Tech Transfer – What Industry is looking for

David Hollinshead – AstraZeneca R&D

”What a Chemist needs to know about Technology Transfer”,
Nottingham July 9th 2009

AstraZeneca
RESEARCH & DEVELOPMENT

Presentation Overview

- Pharma R&D and its interdepency with the UK
- Industry pressures and trends
- What IS industry looking for?
  - Chemical science related needs
- Future perspectives for pharma
- Model examples (CoEBio3 and Nottingham DTC)
- Summary

UK and Pharma have been good bedfellows

- UK attracts more pharma R&D investment than any other EU country
  - Spend of £3.2bn in 2004 (UK #3 behind US & Japan)
- Top global pharma companies have a significant UK R&D presence
  - UK headquarters for GSK and AstraZeneca with significant presence from Pfizer, Lilly, Novartis, Schering-Plough and others
- Pharma contributes significantly to the UK balance of trade
  - 2004 exports exceed £12bn, with trade surplus of £3.4bn
- UK at the forefront of advances in innovative medicines
  - 18 of the world's current top-selling medicines have originated from UK R&D
  - UK displays the highest ratio of first patent files for NMEs relative to R&D spend in the world
- UK supporting a growing biopharmaceutical industry
  - 2nd most productive biopharma product development in the world after US
- Industry recruitment of innovative scientists and skills from universities
  - 2004 employees = 73,000 with 27,000 in R&D and > 250,000 in related activities and services

ABPI – "Facts and statistics from the pharmaceutical industry"

AstraZeneca
RESEARCH & DEVELOPMENT

UK and Pharma have been good bedfellows – Why?

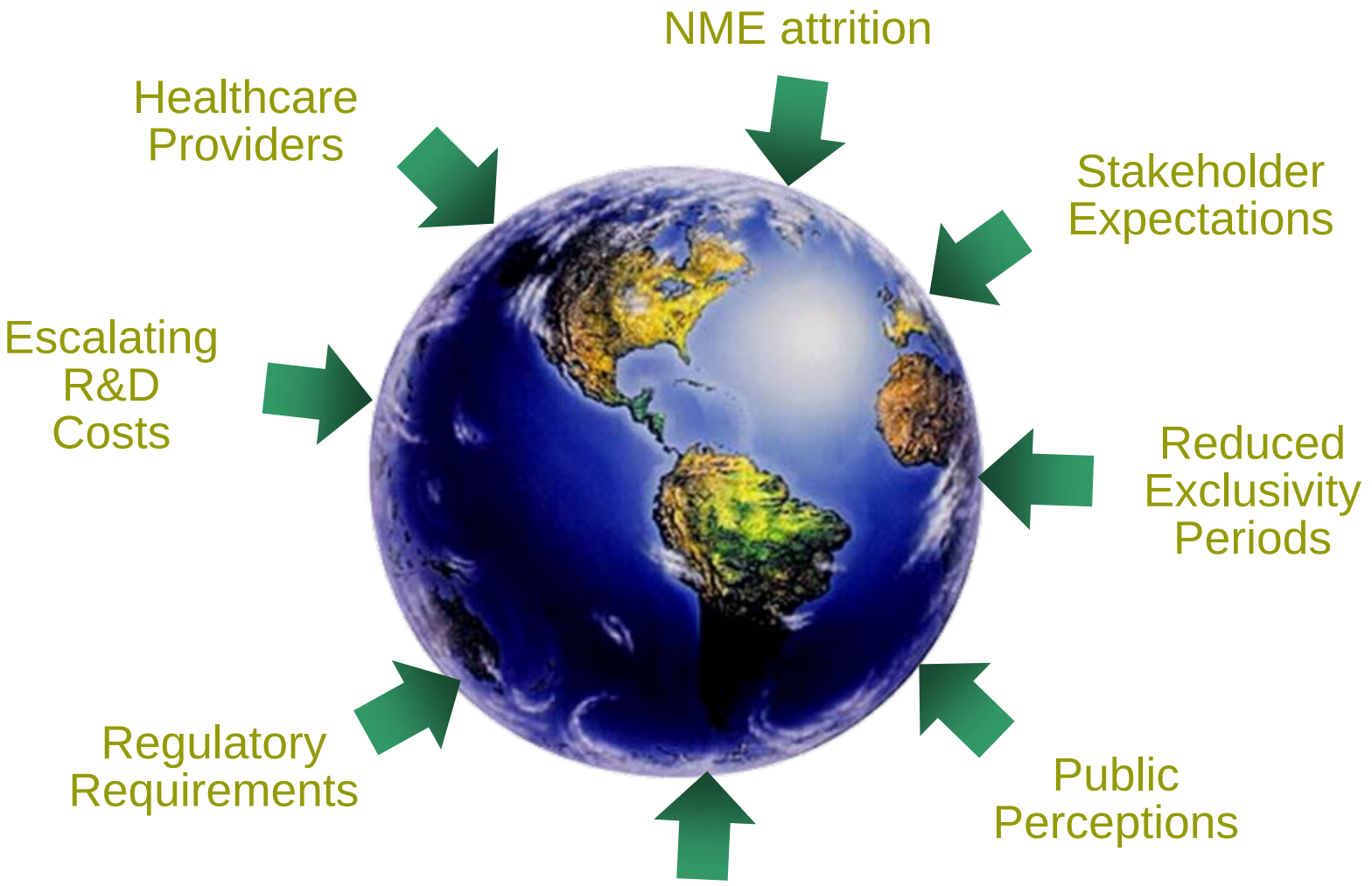
- Four factors keeping R&D in the UK*:

