



BDO DIGITAL

# Mastering Clinical Trial Accounting & Forecasting

DECEMBER 10, 2024

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# With You Today



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## About Condor

Condor is a leading cloud-based clinical finance management software company driving a future where finance accelerates progress in medicine



Unified Platform Integrating Siloed Data Sources



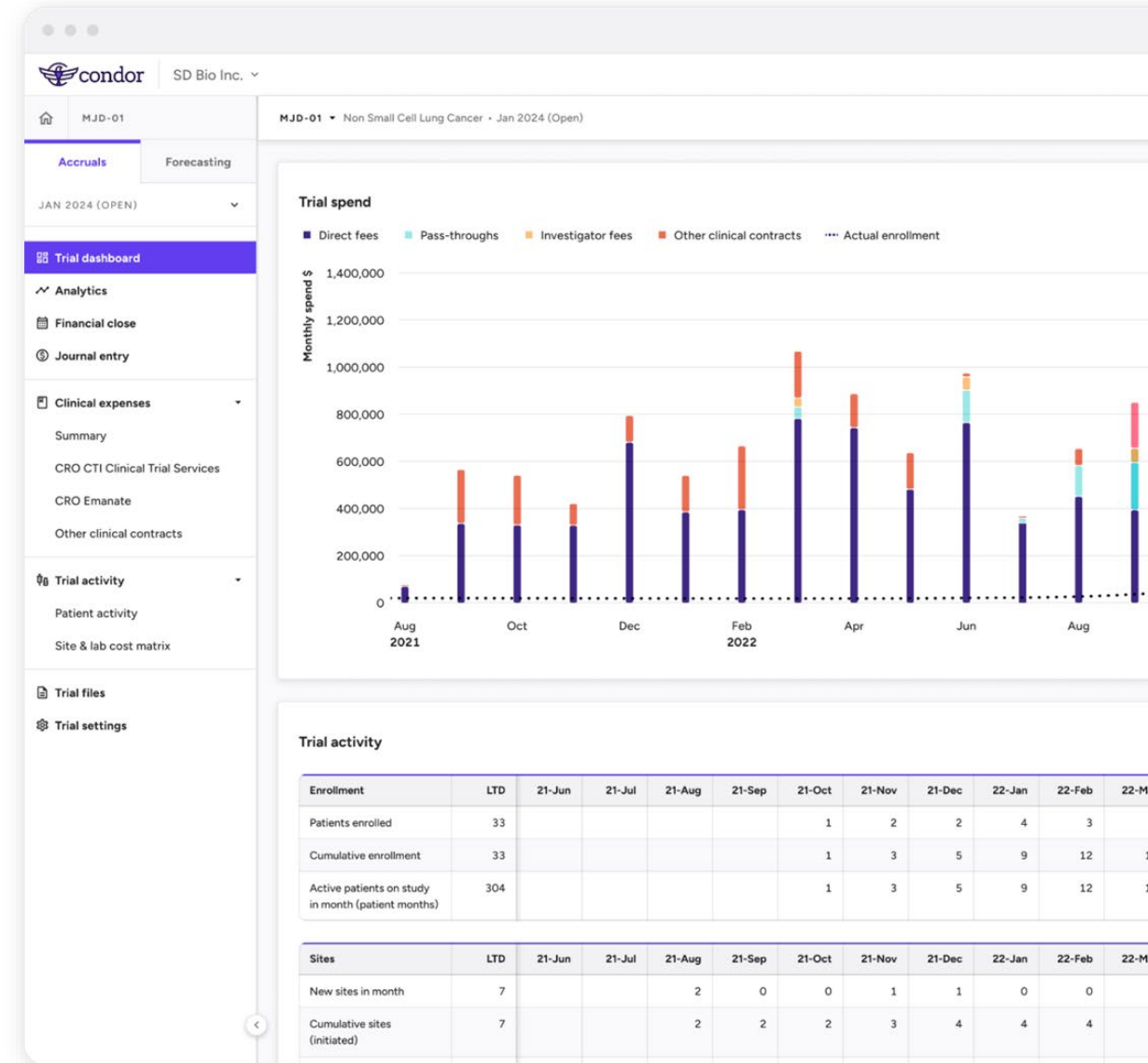
Deep Clinical Finance & Industry Expertise



Automated Intelligence for Clinical Trials Accruals



Advanced Forecasting & Scenario Planning Capabilities



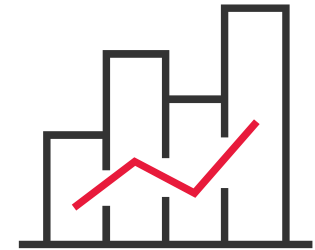
# Learning Objectives



Explain accrual Methods for Clinical Trial Accounting & Forecasting.



