

An update on the UK research based pharmaceutical industry

19 December 2016 V1



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Introduction

These slides offer a useful, referenced resource for members and visitors to our website who wish to share the story about the value of medicines. They complement existing resources available on the ABPI website and will be updated regularly as the ABPI updates other data and content.

**ABPI Corporate Affairs team,
December 2016**



Our story so far....



- Medicines and vaccines have helped deliver improvements in patient health. History shows us the great advances we have made - today we continue to see the potential to eradicate disease and improve health outcomes when we invest in science and adopt and use new medicines.¹
- Trailblazing scientists are the backbone of our industry. These are the people that discover the molecules and develop the medicines to tackle the toughest diseases we face in society.²
- The way we bring new medicines to life is changing. Regulators, scientists and healthcare professionals are working together to ensure access to new medicines and other therapies is accelerated.³
- Patients' involvement in all aspects of healthcare and medicines is increasing. Patients and patient groups are 'at the table' earlier in discussions.⁴
- The future of healthcare is an exciting one – but there are challenges ahead. With innovations in genomics, healthcare data, advanced therapies and innovative technologies, our industry will continue to progress and provide hope to people so they can live longer, healthier and productive lives.⁵



1. CRUK. <http://www.cruk.cam.ac.uk/news/latest-news/death-rates-top-four-cancer-killers-fall-third-over-20-years>
 2. ABPI Schools. <http://www.abpischools.org.uk/topic/howmedicineswork/2/0>
 3. The Accelerated Access Review. P15
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/564145/AAR_final_A.pdf
 4. The Accelerated Access Review. P54.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/564145/AAR_final_A.pdf
 5. Taylor, D. 2016. Affording the future, P1. <http://www.ucl.ac.uk/pharmacy/departments/practice-policy>

Medicines and vaccines have helped deliver improved patient health and overall survival



Medicines are the most common therapeutic intervention.¹



HIV/AIDS – advances over the last few years have contributed to a

85% decline in death rates

and have helped transform the disease from a fatal illness to a chronic condition.²

Death rates for breast, bowel, lung and prostate cancer combined have fallen by almost a third (30%) in the last 20 years.³

Fallen **30%** in the last **20 years**

Total medicine costs in the

UK represent **0.9%** of GDP,

which compares to **1.2%** average across countries including the USA, France, Spain, Germany, Italy, Belgium, Ireland, Austria, Sweden and Denmark.⁴

The NHS in England spends just under

10p in every **£1**

on branded medicines, which represents just under 10% of the overall NHS budget.⁵

Pharma companies have given



1 billion pounds since 2014 via the PPRS to help the NHS buy new medicines.⁶

Patient access to new and innovative medicines can be lower and slower than other countries.⁷



For the first five years after the launch of a new medicine, people in the UK are significantly less likely to have access than people living in other countries.⁷



UK use of new medicines is

11% of the average

compared to other countries in the first year of launch.⁷

There is significant geographical variation in uptake and use of medicines in the UK,



Doctors are not always able to prescribe freely for their patients.

“86% of doctors say they have to negotiate or persuade others to approve a particular medicine or treatment for a proportion of their patients.”⁸

9 out of **10** people believe that the Government should do more to make sure that people across the UK can get the latest medicines when they have a serious or life threatening illness.⁹

1 <https://www.england.nhs.uk/2013/05/med-opt/>

2 PhRMA, Biopharmaceuticals in perspective, spring 2015

3 <http://www.cruk.cam.ac.uk/news/latest-news/death-rates-top-four-cancer-killers-fall-third-over-20-years>

4 IMS Health, World Review Analyst 2013, OECD Health Database. All data accessed December 2013.

5 IMS Health World Review Analyst 2014. World Bank Data (accessed Nov 2014)

6 <http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/090316.aspx>

7 Office for Health Economics analysis for the ABPI

8 NHS England, Innovation Scorecard 2016: <https://www.england.nhs.uk/ourwork/innovation/innovation-scorecard/>

9 http://www.comres.co.uk/wp-content/themes/comres/poll/ABPI_Perceptions_of_NICE_General_Public.pdf

About the ABPI



The ABPI represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients.

Our members supply

81% of all branded medicine used by the NHS,¹

and are researching and developing the majority of the current medicines pipeline,

ensuring that the UK remains at the forefront

in helping prevent and overcome diseases.



Sources



Slide Title	Source
Our story so far, slide 4	Cancer Research UK
Our story so far, slide 4	ABPI Schools.
Our story so far, slide 4	The Accelerated Access Review, Page 15 & 54.
Our story so far, slide 4	Taylor, D. 2016. Affording the future. Page 1
Medicines and vaccines, slide 5	NHS England, Page 1.
Medicines and vaccines, slide 5	PhRMA Biopharmaceuticals in Perspective, Page 6.

Sources



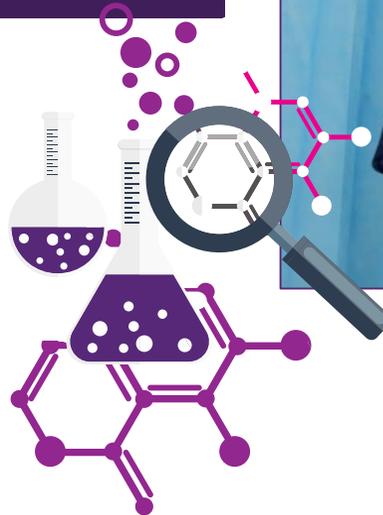
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Medicines and vaccines, slide 5	Cancer Research UK
Medicines and vaccines, slide 5	IMS Health, World Review Analyst 2013, OECD Health Database.
Medicines and vaccines, slide 5	ABPI. Pharmaceutical industry's contribution towards NHS medicines bill hits £1billion, Page 1.
Medicines and vaccines, slide 5	Office for Health Economics analysis for the ABPI
Medicines and vaccines, slide 5	NHS England, Innovation Scorecard 2016
Medicines and vaccines, slide 5	Comres, Page 2
About the ABPI, slide 6	Office of Health Economics analysis for the ABPI

Medicines and vaccines –have helped deliver improved patient health and overall survival¹



Improved outcomes for patients

Patients all over the world are living longer, healthier and more productive lives, thanks to innovative medicines developed by biopharmaceutical companies¹



Effective vaccinations have contributed to the fight against communicable diseases

Italy was the first industrialised country to introduce a programme for routine vaccination against hepatitis B virus (HBV); this program led to an

82% decline in the incidence of HBV

from 1991 to 2010.¹



In England,

infant deaths declined 79%

from 2012 to 2013 as a result of a maternal pertussis vaccination program.²



In 2015 the UK was the first country in the world to offer a vaccine that will help

protect babies against meningitis B

as part of a national childhood immunisation programme. There are around 800,000 babies born each year in the UK.^{3,4,5}



1. Boccalini 2013 .Economic analysis of the first 20 years of universal hepatitis B vaccination program in Italy. Human Vaccines & Immunotherapies.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3899148/>

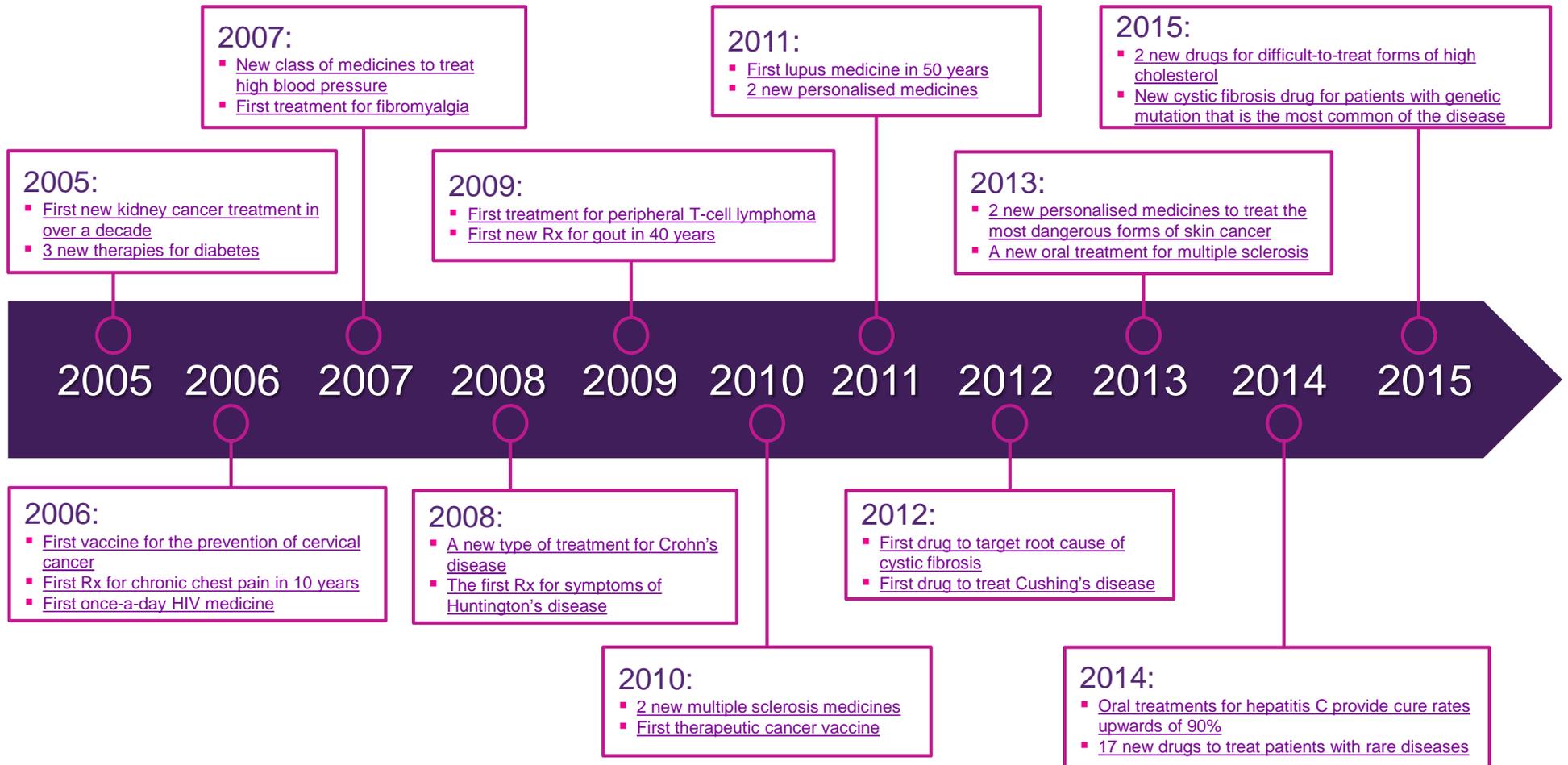
2. Amirthalingam 2014 .Effectiveness of maternal pertussis vaccination in England .The Lancet. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60686-3/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60686-3/abstract)

3. Office for National Statistics. <http://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/bulletins/birthsummarytablesenglandandwales/2015>

4. National Records of Scotland. <http://www.nrscotland.gov.uk/statistics-and-data/statistics/statistics-by-theme/vital-events/general-publications/vital-events-reference-tables/2014/section-3-births>.

5. Northern Ireland Research and Statistics Agency. <http://www.nisra.gov.uk/demography/default.asp8.htm>

Pharmaceutical companies around the world have driven a decade of advances in medicines, as seen in the USA



Pharmaceutical companies around the world have driven a decade of advances in medicines, as seen in the USA - accompanying referencing



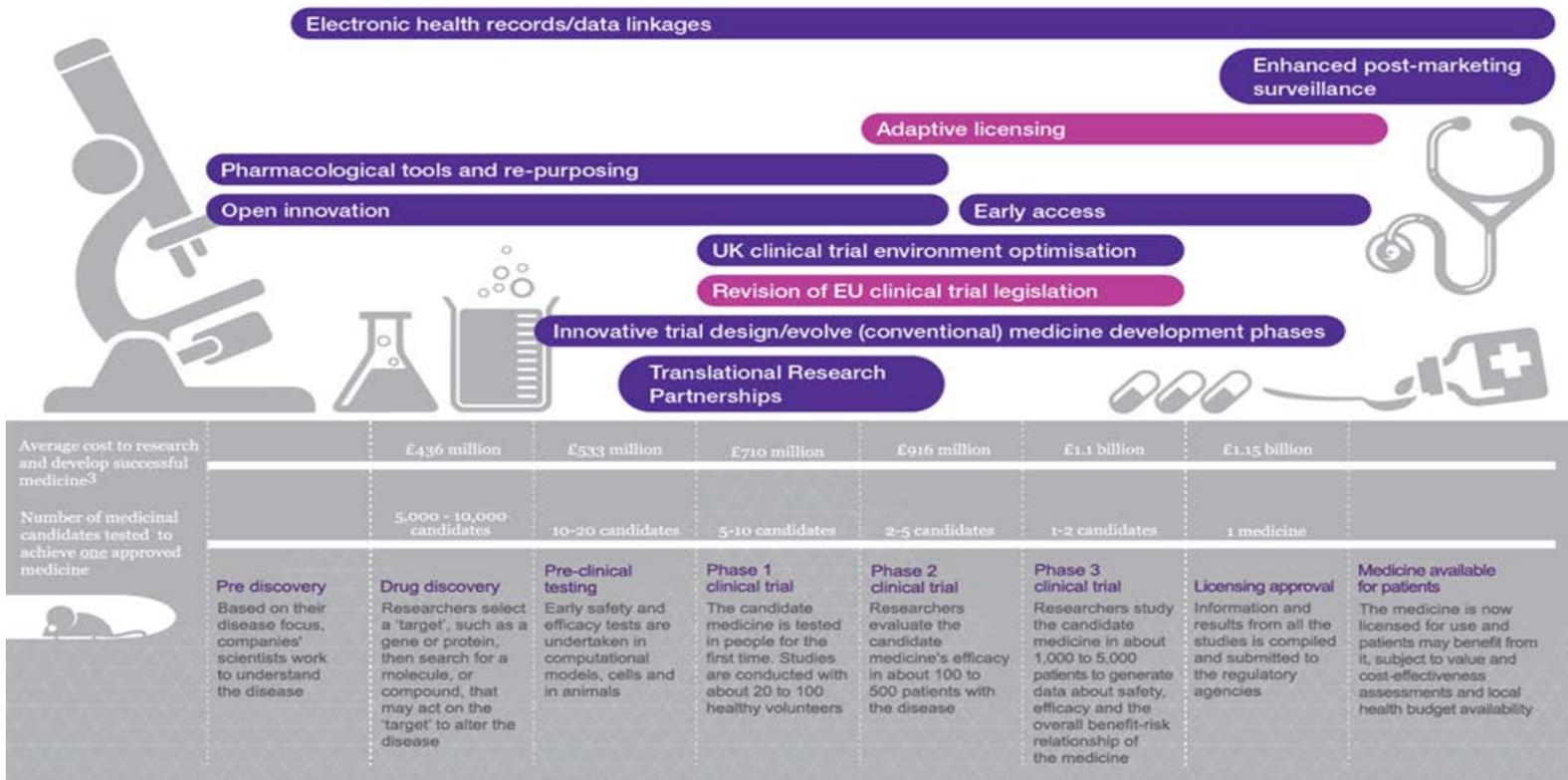
1. FDA Approves New Treatment for Advanced Kidney Cancer. FDA (2005)
2. FDA approved Diabetes Medicines. FDA (2005)
3. FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus. FDA (2006)
4. FDA Approves New Treatment for Chest Pain. (2006)
5. FDA Approves the First Once-a-Day Three-Drug Combination Tablet for Treatment of HIV-1. FDA (2006)
6. FDA Approves New Beta Blocker to Treat High Blood Pressure. FDA (2007)
7. FDA Approves First Drug for Treating Fibromyalgia. FDA (2007)
8. FDA Approves Cimzia to Treat Crohn's Disease. FDA. (2008)
9. FDA Approves First Drug for Treatment of Chorea in Huntington's Disease. FDA. (2008)
10. FDA Approves First Drug for Treatment of Peripheral T-cell Lymphoma. FDA (2009)
11. FDA Approves Colchicine for Acute Gout, Mediterranean Fever. FDA (2009)
12. FDA approves first oral drug to reduce MS relapses. FDA (2010)
13. FDA Approves a Cellular Immunotherapy for Men with Advanced Prostate Cancer . FDA (2010)
14. FDA approves Benlysta to treat lupus. FDA (2011)
15. FDA approves Xalkori with companion diagnostic for a type of late-stage lung cancer- FDA (2011)
16. FDA approves Kalydeco to treat rare form of cystic fibrosis. FDA (2012).
17. FDA approves Korlym for patients with endogenous Cushing's syndrome. FDA (2012)
18. FDA approves two drugs, companion diagnostic test for advanced skin cancer. FDA (2013)
19. FDA approves new multiple sclerosis treatment. FDA (2013)
20. FDA approves first combination pill to treat hepatitis C. FDA (2014)
21. FDA Novel new drugs summary. FDA. (2014)
22. FDA Novel drugs 2015 summary. FDA. (2015)

The pharmaceutical research and development process takes time



Innovation in medicine *R&D and access*

Key
■ Mid-term ABPI/industry focus - UK level
■ Long-term ABPI/industry focus - EU level



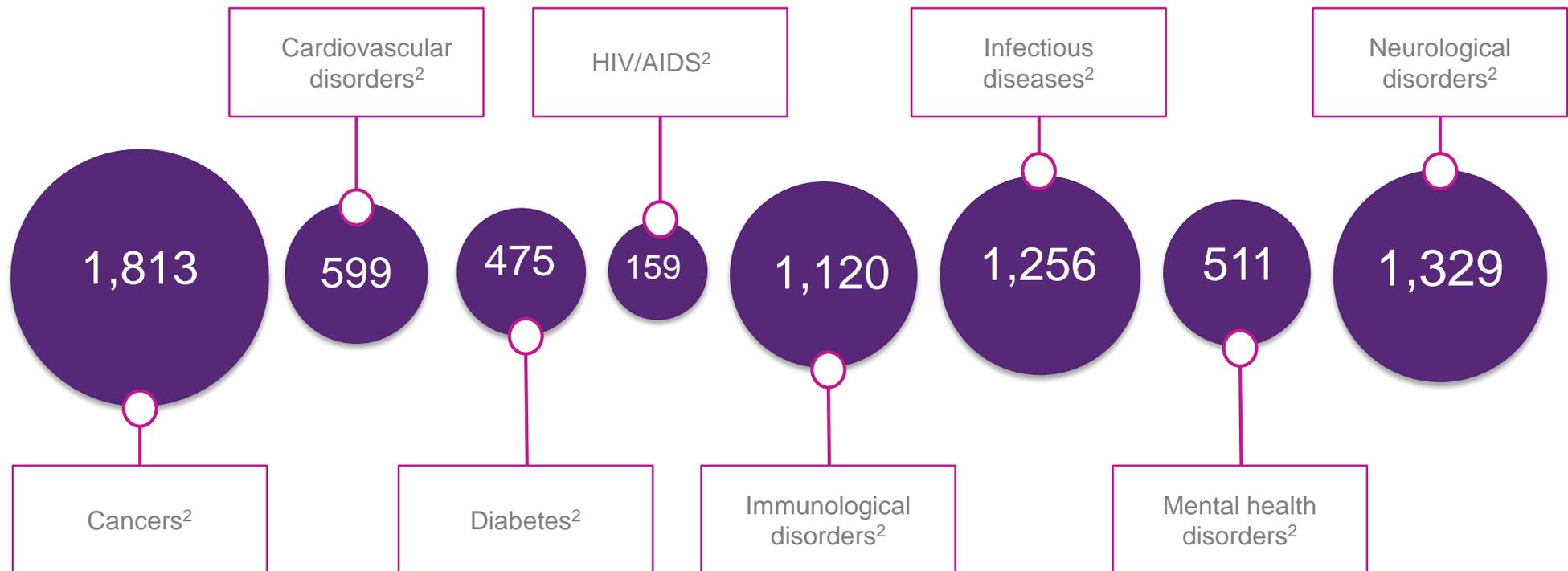
From medicine discovery to EMA approval, developing a new medicine on average takes at least 10 years and can cost £1.15 billion^{1,2}

Just 10-15% of molecules that enter clinical testing are approved³

1. Paul S, Nature Reviews Drug Discovery 9 203-214 (March 2010) | doi:10.1038/nrd3078 In 2010 prices based on Bank of England exchange rate
 2. Hay M, Thomas DW, Craighead JL, Economides C, Rosenthal J. Clinical development success rates for investigational drugs. Nat Biotechnol. 2014 Jan 9;32(1):40-51.
 3. Kola I, Landis J. Opinion: Can the pharmaceutical industry reduce attrition rates? Nat Rev Drug Discov. 2004 Aug;3(8):711-6.

