### JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 17, No. 1, February 2021

"Happy Trials to You"

## How to Use Financial Statements to Manage Your Site By David G. Rossi

For many site managers, financial statements come into play only once a year at tax time. However, reviewing financial statements monthly or quarterly is crucial for monitoring and projecting financial performance and finding opportunities for improvement.

This article will focus on how you can use financial statements and projections (forecasts) to manage your business, as opposed to just calculating your taxes.

There are three basic types of financial statements:

- **Profit & Loss (P&L) Statement**. Also known as the Income Statement, the P&L shows your site's revenue, expenses and profits during a period of time (e.g., the month of December, 2020). Revenue is listed at the top of the statement. Operating costs, interest and taxes are presented below and subtracted from revenue to obtain net income, which is also called the bottom line. Although the term "sales" is often used synonymously with revenue, the latter term has a narrower definition according to generally accepted accounting principles (GAAP) because sales can consist of recorded or "booked" amounts that have not actually been earned (e.g., delivered) and thus may or may not have been recognized as revenue.
- Cash Flow Statement. Also known as Sources and Uses of Cash, the Cash Flow Statement reports how much cash your site had at the beginning of a period of time, how much cash came in and went out during that period of time, and much cash you ended up with at the end of that period of time. You have probably heard the adage that cash is king. Many businesses have collapsed when they ramped up cash expenditures to support rapid revenue growth, but their bank account emptied when their customers (e.g., study sponsors) paid slowly. Net income listed on a P&L Statement cannot save a business that runs out of cash.
- Balance Sheet. The Balance Sheet is a report of your site's assets (what you own), your liabilities (what you owe) and the owner's equity (the amount invested and earned in the business) as of a given date (e.g., Dec. 31, 2020). The two sides of a balance sheet — assets on one side and liabilities and owner's equity on the other — total to the same number and are thus, by definition, "in balance." In contrast to the P&L, which covers a period of time, the balance sheet is a snapshot of a company's position at a specific point in time. The Balance Sheet is primarily used to assess the solvency and liquidity of a business. Businesses become insolvent when liabilities exceed assets and the assets are not "liquid" enough to be converted into cash in time to pay amounts owed to lenders and others (e.g., a landlord). In comparing a P&L Statement to a Balance Sheet, it is also important to understand the difference between "cost" and "expense." Cost is what you pay for something, like a freezer. Expense is how much of that cost is charged to your business during a period of time. Many costs (e.g., rent) are charged immediately as expenses, but the cost of "fixed" assets, such as a freezer, are "expensed" over a period of time as "depreciation." "Amortization" is like depreciation but for intangible costs, such as patent filing fees.

Expanding on these three basic types of financial statements, it is important to keep in mind that managing a business is more about the future than the past. You can look forward by

developing projected versions of the statements above, especially the P&L Statement and Cash Flow Statement.

For financial management purposes, the most important part of the Balance Sheet is accounts receivable — the money that customers owe to your site. An Accounts Receivable Aging Statement lists these amounts in order from oldest to most recent. For most businesses, it takes time for customers to pay invoices, so older invoices are more likely to be paid sooner than newer invoices. However, once an invoice gets beyond a certain age, usually 60 to 90 days, collection becomes less likely as there may be some accounting problem, dispute or inability to pay. Some study sponsors may delay paying their bills until you ask — or demand — payment.

The P&L Statement, projected Cash Flow Statement, and Accounts Receivable Aging Statement below are for a hypothetical independent research site named Research Site LLC. Each is offered as an illustration of the concepts above and to discuss how they can be useful to the financial management of your research site. These same three statements can also be generated for the clinical research department of a medical clinic, community hospital, or academic medical center. If you have "financial accountability," these statements are essential.

#### **Profit & Loss Statement**

Figure 1, an example of a P&L Statement for Research Site LLC. Revenue (or gross profit) earned by Research Site LLC, during 2019, is at the top of the statement. Expenses follow, with profit (or net Income) at the bottom. In this simple example, the \$187,500 profit earned by Research Site LLC in 2019 equals revenue (\$600,000) minus total expenses (\$412,000) and minus another category of entries called Net Other Income/Expenses (\$500), which is explained below.

Research Site LLC uses the accrual basis for accounting. Under the accrual basis, revenue and expenses are recorded in the accounting periods when a "reportable event" actually occurs, rather than when the cash flow associated with that event occurs. For example, with accrual accounting, revenue may be recognized when a site enters the data in the EDC system for a patient visit. With cash accounting, revenue is recognized when the site actually receives payment for entering the data. Cash accounting defers revenue recognition and, therefore, taxes for a profitable business. However, accrual accounting gives a much more accurate picture of the business for management purposes.

