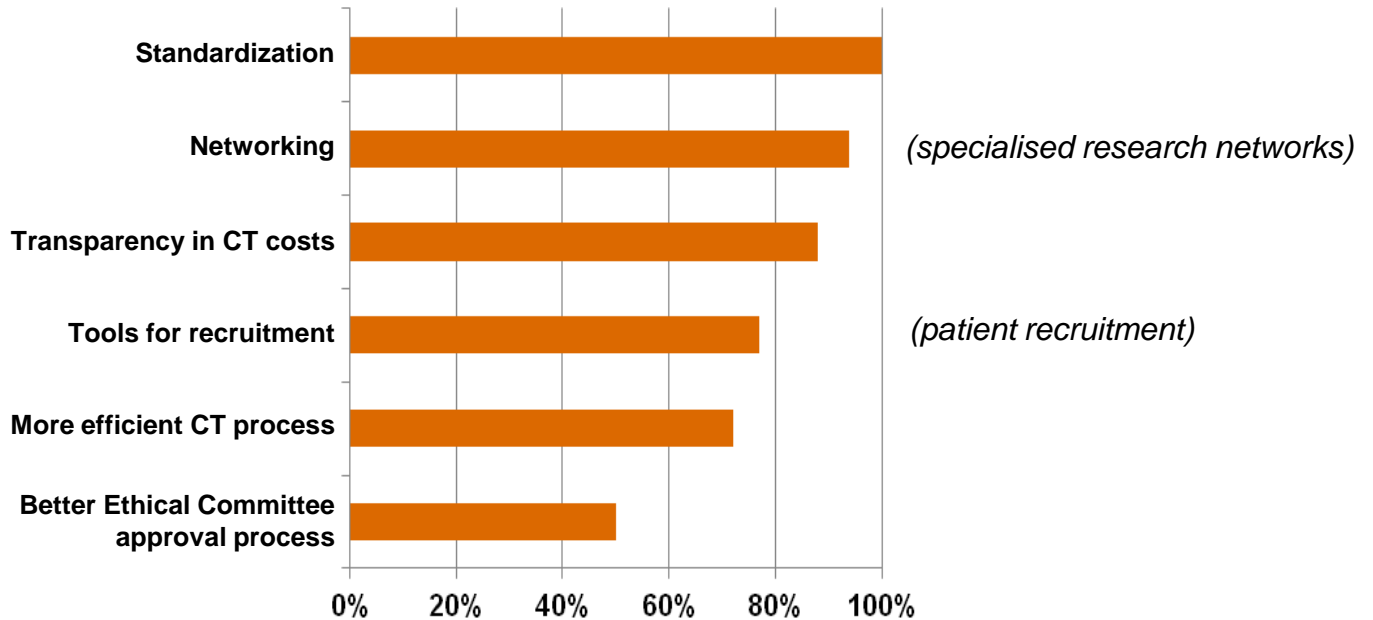
- Translational research will drive additional data gathering and CTs
- Upgrade local expertise, ameliorate legal framework for biobanks, maintain timelines.

Stakeholder needs in order to allocate more CTs in Belgium



What changes are needed for your organisation to allocate more CTs to Belgium?

Percentage of respondents that want...



PUBLIC-PRIVATE DRIVEN



LEAD: MINISTRY OF HEALTH

- “Healthy Growth” Plan
- Improving conditions for private-public partnerships in health research & innovation



LEAD: ABPI & MHRA

- Improving legal framework (IPO, clarity, ...)
- Access to information for industry (toolkits, web, routemaps, ...)



LEAD: LEEM & CeNGEPS (public-private)

- Development of national network of CT centres
- Patient recruitment (CT registry, website, awareness, ...)



LEAD: NEFARMA

- Standardization/one-stop shop concept (forms, contracts,...)
- Professionalization (performance monitoring, training, ...)
- Patient participation (volunteer registry, ...)



LEAD: INFARMA

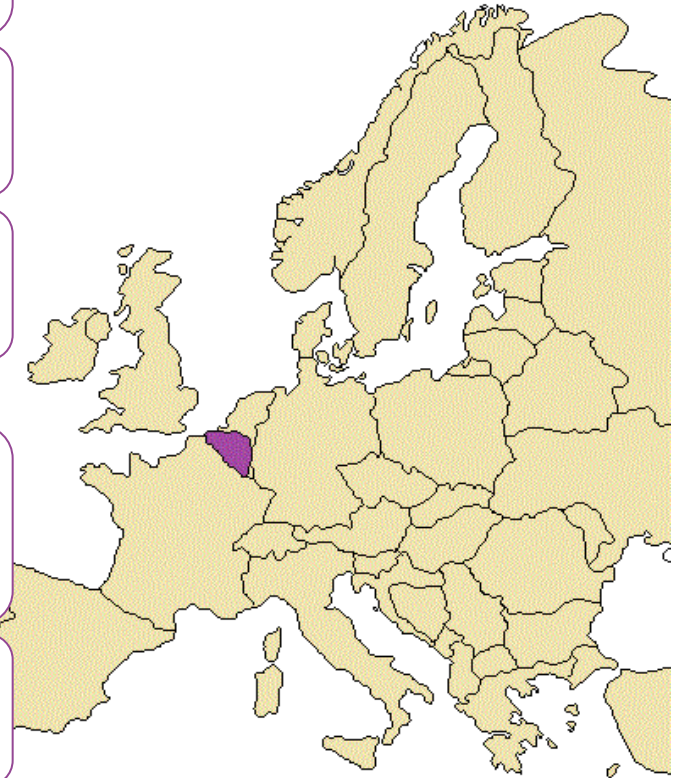
- Advocacy activities (gov't, industry, ...) & public education
- Transparency (self-regulation doc, CT registry websites)