As of 2016, 7000 new medicines are in development globally across a number of different diseases

With over 7000 new medicines in development, the exciting new wave of medical innovation will play a key role in **addressing the challenges faced by patients and healthcare systems¹**.



1. Outcomes-driven sustainable healthcare. <http://www.efpia.eu/topics/innovation/outcomes>

2. Prescription Medicines: Costs in Context. August 2016. <http://www.phrma.org/report/prescription-medicines-costs-in-context> (references all figures in graphic)

Discovering new technologies to develop new medicines is central to our industry



Working in partnership

- New science is so complex that no organisation holds all the knowledge to make new medicines alone.
- We increasingly work in partnership to share expertise to develop new medicines more quickly.

SGC – a partnership of industry partners and world-leading academics, working to understand the function of parts of our genetic code that have previously not been studied. This helps accelerate our understanding of the body in both health and disease, highlighting possible targets for new medicines.¹

Open targets – a partnership between UK academics and biopharma companies looking to associate diseases with molecules in the body which may could be targeted by new medicines.²

Cutting edge science and technology

- Companies use cutting edge science and technology to accelerate the discovery and development of innovative medicines

Clustered regularly interspaced short palindromic repeats (CRISPR) – is a new technology that lets scientists precisely edit genetic code. It can be used in many different ways by our industry to help discover new medicines. For example it can be used to create cell lines which model an individual's cancer, which can help scientists develop new personalised therapies.³

Basic biology to new medicines

- Industry scientists work in partnership with others to understand diseases, and translate this into new medicines

NEWMEDS IMI project – companies and academics work to create new models of schizophrenia and depression, to better understand the diseases, and help identify possible mechanisms to treat them.⁴

U-Biopred IMI project – companies and academics work to divide asthma patients into groups based on the different molecular basis of their illness. This will help scientists and doctors understand why patients respond different to treatment, and develop news therapies.⁵

1. SGC (2016). **Pioneering Science to Inspire Pioneering Medicines**. http://www.thesgc.org/about/what_is_the_sgc

2. Open Targets (2016). Overview. <https://www.opentargets.org/>

3. Sander, J. and Joung, J. (2014). CRISPR-Cas systems for editing, regulating and targeting genomes. *Nature Biotechnology*. 32, 347–355. <https://www.ncbi.nlm.nih.gov/pubmed/24584096>

4. Innovative Medicines Initiative (2016). Introducing IMI. <https://www.imi.europa.eu/content/mission>

5. Innovative Medicines Initiative (2016, a).U-BIOPRED: Unbiased biomarkers for the prediction of respiratory disease outcomes. <https://www.imi.europa.eu/content/u-biopred>

Animals in research currently play a central role in discovery and development of new medicines



The role of animal research in developing new medicines

abpi
Bringing medicines to life

2016 is the 140th anniversary of the regulation of scientific research using animals in the UK

2016 is the 30th anniversary of the current regulation of animal research in the UK
(This only allows research to be conducted where the likely benefits of research justify any possible distress to the animals, and where there is no alternative approach that could be used.)

APPROVED 3

You need 3 different licences approved by the Home Office before you can conduct any research using animals in the UK

Research using animals has played a key role in the development of medicines for diseases including cancer, diabetes, and Parkinson's disease

All new medicines must be tested on animals before they can be tested on humans, for human safety

Industry has been collaborating with the National Centre for the 3Rs to **reduce, replace and refine** the use of animals in research for 11 years
<https://www.nc3rs.org.uk/>

3Rs

Animals used in research are cared for by highly skilled technicians, who have undergone rigorous training in animal welfare

In 2014, 3.8 million animals were used in scientific research in the UK (number of animals used for the first time in 2014, Home Office annual statistics for 2014)

Over 90% of procedures on animals in research in the UK involve rats, mice, birds, or fish. Home Office annual statistics for 2014
(https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499568/spanimals14.pdf)

Pharmaceutical companies have made continued advances against rare diseases

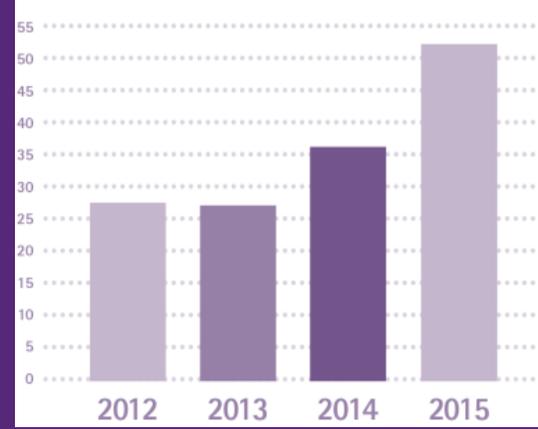


There are approximately **7,000** different rare diseases worldwide



1 in 10 individuals in the USA are living with a rare disease¹

% of NAS With Orphan Drug Status 2012-15



Percentage of New Active Substances (NAS) launched with orphan drug status 2012-2015²

Approximately

246,000 people

In the EU 28 are affected by a rare disease
6% - 8% of the EU population³

1. Rare Diseases A Report on Orphan Drugs in the Pipeline. 2013. America's Biopharmaceutical Research Companies http://phrma-docs.phrma.org/sites/default/files/pdf/Rare_Diseases_2013.pdf
2. Pharma R&D Annual Review 2016 Supplement: New Active Substances launched during 2015. https://citeline.com/wp-content/uploads/RD_NAS_2016.pdf
3. EURare Diseases Policy. EUROCAT. <http://www.eurocat-network.eu/aboutus/eurarediseasespolicy>

Industry/Academic partnerships are strengthening; new initiatives are underway



University of Manchester

NorthWest Centre for Advanced Drug Delivery

Translational science centre

AstraZeneca

Goal to expand partnership with other academics and the NHS

The **NorthWest Centre for Advanced Drug Delivery** (NoWCADD) is a translational science centre based at the University of Manchester specialising in the development of novel nanotechnologies for cancer therapy. The centre is funded via its collaboration with AstraZeneca and is actively seeking additional partners from academia and the NHS. The University of Manchester is also home to the **Centre for Applied Pharmacokinetic Research** (CAPKR), which was set up in 1996 with multiple industry supporters, and the **Manchester Collaborative Centre for Inflammation Research** (MCCIR) involving GSK and AstraZeneca.

Open Science

The newly fostered **GSK-Crick** open collaboration is another example of shared science, with the most important driving force being the exchange of people between the two organisations. Integrated teams of researchers will be working on early-stage research to unravel the underlying pathology of human disease which will have huge potential for boosting the development of successful, innovative treatments.

The **Centre for Therapeutic Target Validation** (CTTV) in Cambridge was pioneered in 2014 by three world-leading organisations: the Wellcome Trust Sanger Institute, the European Bioinformatics Institute (EMBL-EBI), Biogen and GSK. Each are sharing their proficiencies in areas such as genomics, bioinformatics, disease biology and drug discovery. The centre is committed to helping all researchers identify targets, as the data is openly available via its Target Validation Platform – an online searchable database.

Centre for Therapeutic Target Validation

Harnessing 'big data'

Welcome Trust, EMBL-EBI
Biogen, GSK

Industry/Academic partnerships are strengthening; new initiatives are underway



- The Experimental Cancer Medicine Centre combinations alliance – where CRUK, ECMCs, and industry work together to facilitate testing of novel combination therapy through investigator led studies
Info here: <http://www.ecmcnetwork.org.uk/combinations-alliance-industry>
- CRUK Stratified medicine programme – a large stratified medicines lung cancer trial led by CRUK, with treatment supported by AZ and Pfizer
Info here: <http://www.cancerresearchuk.org/funding-for-researchers/how-we-deliver-research/our-research-partnerships/stratified-medicine-programme>
- Genomics England – Pharmaceutical companies are working in a consortium to work with Genomics England to begin to scope how the data can be used for research into new diagnostics and treatments
Info here: <https://www.genomicsengland.co.uk/working-with-industry/>

Sources



Slide Title	Source
Medicines and vaccines –have helped deliver improved patient health and overall survival, slide 9	UCL School of Pharmacy: Affording the Future? The role of cost effectiveness thresholds in determining NHS patient access to high quality care in the post-Brexit era.
Improved outcomes for patients, slide 10	Jackman D. January 2016. Page 1. The Value of Pharmaceutical Products to Patients and the Healthcare System Versus the Cost.
Effective vaccinations have contributed to the fight against communicable diseases, slide 11	Boccalini 2013 .Economic analysis of the first 20 years of universal hepatitis B vaccination program in Italy .Human Vaccines & Immunotherapies
Effective vaccinations have contributed to the fight against communicable diseases, slide 11	Amirthalingam 2014 .Effectiveness of maternal pertussis vaccination in England .The Lancet.
Effective vaccinations have contributed to the fight against communicable diseases, slide 11	Office for National Statistics
Effective vaccinations have contributed to the fight against communicable diseases, slide 11	National Records of Scotland
Effective vaccinations have contributed to the fight against communicable diseases, slide 11	Northern Ireland Research and Statistics Agency.

Sources



Slide Title	Source
Pharmaceutical companies around the world have driven a decade of advances in medicines, as seen in the USA., slide 12	FDA Novel Drugs 2015 Summary.
Pharmaceutical companies around the world have driven a decade of advances in medicines, as seen in the USA, slide 12	FDA approves first combination pill to treat hepatitis C 2014
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Pharmaceutical companies around the world have driven a decade of advances in medicines, as seen in the USA., slide 12	FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus 2006.
Pharmaceutical companies around the world have driven a decade of advances in medicines, as seen in the USA., slide 12	FDA-Approved Diabetes Medicines 2005.
Pharmaceutical companies around the world have driven a decade of advances in medicines, as seen in the USA., slide 12	FDA Approves New Treatment for Advanced Kidney Cancer 2005.

Sources



Slide Title	Source
The pharmaceutical research and development process takes time, slide 14	Paul S, Nature Reviews Drug Discovery 203-214 (March 2010) doi:10.1038/nrd3078 In 2010 prices based on Bank of England exchange rate
The pharmaceutical research and development process takes time, slide 14	Hay M, Thomas DW, Craighead JL, Economides C, Rosenthal J. Clinical development success rates for investigational drugs. Nat Biotechnol. 2014 Jan 9;32(1):40–51.
The pharmaceutical research and development process takes time, slide 14	Kola I, Landis J. Opinion: Can the pharmaceutical industry reduce attrition rates? Nat Rev Drug Discov. 2004 Aug;3(8):711–6.
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As of 2016 7000 new medicines are in development globally across a number of different diseases, slide 15	Prescription Medicines: Costs in Context. August 2016.
Discovering new technologies to develop new medicines is central to our industry, slide 16	Sander, J. and Joung, J. (2014). CRISPR-Cas systems for editing, regulating and targeting genomes. Nature Biotechnology. 32, 347–355.

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Discovering new technologies to develop new medicines is central to our industry, slide 16	Open Targets (2016). Overview
Discovering new technologies to develop new medicines is central to our industry, slide 16	Innovative Medicines Initiative (2016). Introducing IMI
Discovering new technologies to develop new medicines is central to our industry, slide 16	Innovative Medicines Initiative (2016, a).U-BIOPRED: Unbiased biomarkers for the prediction of respiratory disease outcomes.
Animals in research currently plays a central role in discovery and development of new medicines, slide 17	Annual Statistics of Scientific Procedures on Living Animals
Pharmaceutical companies have made continued advances against rare diseases, slide 18	Rare Diseases A Report on Orphan Drugs in the Pipeline. 2013. America's Biopharmaceutical Research Companies.
Pharmaceutical companies have made continued advances against rare diseases, slide 18	Pharma R&D Annual Review 2016 Supplement: New Active Substances launched during 2015.
Pharmaceutical companies have made continued advances against rare diseases, slide 18	EURare Diseases Policy. EUROCAT.

Our trailblazing scientists are the backbone of the industry and are working to improve the world¹



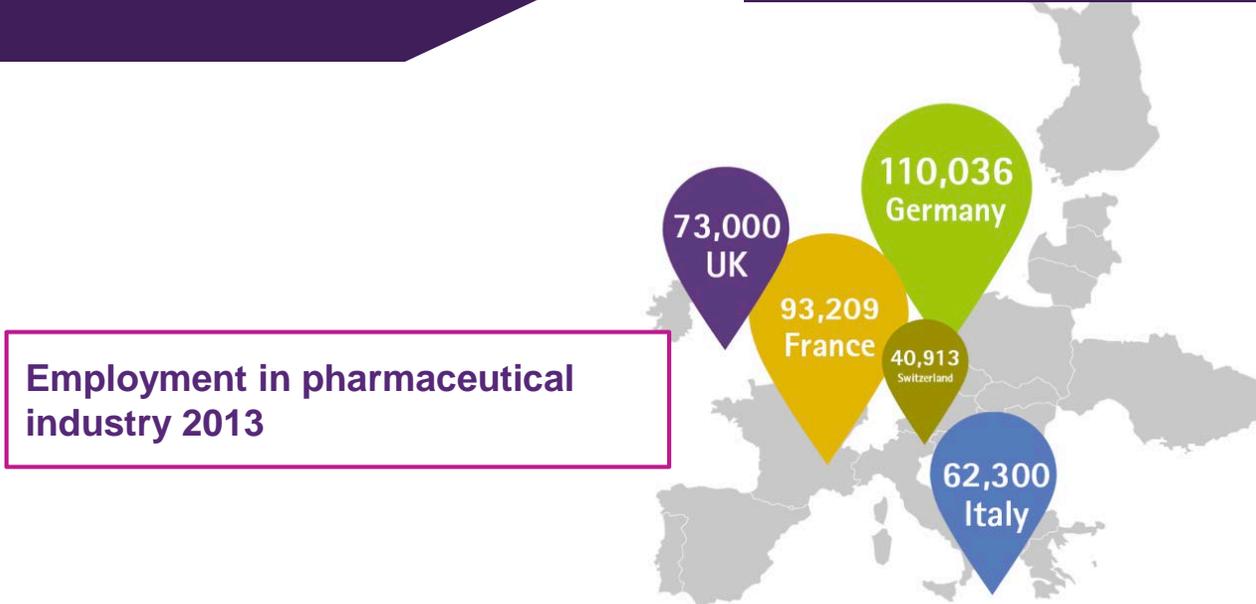
Our scientists are working to improve the world

The trailblazers in the life sciences industry are the scientists that discover the molecules and develop the medicines to tackle the toughest diseases we face in society.¹

Who are the new pioneers stepping into the shoes of Sir Alexander Fleming, Louis Pasteur and Henry Wellcome? How do they add value to our economy as well as keeping patients and their families healthy?



The pharmaceutical industry makes a significant contribution to the European economy

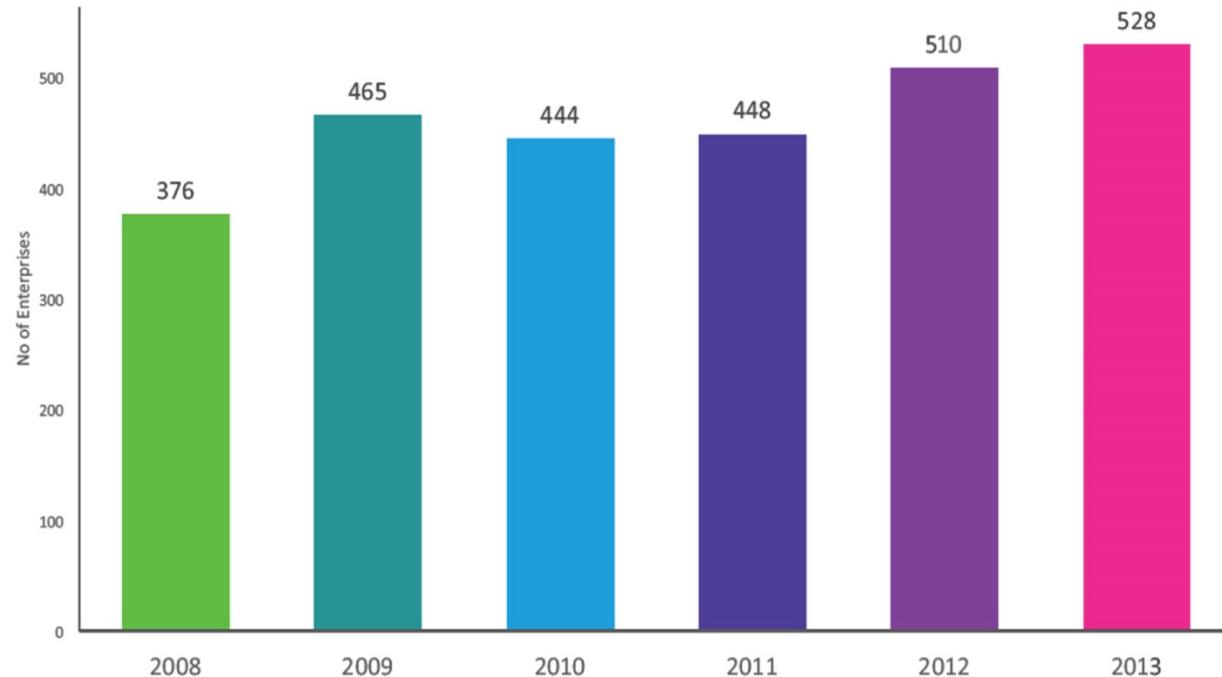


1. The Pharmaceutical Industry in Figures, 2016. EFPIA. <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>

The pharmaceutical sector represents an important sector for growth and employment in the UK



Number of pharmaceutical enterprises operating in the UK



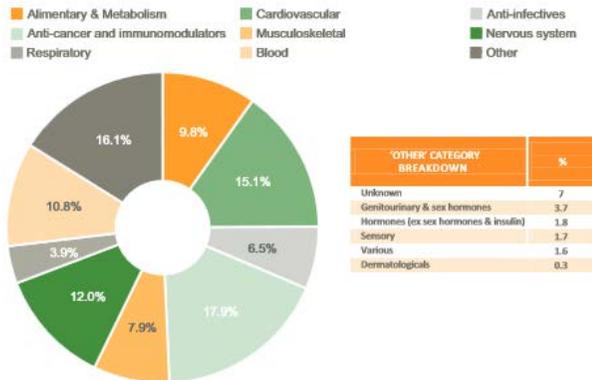
Pharmaceutical companies are the largest funder of R&D for chronic and deadly diseases in the UK



