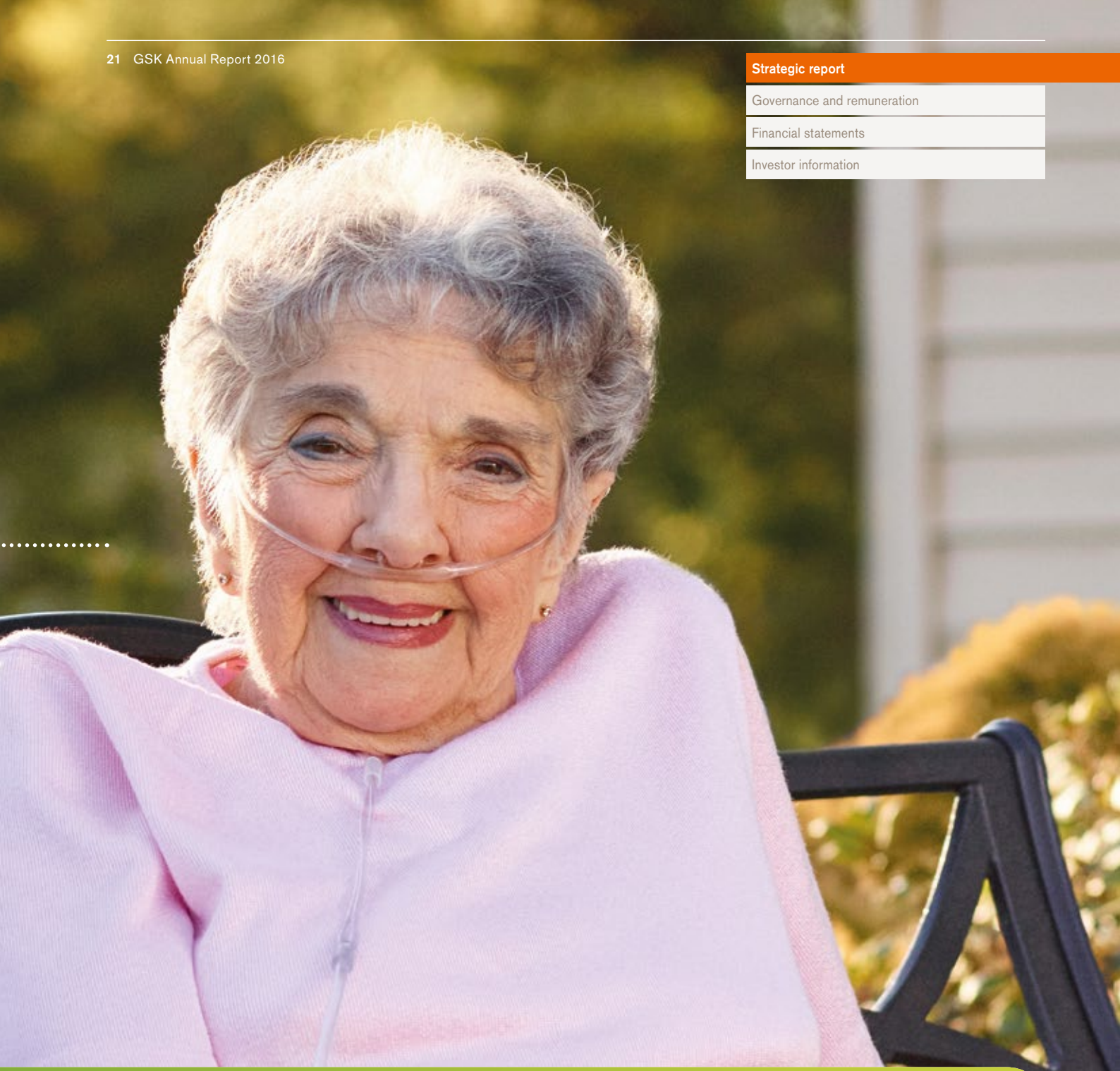
As a leader in respiratory, GSK has been at the forefront of research in this area for over 45 years.

Pharmaceuticals

Our Pharmaceuticals business discovers, develops and commercialises medicines to treat a broad range of the world's most common acute and chronic diseases.



