# Challenges in medicines development

## Pre-clinical research

<table>
<thead>
<tr>
<th>Closed &amp; open innovation</th>
<th>Drug disc.</th>
<th>Pre-clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 - 6 years</td>
<td>10 000 compounds</td>
</tr>
<tr>
<td></td>
<td></td>
<td>250 compounds</td>
</tr>
</tbody>
</table>

## Clinical Trials

<table>
<thead>
<tr>
<th>Phase</th>
<th>No. patients / subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20-100</td>
</tr>
<tr>
<td>2</td>
<td>100-500</td>
</tr>
<tr>
<td>3</td>
<td>1000-5000</td>
</tr>
</tbody>
</table>

## Regulatory review

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filing</td>
<td>2 – 5 years</td>
</tr>
<tr>
<td>Approval</td>
<td></td>
</tr>
<tr>
<td>HTA assessment</td>
<td></td>
</tr>
<tr>
<td>Price / reimbursement</td>
<td></td>
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</tbody>
</table>

## Drug disc.

- 5 000 therapies
- 10 000 compounds
- 250 compounds

## Therapies

- 1 therapy

## Compounds

- 250 compounds
- 10 000 compounds
- 5 000 compounds

## Real world evidence

- Pharmacovigilance
- Real world evidence
IMI – Europe’s partnership for health

IMI > €5 bn

€2.5 bn

Partnership 2008 - 2024

€2.5 bn

EFPIA

IMI – Innovative Medicines Initiative
IMI 2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines
IMI socio-economic impacts – some numbers

- 2,272 FTE jobs directly associated with IMI projects
- 169 SMEs
- 13 spin-offs
- 1,134 scientific publications
- 65 clinical studies
- 20 patent applications
- 460+ biological marker candidates for better diagnosis & treatment
- 25+ new tools to facilitate drug development
- 2272 FTE jobs
- 169 SMEs
- 13 spin-offs
- 1134 scientific publications
- 65 clinical studies
- 460+ biological marker candidates
- 25+ new tools
- 20 patent applications
When pharmaceutical companies share data & collaborate with unis & SMEs...

The problem
Often, researchers only discover that a potential medicine is toxic to a vital organ (e.g. heart, kidneys, liver…) very late in drug development… after they have invested significant time and money in it!

The eTOX solution
A computer tool to detect toxicity issues early in drug development

Input = 2D structure of a possible drug

Output = possible effect on heart – ECG result!
Birth of a successful new organisation – the Open PHACTS Foundation

- Data & facts from multiple public sources
- Open PHACTS Discovery Platform + apps
- Makes it easier to find & analyse info for drug research

- Platform success → Open PHACTS Foundation created
- Foundation now a partner in two Horizon 2020 projects
- Expertise in linking data, data interoperability, etc.

**Big Data Europe**
Aim: integrate existing big data infrastructures → interoperable, large-scale, multi-lingual data assets.

**EU-ToxRisk**
Aim: achieve a paradigm shift in toxicology towards a more efficient and animal-free chemical safety assessment.
European Lead Factory – breathing new life into drug discovery programmes

The project combines…

- the **innovation** of academia,
- the **agility** of SMEs,
- the **experience** of pharma.
- **funding** from the EU
- an award-winning IP model

"Access to the European Lead Factory has **fast-forwarded our drug discovery programme in the field of oncology** by several years."

Huib Ovaa, Netherlands Cancer Institute
IMI Ebola+ programme – building infrastructures for local communities

Kambia, Sierra Leone

Vaccine storage facility built to facilitate clinical trial of Ebola vaccine

Local staff also benefit from training
A quick quiz

The answer is 17 years

What is the question?
Oldest IMI projects = 6 years! The fact we are already having an impact demonstrates **success of PPP model**

IMI allows **unprecedented collaboration** amongst pharmaceutical companies

IMI is delivering results that could not be achieved through other programmes and represents **good value for money** for Europe

In IMI projects, **all partners benefit** from networking, new knowledge, new opportunities, new tools and resources

In health research, IMI is a unique, successful initiative that **Europe can be proud of**
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- E-mail us infodesk@imi.europa.eu
Thank you

Pierre Meulien
IMI Executive Director