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Centralisation of Investigator Payments:

From Requirement to Strategic Planning & Management Tool

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Agenda

- Why Centralise Investigator Payments?
  - Complexity of Investigator Payments
  - Transparency Requirements
  - Costs & Administration
  - Site-Sponsor Relationships
- Using Centralised Data for Strategic Planning & Management
  - Budgeting & Contract Negotiation
  - Managing Speed & Accuracy of Payments
  - Assessing Liabilities & Cash-flow Management
  - Trial Wrap-Up & Future Planning
- Discussion Questions

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Why Centralise Investigator Payments?

Complexity of Investigator Payments

- Investigator payments on average account for 48% of the total trial cost[1]
- Protocols increasing in complexity over time (nearly doubled from 2000 – 2011)[2]
- Sites are now in all regions using all languages and currencies
- Difficult for operational teams to manage this complexity
  - Typical Phase 3 Study includes up to **50,000 payment milestones**, 200 sites with up to 3 contracts each in multiple countries, 1,200 patients, 14 visits each

[1]Source: Applied Clinical Trials "Benchmarking Investigator Payments" Author: Jeremy Klein, 2012

[2]Source: Applied Clinical Trials "Protocol Complexity" Author: Medidata, 2012

Transparency Requirements

- Increase in transparency laws essentially making payment data centralization a requirement
  - Sunshine Act in the US
  - The European Federation of Pharmaceutical Industries and Associations (EFPIA)
  - France's disclosure law has stricter reporting requirements as compared to the draft EFPIA code
- Need to report at a payee level
- Need to capture specifics about each payee e.g. NPI

Costs & Administration

- Due to costly, multi-step manual processes, sponsors & CROS incur huge costs to process a single payment; the average clinical payment costs $125

- Site payments are typically managed in-house by the sponsor or outsourced to a CRO. Both require inefficient manual processes:
  - CRAs spending time validating payments
  - CRAs spending time answering queries
  - Interfaces between EDC & CTMS
  - Interfaces between CTMS & Financials
  - Double entry of data

Site-Sponsor Relationships

- Manual processes mean increased time to process invoices and make payments to sites and CROs
  - 40% of sites see slow payments and reimbursements from sponsors as a primary operating concern[1]
  - 37% of investigator payments currently take >90 days[2]
- The number of sites that are taking part in clinical trials is not increasing
- The need to ensure that sites are happy is prevalent within Pharma and CROs

[1]Source: CenterWatch Survey of Global Investigative Sites 2011; N=1,205

[2]Source: CenterWatch, 2012 Survey of 257 Global Investigative Sites

How can centralising payments assist?

Area	Description
Complexity of payments	Centrally managed protocol structure for all sites Ability to pay by procedure , by visit Rules for screenfails , early withdrawals Multiple Payees
Transparency	All country payments available for reporting All payments per PI can be grouped together
Cost & Administration	Visibility of data reduces queries Traceability from operational activity to payment
Site / Sponsor relationship	Ability to pay on-time – 30 / 60/90 days Ability to pay electronic / manual payments
Operational Reporting	Accruals , Regulatory , Benchmarking

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Using Centralised Data for Strategic Management & Planning

Budgeting & Contract Negotiation

- Integration of actual costs with contracted costs and budget data enables the following at a study level:

- Comparison of budget costs v contracted costs
  - Budget patient costs v contracted patient costs
  - Budget patient enrolment v contracted enrolment

- Comparison of budget costs v actual costs
  - Budget patient costs v actual patient costs
  - Budget patient enrolment v actual enrolment

