The symbiotic emergence of the world wide web and the Internet is one of the major developments of the final decade of second millennium. Entire industries have undergone great upheavals as "B2C" and "B2B’ paradigms rearrange market valuations. It is thus not surprising that these same forces are creating significant challenges as well as opportunities in pharmaceutical R&D. These slides examine the interactions between the ongoing revolution in information technology (IT) and the change in the profile of the discovery and development pipeline of the pharmaceutical industry. The "classical” role of IT in pharmaceutical R&D is cycle compression. The R&D pipeline can be viewed as a funnel of attrition, with time on the abscissa and the ordinate representing the number of candidate compounds. The acceleration of information flow via the appropriate injection of IT can reduce the time from discovery to market as visualized in slide 1. In the new paradigm, the goal of cycle compression remains, but additional challenges are raised by the changing profile. Thanks to new technologies such as genomics and combinatorial chemistry, there is dramatic growth in the number of targets and size of the compound library. But on the clinical side, societal limitations suggest that we cannot have a corresponding increase in the number of clinical trials. Hence IT must meet the challenge of providing “superior filters”. In the new paradigm, compounds that make it to human trials must have lower attrition rates, ostensibly because they were selected from a far larger universe of candidates. The partnership between emerging data-intensive disciplines such as systems biology and IT can achieve this vision.
New Drug Development Timeline for USA

Drug Development Timeline for USA

Bibliography

All data and timeline information on the Drug Development Timeline came from the published literature listed below.

US Drug and Biologic Approvals in 1996
Beary JF, Robillard LE, Woollett GR, Siegfried JD, White TX, Shriver DA

Sustaining Innovation in US Pharmaceuticals: Intellectual Property Protection and the Role of Patents
CDER 1997 Report to the Nation: Improving Public Health Through Human Drugs
Boston: Boston Consulting Group, 1996 pages 37-38

Patent Fundamentals for Scientists and Engineers
Gordon, Thomas T. and Cookfair, Arthur S.
Boca Raton: CRC Lewis, 1995 page 5

Clinical Research in Pharmaceutical Development
Kuhlmann J

Multinational Pharmaceutical Companies: Principles and Practices
Spilker, Bert

Inside the Drug Industry
Spilker, Bert and Cuatrecasas, Pedro
Barcelona: Prous Science Publishers, 1990 page 45

New Drug Development: A Regulatory Overview
Mathias, Mark P. and Evans, Anne G.
Walther, MA: PAREXEL International Corporation pages 6-16, 19, 129-130,146-147

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