The Webscout

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What happens pre-approval?

The theme of this issue made me wonder what it is that happens before approval of a new medication. Of course, it is clinical development, notably phase II and phase III studies. But many years have already passed before a drug reaches this particular development phase and many drugs have failed on the way to that point. Only 1 out of 5000 to 10 000 development compounds makes it to the market and this process can take up to 15 years.

http://www.innovation.org is a project of the pharmaceutical industry in the USA with the mission to create awareness and encourage discussion about the pharmaceutical development process, its challenges, and its future promise. On their website you can download a brochure on drug discovery and development from

http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

or alternatively learn about the process by watching this video:

http://www.innovation.org/index.cfm/InsideDrugDiscovery/Inside_Drug_Discovery.

When I was looking for a good presentation about pre-clinical research, I came across this piece of work:

http://altweb.jhsph.edu/altex/30_3/FFTHartung. pdf.

The author critically reviews the relevance of pre-clinical studies for drug development and considers different aspects of the pre-clinical phase. He addresses issues such as the limitations of animal testing for toxicity assessment, the predictive value of animal disease models, the non-reproducibility of basic research results, and the shortcomings of *in vitro* testing.

Pre-clinical development planning is a complex task. What kinds of pre-clinical studies and data are required for drug approval? For a first impression, you can have a look at the requirements of the submission dossier, the CTD (common technical document):

http://ec.europa.eu/health/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf.

Pre-clinical data go into Section 2.4, the non-clinical overview, and Section 2.6, the non-clinical summary. From Section 2.6, you can already get some idea of the kind of pharmacology, pharmacokinetics, and toxicology data that is required and how it should be presented.

You can find a basic overview on pre-clinical study types, their objectives, and aspects such as duration and outcome measures at

http://www.pacificbiolabs.com/tox_regulatory.asp.

Good pre-clinical planning will avoid potentially harmful and costly clinical trials. The following slideshow summarises some important points to consider in early development:

http://www.powershow.com/view1/74134-ZDc1Z/Points_to_Consider_in_Preclinical_Development_powerpoint_ppt_presentation.

If you want to gain a broader insight into drug development, this free online course is a wonderful resource:

https://www.coursera.org/course/drugdiscovery.

It covers the whole process from the bench to the patient. It will give you a basic understanding of research approaches and regulatory requirements.

Did this Webscout section help you or do you have any questions or suggestions? Please feel free to get in touch and share your thoughts.

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