

No.1

We disclose all applicable clinical trial data on [shiretrials.com](https://www.shire.com/clinical-trials) and other websites. We have been recognized by AllTrials as the number one pharmaceutical company for clinical disclosure.

4

Ethics and transparency

Upholding high standards of ethics and transparency is fundamental to everything we do. We hold ourselves accountable for operating ethically and responsibly, and ensure we are transparent with our stakeholders. This includes implementing the right policies and procedures so that we meet the highest standards of integrity across all parts of our business and in all our business relationships.

46 Ethical business conduct
49 Clinical trial transparency



Ethics and transparency

Why it matters

Shire is now the leading global biotech serving patients with rare diseases. We strive to deliver strong results in order to maintain our leadership position and bring greater benefits to our patients. How we achieve these results is of equal, if not greater, importance than the results themselves, creating a need for us to behave ethically, transparently, and with integrity at all times. It is absolutely fundamental that everyone working at or on behalf of Shire understands our focus on this commitment.



Our approach

We are committed to the highest standards of ethics and integrity. This means ensuring we have the right policies and procedures in place and helping all of our employees, especially our managers, understand how to foster a culture based on ethics, Responsibility, and transparency.



Our commitment to doing business with high standards of ethics and integrity helps us earn and maintain the trust of the patients and communities we serve.



Jennie Orrico
Chief Compliance and Risk Officer

Ethics and transparency

Ethical business conduct

There are key areas of ethical business conduct that remain at the forefront of our Company and the work we do year on year. These areas require constant monitoring and development and are outlined in this section.



Ethical conduct

[Our Code of Ethics](#) outlines our expectations for doing business with integrity. It highlights where employees may need to be alert to situations that pose ethical questions and provides guidance on how to make the right decisions. New employees are required to read and commit to the Code of Ethics when joining Shire, and all employees must review and renew their commitment every year. During 2016, we worked to ensure that all employees of our newly combined Company have read the Code of Ethics and understand the implications for them.

Anti-bribery and corruption

We do not tolerate bribery or corruption. Everyone working for or with Shire, including partners and suppliers, must ensure they work without engaging in any form of bribery or corruption. Employees have access to our Anti-Bribery and Corruption (ABC) policy and receive training on the policy when they join the Company and annually thereafter. Additional training is provided to employees working in areas with a higher risk of bribery and corruption.

Ethical marketing, selling, and professional support

Given our commitment to developing treatments for rare diseases, we focus our scientific and commercial efforts toward specialty physicians. In addition to our medicines, we also provide these physicians with information and data relating to our therapeutic areas. We want to develop strong and transparent relationships with physicians, as well as with patient groups, to build trust and raise awareness of rare diseases, in order to improve access to medicines for patients.

We adhere to the most stringent commercial and medical regulatory requirements and obey industry promotional and non-promotional guidelines for each country in which we operate. We do this by training our Sales, Marketing, and Medical Science Liaison (MSL) professionals so that they have a thorough understanding of these guidelines and requirements. [Read more on our approach to ethical conduct.](#)

Our code of ethics outlines our expectations for doing business with integrity. We make sure all employees have read the code and understand its implications.

Ethical business conduct continued

Bioethics and animal welfare

We are committed to researching and developing new, well-differentiated medicines that provide meaningful patient benefits, but we must comply with the rules and regulations that govern our industry. Great progress has been made in recent years to reduce and improve the use of animals in pharmaceutical research and development. Until validated alternatives become available, however, health and drug regulatory authorities around the world continue to require animal testing to support the clinical development and registration of new medical products.

We have clear ethical standards, principles, and processes governing the necessary use of animals during research, development, and registration of new medicines at Shire. Our facilities that work with animals are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AALAC), reinforcing our commitment to responsible animal research. We also practice the “3R” guiding principles for the ethical use of animals in testing:

- **REDUCE** the number of animals used to the minimum necessary for scientific validity.
- **REPLACE** the use of animals as scientifically-validated alternatives become available.
- **REFINE** the methods and techniques applied to improve the wellbeing of the animals used.



We recognize the importance of respecting the human rights and fundamental freedoms of all.

Since our combination with Baxalta, we have been developing our Global Animal Welfare policy. This will outline the principles, processes, and ethical standards governing the necessary use of animals in our work, and describe the overall process for justifying and tracking internal and external animal studies at Shire.

Human rights

We recognize the importance of observing the human rights and fundamental freedoms of all. We support the UN Universal Declaration of Human Rights and commit to the principles of the International Labor Organization’s Declaration on Fundamental Principles and Rights at Work. It is particularly important that we safeguard the rights of those taking part in our clinical trials. We do this through the informed consent of trial participants and adhering to the International Conference on Harmonization of Good Clinical Practice Guidelines.

