

# Business development and licensing in the era of 'Open Innovation'

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19<sup>th</sup> September 2012

Innovative Healthcare Meeting





# Outline

- Introduction
- Drivers of change
- Open Innovation
- Leveraging internal assets – HI / LG partnerships
- Challenges & considerations





# Industry Outlook

## Growth Sector

- Increasing and ageing **populations**
- Expanding populations in **new markets**
- Significant **unmet medical need**
- Continued **scientific and technological advance**

## Returns under pressure

- Decline in **R&D productivity**
- Established market **price pressure**
- **Patent expiries** and **generalisation**

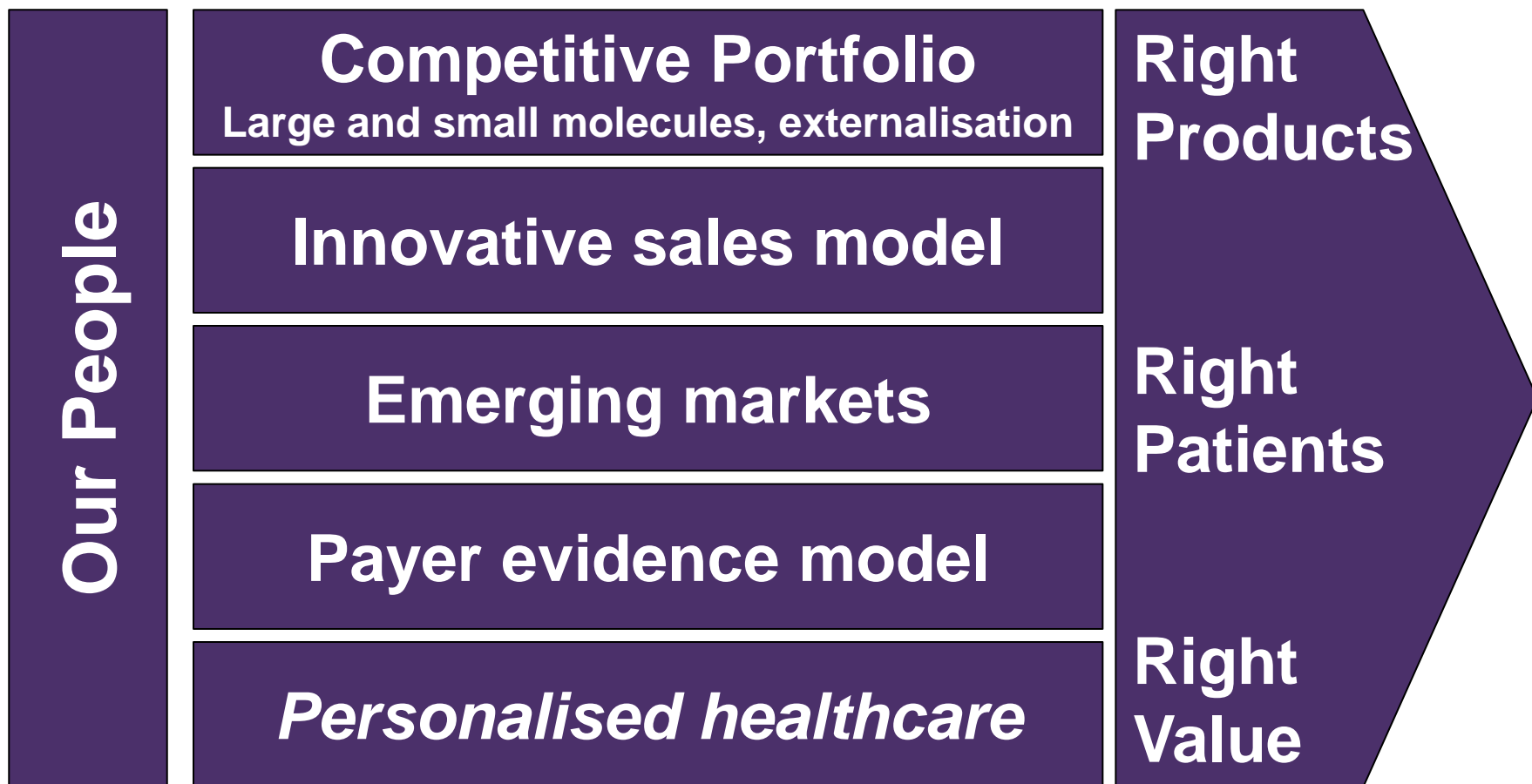
## Leading players will continue to earn attractive returns

- Increased **R&D productivity** opportunities
- Adapting **sales and marketing model**
- Further **cost reduction potential**
- Improved **investment discipline**





# Our response to the changing environment





# AstraZeneca built a truly global emerging markets prescription drug business (2011 Sales)





# Success through collaboration. Because health connects us all

Partnering is a core business priority and our commitment is long-term.

More than 60 critical deals completed over the last three years, including five key late stage deals in the last 24 months.

Over 1000 active partnerships around the world; and we would like more.

We are looking for as much as 40% of our pipeline to be sourced from quality external alliances by 2014

Six out of the next eight potential near term launches are through external collaboration.



The pipeline is the number-one priority and externalisation will be a way of life going forward



