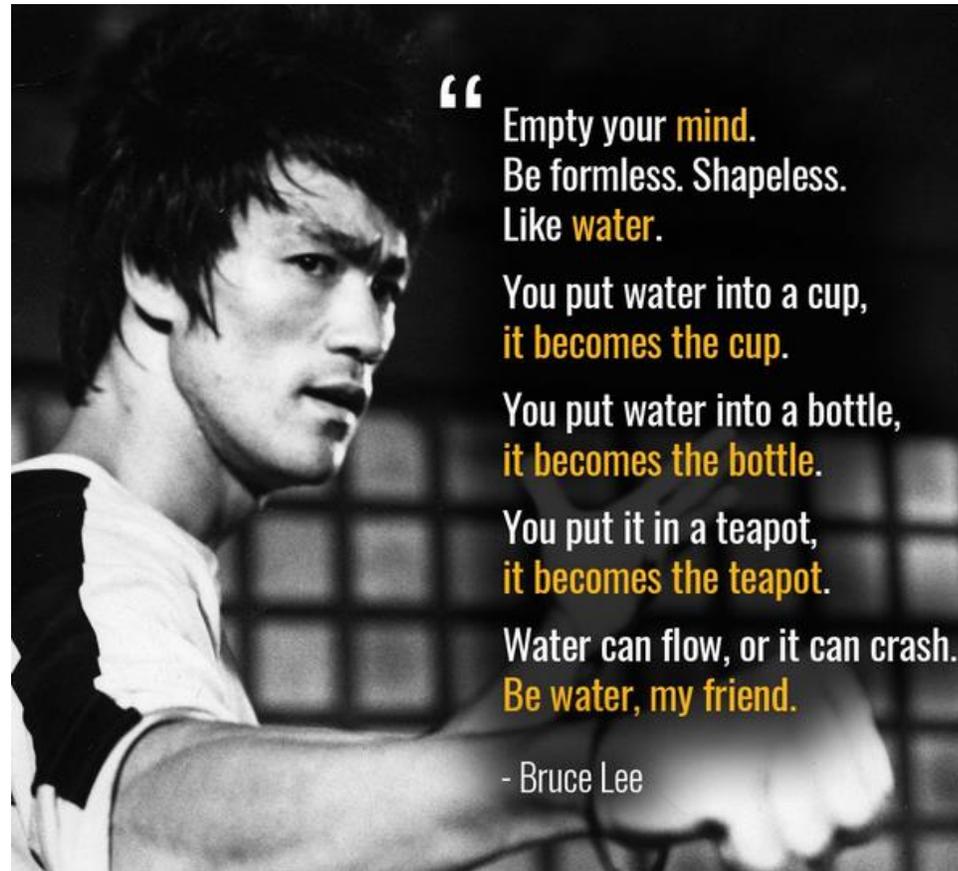


THE 7 WONDROUS CONCEPTS THAT WILL IMPROVE YOUR R&D FINANCIAL ACCRUALS PROCESS

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Accruals can be shaped like water



Simple fixes can have big impacts



Goal of this Presentation

Discuss SEVEN points of focus that will make your financial accruals efforts easier and your lives more wonderful

(Based on real-life experiences and anguish)

What are “Financial Accruals?”

- Estimated value of activities performed over a period of time (Accounting requirement)

How do companies estimate accruals?

- Many different ways. Build in-house models? Use vendors or consultants specializing in providing accruals? Ask your vendors to email you an estimate?

Why are we talking about this?

- It continues to be a big challenge in the clinical trials world

Seven Important Accruals Concepts

1. Accounting (“Accruals concept”)
2. Simplicity
3. SOX
4. Perspective
5. Auto-reversal magic
6. Invoices
7. NAAP

Accounting (“Accruals Concept”)

□ Accrual versus Cash concept

Remember: accruals are when the work is performed, not when payment is made

When it comes to accruals and budgeting, people often think on a cash basis. Examples:

- Expect \$1M milestone payments in Q1 and Q4, so budget \$1M in Q1 and \$1M in Q4
- “Accounting needs an accrual; call the vendor and ask them how much their next invoice is.”

