

TH302: Clinical Trial Billing: Getting All the Money You Deserve

presented by:

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Reversed, this would be a perfectly normal conversation.

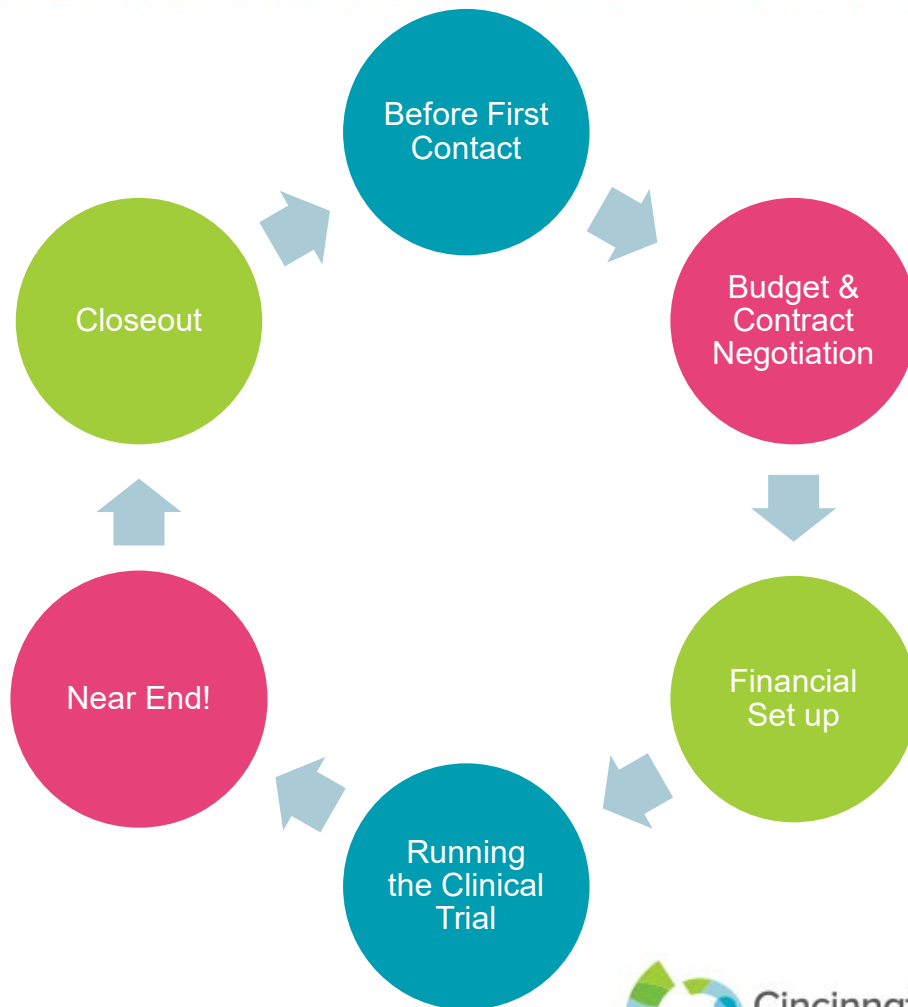


SOCIETY OF
RESEARCH
ADMINISTRATORS
INTERNATIONAL



Outline

- Before first contact
- Initial negotiations (resistance is not futile)
- Initial setup
- During trial
- Near trial end
- Closeout



Who's in the audience?

What's your role:

- a. Research Coordinator
- b. Central office finance related staff
- c. Department finance related staff
- d. Industry/CRO/Pharma employee
- e. Other

How long have you been in research administration?

- A. 0-1 year
- B. 1-3 years
- C. 3-5 years
- D. 5-10 years
- E. 10+ years. (I look so young because I started before child labor laws)

Before First Contact

Before First Contact - Costs

- Know your costs first
 - Institutional Compendiums (CPT codes help!)
 - External Divisional/Institutional input
 - Research Specific Clinical Areas
 - Standard of Care (SOC)
 - Ancillary Costs: IRB, Investigational Pharmacy, Marketing, etc.
- Don't forget your own effort/time
- Indirects

Before First Contact - Process

- What are your institutional rules?
 - What rules must be followed in order to obtain your Institutional Signature
 - Policies on allowable costs
 - Safety Procedures/Adverse Events
- What are your Roles and Responsibilities?
 - Who Negotiates
 - Division or central Accounting responsible for Billing

Before First Contact - Resources

- Who can help
 - Institutional Budget Negotiator
 - Contracts Department
- Templates
 - Is there a trial that was conducted with similar procedures?
 - What worked and what did not
 - Did you come out in the “black”
- Know your studies
 - Work with the PIs and Research Coordinators

Initial Negotiations

Don't let them sock it to you!



This is NOT how it should be:

Drug Co. HQ



Academic Medical Center



DO not accept the first offer!