LEAD: Pharma.be

- Standardization of documents (IC, contracts...)
- Professionalization (website, working groups with agencies)

SECTOR DRIVEN






Relevance of other country best practices for Belgium

PUBLIC-PRIVATE DRIVEN

-  LEAD: MINISTRY OF HEALTH
 - "Healthy Growth" Plan
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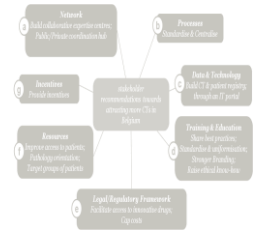
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- **“One-Stop-Shop”**
- **IT portal** for:
 - submitting CT applications
 - Informing on CTs
 - transparent data sharing
- Stronger **branding of country** as a R&D/Health/Innovation centre (e.g. enhance visibility of academic potential, etc.)
- **Standardisation of study related documents, processes**
- Voluntary **patient registry**
- **Specialised research networks**
- Public/private initiative to support clinical research activities (e.g. CeNGEPS)

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3 key Strategic Initiatives can help attract more CTs to Belgium

RECOMMENDATIONS



STRATEGIC INITIATIVES

- Public/Private coordination hub
- Standardise & Centralise
- Stronger branding
- Improve access to patients

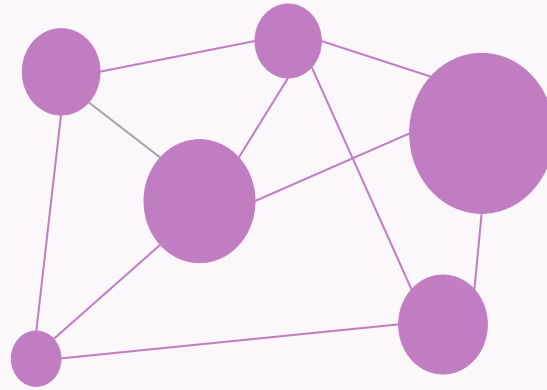
**Standardisation
One stop shop**

2



1

**Network of Specialised Centres (CoE)
with specific patient populations**



- Build expertise networks
- Share best practices & ethical know-how
- Improve access to patients, target groups of patients, pathology orientation

3

Supportive Governmental Framework

- Build CT & Patient Registry through IT portal
- Standardisation & uniformisation
- Facilitate access to innovative drugs & cap costs
- Provide supportive incentives

Actions proposed to each of the different stakeholders

<i>Strategic Initiatives</i>	
1 <i>Standardization</i>	
<i>Sponsors</i>	Enhance communication
<i>CROs, In-& Outsourcing Providers</i>	Enhance communication
<i>National Competent Authorities</i>	Create Portal
<i>Hospital Directions</i>	Standardise processes
<i>Investigators</i>	Standardise Fees
<i>Ethical Committees</i>	Centralise processes
<i>Patient Organisations</i>	Involve Patients

Actions proposed to each of the different stakeholders

	<i>Strategic Initiatives</i>	
	1 <i>Standardization</i>	2 <i>Network of Specialised Centres</i>
<i>Sponsors</i>	Enhance communication	Improve collaborations
<i>CROs, In-& Outsourcing Providers</i>	Enhance communication	Collaborate & Communicate
<i>National Competent Authorities</i>	Create Portal	Coordination & Accreditation
<i>Hospital Directions</i>	Standardise processes	Collaborate & Specialise
<i>Investigators</i>	Standardise Fees	Specialise
<i>Ethical Committees</i>	Centralise processes	Collaborate
<i>Patient Organisations</i>	Involve Patients	Partner with centres

Actions proposed to each of the different stakeholders

	<i>Strategic Initiatives</i>		
	1 <i>Standardization</i>	2 <i>Network of Specialised Centres</i>	3 <i>Supportive Governmental Framework</i>
Sponsors	Enhance communication	Improve collaborations	Liaise to shape Policy
CROs, In-& Outsourcing Providers	Enhance communication	Collaborate & Communicate	Liaise to shape Policy
National Competent Authorities	Create Portal	Coordination & Accreditation	Control costs & Enable access to innovative drugs
Hospital Directions	Standardise processes	Collaborate & Specialise	Collaborate on best practice guidelines
Investigators	Standardise Fees	Specialise	Input on CT registry
Ethical Committees	Centralise processes	Collaborate	Collaborate on best practice guidelines
Patient Organisations	Involve Patients	Partner with centres	Liaise to shape Policy

CTs are core for the pharma sector. For Belgium this research is strategically and economically important. To take maximum advantage of this opportunity, stakeholders should work towards:

**Standardisation
(One stop shop)**

**Network of
Specialised
Centres**

**Supportive
Governmental
Framework**

Thank you!



PwC for:

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