



Innovative Medicines Initiative

# The role of SMEs in therapeutic innovation EFPIA's vision

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# SMEs are more important in Pharma today

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- The changed ecosystem
- The relationship between SMEs and Pharma
- SMEs in public/private partnerships
  - EBiSC as an example



# The Pharma Ecosystem: The old model



Large Vertically Integrated Sites

Internal

- Regulatory
- Pharmacovigilance
- QA/QC
- Development Ops
- Clinical Dev
- Experimental Medicine
- Supply Chain
- Final Manufacturing
- Bulk Synthesis
- Drug Safety
- Tableting
- Metabolism
- Screening
- Biologic Target Validation
- Medicinal Chemistry
- Exploratory Research



External

- Research Grants
- In-License & M&A

- Development Functions
- Enabling Lines/Functions
- Research Functions



# The Pharma Ecosystem: The new model

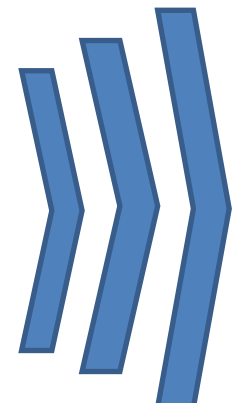


Dynamic ecosystem today

## Internal

**Global support network**  
Regulatory and Supply  
Platform functions

**Empowered Research Unit**  
Biologic Target  
Validation/exploratory research  
Identify small molecule and biologic NMEs  
Proof of concept P2  
**Development**



## External

### Service providers

<b>Clinical trials</b> – Parexel, Quintiles
<b>QA/QC</b> – Parexel, Quintiles
<b>Dev Ops</b> – Parexel, Quintiles
<b>Experimental medicine</b> – Tessella, P1vital, Imanova, Cantab
<b>Supply Chain</b> – Fisher
<b>Final Manufacturing</b> – Lonza, Aptuit
<b>Bulk Synthesis</b> – Peakdale, Lonza
<b>Drug Safety</b> – Huntingdon Life sciences, Covance, Chantest
<b>Tabletting</b> – AMRI, aptuit
<b>Metabolism</b> – Quotient, York, Covance
<b>Screening</b> – Wuxi, Galapagos, Evotec, Essen
<b>Med Chem</b> – Wuxi, Peakdale

