Innovation starts here

At the core of Lilly Research Laboratories’ mission is discovering and developing innovative therapies for many of the world’s unmet medical needs.

In innovation research, the focus is on treatments for Alzheimer’s disease and other neurodegenerative diseases, cognitive disorders and, more recently, sleep disorders, including insomnia. In development, scientists collaborate with colleagues around the world on the broader Lilly research and development portfolio, working on potential medicines for the treatment of cancer, diabetes, neuroscience and auto-immune disorders.

Continuing investment at Erl Wood means that world class scientists have world class facilities in which to pursue their objectives. But despite advances in technology and in the understanding of biological systems, drug discovery is still a lengthy, expensive and difficult process with a high rate of attrition. Typically only one in 10,000 molecules synthesised in discovery laboratories gets to market and only one in seven of those is a commercial success. Currently, the average research and development cost of each New Molecular Entity (NME) is more than £1 billion.

The site also provides a physical environment that is in harmony with its surroundings and which seeks to minimise its impact on the environment.

Teamwork and communication are key to being successful at developing new treatments for disease. This brochure provides an overview of how people working in the many different functions on site work together in the highly complex process of drug discovery and development.

A tradition of innovation
Eli Lilly and Company was founded in 1876 by Colonel Eli Lilly in Indianapolis, U.S. A 38 year old pharmacist and veteran of the U.S. Civil War, Colonel Lilly was frustrated by the ineffective and often poorly prepared medicine of the day and set himself the task of founding a company to manufacture pharmaceutical products of the highest possible quality.

As his business flourished, in 1886 he hired a young chemist to work as a full-time scientist to use and improve upon the latest techniques for quality evaluation. Together they laid the foundation for a dedication to quality and the discovery of new and better pharmaceuticals.

Since those early days Lilly has grown to become one of the world’s largest research based pharmaceutical companies, with over 35,000 employees and annual sales of over £20 billion.

Approximately 20 per cent of sales revenues, some £4.8 billion in 2010, are ploughed back into R&D each year and 20 per cent of the company’s workforce is engaged in R&D activities. Lilly is among industry leaders in our commitment to Research and Development. Eli Lilly, grandson of the company’s founder, described research as “the heart of the foundation, the soul of the enterprise”.

This continuing commitment to researching innovative medicines that deliver real value to patients and healthcare providers, has resulted in a product portfolio spanning oncology, diabetes, depression, schizophrenia, bi-polar disorder, attention deficit hyperactivity disorder, erectile dysfunction, osteoporosis and growth disorders.

The company’s guiding principles of ‘integrity, excellence and respect for people’ are as valid today as they were over 100 years ago.
Drug Discovery

In the past, many medicines were discovered either by identifying the active ingredient in traditional remedies or by serendipitous discovery. More recently, understanding how diseases are controlled at the molecular and physiological level has become key to creating new medicines. Even with this greater understanding, the drug discovery process is far from routine.

Discovery is focused on creating new molecular entities (NMEs), which have promising activity against a particular biological target, for example an enzyme or a receptor (a protein that receives chemical signals and helps turn them into a biological action), thought to be important in disease and so have the potential to become a drug.

By the end of the discovery phase information is gathered about target engagement (whether the drug can get to and interact with the biological target in animals) and “structure activity relationships”, but little is known about the how the human body will react to the medicine (safety, toxicity). In spite of the numerous scientific advances in all fields relating to drug discovery and development, the process is unpredictable and far from routine. In fact, launching a new medicine is more difficult today than it has ever been; the number of molecules approved by regulators has dropped substantially over the last decade and for every medicine that is successfully launched, an average of 5,000-10,000 potential medicines were prepared and tested during drug discovery.

Discovery encompasses a wide variety of scientific activities focused on identifying new targets and confirming their role in disease. This is a highly collaborative endeavour, where Lilly scientists at Erl Wood cooperate with colleagues at other Lilly R&D sites in the USA, Spain and China and with external partners in the life and health sciences. All research during this phase is covered by Good Research Practice (GRP) guidelines which ensure that all experiments are carried out in a safe, ethical, thorough and reproducible fashion.

Target Validation
When Lilly begins the search for a potential new medicine, a large amount of information is required to establish the approach used in the discovery programme. Firstly, the disease mechanism (how the disease occurs at the molecular level) must be understood so that suitable points to intercept a particular metabolic or signalling pathway that is specific to a disease condition or pathology, can be identified. These points are typically proteins that regulate the production or effect of biomolecules that are key to the biological process in question and are referred to as drug targets. During target validation an understanding is gained of how the target functions in normal physiology and how it is involved in the disease state. This may come from, for example, genetic linkage studies in humans that show an association between mutations in the biological target and certain disease states, or by removing a gene in animals to see if this reproduces the disease state. This is known as the gene “knockout” approach and it allows scientists to check that their hypothesis is valid, although this does not mean that success is guaranteed if a suitable drug is found.