Academic productivity is important

but it doesn't pay the bills

- Keep the PI out of the negotiations



Potential Legal Issues

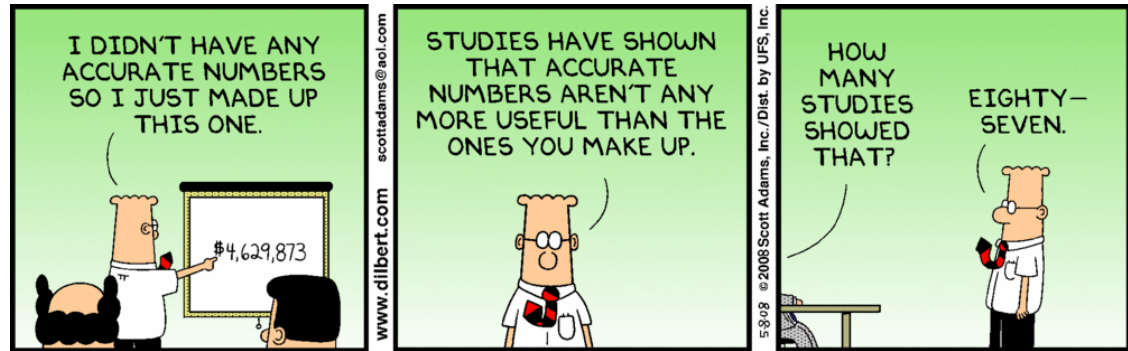
- A non-profit institution could jeopardize their non-profit status
 - The study needs to run in the “black”



A non-profit
CANNOT
subsidize a
for profit

Be sure to include:

- Startup costs
- Marketing
- Storage
- Monitoring
- Adverse events
- Unscheduled visits
- Patient Stipend/Travel Reimbursement
- Changes to:
 - Protocol
 - Schedule
- Amendments



What if they plead poverty?



With this much money, the only intervention we can do is “Flip a Coin”!

It's not just you!

How many people have been told by a CRO/Sponsor that their institution is coming in as one of the highest sites in cost?

- Yes
- No

Initial Setup/startup

Startup costs

- Have a mechanism in place to bill for startup right away
- System for milestone payments
- System for invoiceables
 - Shared Documents



