



# Medidata Payments

Site Payments – Best Practices

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# Presenting Today



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# Challenges Exist

- Regional Issues
  - US is quite straightforward and well identified
  - Europe has multiple countries resulting in unique complexities
    - Budget development and approvals
    - Currency variations
    - Investigators with multiple IDs
    - Tax & VAT Calculations



# VAT and Tax Challenges

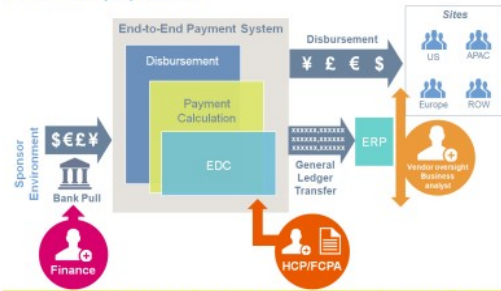
## What is VAT?

*The Value Added Tax (or VAT), in the European Union is a general, broadly based consumption tax assessed on the value added to goods and services.*

- Varying rates of VAT by country impacts
  - Budget development
  - Invoice development and reimbursement
  - Site resources for invoice development and reconciliation
- VAT recovery can take years (e.g. Italy)

# In-House vs. Outsourcing

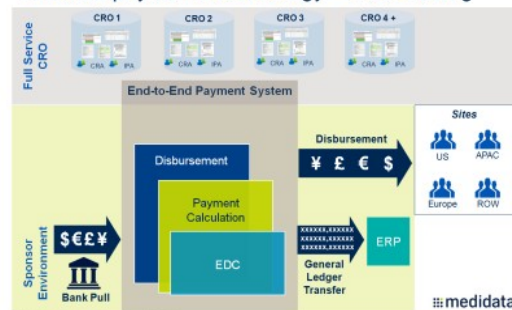
## In house payments



Sponsor Payment Technology In-House Improves Financial Accountability

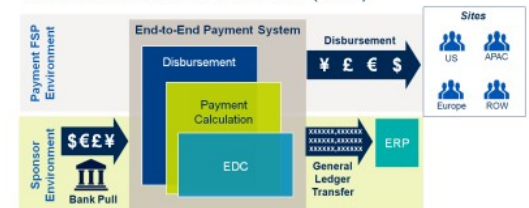
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## In house payments technology – CROs using



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## Functional Service Provider (FSP)

