Facilitating Partnerships between Pharma and Academia

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Opportunities for Commercialising Drug Discovery in the Academic Sector
London

AstraZeneca

Outline of Presentation

- Introduction
  - Pharma industry's grand challenge – increasing productivity
  - Key challenges to improve productivity
  - How is Industry responding?

- Role of Academia – Partnering with Pharma
  - Traditional partnership models
  - Opportunities for new partnership models
  - Pre-competitive models

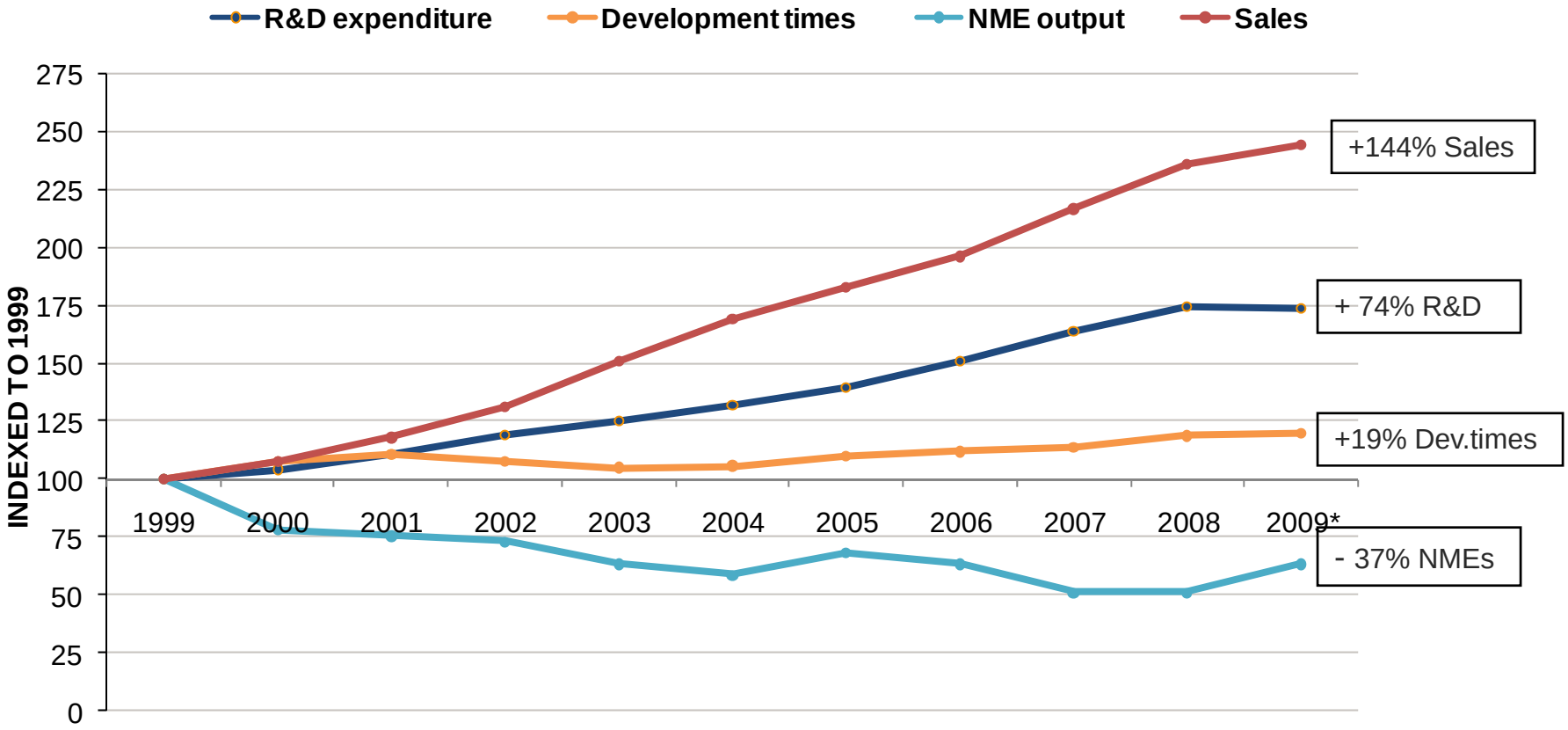
- How can we facilitate better partnerships?
  - What are the main challenges?
    - Changing mindsets
    - Understanding needs and drivers
    - Leveraging Assets
    - Valuing Technology

