



The next generation biopharma leader

# Drug Development Process

## Where it all begins

A new drug starts as an idea or hypothesis based on exciting or unexplained observations.

Sources for new ideas include scientific data and literature, scientific research undertaken at universities and university hospitals, patent

information, patient focus groups, international symposia and explorative research in company laboratories.

Research

Year 1	2	3	4	5	6	7	8	9	10	11	12	13
<b>Exploratory Research</b> Hit identification, UCB SLAM												
<b>Research phase</b> Lead discovery and lead optimisation												
The hypothesis is validated using biochemical methods and in vivo testing to ensure that the scientific approach is relevant to the disease of interest. The relevant biology is investigated and drug starting points identified.		<b>Pre-clinical phase</b> Manufacturing Pre-clinical dev. IND application				<b>Manufacturing</b> The manufacturing process for the new drug is initiated and developed to produce it in sufficient quantities for pre-clinical testing and clinical trial purposes. The new drug must be ready for full manufacture before the start of Phase III trials. This phase continues throughout development.			<b>Pre-clinical development</b> Pre-clinical development begins before clinical trials or testing in humans may begin and during which important safety and pharmacology data are collected. The main goals of pre-clinical studies are to determine the new drug's pharmacodynamics, pharmacokinetics, ADME and toxicity using blood and tissues. Further pre-clinical development may continue as the new drug progresses through clinical trials.		<b>Application for Investigational New Drug</b> An application for an IND is made to the FDA, EMEA and/or other regulatory agencies for permission to administer a new drug to humans in clinical trials.	



Development

<b>Clinical development</b>		
Phase I	Phase II	Phase III
Phase I trials are conducted primarily to determine how the new drug works in humans, its safety profile and to predict its dosage range. It typically involves between fifty and one hundred healthy volunteers.	Phase II trials test for efficacy as well as safety and side effects in a group of between one hundred to three hundred patients with the condition for which the new drug is being developed.	Phase III trials involve a much larger group of patients, between several hundred and several thousand, which will help determine if the new drug can be considered both safe and effective. It will usually involve a control group using standard treatment or a placebo as a comparison.
<b>Product registration &amp; approval</b>		
<b>Marketing &amp; launch</b>		
A pre-marketing strategy may have been instigated as early as Phase I trials to ensure that the market's needs are incorporated into the new drug's overall development, but more usually during the later phases when clinical results are promoted at international symposia in order to develop an awareness amongst the medical community who will ultimately be prescribing the new product. A sales force will be trained and will begin an intense sales and marketing campaign prior to launch		
	<b>New drug application</b> When a product is considered safe and effective from Phase III trials, it must be authorised in each individual country before it can be marketed. All data generated about the molecule is collected and submitted to the regulatory authorities in the US (FDA), European Union (EMA) and Japan (PMDA) and other countries which may require their own national approvals.	<b>Phase IV trials</b> Phase IV trials are conducted after a new drug has been granted a licence, approved and launched. In these studies, the new drug is prescribed in an everyday healthcare environment using a much larger group of participants (two to five thousand patients). This enables new treatment uses for the new drug to be developed, comparisons with other treatments for the same condition to be made, and determination of the clinical effectiveness of the new drug in a wider variety of patient types, and more rare side effects, if any, may be detected.