Grow

£16.1bn

2016 Pharmaceutical reported sales were up 14% AER and 3% CER[a] (4% pro-forma CER). Sales of new products were 24% of Pharmaceutical sales.

Deliver

3

There were three filings with regulators in 2016 for Closed Triple, *Benlysta* subcutaneous and sirukumab.

Simplify

34.1%

Operating profit margin in 2016 was 34.1%, 3.7 percentage points higher than in 2015 and 1.2 percentage points higher on a CER pro-forma basis.

Responsible business

6

We have launched our last six new products in the US priced similar to or below those we aim to replace.

Footnote

a We use a number of adjusted, non-IFRS, measures to report the performance of our business, as described on page 57, including core results, free cash flow and CER and pro-forma growth rates. Non-IFRS measures may be considered in addition to, but not as a substitute for or superior to, information presented in accordance with IFRS.

Pharmaceuticals

We improve healthcare by preventing disease, treating illness and seeking long-lasting solutions for chronic and acute conditions including rare diseases.

Overview

Our Pharmaceuticals business has a portfolio of innovative and established medicines across a broad range of therapy areas, including respiratory and HIV, in which we are global leaders, as well as immuno-inflammation, anti-infectives, urology and rare diseases. Around a quarter of Pharmaceutical sales come from products launched over the past four years.

Respiratory

We have the industry's broadest range of inhaled respiratory products. Our respiratory portfolio is the largest contributor to Pharmaceutical sales and our expectation is that by 2020, nine products will account for approximately 90% of respiratory sales, compared to four in 2015.

In the past four years, we have launched a new generation of respiratory products including *Nucala (mepolizumab)* and our *Ellipta* portfolio.

HIV

Our global HIV business is managed through ViiV Healthcare, a company 78.3% owned by GSK, with Pfizer and Shionogi the other shareholders.

ViiV Healthcare is growing rapidly, and accounts for over 20% of Pharmaceutical sales. This was led by strong demand for *Tivicay* (dolutegravir), an innovative integrase strand transfer inhibitor, and *Triumeq*, a single-pill treatment combining dolutegravir, abacavir and lamivudine.

Specialty products

Our Specialty products portfolio includes medicines such as *Benlysta*, a treatment for lupus disease, and *Tanzeum/Eperzan*, for Type 2 diabetes.

Classic and Established products

Our Classic and Established products include over 400 post-patent medicines in the areas of anti-infectives, allergy, neurosciences, dermatology, respiratory and urology. Many of these medicines continue to be the top-selling brand in their therapy area. These products are an important part of our emerging markets business, where we sell 47% more volume than our nearest competitor.

A leader in respiratory

As a leader in respiratory, GSK has been at the forefront of research in this area for over 45 years.

Today we have over 13,500 patients in clinical studies investigating chronic obstructive pulmonary disease (COPD) in almost 40 countries. We believe that insights from this research, alongside our early phase scientific discovery, will help us meet patient needs well into the future.

Our new generation of inhaled respiratory medicines are clear evidence of the benefits of our research. This range – including *Anoro Ellipta*, the world's leading long-acting muscarinic antagonist/long-acting beta-agonist against COPD by value – is giving physicians the unprecedented choice to provide the right treatment to the right patient.

This year, we filed for regulatory approval for our Closed Triple therapy in the US and Europe. If approved, this will be the first COPD treatment to combine three vital once-daily treatments in a single inhaler.

This will ensure patients get the full benefits, in one inhalation, from all their treatments. Research shows that patients taking the medicine experienced improved lung function, a higher quality of life and fewer exacerbations compared to a leading twice-daily treatment.

Looking beyond inhaled medicines, we are now tackling the areas of highest unmet need in respiratory diseases.
In 2015 we launched *Nucala*, our first injectable biologic treatment for severe eosinophilic asthma. Study results showed that, for patients using *Nucala*, the risk of experiencing an asthma attack requiring emergency hospital care was half that of those receiving the current standard of care.

Grow

Sales of our Respiratory products returned to growth of 2% in 2016.

All growth rates are at CER, a non-IFRS measure as described on page 57, unless otherwise stated.

2016 performance summary

Reported Pharmaceutical sales were £16,104 million, up 14% at actual rates and 3% CER. Adjusting for the disposal of the Oncology business to Novartis in 2015, pro-forma turnover was up 4% CER.

