



I have a bee in my bonnet...
The reality of being a worker bee

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SITE BUDGETS & CONTRACTS – ISSUES

Burdens identified



- Frequency of payment
- Retainers
- Start-up fees
- Archiving fees
- Back-up information required
- Miscellaneous

Frequency of payment



Frequency of payment



- 51% of sites are paid quarterly
- In reality – these sites are paid 4,5 – 6 months after completing work
- In sites > 5 years old, 77% stated that 30 day payment terms were “very valuable” yet only 28% of them receive 30 day payments
- EDC and rationale for site payments – sites are paid for delivering data. On average, data is submitted by EDC in almost 100% of trials, and is usually submitted within a few days. Why quarterly payments?

Frequency of payment



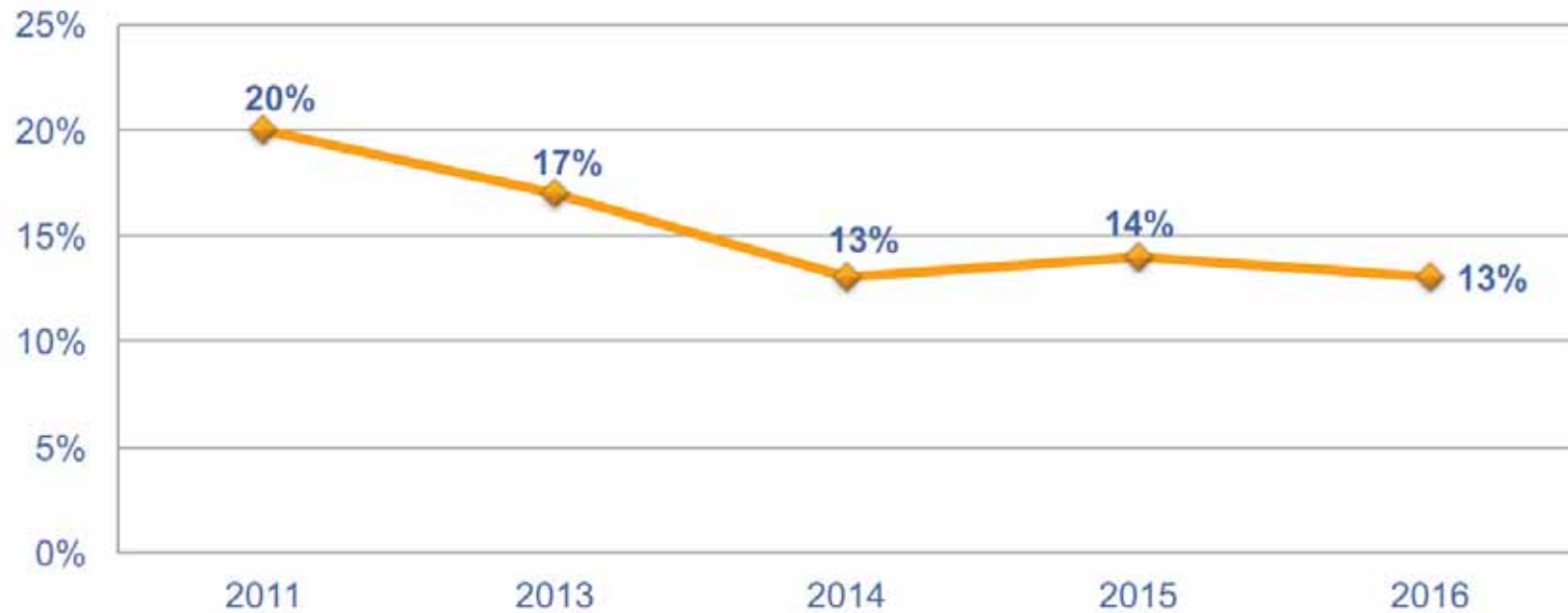
Sites With Less than Three Months Operating Cash