What we did in 2016

Responding to the Modern Slavery Act

As our Company continues to grow, our compliance programs must evolve to support our growth and continue to add value. This year, we have prepared our statement in response to Section 54 of the Modern Slavery Act 2015, outlining our policies and action to identify and tackle the risks of modern slavery throughout our business and supply chain. It covers Shire’s financial year from January 1 to December 31, 2016 and is published on our website, shire.com.

We have prepared our statement on Modern Day Slavery, outlining our policies and actions to tackle the risks of modern slavery across our business and supply chain.



Ethical business conduct

continued

Enhancing the transparency of our political engagement

We support and contribute to political candidates in the United States who share Shire's commitment to patient access and innovation.

We respect all local, federal and national political customs everywhere we operate and comply with applicable laws, regulations and industry standards governing these contributions.

Following the merger with Baxalta, Shire created a unified Political Action Committee (PAC), integrating our political engagement activities and policies. PAC funds are generated from voluntary contributions from eligible Shire employees.

Shire's Public Affairs team maintains clear rules and procedures governing the activities of our PAC, which conducts our political engagement.

In 2016, Shire's PAC made political contributions totaling \$32,500 to candidates in the United States.



Training employees and third parties

We are committed to providing effective compliance training for all of our employees, including through our online e-learning modules, which were updated this year. These modules cover our Code of Ethics, anti-bribery principles, transparency requirements, and global healthcare guidelines, which enables our business to operate compliantly in our industry.

In many countries, third party partners work on our behalf to deliver, market, and sell our products. We hold them to the same standards we apply to ourselves. To help them understand our requirements, we ran an online training course for partners around the world on our Anti-Bribery and Corruption (ABC) policy and Code of Ethics.

Monitoring compliance

We use internal auditing and monitoring programs to assess the effectiveness of our compliance programs and help us make adjustments where appropriate. In 2016, we added real-time analytics to our compliance monitoring program to increase awareness and potential identification of compliance risk.



Shire PAC

Ethics and transparency Clinical trial transparency

Across Shire, we follow the [Principles for Responsible Clinical Trial Data Sharing](#) that were jointly adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries Association (EFPIA) in 2014.

We pledge to share clinical trial data in a responsible manner, consistent with the following principles:

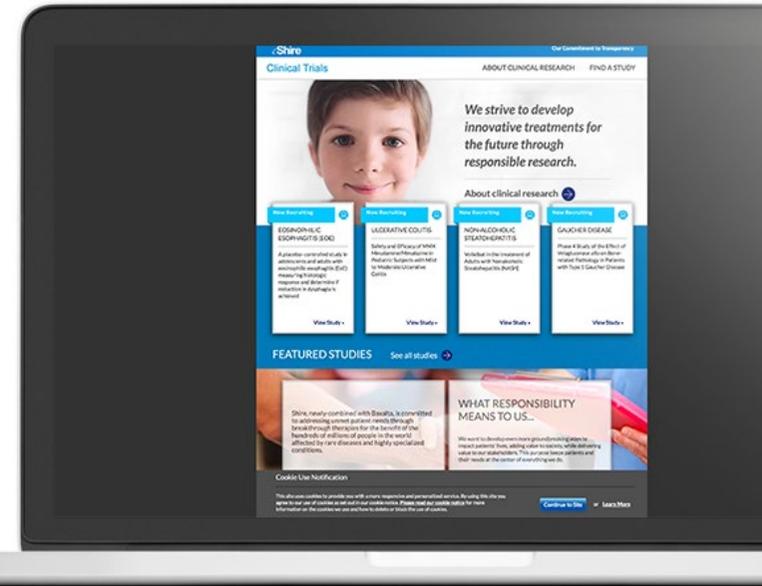
- Safeguarding the privacy of patients.
- Preserving scientific rigor and trust in regulatory systems.
- Maintaining incentive for investments in biomedical research.

We disclose clinical trial information on public registers and websites at a number of points across the trial process, including: prior to patient recruitment; within one year after study completion; following marketing authorization; and when investigational research programs have been discontinued.

Our dedicated clinical trials website, [shiretrials.com](#), uses filters to enhance the search function, providing easy access to detailed information about our clinical trials for patients and other stakeholders. We also post Clinical Study Reports, which provide a short overview of the purpose and results of the clinical trials, for all Shire-sponsored clinical studies within 18 months of trial completion.