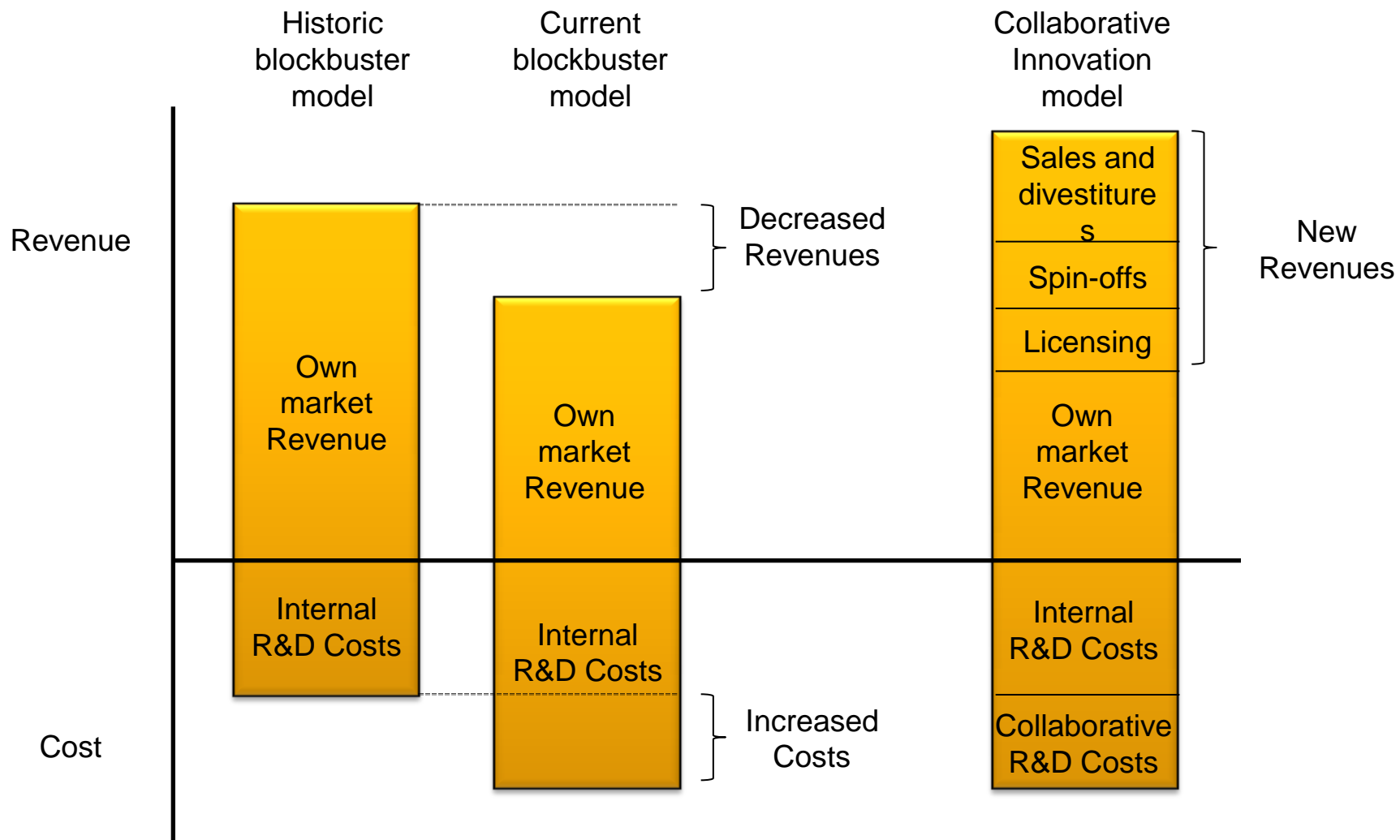
# Drivers of Pharma 2.0

- Cost reduction in R&D
- Complexity of drug discovery
- Impact of genomics and data generation
- Understanding of biological systems
- Separation between basic science and translational medicine