Frequency of payment



Site Profit Margin



Retainers



Retainers



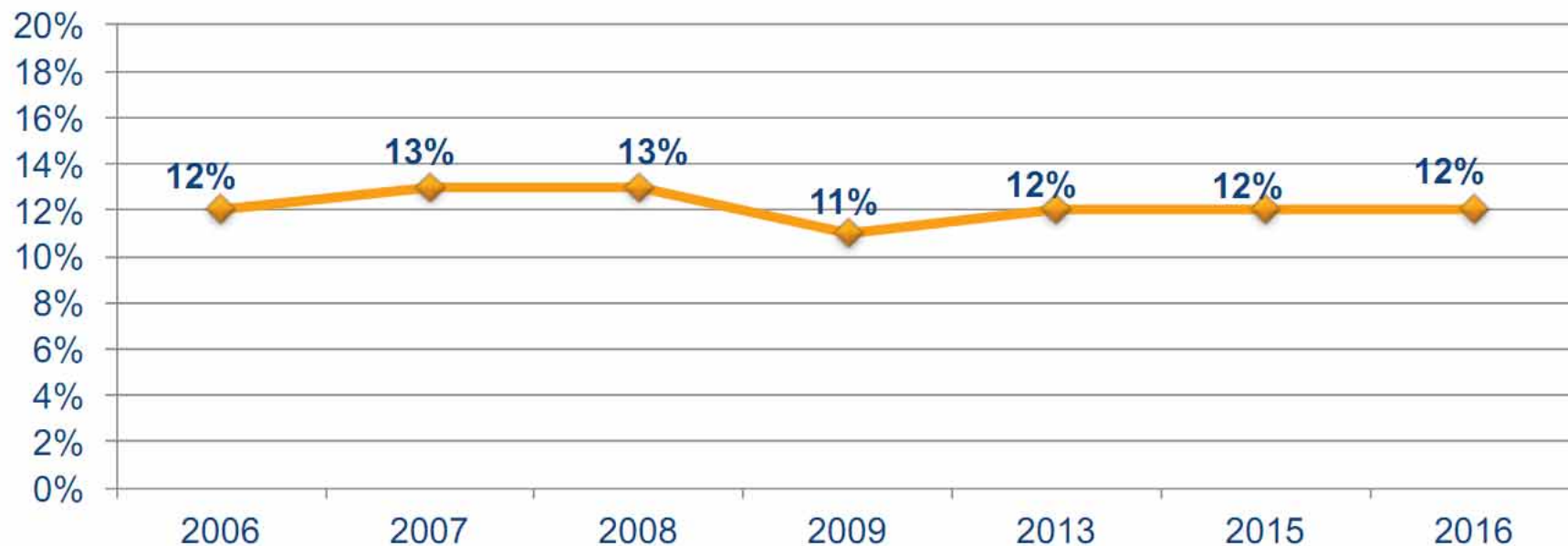
- Retainer payments evolved as insurance for industry to assure sites completed various study related activities, and specifically query resolution. Today, as almost 100% of studies are conducted using EDC, sponsors and CROs have full transparency into the sites' attention to the resolution of their queries, yet holdback payments remain.
- Final payment is often contingent upon the study being closed, the database being locked, and all sites being closed out. Individual sites are thus “held hostage” to the activities of other sites in the study. A site can and should only be held responsible for the work they are to do.

Retainers



Withholding Trends

58% of US contracts have holdback
37% of OUS contracts have holdback



Start-up fees



Start-up fees



- Is this a fee that should be charged, or is this an expected part of doing trials?