Reconcile actuals to accruals for clinical trial accounting.



Forecast accurately the clinical trial costs and timing of expenses using both historical and AI based forecasting methods.

## Agenda for Today

**1**

**Accrual Methods, Tools and Audit Readiness**

**2**

**Reconciling Actuals and Accruals**

**3**

**Forecasting Using Historical Data and AI**

**4**

**Clinical System and Financial System Integration**

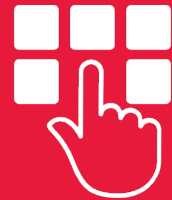
**5**

**Conclusion and Q&A**



# Audience Insights

What stage is your company in?



Select your answer in  
the panel to the right

# 01

## Accrual Methods, Tools and Audit Readiness

# Accrual Accounting

Measures financial performance by recognizing economic events regardless of when cash transactions occur

Simply put – an accrual is an estimate of billable work over a given time period so that the period in which the expense is recorded matches when it was incurred





# Understanding Clinical Trial Accruals



## Startup Stage

- ▶ Costs during this phase include site recruitment, database setup, other clinical and regulatory setup fees.
- ▶ Costs are generally recognized using a straight-line attribution over the estimated start-up period, as well as variable costs associated with site recruitment.



## Enrollment & Clinical Conduct Stage

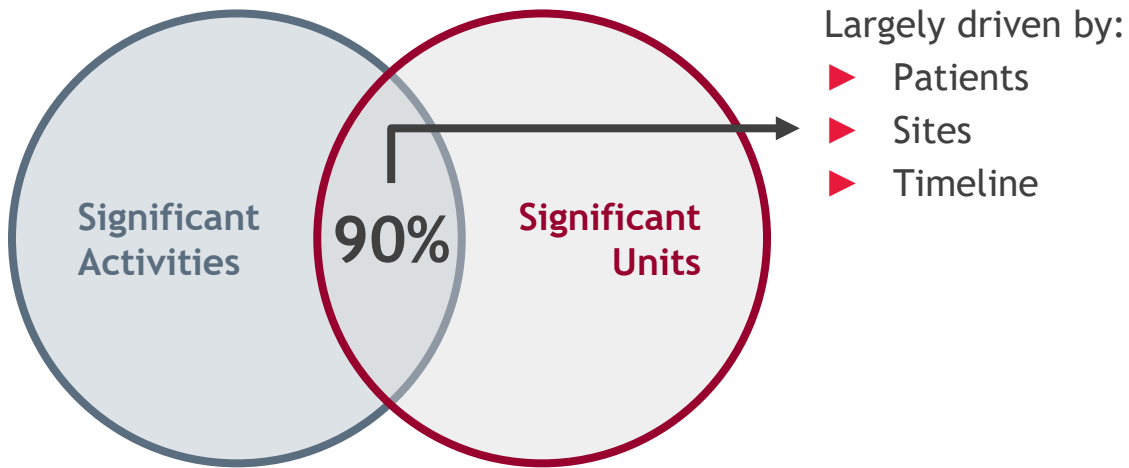
- ▶ Represents majority of clinical study costs, such as patient screening, enrollment, ongoing treatment, and other clinical & site monitoring service and fees.
- ▶ Accruals in this phase are often based on activity data – number of active sites, patients enrolled, patient visits & procedures during timelines.



## Close Out Stage

- ▶ Activities include statistical review, data cleaning, regulatory review and submissions.
- ▶ Accruals during this phase are generally like the startup phase – straight-line over estimated wrap-up period.