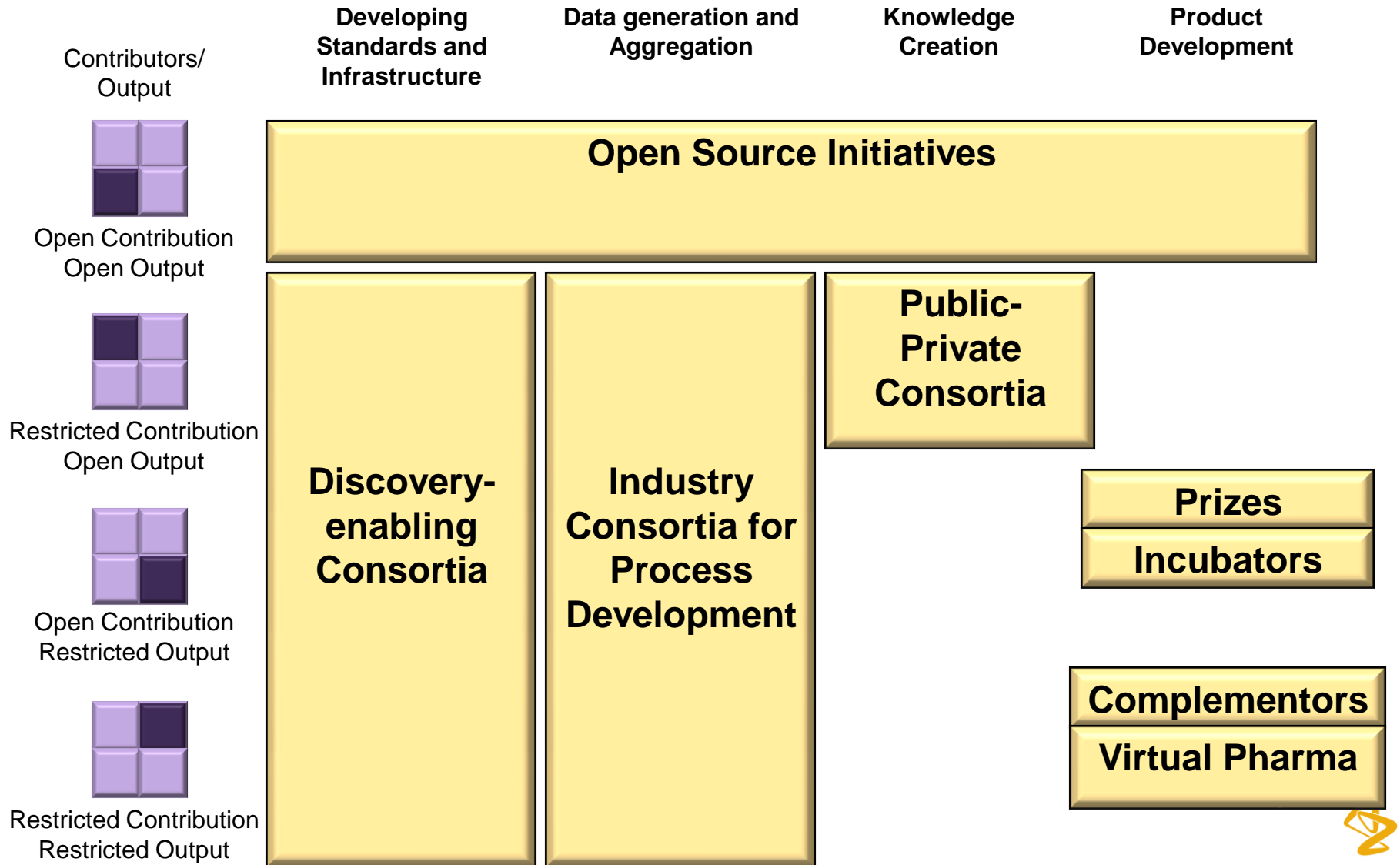


# Open Innovation



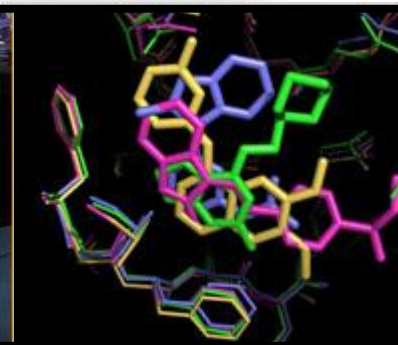
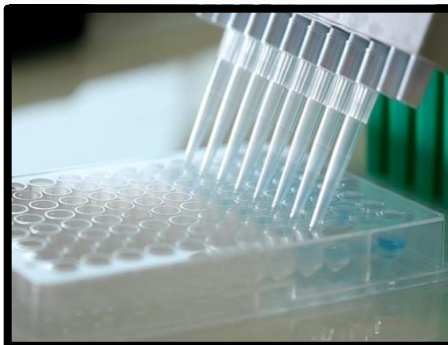
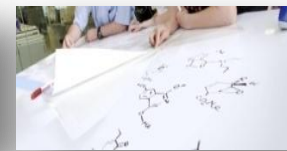


# Open Innovation collaboration models





## External Partnering to Exploit AZ Compounds and Screening (EPECS)



### **1. Increasing the number, diversity and quality of hits and leads for high value AstraZeneca Targets**

- Leveraging drug discovery expertise & subset(s) of AZ compound collection to build partnership

### **2. Support open innovation through the prosecution of innovative targets and lead molecules in collaboration with academia**

- Accessing external innovation in disease biology/target selection

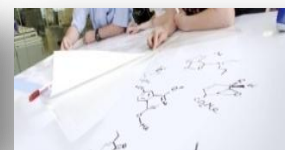
### **3. Support neglected disease strategy through the provision of AZ compounds to support discovery screens**

- Supporting research in neglected diseases that we cannot pursue independently





## Strategic Focus: External LG Partnering Opportunities



**Creating additional value from AZ's compound collection and screening capabilities**

### **Deliverables to AstraZeneca**

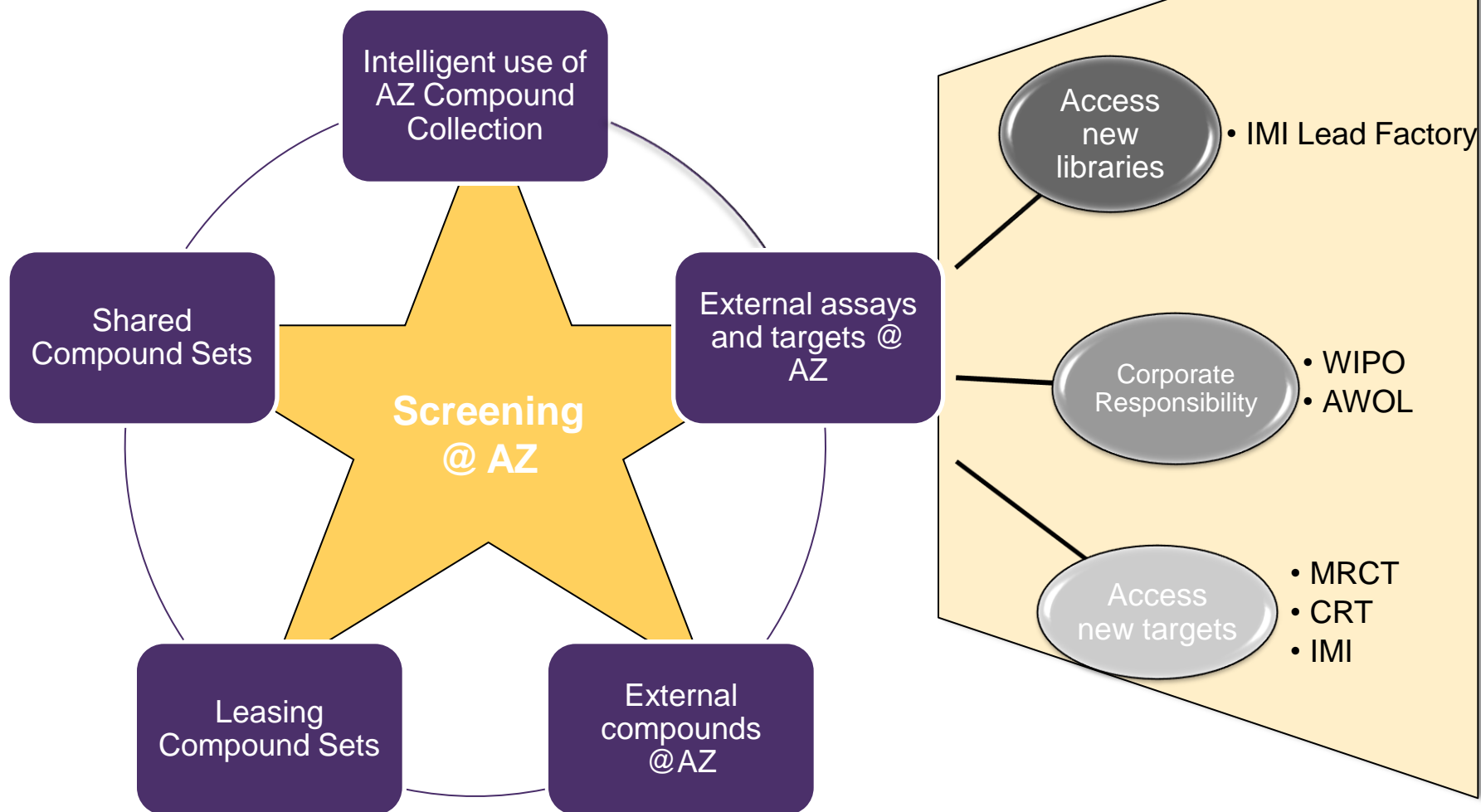
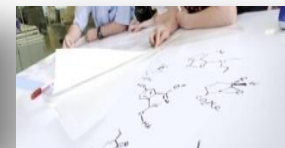
1. Novel chemical equity to support internal discovery
2. Novel project opportunities to enhance internal portfolio
3. Relationship building with academia

There are several ongoing partnerships, and others in development.