- Access to skills and knowledge
- A good regulatory environment
- A competitive cost base for collaborative research
- A market that supports innovation

*ABPI response to the House of Commons Science and Technology Committee Inquiry, Strategic Science Provision in English Universities (2005)

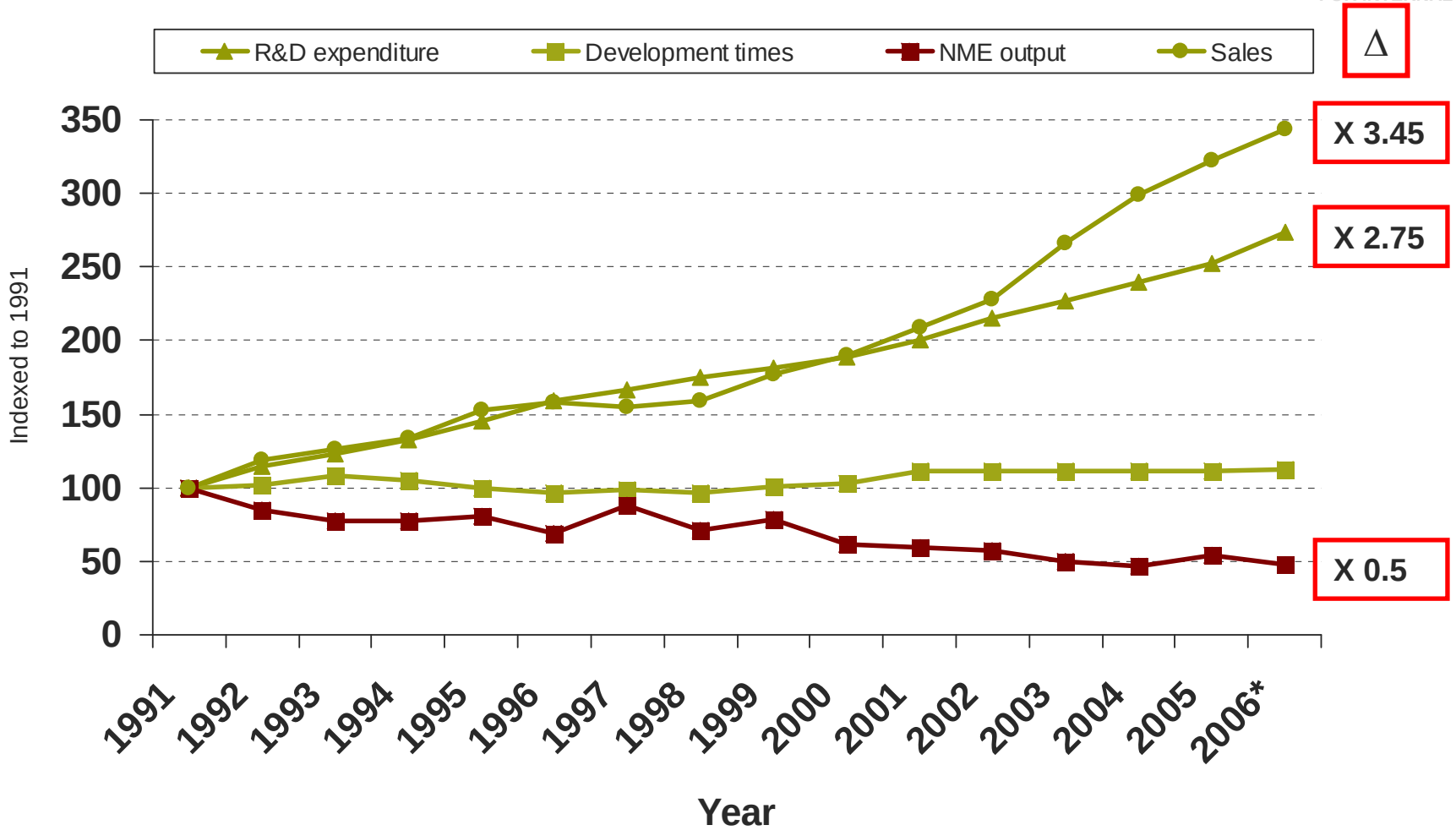
AstraZeneca
RESEARCH & DEVELOPMENT

Our Pharma World is Changing……



AstraZeneca
RESEARCH & DEVELOPMENT

Global R&D Productivity 1991 - 2006



* The development time data point for 2006 includes data from 2005 and 2006 only

Source: CMR International & IMS Health

AstraZeneca
RESEARCH & DEVELOPMENT

Changing shape of Pharma in the UK

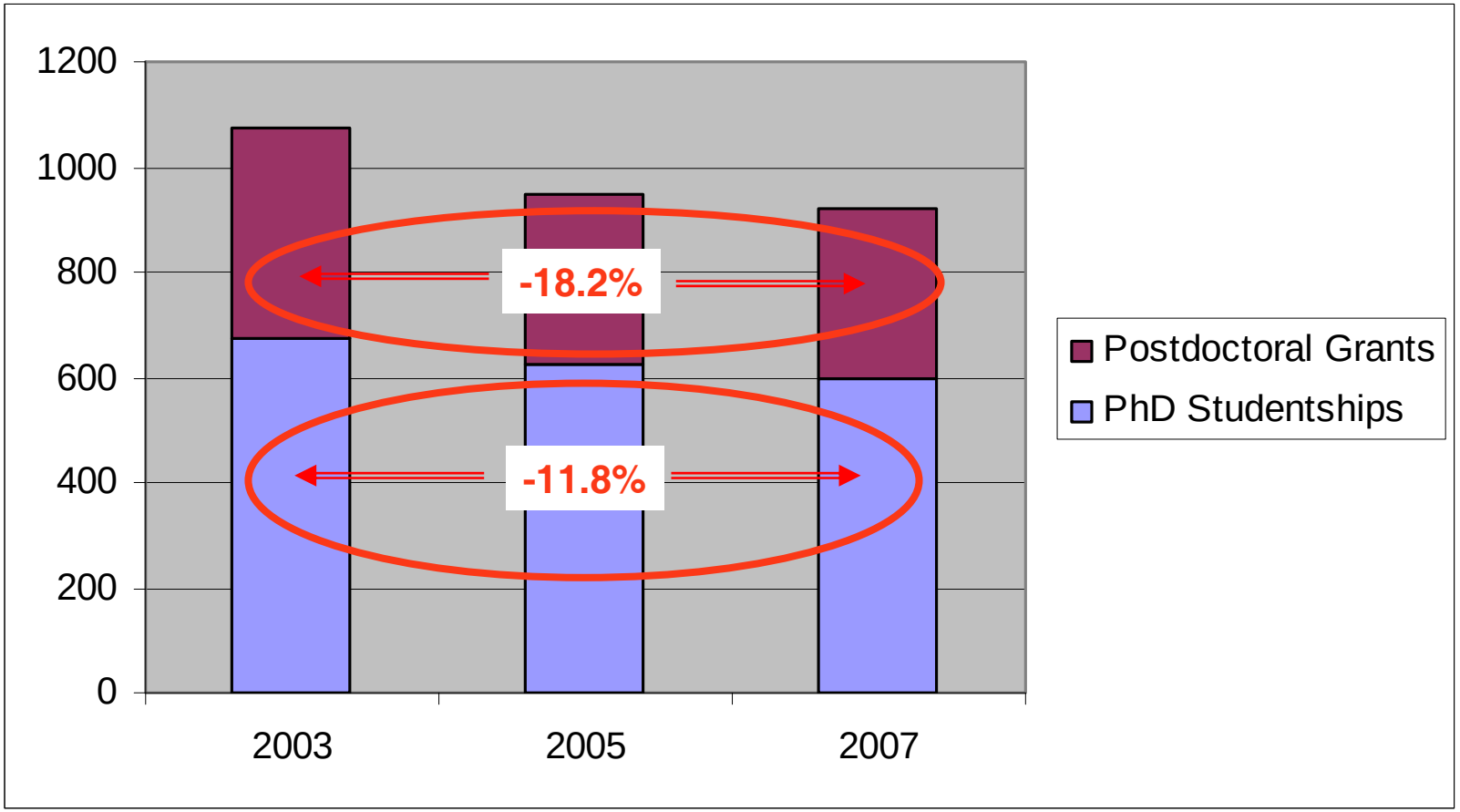
- UK R&D investment
  - A decline in R&D investment unrelated to merger or takeover began in 2003
  - R&D capital investment has been in decline since 2000
- From an ABPI 2008 survey:
  - 35% of companies expected to continue to reduce R&D investment (current standing of £4bn pa)
  - Investment in building and equipment assets is expected to decline by a similar number of companies (36%)
  - Number of UK clinical trials is expected to drop by 46%
  - Level of manufacturing is forecast to decrease by 42%

ABPI Phamatopics, June, 2008

AstraZeneca
RESEARCH & DEVELOPMENT

Changing shape of Pharma in the UK

Investment in University research is declining



ABPI – Pharmaceutical Industry support for collaborative research in the UK, Dec 2007