Start-up fees



Total hours minimum: 40 hrs =1 working week

Start-up fees



Procedure	Description	Total	
Administrative Start-up Fee	This is a one time non-refundable fee.	\$11,277.00	
Administrative Annual Fee	Administrative Annual Fee	\$2,835.00	
Amendment Fee	This is a non-refundable fee charged for each sponsor required IRB amendment and sponsor prompted Budget or Contract.	Regulatory	\$428.40
		Financial	\$378.00
Pre-Screening Fee	This is a non-refundable quarterly fee and only requested if applicable to the study.	Outpatient	\$907.20
		Inpatient	\$2,419.20
Remote Monitoring Fee	This non-refundable fee is charged per occurrence and only if applicable to the study.	0-1 pts	\$384.30
		2-5 pts	\$648.90
Administrative Close-Out Fee	This is a one time non-refundable fee.	\$2,299.50	
Archiving Fee	This is a one time non-refundable fee.	\$945.00	
Pharmacy Fee	This is a one time non-refundable fee. This applies only if the study drug is stored in the Satellite Pharmacy.	Simple	\$1,039.50
		Complex	\$1,512.00
Pharmacy Annual Fee	This is an annual non-refundable fee. This applies only if the study drug is stored in the Satellite Pharmacy.	Simple	\$4,252.50
		Complex	\$4,866.75
Pharmacy Close-out Fee	This is a one time non-refundable fee. This fee applies only if the study drug is stored in the Satellite Pharmacy.	\$756.00	

Archiving fees



Archiving fees



- How can you fix an archiving fee when you don't know what will be archived?
- Actual quotes used? What is the price to archive 8 boxes for 15 years? What about retrieving these boxes to add in safety data, audits, etc

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INITIAL COST: R 2 100

15 YEAR ARCHIVING COST: R 12 500

Back-up information required



Back-up information required



- Invoices are based on a payment tracker received from Sponsor
- Invoices are rejected if they do not include the protocol name and number, investigator name, and details of each payment line item including subject identifier, visit number, visit date and procedures outlined if the payment is for items outside the visit payment
- It is NOT possible to refer to a payment tracker
- It is NOT possible to re-write accounting software to include the required information – **OVERKILL?**



SOUTH AFRICAN SITES PERCEPTIVE

Talking to.....



- Communication
- Start-up fees
- Frequency of payment
- Retainers
- Archiving fees
- Capacity building

Communication



- Dedicated contract person to deal with payment challenges
 - Start-up team
 - Contract team
 - Monitoring team (Protocol, ICH-GCP, Compliance)
 - Close-out activities (Archive, final payment)
- Escalation contact person
 - Contract has dispute resolution clause which is a legal and formal route, any payment delays, challenges are routed through monitor
- Benchmarking
 - Sites are informed of a benchmark exercise for proposed study budget

Start-up Activities



- Site overheads should NOT be part of per patient investigator fees
 - budget not specific...photocopy, electricity, water, etc.
- Feasibility, SSV, and IM are born to site prior to budget negotiation
- Site submission of essential documents and initiation visit preparation. i.e. training, systems access and management of inventory supply.
- Start-up fee does NOT covering patient transport and third party vendor fees. i.e. X-rays if contracted to site.
- Sponsor/CRO not willing to advance site a float

Frequency of payment



- Payment terms of 30 days ends up being 60 days...adherence
 - 30 days from date of invoice, ?RBM , vs Hrly fee
- Payment not linked to milestone such as data entry within 2-5 days as per CTA
- Start up fee payment received 30-45 days after site initiation
- Clause on initial payment depending on Europe site enrolment.
- Sponsor insisting on quarterly payment even during negotiation

Retainers



- 10-15 % retained on per patient while data is available.
- Annually sites staff is required to renew their council licenses, indemnity and GCP.
- Sponsor consideration for study halt, recruitment challenges and ad-hoc regulatory pause.
- Budgets don't improve over-time

Archiving fees



- Site is required to archive and retain trial documents for 15 years but unwilling to pay pass through cost directly to the company.
- Document retrieval is based on the need at a later stage – site cannot predict frequency, cost should be born to sponsor

Mutual Collaboration



- Start up should enable site to prepare for success
- Industry standards to be developed and implemented for site payment
- Industry standards for trial monitors (CRA) to ensure comprehensive site support
- CTA be more developmental to site challenges – future work
- Frequent CTA review / discussion by parties
- General survey / questionnaire on site experiences in South Africa



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