Another important P&L Statement concept is net operating income, the income derived from your site's core business (*i.e.*, the conduct of clinical trials for an independent site). "Other Income" is income your site might receive from peripheral activities, such as interest on money saved in a bank. Similarly, other expenses are expenses peripheral to your core business. Research Site LLC has only one item listed under Other Income/Expenses," which is \$500 of credit card interest paid in 2019.

You may have heard the term EBITDA (to sound like a finance pro, pronounce it "ee-bit-dah"), an acronym for Earnings Before Interest, Depreciation and Amortization. EBITDA is a measure of the core earning power of a business.

Companies that acquire independent clinical research sites typically value them at a multiple of three to four times a site's annual EBITDA. Because Research Site LLC had only \$500 of interest expense and no depreciation or amortization in 2019, its EBITDA for that year was \$188,000.

# Figure 1. Research Site LLC Profit & Loss Statement

Jan. 1 – Dec, 31, 2019

	Total
Income:	
Sponsor 1	
Study 1-1	200,000
Study 1-2	200,000
Total Sponsor 1	400,000
Sponsor 2	
Study 2-1	
Study 2-2	200,000
Total Sponsor 2	200,000
Gross Profit	600,000
Expenses:	
Advertising	1,500
Employees and Consultants:	
Employee Payroll	250,000
Health Insurance	60,000
Licenses	1,500
Total Employees and Consultants	311,500
Insurance	15,000
Medical Supplies and Repairs	5,000
Office	10,000
Rent	48,000
Subject Expenses	15,000
Utilities	6,000
Total Expenses	412,000
Net Operating Income	188,000
Other Income & Expenses:	
Credit Card Interest Expense	500
Net Other Income	500
Net Income	187,500

#### **Projected Cash Flow Statement**

Research Site LLC developed the cash flow projection below at the end of 2019 for the first three months of 2020. It represents the actual cash that Research Site LLC expects to receive and pay out during these months.

Some of the cash expected to be received will be for work already performed, such as payment for a research visit 30 days ago; the rest will be for work not yet performed, such as advance payment for study start-up fees from a sponsor. Similarly, some of the

cash expected to be paid out will be for expenses already incurred and the rest for expenses that are prepaid.

Projected cash flow statements most often look three to six months ahead and are updated on a monthly basis. The projection period should be long enough for planning purposes, but not so long that the numbers are just guesses.

The devil is definitely in the details for Projected Cash Flow Statements. To make an accurate projection, sites often need to look at every study down to the study visit, as well as the contract payment terms and the payment history for each study sponsor. It is also essential to forecast patient enrollment and retention. A clinical trial management system (CTMS) can assist you in preparing this report.

Figure 2 shows that Research Site LLC starts with a \$25,000 cash balance on hand at the end of 2019, a fairly low cash reserve for a business that does over \$500,000 in annual revenue. It forecasts that Study 1 and Study 2 from Sponsor 1 will close and pay their final closeout fee (holdback) in March. On the expense side, Research Site LLC has a few "front-loaded" annual expenses, such as an insurance policy premium of \$10,000 due in January. Cash looks tight for January and February, so Research Site LLC should make sure collections come in on time and defer discretionary expenses until March. In the chart, BOM stands for "Beginning of Month" and EOM stands for "End of Month."

Figure 2.
Research Site LLC
3-Month Cash Flow Projection

Jan. 1 – March 31, 2020

	BOM January	EOM January	EOM February	EOM March
Cash on Hand	25,000	25,000	32,347	51,194
Sponsor 1: Study 1 Sponsor 2: Study 2 Sponsor 2: Study 3 Sponsor 2: Study 4 Total Cash Received	25,000	0 0 25,000 25,000 50,000	0 0 25,000 25,000 50,000	25,000 25,000 25,000 25,000 100,000
Advertising Employee Payroll Health Insurance Licenses Insurance Medical Supplies General Office Expenses Rent Subject Expenses Utilities Total Cash Paid Out		0 20,833 5,000 1,500 10,000 433 887 2,500 1,250 250 <b>42,653</b>	5,000 0 433 887 2,500 1,250 250	500 20,833 5,000 0 0 433 887 2,500 1,250 250 <b>31,653</b>
Cash on Hand	25,000	32,347	51,194	119,541

#### **Accounts Receivable Aging Report**

Figure 3, Research Site LLC's Accounts Receivable Aging Report, shows unpaid amounts for patient visits and other charges. In addition to identifying overdue amounts for Accounts Receivable follow up, this report helps forecast collections for the Projected Cash Flow

Statement. In addition, banks and other lending institutions often want to see this report when considering whether to extend credit.