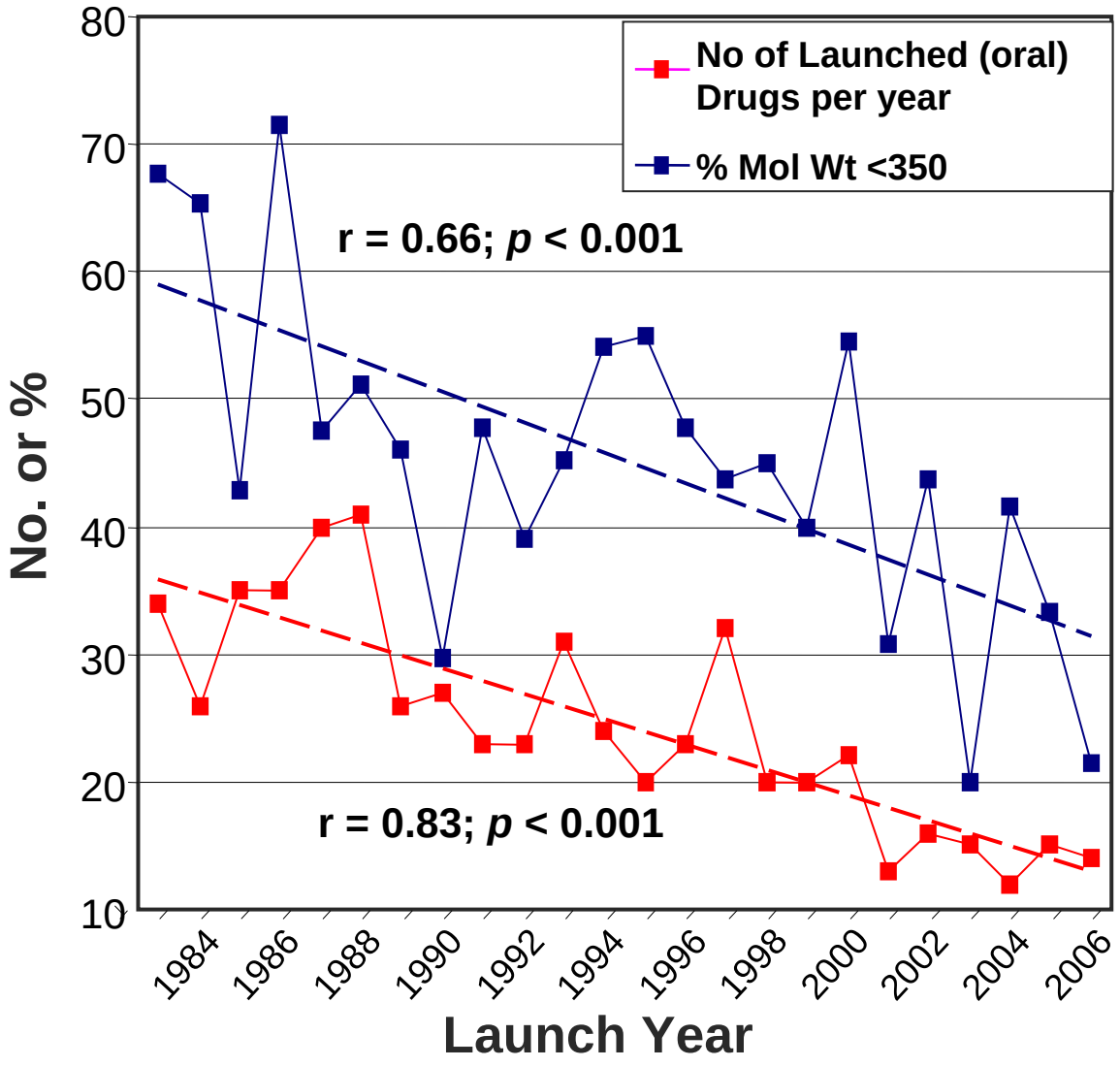
AstraZeneca
RESEARCH & DEVELOPMENT

What is industry looking for??