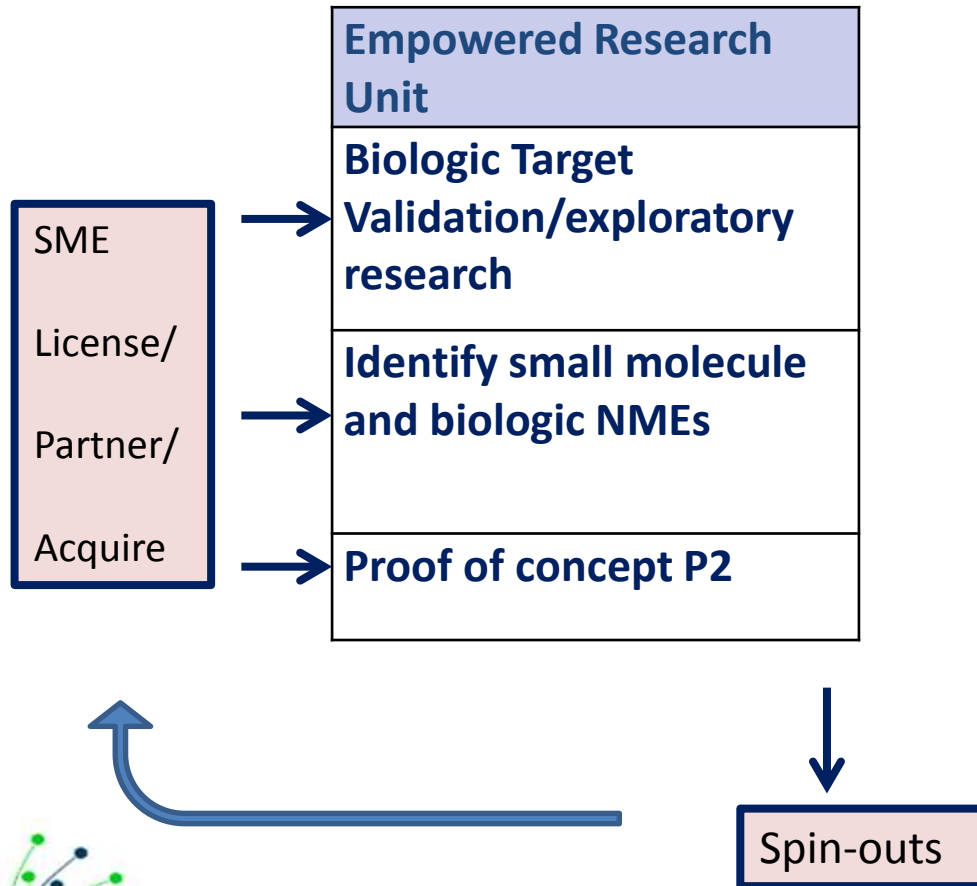
SME  
License/  
Partner/  
Acquire



Spin-outs



# SMEs are more important to Pharma

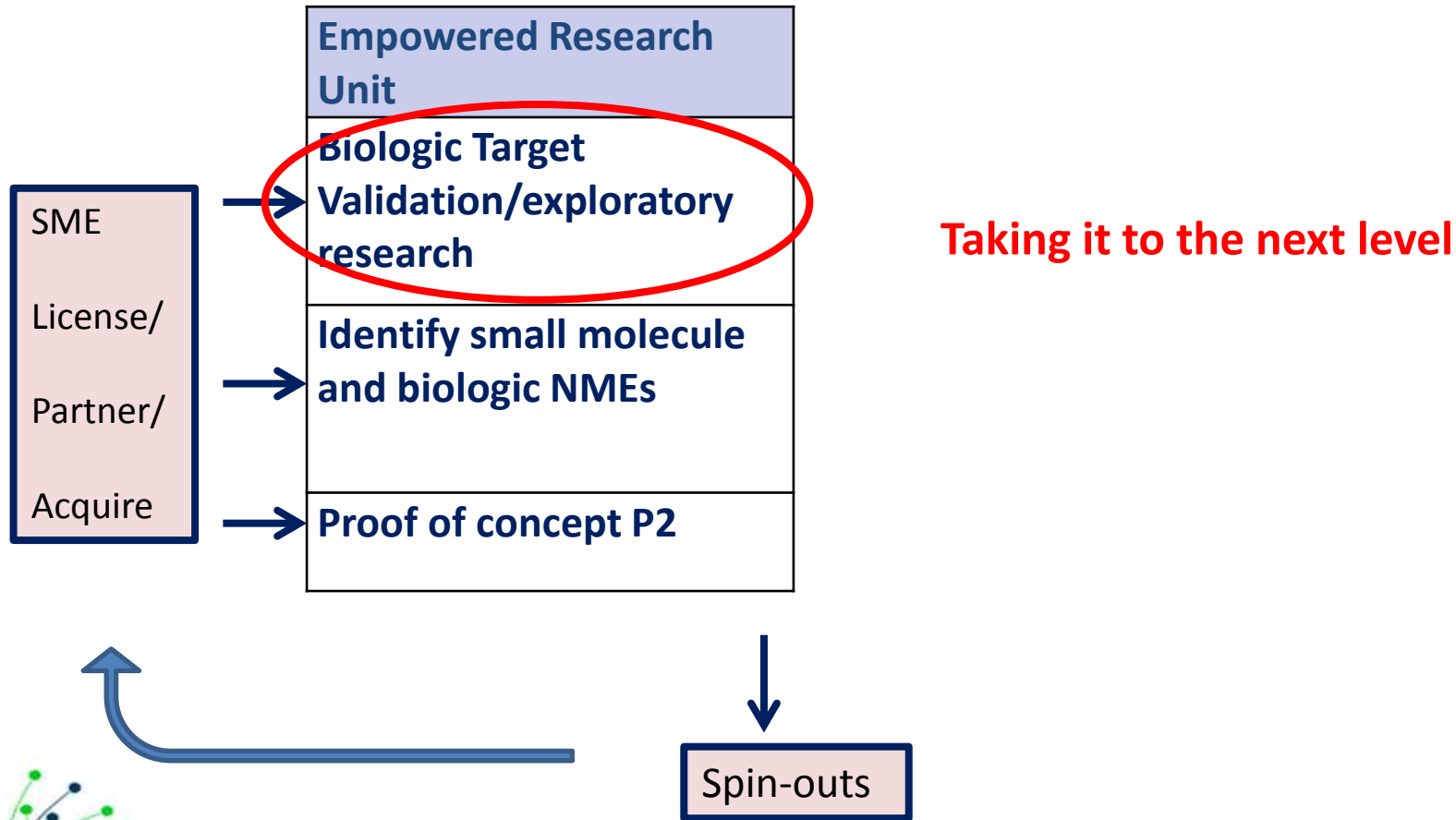


- Pharma have VC Investment groups
- Research – decision makers
- Cycling of assets
- Number of deals increasing
- More ‘virtual’ Research Units  
-External Innovation

Non



# SMEs are more important to Pharma



Non



# EBiSC – European BANK of induced pluripotent Stem Cells



- Generates & distributes standardized, QC, iPS cell lines
  - International distribution capability
  - Catalogue of 3,000-10,000 cell lines
  - Can generate bespoke lines, provide services
- Launched 1<sup>st</sup> Jan 2014, IMI/Pharma funded.
- 3 year duration → self-sustaining
- 26 partners: Co-ordinated by Pfizer and Roslin Cells Ltd