- Concluding Remarks

Our challenges globally

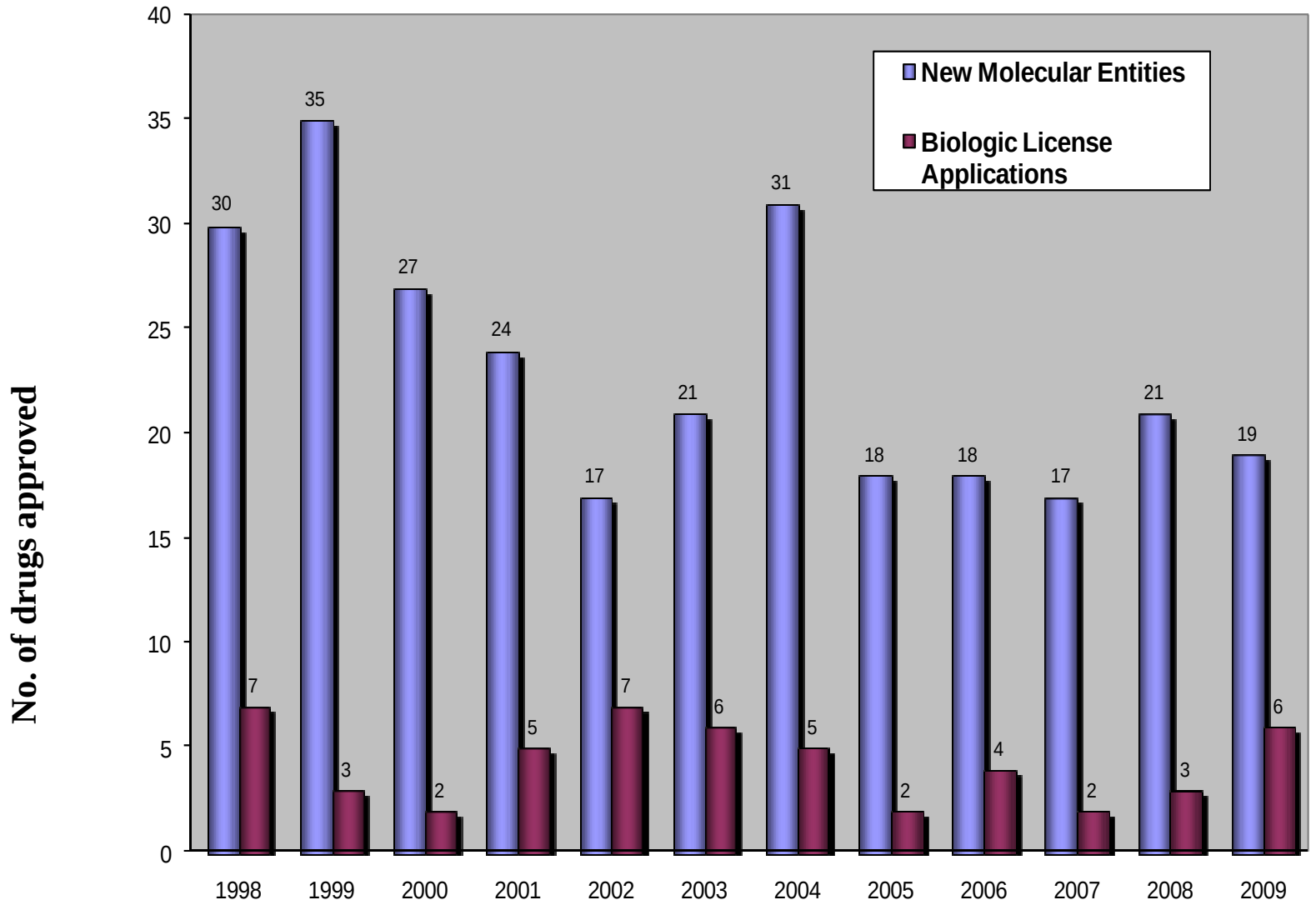
Industry overview: Global R&D expenditure, development times, global sales and NME output

Although global sales of ethical pharmaceuticals continued to rise in 2009, R&D expenditure declined for the first time (0.3%). NME output increased in 2009, but numbers are still more than 30% lower than in 1999. Development times have risen slightly. The widening gap between the global sales and R&D curves may be attributable to the rise in generic drug sales.