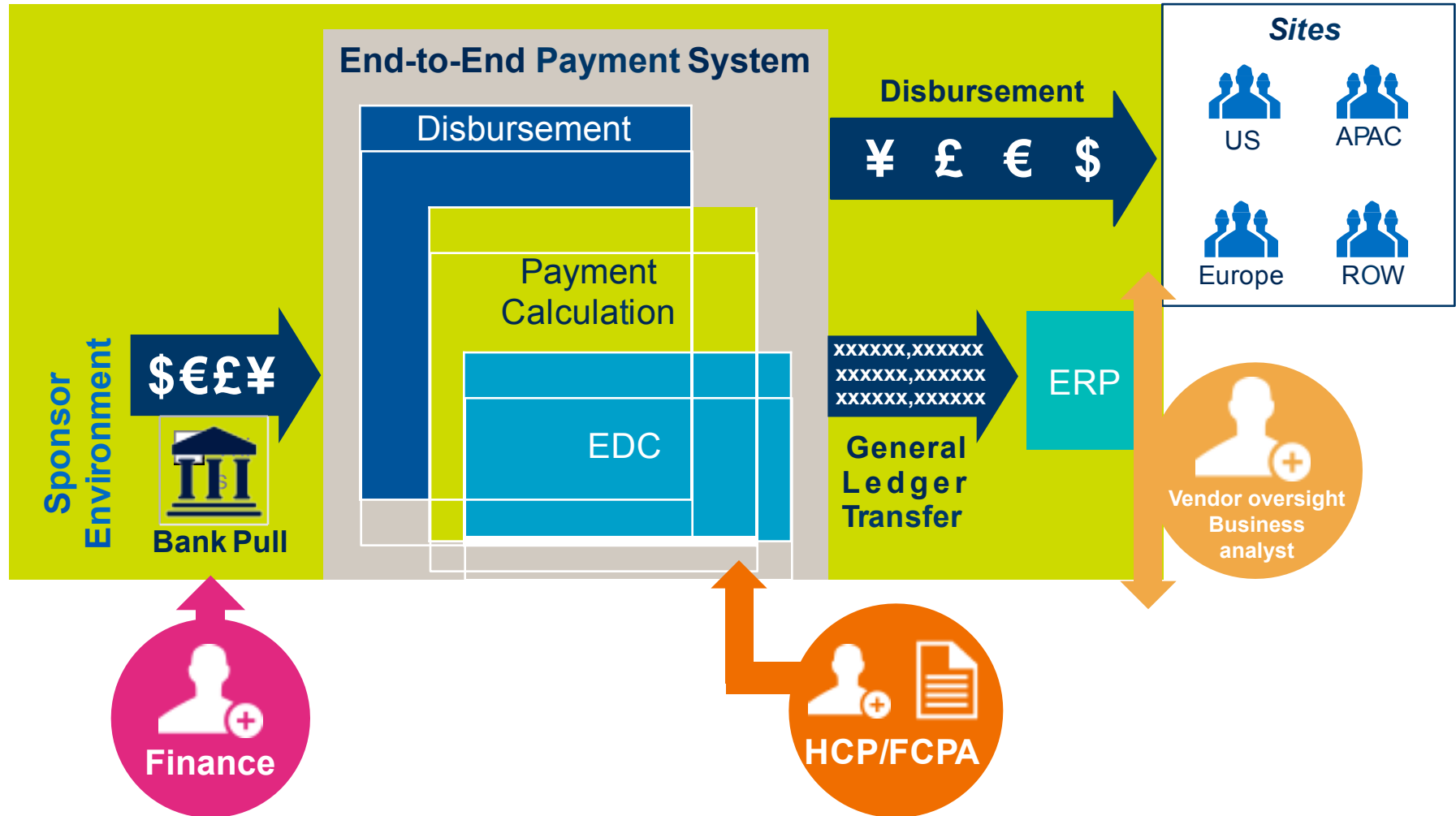


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