Clinical trials

We are committed to delivering consistently high standards of ethical practice and scientific conduct in all trials worldwide, whether conducted by us or by third parties on our behalf. We are also committed to transparency of registration and results of all clinical trials – whether the outcome is positive or negative. Our key principles for conducting clinical trials are outlined in our Bioethics Policy.

Our approach

Clinical trials are the means by which we study the effects of a potential new medicine in humans. Potential new medicines normally undergo three phases of testing before they are submitted to regulatory authorities for approval to market.

At any one time, AstraZeneca may have hundreds of clinical trials underway in different locations around the world. We take very seriously our responsibility to deliver consistently high standards of ethical practice and scientific conduct in all our trials, wherever they take place.

A potential new medicine is tested in humans only after rigorous and extensive pre-clinical research has confirmed its potential efficacy and safety. All medicines have side effects that may affect some people and so the safety of any medicine needs to be assessed in terms of its benefit and risk profile.

We can’t eliminate completely the risks to clinical trial participants, but we aim to minimise these as much as possible. Our top priority is to make sure that those taking part in our studies are not exposed to any unnecessary risks and that, before they give their consent, they understand fully what taking part in a trial means.
Implementing the highest standards

Our standards are global and apply to all AstraZeneca clinical trials, in all locations, whether they are being conducted by us or on our behalf by external contract research organisations (CRO). If our policies differ from local regulations, we adopt whichever standard is higher.

Our Standard Operating Procedures and Policies require that all staff involved in clinical trials and all investigators are trained in International Conference on Harmonisation guidelines and local Good Clinical Practice regulations. Our standards apply to all AstraZeneca-sponsored clinical trials, in all locations but the conduct of our trials in emerging countries is a specific focus for our compliance monitoring and assurance activities.

We have a robust monitoring system in place, which includes regular visits by AstraZeneca or the CRO working on our behalf to confirm conduct of the study according to the protocol, and review of the informed consent process and documentation. In addition, our independent compliance organisation conducts a wide range of audits of our clinical research-related activities, whether they are being done in-house or by third parties.

Any identified deviations or breaches are taken very seriously and investigated thoroughly, and action taken as appropriate to correct them and prevent recurrence. Examples of action we might take include training of internal staff or investigators and changes in procedures or documents to clarify processes. If necessary, we would discontinue the use of sites or investigators in further trials. Ethics Committees and regulatory authorities are informed, as appropriate.

Selecting a trial location

We conduct an increasing number of our clinical trials at multiple sites in several different countries. A broad geographic span helps us to ensure that those taking part in our studies reflect the diversity of patients around the world for whom the new medicine is intended. This approach also helps to identify the types of people for whom the treatment may be most beneficial.

We only conduct studies in countries where there are regulatory bodies and/or independent ethics committees who authorise all studies that take place and approve the protocols for all clinical trials.

Infrastructure

We only conduct trials in countries where there are experienced and independent ethics committees and a robust regulatory regime.

Facilities and training

There must be adequate numbers of trained healthcare professionals, and well-equipped hospitals and laboratories.

Availability of patients

There must be sufficient numbers of patients willing to participate in a trial.

Prevalence of disease

Some diseases are more prevalent in particular countries or regions.

Current medical treatment

Trials often compare a new compound against current treatments. We select locations where the treatment we wish to test against is commonly used.

Cost efficiency

Despite the regulatory requirement to conduct more trials involving greater numbers of patients, cost efficiencies must always be achieved without compromising either our ethical commitment to participants or the quality of the research.

Local regulatory requirements

In some countries, regulatory authorities require trials to be carried out locally before a new medicine can be submitted for regulatory approval.
Ensuring informed consent

We have a responsibility to ensure that anyone taking part in one of our clinical trials fully understands the potential benefits and risks before they sign up.

Our informed consent process ensures that, along with information on benefits and risks, participants understand the purpose of the trial and how it will be conducted. We also make it clear that they could potentially receive a comparator drug or placebo rather than the new treatment and the likelihood for that. The fact that participants can withdraw from the trial at any time without giving a reason and without impact for their future care is also made clear.

We also make sure that information is made available in a language that the participant is able to understand. In countries where literacy levels are low, or where participants are unable to read, the written information is read and explained to them before signing. An independent witness must be present throughout the whole process and must confirm that the participant has received and understood all the information they need to give their informed consent. The witness must also sign and date the consent form.

We work on an ongoing basis with regulatory authorities and our trade associations to ensure consent forms strike the right balance between detail and readability. Much of the detail included is required by law, but they must also be easily understood by participants. The informed consent process is included in our monitoring and auditing of clinical trials.

Clinical trials transparency

AstraZeneca has a long-standing commitment to making information about our clinical research publicly available. We believe that transparency enhances the scientific understanding of how our medicines work and is in the medical interest of our patients.

We publish information on the registration and results of all new and ongoing AstraZeneca-sponsored clinical trials for all products in all phases, including marketed medicines, drugs in development and drugs whose further development has been discontinued. We post results, irrespective of whether they are favourable or unfavourable to AstraZeneca.

Details of our commitment to the transparency of trial information, including registration, protocols, results and access to data, can be found on our dedicated website, www.astrazenecaclinicaltrials.com.

As of 28 October 2014, we had 2,724 registered investigational clinical studies and, in line with our policy or legal requirements, had posted the results and/or clinical study reports and synopses relating to more than half of these on various websites, including our own dedicated clinical trials website.
Evolving our Transparency Policy

As a result of the European Federation of Pharmaceutical Industries and Associations (EFPIA)/Pharmaceutical Research and Manufacturers of America (PhRMA) Responsible Data Sharing Principles as well as emerging European Medicines Agency (EMA) Policy and the new EU Clinical Trial Policy and Regulation, we continue to evolve and streamline our policies, processes and systems for trial transparency.

We made positive progress in 2014 towards a number of initiatives designed to demonstrate our commitment to transparency in clinical trials. The groundwork achieved in 2014 means we are now in a position to implement the following in 2015:

- **A Data Transparency Portal** to allow researchers to submit a request to access de-identified patient level data through our portal www.astrazenecaclinicaltrials.com.

- **A Scientific Review Board** to review and approve requests. Once the request has been approved, access to the de-identified data will be provided through a secure mechanism. We will support requests for trials starting in 2009 or later. Requests for data from earlier trials will be reviewed on a case-by-case basis.

- **Lay Language Summaries** of results, to be made available via the portal to all participants in an AstraZeneca-sponsored clinical trial in the same language as their signed Informed Consent Form. Results will also be available through the EU portal when it comes online in 2016.

- **The ability to post Clinical Study Reports (CSR)** and related documents to our website and the EU portal when it comes online. The CSR package will include the CSR, Appendix, Protocol, sample Case Report Form and Study Statistical Analysis Plan and will be edited to remove proprietary information, or information that could be used to identify a patient.