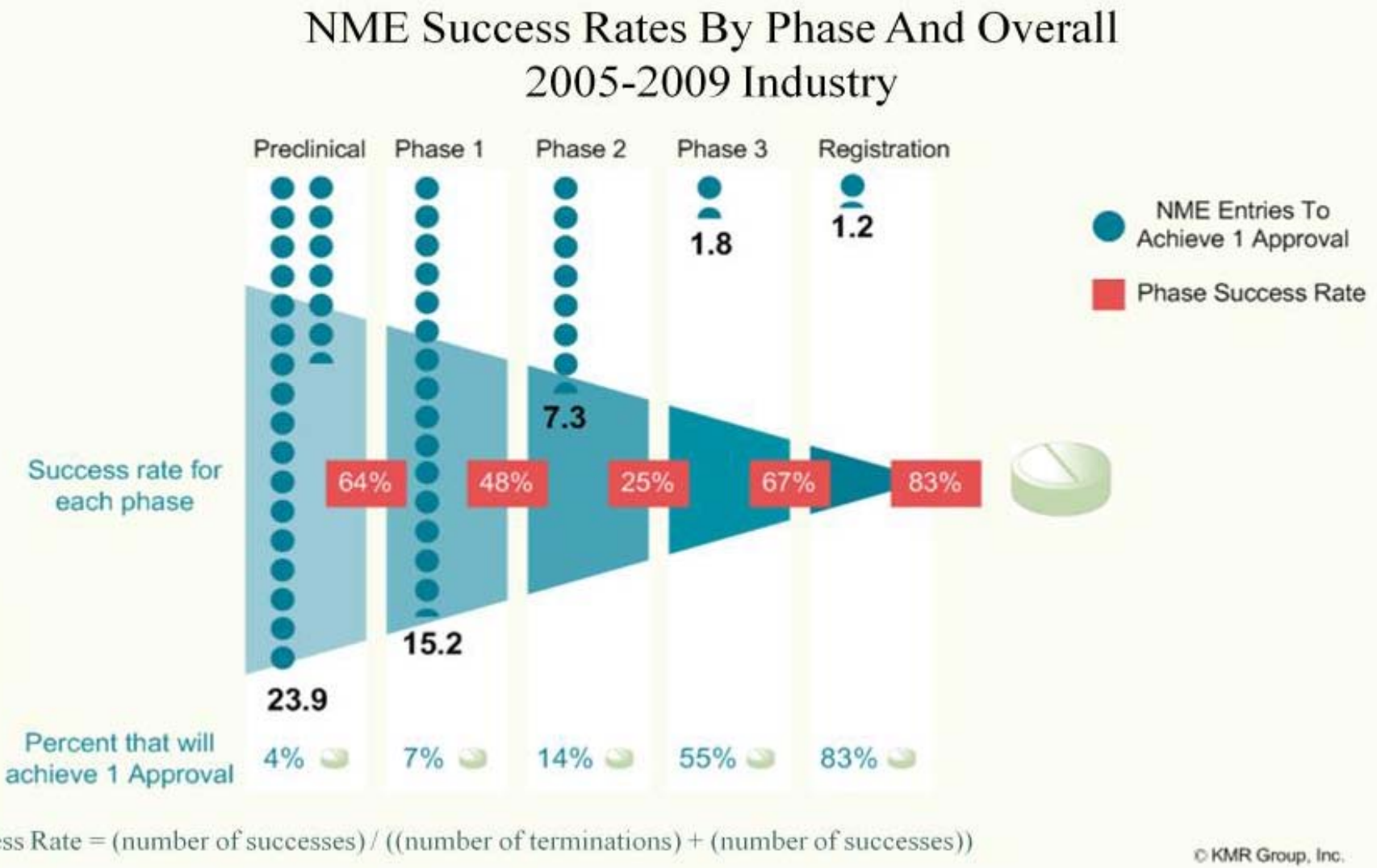
*The development time data point for 2009 includes data from 2008 and 2009 only
Source: CMR International (2010 FactBook) & IMS Health

FDA drug approvals



Adapted from *Nature Reviews Drug Discovery* **9**, 89-92 (February 2010)