Another approach is the use of previously published ‘tool’ compounds that selectively block or activate the target in normal subjects to determine if the disease state is reproduced. These ‘tool’ compounds are typically not suitable for use as drugs for a variety of reasons, but can be used to gain better understanding of the disease. During this stage it is important to determine whether the target is ‘druggable’. This means that it is capable of binding a small molecule and that its activity can be modulated by this binding.

To be able to identify potential drug molecules, biological studies, known as assays, that show how well a compound is capable of interacting with the chosen target are needed. Biologists therefore seek to create in vitro assays to test these compounds in artificial environments that are closer to living systems that is it not possible to model in vivo.

Lilly as part of a FIPNet
With R&D being such a high-risk endeavour, Lilly uses strategic alliances with other companies and research institutions that allows access to new technologies and skills, providing synergies that maximise the chances of delivering medicines to patients and reducing the cost, and therefore the risk, in doing so.

FIPNet refers to Lilly being part of a Fully Integrated Pharmaceutical Network. Rather than Lilly possessing all of the capabilities to perform drug discovery and development internally, the company collaborates with external companies and academics. This provides a greater flexibility for all parties and allows Lilly to share some of the risk, and benefits, with them.

The Global External Research Development (GERD) group are responsible for identifying opportunities for collaborations and partnerships with other pharmaceutical or biotechnology companies and academia. These collaborations may be to access scientific and medical capabilities or capacity, as well as the more traditional search for new drug candidates.

Chorus Europe is the latest addition to the teams at Erl Wood. Chorus is Lilly’s independently operating, early phase integrated drug development unit. It uses as radically different clinical development process – rapid “Proof of concept” – and was based on the assumption that early stage compounds are more likely to fail than succeed – so getting to a decision point very quickly is critical. Another unique feature of the Chorus teams is that they are part funded through venture capital in addition to contributions from Lilly.

In vitro and In vivo
A biological experiment that is performed in vitro (from the latin ‘within glass’), is performed in a controlled environment such as a test tube or petri dish, while an in vivo (from the latin ‘with the living’) study is one that is performed in a whole live organism. It is necessary to determine actions in vivo because these are more meaningful as interactions that occur in living systems that is it not possible to model in vitro.
systems using cells that have been specially modified to produce a pure, concentrated form of the target protein. In order to develop these cell lines, the DNA sequence of the target protein must be identified. When searching for new drugs, it is important to find molecules that interact specifically with the biological target, so developing assays of this type may provide an early indication of how likely a potential drug candidate is to achieve this goal.

These assays form the basis of the next phase of discovery, understanding how well small molecules interact with this target. In addition, the three-dimensional structure of the target may be determined.

### Lead Generation

Having isolated pure target proteins, biologists can test molecules that have been prepared by chemists for their degree of interaction with the target.

Discovery chemistry begins with the identification of active compounds, often called ‘hits’. The ideal would see only activity at the desired target with no activity on other targets, though this is seldom achieved. This property is called selectivity. The ‘hits’ are compounds that interact with the target to some extent (although most likely in a sub-optimal fashion), but are quite unlikely to have suitable properties for a drug. Molecules having these suitable properties must be found before development of a safe and efficacious drug can begin.

Chemists seek new molecules aiming to improve how well they interact with the target and also improve other properties of the molecule. They can study the data that is obtained from the biological assays, to investigate how changes in molecular structure might affect the affinity and drug-like properties (Structure-Activity Relationships; SAR) and can try to apply this to the design of the next generation of molecules to be made. If through this research compound series begin to show sufficient promise, then these can be moved forward to the next stage of the process, called Lead Optimisation.

The aim of discovery chemistry in both the ‘lead generation’ and ‘lead optimisation’ phases is to increase activity against the chosen target, reduce activity against unrelated targets and improve the ‘drug-like’ properties of the molecule. In reality, this is an unpredictable and significantly inventive activity.

In order to be an efficacious drug in man, the compound has to be administered by an appropriate route and must reach the biological target effectively enough to elicit the desired response. For an oral drug, the compound must be well absorbed in the digestive system with little variability between patients and must remain in the body for sufficient time to give adequate response. Drugs that are eliminated from the body too rapidly may need to be administered more than once daily, which is often not desirable and leads to some patients failing to take the required dosage.

