ECONOMIC FOOTPRINT OF CTs IN BELGIUM

STRATEGIC PLAN TO PROMOTE CTs

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PwC
Ingrid Maes – Economic footprint of CTs in Belgium
Content

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

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3. Conclusions and recommendations
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)

### Past trends:

<table>
<thead>
<tr>
<th>Group</th>
<th>Nr. of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Authority</td>
<td>2</td>
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<tr>
<td>Research based pharma</td>
<td>17</td>
</tr>
<tr>
<td>CROs</td>
<td>8</td>
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<tr>
<td>Hospital Direction</td>
<td>9</td>
</tr>
<tr>
<td>Ethical Committees</td>
<td>9</td>
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<tr>
<td>HC practitioners/Investigators</td>
<td>5</td>
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<td>Patient Organisations</td>
<td>3</td>
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</table>
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*
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.

**Source:** CTA FAGG database

""clock-stop period" was excluded from this calculation."
70% of CTs are evaluated by 5 leading ECs
General drivers for location choice vs. drivers for choosing Belgium*

“What are the most important factors when choosing the CT location (global)?”

“What are the key drivers for choosing Belgium as a CT location?”

* Chart depicts relative values, not absolutes

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

- **Network**: Build collaborative expertise centres; Public/Private coordination hub
- **Processes**: Standardise & Centralise
- **Data & Technology**: Build CT & patient registry; through an IT portal
- **Training & Education**: Share best practices; Standardise & uniformisation; Stronger Branding; Raise ethical know-how
- **Incentives**: Provide incentives
- **Resources**: Improve access to patients; Pathology orientation; Target groups of patients
- **Legal/Regulatory Framework**: Facilitate access to innovative drugs; Cap costs

**Demand a CT environment that better facilitates the execution of CTs**
Content

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Trends in clinical trials

Past: 2006

Now: 2012

Future: 2020

Future evolutions

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

**Opportunity**

- Increased demand for post approval continuous data gathering, reimbursement renewals (live-licensing)
- Create a network of expertise centres
- 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...

- Standardization
- Networking
- Transparency in CT costs
- Tools for recruitment
- More efficient CT process
- Better Ethical Committee approval process

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(specialised research networks)

(patient recruitment)
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)

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Relevance of other country best practices for Belgium

- **“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)
1. Actual situation on clinical trials in Belgium

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3 key Strategic Initiatives can help attract more CTs to Belgium

**RECOMMENDATIONS**

1. **Network of Specialised Centres (CoE)** with specific patient populations
   - Build expertise networks
   - Share best practices & ethical know-how
   - Improve access to patients
   - Build CT & Patient Registry through IT portal
   - Standardisation & uniformisation
   - Facilitate access to innovative drugs & cap costs
   - Provide supportive incentives

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

3. **Supportive Governmental Framework**
## Actions proposed to each of the different stakeholders

### Strategic Initiatives

1. **Standardization**

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<th>Action Proposed</th>
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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:

THE INITIATIVE
TO PROMOTE CLINICAL TRIALS IN BELGIUM

www.theinitiative.be

Sponsored by:

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