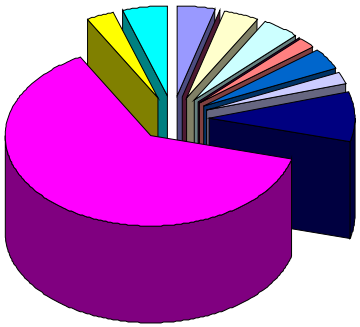
Development Success Rates



Source: The Pharmaceutical Benchmarking Forum

Causes for attrition

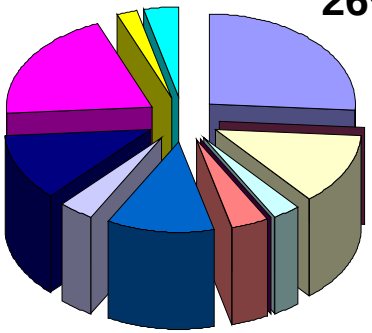
Preclinical



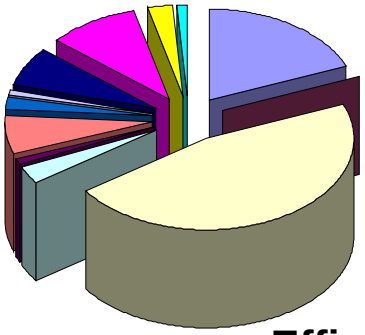
Toxicology 62%

Phase I

Clinical Safety 26%

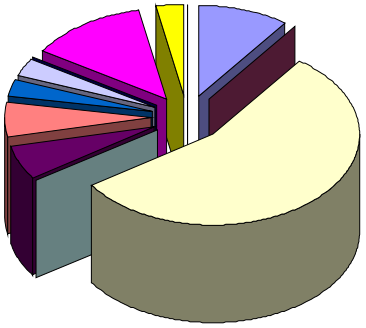


Phase II



Efficacy 47%

Phase III



Efficacy 55%

Clinical Safety	Cost of Goods	Efficacy	Formulation
Legal Divesture	Market Potential	PK/Bioavailability	Resources
Strategic	Toxicology	Unknown	Other

Health Warning !

- Models of R&D Productivity suggest that most pharma companies are not achieving a sufficient output of compounds progressing through the different phases of their portfolios to meet expectations of new medicine production
- Current cost of medicines ~$1.8bn capitalised cost/NME
- Increasing pressure from generics
  - Up to 70% of all prescriptions written in US are for generics
- Significant tranche of patent expirations in next three years will put ~$200bn in annual drug sales at risk
- For every $ lost to generics to 2012, large pharma may only be able to replace a quarter of that with new product revenues

How is Industry responding?

Pharma is adopting a number of strategies which focus on increasing productivity

- Further Investment in:
  - Predictive Sciences (Safety and Efficacy)
  - Personalised Healthcare and Biomarker development
  - New Enabling Technologies and Platforms
- Earlier clinical read-out of PoP/PoC utilising academic translational medicine units
- CD repositioning – maximising value of chemical equity
- Externalisation – spreading net wider to access new science, technology and product opportunities globally

Change operating model and mindset

- Integrating clinical/commercial input earlier in the value chain
  - Proof of Relevance not just Proof of Concept
- Greater use of outsourcing models for non-core deliverables
- Fail early - Fail fast
- Focus resource on projects with higher probability of success

Profound effect on PhII/III attrition will be one metric to understand whether investment is providing a sufficient RoI

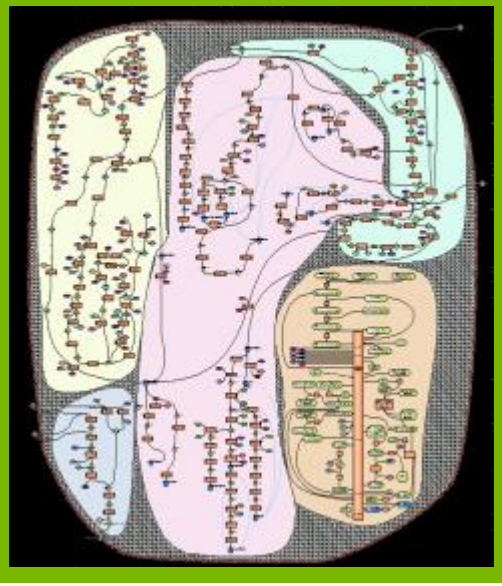
Predictive Science

We apply our extensive scientific expertise in this field to:

- drive greater disease understanding
- ensure the safety of medicines
- improve efficacy & success rate

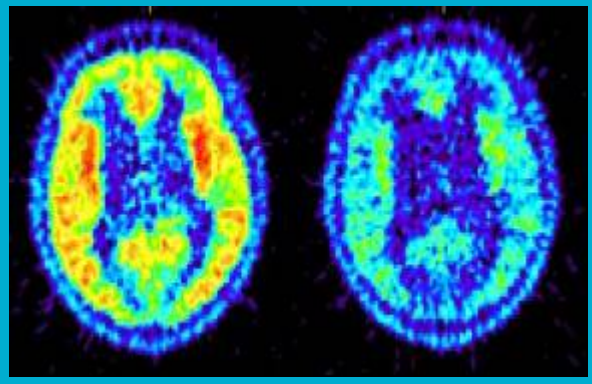
Right Target, Right Tissue/Exposure, Right Safety, Right Patients

Mechanism



Model

Marker



Externalisation

R&D Pipeline

Externally accessed Innovation is an important contributor throughout all phases of the pipeline

