

Integrating Financial Planning for Life Sciences

Strategies for maximizing the value of R&D



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Published by:

Prophix Software Inc.

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Introduction

“Life Sciences” is a term used to describe the branches of science that involve the study of living organisms. The Life Sciences industry is involved in the commercialization of such science and includes the following sectors:

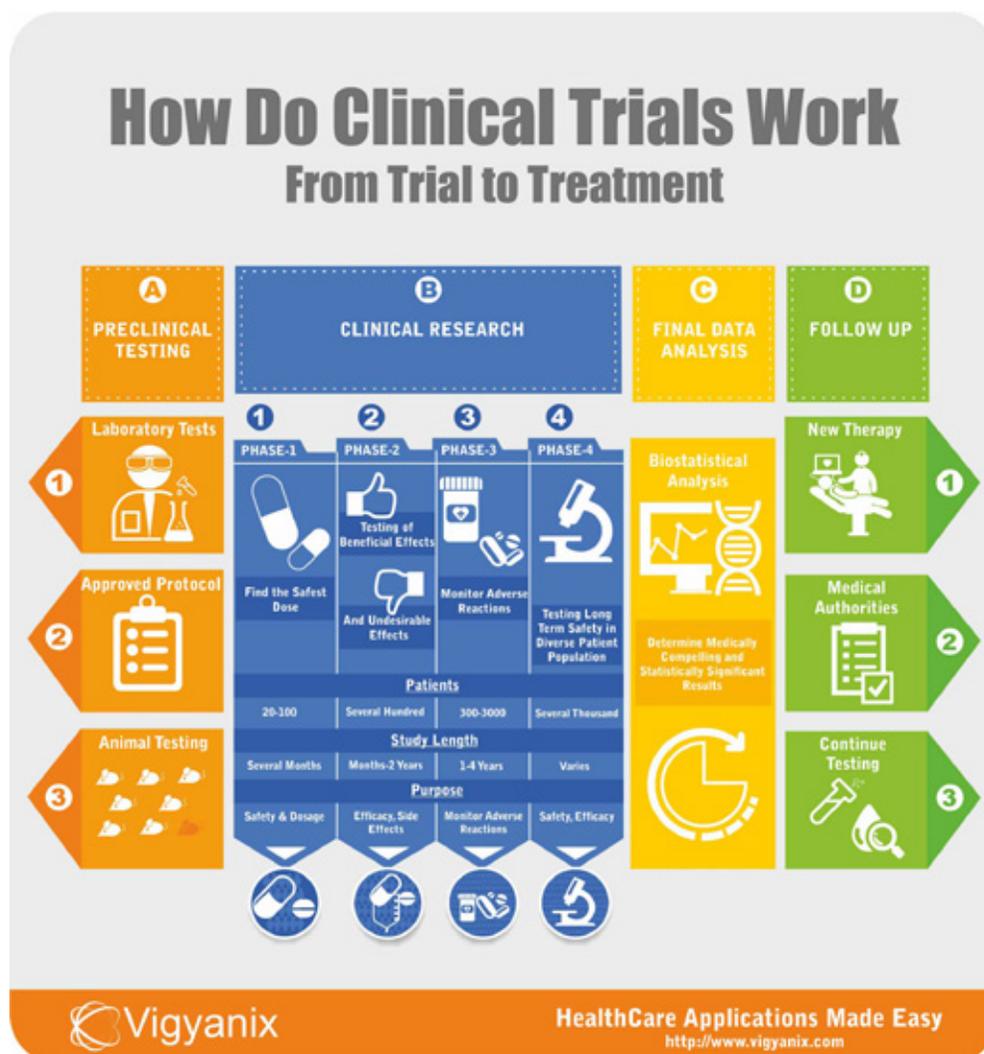
2016 Global Estimate of Sales	Sales in Billion U.S. Dollars	Growth Rate (%)
Pharmaceutical	1,038	2.1
Biotechnology	294	3.7
Genetics	86	8.8
Medical Technology	388	5.1
Distributors	810	6.8

Many Life Sciences products, devices as well as drugs, are highly regulated. Before a drug can be sold it must receive regulatory approval.