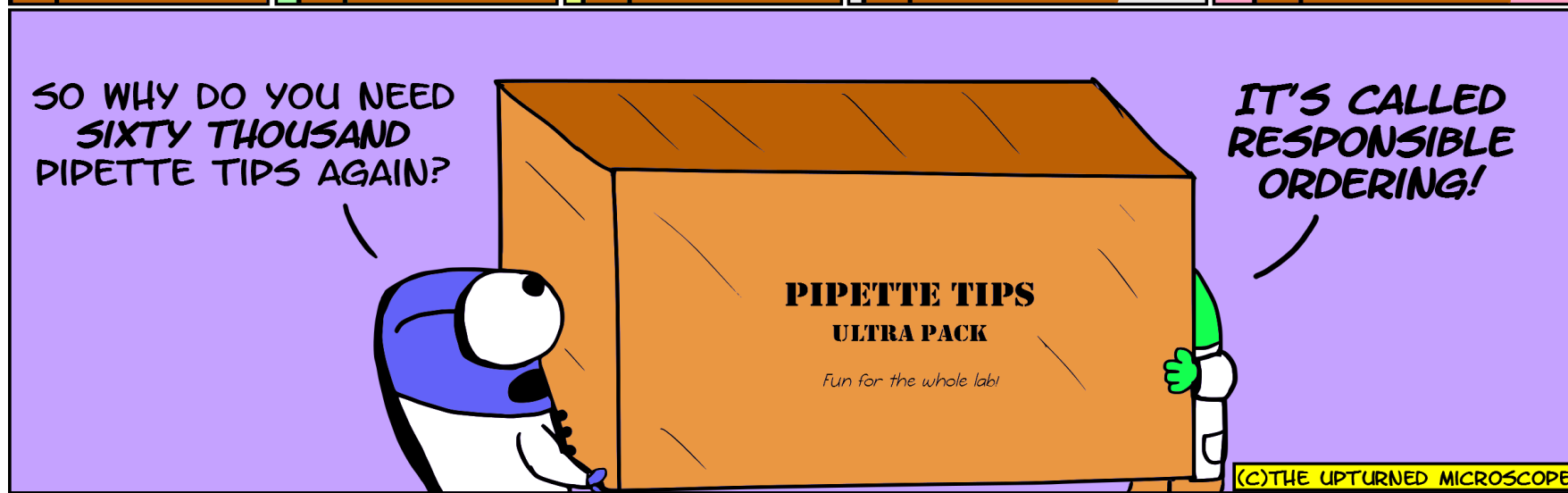
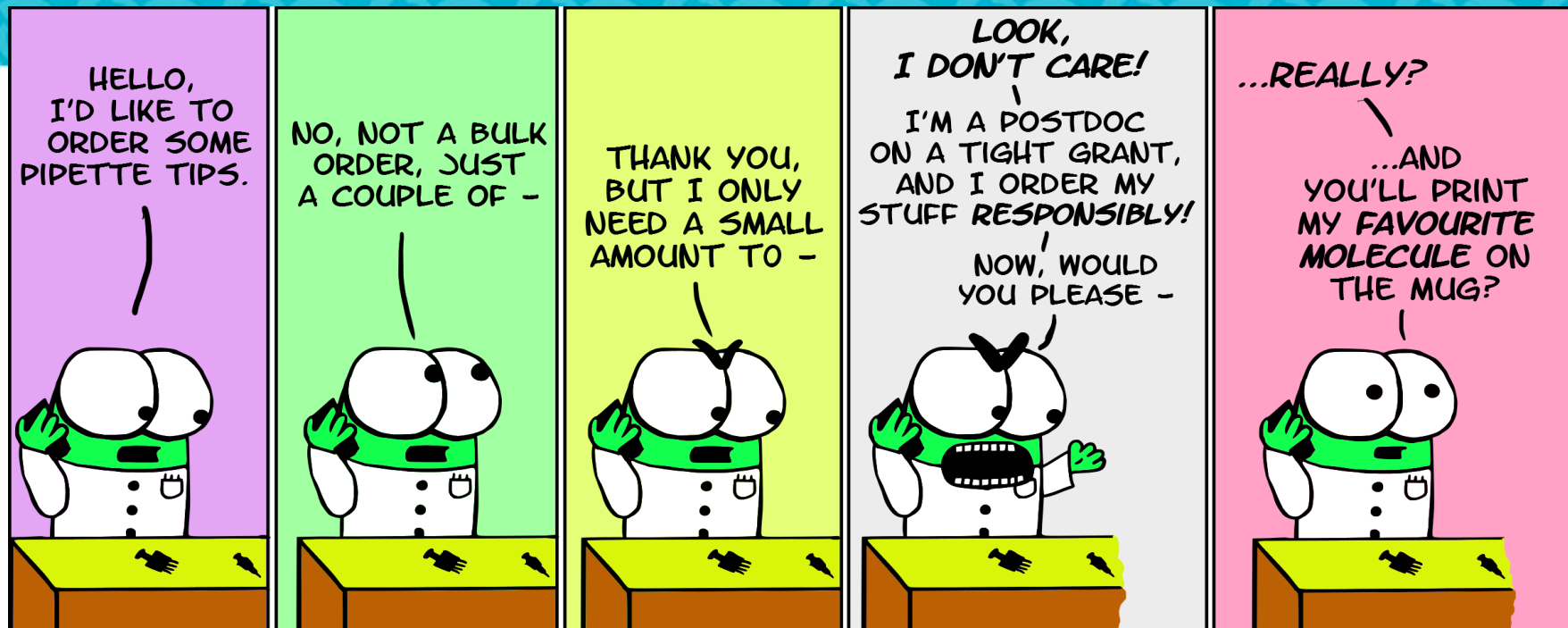
Setup

- Assign staff to study
- Ensure payroll is charged – backwards and forwards
- Billing account in EMR setup
- Mixed visits setup in work queue – who works it?



During the Clinical Trial

Need to monitor spending



Regular Meetings with PI/study staff

- How is recruitment going
- Monitoring scheduled
- Are study staff keeping up
- Any changes



Patient Travel Reimbursement

- Know the rules
 - IRS Taxation
- Triple check the contract for qualifiers like:
 - “up to”
 - “maximum”
 - “not to exceed”
 - “or”
 - “economy”, “modest”
 - “sponsor preapproval”
- Communicate and Get Organized
 - Have a good system of submission of receipts and tracking of payments in place



Invoicing & Tracking Payments

- Keep on top of the Invoiceables!
 - Make a reminder for the “annuals”
 - Have some form of tracking procedural invoiceables with study staff
 - Aging Invoices
- Track Incoming Payments
 - Sometimes Industry automatically pays things that were invoiceables, ex. Screen Fails



Nearing the end

Preparing for the end

- Where will study staff salaries be moved to?
- Will internal accounts be 'blocked' for future charges?
- Will you be receiving withholding at a later date?
- Publication



Closeout

- In the last part of a trial, all members of the study need to work together to ensure no “*surprises*” are awaiting them at the end of a project.
 - This is why monthly monitoring of financial reports are key to a financially successful project
 - Communication plays a large part in successful financial monitoring up to the closeout stage and throughout the closeout stage.
- Lessons learned!





**SHOW
ME THE
MONEY!**

Thank you. Seriously, Thank You!

Please be sure to complete survey that will be emailed from SRA.



Now, go jump in
with both feet and
sock it to 'em!



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