Pharma Collaborations with Academia

Many different types of models have been used. The table outlines some broad examples of these, but other overlapping models exist.
* Existing examples from AZ Portfolio

Model	Examples	Outputs	Ownership of Results
Fee-For-Service/Sponsored Research	Many	Compound testing in defined models Clearly defined deliverables	Sponsoring company
Research Collaboration*	UCL Univ Columbia Karolinska Univ. Manchester	Exploratory research in new targets, mechanisms and diseases	Sponsoring company or can be split between company and Univ
Institutional Funding	J+J/Scripps Pfizer/Scripps Beeson Gregory/Oxford	Innovative science and technology	Owned by institution with option to license/commercialise for company
Competitive Consortia	Pfizer/CTSA Pharmaportal Lilly Pfizer Merck/Asian Cancer Structural Genomics Consortium	Exploratory research in new targets, mechanisms and diseases	Sponsoring company or can be split between company and Univ dependent upon nature of project
Pre-competitive Consortia	IMII consortium Pistoia Alliance SAEC Consortium	Exploratory research in areas of new technology development and application	Owned by originating party but open data sharing via web-based portals Ready availability of research use licenses
Strategic Collaboration	Pfizer/Wash U Sanofi/Harvard Wyeth/Scottish Univs TMRI	Exploratory research in new targets, mechanisms and diseases Compound repositioning	Sponsoring company or can be split between company and Univ, dependent upon nature of project

Rise of Academic Drug Discovery Units

- Drive to refocus pharma resources on product candidates which occupy later stages of the value chain

- Challenge of restocking early stage pipelines with innovative projects against novel drug targets is clear

- Recent emergence of academic units with capabilities in early drug discovery is one mechanism in which the gap between early and late stage development is being addressed

- Availability of experienced drug hunters from pharma is supporting growth of these centres

- Links with Academic Translational Medicine Centres offer the opportunity to drive “learn and confirm” approach to clinical validation

- These provide rich sources of collaboration between pharma and academia

- **MRC Technology Centre for Therapeutics Discovery** (London, UK)
Translates innovative biology into late stage therapeutic assets. Activities inc. HTS, Comp Chem, Med Chem and ADMET

- **Imperial College Drug Discovery Centre** (London, U.K)
Integrated drug discovery unit with capabilities across value chain of DD.

- **Cancer Research Technology** (London, U.K.)
Undertakes collaborative drug discovery programmes with academics to translate new target discoveries into new candidate drugs

- **Drug Discovery Unit, Univ. Dundee** (U.K.)
Translating basic science into lead compounds for target validation through to pre-clinical drug candidates

- **European Screening Port** (Hamburg, Germany)
Fee-for-service model to provide academic scientists with HTS, hit identification and med chem capabilities

What are Pre-Competitive consortia?

Pre-competitive Collaboration

Drivers

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

Focus on challenges that cannot be readily be addressed by a single individual or organisation

- Scope
- Not easily commercialised
- Large data requirements
- Standardisation

Outputs

- Developing Standards and Infrastructure
- Data generation and aggregation
- Knowledge creation
- Product development

Facilitating better partnerships

"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"