# EPECS as an innovative model for accessing compounds and targets @AZ





# AstraZeneca – MRCT Screening collaboration

Opportunity to create additional value from AZ compound collection through direct collaboration with academic screening centre

- Access external innovation in disease biology/target selection
- Using subset(s) of AZ compound collection to attract partnership and drive exploratory drug discovery research
- Delivering additional opportunities to broaden choice in early portfolio
- Supporting research in neglected diseases to help develop noncommercial opportunities

## «AstraZeneca» и «MRC Technology» объявили о сотрудничестве

[#748 (27) 12.07.2010]



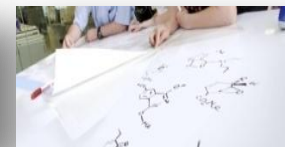
5 июля «AstraZeneca plc» и британская компания «MRC Technologies Inc.» объявили о новом стратегическом сотрудничестве, призванном предоставить доступ к своему портфолио препаратов-кандидатов, что позволит проводить поиск новых лекарственных средств для терапии различных заболеваний. Представители «AstraZeneca» отмечают, что в рамках первого этапа сделки «MRC Technology» проведет скрининг продуктов, содержащихся в продуктовом портфеле компании в таких терапевтических областях, как противораковые, сердечно-сосудистые средства и препараты для лечения инфекционных заболеваний, а также заболевания нервной системы.

A screenshot of a Financial Times (FT.com) article. The page header shows the date 'Monday Jul 12 2010' and 'All times are London time'. The main navigation bar includes 'SEARCH', 'Go', 'QUOTES', and another 'Go'. The article is categorized under 'COMPANIES' and 'Pharmaceuticals'. The title is 'AstraZeneca secures deal with academia' by Andrew Jack, Pharmaceuticals Correspondent, published on July 5, 2010. The article text states that AstraZeneca, an Anglo-Swedish pharmaceutical company, is sharing many of its experimental drug compounds with academic researchers in a deal that will give them privileged access to early-stage science. The company will combine up to 100,000 compounds from its proprietary 'library' with 50,000 controlled by the commercial spin-off arm of the UK's Medical Research Council, the government-backed funder of academic science. The deal will allow both sides the chance to test or 'screen' for efficacy of a broader range of potential future drugs against a greater variety of... A sidebar on the left lists various categories like Front page, World, Companies, Energy, Industrials, Transport, Retail &amp; Consumer, Health, Health Care, Pharmaceuticals, Technology, Media, Telecoms, Financials, By region, Columnists, and Companies A-Z. A small 'EDITOR'S CHOICE' badge is visible on the right side of the article.

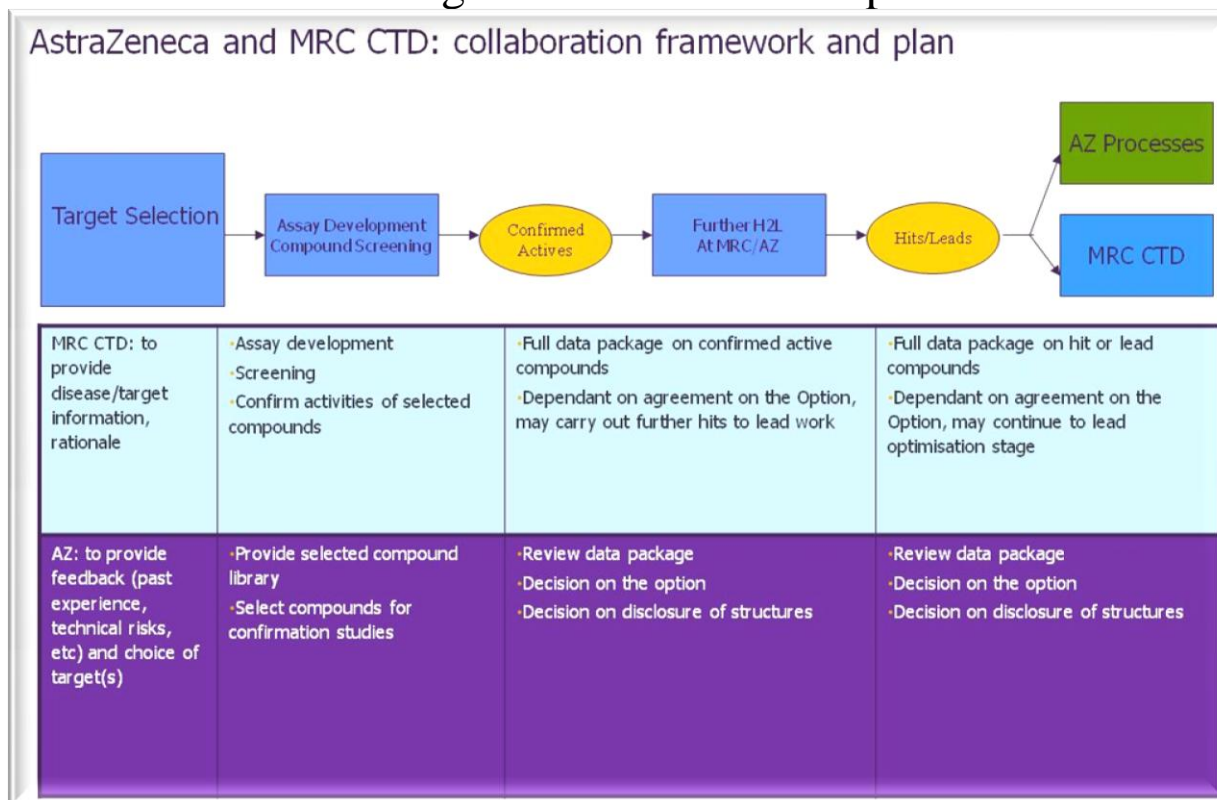




# AZ – MRCT Model



- AZ and MRCT can each select targets
- Combined power of the 2 cpd libraries
- Active involvement of PI researchers in TV, DL, HI
- Shared risk and making best of combined expertise