Generic model for business improvements

AstraZeneca
RESEARCH & DEVELOPMENT

a) Medchem - Better quality (less complex?) drug candidates

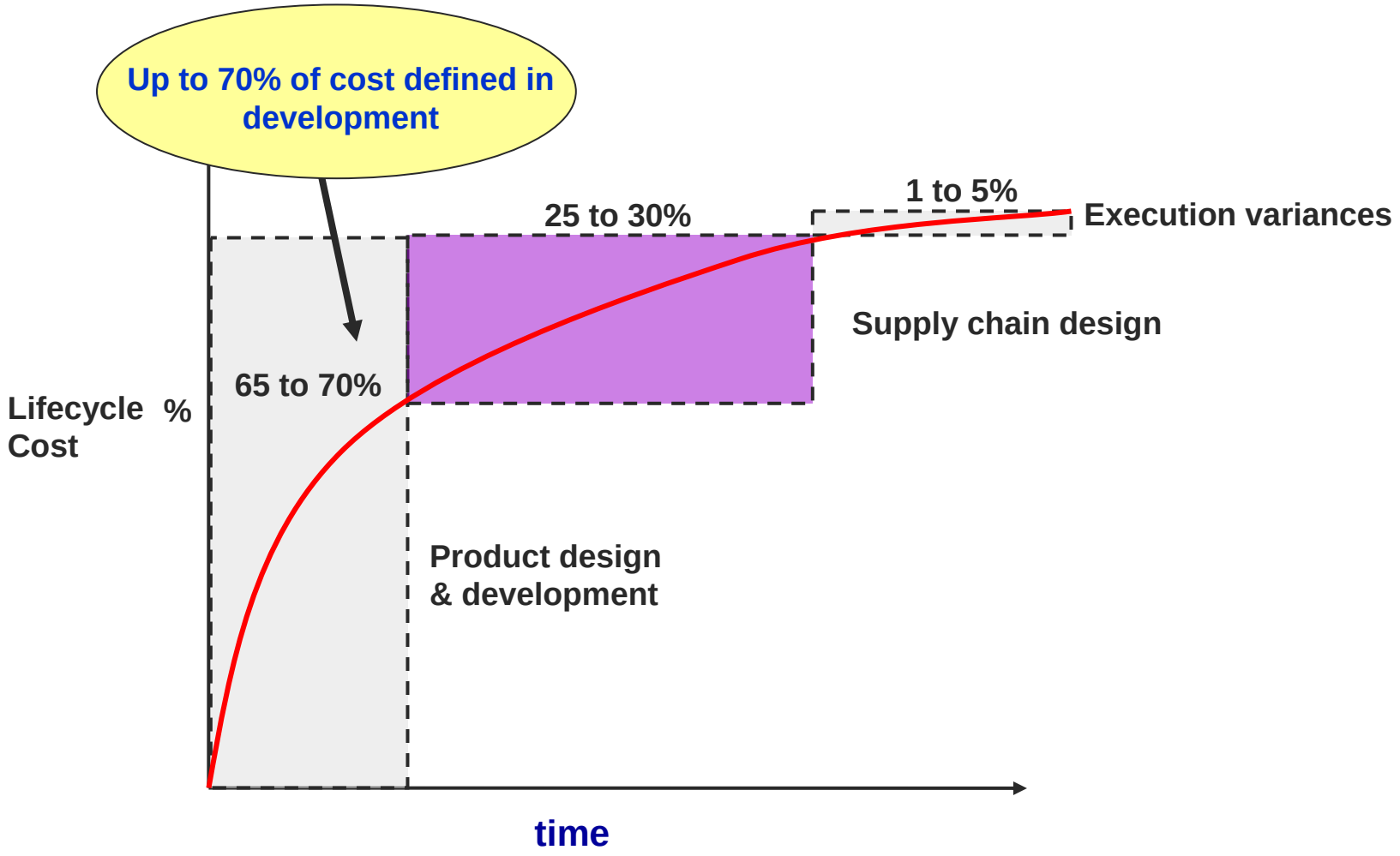


Physical properties of oral drugs increase over time
Development hurdles increase

PD Leeson & B Springthorpe (2007). Nature Reviews Drug Discovery 6, 881-890

AstraZeneca
RESEARCH & DEVELOPMENT

b) Process chem - Cost effective manufacturing processes



AstraZeneca
RESEARCH & DEVELOPMENT

c) Skills – Chemistry related skills gaps

Discipline	2005	2008
Analytical and Physical Chemistry	 **Q N F M** Non Graduate Graduate PhD Post-Doc	 **Q N F M** Non Graduate Graduate PhD Post-Doc
Synthetic Organic / Process Chemistry	 **Q N F M** Non Graduate Graduate PhD Post-Doc	 **Q N F M** Non Graduate Graduate PhD Post-Doc
Chemical and Process Engineering	 **Q N F M** Non Graduate Graduate PhD Post-Doc	 **Q N F M** Non Graduate Graduate PhD Post-Doc
Computational Chemistry	emerging discipline - not graded in 2005	 **Q N F M** Non Graduate Graduate PhD Post-Doc