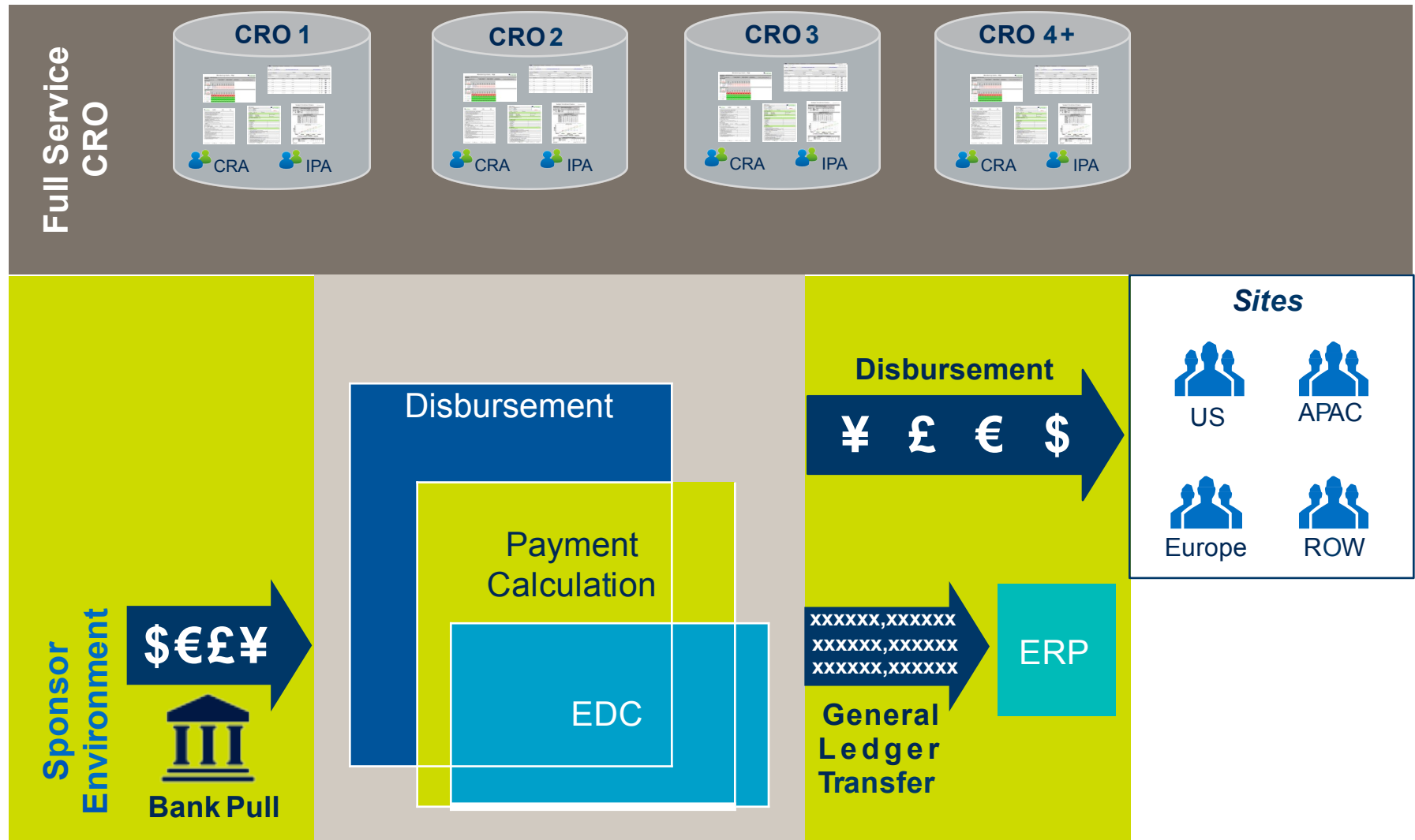
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# In House Payments