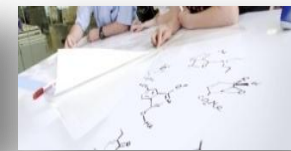


Have run several collaboration projects and continue to do so





### 3) AZ Collaborating with CRT



## Press Release

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### CRT and AstraZeneca form major alliance to create cancer metabolism drugs

Sunday 7 February 2010

#### Cancer Research Technology Press Release

Cancer Research UK's commercialisation and development arm, [Cancer Research Technology](#) (CRT), today announced it has teamed up with biopharmaceutical business, [AstraZeneca](#) in a major, multi-project alliance, in which around 30 scientists will be focused on creating a stream of new anti-cancer drugs, it is announced today (Sunday).

The three-year alliance will work on a portfolio of projects carefully selected by CRT from Cancer Research UK's portfolio of biological research in the emerging field of cancer metabolism.





## Collaborating with CRT



Multiple ongoing projects with equal resourcing across AZ and CRT

Can use both libraries, and develop assays & screen at either site

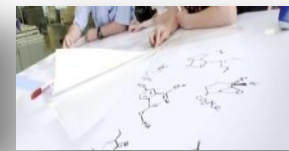
Shared chemistry, TV, screening etc

- Target ideas from Cancer Labs across UK
- Leading UK academic Oncology screening centre & Major UK-based Oncology Pharma group
- High quality TV at AZ & CRUK PIs
- Complementary expertise and compatible interests: win-win





## 4) Collaboration between Pharma



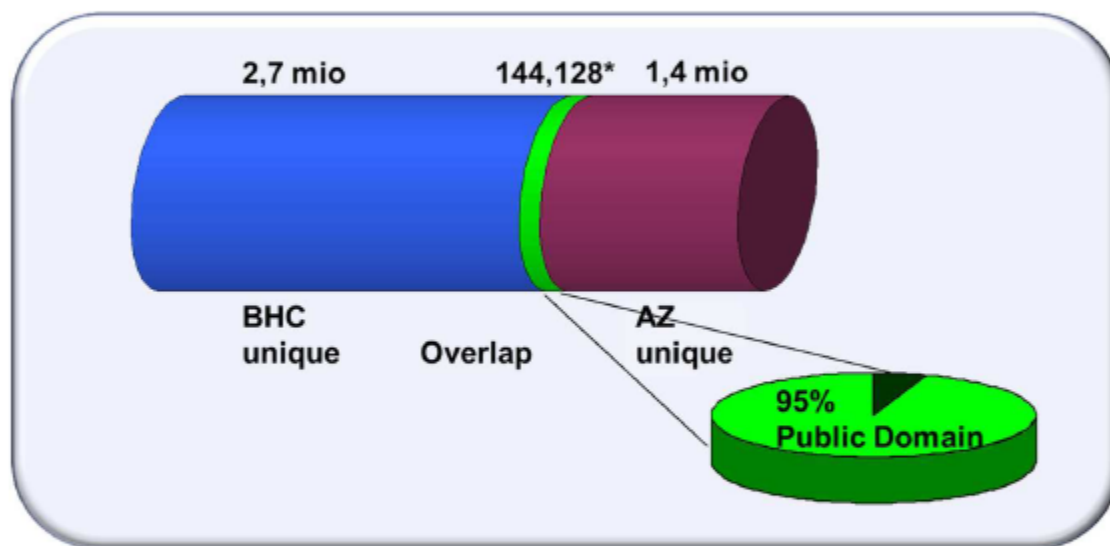
- Pioneering joint initiative of Bayer Healthcare Pharmaceuticals and AstraZeneca





# Motivation

- HTS of large unbiased compound collections provide major route towards innovative small molecule drug candidates



- Library comparison (based on 2-D descriptors) revealed only negligible overlap
- Expanding accessible chemical space provides additional opportunities for difficult targets



## 5) Neglected Tropical Diseases



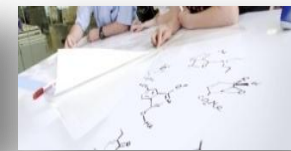
### Opening up Pharma library & HTS Infrastructure to academic scientists – WIPO Re:Search

Access to AstraZeneca library collections (3 per annum) for target-based screening related to NTD	
SUBMISSION ID	1403
<u>Contact Details</u>	
Provider	AstraZeneca - AZ BIO Ventures for Global Health 221 Main Street, Suite 1600 San Francisco, CA 94105 USA Tel: +1 415 446 94 43 <a href="mailto:partnershiphub@bvqh.org">partnershiphub@bvqh.org</a>
Partnership Hub Coordinator Name	
<u>Submission Summary</u>	
Title	Access to AstraZeneca library collections (3 per annum) for target-based screening related to NTD
Executive Summary/Abstract	AZ will commit to enabling up to 3 full collection or large library screens per annum using the AZ compound collection, to identify and determine potency of small molecule hits against novel targets for NTDs. These screens will be performed within AZ corporate High Throughput Screening facilities. It is expected that the screens would be developed and performed by individuals from external academic groups, who will receive appropriate training in screening and data analysis from AZ scientists, and enabling support in terms of compound plating. The visiting scientists would be expected to ensure they have external funding covering salary, accommodation, and consumables expenses for this work; further HI and LI workup on selected active molecules would be expected to be performed by them in their home facilities.
Keywords	Hits; data analysis; target-based; HTS Screening;