SKILLS NEEDS FOR BIOMEDICAL RESEARCH
ABPI Oct 2008

Q Quality - Candidate quality
N Number - Candidate numbers
F Future - Future of the discipline
M Manufacturing - Priority for manufacturing disciplines

AstraZeneca
RESEARCH & DEVELOPMENT

Selected scientific challenges in chemical sciences

- Medicinal challenges
  - A.1 To 'transform' the design (& synthesis) of small molecules such as to interact with any genomic protein (Quality)
  - A.2 To underpin science leading to predictive toxicology (Speed/Quality)
  - A.3 To support clinical studies with chemical tools (Speed/Quality)
  - A.4 To deliver the next generation of biological drugs (Quality)
  - A.5 To understand and exploit selective tissue delivery (Quality)

UK Heads of Medicinal Chemistry, Oct 2008

- Process / manufacturing challenges
  - Greener design (Quality)
  - Chemistry on scale (Speed/Cost)
  - Understanding of processes (Quality)

ACS Green Chemistry & joint pharma publications

AstraZeneca
RESEARCH & DEVELOPMENT

Selected scientific challenges in formulation research

- Speed
  - Understand, predict and determine drug solubility and dissolution in simple and complex environments
  - Use *in-silico* methods to predict physicochemical properties of drugs & formulation design
  - Understand the relationship between material properties and product performance to facilitate rational formulation & process design
- Quality
  - Understand crystallisation and its relation to performance
  - Understand, predict and determine drug & dosage form behaviour in simple and complex environments including physical & chemical stability
  - Understand molecular, microscopic and macroscopic processes and interactions that occur during pharmaceutical processing
  - Characterise macromolecules (inc biologics and complex excipients) & understand interactions to design better formulations or processes
- Cost
  - High throughput formulation at small scale with integrated techniques to measure performance and quality
  - Design of particles with improved processing and product performance including improved delivery to the lung

AstraZeneca
RESEARCH & DEVELOPMENT

Improved Tech Transfer through more strategic partnering

- Pharma is seeking selective, strategic (global) partnerships with (interdisciplinary) centres in areas of sustainable R&D business need
- Business needs are changing – industry becomes the ‘translator’ of activity - not necessarily the originator
- Business strategies more clearly question what industry delivers through internal vs external application
- Shared objectives/ common goals - an essential requirement for strategic partnering
- Transparent, internationally competitive cost base for research
- Shared risk / shared gain preferred
- Facile, appropriate IP protection and ownership
- Partnership on drug projects through more “Open Innovation” is gaining popularity

AstraZeneca
RESEARCH & DEVELOPMENT

Open Innovation - perceived benefits

- Not all the necessary experience or knowledge exists within pharma
- External R&D can create significant value: internal R&D is needed to claim some portion of that value
- We don’t have to originate the research to profit from it
- Building a better business model is better than getting to market first
- Making use of internal and external ideas is a winning formula
- We should profit from others’ use of our IP, and buy others’ IP whenever it advances our business model

H Chesbrough, “Open Innovation: The New Imperative for Creating and Profiting from Technology” (Harvard Business School Press)

Open Innovation ‘Palette’

- Shared objectives – shared goals – relevant projects

- Fluid interface for exchanging ideas and information
- Flexibility to new partners
- Staff exchanges
- Industrial professorships
- Collaboration tools (IT, governance, framework agts, other)
- Shared assets / facilities / technologies
- Exploiting existing IP eg drug candidates, compound collections, technologies
- Support for innovation & wider exploitation