Pharmaceutical R&D Investment in the United Kingdom, 2012, by Disease Area

Total R&D expenditure in 2009 by Therapeutic area

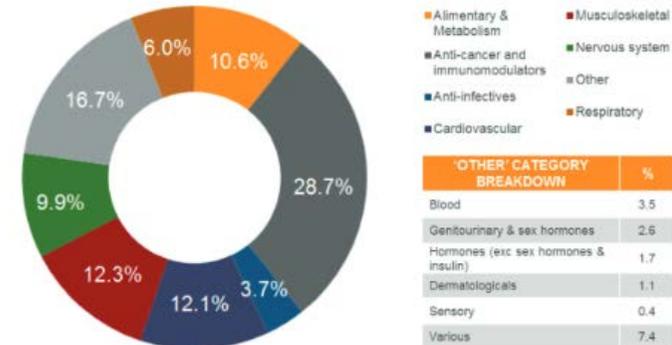
Total R&D expenditure in 2009 by Therapeutic area



The proportion of total R&D expenditure by therapeutic area presented in this figure is based on data from 20 companies (7 Major, 13 Mid and Other). Total R&D expenditure represented = US\$32.82bn

Total R&D expenditure in 2014 by Therapeutic area

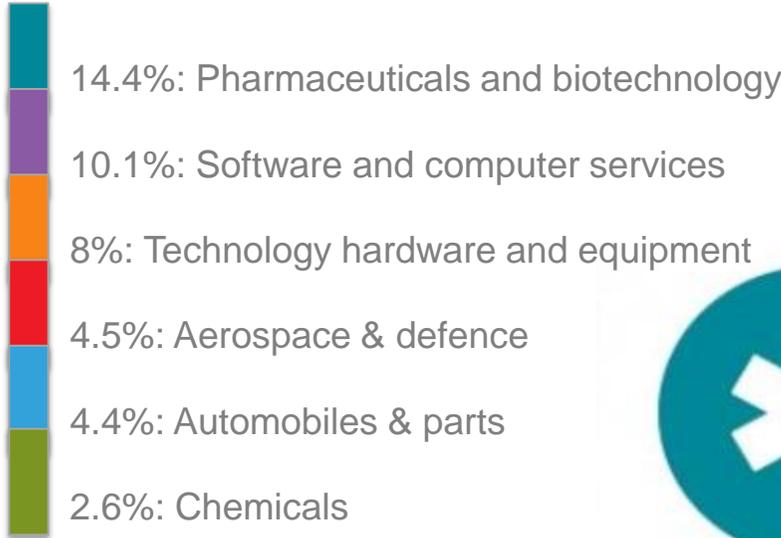
Total R&D expenditure in 2014 by Therapeutic area



The UK invest more of our revenue in generating new knowledge through R&D than other sectors across Europe



Research & development spending as a percentage of net sales, 2014

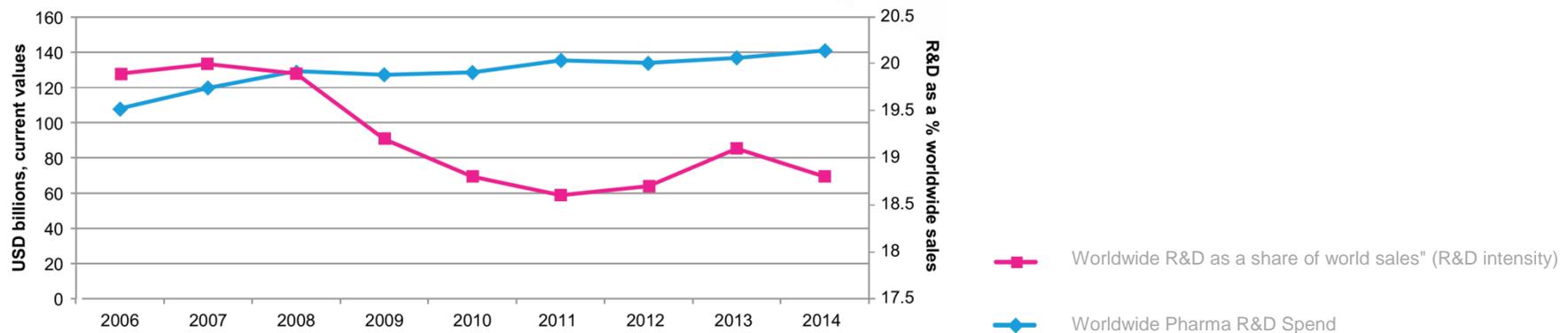


Industrial sectors ranked by R&D intensity (R&D as a percentage of net sales) Note: data relate to the top 2,500 companies with registered offices in the EU (608), Japan (360), the USA (829) and the Rest of the World (703), ranked by total worldwide R&D investment (with R&D investment above €17.9M) –

Worldwide Pharmaceutical R&D expenditure

According to EvaluatePharma¹ the **worldwide pharmaceutical industry invested over \$1.2 trillion in R&D** in the decade from 2004 to 2014 and they forecast an annual investment of \$162 billion by 2020. The figures below demonstrate that this **investment is growing moderately**, with only a recent decline in 2012 followed by a return to growth in worldwide R&D expenditure. The R&D intensity (R&D expenditure as a share of sales) however has declined, although at 18.8% in 2014, still one of the highest of any sector globally. **The US retains the highest share of R&D expenditure. In Europe, the UK has the highest share** if we exclude exchange rate effects.

Worldwide Pharmaceutical R&D expenditure

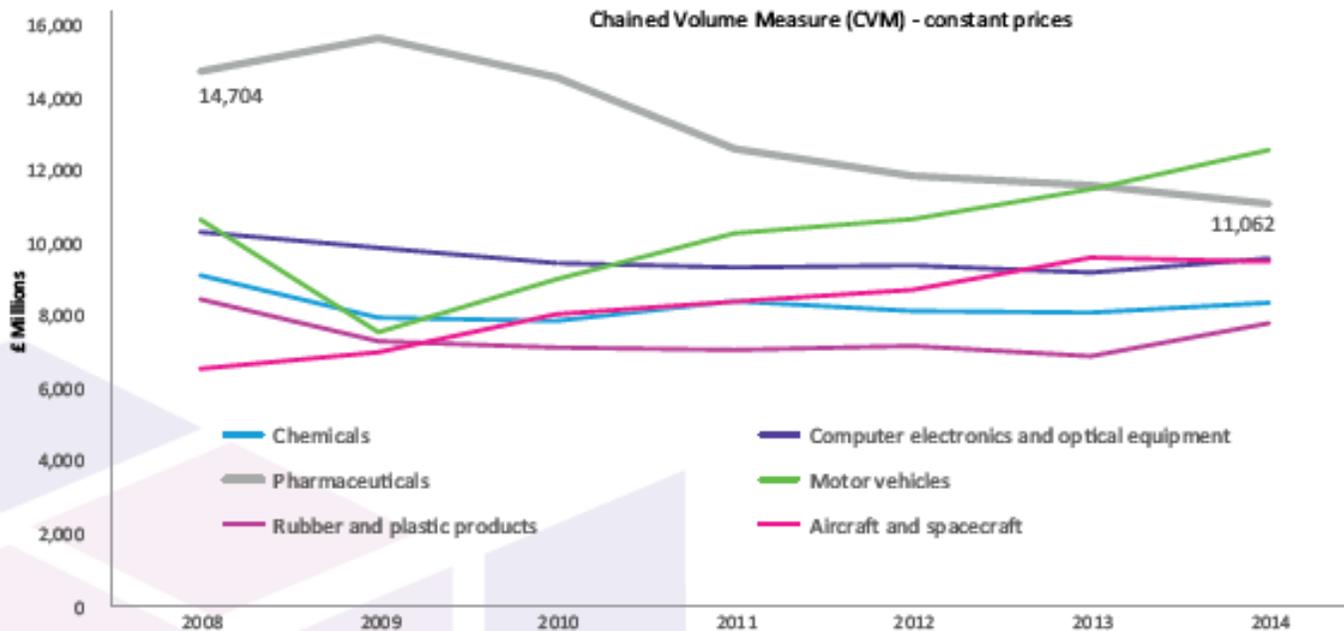


1. EvaluatePharma. World Preview 2014, Outlook to 2020. P.15. (London, 2014)

NOTES: EvaluatePharma date this analysis to 1st June 2014. Industry sales are based on the top 500 pharmaceutical and biotech companies.

The pharmaceutical sector adds the most value to the economy per employee

Gross Value Added (GVA)¹



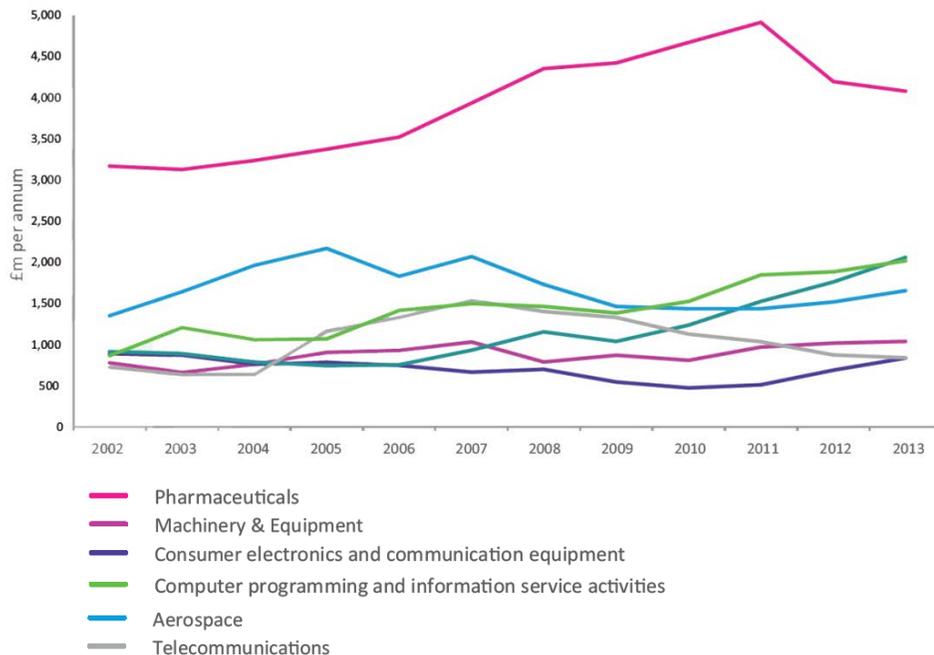
Pharmaceutical employees in Europe are generating **80% more value** per employee than other industries²

1. Office for National Statistics
2. Health Advances analysis; Eurostat Database.

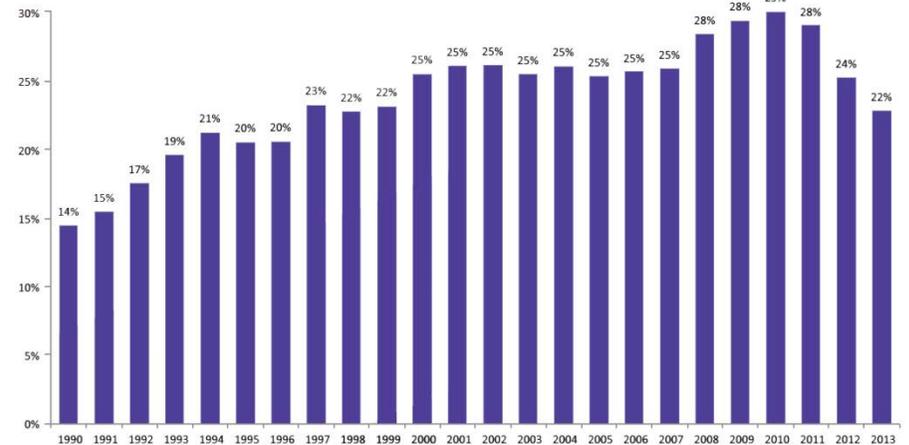
In the UK pharmaceuticals remain the highest research & development spending sector



Leading industries for UK R&D expenditure



Pharmaceutical R&D as a percent of all industry R&D



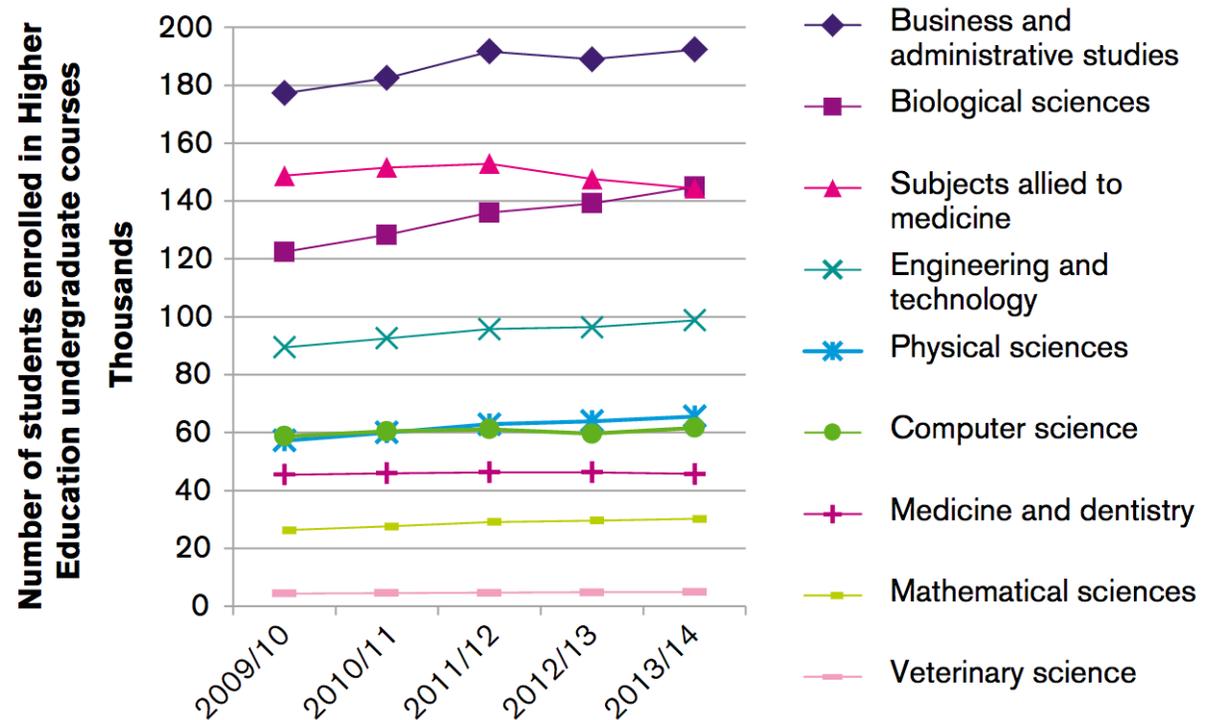
SOURCE: UK Office for National Statistics (ONS), Business Enterprise Research and Development (BERD) survey 2013

NOTES: The BERD survey is conducted annually by ONS. As part of the 2013 survey, approximately 5,400 questionnaires were sent to businesses known to perform R&D. This included around 400 of the largest R&D spenders, which accounted for approximately 77% of the 2013 total R&D expenditure estimate. Smaller R&D performers and others believed to be performing R&D were selected using various sampling fractions. Industry product group and business employment size were the stratification variables. Completed questionnaire were returned by 5,112 businesses, representing a response rate of 95%. The data are reported irrespective of the residence of the ultimate owner, but overseas activities of affiliates of UK businesses are not included.

The number of science, technology, engineering and maths (STEM) graduates has increased by 18 per cent over the past 10 years in the UK



Number of students enrolled in Higher Education per subject between 2009 and 2014^{1,2} (HESA 2014)



1. HESA 2014. <https://www.hesa.ac.uk/>

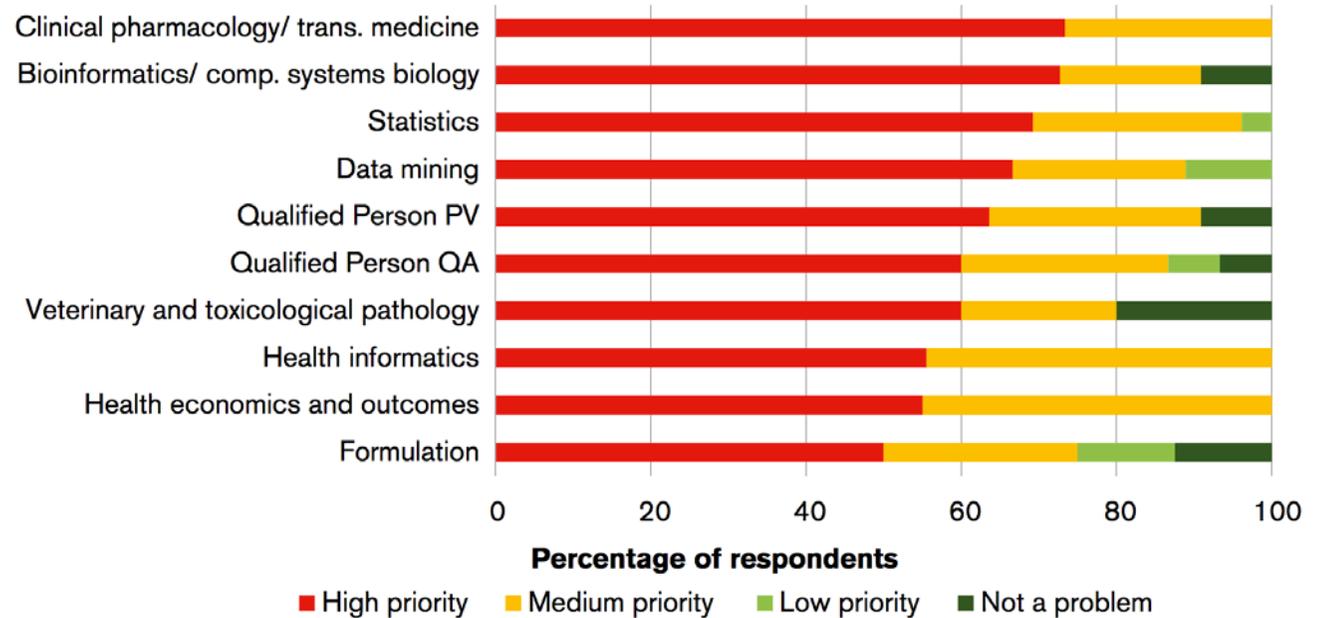
2. Bridging the skills gap in the biopharmaceutical industry: Maintaining the UK's leading position in life sciences. ABPI, Page 10. November 2015

The priorities identified when looking at the pharmaceutical industry skills gap

Top priorities

- The data obtained were analysed in order to determine top priority areas where immediate action is required to address skills gaps.
- Any discipline area with over 50% of respondents identifying it a high priority was considered a top concern and thus was further analysed.