## Working with key experts and charities



## Opening up Pharma library to academic NTD scientists

### WIPO

- We can host up to 3 HTS p.a. for NTDs

### Gates, DNDi

- We ship subsets of screening libraries or late stage assets to NTD researchers
- e.g. LSTM Anti-Wolbachia initiative

### AstraZeneca (AZ)

AstraZeneca (AZ) is proud to be a part of the WIPO Re:Search initiative, which we joined as a founding member in 2011, and we are committed to sharing our intellectual property with prospective partners who have the same passion for advancing research in neglected tropical diseases, including TB and malaria. AstraZeneca is proud to make a commitment that all patents owned by AstraZeneca or MedImmune should be used to promote NTD R&D and will therefore be available for royalty-free licensing under the terms of the WIPO Re:Search Guiding Principles. In view of this commitment, AZ is contributing the entire portfolio of patents and published patent applications which it owns, to WIPO Re:Search for license as above, subject only to any conflicting obligations to third parties existing prior to the request for such license. There is no intention to imply that all our contributed patent rights will have relevance to NTDs but in making this broad commitment we make clear that any such rights will be available to promote NTD R&D anywhere in the world [\[ID 1421\]](#). Since we are taking a whole portfolio approach to our patent contribution, we will not list all patent rights contributed, because AstraZeneca patents can easily be identified on public databases such as WIPO's. Some patents which we believe will be of immediate relevance for NTDs have been included in Re:Search at launch and are mentioned below. We will work with Users to specifically identify patents of particular interest and amend the website to make specific reference to these.



 River blindness is the 2nd leading cause of blindness caused by infection worldwide

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 Elephantiasis is the 2nd leading cause of global disability

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500,000



**PEOPLE BLIND**  
DUE TO RIVER BLINDNESS



A close-up photograph of a multi-well microplate, showing rows of wells filled with a dark blue liquid. The image is slightly blurred, creating a sense of depth and scientific precision.

## ***Joint European Compound Library and Screening Centre***



# Unique Proposition



- Expanding chemical space for drug discovery projects
- Industry-like early discovery platform to public drug discovery projects
- Utilizes pharma's corporate compound collections beyond individual research & marketing strategies for the benefit of the patient
- Fosters private-public partnerships in early drug discovery





# 1) IMI Lead Factory

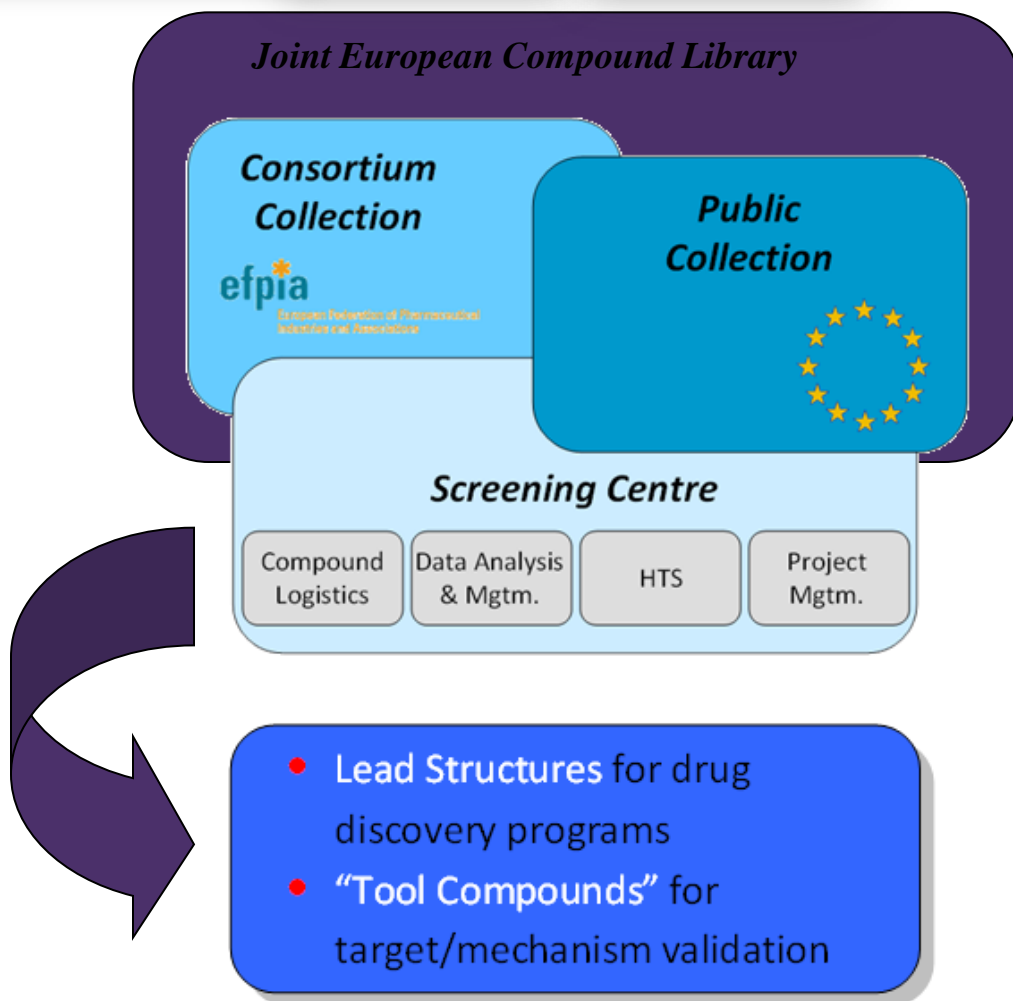


1. A comprehensive *Joint European Compound Library (JECL)* accessible for private and public lead discovery projects

- JECL is comprised of a *Pharma Consortium Collection* (300k compounds) and a *Public Collection* (up to 200k compounds) generated in the context of this project

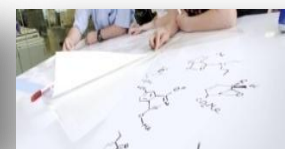
2. A **Screening Centre** – as an independent novel business entity – takes responsibility for cpd. logistics, HTS (internal and out-sourced), data analysis & handling, and project mgmt.