Figure 3. **Research Site LLC Accounts Receivable Aging Report** 

Jan. 1 – March 31, 2020

				Days
Study	Visit or Invoice	Subject #	Amount	Unpaid
Sponsor 2: Study 3	Visit 2.166	301	750	75
Sponsor 2: Study 4	Visit 1 - Screening	400	2,250	67
Sponsor 2: Study 4	Visit 7	401	900	59
Sponsor 2: Study 4	Visit ET	402	1,800	48
Sponsor 2: Study 3	Visit 2.147	302	11,125	37
Sponsor 2: Study 4	Visit 3	403	900	32
Sponsor 2: Study 4	Visit 13	404	1,125	30
Sponsor 2: Study 4	Visit 22	405	1,275	27
Sponsor 2: Study 4	Visit 23	406	1,275	20
Sponsor 2: Study 3	Visit 2.90	303	747	19
Sponsor 2: Study 4	Visit 5	407	375	19
Sponsor 2: Study 3	Visit 2.78	304	675	18
Sponsor 2: Study 4	Invoice No. 2464	N/A	450	17
Sponsor 2: Study 3	Visit 2.150	305	675	16
Sponsor 2: Study 3	Visit 2.97	306	1,125	16
Sponsor 2: Study 3	Visit 2.92	307	1,350	16
Sponsor 2: Study 3	Visit 2.140	308	1,200	13
Sponsor 2: Study 4	Invoice No. 2465	N/A	525	13
Sponsor 2: Study 3	Visit 2.156	309	2,100	12
Sponsor 2: Study 3	Visit 2.98	310	675	11
Sponsor 2: Study 4	Visit 1 - Screening	408	6,750	11
Sponsor 2: Study 4	Visit 6	410	2,250	9
Sponsor 2: Study 4	Visit 2 - Baseline	411	1,200	9
Sponsor 2: Study 3	Visit 2.156	313	1,350	8
Sponsor 2: Study 3	Visit 2.156	314	1,350	8
Sponsor 2: Study 3	Invoice No. 2343	315	1,200	8
Sponsor 2: Study 3	Invoice No. 2342	N/A	1,500	6
Sponsor 2: Study 3	Visit 2.92	316	1,500	5
Sponsor 2: Study 3	Visit 2.106	317	1,350	5
Sponsor 2: Study 3	Visit 2.176	318	675	5
Sponsor 2: Study 3	Visit 2.156	319	1,650	4
Sponsor 2: Study 4	Visit 3	412	1,350	4
Sponsor 2: Study 3	Visit 2.158	320	900	3
Sponsor 2: Study 3	Visit 2.15	321	675	3
Sponsor 2: Study 4	Visit 17	413	675	3
Sponsor 2: Study 4	Invoice No. 2470	N/A	750	3
Sponsor 2: Study 4	Visit 2 - Baseline	414	2,850	2
Sponsor 2: Study 4	Visit 7	415	1,200	2
		TOTAL	65,092	

#### Conclusion

Few clinical research sites have the luxury of letting their financials take care of themselves. With the financial statements described above, site managers can assess the financial health of the business, review trends, plan growth, and forecast cash shortfalls or surpluses.

Beyond site management, current and potential investors, along with sources of credit, will want to see credible financial statements and projections that support your ability to generate cash and service debt. If your site is considering a potential sale in the future, several years of accurate and well-documented financial statements are essential. They will increase the valuation you might receive from a potential buyer by helping them understand how your site has and will perform over time.

#### Resources

Bragg, Steven M., CPA, GAAP Guidebook 2019 Edition (Accounting Tools, Inc., 2018).

Hawkins, David F., Revenue Recognition and Reporting, (Harvard Business School Publishing, March 2001).

Hertenstein Julie H. and McKinnon Sharon M., Solving the Puzzle of the Cash Flow Statement (Business Horizons, January-February 1997).

Brigham Eugene F. and Houston Joel F., Fundamentals of Financial Management, 12<sup>th</sup> Edition, (South-Western College, 2009).

Clark, James MD, "The 101 of Clinical Research Forecasting," CRIO, accessed 10/11/2020 at https://www.clinicalresearch.io/blog/agreements-budgets/forecasting-clinical-research-crio/

#### Author

David G. Rossi is chief operating officer and general counsel of Adams Clinical, an independent clinical research site in Boston, focusing on late-phase CNS studies. Contact him at 1.617.744.8542 or drossi@adamsclinical.com.