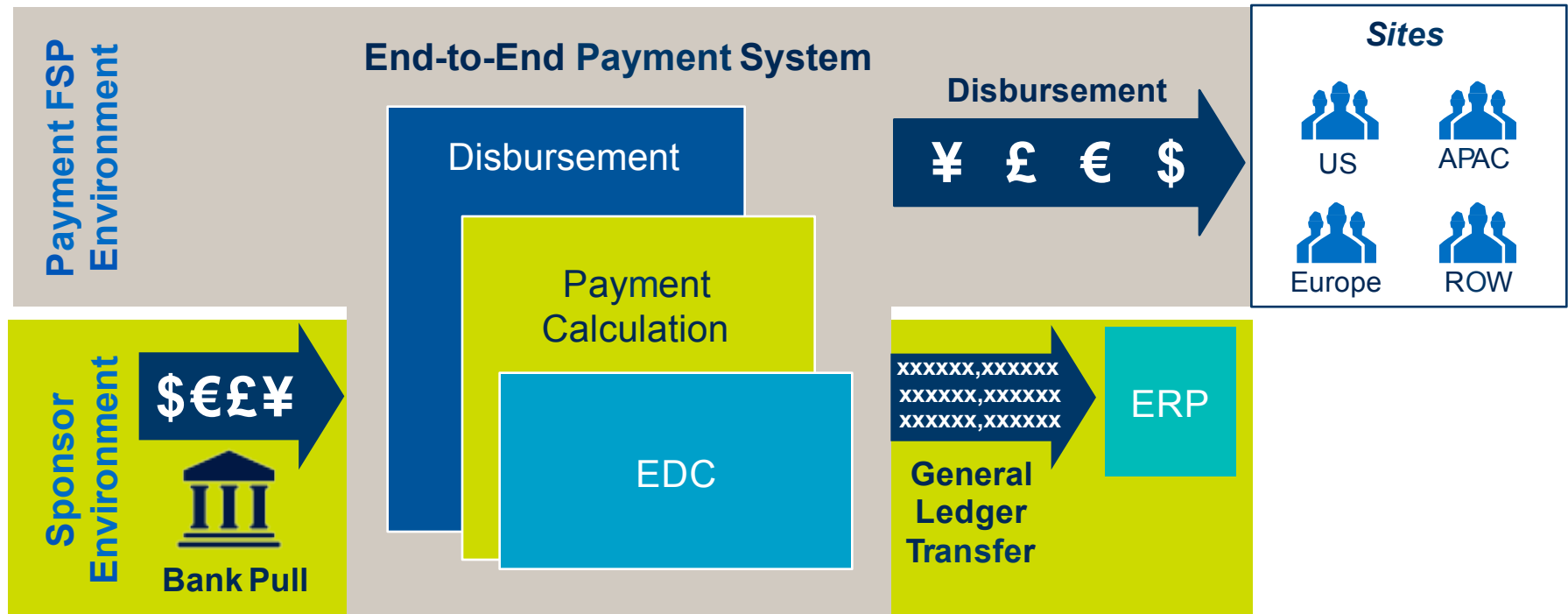


Sponsor Payment Technology In-House Improves Financial Accountability

# In House Payments – CROs Using



# Outsourcing to a Full Service Provider





# Payment Model Considerations

## In House

- Retain complete control of payments process
- Maintain close contact with end to end process
- Entire process managed through internal staffing
- Reduce parties involved in the payments process

## CRO Oversight

- Maintain outsourced model
- Maintain site relationship and single contact
- Drive down year on year study service cost
- Provides service leverage with CROs across all services

## Fully Outsourced

- Maintain outsourced model
- Remove issues from CROs site teams, such as CRAs
- Drive down year on year service cost
- Reduced service costs through using dedicated Payments resources
- Higher levels of responsive to site and sponsor queries through dedicated highly available resources
- Single vendor responsible for all studies provides repeatability and economies of scale

# What Challenges Do Sponsors Experience

EDC



SITE PAYMENTS

# How we are addressing the Challenges

- One of the options Celgene is looking into is moving into a unified platform (Medidata Clinical Cloud) to enhance capabilities in data management, study planning and design, trial operations, analytics and patient engagement.
- At the moment the most common solution is outsourcing the payments to CROs.

# **Best Practices in Site Payment**

## **Marcus Thornton**

# As Evidenced From Sites



“Our center takes on the, the majority of the risk upfront for clinical trials. We fund the operation. There have been instances **beyond 12 months** where we haven't been fully reimbursed.”

– *Lucas Litewka*

*Director, Clinical Trials Centre,  
University of the Sunshine Coast, Australia*

“It has never been so difficult in 23 years of participating in clinical trials to get your money in the door for work done. I have spent hours on the phone, teleconferences, and have been unable to retrieve **over five figures.**”

– *Kathleen Mostek, RN, CCRC*

*Director, MidMichigan Medical Center, Cardiovascular Research, USA*



# Dual Impact of Payment Delays and Inaccuracies

	Percent of Sites That Agree
Slow payment terms & witholding money places site in <b>financial stress</b>	71%
Sites pay greater attention on studies that have better payment terms	51%
When sites have a high ratio of sites that have better payment terms	30%

Why so much attention on payments?



- Reduces patient enrollment rates

- Increased investigator turnover rate
  - 40% annually
  - High proportion of novice sites<sup>2</sup>

1. SCRS Site Solutions Summit. Survey of Investigative Sites in the US; 2013. n=108.

2. Tufts CSDD, Global Site Landscape: A 2013 Assessment.

# Payment Teams

## Challenges

### Challenges

- Payments Set up in intricate
- Ongoing payment processing is manual and difficult
- Difficult communication with Sites
- ESCROW and funds management with CRO and Sponsor

# Payment Teams

## Challenges, Causes

Challenges	Causes
<ul style="list-style-type: none"><li>• Payments Set up</li><li>• Ongoing payment processing is manual and difficult</li><li>• Difficult communication with Sites</li><li>• ESCROW and funds management with CRO and Sponsor</li></ul>	<ul style="list-style-type: none"><li>• Contract terms are hard to implement</li><li>• Data requirements are too onerous</li><li>• Incentive clauses are difficult to manage</li><li>• Visibility and transparency for sites is poor</li><li>• Sites struggle with invoicing for work done and indirect taxes</li><li>• CROs use custom tools or CTMS for payments processing</li><li>• Poor reporting for CRO systems creating funding issues</li></ul>