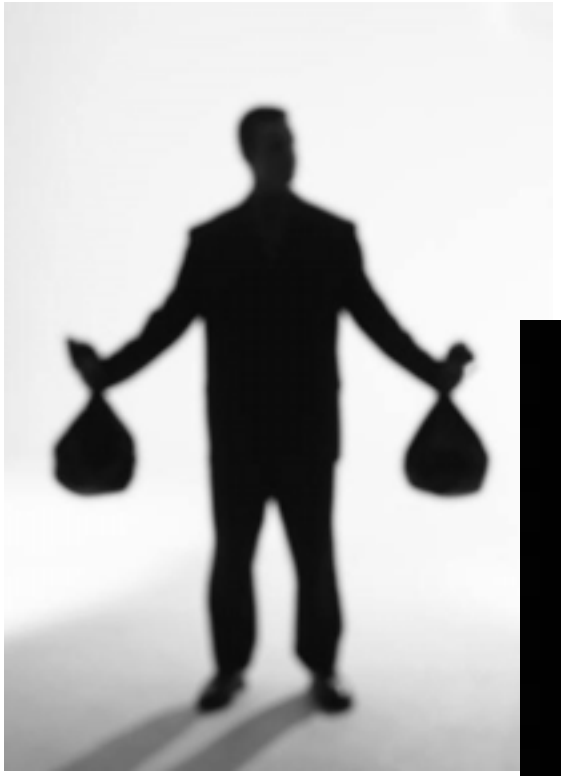
David Brennan, CEO, AstraZeneca

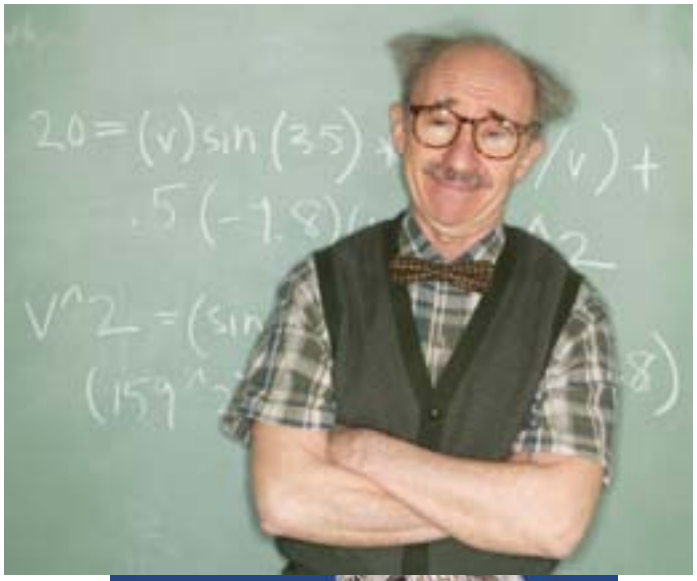
To address the challenge of increasing productivity, it is essential that new models of partnership between pharma and academia are considered

4 areas to consider:

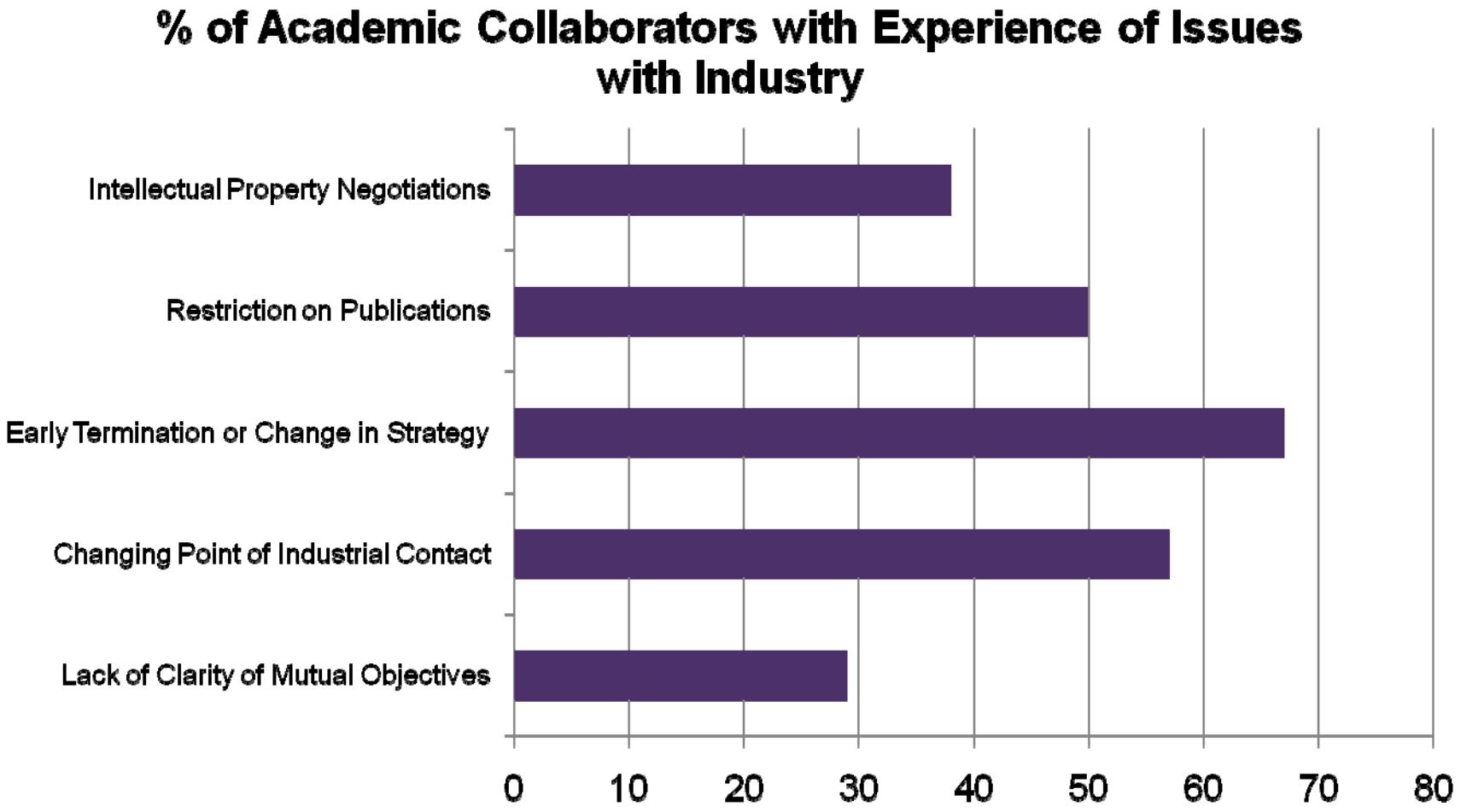
a) Changing Mindsets
b) Sharing and understanding needs and drivers
c) Leveraging assets
d) Valuing technologies