# Introduction to Industry-Standard Costing Methodologies



## KEY DATA USED

### Systems:

- ▶ EDC (Clinical)
- ▶ IRT / CTMS (Clinical)
- ▶ Procurement (Finance)
- ▶ ERP (Accounting)

### Budgets / Data:

- ▶ Clinical Site Agreements
- ▶ CRO / Vendor Budgets
- ▶ CRO / Vendor Updates

## SIGNIFICANT ACTIVITIES

### Investigator Fees & Labs

- ▶ Protocol Screenings & Visits
- ▶ Invoiceable Procedures
- ▶ Central & Specialty Labs
- ▶ Drug dosing
- ▶ Other producers (i.e., home health, surveys, wearables)

## KEY MEASUREMENTS

- ▶ Avg patient cost
- ▶ Per visit / procedure
- ▶ Avg site cost
- ▶ Per site (admin)

### CRO & Other Services

- ▶ Project Mgmt
- ▶ Study Mgmt & Monitoring
- ▶ Safety Monitoring
- ▶ Site Recruitment & Monitoring
- ▶ Meetings & Teleconferences

- ▶ Timeline
- ▶ Enrollment rate
- ▶ Treatment duration
- ▶ Site activity

# Challenges In Accrual Estimation - One Size Does Not Fit All



**Materiality of  
Trial / Company**

+

**Complexity of Contracts:**  
Different arrangements and  
diverse services from CROs  
and other vendors



**Constant Changes:**

Scope changes as more  
information is obtained  
during the trial. Elusive  
numbers muddled with  
constant contractual  
changes.



**Data Limitations:**

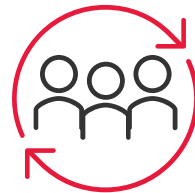
Reliance on manual  
spreadsheets and incomplete  
or unreliable vendor reports  
increases the risk of errors.  
A lack of timely information  
often results in inaccurate  
accrual estimations.

# Best Practices for Effective Accrual Management and Audit Readiness



## Automation & Integrations

- ▶ **Consistency in Methods:** Align on key drivers and activities with clinical, then verify through reconciliation
- ▶ **Streamline Accrual Process:** Integrate databases, systems and vendor updates
- ▶ **Improve Accuracy:** Implement automated matching & reconciliation of project status updates and invoices



## Collaboration

- ▶ **Internal:** Establish clinical and finance team collaboration to ensure operational data for performed work is accurately and promptly used for accrual calculations
- ▶ **Vendors:** Establish a robust communication framework with vendors to address informal amendments to contracts to ensure all financial obligations are accounted for



## Internal Controls

- ▶ **Accuracy and Compliance:** Regularly review clinical contracts and accrual estimates against financial terms
- ▶ **Quarterly CRO Communication:** To validate unbilled amounts, reducing unexpected expenses

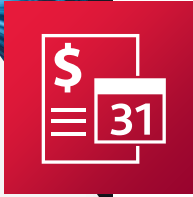
# 02

## Reconciling Actuals and Accruals



## RECONCILING ACTUALS AND ACCRUALS IN CLINICAL TRIALS

# Common Challenges



### Delayed Vendor Invoicing

- ▶ Vendors often invoice well after expenses have been incurred complicating the reconciliation process
- ▶ Particularly common for investigator expenses, leading to challenges in accurate financial reporting



### Data Silos and Manual Errors

- ▶ Many organizations use Excel spreadsheets and manual data entry for managing accruals
- ▶ This leads to inefficiencies, higher risks of clerical errors, and difficulties in keeping track of trial activity data across multiple sites and countries

# Best Practices For Reconciliation

## Vendor Communication

- ▶ Establish a communication framework with vendors during MSA and SOW review
- ▶ Require clinical data as part of quarterly financial updates (i.e., EDC, IRT, CTMS reports)
- ▶ Agree on reporting timelines (i.e., Business Day 3)
- ▶ Yes, you can get excel files for budgets, unit trackers and anything else

## Clinical Collaboration

- ▶ Partner with Clinical and FP&A on activity drivers and methodology as SOW is executed, realign for each amendment
- ▶ Partner with Clinical to confirm operational updates each quarter (i.e., patients, sites, timeline)
- ▶ Monthly updates with clinical to discuss contractual changes in negotiation