# Payment Teams

## Challenges, Causes and Effects

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<ul style="list-style-type: none"><li>• Payments Set up</li><li>• Ongoing payment processing is manual and difficult</li><li>• Difficult communication with Sites</li><li>• ESCROW and funds management with CRO and Sponsor</li></ul>	<ul style="list-style-type: none"><li>• Contract terms are hard to implement</li><li>• Data requirements are too onerous</li><li>• Incentive clauses are difficult to manage</li><li>• Visibility and transparency for sites is poor</li><li>• Sites struggle with invoicing for work done and indirect taxes</li><li>• CROs use custom tools or CTMS for payments processing</li><li>• Poor reporting for CRO systems creating funding issues</li></ul>	<ul style="list-style-type: none"><li>• Uncomfortable contract terms for sites</li><li>• Sites reimbursed 120 to 180 days after cost incurred</li><li>• Sites are frustrated because of billing rules</li><li>• ESCROW funds frequently over spent</li><li>• Sponsors upset with CROs for over funding</li><li>• CRO under strain due to funding constraints</li><li>• Sponsors are over charged by CROs</li></ul>

# Organisational Silos – CRO and Sponsors

- A relay of multiple hand offs
- Cross functional teams
- Different applications
- Manual processes
- Set up is hard because of decisions made up stream



# How Do We Overcome this?



# Improve Budgeting and Contracting

- Remove Screen fail ratios
- Automate Holdback processing
- Automate Pre payments
- Improve Indirect tax processing
- Improve Splits at the point of invoice
- Implement robust procedure payments
- Implement improved payments triggers – data entered /reviewed v SDV