Performance reflected a return to growth of the respiratory business, which grew 2%. Sales of new Respiratory products launched over the last four years, including our *Ellipta* based products *Breo*, *Anoro*, *Arnuity* and *Incruse* as well as biologic *Nucala*, more than doubled to £1,052 million. HIV sales increased 37% to £3,556 million, with the US up 46%. This was driven primarily by strong performances from both *Triumeq* and *Tivicay*, with sales of £1,735 million and £953 million.

Sales of new Pharmaceutical products were £3,861 million and now account for 24% of total Pharmaceutical sales.

US Pharmaceutical sales were £4,705 million and declined 1% on a reported basis (up 1% pro-forma). Respiratory sales grew 7%, and sales of new Respiratory products were £654 million, exceeding the decline in *Advair*.

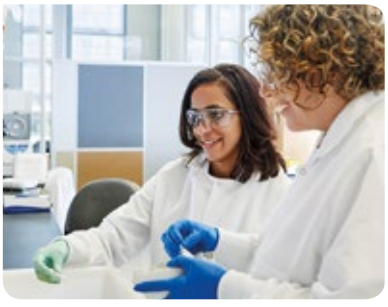
In Europe, Pharmaceutical reported sales declined 8% (5% pro-forma). Respiratory sales declined by 10%, reflecting the ongoing transition to the new Respiratory portfolio and generic competition to *Seretide*. This was partly offset by growth in the new Respiratory products, which recorded sales of £225 million. Established products were down 4% to £513 million.

International sales were £4,976 million, down 5% (4% pro-forma). Sales in Emerging Markets were impacted by the decline in the China business, primarily as a result of the ongoing reshaping programme and broader Healthcare reforms, including price reductions.

Worldwide HIV sales increased 37% to £3,556 million, with the US up 46%, Europe up 29% and International up 21%. This growth was primarily driven by strong performance from *Triumeq* and *Tivicay*.

In 2016, we continued to implement our new commercial model. We stopped payments to HCPs to speak on our behalf in January and continued our drive to recruit HCPs as internal medical experts. In addition, we continued to roll out digital tools to further our medical education efforts. Following medical product information sessions with GSK experts in over 60 countries, 92% of more than 42,000 HCPs agreed that the interaction helped them make a more informed decision benefiting patient care. Around 79% rated their experience as superior to similar interactions with other pharmaceutical companies.

We are working hard in early stage research to find a cure for HIV/AIDS



We have formed a unique partnership to accelerate the search for an HIV cure.

More than 36 million men, women and children around the world live with HIV. As a leading research-based pharmaceutical and healthcare company, we have a legacy of success in developing treatments for HIV.

GSK has a strong pipeline of new medicines and our HIV scientists continue to work towards the goal of one day finding a cure for the HIV/AIDS epidemic.

We continue to invest in the HIV Cure Center and Qura Therapeutics, our unique joint-ownership collaboration created in 2015 with The University of North Carolina (UNC-Chapel Hill), with a single focus on finding a cure for HIV/AIDS.

This partnership is recruiting top talent from around the world and redefining the traditional way of conducting research in HIV/AIDS. One of the approaches being investigated is known as 'shock and kill' which seeks to reveal the hidden virus that persists in people with HIV infection despite successful drug therapy, and augment the patient's immune system to clear these last traces of the virus and infected cells.

Pharmaceuticals continued

Deliver

In 2016, we achieved accelerated filing for the first once-daily Closed Triple therapy for COPD, received approval in Europe for our first gene therapy medicine and obtained positive data to support a new single tablet two-drug HIV regimen.

Our Pharmaceuticals R&D organisation drives discovery and development in several areas of research, including respiratory, HIV, infectious diseases, immuno-inflammation, oncology and rare diseases.