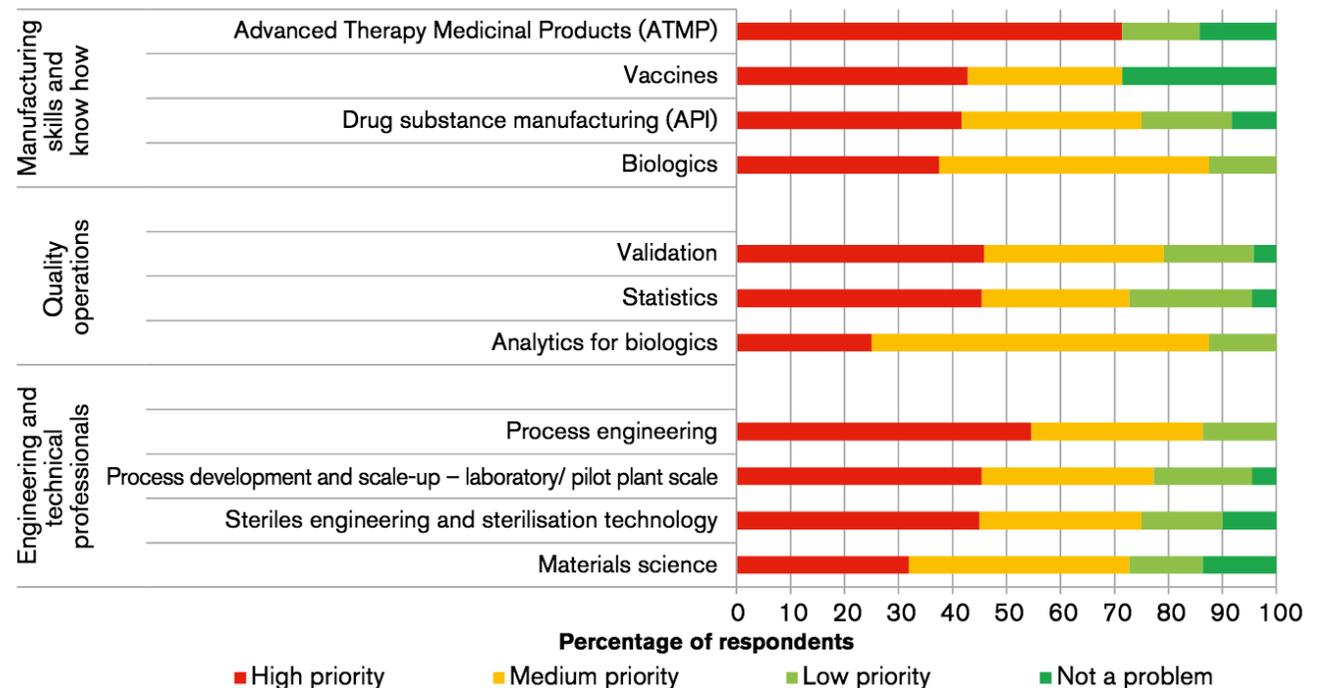
Percentage of respondents rating each top priority discipline as high, medium or low priority or identifying it as 'not a problem'



There are specific skills needed in manufacturing

Manufacturing top priority areas

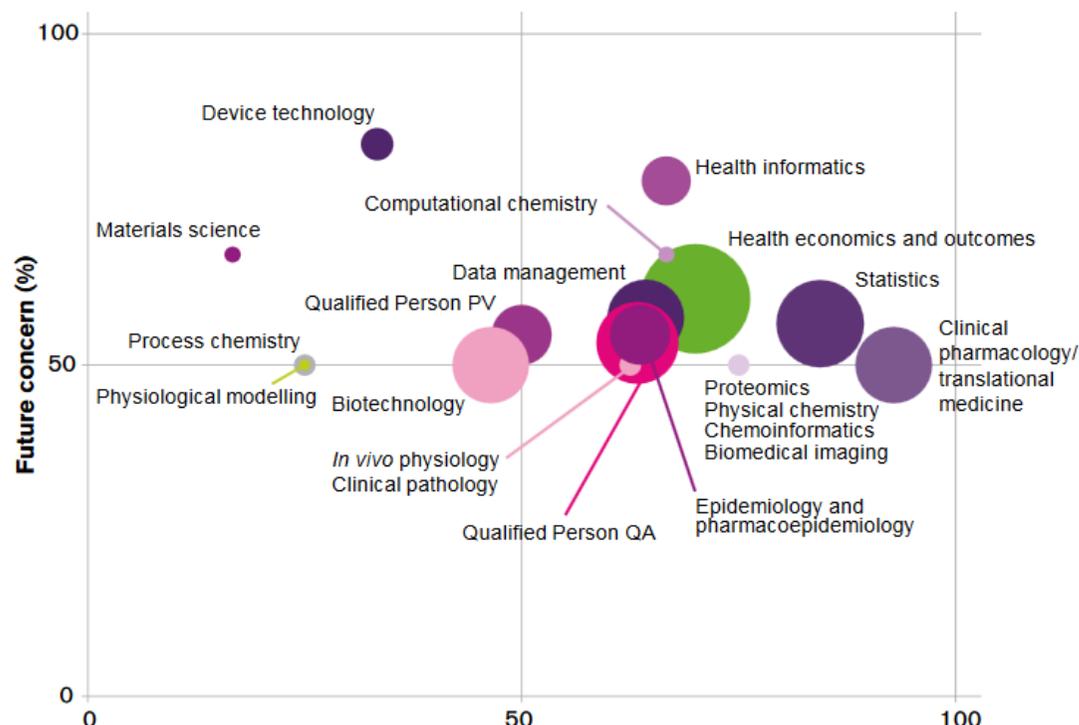
Percentage of respondents rating each manufacturing discipline as high, medium or low priority or identifying it as 'not a problem'



Identifying future issues for the sector and skills

Future issues

- Percentage of respondents rating each discipline area as a future concern vs. a current concern. (Only areas rated as a current and future concern by at least 50% of respondents are shown.)
- Size of bubbles represents the number of respondents in each area
- In vivo physiology and clinical pathology have overlapping data, as have proteomics, physical chemistry, chemoinformatics and biomedical imaging.



How can we bridge the skills gap in the pharmaceutical industry in the future?



- The Science Industry Partnership (SIP) Board should review the evidence and consider action that could be taken through the SIP to address the skills concerns identified.
- Where evidence suggests that high level and professional skills are concerns across both industry and academia, action will be sought through the Research Councils and appropriate Professional Bodies.
- The pipeline for the development of appropriate mathematical skills must be considered from primary education through to Masters and PhD graduate level training.
- ABPI Expert Network Groups, and the Medicines Manufacturing Industry Partnership (MMIP) Skills group (for manufacturing concerns), should monitor the critical disciplines in their area, make recommendations on action and raise concerns when it is becoming more difficult to recruit people with the skills required or when new needs are identified.



Addressing the skills needs identified in 2015 is not expected to be easy, in particular taking into consideration the challenging financial climate, but it is essential that they are addressed if the life science and health sectors are to continue to flourish in the UK. Many of the skills requirements affect not only pharmaceutical companies, but other life science companies, the academic science base and the NHS. In addition, by addressing the concerns identified, the UK could become a world-leading destination for the growth of the life science sector.



The pharmaceutical industry is an active partner in bridging the skills gap (I)



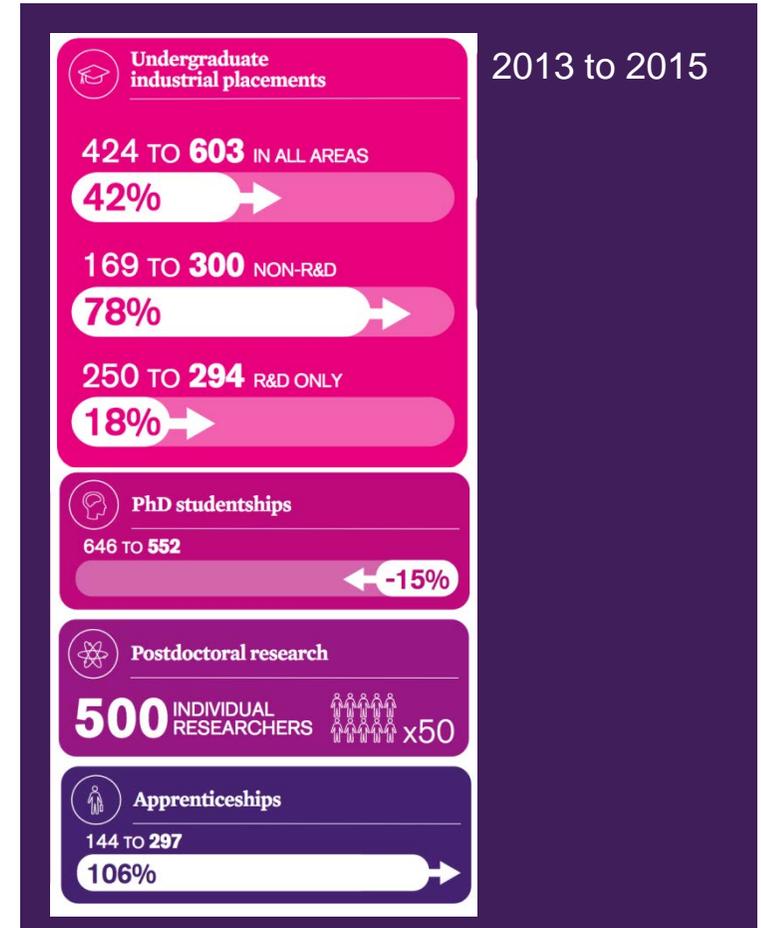
- Every two years the Association of the British Pharmaceutical Industry (ABPI) carries out research in the form of a survey to identify collaboration and other links between industry and academia. These links can range from interactions with undergraduates to postdoctoral researchers, fellows and professors. This report presents results from the 2015 survey and comparisons with data gathered since 2003, when the survey was established.



- The ABPI and its member companies are proud of the industry's active links with academia and its role in bridging the skills gap in education. These links range from interactions with undergraduates to post-doctoral researchers, fellows and professors.



- Recent years have seen an increase in the number of training opportunities for young people in pharmaceutical companies. This includes a huge increase in the number of apprenticeships offered in all areas and at all levels.
- At the end of 2015 there were a large number of young people undergoing training linked to pharmaceutical companies. Of these:
 - 294 are undergraduate industrial placements (R&D)
 - 300 are undergraduate industrial placements (non R&D)
 - 552 are PhD studentships
 - 500 are individual researchers involved in post-doctoral research
 - 297 are undertaking apprenticeships

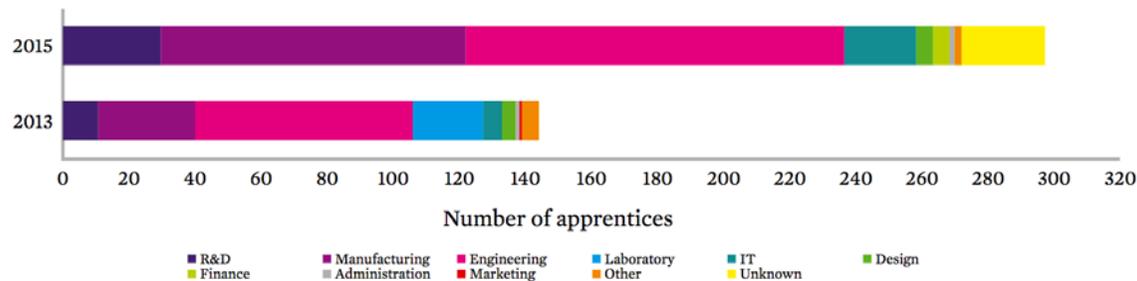


The pharmaceutical industry is an active partner in bridging the skills gap (II)



Aside from the ‘traditional’ R&D career path from undergraduate student to postdoctoral researcher and beyond, there is a growing emphasis on apprenticeships in the UK which is in part due to the Science Industry Partnership (SIP).¹ 2015 has seen a 106% increase in the number of apprentices being trained within the UK pharmaceutical industry, from 144 to 297; 10% (30/297) of which are in R&D – up from 8% (11/144) in 2013. The proportion of manufacturing apprenticeships has also gone up from 20% (29/144) to 31% (92/297).

Apprenticeships



Trends in the number of apprentices separated into business area in 2015 vs. 2013.

NOTE: No data was collected on apprenticeships before 2013. ‘Manufacturing’ includes apprentices in production, quality and supply chain.

COMMENTS: The total numbers of apprentices for each year were 144 in 2013 and 297 in 2015. Apprenticeships in R&D, manufacturing, engineering and IT account for a larger percentage of total apprentices in 2015 compared to 2013, suggesting that there is a greater emphasis on apprentice training in these business areas.

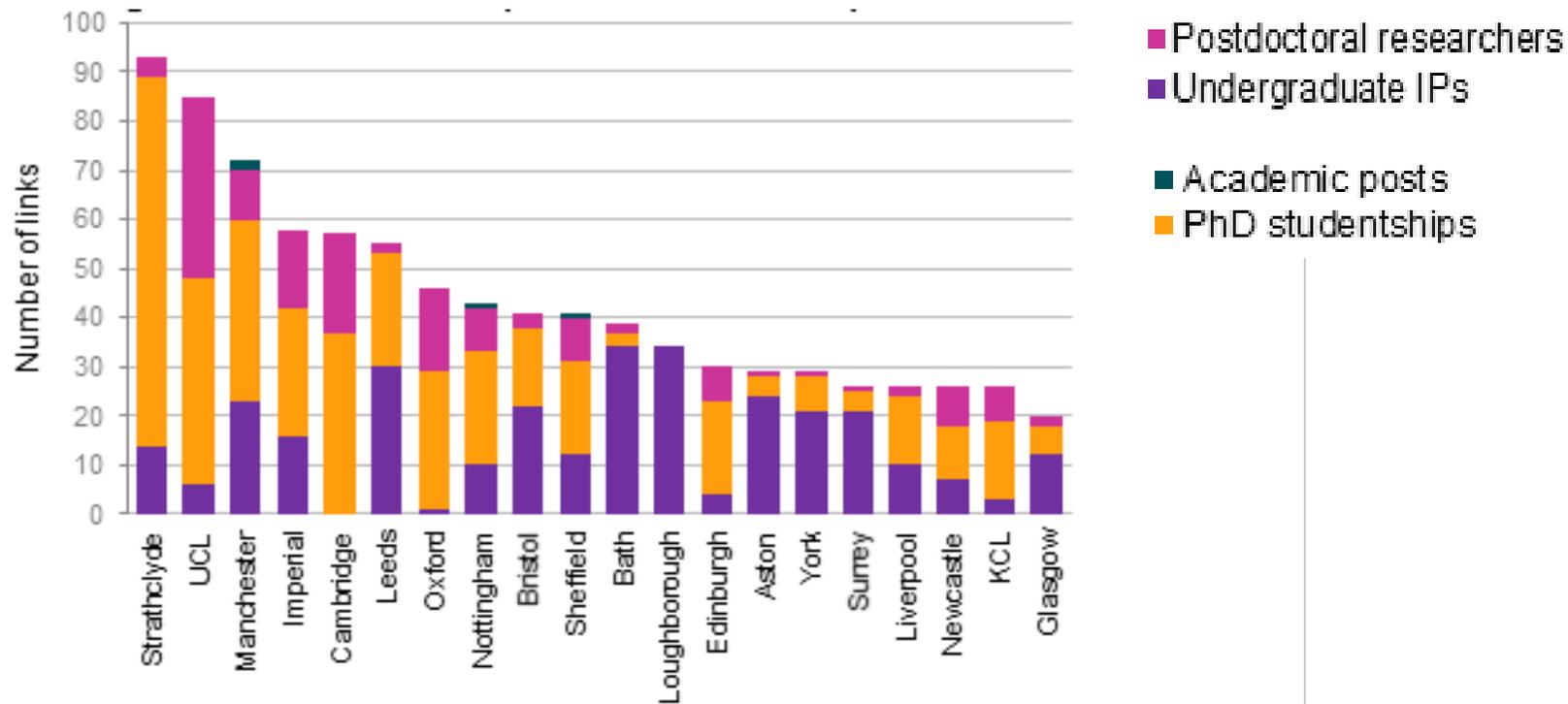
“ The apprenticeship scheme at Pfizer has given me an amazing opportunity to gain industry experience in a laboratory working with some incredibly talented scientists. It has allowed me to gain my academic qualifications whilst also learning and developing practical skills in an exciting and supportive workplace. ”

Charlotte Carr, apprentice,
Pfizer UK Global supply

1. Apprenticeship. Science Industry Partnerships. <http://www.scienceindustrypartnership.com/apprenticeships/>
Source: Developing talent and partnerships to create new medicines, ABPI, Page 11, September 2016

The pharmaceutical industry working with academia

Overall top 20 academic institutions for education and training interactions with UK pharmaceutical companies



We are heavily involved in finding the Science, Technology, Engineering and Mathematics (STEM) employees for the future



- ABPI members have 829 'STEM ambassadors' - a programme run by the Science, Technology, Engineering and Mathematics Network (STEMNET).
- Pfizer have over 30 STEM ambassadors and are also involved at a practical level in supporting the STEM students of the future with initiatives such as:
 - Lab in a Box – supporting practical chemistry in schools
 - Community Lab – providing students with an experience of practical chemistry
 - The SIP (Science Industry Partnership) ambassador programme – bringing older students into contact with practising scientists
- GSK have nearly 400 Ambassadors and have supported the STEM ambassador programme launch providing inspiring and engaging STEM programmes including:
 - EDT: Industrial Cadets and G04SET
 - Work Experience, Apprenticeships and Placements
 - STEM & SIP Ambassador Programmes
 - Hands-on STEM workshops in the classroom
 - STEM in Schools – a STEM Careers outreach programme



Judith from GSK (picture below) - 'The students have loved it - we're bringing science to life in products they see in their house every day. It also enables me to get a fresh perspective outside the day job and keep my passion for science alive when I see others get excited by it.'



Sources



Slide Title	Source
Our trailblazing scientists are the backbone of the industry and are working to improve the world, slide 28	Accelerated Access Review Report (page 15, C. The Challenge)
Our scientists are working to improve the world, slide 29	Accelerated Access Review Report (page 15, C. The Challenge)
The pharmaceutical industry makes a significant contribution to the European economy, slide 30	EFPIA. The Pharmaceutical Industry in Figures.
The pharmaceutical sector represents an important sector for growth and employment in the UK, slide 31	ONS Annual Business Survey 2013, Section C Manufacturing.
Pharmaceutical companies are the largest funder of R&D for chronic and deadly diseases in the UK, slide 32	ABPI R&D Sourcebook 2015, Page 23.
The UK invest more of our revenue in generating new knowledge through R&D than other sectors across Europe, slide 33	The 2015 EU industrial R&D investment scoreboard, European Commission. Page 48.
Worldwide Pharmaceutical R&D expenditure, slide 34	EvaluatePharma. World Preview 2014, Outlook to 2020. Page 15.
The pharmaceutical sector adds the most value to the economy per employee, slide 35	Office for National Statistics
The pharmaceutical sector adds the most value to the economy per employee, slide 35	Health Advances analysis; Eurostat Database.
In the UK pharmaceuticals remain the highest research & development spending sector, slide 36	UK Office for National Statistics (ONS), Business Enterprise Research and Development (BERD)
In the UK pharmaceuticals remain the highest research & development spending sector, slide 36	ABPI R&D Sourcebook 2015, Page 22.

Sources



Slide Title	Source
The number of science, technology, engineering and maths (STEM) graduates has increased by 18 per cent over the past 10 years in the UK, slide 37	HESA 2014.
The number of science, technology, engineering and maths (STEM) graduates has increased by 18 per cent over the past 10 years in the UK, slide 37	ABPI. Bridging the skills gap in the biopharmaceutical industry: Maintaining the UK's leading position in life sciences. Page 10.
The priorities identified when looking at the pharmaceutical industry skills gap, slide 38	ABPI. Bridging the skills gap in the biopharmaceutical industry: Maintaining the UK's leading position in life sciences. Page 6.
There are specific skills needed in manufacturing, slide 39	ABPI. Bridging the skills gap in the biopharmaceutical industry: Maintaining the UK's leading position in life sciences. Page 20
Identifying future issues for the sector and skills, slide 40	ABPI. Bridging the skills gap in the biopharmaceutical industry: Maintaining the UK's leading position in life sciences. Page 35.
How can we bridge the skills gap in the pharmaceutical industry in the future? (1), slide 41	ABPI. Bridging the skills gap in the biopharmaceutical industry: Maintaining the UK's leading position in life sciences. Page 38.
The pharmaceutical industry is an active partner in bridging the skills gap (1), slide 42	Developing talent and partnerships to create new medicines, ABPI, September 2016. Page 4.
The pharmaceutical industry is an active partner in bridging the skills gap (2), slide 43	Science Industry Partnerships.
The pharmaceutical industry working with academia, slide 44	Developing talent and partnerships to create new medicines, ABPI, September 2016. Page 21.