The Pharmaceutical industry involves potentially large investments in research & development (R&D) in the hopes that a drug can be commercialized. This is a risky business because:

- It takes 10-15 years on average to develop a drug but less than 12% of drugs in clinical trials are approved for market
- Only 20% of marketed drugs earn enough revenue to cover R&D costs; Pharma companies make an average of 50% of their revenue from their top three products

Other Life Sciences businesses have different risk profiles. Medical Technology companies tend to have a larger number of successful products, whereas Biotechnology companies tend to have fewer. This may reflect consolidation in these sectors and the relative maturity of these businesses.



▲ Source: [Vigyanix](http://www.vigyanix.com)

Forecasting for Life Sciences

Forecasting revenues in these industries can be very difficult. There are three main events that determine the success of a drug or a medical device:

Regulatory approval

The timing of regulatory approval can be difficult to forecast but it is important from an accounting perspective. Final regulatory approval provides substantial evidence, at which point, all the criteria for capitalization of in-house R&D costs as intangible assets has been met.

Insurance and medical approval

Here “insurance” means insurance companies including Medicare/Medicaid in the U.S., and in other countries government health schemes, such as OHIP in Ontario. A drug must get on the **‘formulary’** of each insurer. The formulary is a list that means an insurer will accept the drug/procedure at a specified price.



The success of a product depends on it being accepted, not only by insurance companies but also by the medical profession. This can involve meeting with individual doctors, influencing thought leaders and presenting at conferences. Getting a product on a hospital formulary is a sales exercise that can be like running a political campaign; both require money, finesse, diplomacy, politicking and, most importantly, a platform with substance.

Patent protection

Once patented, a Pharma company has 20 years in which to reap the benefits of their R&D investment. It is a race to maximize sales before generic drug manufacturers can compete. The end of a drug's patent protection is called the '**patent cliff**'.

Planning requires many different scenarios, depending on when or if a drug gets regulatory approval and when or if insurers include the drug in their formulary. Inclusion in the formulary of a large insurer such as Medicare can also give rise to added sales and marketing costs, such as hiring or educating sales reps who visit doctors. Or in the U.S., this can also include television advertising.

Finance and Life Sciences

Accounting in Life Sciences companies can also be complex. For example, small companies may have innovative R&D funding arrangements with diverse terms and conditions.

Passive third-party investors often provide the funds to offset the cost of R&D programs in exchange for milestone payments or other forms of consideration (typically sales-based royalties) that are contingent on the successful development and related approval for the compound(s) being researched.

All of the above means that adequately planning a Life Sciences business can be very difficult and is more than just preparing an annual budget and entering forecasts into general ledger accounts.



For example, the Office of Finance in a Life Sciences company may have to cope with issues such as:

Management may make decisions about the funding of individual R&D projects, either increasing or decreasing investments based on changes in the competitive environment. These decisions can affect short-term costs.

A product may be close to receiving regulatory approval. As soon as this happens, associated R&D costs can be capitalized. If it is close to the end of the company's fiscal year, this event can materially affect annual statements.

Another product might be added to the formulary of a major insurer, such as U.S. Medicare. This event can trigger investments in sales and marketing, as well as a need for extra production. Revenue forecasts, perhaps for years in the future, will need to be revised.

An insurer may seek to renegotiate the price paid for a formulary product in return for a guaranteed volume commitment. If this happens, a completely new product revenue forecast will need to be developed.

All forecasts for disparate products need to be individually calculated and consolidated into the company's plans. This illustrates a need for Integrated Financial Planning (IFP), where forecasting is done on a regular basis, at a detailed level, in multiple areas of a company's business.

In the Life Sciences business, forecasts can change almost at a moment's notice. The result is not just a profitability forecast for individual products or projects but can also include income statements, balance sheets and future cash requirements. Accurate planning will take away 'surprises,' such as a sudden unforeseen need to raise capital.

Prophix is an excellent vehicle for going beyond a simple budget by having multiple scenarios that calculate the effect of the commercial success of multiple products, as well as R&D costs. With Prophix, companies can perform true Integrated Financial Planning.

About Prophix

Prophix develops innovative software that automates critical financial processes such as budgeting, planning, consolidation and reporting — improving a company's profitability and minimizing its risks. Thousands of forward-looking organizations in more than 90 countries use software from Prophix to gain increased visibility and insight into their business performance.

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