2016 progress

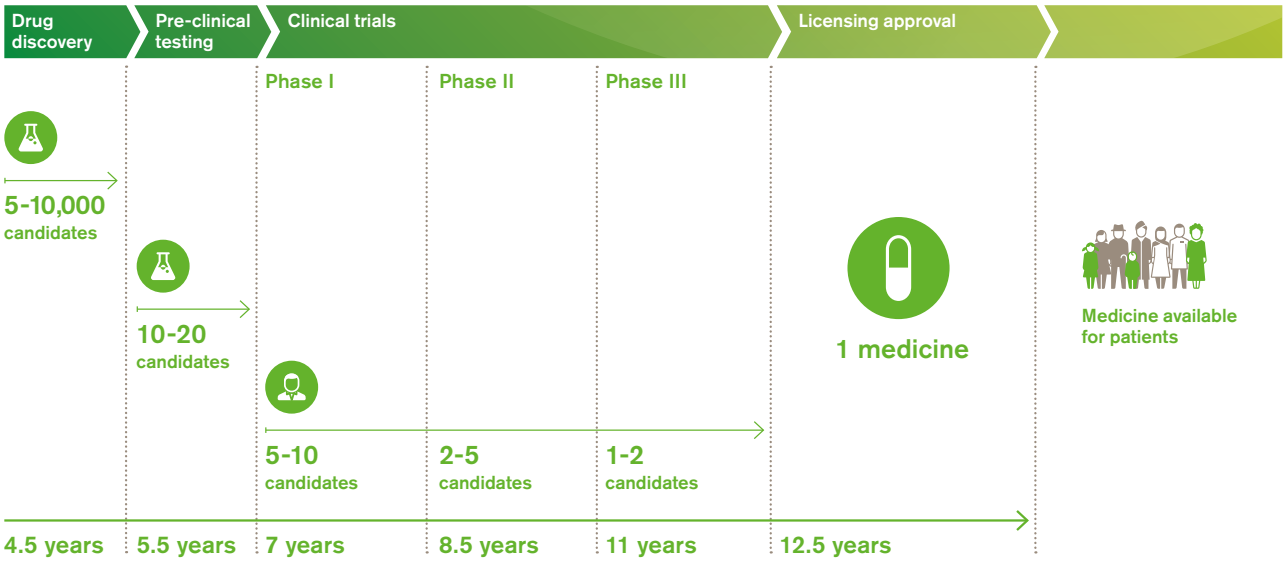
We continued to see progress across all stages of our R&D pipeline. In respiratory, we filed our once-daily Closed Triple therapy for COPD for regulatory approval in both Europe and the US, bringing forward our original US filing date by 18 months. We also announced positive results from the pioneering COPD Salford Lung Study. The study showed that, compared to those receiving usual standard of care, COPD patients using *Relvar/Breo Ellipta* achieved a superior reduction in exacerbations in an everyday clinical practice setting.

We also strengthened the prospects for our next wave of respiratory medicines with the in-licensing of a novel anti-IL33R antibody for severe asthma, and new data supporting the progression of a potential oral treatment, danirixin, into phase IIb clinical development for potential use in treating patients with COPD.

Our HIV pipeline contains a number of promising medicines and regimens, with innovative formulations, mode of action and delivery methods. We announced positive results from two phase III studies evaluating a two-drug regimen combining dolutegravir and rilpivirine (*Edurant*, a Janssen medicine). By breaking the mould of conventional three-drug treatments, this therapy could reduce and streamline HIV medication in the future.

We have three further HIV programmes in phase III: a new attachment inhibitor; another two-drug regimen, combining dolutegravir and lamivudine; and cabotegravir, a once-monthly injectable therapy, which combined with long-acting rilpivirine could also make HIV treatment simpler and easier to adhere to. In addition, we announced the start of a phase III study to evaluate long-acting cabotegravir as an injection every two months, for prevention in men who have sex with men at risk of HIV infection. We also completed the acquisitions of the BMS HIV pipeline and discovery teams and programmes, which have now been fully integrated into ViiV Healthcare's R&D organisation.

Timeline and development stages for a pharmaceutical product (industry average)



Source: ABPI

20-30

assets with data expected by the end of 2018.

We continued to strengthen our emerging immuno-inflammation portfolio, with regulatory filings in Europe and the US; a subcutaneous formulation of *Benlysta*, our treatment for systemic lupus disease currently available as an IV formulation; and sirukumab, an investigational IL-6 treatment for rheumatoid arthritis which we are co-developing with Janssen. If approved, both treatments will be self-administered at home, making them a convenient treatment option for patients.

In 2016, we also gained approval of *Strimvelis*, the first corrective gene therapy for children suffering from the very rare disease ADA-SCID (adenosine deaminase severe combined immunodeficiency) – see case study below.