Patient involvement in the development of medicines



The pharmaceutical industry is working in different ways with patients and healthcare professionals

- Industry is working in different ways to engage with healthcare professionals, patients and patient groups as the science changes.
- Patient groups are 'at the table' earlier in discussions, becoming more involved in clinical trials and transparency is increasing. Increasingly patients and patient groups are actively engaging in the process of how medicines are developed to provide valuable insight.¹
- More and different groups are taking responsibility for putting together the evidence and undertaking the assessment of medicines.
- As the Accelerated Access Review recognises 'Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway. The NHS should use a common set of principles describing what good partnership with patients and the public looks like along the whole innovation pathway.'²



1. <https://www.eupati.eu/>

2. The Accelerated Access Review: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/564145/AAR_final_A.pdf

Patients First Conference – AMRC and ABPI



Patients and representatives from across the medical research sector came together in November 2016 at the inaugural Patients First Conference, hosted jointly by the Association of Medical Research Charities (AMRC) and the Association of the British Pharmaceutical Industry (ABPI), to explore how medical research can deliver better outcomes for patients.

The event brought together over 300 delegates – including patients, charities, industry, research bodies, funders and government – who, with a shared recognition that patients play a vital role in medical research, explored how they can collaborate to put patients first, involving them in research and development through to care and access to treatment, to ultimately deliver them the best outcomes.¹

1. <http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/Patients-health-and-research-experts-unite-to-put-patients-first-in-medical-research.aspx>

Patient involvement in medicine development - from theory to reality¹



What is EUPATI?

eupati.eu/what-is-eupati/

The European Patients' Academy (EUPATI) is a pan-European Innovative Medicines Initiative (<http://www.imi.europa.eu/>) project of 33 organizations, led by the European Patients' Forum, with partners from patient organizations (the European Genetic Alliance, the European AIDS Treatment Group, and EURORDIS), universities and not-for-profit organisations, along with a number of pharmaceutical companies.

We focus on education and training to increase the capacity and capability of patients to understand and contribute to medicines research and development and also improve the availability of objective, reliable, patient-friendly information for the public.

EUPATI Webinar

How to enable meaningful patient contribution to ethical review?



EUPATI 2014 Workshop: Reaching a Public Audience on Medicines Development



Alongside its patient expert training programme, the patient-led European Patients' Academy (EUPATI) has set out to inform the European patient community on how new medical treatments are developed. More than 150 representatives from patient organisations, academia, industry and regulatory affairs met in Warsaw on 2 April 2014 to plan the next stage of an ambitious European project aimed at increasing the knowledge of the lay public about the development process of new medicines. The input received at the workshop will help shape the project's strategy. Here you find the press release, our Twitter wall, as well as presentations and movies shown during the EUPATI 2014 Workshop.

We are committed to transparency, setting and following high standards for how we behave



- All ABPI members are required to adhere to the ABPI Code of Practice for the Pharmaceutical Industry and has strong support from the MHRA who have agreed to abide by the ABPI Code of Practice.
- It also applies to non-members who have agreed to abide by the ABPI Code of Practice
- Administered by the Prescription Medicines Code of Practice Authority (PMCPA) , a self-regulatory body operates the code at arm's length from the ABPI.
- The PMCPA is a not-for-profit body which was established by the ABPI on 1 January 1993.
- The code includes specific requirements on relationships with patient organisations under Clause 27.
- The ABPI Medical Representatives Exam is taken by representatives who call upon healthcare professionals. An appropriate examination must be taken by all representatives working for companies who have agreed to abide by the ABPI Code within one year of employment and passed within two years.

A screenshot of the PMCPA website. The top header is blue with 'PMCPA' in white and 'Prescription Medicines Code of Practice Authority' in smaller white text. Below this is a white section titled 'Clause 27 - Relationships with Patient Organisations'. Underneath is a blue bar with 'Section:' followed by a list of links: '27.1 | 27.2 | 27.3 | 27.4 | 27.5 | 27.6 | 27.7 | 27.8 | 27.9 | Supplementary Information |'. The main content area is white and contains the text of Clause 27.1: '27.1 Pharmaceutical companies can interact with patient organisations or any user organisation such as disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers. Companies must respect the independence of patient organisations.' There are two blue links: 'Supplementary Information' and 'Back to top'. At the bottom of the white section is a small line of text: '27.2 When working with patient organisations, companies must ensure that the'. Below the white section is a large blue rectangular area containing the ABPI logo at the top, followed by the text 'CODE OF PRACTICE for the PHARMACEUTICAL INDUSTRY' and the year '2016'. At the bottom of this blue area is the PMCPA logo and name.

We launched the ABPI Patient Organisation Forum (POF) in 2014¹



Brings together representatives of the pharmaceutical industry and patient and charity groups in an open forum

Aims

- To identify areas of mutual interest
- To promote understanding
- To develop joint working on policy and practice, where appropriate

By facilitating ongoing dialogue, open discussions and information sharing on issues of common interest, including healthcare policy

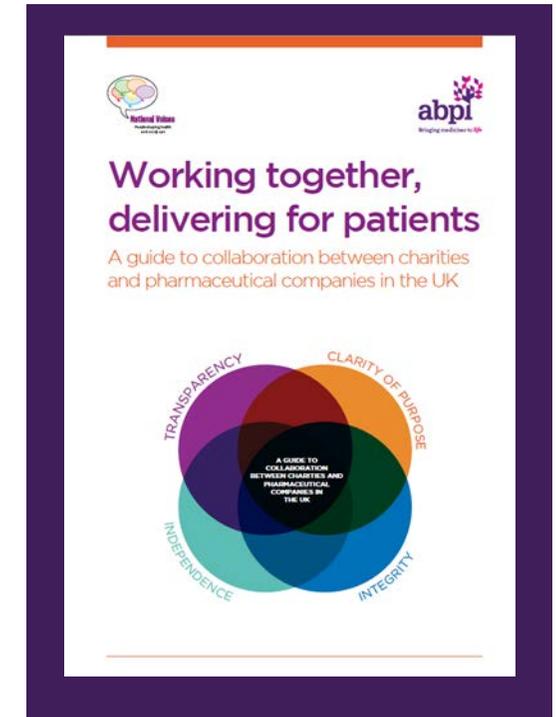
Strong governance and co-operation

- Supported by **steering group** of patient groups and company representatives
- All **meetings co-chaired** by a member company representative and patient group representative
- **Transparency:** Summaries of meetings and attendance published on the ABPI website ¹

Together we produced the 'Patient Guide'



- ABPI and National Voices jointly produced a [guide](#)¹ to collaboration between pharmaceutical companies and charities. The guide aims to promote transparency and accountability in collaborative working and to serve as a practical 'how to' guide for all parties. This has also been part of the ABPI Code of Practice since 2006.
- It has been led by a steering group, chaired by Harry Cayton CBE, Chief Executive of the Professional Standards Authority.
- The project included two workshops, a survey and a series of interviews to consult stakeholders and help shape the guide.
- The guide was published in July 2015.
- Together the pharmaceutical industry is actively engaging in activities that support patients



1. National Voices and ABPI 'Working together, delivering for patients: A guide to collaboration between charities and pharmaceutical companies in the UK' http://www.abpi.org.uk/our-work/library/Documents/ABPI_NV_Guide_FINAL.pdf

Transparency in clinical trials



- The ABPI is a strong advocate for transparency in clinical trial information. It is a requirement of the ABPI Code of Practice and has been for several years. This is included in the [EFPIA Code of Practice](#).¹
- Companies are required to publish all clinical trial results within one year of marketing authorisation and publically register new clinical trials within 21 days of the first patient being enrolled.
- In February 2013 the ABPI launched a [disclosure toolkit](#) for companies to help them meet the requirements for clinical trial transparency under the ABPI Code of Practice.²
- This toolkit provides good practice guidelines, disclosure checklists and a template standard operating procedure for pharmaceutical companies.
- These materials are updated regularly in line with changes to international regulatory requirements.
- Companies have also signed up to the EFPIA-PhRMA principles³ for responsible clinical trial data sharing to enhance research and data sharing efforts by making additional information available to the public, patients who participate in clinical trials and qualified researchers.⁴ Ultimately this move aims to benefit patients and foster scientific discovery.



Advancing science and improving care, Astellas, Bayer, Boehringer Ingelheim, Daiichi Sankyo, Eisai, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and ViiV Healthcare all sponsor [ClinicalStudyDataRequest.com](#)⁵ which allows researchers to request access to anonymised patient-level data from clinical studies to conduct further research.

GSK was the first company to sign up to All Trials in 2013, which calls for the registration of clinical trials and the disclosure of trial results and clinical study reports⁵ (CSRs). CSRs are the formal study reports that we prepare, to provide more detail on the design, methods and results of our clinical trials.

1. EFPIA Code. <http://transparency.efpia.eu/the-efpia-code-2>

2. ABPI Clinical Trial Disclosure Kit. <http://www.abpi.org.uk/our-work/library/guidelines/Pages/ABPI-disclosure-toolkit.aspx>

3. EFPIA.Joint EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing Become Effective. <http://efpia.eu/mediaroom/132/43/Joint-EFPIA-PhRMA-Principles-for-Responsible-Clinical-Trial-Data-Sharing-Become-Effective>

4. EUPATI. Clinical development and trials. <https://www.eupati.eu/category/clinical-development-and-trials/>

5. Clinical Study Data Request: <https://clinicalstudydatarequest.com/>

Improvements in clinical trial transparency



- Research shows industry commitment to greater transparency of company-sponsored current and future clinical trials is making a difference.
- The disclosure rates of results for clinical trials for medicines licensed in Europe between 2009-2013 has seen a steady improvement from 71% in 2009¹ to 90% in 2013².
- Companies are developing innovative processes and solutions to share clinical trial data with researchers to enable greater advances in scientific discovery and patient care.³
- The [EFPIA responsible transparency platform](#) provides a gateway to many of these solutions.



We are seeing a sustained trend towards improved disclosure of industry-sponsored trials associated with new medicines.⁴

Dr Bryan Deane



1. Rawal B & Deane BR. 2014. read Clinical trial transparency: an assessment of the disclosure of results of company-sponsored trials associated with new medicines approved recently in Europe. <http://www.tandfonline.com/doi/abs/10.1185/03007995.2015.1047749>

2. Deane BR & Sivarajah J. Nov 2016. Clinical trial transparency update: an assessment of the disclosure of results of company –sponsored trials associated with new medicines approved in Europe in 2013 <https://www.ncbi.nlm.nih.gov/pubmed/27869482>

3. EFPIA Clinical Trial Data Portal Gateway

4. ABPI Press Release - <http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/90-per-cent-of-pharmaceutical-industry-led-clinical-trials-now-published.-says-new-study.aspx>

Sources



Slide Title	Source
The pharmaceutical industry is working in different ways with patients and healthcare professionals, slide 49	The Accelerated Access Review:
The pharmaceutical industry is working in different ways with patients and healthcare professionals, slide 49	European Patients Academy (EUPATI)
Patients First Conference – AMRC and ABPI, slide 50	ABPI Media Centre
Patient involvement in medicine development - from theory to reality, slide 51	European Patients Academy (EUPATI)
We are committed to transparency, setting and following high standards for how we behave, slide 52	Prescription Medicines Code of Practice Authority
We launched the ABPI Patient Organisation Forum (POF) in 2014, slide 53	ABPI. Patient Organisation Forum.
Together we produced the 'Patient Guide', slide 54	National Voices and ABPI 'Working together, delivering for patients: A guide to collaboration between charities and pharmaceutical companies in the UK'
Transparency in partnership with healthcare professionals and healthcare organisations, slide 55	ABPI: Disclosure UK Database
Transparency in clinical trials, slide 56	The EFPIA Code.
Transparency in clinical trials, slide 56	ABPI clinical trial disclosure toolkit
Transparency in clinical trials, slide 56	EFPIA. Joint EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing Become Effective

Sources



Slide Title	Source
Transparency in clinical trials, slide 56	EUPATI. Clinical development and trials.
Transparency in clinical trials, slide 56	Clinical Study Data Request.
Improvements in clinical trial transparency , slide 57	Rawal B & Deane BR. 2014. Clinical trial transparency: an assessment of the disclosure of results of company-sponsored trials associated with new medicines approved recently in Europe.
Improvements in clinical trial transparency, slide 57	Deane BR & Sivarajah J. Nov 2016. Clinical trial transparency update: an assessment of the disclosure of results of company sponsored trials associated with new medicines approved in Europe in 2013
Improvements in clinical trial transparency, slide 57	EFPIA Clinical Trial Data Portal Gateway.
Improvements in clinical trial transparency, slide 57	ABPI. 90% of pharmaceutical industry led clinical trials now published.

Innovation flourishes in the right environment



The enabling conditions for innovation

Innovation cannot happen without a number of enabling conditions; access to world-class researchers, political and financial stability, and a strong manufacturing capacity and capability.¹



Manufacturing is an important part of our story in the UK



Manufacturing has a critical part to play in the success of the pharmaceutical industry in the UK and is an important part of our contribution to the economy and society.

We are recognised as a world-class centre for medicines manufacturing and are in partnership with Government to create an active and thriving environment for medicines manufacturing.



The UK pharmaceutical industry goes beyond science to manufacturing and the full supply chain



Life Sciences Service and Supply Chain in 2015¹

The Life Sciences service and supply chain includes companies producing specialist products and services to support the industry R&D, clinical and manufacturing activities in the UK and globally.



Largest supply chain segments by both employment and revenue.



Clinical Research Organisations



Equipment and Consumables Suppliers



Contract and Manufacturing

Supply chain split

Biopharmaceuticals



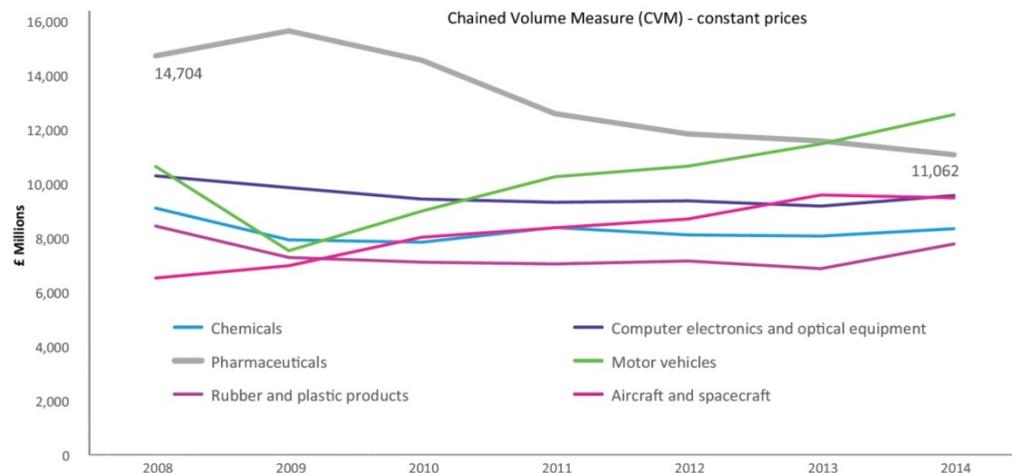
Medical Technology



The Medicines Manufacturing Industry Partnership (MMIP)



- MMIP was established by Government and industry in 2014 to ensure the UK is recognised as a world-class centre for medicines manufacturing.
- Although the pharma sector has been leading other sectors in GVA, the total contribution is falling, calling for a co-ordinated effort to support the UKs manufacturing base.
- MMIP's 3 year mission is to:
 - increase the relative global proportion of medicines manufacturing investment in the UK
 - act as a strong coordinated voice for the medicines manufacturing sector
 - Identify measures to improve the global competitiveness of UK medicines manufacturing
 - promote the benefits of the UK as a location of choice for medicines manufacturing



MMIP: Creating an attractive and thriving environment for medicines manufacturing

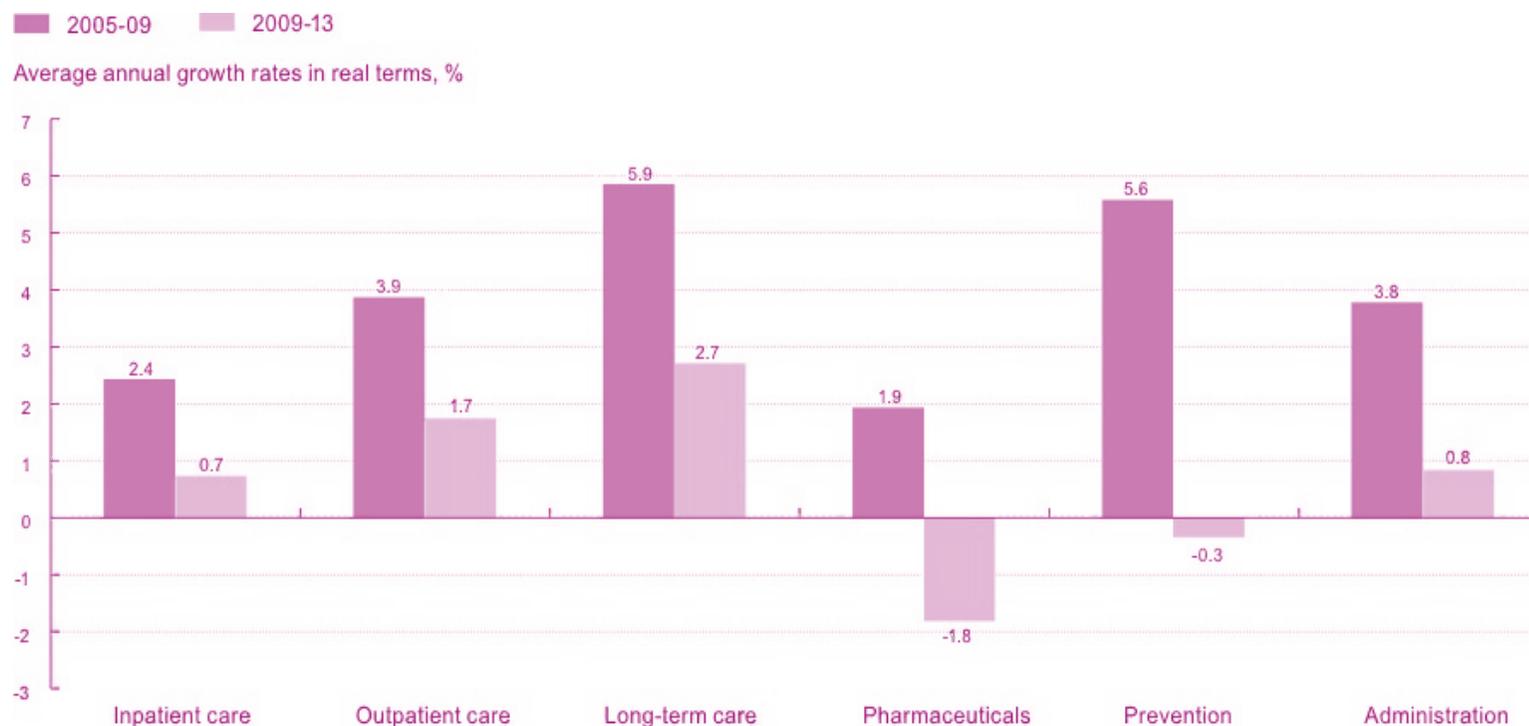


- Since its formation the MMIP has:
 - Set up a ministerial taskforce to anchor the manufacturing of Advanced Therapy Medicinal Products in the UK.
 - The Knowledge Transfer Network has developed a portal that maps the UK's medicines manufacturing capabilities. mmlandscape.ktn-uk.org
 - In collaboration with MMIP, MHRA Innovation Office has published case studies highlighting how it supports manufacturers to navigate regulatory requirements. www.gov.uk/government/groups/mhra-innovation-office
 - Secured funding for the Advanced Digital Design of Pharmaceutical Therapeutics programme, which allows for the digital design of manufacturing processes.
 - Supporting the generation of the SIP report, working in co-ordination with the ABPI skills team and providing industry's objectives on skills development
 - Continuing to work on the GVA assessment and developed a [fiscal guide](#) explaining the UK's investment and financial offerings