## Analytics & Documentation

- ▶ Review monthly expense trends and correlation to enrollment as part of financial close process
- ▶ Partner with clinical to set expectations on costs based expected enrollment and timeline - compare results against these expectations
- ▶ Document confirmations, reviews, expectations, and any adjustments as part of the review process

# Best Practices For Reconciliation

## Use Technology To Address Complexity

- ▶ Consider implementing purpose-built financial tools to automate reconciliation
- ▶ Consider clinical trial management tools that can handle the complexity of global trials involving multiple vendors and sites
- ▶ Integrate systems to automate data flows
- ▶ Technology solutions capture critical documentation and provide auditability

## Validate, Monitor & Document

- ▶ Institute a robust confirmation, review and approvals process across clinical and finance
- ▶ Demonstrate the design & effectiveness of internal control framework
- ▶ Incorporate validation checks to avoid contradictory evidence (including collaboration among teams & vendors)

## Audience Insights

What financial/accounting software  
does your company use today?



Select your answer in  
the panel to the right

# 03

## Forecasting Using Historical Data and AI



# Forecasting Approaches for Clinical Trial Costs

Forecasting clinical trial costs is essential to maintaining financial control and achieving accurate budget management across various phases of a clinical trial.

KEY COST FACTORS  
**Clinical Trial  
Forecasting**



### **Patient Recruitment and Treatment Costs**

- ▶ Represent a significant portion of trial expenses
- ▶ Forecasting must consider variability in recruitment rates and costs per patient across geographies and study phases



### **Vendor Costs and Contracts**

- ▶ CROs costs such as site management, data management, and monitoring
- ▶ Forecast both fixed and variable components
- ▶ Automating vendor comparisons can shorten contract timelines and improve accuracy

# Six Strategies for Accurate Forecasting and Budgeting

- 1. Utilize Industry-Standard Costing Methodologies**  
Facilitates quick and reliable budget creation, ensuring consistency and reducing time spent on budget development.
- 2. Leverage Industry Intelligence**  
Use aggregated data from industry benchmarks to make informed decisions, particularly in negotiating with CROs.
- 3. Automate CRO Budgeting & Change Orders**  
Replace manual processes with automation to compare CRO changes, reducing inconsistencies and shortening contract negotiations.
- 4. Rapid Scenario Planning**  
Use a single source to evaluate multiple study scenarios, avoiding the errors and time consumption of spreadsheet-based planning.
- 5. Replace Manual Spreadsheet**  
Minimize manual errors and speed up the process by switching to technology-based forecasting solutions.
- 6. Simplify Program and Trial View of Costs**  
Centralize planning details to better understand resource demands across all studies, helping optimize program management.

# Best Practices for Reliable Forecasting



## Historical Data Analysis

- ▶ Leveraging historical trial data to predict costs is key
- ▶ Use past trends – patient enrollment rates, site activation timelines, and treatment periods—to inform predictions



## Patient-Activity Based

- ▶ Estimating costs based on patient activities, such as the number of screening visits, patient enrollment, and treatment monitoring
- ▶ Patient enrollment is a critical driver of cost forecasts



## Scenarios & Benchmarks

- ▶ Multiple scenarios should be calculated to account for unique challenges such as site initiation and enrollment delays
- ▶ Consider financial benchmarking with similar vendors, therapeutics areas and phases of trials

## Unified Source of Truth:

- ▶ Integrating clinical and financial systems (e.g., CTMS, ERP, FP&A platforms) creates a unified source of truth, enabling real-time data access for accurate financial planning.
- ▶ Apply consistent methodologies between accruals and forecasting to bridge actuals to forecast and facilitate flux variance explanations.