Changing Mindsets - Preconceptions





Building the Collaborative Experience



Vallance P. *et al* ; Clin. Pharm. Ther. **87** (5) 525 - 527 (2010)

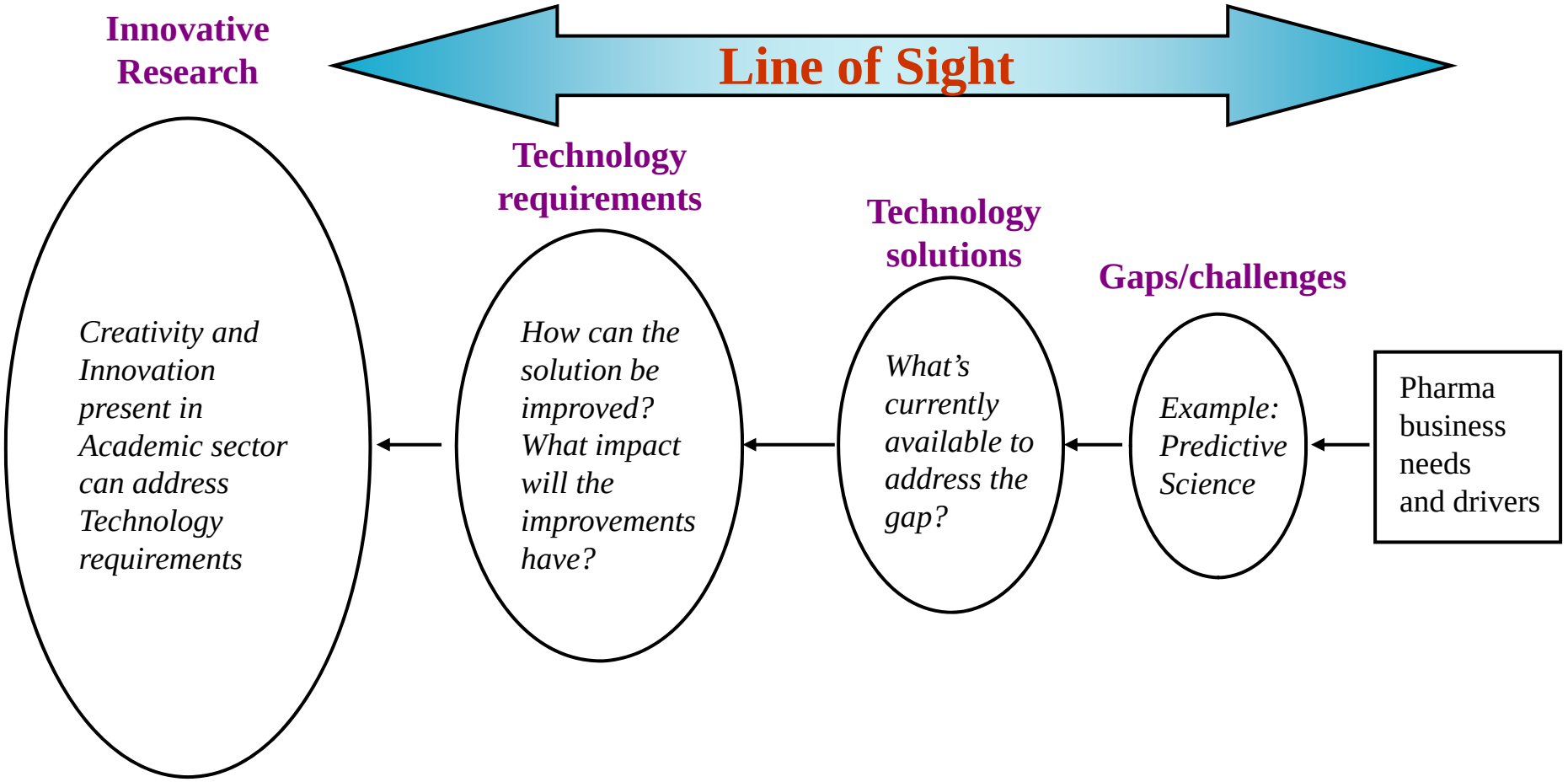
Building a Collaborative Mindset

Focus on discussing the problem, not just seeking pre-determined solutions

Identify and discuss joint contribution

- What are each contributing and where does this fit?
- Take responsibility for your contribution early
- Don’t apportion blame – if there’s a problem, share and discuss. Your collaborator may have an unexpected solution
- Acknowledging joint contribution builds trust and puts the focus on joint problem-solving

Understanding Technology Needs



Publicising Needs

- Areas of interest for Partnering are identified on website

- Therapeutic Areas
  - Oncology
  - Respiratory/Inflammation
  - Infection
  - Neuroscience
  - Cardiovascular/Metabolism/Diabetes

- Enabling Technology
- Personalised Healthcare
- New Opportunities
- China/Japan

- Early stage and late stage interests

http://www.astrazeneca.com/Partnering

Leveraging Assets

Recent collaborations that provide access to AZ Compound Collection

Reuters : AstraZeneca agrees drug discovery tie-up with MRC
7:43am UTC+0100
Mon Jul 5, 2010 5:37am EDT
* Astra, MRC to screen combined library of 150,000 compounds
* Cancer, cardiovascular, neuroscience and infection targets
* (Adds detail)
LONDON, July 5 (Reuters) - Anglo-Swedish drugmaker AstraZeneca (AZN.L) said on Monday it would share chemical compounds with the UK's Medical Research Council (MRC) to help identify potential new treatments for serious diseases.
The tie-up fits into AstraZeneca's strategy of scaling back its own drug discovery research in certain areas to cut costs and focus research and development efforts. [ID:nLDE62019Q] AstraZeneca said MRC Technology, the commercial arm of the MRC, would screen up to 150,000 compounds, made up of 100,000 from AstraZeneca's collection and about 50,000 from the MRC library, against selected biological targets.
Initial screening would be in the areas of cancer, cardiovascular, neuroscience and infection, the drugmaker said.
Both companies would retain ownership of their respective compounds, it said, and a joint committee would review the results and decide how to go ahead with any compounds that showed promise as potential drug candidates.
"As part of our increasing drive to access innovation from external sources, there's real value in collaborating with organisations such as MRC Technology with a track record of success in biomedical research including new areas of disease biology," said Jin Li, director global compound sciences at AstraZeneca.