## 6 SMEs

Roslin Cells (Consortium Manager),  
ARTTIC, (project administration),  
Douglas Connect (info mgmt), European  
Screening Port (automation)  
Definigen (functional assays),  
Bioneer (iPS cell line generation)

## 8 universities

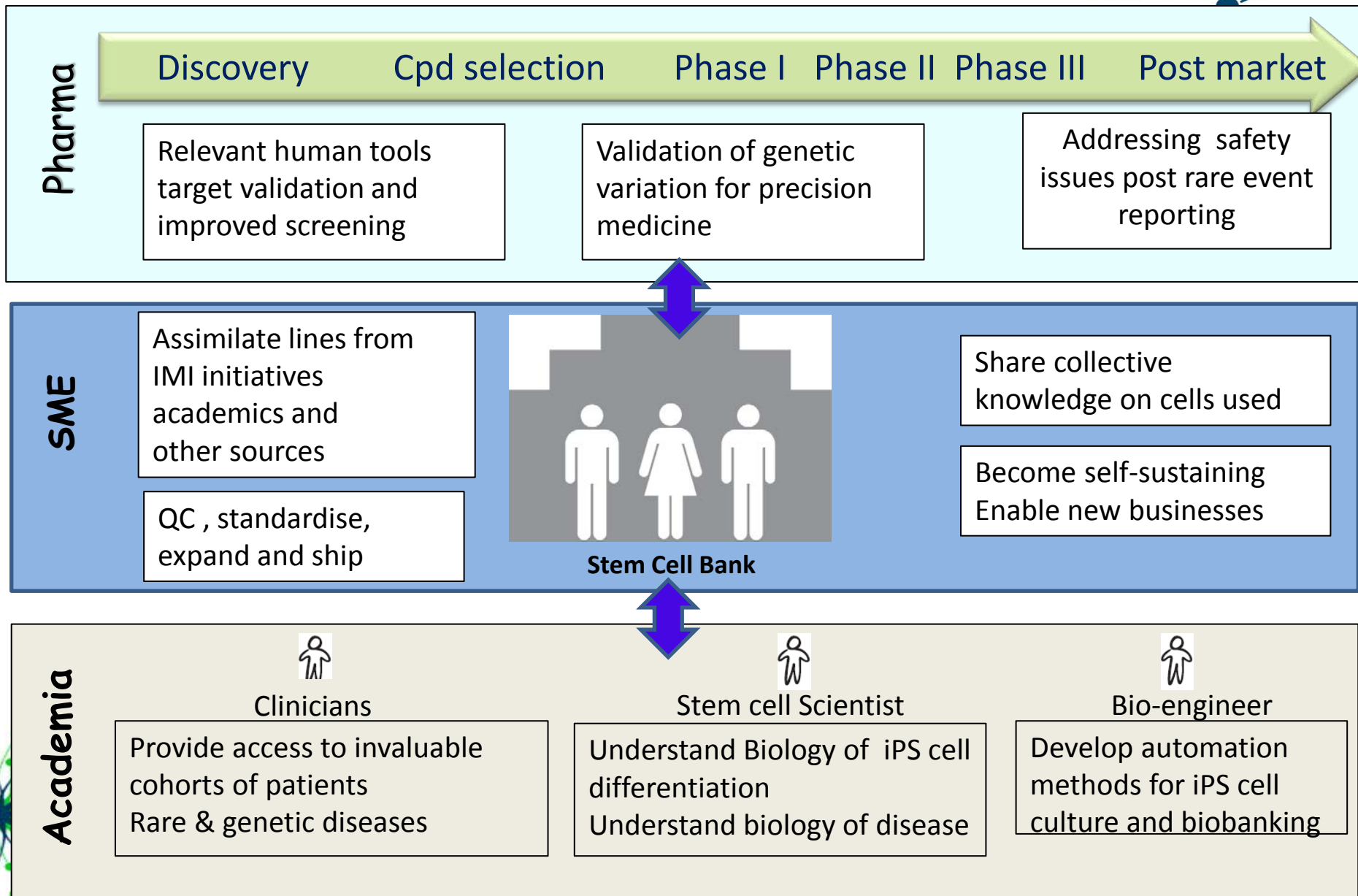
Edinburgh,  
Cologne, Bonn,  
Newcastle,  
Charité (Berlin),  
Hannover,  
University College London,  
Hubrecht Institute.  
Plus other banks and university  
entities

## 6 pharma

Pfizer  
Novo Nordisk  
AZ, UCB  
Janssen  
Lundbeck



# Contributions and Impact





# Why SMEs?



## Focused

- Project management /commitment
- Used to dealing with Pharma / milestones

## Flexible

- Operational plans fit for changing science
- Realistic BD expectations

## Growth drivers

- Investable spin-offs better led by SMEs
- Longer lasting benefit for EU