Biocatalysis, Biotransformation & Biocatalytic Manufacture

- CoEBio3 – “largest global organisation dedicated to developing biocatalytic processes” – Director, Nick Turner
  - Response to industrial need and emerging ‘White Biotech’
  - Manchester (MIB) selected as core research facility, with hubs and 12 PIs at York, Strathclyde and Heriot-Watt providing complementary expertise
  - Scale-up (NIBF) through Centre for Process Innovation (CPI) at Wilton
  - Industry affiliates drawn from pharma, fine chemicals and biotech

CoEBio3
Centre of Excellence for Biocatalysis, Biotransformations and Biocatalytic Manufacture

AstraZeneca
RESEARCH & DEVELOPMENT

CoEBio3 Model – Benefits to Successful Tech Transfer

- Full technology complement (from basic research to manufacture)
- Priority access to NIBF at CPI Wilton, at preferential rate
- Integrated knowledge base across biocatalysis R&D
- Secondment of industrial scientists to the Centre, for take-up of new techniques
- Tailored training courses for industrialists
- Industry-academia ‘club’ for sharing common problems/issues
- Affiliates membership funds used to generate PhD studentships and strategic research
- Effective model for proposal of Research projects in response to industry needs, and governance
- DTI and EPSRC/BBRSC financial support
- Facile IP model
- Successful projects through shared objectives!

AstraZeneca
RESEARCH & DEVELOPMENT

DTC in Targeted Therapeutics – Science and Skills

- AZ/EPSRC/Nottingham Doctoral Training Centre established 2005
- 1st DTC developed in partnership with industry (£2.5m funding jointly from EPSRC/AZ)
- Founding vision for an AZ strategic (sustainable) partner and Centre of Excellence focused on a scientific need and associated skills delivering:
  - High quality students, education, training
  - High quality science and projects
- 4yr PhD funding equating to 1yr Master's training / 3yr doctoral research
- Research aimed at development and delivery of therapeutic agents to target sites in the human body
  - Drug delivery systems
  - Novel formulation design
  - Pharmaceutical nanotechnology
  - Biopharmaceuticals
  - Material characterisation

The University of Nottingham

EPSRC

AstraZeneca
RESEARCH & DEVELOPMENT

Targeted Therapeutics DTC Model

- Strong, regular contact between AZ scientists, and Nottingham School of Pharmacy academics & students
  - Shared ideas, resources, colloquia and training initiatives
- DTC places are highly sought after, attracting high quality students
- AZ scientific challenges are incorporated into PhD research projects
- Facile IP model
- Projects outcomes emerging with real chance of IP filing and founding of start-up companies

- Anticipated flow of suitably skilled students into industry in the near future

UK Chemistry can add value

- Internationally competitive research
  - Chemical biology (bioananalytical, biomaterials, biocatalysis), materials & supramolecular chemistry, synthesis & theory
  - Multi-disciplinary efforts have expanded – but could be more
- Industry-academic relations are good
- Positive trends
  - Good infrastructure
  - Vigorous, successful spin-outs & licensing across disciplines
  - PhD training and excellent DTC examples
- Areas for emphasis & encouragement by RCUK
  - Energy
  - Drug Discovery
  - Materials for Medicine

EPSRC International Review of Chemistry
Chemistry for the Next Decade & Beyond (April 2009)

AstraZeneca
RESEARCH & DEVELOPMENT

Summary

- Pharma R&D investment and needs of the external environment are changing
- Industry is not an alternative research council
  - Industry focused on improvements in Speed, Cost, Quality to justify external spend
- Strategic partnering increasing across the Biomedical Research spectrum
  - Shared risk/shared gain
  - More open innovation in R&D
- Industry can better describe its needs to academia and to funding bodies in pursuit of innovation
- Cross-pharma collaboration on pre-competitive programmes is increasing
- Research Council support for International Review outcomes would be justified eg multidisciplinary centres in academic drug discovery