We started several phase II studies including: one to evaluate an anti-GM-CSF (anti-granulocyte macrophage colony-stimulating factor) monoclonal antibody for inflammatory hand osteoarthritis; the other assessing an oral RIP1 kinase inhibitor, for rheumatoid arthritis and psoriasis patients.

We also received positive phase II data for our first-in-class antibacterial gepotidacin, in treating gonorrhoea, for which the US Food and Drug Administration (FDA) has granted fast-track status on the basis of the serious unmet need for new medicines in this area.

In oncology, we have 11 assets in clinical development and have seen encouraging developments in our core areas of immuno-oncology, cell therapy and epigenetics. During the year, the FDA granted breakthrough therapy status to the affinity enhanced T-cell therapy, which targets the antigen NY-ESO in synovial cancer that we are developing with Adaptimmune.

During 2016, we terminated the development of losmapimod for COPD following analysis of phase II results, and halted development of the HIV maturation inhibitor 3532795 in favour of other maturation inhibitors in our pipeline that may have a better profile.

2017/2018 milestones

The coming two years will be significant for the pharmaceutical pipeline, marking the start of another intense period of R&D activity for the company, as we expect important data on between 20 and 30 assets in areas including HIV, respiratory, immuno-inflammation and oncology.

Approval of GSK's first gene therapy opens new chapter in treatment of rare diseases

Strimvelis®▼

The application of groundbreaking technology has resulted in the world's first corrective gene therapy for children.

The European Commission's approval of *Strimvelis*, a one-time treatment for ADA-SCID (adenosine deaminase severe combined immunodeficiency) is the first authorisation of a corrective stem cell gene therapy for children and a major milestone in our commitment to developing innovative transformative medicines.

ADA-SCID, which is caused by a faulty gene inherited from both parents, affects around 15 newborns in Europe each year. A child born with ADA-SCID does not have a healthy, fully-functioning immune system and, as a consequence, is unable to fight off everyday infections. The treatment involves correcting this often fatal disorder using the patient's own cells.

The development of *Strimvelis* follows a collaboration between GSK and the original Italian developers, the San Raffaele Telethon Institute for Gene Therapy in Milan, Italy.

Working together, we took an experimental medicine procedure and developed rigorous manufacturing and quality control systems to ensure it could be evaluated by regulators.

A 100% survival rate three years after treatment was observed for all children in the pivotal study. Every child receiving *Strimvelis* who contributed to the marketing authorisation data package is alive today. Patients referred for treatment will receive the gene therapy at Ospedale San Raffaele.

We hope *Strimvelis* will be the first of a number of innovative gene therapy medicines that we will bring to patients over the next few years.

Two further programmes using the same platform, in metachromatic leukodystropy and Wiskott-Aldrich syndrome, are both in clinical trials.

Pharmaceuticals continued

Deliver *continued*

1,500

Our range of partners includes academic institutions, public-private partnerships, and pharmaceutical and biotechnology companies.

Pharmaceuticals R&D approach

We focus our investment on areas where we believe there are the most attractive opportunities, having considered patient need, market opportunity and scientific understanding. We concentrate on mechanisms that might slow down or reverse the course of diseases and present opportunities to achieve remission or cure.

Our early research efforts centre on around 30 discovery performance units. These nimble units have their own budgets and project accountability, so are different from the traditional hierarchical R&D model. They help us to maintain flexibility, create agility, and enable us to focus on the most promising early opportunities.

As a treatment advances, Medicines Development Teams of multi-disciplinary specialists ensure its progress from investigational medicine and later stage development to filing with regulators and ongoing evidence generation.

Strategic issues and overall budget management are overseen by the R&D management team. Robust governance boards manage investment, technical, scientific and commercial decisions throughout a molecule's lifecycle.

Collaboration with external partners is an important part of our approach. We partner with more than 1,500 organisations around the world, including academic institutions, public-private partnerships, and other pharmaceutical and biotechnology companies.

Collaborating with the Francis Crick Institute

GSK joins forces with world-leading biomedical research centre.

A landmark collaboration between GSK and the Francis Crick Institute aims to achieve new breakthroughs in understanding and treating diseases.