For these reasons, the solubility, permeability and metabolism (i.e. how the molecule is altered by chemical reaction in order for it to be more readily excreted from the body) of compounds are among the key properties which are studied at an early stage in discovery, contributing very significantly to the medicinal chemistry efforts. Both experimental and computationally predicted data are used to try to learn more about the properties of the molecule at a very early stage.

In a similar fashion, the potential that a drug will interact with co-administered medications is also studied to help minimise the risk of the two drugs in combination causing side effects that would not be present for each single drug (drug-drug interactions). These concerns are addressed by the ADME (Absorption, Distribution, Metabolism & Excretion) group.

During the lead generation phase, biologists will look to develop disease models that will provide an understanding of how well the molecule might affect the disease state in real systems. These models are typically very specialised and may be performed in vitro using tissue samples or in vivo models where appropriate.

Statisticians help biologists by identifying appropriate outcomes from experiments to characterise drug effects. They identify appropriate methods and build tools so that biologists can produce the results on an on-going basis. Techniques are also developed to monitor study quality and estimate the overall variation in the experimental outcomes, which is used to guide decisions.

The ability to obtain pure isolated protein may allow structural information to be obtained about the target. Using this information to improve the interaction of the molecule with the target is known as Structure-Based Drug Discovery.

Two main approaches are used here at Erl-Wood:

- **Fragment-based Drug Discovery (FBDD)**, in general terms, involves finding very small molecules (fragments) that interact weakly with the target and then using the structural knowledge of the target to add structural elements to the fragments to enhance these interactions.

- **Computer aided drug discovery (CADD)**, in general terms, involves building computational models of the target and potential drug molecules (that need not have been made in the lab) and simulating their interaction. This can be done using either structural knowledge of the target or knowledge of other molecules that are known to interact with the target. One of the issues with this approach is that it is very difficult to predict and control the drug-like properties of the molecules.

Both of these drug discovery methods are complementary to existing approaches.

### Lead Optimisation

Once one or more lead molecules are identified, further research in terms of their target engagement,
While patents are expected to last 20 years and-a-half years is available in some countries if certain criteria are met.

Inventions that can be the subject of patent protection include new molecular entities, combinations of substances, manufacturing processes and new applications for known chemical substances. Patents must be filed in each country in which protection is required and typically last around 20 years. A term extension of up to five-and-a-half years is available in some countries if certain criteria are met.

Innovative companies only have limited patent life in which to get a return on the investment in research before competition from generics can significantly impact sales. Patents must be filed in each country in which protection is required and typically last around 20 years. A term extension of up to five-and-a-half years is available in some countries if certain criteria are met.

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Pharmacokinetics are the data that describe how the body absorbs, distributes, metabolises and excretes the drug, while pharmacodynamics are the data that describe what the drug does to the body; that is, how the drug affects the body. It is useful if data can be obtained in animals in order to examine this relationship early on in the discovery/development process and PKPD scientists may become involved at this stage. A good understanding of the predicted human PKPD relationship can allow a team to select molecules likely to have an optimal ‘window’ between drug potency and potential adverse effects. At a high level, the role of the PKPD scientist is in estimating an efficacious dose involves two stages: firstly, understanding the predicted pharmacokinetics of the drug based on animal and in vitro data and, secondly, understanding the pharmacodynamics of the drug and how these relate to the exposures predicted to be observed in the first volunteers given the drug.

As molecules are developed that start to have the desired properties for a potential drug, synthetic methods are optimised to allow the preparation of larger quantities of materials in a more reliable and efficient manner. One of the primary objectives of the Discovery Chemistry Synthesis Group (DCSG) is to develop and execute synthetic routes that can supply materials for early studies right the way through to early manufacturing. These materials are also used to take a first look at the formulation of the potential drug.

By the end of lead optimisation, promising compounds should have sufficient target potency and selectivity and favourable drug-like properties and there will be a good understanding of their biological effects in animals.

A safe workplace in a hazardous environment

In creating NME’s that are intended to interact with biological systems, it is inherently the case that little or nothing is known about their toxicity in humans. As such, it is important to ensure that all employees are protected from undesirable exposure to chemical, physical and biological hazards that exist in the workplace. The Occupational Health team aims to identify and eliminate risks before harm can occur. This involves monitoring and assessing employee health and the working environment.
Drug Development

The process of drug discovery involves the identification of ‘candidate molecules’, synthesis, characterisation, screening, and assays for therapeutic efficacy. Once a compound has shown its value in these tests, it will begin the process of drug development prior to clinical trials, which will teach us more about the safety, pharmacokinetics and metabolism of this NME in humans.