Simple Remedy #1

- ❑ Educate and refresh non-Finance folks on the accruals concept
- ❑ Educate Finance folks on clinical study nuances

Example: CROs billing 3rd party vendors can be for work in previous periods (may have taken several months before 3rd party vendor billed the CRO)

Simplicity

- ❑ Different biopharma companies use different accruals methodologies with a wide range of complexity
- ❑ Some companies use many different complex methodologies for different activities
- ❑ Amount of financial and personnel resources used for accruals process vary significantly between companies

Simple Remedy #2

- ❑ Determine the simplest methodology and model for your company's risk level and circumstances
- ❑ Convince the Accounting Dept that the 80/20 rule CAN apply to accruals (ok...maybe 90/10)
- ❑ Example: instead of detailed accrual methodology for all contracts, use detailed/complex methods for contracts over \$X, and "straight-line" contracts under \$X

SOX (Sarbanes-Oxley)

- ❑ Enacted in 2002 in response to Enron, WorldCom, and other bad guys
- ❑ Not only are the numbers audited, processes are also scrutinized
 - Need detailed documentation of every financial controls step
 - Each step is scrutinized/audited
- ❑ Also referred to as the “KAPE” act

Simple Remedy #3

- ❑ Make each SOX control step for financial accruals as simple as possible
- ❑ Document as few MANDATORY steps as possible
- ❑ Example: instead of formally documenting four layers of review to impress the auditors, document two or three if that suffices for adequate controls (you can STILL perform four or more reviews if you want to...)
- ❑ Recommendation: review your SOX control processes for opportunities to simplify

Proper Perspective

- ❑ Accruals are ESTIMATES; not expected to be perfectly exact
- ❑ Some big companies “straight-line” ALL of their vendor contracts
- ❑ If asked approximately how many grains of sand are on Waikiki Beach, would you physically count every grain of sand or use a method to approximate?

Simple Remedy #4

- ❑ Review your company's accrual methodologies for opportunities to simplify

- ❑ Examples:
 - Can contracts below certain materiality level be “straight-lined?”

 - Instead of accruing for several hundred global investigator sites individually, can you accrue certain regions in aggregate?

 - Instead of trying to accrue every CRO “pass-thru” or site “invoiceable”, can you ignore due to low materiality?

Auto-Reversing Accruals

- ❑ Accounting Depts perform monthly/quarterly magic acts known as auto-reversing entries
- ❑ Accruals are typically auto-reversing entries
- ❑ Example:
 - January: accrue \$1,000 for estimated work performed
 - February 1: system “auto-reverses that amount so start February with (\$1,000)
 - When \$1,000 invoice is received and paid in February, the net balance in Feb is \$0

Auto-Reversing Accruals

- ❑ Ensures activity is expensed in the period it is performed
- ❑ Ensures no expense hit in the period when the payment is made (if activity occurred in a prior period)
- ❑ Ensures corrections to over-accruals and under-accruals are automatically performed
 - Example: If accrue \$1,000 in January and invoice is \$1,200 in February, there will be a \$200 “adjustment” charge in February (negative \$1,000 from auto-reversal offset by \$1,200 invoice expensed)

Simple Remedy #5

- ❑ Familiarize Clinical and R&D business partners on the auto-reversing entry concept
- ❑ Provide comfort level to business partners who are reluctant to provide accrual estimates due to uncertainty
- ❑ Underscore that business partner estimates are preferable to Accountants doing a “last resorts” estimate

Invoice Idiosyncrasies

- ❑ When providing accruals, status of related invoices must be factored in. Risk of double-counting or missing booking an expense
 - Is the invoice received by AP but not yet paid?
 - Is the invoice received by AP but not yet posted?
 - Is the invoice received but still sitting on CTM's desk?

Invoice Idiosyncrasies

□ EXAMPLE:

- Clinical Supply Chain estimates month's expense for Contract X is \$200K
- An invoice for Contract X has been received for \$100K during the month
- What should the accrual amount be?
 - \$100K if invoice is "posted" by AP
 - \$200K if invoice is not posted or sitting in someone's inbox

Simple Remedy #6

- ❑ Establish a simple-to-follow rule for how to treat invoices for accrual purposes
- ❑ Example: “When providing accrual estimates, R&D partners should ignore invoices received or not received.”

Let Accountants handle the necessary invoice-related adjustments

NAAP

- ❑ GAAP = Generally Accepted Accounting Principles
- ❑ NAAP = No Accepted Accruals Principles
- ❑ Some general guidance
 - Simple methods can be riskier (example: “straight line” is generally riskier than models-based)
 - Different companies can accept different risk levels
 - What is “acceptable” risk is subjective

Simple Remedy #7

- ❑ Determine the most acceptable risk levels for your company
 - Discuss with CEO/ CFO / Corporate Controller
 - Discuss with external auditors

- ❑ Provide “pro forma” analysis to demonstrate risk materiality

In Summary

Focusing on these seven concepts will make your accruals effort a less burdensome process

- Accounting concept
- Simplicity
- SOX
- Perspective
- Auto-reversing entries
- Invoices
- NAAP

THANK YOU!
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