# 04

## Clinical System and Financial System Integration



## Audience Insights

**Does your organization plan to leverage clinical accounting FP&A software?**

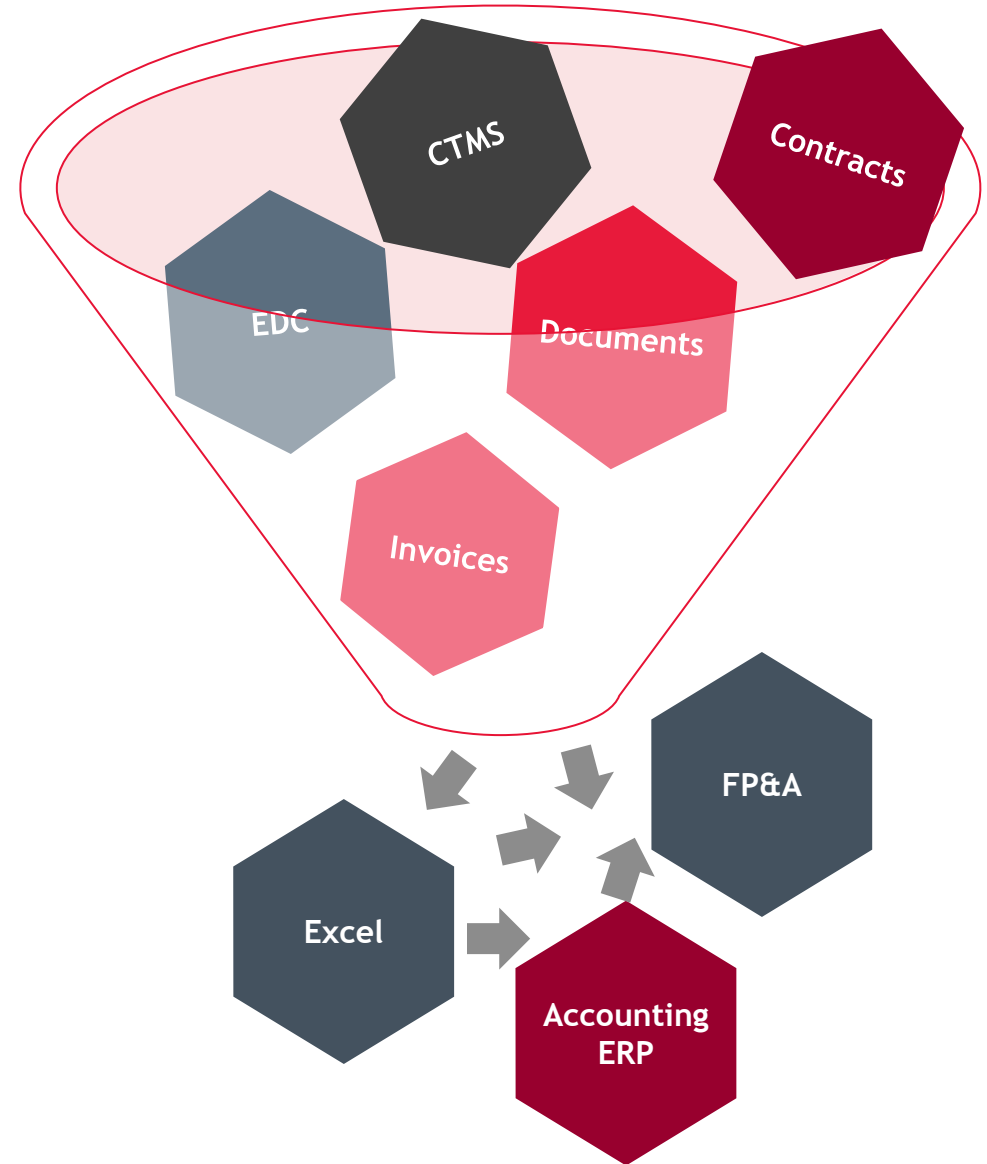


**Select your answer in the panel to the right**

# Technology Without Integration

## The Right Tools, But Complexity Grows

- ▶ As complexity grows, tools are added
- ▶ Data silos grow, creating repetitive tasks to retrieve and input data across multiple systems
- ▶ Accruals, actuals, reconciliation, forecasting, validating, documenting and approving can become more complex
- ▶ Lack of communication between tools is inefficient, requiring manual workarounds and risks introducing human error



# Integration Best Practices

- ▶ Integrate systems to streamline data consolidation and automate multiple business processes
- ▶ Clinical Trial Accounting Software like Condor automates accruals, reconciliation and increases forecast accuracy, using data from all connected systems
- ▶ Integration to ERP systems (example NetSuite) connects PO to clinical trials and automates JE posting
- ▶ Automatically updates forecasts, budgets and reporting in FP&A systems and BI tools