Total OECD healthcare expenditure has seen constant growth while spending on medicines has decreased by 1.8% per annum in recent years

Growth rates of health spending for selected functions per capita, OECD average, 2005-2013



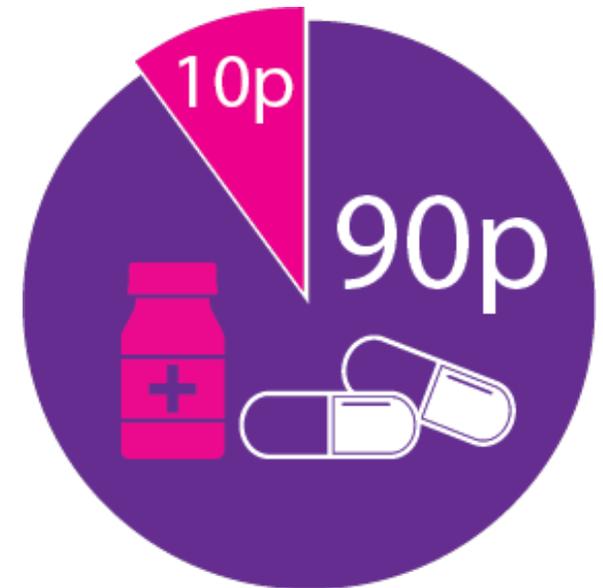
Putting medicines spend into perspective

The NHS in England is estimated to spend just under

10p in every **£1**

on branded medicines, which represents just under

10% of the overall NHS budget



These figures are estimated

Industry's contribution to the funding of UK medicines: the Pharmaceutical Price Regulation Scheme (PPRS)



Unique deal underwrites branded medicines growth,
through direct industry payments to DH



Agreed growth rates



It is estimated that industry will have paid back

£1.296bn*

up to the end of 2015, since the Scheme's inception

£3bn estimated total over 5 years



* As at June 2016

The current PPRS provides a one-off opportunity

- For patients and clinicians, the PPRS provides an opportunity to find the right level of usage of branded medicines, based on clinical factors rather than cost
- For the NHS, medicines bill growth has been underwritten, so commissioners can remove barriers to clinicians choosing which medicines to use
- The PPRS is a single, holistic UK agreement covering the relevant issues which underpin the pricing of NHS branded medicines
- The scheme is designed to support the NHS by ensuring that the branded medicines bill in the UK stays within agreed limits. The 5 year deal gives stability and predictability for industry, Government and the NHS
- Through the PPRS, the ABPI has worked with the Department of Health and NHS England to focus on access to innovative medicines for patients, including via the NHS RightCare programme. It is a programme committed to improving people's health and outcomes. It makes sure that the right person has the right care, in the right place, at the right time, making the best use of available resources.¹
- The deal also aims to encourage innovation and the development of high value treatments, by promoting a strong and profitable pharmaceutical industry capable of and willing to invest in research and development to encourage the future availability of new and improved medicines for the benefit of patients



Ensuring a regulatory framework that protects and rewards innovation



- We are working with Government and other organisations across Life Sciences to determine how to create a world-leading life sciences environment in the UK outside of the EU. This will include:
 - Identifying optimal position for the life sciences sector against potential exit scenarios and generating ideas for agile approaches to overcome barriers and mitigate risks
 - Identifying opportunities to make the UK domestic landscape as strong and attractive as possible for the life sciences industry
 - Providing options for how the UK can negotiate with the EU and relevant EU life sciences bodies to obtain the optimal outcome for UK and European industry, health systems and patients
 - Ensuring a framework for a continued dialogue between the life science industry and the government on these issues
- **Key issues for the pharmaceutical industry in EU negotiations**
 - Securing predictable funding and collaboration for scientific research
 - Securing the ability to trade and move goods and capital across borders
 - Securing regulatory co-operation
 - Securing access to the best talent

The image shows the cover of a report titled 'Manifesto for a strong UK economy outside the EU'. The cover is white with a purple border. At the top right is the abpi logo with the tagline 'Bringing medicines to life'. The title is in a large, purple, serif font. Below the title is a short paragraph in black text. Further down is another paragraph, followed by a list of three bullet points in purple text. At the bottom, there is contact information for Aulrey Yvernault, Director of Government & External Affairs, and the full name and address of the Association of the British Pharmaceutical Industry.


Bringing medicines to life

Manifesto for a strong UK economy outside the EU

The pharmaceutical industry in the UK is key to the success of the UK economy. The global pharmaceutical market is growing, with the UK a world leading manufacturer and exporter. The industry is also the UK's biggest investor in research and development.

Through the life-saving medicines it provides for patients, it supports the NHS to profoundly change the lives of millions of people.

Leaving the EU will present significant challenges to the stability of the industry in the UK. At this critical time, it is vital that we send a strong message that the UK is open for business. The ABPI is calling on the UK's political leaders to ensure that the roadmap for the UK leaving the EU secures the future of our country's pharmaceutical industry.

- **Minimise business uncertainty:** for a sector that plans a decade ahead, it is critical to maintain long-term frameworks and policies and to ensure there is thorough discussion with the pharmaceutical industry on measures affecting it, including in the negotiations with the EU on the terms of the UK's exit.
- **Open the UK to the world:** set up a government-industry taskforce to align the UK regulatory regime for medicines with established international regimes; and maintain the ability of companies to retain and recruit highly-skilled employees from the UK, the EU and the rest of the world.
- **Promote innovation for a strong, competitive UK:** mitigate some of the challenges of leaving the EU by putting innovation at the heart of a new approach to industrial strategy, investing in science and innovation and making the NHS a powerhouse for the economy by enabling it to give fast and fair access to new medicines for all patients.

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Sources

Slide Title	Source
The enabling conditions for innovation, slide 61	ABPI. 2016. EU Life Sciences Transition Programme Report, for the UK EU Life Sciences Steering Committee
Manufacturing is an important part of our story in the UK, slide 62	ABPI. Medicines Manufacturing Industry Partnership.
The UK pharmaceutical industry goes beyond science to manufacturing and the full supply chain, slide 63	UK Life Sciences Strength & Opportunity 2015.
The Medicines Manufacturing Industry Partnership (MMIP), slide 64	ABPI R&D Sourcebook 2015, Page 18.
Total OECD healthcare expenditure has seen constant growth while spending on medicines has decreased by 1.8% per annum in recent years, slide 66	OECD Health at a Glance (2015)
Putting medicines spend into perspective, slide 67	Office of Health Economics
Industry's contribution to the funding of UK medicines: the Pharmaceutical Price Regulation Scheme (PPRS), slide 68	ABPI News Release – Industry contribution to NHS medicines bill almost £1.3bn, but overall spend remains flat
The current PPRS provides a one-off opportunity, slide 69	NHS England RightCare

The future is exciting with challenges that
can be overcome¹



Despite great progress, there are challenges we must address across Europe

Innovation is challenging

- Industry is tackling more complex disease areas
- Longer, more complex clinical trials
- Higher regulatory hurdles
- Increased cost of R&D



Investment in innovation increasingly risky

- Government payers encouraging off label use of therapies to save money
 - Flourishing parallel trade
 - Fiscal austerity measures
 - Unknown IP environment

Challenges exist impeding patient access

- Complex HTA processes delaying patient access
- Clinical guidelines and restrictive cost-effectiveness requirements limiting access to best care
- Contracting and tendering limiting therapeutic options

Healthcare systems in Europe face significant challenges in expanding access to healthcare while managing finite resources



Several challenges to overcome for health care systems to focus on patient outcomes

- 1** Lack of public and political awareness
 - Low awareness of outcomes inequality, some of which are resulting from practice variation
- 2** Suboptimal outcome measurement & transparency
 - Lack of a standard definitions, measurement and transparency of outcomes data
- 3** Few proofs of concepts
 - Lack of comprehensive examples demonstrating what can be achieved through an outcomes-focused system
- 4** Health systems structural barriers
 - Structural barriers in healthcare systems to move towards outcome-focused system

It is important that we get the future R&D and regulatory pathways right in the UK



Science and technologies, as well as new sources of information, offer a wealth of opportunities to optimise R&D. It is essential that these advances are also reflected in regulatory and clinical practice to ensure that this potential is realised – and that patients can obtain much needed prevention and treatments much faster.

- The AAR sets out a bold new vision of better, cheaper and faster adoption of innovation through:
 - 1. Establishing streamlined mechanisms for prioritising emerging technologies and identifying strategically important innovations**
 - 2. Working with innovators to accelerate approvals speed up adoption and evaluate technologies efficiently using new data sources; and**
 - 3. Aligning national organisations to transform the NHS's ability to adopt the right innovations rapidly**



The Accelerated Access Review is an important foundation for building a Life Sciences Industrial Strategy and opens the door to greater collaboration between innovators, patients and the NHS to make the UK a world leader in researching, developing and using new treatments and technologies. The report recommends: the following around R&D & regulatory pathways.

- NICE should review its health technology assessment processes and methods to ensure they are fit for purpose to assess new types of emerging products and enable access to the products the NHS needs.
- NICE should develop a flexible health technology assessment pathway that can be tailored to a product's value proposition.
- NICE should refocus its work to place more emphasis on medical technologies, diagnostics and precision medicine tools, and a funding requirement should apply or those products that improve efficiency
- There should be a single set of clear national and local commissioning arrangements to get medical technologies, diagnostics, pharmaceuticals and digital products to patients

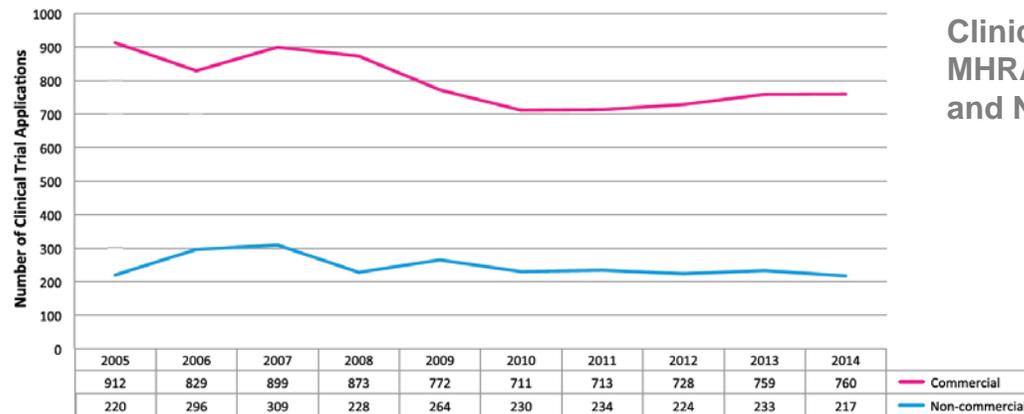
We want to retain the UK as a base for clinical trials

The UK is a base for excellence in clinical trials

– more than 618,000 people participated in clinical research in England in 2014

The Life Science Competitiveness Indicators, which reviewed the relative shares of patients recruited to global studies across all trial phases, revealed that the **UK has seen a decline its share of patients over time (2008 to 2012)**

According to the MHRA, the **number of applications for clinical trials in the UK has declined** since 2005 but amounted to 760 applications received in 2014. The UK National Institute for Health Research (NIHR) calculated that **more than 618,000 people participated in clinical research in the NHS in England in 2014**, with 35,000 participants recruited to studies sponsored by the pharmaceutical industry (an increase of 35% over the previous year)³. To put this in global context, in 2013, pharmaceutical companies sponsored 6,199 trials across the US involving 1.1 million participants¹.



Clinical Trial Applications Received by MHRA 2005-2014 All phases; Commercial and Non-Commercial

We want to retain the UK as a global destination for manufacturing



Opportunities

- Patients becoming partners in their own healthcare. packaging, design and content have to facilitate interactions and provision of information. Compliance benefits.
- Impact of “digital” on factory design and operation; using big data/ informatics - process control, connected supply chain
- How regulatory requirements keep pace with and adapt to recognise new technologies

Solutions

- Impact of Intelligent Products (and how we supply) devices and packaging coupled with ‘wearables’ and digitised medicine
- Manufacturing technologies and effective supply chains for new product types (such as those needed for ATMPs)
- Continued shift towards personalised medicines require ever more flexible and adaptable supply chains

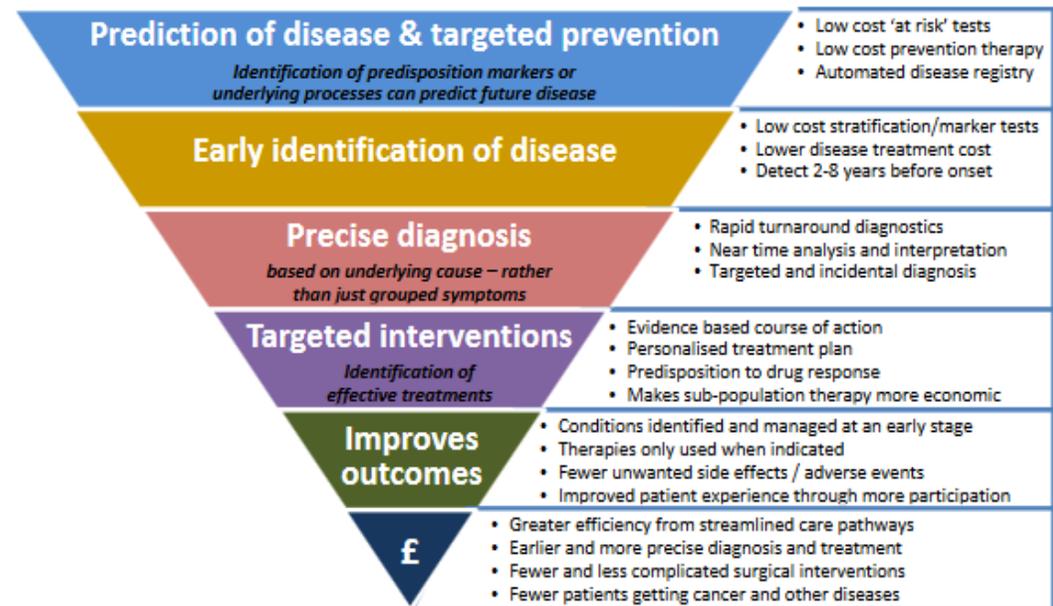
Challenges¹

- Availability of skilled people to sustain, correct and deliver future technologies
- Availability of funding (government and private)
- Incomplete infrastructure of national facilities and capabilities to support product and technology development
- Attractiveness of UK tax structure

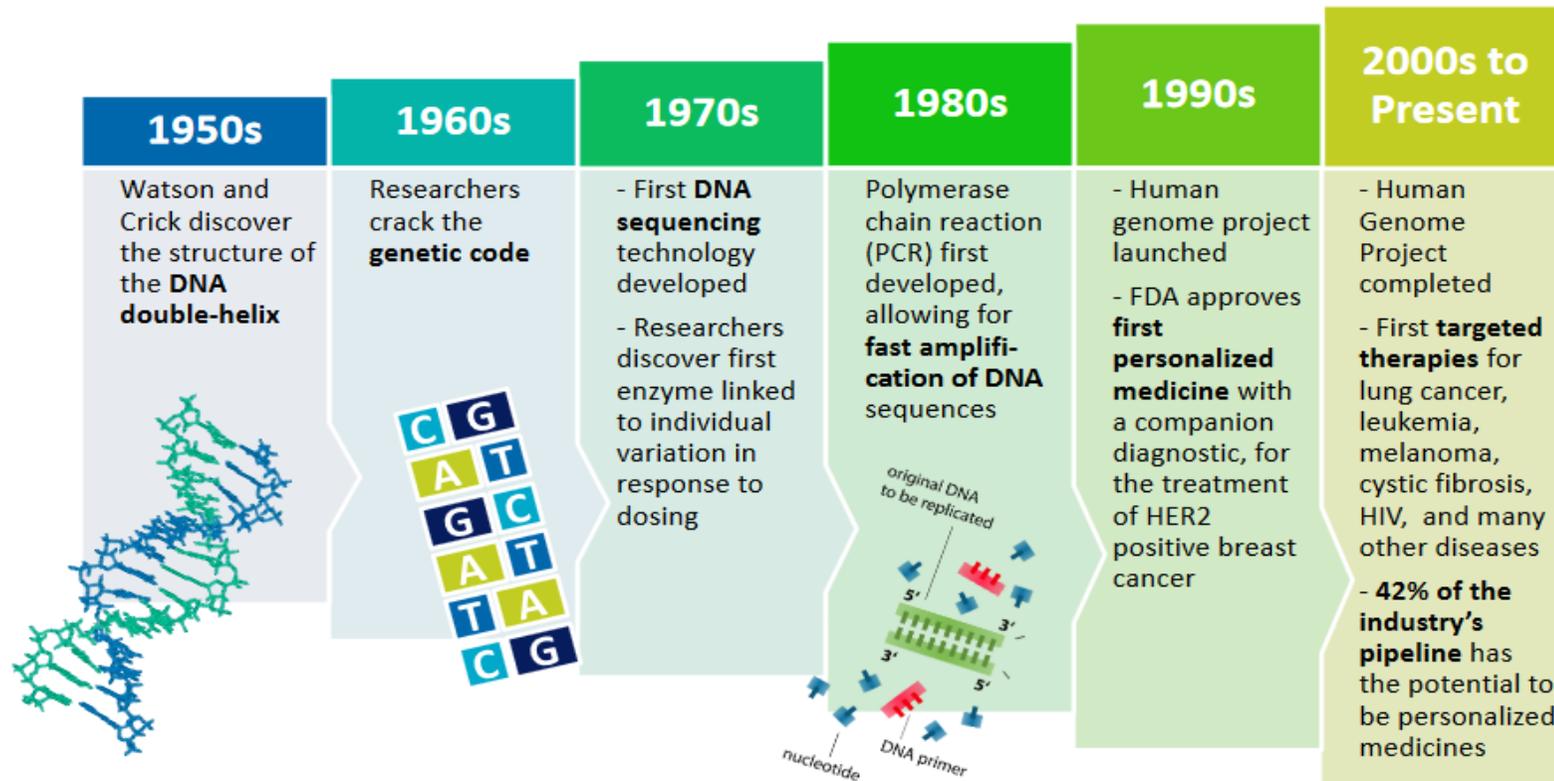
What is personalised medicine?

