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Learn the Basics About the Pharmaceutical Industry in 20 Minutes

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ABSTRACT

The pharmaceutical industry is the discovery, development, and manufacturing of medications by public and private organizations. The creation of these medications spans centuries if not millenniums. But what are some of the key aspects of the pharmaceutical industry that are important to SAS users? In this paper and presentation, we will spend time on the key aspects of the industry and how analytics is prominent in medical research and development.

INTRODUCTION

The pharmaceutical industry is the discovery, development, and manufacturing of medications by public and private organizations. The creation of these medications spans centuries if not millenniums. But what are some of the key aspects of the pharmaceutical industry that are important to SAS users? In this paper and presentation, we will spend time on the key aspects of the industry and how analytics is prominent in medical research and development.

THE BEGINNING OF THE PHARMACEUTICAL INDUSTRY

In the 1880s, two sources started the modern pharmaceutical industry: apothecaries and dye and chemical companies. Apothecaries are defined as a person who prepared and sold medicines and drugs. Interestingly, it is derived from the word apotheca which means a place where wine, spices and herbs were stored. Merck began as a small apothecary shop back in 1668, moving to the wholesale production of drugs in the 1840's. Many of the common drug companies we know today began as apothecaries: Abbott, Eli Lilly, Upjohn/Parke-Davis (now Pfizer) and Squibb (now Bristol Myers Squibb). The dye and chemical companies were focused on manufacturing and selling synthetic dyestuffs. At the time of industrialization, the main market for these companies was the textile industry. However, this chemical research into creating dyes gave rise to useful and valuable materials such as antiseptic substances that could be used to treat bacterial infections. Common dye and chemical companies from the 1800s include: Bayer, Sandoz and Pfizer.

PHARMA IN 1930'S

Early in the 1930's, medicines were dispensed by physicians directly to patients. There were no prescriptions. Local pharmacists provide nearly 50% of medicines. At the time, the industry was just starting to develop medicines to treat heart conditions, infectious disease, pain, and other conditions. The industry was set for growth as it was at the center of science, medicine, and growing healthcare needs.

MID 20TH CENTURY: PHARMA'S GOLDEN ERA

Imagine halving infancy deaths, cutting maternal deaths from infections by 90%+, treating and curing tuberculosis, diphtheria and pneumonia illnesses. Several new classes of medicines were invented in the mid 20th century. Support for research accelerated during World War II. For example, antimalarials, cortisone, and penicillin were all developed by programs sponsored by the US government. Antibiotic profits enabled companies to expand in-house research and development and build research parks to develop more breakthrough medicines.

During this time, new analytical techniques and technology help aid in the identification of the "make-up" of antibiotics, steroids, and other medicinal ideas. The days of scientists working in beakers and test-tubes moved to tiny samples and molecular models. This led to more knowledge of the structure of molecules and how they react on a living matter. Antipsychotics, antidepressants, and antihistamines were now developed.

Safety regulations in the US became a reality in 1937. The 1938 Food, Drug & Cosmetic Act was approved after more than 100 people died from a syrup. A medicines preclinical and clinical test results were now required to be reviewed – and could be used to block its marketing. Other countries also put in place regulations to add additional governmental control for the testing and manufacturing of medicines. Additionally, over the counter (OTC) medicines were distinguished from prescriptions. Double-blind, controlled trials were now promoted as the gold standard for new medicinal products.

OVERVIEW OF CLINICAL TRIALS

Clinical trials are studies that test whether a medical method (strategy, treatment, device) is safe and effective for humans. As the gold standard, they provide the best data for making decisions on safety and effectiveness. In 2019, it was estimated to get a new prescription medicine to market cost nearly $2B US dollars and only ~12% succeed in getting to market. The time it takes to get from ideation to market of a prescription medicine takes ~12 years to regulatory approval.

Within clinical research, there are four (4) phases of clinical trials: Phase I, Phase II, Phase III and Phase IV. In Phase I, the clinical trials are meant to identify what dosage of a medicine is safe. Ten (10) to twenty (20) subjects are enrolled in these studies. Phase II clinical trials are meant to show if the medicine works – does it have efficacy. These studies have twenty (20) to two hundred (200) subjects enrolled. In Phase III, clinical trials are compared to placebo (sugar pill for example) or a comparator drug. These clinical trials have greater than one thousand (1,000) subjects enrolled. Both safety and efficacy are analyzed in these studies. Finally, Phase IV clinical trials look at how the medicine is doing in the 'real world.' These trials are not always required and may be competitive.

SAS AND CLINICAL TRIALS

In the late 1960's, the National Institute of Health funded a project at NC State University to have regression and analysis of variance routines created by Anthony Barr to run on IBM's mainframe. Jim Goodnight, one of Barr's students, developed the statistical routines. The first release of SAS was done in 1972. Additional individuals contributed to the software's routines including John Saul who helped with econometrics, time series, and matrix algebra routines.

As mentioned above, double-blind controlled trials were the gold standard for medicinal products. These clinical trials require data access, data management, data integration, analysis, and reporting. To many, SAS is the industry standard for data and analyses. It is a flexible platform that provides the ability many ways to perform ETL (extract transform load) to industry standards such as CDISC SDTM and ADaM, statistical analyses, and producing tables, listings, and figures for clinical trial submissions.

A great overview of a clinical study and the components that go into it, as well as the time and cost can be found in Venky Chakravarthy's 2018 paper titled "The Anatomy of Clinical Trials Data: A Beginner's Guide."

CONCLUSION

The pharmaceutical industry is one of the largest industries in the world. In 2021, revenues in the industry totaled over $1.25 trillion US dollars. What started in botanicals, dye, and chemicals is now providing lifesaving medicines to billions worldwide. To get medicines approved through regulatory agencies, double-blind controlled trials are the gold standard. Using SAS and other analytical software, the data, analyses, and reporting can be completed and submitted for approval.

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