# What To Look For: Technology, Implementation & Integration

## Clinical Trial Financial Software: Condor

- ▶ Robust & comprehensive audit trail
- ▶ CRO & Other Clinical reconciliations
- ▶ Change order tracking & Invoice recon
- ▶ Foreign currency gain/loss conversions
- ▶ Clinical, FP&A, and Accounting workflows
- ▶ Flexibility for size and scope of materiality
  - Granularity and precision by trial
  - Program level views for large global studies



## Experienced Partner Like BDO

- ▶ Life Sciences Focus
- ▶ GMP Validated NetSuite Deployment
- ▶ Global Footprint
- ▶ Experienced Consultants
- ▶ Goes Beyond Technical Knowledge, Understands Business Processes and Workflows
- ▶ Integration Expertise



# 05

## Conclusion and Q&A



# Key Takeaways

## 01

Financial complexity grows exponentially with each new trial

## 02

Process and systems must demonstrate financial control to auditors, investors and executives

## 03

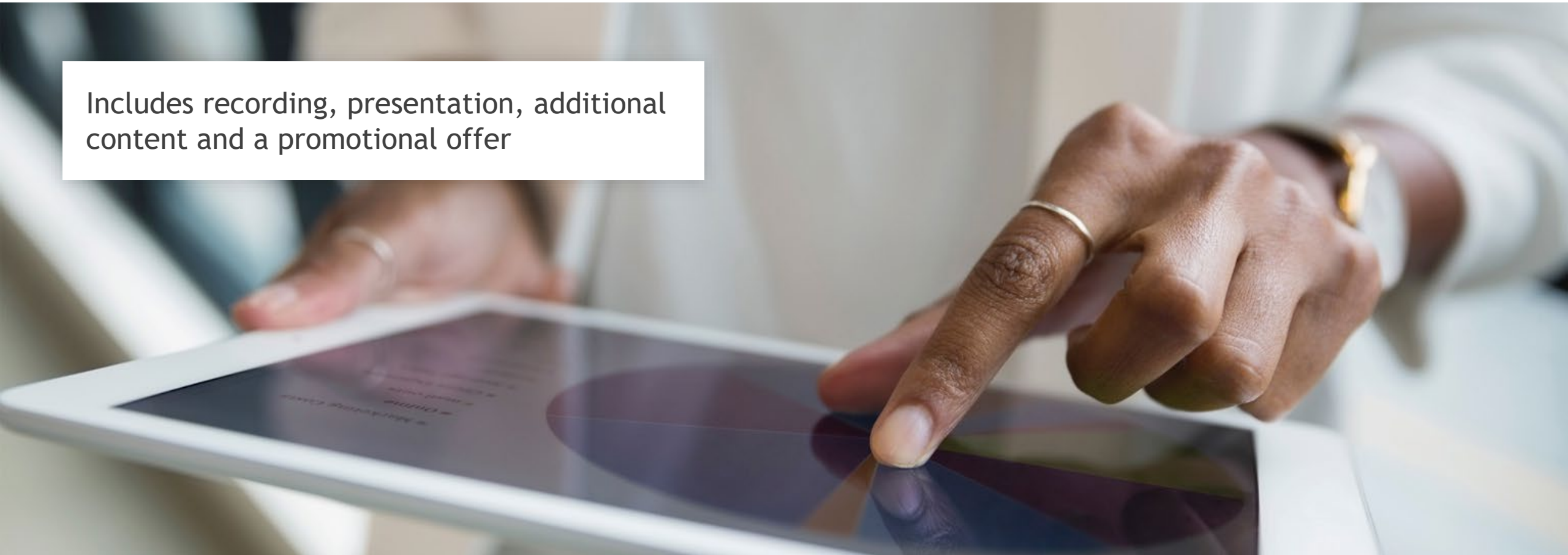
Planning accuracy can be improved by incorporating additional data into budgets and forecasts

## 04

Software solutions like Condor or other CTFS systems automate accruals, reconciliation and forecasts

# Watch for the Post Event Email

Includes recording, presentation, additional content and a promotional offer



# More Information

- ▶ Contact us for more info on Condor, NetSuite or clinical trial financial questions



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# Thank You!

Questions?



A modern office interior featuring a staircase with a glass railing on the left and a reception desk with a large window on the right. The reception desk has the BDO logo on it. The office is well-lit with natural light from the window.

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