An experimental drug is first tested in the laboratory and in animal studies. After this pre-clinical testing, the medicine can advance to clinical testing and development. Unfortunately, most new molecular entities fail during development, either because they have some unacceptable toxicity, or because they simply do not provide enough benefit in clinical trials.

Launching a new drug has never been harder than it is today and will continue to get harder as time passes; more data is required from clinical trials than ever before and those who pay for these medicines (governments and insurers) are ever more vigilant about the cost of treatment.

First Human Dose Preparation
Before the NME can be studied in humans, a number of issues must be addressed. Firstly, practical methods for the preparation of very large quantities of the NME to the high standards required for the upcoming trials must be developed. This requires the Chemical Process Research and Development team (based in Indianapolis) to begin optimising the synthetic route and ensure that the material can be made on manufacturing scale when required. This also requires the development of analytical methods to characterise the physicochemical properties of the molecule including its chemical structure, physical properties, stability and presence of impurities (Pharmaceutical Analysis). Together these processes are known in preclinical development as CMC: Chemistry, Manufacturing and Control.

Secondly, the method of administration of the molecule must also be considered. Finding the most appropriate method to deliver the best possible biological response in humans – for example, capsules, tablets, injections or aerosols – is key to progression. In preparation for a clinical trial, it is important to understand what dose to give the first human volunteers who will take the drug. If the dose is too high, the risk of causing toxicity is higher, too low and the chances of reaching exposures that produce efficacy are reduced. It can be very difficult to understand where to target the dose in humans and this is the main aim of the PKPD scientist at this stage of the process.

Preclinical and CMC data must be submitted to the appropriate national or international regulatory body for approval before clinical trials can begin. This interaction with the regulators is handled by the Regulatory Affairs group. The Erl Wood Regulatory Affairs group coordinates regulatory activities for European countries and Australia and works directly with the European Medicines Agency (EMA).

In Europe, a Clinical Trial Application (CTA) is submitted to the national competent authorities in the countries in which the trial will be conducted and in the USA an Investigational New Drug Application (IND) is submitted to the Food and Drug Administration (FDA).

Clinical trials are required before the regulatory authority approves marketing of the drug or device, or a new dose of the drug, for use on patients. Trials are typically designed to assess the safety and efficacy of a new medication on a specific kind of patient or for an existing medication in a new indication (i.e. a disease for which the drug is not already approved).

In order to demonstrate the efficacy of a potential new drug, development and submission strategies must be put in place to ensure that the correct data is collected and shared with the regulators in the most appropriate manner. This is extremely important in ensuring that the regulators are able to make the correct decision on approving this potential drug.
Drug Development

by the World Medical Association

standard for the European Union

Practice standards. This provides a unified

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enough patients to test the drug’s
efficacy can take several years.

All such trials must be conducted
ethically and they are reviewed and

approved by ethics committees with

all trial participants made aware of

the risks and potential benefits of the

must give informed consent

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In these larger clinical trials, large

amounts of data may be collected

that describe the behaviour of the

drug in patients. This can be used

to investigate the impact of patient

characteristics (e.g. body weight,
gender, ethnicity or genetic or

environmental factors) on the action

of the drug. If the variability in drug

action as a result of these factors, or

‘covariates’, is known then doses

may be ‘individualised’ based on a

subject’s characteristics. This is

known as tailored therapeutics, where
drugs and their doses can be

tailored to the individual patient.

The most effective dosages for

the potential drug are determined

and the most appropriate method of
delivery (e.g., tablets, extended

release capsules, infusions, injections, etc.) is also studied.

Phase III Clinical Trials

In Phase I trials, the drug is tested in

Phase II Clinical Trials

In Phase II trials, the drug is given
to a larger group of people (typically

100-300) who have the disease that

the drug is intended to treat so as
to test its efficacy, determine the
effective dose range and further

evaluate its safety.

For every five molecules that

enter phase II only two go on to

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Phase III Clinical Trials

For every two molecules that

enter phase III only one goes

on to registration. These trials
typically last approximately

three years.

The drug is given to large numbers

of people (typically 1000-3000) to

explore further its effectiveness,

monitor its safety, compare it to

commonly used treatments (for

which a large amount of data is

known), and collect information that

will allow the drug or treatment to

be used safely.