Personalised medicine is about moving away from a 'one size fits all' approach to the treatment and care of patients with a particular condition, to using diagnostics, genomics, data analytics and other emergent technologies to identify the underlying cause of disease.¹

Figure 1: Personalised Medicine – improving outcomes



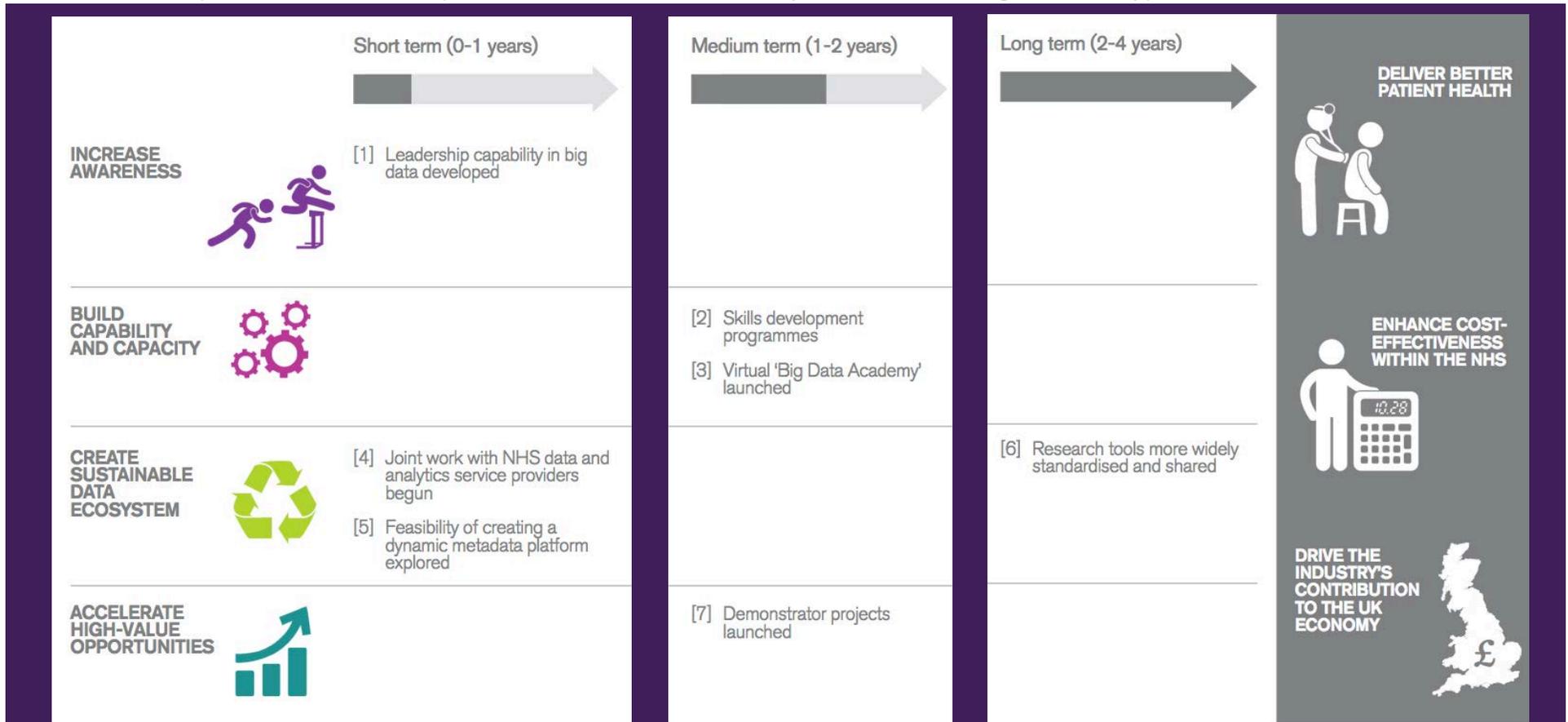
Scientific advances fuel personalised medicines



- L Pray, "Discovery of DNA structure and function: Watson and Crick," Nature Education, 2008; 1(1):100; Office of National Institutes of Health History, "Exhibit: Deciphering the Genetic Code: Marshall Nirenberg," <http://history.nih.gov/exhibits/nirenberg/index.htm>; Scitable by Nature Education, "The Order of Nucleotides in a Gene Is Revealed by DNA Sequencing," <http://www.nature.com/scitable/topicpage/the-order-of-nucleotides-in-a-gene-6525806>;
- PJ Murphy, "The Development of Drug Metabolism Research as Expressed in the Publications of ASPET: Part 3, 1984–2008," Drug Metab Dispos, 2008 Oct;36(10):1977-82; National Center for Biotechnology Information, "Polymerase Chain Reaction," <http://www.ncbi.nlm.nih.gov/probe/docs/techpcr/>; NIH,
- Fact Sheet: Human Genome Project," [http://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject\(NHGRI\).pdf](http://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject(NHGRI).pdf), Oct 2010; U.S. FDA, "Paving the Way for Personalized Medicine," Oct 2013; Tufts Center for the Study of Drug Development, "Impact Report," Volume 17, No.3, May/June 2015.

The role of data now and in the future is becoming more important

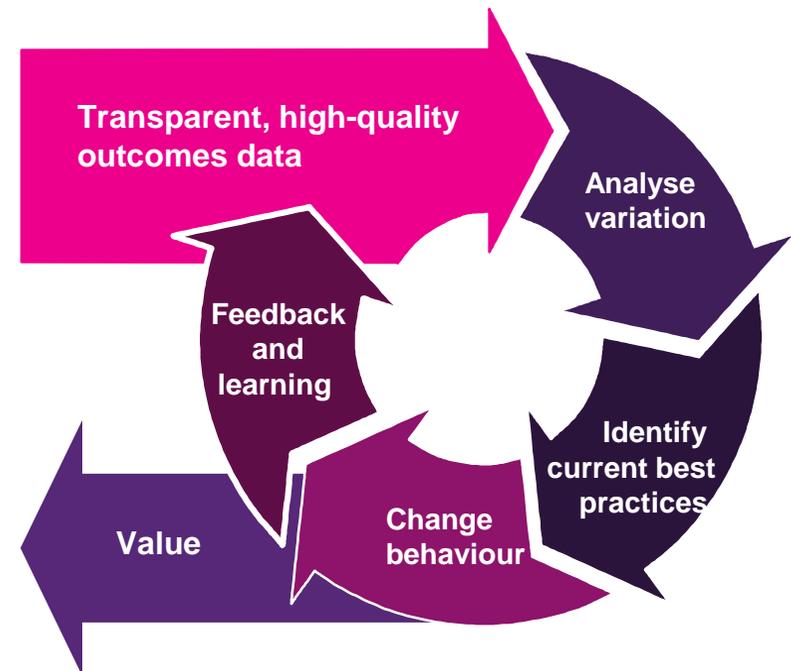
Big data is a common theme underpinning many of the proposed solutions to the challenges facing the NHS, the life sciences research community and the pharmaceutical industry. Big data technologies make it easier to work with large datasets, link different datasets, detect patterns in real time, predict outcomes, undertake dynamic risk scoring and test hypotheses.



Industry is keen to engage in the debate and to partner with government to deliver outcomes driven sustainable healthcare systems

The objective of outcomes-focused healthcare systems is to deliver **better patient outcomes** at the **same or lower cost...**

Relying on **quality outcome data** as starting point to improve care cycle

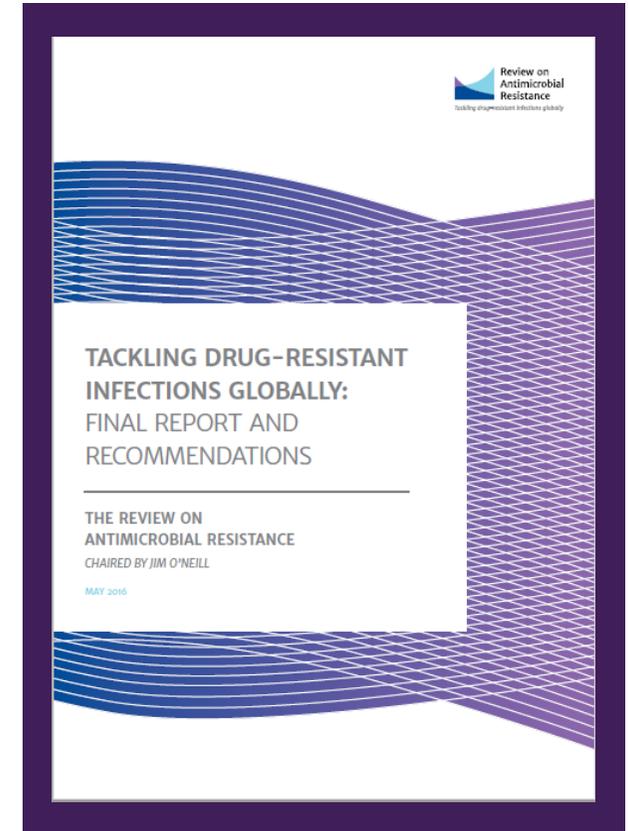


Benefits of a focus on outcomes: improved patient outcomes, reduced variation, reduced medical cost, continuous improvement

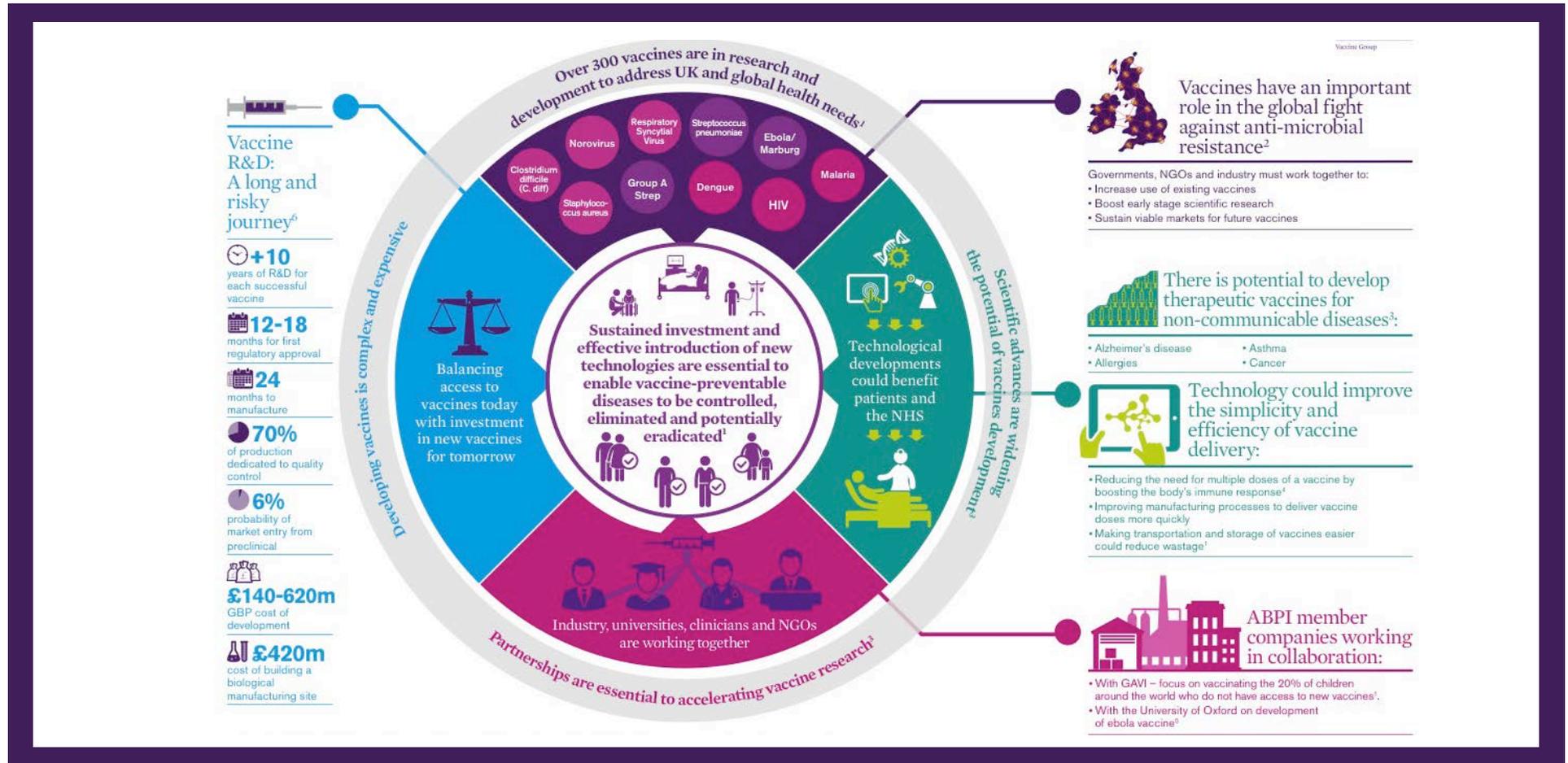
The pharmaceutical industry is working hard to tackle Antimicrobial Resistance



- The May 2016 announcement from the UK Government on Antimicrobial Resistance was an important step forward in the collective action that must now begin to address drug resistance and the rise of the superbug.
- The pharmaceutical industry is committed to playing its part, but keeping antibiotics effective is everybody's responsibility, and detecting, preventing and controlling resistance requires a strategic, coordinated, and sustained global and local response.
- National government action and funding is a crucial component and we stand ready to work alongside policymakers, as well as the NHS, patients, healthcare providers, academia and the agricultural community in this fight.



Industry is committed to the future development of vaccines



Industry is committed to the future development of vaccines - referencing



1. IFPMA, Innovation for a Healthier World <http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA-ComplexJourney-FINAL-Digital.pdf>
2. Review on antimicrobial resistance. 'Vaccines and Alternative Approaches: Reducing our dependence on antimicrobials' 2016. https://amr-review.org/sites/default/files/Vaccines%20and%20alternatives_v4_LR.pdf
3. Medical Research Council, Review of Vaccine Research 2014 <https://www.mrc.ac.uk/documents/doc/mrc-review-of-vaccines-research-2014/>
4. <https://www.science.org.au/6-what-does-future-hold-vaccination>
5. World Health Organisation, Ebola vaccines, therapies and diagnostics Q&A 6/10/15. http://www.who.int/medicines/emp_ebola_q_as/en/
6. IFPMA Maintaining the Vaccines Innovation Edge infographic. <http://www.ifpma.org/resource-centre/maintaining-the-vaccines-innovation-edge/>

Medicines are part of the solution and more can be done together with Government



Improve efficiency

Look at all healthcare costs, reduce administrative costs and waste, and improve efficiency.



Pay for value

Support evidence-based care and empowered patients and providers, backed by sound research and strong quality measures.



Find solutions

Avoid blanket policies that chill investment, and collaborate to find new approaches.



CONTINUE DEVELOPING INNOVATIVE THERAPIES, PROMOTE MEDICATION ADHERANCE, MAINTAIN EFFORTS TO SUPPORT BROAD PATIENT ACCESS

Sources



Slide Title	Source
The future is exciting with challenges that can be overcome, slide 72	Accelerated Access Review Final Report.
Despite great progress, there are challenges we must address across Europe, slide 73	EFPIA, From innovation to outcomes, medicines costs in context. Page 52.
Healthcare systems in Europe face significant challenges in expanding access to healthcare while managing finite resources, slide 74	EFPIA, From innovation to outcomes, medicines costs in context. Page 37.
Several challenges to overcome for health care systems to focus on patient outcomes, slide 75	EFPIA. Healthier future external slide set, Shaping sustainable, outcomes-driven healthcare in Europe. Page 8.
It is important that we get the future R&D and regulatory pathways right, slide 76	The Accelerated Access Review: Page 41.
We want to retain the UK as a base for clinical trials, slide 77	ABPI R&D Sourcebook 2015 . Page 26.
We want to retain the UK as a global destination for manufacturing, slide 78	McCubbin, I. (Chair of MMIP) 'Foreword from Co-Chairs of ATMT'
What is personalised medicine?, slide 79	NHS England. Personalised Medicines Board Paper.
Scientific advances fuel personalised medicines, slide 80	L Pray, "Discovery of DNA structure and function: Watson and Crick," Nature Education, 2008; 1(1):100;
Scientific advances fuel personalised medicines, slide 80	PJ Murphy, "The Development of Drug Metabolism Research as Expressed in the Publications of ASPET: Part 3, 1984–2008," Drug Metab Dispos, 2008 Oct;36(10):1977-82; National Center for Biotechnology Information, "Polymerase Chain Reaction."
Scientific advances fuel personalised medicines, slide 80	Fact Sheet: Human Genome Project "Paving the Way for Personalized Medicine," Oct 2013; Tufts Center for the Study of Drug Development, "Impact Report," Volume 17, No.3, May/June 2015

Sources



Slide Title	Source
The role of data now and in the future is becoming more important, slide 81	ABPI Big Data Roadmap 2013. Page 13.
Industry is keen to engage in the debate and to partner with government to deliver outcomes driven sustainable healthcare systems, slide 82	EFPIA, From innovation to outcomes, medicines costs in context
The pharmaceutical industry is working hard to tackle Antimicrobial Resistance, slide 83	Tackling drug-resistant infections globally. Final report and recommendations.
Industry is committed to the future development of vaccines, slide 84	IFPMA, Innovation for a Healthier World, Page 15.
Industry is committed to the future development of vaccines, slide 84	Review on antimicrobial resistance. 'Vaccines and Alternative Approaches: Reducing our dependence on antimicrobials'. Page 3.
Industry is committed to the future development of vaccines, slide 84	Medical Research Council, Review of Vaccine Research 2014. Page 8.
Industry is committed to the future development of vaccines, slide 84	Australian Academy of Science. What does the future hold for vaccination?
Industry is committed to the future development of vaccines, slide 84	World Health Organisation, Ebola vaccines, therapies and diagnostics
Industry is committed to the future development of vaccines, slide 84	PMA Maintaining the Vaccines Innovation Edge infographic.
Medicines are part of the solution and more can be done together with Government, slide 86	EFPIA, From innovation to outcomes, medicines costs in context. Page 2.

Thank you to the following organisations and companies



- EFPIA
- PhRMA
- Companies who have supported us with examples listed here:
 - Abbvie
 - Amgen
 - AstraZeneca
 - Boehringer Ingelheim
 - Gavi
 - GlaxoSmithKline
 - Janssen
 - MerckSerono
 - Novartis
 - Novo Nordisk
 - Pfizer
 - PharmaMar
 - Sanofi



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Examples from industry



Leading the way in transparency

Our members have lead the way in transparency

- **GSK was the first company to sign up to All Trials in 2013**, which calls for the registration of clinical trials and the disclosure of trial results and clinical study reports (CSRs). CSRs are the formal study reports that we prepare, to provide more detail on the design, methods and results of our clinical trials.
- 2013 was the same year **GSK launched a web-based system for researchers** from the scientific community to request access to the anonymised patient-level data from our studies.
- In 2004, **GSK launched a clinical trial register** – a place where information about the clinical research GSK carries out on existing medicines could be posted.





Working in partnership

Bringing to life how our industry works

The pharmaceutical industry works in many different ways with its partners across patients, the NHS, governments and academia

We are committed to being active partners, whether that is inspiring the next generation of scientists, supporting new approaches to healthcare delivery, improving public health crisis or contributing to people's health



Beyond our medicines – an industry working in partnership

- Pharmaceutical members are committed to being in active partnership with the NHS and patient organisations.
- Examples of joint working include:
 - Arthritis Research UK and Pfizer
 - Implementing NICE Clinical Guidelines on Atrial Fibrillation (CG180) across Oldham CCG using the Rapid Adoption Innovation Framework (RAIF) (Oldham CCG, Boehringer Ingelheim Ltd, Bayer PLC, and Pfizer Ltd)
 - Salford Lung Study - working with GSK, North West e-Health (NWEH), The University of Manchester, Salford Royal NHS FT, University Hospital of South Manchester (UHSM), NHS Salford and GPs and community pharmacists.
 - Brighton & Hove CCG and NHS Grampian Joint Working projects with GSK aim to support the delivery of improved patient adherence, medicines optimisation and reductions in medicines wastage, by rolling out the “Complete The Cycle” inhaler recycling scheme to local pharmacies and through training and up skilling pharmacists involved in this project.



Beyond our medicines – an industry working in partnership

- Pharmaceutical members are committed to being in active partnership with the NHS and patient organisations.
- Examples of joint working include:
 - Improving anticoagulation in patients with atrial fibrillation in partnership with Nene CCG, Northamptonshire and West Hampshire CCG and Boehringer Ingelheim
 - Partnering with the NHS under the NHS Leadership Academy NHS Fellows programme in partnership with Boehringer Ingelheim



EPIFFany: (Effective Performance Insight for the Future) Working in partnership with the NHS



- EPIFFany is an example of successful joint working with the University Hospitals of Leicester NHS Trust and Pfizer Ltd to improve the prescribing performance of junior doctors.
- The innovation was developed by the EPIFFany team, led by Dr Rakesh Patel (University of Nottingham) and Dr William Green (University of Leicester). It was piloted at Leicester General Hospital and subsequently pioneered at Pilgrim Hospital in Boston, Lincolnshire.
- During the four month project, the rate of junior doctor prescribing errors fell by 60%, saving approximately 500 bed days and potentially £300,000 from avoidable medication errors.
- A ground-breaking intervention to improve junior doctors' performance – designed in Leicester and developed in Lincolnshire and with support from partners including the East Midlands Academic Health Science Network, Health Education England East Midlands, the BMJ, UpToDate and Pfizer– is attracting global interest and has been shortlisted for a prestigious award.