Budgeting & Contract Negotiation

- Comparing Budgeted Costs to Actuals: An Example

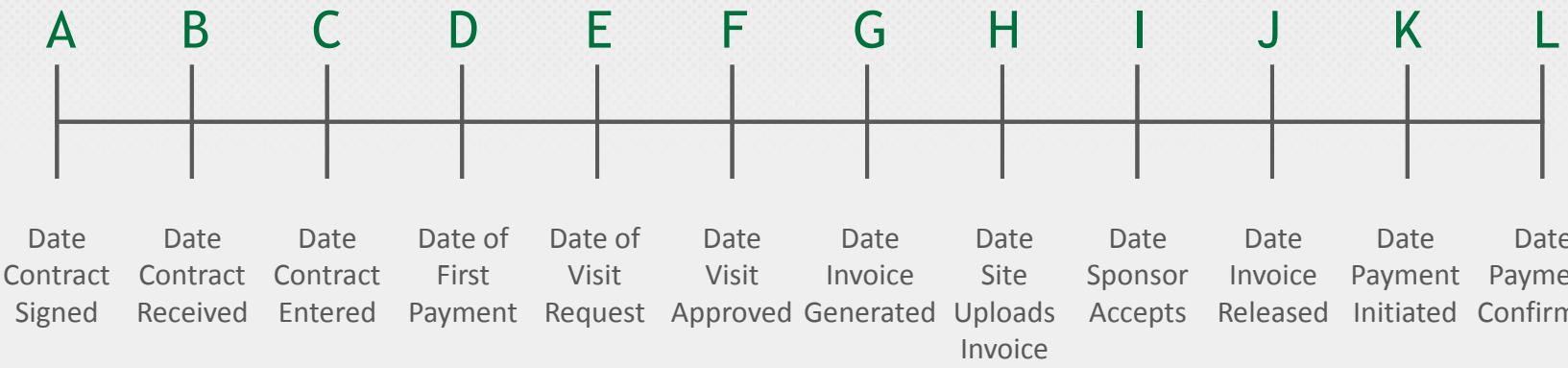
Country	Currency	Site	Site Name	Patient Rate	Planned Enrollment	Total Planned Patient Cost	Actual Enrollment	Total Actual Patient Cost	Site Cost	Number of Sites	Total Site Cost	Total Costs Patient & Site (Planned Enrollment)	Total Costs Patient & Site (Actual Enrollment)
US	USD	1	Clark Demo Clinic	$900.00	12	$10,800.00	8	$7,200.00	$370.00	1	$370.00	$11,170.00	$7,570.00
		2	Smith Demo Clinic	$1,100.00	8	$8,800.00	8	$8,800.00	$420.00	1	$420.00	$9,220.00	$9,220.00
		3	Taylor Demo Clinic	$1,200.00	6	$7,200.00	5	$6,000.00	$280.00	1	$280.00	$7,480.00	$6,280.00
	Contracted				26	$26,800.00				3	$1,070.00	$27,870.00	
	Actual						21	$22,000.00					$23,070.00
	Budget			$1,000.00	20	$20,000.00	20	$20,000.00	$800.00	2	$1,600.00	$21,600.00	$21,600.00
	Variance											29%	7%

E.g

- Countries performing as expected
- Sites performing / not performing

Managing Speed & Accuracy of Payments

- Centralised data allows insight into performance metrics on payment speed & accuracy across various milestones



- L – E: Payment Date v Activity Date
- H – G: Proforma Date v Invoice Date
- D – A : Site FPI v Site Contract Date

Assessing Liabilities & Cashflow Management

- Centralised data gives visibility to cashflow needs – analysis of protocol assists in this process
  - Using the protocol to predict cash outflows & future costs
  - Enables projection of potential visits and costs

Sequence	Milestone	Days Between Visit	Withdrawal Percent	Investigator Amount	Patient Reimbursement	Patient Invoiceables	Forecast Payment
1	Screening	1		1000	200		1200
2	Baseline	28		2000	200	2000	4200
3	Cycle 1	28		3000	200		3200
4	Cycle 2	28		3000	200	2000	5200
5	Cycle 3	28		3000	200		3200
6	Cycle 4	28		3000	200		3200
7	Cycle 5	28		3000	200		3200
8	Cycle 6	28		3000	200		3200
9	Cycle 7	28		3000	200		3200
10	Cycle 8	28		3000	200	2000	5200

Assessing Liabilities & Cashflow Management

- Centralised data also increases visibility of liabilities
  - Enables matching contracts v. actuals

Site Name	Currency	Per Subject Cost	Expected Enrollment	Total Subject Cost	Contracted Manual Costs	Manual Percent of EDC	Actual Manual Costs	EDC Exposure	Manual Exposure
Site A	USD	9,526.00	1	9,526.00	6,955.00	73%	4,930.00	9,026.00	2,025.00
Site B	USD	11,333.00	6	67,998.00	18,588.00	27%	39,512.35	5,619.00	-20,924.35
Site C	USD	9,475.00	3	28,426.50	11,822.00	42%	23,802.00	-19,093.00	-11,980.00
Site D	USD	9,591.00	1	9,591.00	14,738.00	154%	10,038.00	1,852.00	4,700.00
Site E	USD	9,846.00	2	19,692.00	9,550.00	48%	5,730.25	-15,774.00	3,819.75
Site F	USD	7,317.00	2	14,634.00	7,625.00	52%	31,389.51	-28,536.00	-23,764.51

Trial Wrap-Up & Future Planning

- 2011 Analysis conducted by Pfizer and Lilly found that investigative sites that have performed well on one study are 70% more likely to perform well on subsequent studies[1]

- A 2008 peer-reviewed study published in *Clinical Trials* showed that adjustments to study duration, **number of sites**, EDC usage, & **site management** reduced the cost of a trial, initially designed to cost $421 million, by anywhere from 59% to 90% without compromising the scientific validity of the results[2]

[1]Source: Applied Clinical Trials "Predicting Successful Site Performance" Author: Ken Getz 2011

[2]Source: Clinical Trials "Sensible Approaches for Reducing Clinical Trials Costs" 2008

Trial Wrap-Up & Future Planning

- Reviewing budget v. actuals to determine variables, use for future planning
  - How many budgeted patients v contracted patients v actual patients
  - How many contracted sites v live sites
  - Costs per country , per site
  - Invoice management per site , per country
  - Payees per country , per site
- At a macro level, analysis across multiple studies
  - Therapeutic Area
  - Country performance
  - Site Performance
  - Provides information for better site selection

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Discussion Questions:

1. How do your trial budgets typically compare to actual costs?

2. What metrics do you currently use to track and assess the financial status of the trial?

3. How do you use past experience to inform site selection & enrollment predictions?