Ethics in Clinical Research

The Declaration of Helsinki was developed

by the World Medical Association (WMA), as a

set of ethical principles regarding human

clinical trials. This declaration states

that the individual has the right to make

informed decision regarding participation

in research, both initially and during

the course of the research. The investigator’s

duty must be solely to the patient or

volunteer and the subject’s welfare must

always take precedence over the interests

of science.

All clinical studies should be carried out

according to International Conference on

Harmonisation (ICH) / WHO Good Clinical

Practice standards. This provides a unified

standard for the European Union (EU),

Japan, and the United States, as well as

Australia, Canada, Scandinavia. Thus, any

country that adopts this guideline will

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drugs are safe and well tolerated (human

pharmacokinetic profile). The pharmacokinetics of the drug in the human volunteers may be continually assessed to ensure that a safe and efficacious exposure range can be defined for future trials and that the variability in pharmacokinetics between patients is such that patient’s exposures may be maintained within a range where the drug can be effective (‘therapeutic window’). For biological targets that have not previously been tackled by drug-like molecules, Phase I clinical trials can offer the opportunity to obtain proof-of-concept, where the efficacy in humans can first be assessed, however this is most commonly obtained in the next stage of clinical

Registration

Once a drug has proved satisfactory in Phase III trials, the results are combined into a large document containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life. This collection of information makes up the ‘regulatory submission’ that is provided for review to the appropriate regulatory authorities in different countries. This step is known as registration. If regulators agree that the data prove the quality, efficacy and safety of the drug, a marketing authorisation is granted. The drug can now be made commercially available to patients. The task of assembling registration documents for worldwide use is very complex as countries have different regulations and format requirements. Registration can take months to years, depending on how the data is interpreted and whether further trials are required to satisfy individual regulators.

If the registration documents that were compiled for the registration of Efient (Prasugrel) with the FDA had been printed out on standard paper and stacked, the resulting tower would have been as tall as the Empire State Building.

Having discovered and developed a potential new medicine, its commercial potential must be realised to try to recover the R&D outlay. To do so, this NME must become a product. This involves creating a brand and ensuring that both prescribers and payers are aware of the product and its benefits to patients. To ensure that new medicines meet unmet medical needs and

Better than Placebo?

These trials are often randomised and ‘double-blinded’. This means that during the trial, neither the investigator nor the participant know who in the trial is getting the new drug or a placebo (inactive) pill or another medicine that is already established as the standard of care for the treatment of the disease being studied.

Because of their size and long duration, they are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical conditions (medical conditions that are either long lasting or recurrent).

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Drug Development

Global product protection security team
At the completion of the phase III trial and prior to market approval, a risk assessment is carried out into the likelihood of the new product being counterfeited. Counterfeit medicines are manufactured to look identical to the genuine product, including the packaging, to encourage the patient to believe they have the genuine product. The medicine itself may or may not contain the correct active ingredient, and even if it does this may not necessarily be at the correct quality or dosage and may contain other impurities. Counterfeit medicines are a global problem and a serious threat to public health. Lilly’s Global Product Protection Security Team monitors the internet to identify what is for sale and makes test purchases to establish the provenance of the product being sold. A number of successful criminal and civil actions have followed.

offer value to payers, patients and shareholders, there is a new product planning process that spans early clinical development through to the introduction of the medicine in countries around the world. Recently, Lilly formed business units for different therapy areas designed to ensure that the company develops and commercialises medicines that meet patients’ needs and to speed the delivery of healthcare providers in the EU with evidence that the new products are not only safe and efficacious, but also provide value for money.

All pharmacovigilance activities are strictly regulated and controlled internally and externally to ensure that Lilly products are used by healthcare providers for the right patients in the right way and at the right dose – thus ensuring that medicines bring a true benefit to patients.

It is also the responsibility of the Regulatory Affairs group to ensure that all marketing authorisations are kept up-to-date thereby allowing the products to stay on the market, particularly in the early life of a medicine, when it is more likely that changes will be made to the prescribing information.

After a period of time on the market, some medicines are found to be useful for the treatment of conditions that they were not originally intended for. Medicines must be approved for use in these new conditions in much the same way as when they were originally registered. Also, new formulations (e.g. a change of tablet composition or manufacturing method) can be made to improve the effectiveness of the medicine, but similar requirements must be met. A range of other functions are based at the site to support all the teams more directly involved in drug discovery and development – without whom the site would not function. These include Facilities Management (including Project and Instrument Engineering), Finance, Procurement, Human Resources, Environment, Health & Safety, Occupational Health and IT.

Supporting functions at Erl Wood
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