EPIFFany

University Hospitals
of Leicester 
NHS Trust



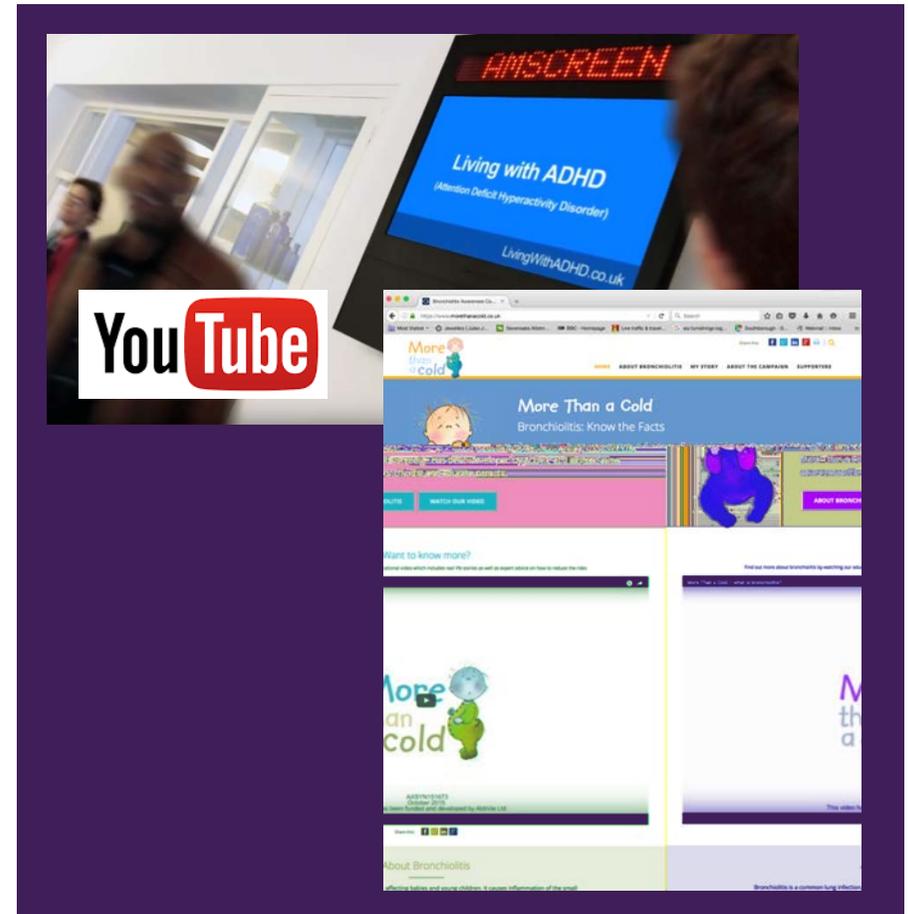
The pharmaceutical industry is actively engaging in activities that support patients' lives



Janssen: Living with ADHD - Janssen produced a YouTube film and microsite to kick start a proper debate about living with Attention Deficit Hyperactivity Disorder (ADHD) so that parents, teachers and doctors can help make sure that children with ADHD get the help and support they need. To date, the film has received over 210,000 views, making it one of the most viewed pharma videos in Europe.



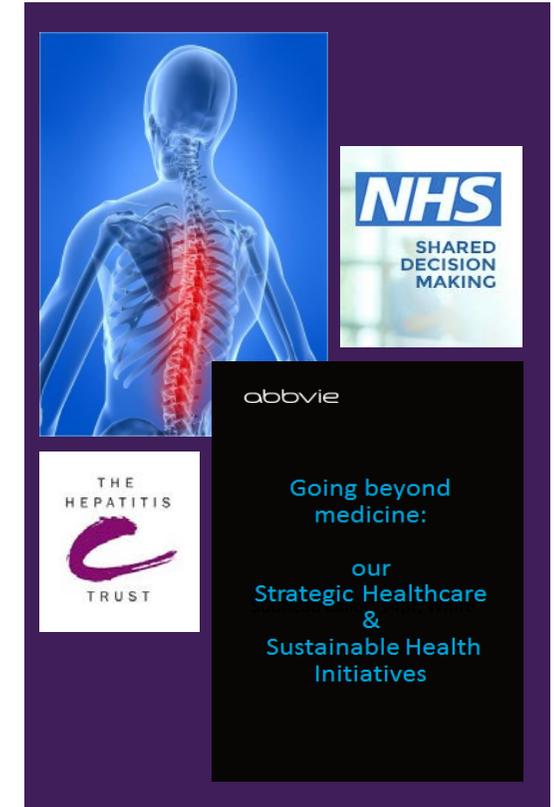
AbbVie: The More Than a Cold campaign aims to raise awareness of bronchiolitis and provide information to parents. It is organised and funded by the pharmaceutical company AbbVie and supported by Bliss, the British Lung Foundation, NCT, Tamba, Tiny Tickers, Tiny Lives and WellChild.



Sustainable Healthcare: supporting new approaches to healthcare delivery



- The need for more sustainable healthcare approaches to accommodate rising demand and demographic pressure is much commented on. Within England for example a quarter of people – some 15 million – have a long-term condition and around 70% of the NHS budget is spent on care for people with such a condition.
- AbbVie has established and dedicates resources and expertise to its Sustainable Healthcare programme, bringing together a multidisciplinary group of independent experts into the Sustainable Healthcare Steering Group who identified key areas with opportunity to improve the sustainability of our healthcare services.
- Through this programme, AbbVie has launched three pilot studies looking at how to build sustainability into the NHS:
 - A three year partnership with the Hepatitis C trust and Addaction, two charities, to help them develop a programme that provides workforce development alongside ‘buddying’ and peer to peer support for people who are undergoing treatment, and the creation of Community treatment centres.
 - Creating the UK’s first early intervention clinic (EIC) for people who have been signed off from work with a musculoskeletal disorder so they can stay in or return to work as soon as they can. The EIC has recently begun accepting new patients in Leeds.
 - A new, shared decision-making tool to improve conversations and decisions about health and work between patients and their healthcare professionals.



We take partnerships seriously

- In the UK we partner with national charities, social enterprises and international non-governmental organisations (NGOs) who are committed to making a sustainable difference to people's lives in under-served communities. An example of our CSR work in the UK includes our contribution towards Save the Children's Families and Schools Together (FAST) programme.
- Johnson & Johnson has partnered with Save the Children and in the UK, Janssen is specifically contributing the FAST programme - an award-winning programme that brings parents, children, teachers and the wider community together, to make sure young children get the support they need to fulfil their potential at school – and in life.
- Janssen employees have taken part in a variety of fundraising activities which will be match-funded by Janssen and will go towards supporting another round of the programme. To date the FAST programme has transformed thousands of lives and according to statistics for 2013-14, the Programme made the following difference to the lives of those involved:
 - Children's behavioural problems decreased by 26%
 - Family conflicts dropped by 24%
 - 74% of parents felt more able to support their child in his or her education



Ensuring a future skills base

Cancer Research UK-MedImmune Alliance Laboratory

- The Cancer Research UK-MedImmune Alliance Laboratory is focused on the discovery and development of novel biologics to treat and diagnose cancer.
- The laboratory, located on Granta Park in Cambridge, is an innovative collaboration between Cancer Research UK, its commercial arm Cancer Research Technology, and MedImmune, the global biologics research and development arm of AstraZeneca.
- This innovative collaboration brings together Cancer Research UK's cancer biology expertise with MedImmune's world-class antibody engineering technology in a new joint laboratory.
- Scientists from both organisations work side by side, sharing knowledge and expertise to accelerate the development of therapeutic and diagnostic antibodies.

Dr Nigel Blackburn, Cancer Research UK's Director of Drug Development, said:



This exciting initiative gives leading academic scientists access to the latest antibody-engineering technologies and expertise, creating opportunities to translate breakthroughs in our understanding of cancer biology into urgently needed new cancer treatments. The lab is currently working on both therapeutic and diagnostic programmes which address areas of high unmet medical need, including rare and hard to treat cancers. The close and productive relationship between Cancer Research UK and MedImmune is enabling the lab team to rapidly progress novel ideas.



CANCER
RESEARCH
UK

MedImmune

A member of the AstraZeneca Group

AstraZeneca



CANCER RESEARCH UK-MEDIMMUNE ALLIANCE LABORATORY

Boehringer Ingelheim and the NHS have worked together to create an NHS Fellowship position

- **Boehringer Ingelheim (BI) worked with the NHS Leadership Academy to create an NHS Fellowship position, in order to:**
 - Increase understanding between BI and the NHS, and allow partnership working between the two organisations
 - Ensure BI materials and services support the NHS to deliver better health outcomes and experiences for patients, aligned with the RightCare programme
- **An NHS Fellow was seconded to work at BI for two days a week for one year, in addition to their role in the NHS.**
 - This involved advising on how BI could better align with NHS operations, exploring further joint working opportunities between BI and the NHS and advising how BI can support the NHS to meet key future challenges.



I have benefitted greatly from being an NHS Fellow with BI. Over the past year I have expand my experiences, knowledge and leadership skills, enhancing my capability to lead, influence and deal with complexity to help the NHS meet its challenges. This has enabled me to develop within the NHS, becoming a project manager for the Success Regime in Devon and building on my skills and abilities. A great experience both personally and benefitting patients and NHS and BI.



Fran Lowery, Project Manager
Royal Devon and Exeter Foundation
NHS Trust



An exciting opportunity for 3 UK University students

BioCamp is a pioneering three-day seminar that brings the healthcare sector closer to talented students from top universities around the world.

Held at Novartis International Headquarters in Basel, Switzerland, the program offers participants the opportunity to:

- Explore career opportunities in the pharmaceutical and biotech industries
- Interact with key Novartis professionals from a variety of functions who lead our unique approach to drug discovery
- Understand trends and challenges in the healthcare sector
- Receive first-hand experience about running a biotech company
- Network with talented students from other countries

3 UK university students are selected to attend based on their academic record, professional experience and extracurricular activities.

A total of 60 selected students from around the world will be selected and the Biocamp competition individual winners and members of the winning team receive a personalised Novartis internship.

This is an opportunity for Novartis to build relationships with talented UK students that are interested in pursuing a career in science and UK universities are active in helping to promote Biocamp as an opportunity for their students.

We invite local university students focusing on medicine, natural sciences, business administration and/or information technology to apply.

- University students must be actively pursuing academic studies and have at a minimum completed their bachelor (or equivalent) degree.
- We welcome postgraduate PhD-students and post-docs.



British Science Week: inspiring the next generation of scientists



- During British Science Week, GSK hosts an interactive science show at their Ware site aimed at expanding young minds, fuelling imagination and enthusing our country's future scientists and engineers. After eight years, the event is still growing in popularity and 800 pupils – more than ever before – took part during 2016.
- The event is part of GSK's commitment to provide practical support to educators and others professions. It aims to highlight the many advantages and exciting challenges they could have by a choosing a career in science and engineering.



“The day was fantastic and really helped bring science to life for my class – **the children thoroughly enjoyed** it and are still talking about the exciting explosions.”

Local School Teacher

Biotech Experience: Inspiring the next generation of scientists



- Amgen Biotech Experience is an innovative science education programme that provides teacher professional development, teaching materials, and research-grade equipment and supplies to secondary schools – delivering a hands-on molecular biology curriculum. Over 70,000 students and hundreds of science teachers participate each year, learning about the methods scientists use to create biotechnology medicines. Read more: <https://www.amgenbiotechexperience.com/>
- Use the interactive map online to see the growing range of schools in the UK involved in the Amgen Biotech Experience: <https://www.amgenbiotechexperience.com/about/where-we-are>
- In the UK the programme is led by Alison McCree (Site Director) and Karen Stephens (UK Programme Lead) of the University of Hertfordshire STEM Learning Centre, with programme delivery centres in the School of Education at the University of Cambridge, and in the Norwich Teacher Scientist Network.
- More than 50 schools currently participate and a series of teacher training courses, supporting teachers to lead the programme in their schools, are held each year.



300,000 + school science students
have **gained hands-on** experience
with research-grade biotech
equipment

Ebola: the global pharmaceutical industry moving quickly to respond to a public health crisis



- Researchers around the world, across the public and private sectors, are working to develop new ways to prevent the spread of Ebola and treat patients with the virus.
- Currently, there are 8 potential vaccines and treatments in clinical trials and at least 23 more moving through preclinical or earlier studies around the world.
- In addition to collaborating with the global infectious disease community to accelerate the development and manufacturing of innovative vaccines and treatments for Ebola, the pharmaceutical industry is supporting humanitarian efforts to contain and treat the disease.



The pharmaceutical industry's contribution to improving people's health (1)



- Pharmaceutical companies make substantial contributions to improve the effectiveness and efficiency of health systems and to improve access to quality healthcare and medicines through:
 - Training healthcare workers
 - Advancing health information systems
 - Disease awareness campaigns
 - Technology transfer
 - Improving point-of-care service delivery and
 - Investing in health infrastructure.



The pharmaceutical industry's contribution to improving people's health (2)

Our contribution includes:

- **Sanofi's Mental Health Initiatives:** a system-wide approach to improve experiences of people affected by mental disorders in Benin, Madagascar, Mauritania, Morocco, Guatemala, Comoros, Armenia, India, and South Africa.
- **Merck KGaA, Darmstadt, Germany's Capacity Advancement Program (CAP):** improve the quality of diabetes treatment and raises awareness of this disease, especially in low- and middle-income countries.
- **GSK:** A five year £22m charitable partnership created through a £17 million donation from GSK that will provide targeted grants to frontline organisations who are improving health in countries in sub-Saharan Africa and Asia
- The London Declaration unites healthcare companies, BMGF, World Bank, NGOs, and governments in a campaign to eliminate or control 10 NTDs by the year 2020 by:
 - Sustaining or expanding existing medicine donation programs
 - Sharing expertise and compounds to accelerate the development of new medicines
 - Strengthening distribution.



The pharmaceutical industry's contribution to improving people's health (3)

Companies have been developing methods that reduce fiscal barriers to medicines and promote local economic growth:

- Novartis's Arogya Parivar: a social venture through which health educators are recruited and trained on disease prevention and healthcare seeking behaviours and local teams run health camps and mobile clinics in India.
- AstraZeneca's Healthy Heart Africa: employs a sustainable chronic care model to tackle hypertension and cardiovascular disease in Kenya and Ethiopia.
- Novo Nordisk's Base of the Pyramid Project: initiated in 2012, implements sustainable solutions that increase patient access to diabetes treatment and care in resource-limited settings.
- MSD's Project Penny: known locally as Project Sambhav, aims to educate patients and their families about HCV and help manage the cost of treatment.
- PharmaMar's oncological research in the marine environment is conducted with utmost respect for the sea, supporting local knowledge, and the conservation and sustainability of ecosystems in accordance with the Convention on Biological Diversity and Nagoya Protocol.
- Gavi: plays a valuable role in bringing new and under used vaccines to hundreds of millions of children in the world's poorest countries. GSK is one of the largest contributors of vaccines to Gavi, supplying innovative vaccines for rotavirus, pneumococcal disease and cervical cancer, at significantly reduced prices to help accelerate access in developing countries.



The pharmaceutical industry's contribution to improving people's health (4)

- Industry has consistently demonstrated its dedication to using its R&D capabilities to address public health needs to create solutions tailored to locally identified needs.
- In 2016, the Declaration on Combating Antimicrobial Resistance was signed by pharmaceutical, biotechnology and diagnostics companies pledging to continue to invest in R&D to support collaboration between industry and public researchers to develop new antibiotics and diagnostics.
- The Global Health Innovative Technology Fund (GHIT) is the world's first product development fund with pioneering governance, management, and investment approaches, which facilitates international partnerships that bring Japanese innovation, investment, and leadership to the global fight against infectious diseases and poverty in the developing world. GHIT includes Astellas, Chugai, Daiichi Sankyo, Eisai, Shionogi, and Takeda.
- The NTD Drug Discovery Booster project aims to speed up the development of new treatments for Leishmaniasis and Chagas Disease, which 450 million people are at risk of contracting worldwide. The project brings together DNDi, Eisai, Shionogi, Takeda and AstraZeneca.
- GSK has created an Open Lab within Tres Cantos which provides the opportunity for independent researchers to access GSK facilities, resources, and expertise to help them advance their own research projects into diseases of the developing world. A not-for-profit foundation, the Tres Cantos Open Lab Foundation has been set up with £10 million investment for GSK to support these research projects.



Patient Group Partnerships

- Open House Days



Open House Pilot

- In 2015 Janssen was in discussion on a possible collaboration with an oncology patient group. As part of these discussions it became evident that many patient groups, like many stakeholders, are not always aware of how the healthcare industry operates or how a pharmaceutical company can bring its expertise to bear on a shared issue or problem.
- Therefore an “Open House” day was put together to enable the patient group to meet the various teams and functions from across the business and enable them to understand the way Janssen works. This facilitated further discussion around a potential partnership and allowed for a clearer focus on what benefit and value Janssen could bring to a collaborative partnership.



Open House Roll-out

- Since the pilot “Open House” day, Janssen has run a further eight Open House days. These are sometimes therapy area wide where a number of patient groups attend together and in some cases, much like the pilot, they are run one-on-one between a patient group and Janssen with a particular project or partnership in mind.

Feedback

- Every “Open House” day is rated and as such, each further iteration is unique and tailored to the groups in attendance. So far 18 patient groups have attended a Janssen Open House day with further days planned for 2016 and 2017.

Clinical trial transparency at Janssen

YODA agreement

- Janssen believes that transparency of clinical trial data advances science and medicine and is in the best interest of the patients who use our pharmaceutical products and those who prescribe them. We have a unique agreement with Yale School of medicine which independently reviews requests for access to our trial data.
- J&J has partnered with Yale School of Medicine's Open Data Access Project (YODA), an independent third party, which reviews and responds to requests for access to our clinical trials data. This is the first time any company has collaborated with a completely independent third party to review and make decisions regarding every request for clinical data, helping to set a new industry standard for clinical data sharing.
- Yale School of Medicine is one of the most highly respected groups in this field and views this agreement as historical.

Janssen Global Trial Finder

- In August Janssen launched a new public facing website, the Janssen Global Trial Finder <http://globaltrialfinder.janssen.com/>
- The website has a wealth of information about clinical trials, how they are conducted, participation and answers FAQs on this topics.
- The site also has a search facility that allows users to search for information on Janssen clinical trials by condition or location.

Sources

Slide Title	Source
Our members have lead the way in transparency, slide 93	www.alltrials.net/supporters/organisations/gsk-statement
The pharmaceutical industry's contribution to improving people's health (1), slide 110	The United Nations Secretary-General's High-Level Panel on Access to Medicines Report.
The pharmaceutical industry's contribution to improving people's health (2), slide 111	The United Nations Secretary-General's High-Level Panel on Access to Medicines Report.
The pharmaceutical industry's contribution to improving people's health (3), slide 112	The United Nations Secretary-General's High-Level Panel on Access to Medicines Report.
The pharmaceutical industry's contribution to improving people's health (4), slide 113	The United Nations Secretary-General's High-Level Panel on Access to Medicines Report.
Patient Group Partnerships - Open House Days, slide 114	Janssen - PHGB/NPR/0916/0003
Clinical trial transparency at Janssen, slide 115	Janssen - PHGB/NPR/0916/0003

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