- Screening Centre functions as a market place to broker public-private discovery projects with the Pharma Consortium

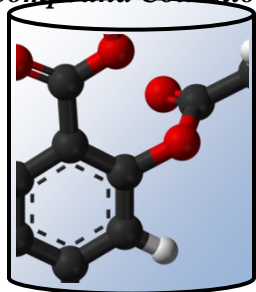




# IMI Lead Factory Objectives



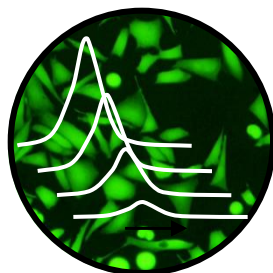
*Joint European  
Compound Collection*



up to 500000 cpds.

**X**

*Target/Assay*



*Hit  
Characterization*



*MedChem  
Follow-Up*

*Qualified  
Hit List*



**Hit-to-Lead  
Optimization**



**Tool Cpd. for  
Target Research**



- ❑ Provide access to comprehensive, high-quality Joint EU Compound Collection
- ❑ Generate “Qualified Hits” for subsequent refinement in drug development process or serving as tool compounds in target research
- ❑ Establish novel platform to foster public-private collaboration
- ❑ Generate broad knowledge base (Qualified Hits x 240 projects) to directly exploit results or deduce future library design strategies

*A ‘controlled experiment’ to broaden scope of pre-competitive research into early stage drug discovery : Collaborative exploitation of compound collections*





### Academia

- ❑ Access to industry-like small molecule discovery platform to identify quality hit compounds translating cutting-edge projects to drug discovery or target research programmes
- ❑ Access to extended expert workbench to realize innovative chemistry proposals => introduce your chemistry to broad pharmaceutical screening activities
- ❑ Funding source to translate ideas into value

### SMEs

- ❑ Platform to establish early research collaborations
- ❑ Unique public-private consortium in the field of early drug discovery => focus on value (IP) generation

### Patients' Organizations

- ❑ Industry-like discovery engine for projects also outside of pharma focus (e.g. orphan diseases)





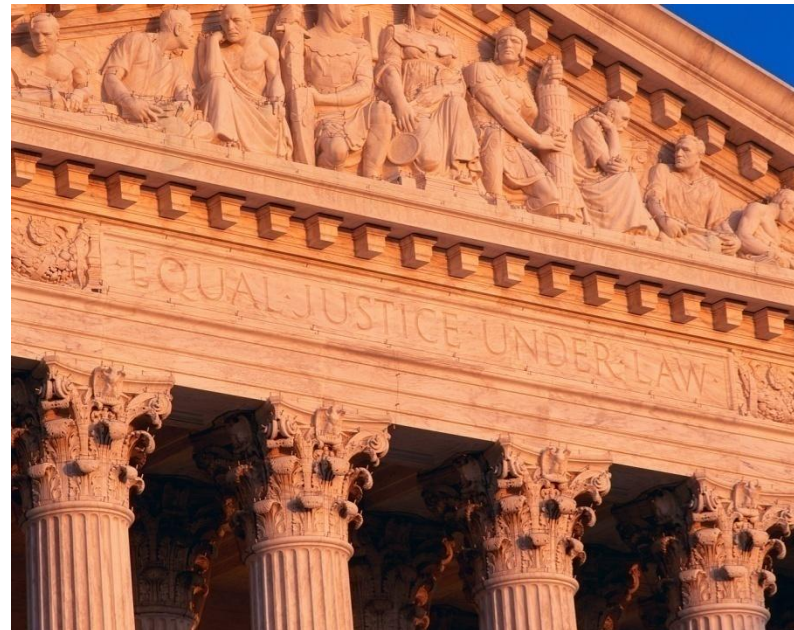
# IP Considerations

“IP rights are the currency that fuels open innovation”

Bernard Munos, Eli Lilly

Depends upon the context...

- Open innovation is not Open Access
- What is precompetitive for one may not be for another
- Where does the value lie in IP?
- Focus on the task
- Legacy IP strategies





# Legal Considerations

“At one point there were 35 lawyers sitting around a table negotiating the consortium contract”

Jacky Vonderscher, former Global Head Biomarker Development, Novartis

- Anti-trust
- Clear articulation of purpose
- Capture organisational learning
  - Consistency in counsel
  - Precedent agreements





# Management Considerations

“The complexity of communication and data sharing increases in an almost exponential fashion as more partners are involved”

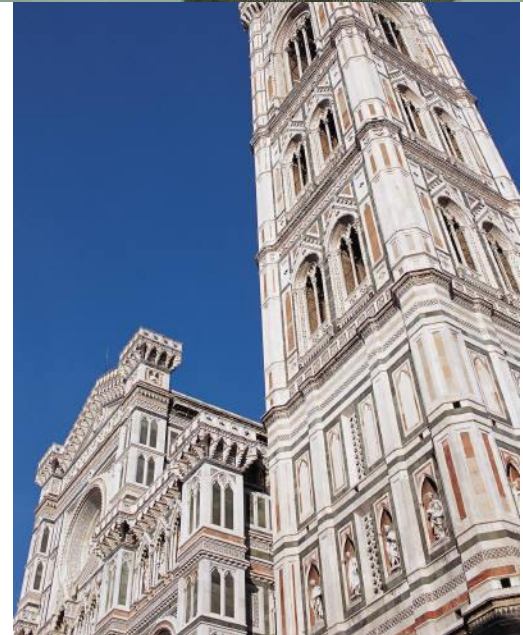
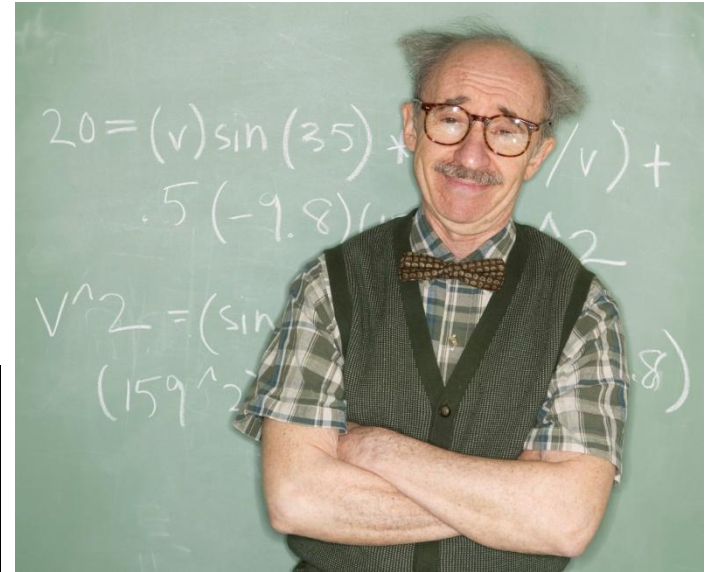
Vargas, G. *et al*; Clin. Pharm. & Ther. **87** (5) 527-529 (2010)