The open innovation collaboration combines our pharmaceutical R&D expertise with the Crick's deep knowledge of disease biology.

Our mutual aim is to explore new avenues of medical research and drug discovery across a range of diseases. The collaboration takes a 'LinkLabs' approach to working, with teams of scientists from each organisation working side-by-side in integrated teams at the Crick's world-leading centre of biomedical research in the heart of London and GSK's global R&D hub in Stevenage. GSK and the Crick believe this fluid interchange of skills and ideas benefits both sides, introducing new ways of working and stimulating the development of novel approaches to problems. By pooling our knowledge and resources we hope the collaboration will ultimately improve the success rate for discovering new medicines.

In the spirit of open innovation, research findings from the collaboration will be shared externally, via joint publication in peer-reviewed journals. This will enable important discoveries to be applied across the research community, maximising the potential to progress scientific understanding and accelerate the development of treatments for patients.

The Francis Crick Institute is a charity funded by the Medical Research Council, Cancer Research UK, the Wellcome Trust, University College London, Imperial College London and King's College London.

Simplify

Our supply chain transformation programme has delivered significant reductions in manufacturing costs and streamlined our external supply network.

In 2016, we continued to reshape our Pharmaceuticals business and reduce complexity in our supply chain while maintaining our commitment to quality.

Cost savings generated in the Pharmaceutical business have contributed to the delivery of £3 billion of annual savings (including £0.2 billion of currency benefit) for the Group by the end of 2016. Operating profit margin for Pharmaceuticals was 34.1%, 3.7 percentage points higher on a CER basis than in 2015 and 1.2 percentage points higher on a pro-forma CER basis.

In 2016, we completed our three-year transformation programme to move to an end-to-end supply chain. This has delivered improvements in customer service, quality and productivity which, combined with simplification of our portfolio, has delivered a significant reduction in manufacturing costs and streamlined our external supply network by more than 40%.

As part of our commitment to creating a world-class supply chain, in 2016 we agreed a five-year global logistics contract with an international freight company. This contract has been a key enabler to reduce our site costs in the year.

Our enterprise resource planning (ERP) system is enabling better sharing of data to improve planning capabilities. By the end of 2016, the system was live in 10 of our 40 Pharmaceuticals manufacturing sites.

Committed to quality

We are committed to meeting the highest standards through stringent quality control and quality assurance processes. Our medicines and vaccines are manufactured according to current Good Manufacturing Practice (cGMP) regulations, and our internal quality management system.
In 2016, our Pharmaceutical manufacturing sites had 66 regulatory inspections; six had findings which we are resolving.
In July, we received a Warning Letter from the US Food and Drug Administration (FDA) relating to an inspection carried out 12 months earlier at GSK's Worthing, UK, primary manufacturing site. We responded promptly to the FDA to address the points raised and advised them of a programme of work which is now well advanced.

Responsible business

Leading the fight against antimicrobial resistance

We demonstrated our continuing commitment to tackling antimicrobial resistance by signing up to a landmark industry roadmap.

Resistance to antibiotics is becoming a major public health crisis, with 700,000 people dying every year from drug resistant infections. The roadmap commits us, and other participating pharmaceutical companies, to achieving four significant targets by 2020. These include reducing the environmental impact of antibiotics production and ensuring they are only used by patients who need them. The roadmap builds on our January 2016 commitment to the Davos Declaration to combat antibiotic resistance.

We have been active in discovering and developing antibiotics for more than 70 years. Today, our pharmaceuticals focus is on developing new antibiotics and we have an active pipeline of new medicines. In addition, our Vaccines business researches and develops new vaccines to prevent bacterial infections, so saving lives and reducing dependence on antibiotics.

Our most advanced asset in the antibiotics pipeline is gepotidacin, which we developed in collaboration with the US government's Biomedical Advanced Research Development Authority (BARDA). Gepotidacin is now moving towards phase III studies, following positive phase II results in 2016.

The global health threat of antimicrobial resistance requires a multi-stakeholder response, as seen in the industry collaboration beyond last year's roadmap and our work with BARDA. We also partner with other governments and companies to progress research and development into new antibiotics.
We are a member of the Innovative Medicines Initiative's NewDrugs4BadBugs, and are a long-term partner of the Defence Threat Reduction Agency.