What we did in 2016

Improving shiretrials.com
During 2016, we incorporated the data and reports of clinical trials from Baxalta on [shiretrials.com](#). This has grown our robust resource for clinical trial information and data.



“ Clinical trial data transparency is vital for our credibility and to promote innovative research.

”
Jeremy Chadwick, PhD
Head of Clinical Development Operations

Clinical trial transparency continued



#1

We have been recognized as the number one pharmaceutical company for clinical disclosure by AllTrials.



100%

We disclosed 100% of all applicable clinical trials on public websites.

Public disclosure

As part of our commitment to transparency, we disclosed 100 percent of all of our newly combined Company's applicable clinical trials on public websites, in accordance with our policy, and specific requirements in different jurisdictions. We also posted 75 Clinical Study Report synopses on shiretrials.com. Publishing the results of all of our clinical trials has been acknowledged by AllTrials who, this year, recognized Shire as the number one pharmaceutical company for clinical disclosure.

Making disclosure accessible for patients

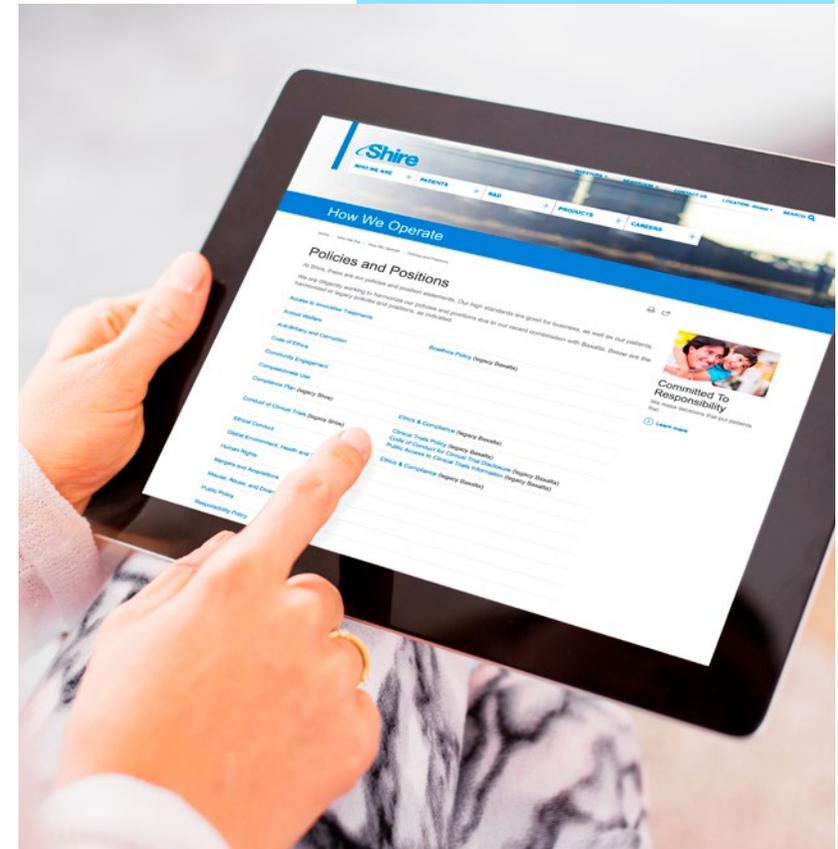
In line with the European Medicines Agency policy, we have developed plain language summaries of clinical study results for patients who participated in our trials. We did this in collaboration with the Center for Information and Study on Clinical Research Participation (CISCRP), a non-profit organization dedicated to engaging the public and patients as partners in the clinical research process. We also established a process and template for responsible data sharing that fulfill the EFPIA/PhRMA requirements and meet the expectations of the EU Clinical Trials Register.

What we will do in 2017

- » Continue to distribute our Code of Ethics to all employees and ensure all have taken the associated e-learning training modules.
- » Continue to reach the highest levels of clinical trial disclosure and commit to a target of >95 percent timely clinical trial registration/ results reporting.
- » Establish more robust disclosure standards, including providing plain language summaries for the general public via our website, which will exceed EFPIA/PhRMA transparency requirements.
- » Continue to protect patient privacy, especially in rare disease trials, by balancing trial data provision with protection of patients' personal data.



All of our Policies and Positions papers are available on our website



Read more online

[Principles for Responsible Clinical Trial Data Sharing shiretrials.com](http://shiretrials.com)

shiretrials.com

[Our commitment to transparency](#)

[AllTrials launch of Trials Tracker](#)