"This collaboration gives us early access to new disease understanding and related novel drug targets, allowing us to broaden the scope and choice of programmes we take forward."

June 28, 2010
AstraZeneca allows access to potential malaria drugs
by Matthew Dennis
Last Updated:June 28, 2010 13:30

AstraZeneca announced Monday an initiative to allow researchers from the Medicines for Malaria Venture (MMV) access to 500 000 agents in the drugmaker's compound library in an effort to identify drugs for the treatment of malaria, including resistant strains of the disease. AstraZeneca CEO David Brennan noted that collaborative efforts are the only "solutions to today's global health challenges." Under the agreement, MMV scientists will screen the compounds for activity against Plasmodium falciparum, with promising agents progressing through research at AstraZeneca's R&D facility in Bangalore, India, with the aim of identifying candidates for clinical testing. A spokesman for AstraZeneca noted that the intellectual property of the agents would remain with the drugmaker.

Valuing technology

•The contracting process can be complicated by differing valuations of technology and contribution

•Valuing early stage technology is difficult and prone to inaccuracy

•Too much time and effort can be expended in this endeavour

•Potential to impact relationship longer term

•Both parties need to adapt their expectations and strategy to achieve the desired outcome

- Pharma – where academic input removes roadblocks/promotes milestone transitions, this needs to be appropriately recognised through downstream rewards
- Academia – expectations of return from IP need to be based on a realistic assessment of its contribution in context of high project attrition rates and committed costs required to achieve clinical PoC/registration

Concluding Remarks

- The productivity challenges which face the pharmaceutical industry require that we adapt a more collaborative approach to identifying viable solutions
- The skill sets, expertise and interests that exist within pharma and academia are largely non-overlapping but offer clear synergistic opportunities
- Better partnership will require both a more collaborative mindset and a change in culture from both parties
- Shared desire to develop new medicines which address the key unmet needs of patients will facilitate better, more productive partnerships