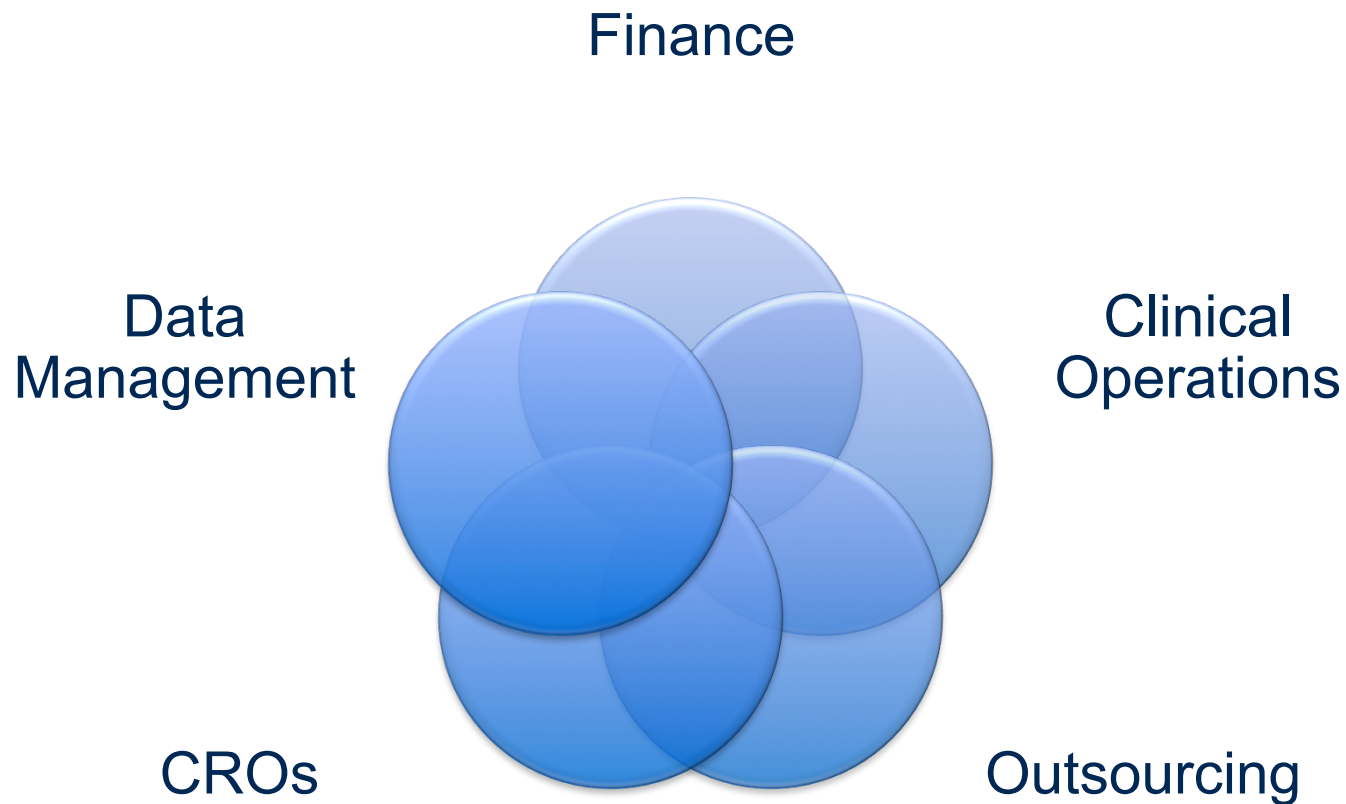
# Organisational Improvements



- Remove barriers between departments
- Create cross study collaboration teams
- Align department goals

# Cross function collaboration

- Different Stakeholders Influencing the Payments process



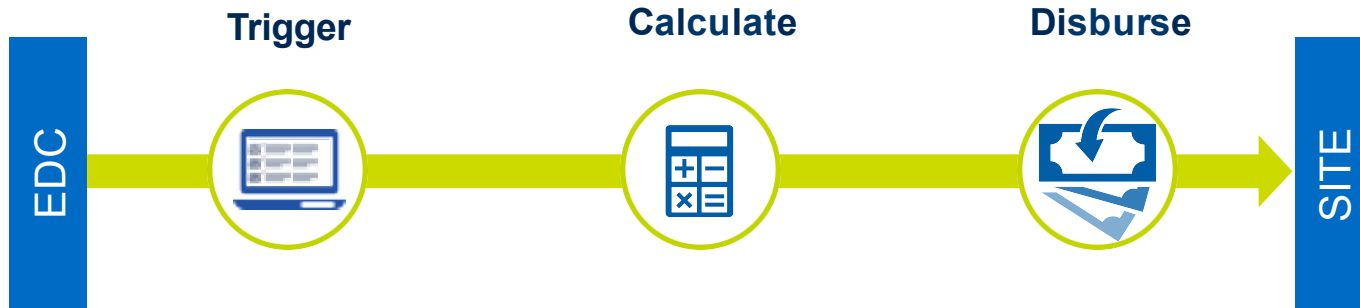
# Technology is a Friend

- Enabling sites to enter data once into an EDC which triggers site payment calculations and disbursement results in:
  - Timely and accurate site payments
  - Reduced errors necessitating reconciliation
  - Increased site satisfaction



Benefits	How
Finance	<ul style="list-style-type: none"><li>• Escrow-free</li><li>• Real-time reporting and projections</li><li>• Predictable currency conversion rates</li></ul>
ClinOps	<ul style="list-style-type: none"><li>• Reduction in data entry requirements</li><li>• Seamless EDC to disbursement process</li><li>• Reduction in site payment inquiries and reconciliations</li></ul>
Sites	<ul style="list-style-type: none"><li>• Faster and more accurate payments</li><li>• Reduction in invoice development and submissions</li><li>• Familiar systems with accreditation and ongoing support</li></ul>
FOR ALL	<ul style="list-style-type: none"><li>• Auditable</li><li>• 24/7 access for status</li></ul>

# How it Works



## Quicker payment processing cycle times

- EDC triggers Visit / Procedure based costs
- EDC auto-populates line item costs

## Advanced Calculation Capabilities

- Split payments (site, individuals, labs)
- Streamlined request-for-invoice process

## Global Payment Processing

- Currency, exchange rates
- Withholding tax
- Flexible payment frequency



Increased site satisfaction with on time and accurate payments



# In Summary

- Site satisfaction is paramount to successful trial execution
- Payment timing and accuracy are a key component to Site satisfaction
- It is the combination of:
  - Early cross-team collaboration for budgets and site selection
  - Adoption of technology to streamline process, increase payment accuracy/timing and escrow-free
  - Accessibility to real-time reporting and projections



Successful site payments and site satisfaction

# Q&A