- High level sponsorship
- Trust is key
- Neutral convener
- Agree policies for governing alliance
- Strong project management
- Timely data sharing
- In kind contributions
- Collaboration mindset





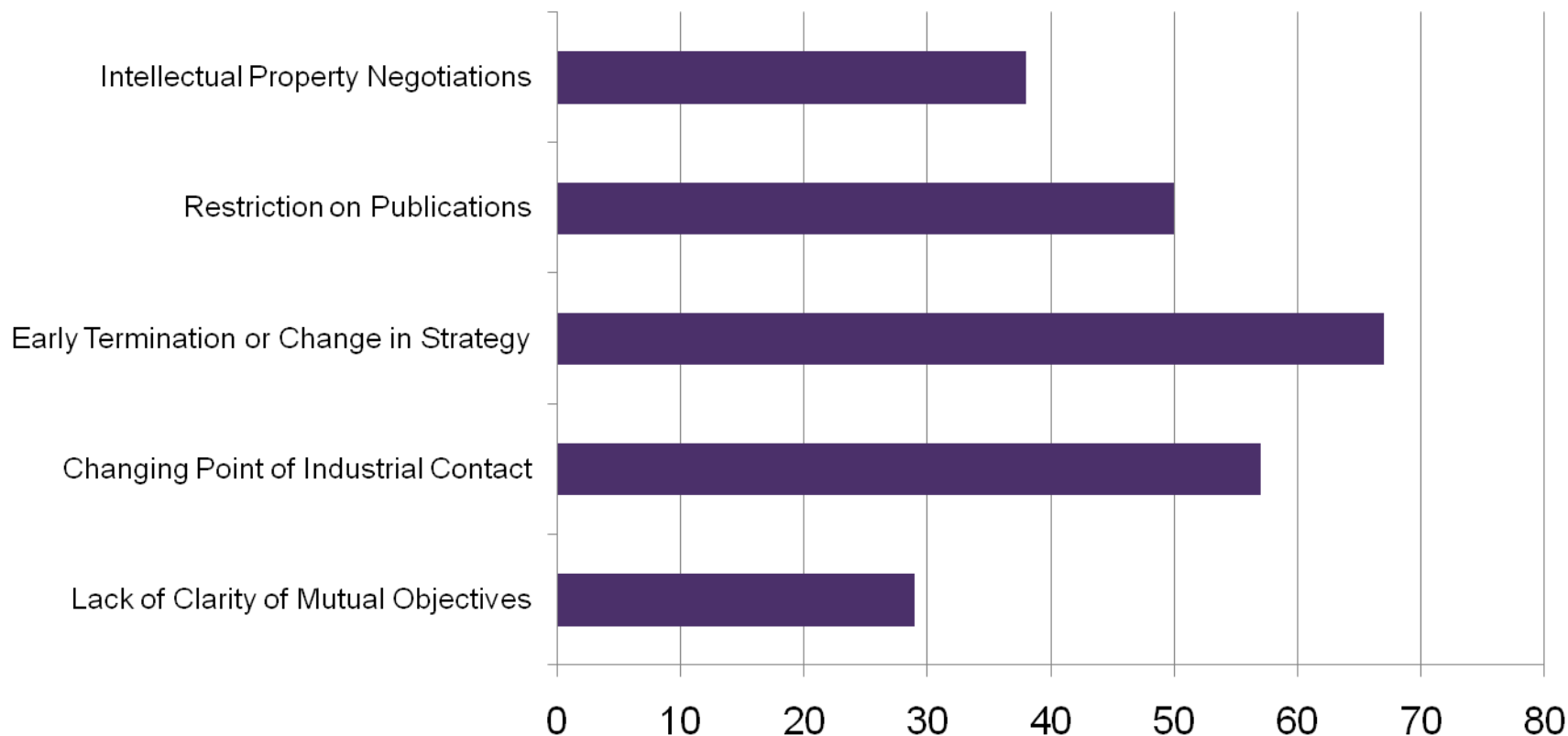
# Preconceptions





# Crossing the Industry/Academic Divide...

## % of Academic Collaborators with Experience of Issues with Industry





# Building a Collaborative Mindset

## Shift From Blame to Contribution

If the goal is to fix a problem, blame is unlikely to be helpful

### Look for and discuss joint contribution

- What are you each contributing?
- Take responsibility for your contribution early
- Help them understand their contribution
- Remember - acknowledging joint contribution builds trust and puts the focus on joint problem-solving





# Future

“Externalisation is not a short-term stopgap to backfill the pipeline. It represents an important change in mindset. We are making a long-term commitment to step up our access to the world of scientific innovation that resides outside AstraZeneca”



David Brennan, CEO





# Why partner with us?

Our exclusive focus on innovative pharmaceutical medicines enables us to invest where the opportunities exist

Our commercial success is underpinned by our global reach and strategy, coupled with local implementation

Our central transaction process allows rapid decision making and streamlined due diligence

Exceptional commercial and R&D presence in emerging markets and Asia

Early involvement of alliance management and continuity through-out the deal life cycle

Expertise in biologics and small molecules from discovery through manufacturing

A commitment to partnering has been embedded in our R&D organisational structure

Line of site strategy via early payer involvement to secure reimbursement and market access

Collaborating with our partners to achieve our mutual corporate goals

